

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Amendment No. 2

to

FORM S-1

REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

CARIS LIFE SCIENCES, INC.

(Exact name of registrant as specified in its charter)

Texas
(State or other jurisdiction of
incorporation or organization)

8071
(Primary Standard Industrial
Classification Code Number)

85-2077369
(I.R.S. Employer
Identification Number)

750 W. John Carpenter Freeway
Suite 800
Irving, TX 75039
Telephone: (866) 771-8946

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

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Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this registration statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. ☐

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐
Non-accelerated filer ☒

Accelerated filer ☐
Smaller reporting company ☐
Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Securities Act. ☐

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

Subject to Completion
Preliminary Prospectus dated June 16, 2025

PROSPECTUS

23,529,412 Shares



Caris Life Sciences, Inc.
Common Stock

This is Caris Life Sciences, Inc.'s initial public offering. We are selling 23,529,412 shares of our common stock.

We expect the public offering price to be between \$19.00 and \$20.00 per share. Currently, no public market exists for shares of our common stock. We have applied to list our common stock on the Nasdaq Global Select Market ("Nasdaq") under the symbol "CAL."

Immediately following the completion of this offering, David D. Halbert, our Founder, Chairman, and Chief Executive Officer, will beneficially own approximately 43.7% of our outstanding shares of common stock, and our existing executive officers (including Mr. Halbert), directors, holders of more than 5% of our outstanding capital stock, and their respective affiliates will collectively beneficially own approximately 65.4% of our outstanding shares of common stock, in each case, based on an assumed initial public offering price of \$19.50 per share, which is the midpoint of the price range set forth on this cover page, and assuming no exercise by the underwriters of their option to purchase additional shares of our common stock. As a result, Mr. Halbert as well as our other existing executive officers, directors, and principal shareholders, if acting together, will be able to control all matters submitted to our shareholders for approval, including the election of directors, amendments to our certificate of formation and bylaws, and the approval of significant corporate transactions. See "Principal Shareholders" for additional information.

At our request, the underwriters have reserved up to 5% of the shares of common stock offered by this prospectus, excluding the additional shares that the underwriters have a 30-day option to purchase, for sale, at the initial public offering price, to certain individuals identified by management, including certain of our directors, officers, employees, and certain other parties related to us. See "Underwriting—Reserved Share Program."

We are an "emerging growth company" as defined under the federal securities laws and, as such, have elected to comply with certain reduced reporting requirements for this prospectus and may elect to do so in future filings. See "Prospectus Summary—Implications of Being an Emerging Growth Company."

Investing in our common stock involves risks that are described in the "Risk Factors" section beginning on page 21 of this prospectus.

	Per Share	Total
Public offering price	\$	\$
Underwriting discount ⁽¹⁾	\$	\$
Proceeds, before expenses, to us	\$	\$

(1) We refer you to "Underwriting" for additional information regarding underwriting compensation.

The underwriters may also exercise their option to purchase up to an additional 3,529,411 shares of common stock from us, at the public offering price, less the underwriting discount, for 30 days after the date of this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

Certain entities affiliated with Neuberger Berman Investment Advisers LLC (collectively, "Neuberger Berman") have indicated an interest in purchasing up to \$75.0 million of shares of our common stock being offered in this offering at the initial public offering price and on the same terms as the other purchasers in this offering. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters could determine to sell more, fewer, or no shares to Neuberger Berman, and Neuberger Berman could determine to purchase more, fewer, or no shares in this offering. The underwriters will receive the same underwriting discounts and commissions on any of our shares of common stock purchased by Neuberger Berman as they will from any other shares of common stock sold to the public in this offering.

The shares will be ready for delivery on or about _____, 2025.

BofA Securities
TD Cowen
BTIG

J.P. Morgan

Evercore ISI

Goldman Sachs & Co. LLC

Citigroup

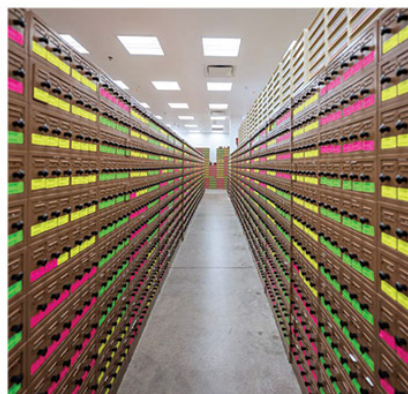
Guggenheim Securities
Wolfe | Nomura Alliance

The date of this prospectus is _____, 2025.

The information in this preliminary prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell, nor does it seek an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.



Where Molecular Science Meets Artificial Intelligence



Clockwise from upper left: The entrance to Caris' Phoenix, Arizona tissue lab building; a patient blood sample being prepared for Caris Assure™ profiling; sequencing machines in Caris' Phoenix, Arizona blood lab; the entrance lobby of Caris' Phoenix, Arizona tissue lab; tissue sample storage in Caris' Phoenix, Arizona tissue lab; a Caris laboratory technician preparing a centrifuge for Caris Assure™ profiling of patient blood samples; a Caris laboratory technician preparing patient blood samples for Caris Assure™ profiling; a Caris laboratory technician microdissecting a patient tissue sample in preparation for MI Profile™ analysis; Caris laboratory technicians in our Phoenix, Arizona blood lab; sequencing machines in Caris' Phoenix, Arizona blood lab.

By the Numbers

Profiling, Data & Technology

849,000+

Unique Cases Profiled

6.5+ Million

Total Tests Completed

13+ Quadrillion

Datapoints
Generated

38+ Billion

Molecular Markers
Measured

220+

AI-Powered
Tools Utilized

51+

Petabytes of
Genomic Data

4.4+ Million

Digitized Slides for
Interpretation & AI Training

580,000+

Matched Molecular & Clinical
Outcomes Database

23,000+

Genes Analyzed per Order
(WES/WTs)

Commercial Reach

5,550+

Regularly Ordering Oncologists
(4+ orders in the last 12 months)

100+

Biopharma
Partners

270+

Commercial
Sales Team Members

96

Caris Precision Oncology
Alliance Members

90+

Payer Reimbursement
Contracts

~60%

Cases Ordered
Electronically

Publications, Patents & People

1,050+

Publications

200+

Patents Granted
(100+ additional pending)

1,700+

Employees

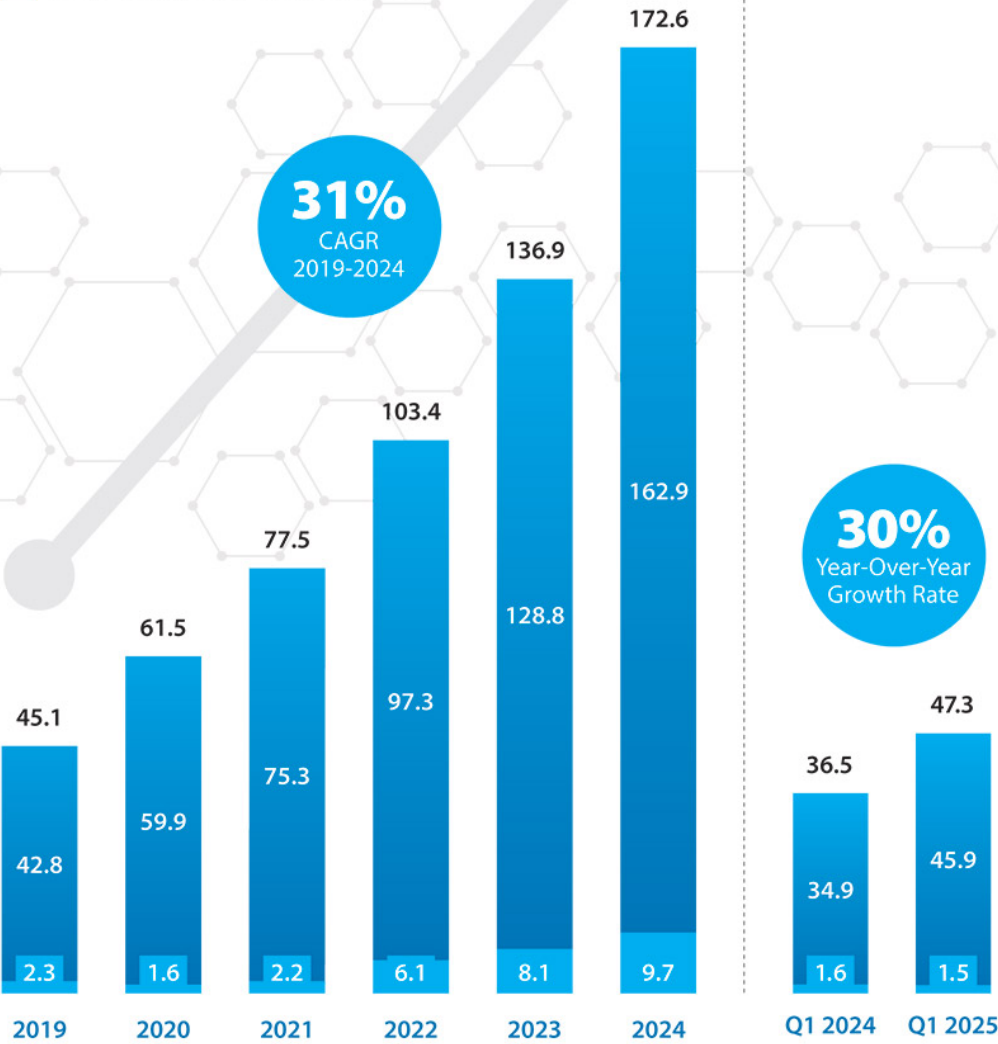
Data points are as of March 31, 2025.

Case Volume Growth

(Thousands*)

Clinical Cases

Biopharma & External Research Cases



*Figures reflect case volume for the periods presented. Figures may not sum precisely due to rounding.

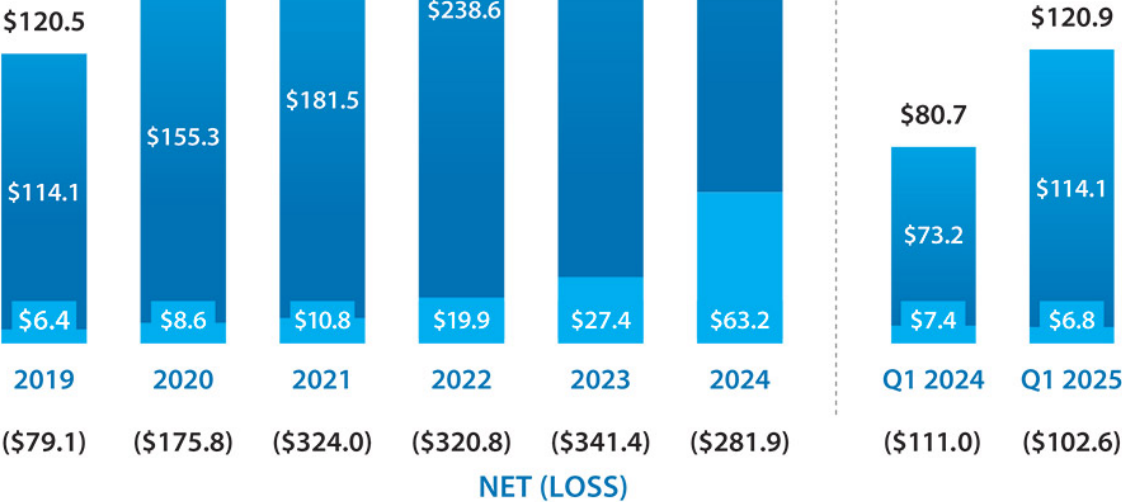
Revenue Growth

(\$ Millions*)

- Molecular Profiling Services
- Pharma Research & Development Services

28%
CAGR
2019-2024

50%
Year-Over-Year
Growth Rate



*Figures reflect revenue for the periods presented. Figures may not sum precisely due to rounding.

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Neither we nor the underwriters have authorized anyone to provide any information or to make any representations other than those contained in this prospectus or in any free writing prospectuses prepared by or on behalf of us or to which we have referred you. We and the underwriters take no responsibility for and can provide no assurance as to the reliability of, any other information that others may give you. This prospectus is an offer to sell only the shares of common stock offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus or in any applicable free writing prospectus is current only as of its date, regardless of its time of delivery or any sale of shares of our common stock. Our business, financial condition, results of operations, and prospects may have changed since that date.

For investors outside the United States: Neither we nor the underwriters have done anything that would permit this offering or possession or distribution of this prospectus or any free writing prospectus we may provide to you in connection with this offering in any jurisdiction where action for that purpose is required, other than in the United States. You are required to inform yourselves about and to observe any restrictions relating to this offering and the distribution of this prospectus and any such free writing prospectus outside of the United States.

TRADEMARKS, TRADE NAMES AND SERVICE MARKS

This prospectus includes our trademarks and trade names, including, without limitation, Caris Life Sciences[®], Caris[®], Caris Discovery[®], Caris Assure[®], MI Profile[®], Molecular Intelligence[®], Caris Precision Oncology Alliance[™], MI Tumor Seek[®], MI Tumor Seek Hybrid[™], ABCDai[™], CODEai[®], ESPai[™], MI Cancer Seek[®], GPSai[™], FOLFIRSTai[®], Caris ChromoSeq[™], MGMTai[™], and our logo, which are protected under applicable intellectual property laws and are our property. This prospectus also contains trademarks, trade names, and service marks of other companies, which are the property of their respective owners. Solely for convenience, trademarks, trade names, and service marks referred to in this prospectus, including logos, artwork, and other visual displays, may appear without the [®], [™] or sm symbols, but such references are not intended to indicate in any way that we or the applicable owner will not assert, to the fullest extent under applicable law, our or its rights or the rights of the applicable licensor to these trademarks, trade names, and service marks. We do not intend our use or display of other parties' trademarks, trade names or service marks to imply a relationship with, or endorsement or sponsorship of us by, any other parties.

ROUNDING ADJUSTMENTS

Certain monetary amounts, percentages, and other figures included elsewhere in this prospectus have been subject to rounding adjustments. Accordingly, figures shown as totals in certain tables or charts may not be the arithmetic aggregation of the figures that precede them, and figures expressed as percentages in the text may not total 100% or, as applicable, when aggregated may not be the arithmetic aggregation of the figures that precede them.

LETTER FROM DAVID DEAN HALBERT, FOUNDER, CHAIRMAN, AND CEO

Hello, my name is David Dean Halbert, and I am the Founder, Chairman, and CEO of Caris Life Sciences. Caris is the first and only company that I've founded without a business model. Our only purpose is to help patients live longer and have a better quality of life by applying personalized medicine to disease. We believe that precise, data-driven, and personalized molecular information is crucial to eradicating chronic health conditions.

As a science-focused company, Caris has been at the forefront of precision medicine from the beginning and has driven the industry forward through our focus on science and investments into technology, instrumentation, facilities, and people. When I started Caris, next-generation sequencing, and other technologies needed to realize the benefits of personalized medicine, did not exist. However, we have benefited from tremendous advances in sequencing technology, cloud computing, and AI technologies to power our expertise and insights in molecular biology. We believe that these advances provide an unmatched resource to develop the next generation of precision medicine solutions.

Our platform is built on the premise that more data enables us to answer questions about biology that could not be answered until now due to limited or narrow information. In the course of completing over 6.5 million tests on over 849,000 cases, we have generated over 13 quadrillion molecular datapoints and measured over 38 billion molecular markers. We measure billions of data points per clinical case using Caris Assure, our universal blood-based whole exome/whole transcriptome sequencing solution, that we have created based on our vast experience in tissue sequencing. We are utilizing this tremendous amount of molecular information to pioneer the transition from intuitive medicine, where decisions for cancer patients are made based on prior experience or intuition, to empirical medicine, where decisions are based on the genetic make-up of each person's disease.

Driven by over 17 years of innovation to help build a better world, we have gained vast expertise in sequencing and data interpretation. We believe we were the first to offer comprehensive molecular profiling as standard practice when we launched whole transcriptome sequencing in 2019, the first to offer whole exome sequencing as standard practice when we introduced our whole exome sequencing solution in 2020, and the first to offer whole exome and whole transcriptome sequencing in blood when we broadly launched Caris Assure in the first quarter of 2024.

We have utilized AI and machine learning algorithms across our dataset to identify approximately 915,000 unique pathogenic mutations, of which only approximately 17,000 were previously identified, with approximately 130 novel pathogenic mutations found on average in each person. We can now identify a person's circulating pathogenic mutations and enable the design of a customized individualized therapy to that specific set of mutations. So, it becomes an individualized, customized immunotherapy. We believe this is going to create the opportunity for physicians to use our solutions to effectively prevent various chronic diseases before they ever get started at the earliest of stages.

It is a very exciting time because technology has finally advanced to the point where it enables this big idea. This is not something that could have been thought of in 2008 or even 2018 because the technologies were not available. Such as large sequencing capacity, AI, and the cloud, all of which have to be utilized to look at all of the different aberrations that are occurring at the molecular level with the outcomes. So over time, it's just going to get better and better and better. We run the same assay in both blood and tissue on every eligible patient sample every day, so the only changes to the assay will be at the bioinformatic level utilizing specially-designed algorithms to provide new insights.

While we specialize in oncology today, we also believe that since we have designed the Caris Assure platform as a universal assay that runs on every coding gene in the blood, it can be utilized to identify alterations that drive other chronic disease states such as cardiovascular disease, neurological conditions, metabolic disorders, and many others.

We exist in a very exciting time of unprecedented technological disruption to benefit mankind and "go where no man has gone before"—something I have described as the molecular revolution—leading me to be bullish on humanity. Never before have we seen a convergence of molecular sequencing power, sophisticated AI technologies, and massive computer processing capabilities. We will continue to harness these and other advanced technologies, pushing the boundaries of what is possible and leading the precision medicine revolution in healthcare.

We feel honored to have served hundreds of thousands of patients in their battle against cancer. I would like to thank our Caris Life Sciences family for their tireless work to help our patients and to build a company that is actively changing the practice of medicine. We are excited about our future and welcome new shareholders that share our vision and passion to improve the human condition.

David Dean Halbert, D.Sc. (h.c.)
Founder, Chairman, and CEO

PROSPECTUS SUMMARY

This summary highlights selected information contained elsewhere in this prospectus and is qualified in its entirety by the more detailed information and financial statements included elsewhere in this prospectus. It does not contain all of the information that may be important to you and your investment decision. You should carefully read this entire prospectus, including the sections titled “Risk Factors,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” and “Special Note Regarding Forward-Looking Statements” and our financial statements and related notes included elsewhere in this prospectus before making an investment decision. In this prospectus, unless context requires otherwise, references to “we,” “us,” “our,” “Caris,” or “the Company” refer to Caris Life Sciences, Inc. and its wholly owned subsidiaries.

Overview

We are a leading, patient-centric, next-generation AI TechBio company and precision medicine pioneer. We develop and commercialize innovative solutions to transform healthcare through the use of comprehensive molecular information and artificial intelligence/machine learning algorithms at scale. Our entire portfolio of precision medicine solutions is designed to benefit patients, with an initial focus on oncology, and serves the clinical, academic, and biopharma markets.

We founded Caris in 2008 with the belief and vision that combining a vast set of consistently generated molecular information with robust data-driven insights could realize the potential of precision medicine for patients. We have spent the last 17 years developing and building our portfolio of comprehensive, proprietary molecular profiling solutions and generating what we believe to be one of the largest and most comprehensive multi-modal clinico-genomic datasets in oncology based on the more than 6.5 million tests we have run on over 849,000 cases, which have generated measurements of over 38 billion molecular markers. Our platform is purpose-built to leverage the convergence of next-generation sequencing (“NGS”), artificial intelligence (“AI”) and machine learning (“ML”) technologies, and high-performance computing. The power of our differentiated Caris platform has enabled us to develop the latest generation of advanced precision medicine diagnostic solutions designed to address the entire cancer care continuum, including early detection, minimal residual disease (“MRD”) tracking, therapy selection, and treatment monitoring, as well as to create molecular signatures and discover and develop novel precision medicine therapeutics. Our current commercial product portfolio is focused on oncology and consists of MI Profile, our tissue-based molecular profiling solution that has generated the majority of our revenue to date, and Caris Assure, our novel, universal blood-based molecular profiling solution that was broadly launched in the first quarter of 2024 for therapy selection.

Dysfunctionality at the molecular level underlies every chronic disease, and this dysfunction is now measurable using techniques such as NGS. Cells are embedded within highly complex biological networks that govern all aspects of life, including how these cells grow, divide, interact, and die. These biological networks and their inherent functions, as well as dysfunctions, are controlled and directed at the molecular level. The precise molecular origins or contributors to a given biological dysfunction, however, are often unknown, and a comprehensive molecular profile is necessary to determine these origins. The central dogma of molecular biology states that genetic information flows in one direction, from DNA, to RNA, to proteins. Our approach is designed to accurately capture the full breadth of the DNA and RNA coding information in cells as well as protein expression through immunohistochemical (“IHC”) tests, constructing a fulsome mosaic of disease, and ultimately unlocking the potential for precision medicine therapeutics to guide individualized patient diagnoses and treatment.

We believe we are well-positioned to realize the full potential of our vision and optimally leverage our vast datasets due to the recent convergence of several advancements in biology, medicine, and technology: (1) the medical community’s understanding and appreciation of the molecular nature of cancer has accelerated in recent years, resulting in a continued increase in molecular profiling of different cancer types and stages; (2) NGS costs have declined, making NGS more accessible to the healthcare ecosystem; (3) cloud-computing architecture has enabled massive scalability, distributed real-time collaboration, and greater cost efficiency for the analysis of previously unmanageable amounts of data; and (4) AI and ML computational capabilities have advanced to allow more effective interrogation of large biological datasets. We believe that our early foresight to generate comprehensive data at scale over the past many years and build a robust, foundational infrastructure have uniquely positioned Caris to leverage the benefits of these

biological and technological advances to deliver transformative and advanced innovations in precision medicine and patient care into the future.

Our purpose-built, proprietary multi-omic profiling solutions capture and analyze molecular information from tissue and blood in a comprehensive manner. We provide whole exome sequencing (“WES”) (all 23,000 encoding DNA genes) and whole transcriptome sequencing (“WTS”) (all 61,000 RNA transcripts that encode proteins) on every eligible patient sample (a sample provided by ordering physicians that contains sufficient genetic material for profiling). Since launching our WTS solution in 2019 and WES solution in 2020, we have performed over 500,000 WES and WTS cases through May 2025, which we believe is more than any other company. We sequence at a sector-leading depth of coverage, which directly correlates with increased accuracy and detection of low frequency molecular markers of relevance. MI Cancer Seek, our U.S. Food and Drug Administration (“FDA”)-approved companion diagnostic assay to identify cancer patients who may benefit from treatment with targeted therapies (a component of MI Profile), consistently reaches 1,500 times depth of coverage for clinically relevant DNA genes, which is a higher sequencing depth than other assays available in the marketplace based on reported depths of coverage, and 300 times depth of coverage for the whole exome. Caris Assure features a raw average sequencing depth of 8,000 times for clinically relevant genes, similarly a higher sequencing depth than other assays available in the marketplace based on reported depths of coverage. We generate tens of billions of datapoints per clinical case to reveal an individualized molecular blueprint of the patient’s disease. We believe this approach best positions us to provide actionable treatment pathways from targeted therapies to drive superior clinical outcomes for patients while also generating a rich dataset to power insights and innovation. To our knowledge, we remain the only genomic profiling company to consistently utilize WES and WTS as standard practice on every eligible patient sample. We also evaluate protein molecular markers through an extensive menu of IHC tests performed in a tumor-type specific manner, which in combination with WES and WTS, provide a comprehensive view of a patient’s disease.

Our in-depth profiling of patient samples has led to the creation of what we believe to be one of the largest and most comprehensive multi-modal clinico-genomic datasets in oncology, including genomic data, clinical data, digitized slide images, and remnant tissue. As of March 31, 2025, we have run more than 6.5 million tests on over 849,000 cases, which have generated measurements of over 38 billion molecular markers. Leveraging high-powered computing and AI/ML algorithms, we, and our biopharma and research partners who use our data and bioinformatics services, analyze our datasets to determine the key molecular characteristics of a particular disease or dysfunction that drives disease, enabling signature identification and drug target discovery. As a leader in the transition to WES/WTS sequencing through our launch of a WTS solution in 2019 and a WES solution the following year, we believe we have more molecular data and information than any other company and are well-positioned to make precision medicine widely accessible.

Our molecular profiling solutions and the data generated by our multi-omic technology platform provide value to our more than 100 biopharma partners, such as Moderna, AbbVie, Xencor, and Merck KGaA, through partnerships that aim to increase the probability of technical and regulatory success of their therapeutic pipelines. In addition to biopharma, we leverage our datasets to partner with outside academic centers and researchers to further advance precision oncology research. The Caris Precision Oncology Alliance (“Caris POA”), which we established in 2015, is a growing network of leading cancer centers and research consortia across the globe that collaborate to advance precision oncology and biomarker-driven research, with its members working together to establish and optimize standards of care for molecular testing through innovative research to improve clinical outcomes for cancer patients. As of March 31, 2025, the Caris POA was comprised of 96 members, including 45 National Cancer Institute (“NCI”)-designated comprehensive cancer centers. This academic-industry collaborative network has been exceptionally productive with over 145 peer-reviewed manuscripts published since the beginning of 2022. Close connectivity with this vast network of key opinion leaders (“KOLs”) in oncology clinical care, research, and drug development has enabled us to remain at the forefront of precision oncology and closely attuned to the key needs of the most sophisticated researchers.

Our Caris platform is designed to create a virtuous cycle that can enable continued innovation and improved impact for patients and physicians. We believe our comprehensive approach to profiling will continue to drive demand for our genomic profiling capabilities, leading to further expansion of our clinico-genomic datasets, which provide additional valuable inputs to develop and enhance our solutions, with the

ultimate goal of contributing to improved patient results. This continuous feedback loop enabled us to develop Caris Assure, which utilized genomic data generated by MI Profile to inform our blood-based bioinformatics algorithms, allowing us to detect previously unknown features and signals in the blood that provide advanced insights into disease development. We believe we will be able to further leverage this process to continue meaningful innovation in precision oncology as well as other chronic disease states, including cardiology, neurology, and metabolic conditions.

Our global annual clinical case volume has been growing rapidly, with year-over-year growth of 29% in 2022, 32% in 2023, 26% in 2024, and 31% in the first quarter of 2025, primarily driven by MI Profile. With our broad commercial launch of Caris Assure for therapy selection in the first quarter of 2024 and the FDA approval of MI Cancer Seek as a companion diagnostic in the fourth quarter of 2024 followed by the broad commercial launch of MI Cancer Seek in the first quarter of 2025 as the NGS component of MI Profile, we believe that increased profiling volumes will meaningfully contribute to our growth in 2025 and beyond. For the years ended December 31, 2024 and 2023, we generated total revenue of \$412.3 million and \$306.1 million, respectively. For the three months ended March 31, 2025 and 2024, we generated total revenue of \$120.9 million and \$80.7 million, respectively. We have incurred net losses and negative cash flows from operations since inception. For the years ended December 31, 2024 and 2023, we incurred net losses of \$257.1 million and \$341.4 million, respectively. For the three months ended March 31, 2025 and 2024, we incurred net losses of \$102.6 million and \$111.0 million, respectively. Our Adjusted EBITDA was \$(189.6) million and \$(255.3) million for the years ended December 31, 2024 and 2023, respectively. Our Adjusted EBITDA was \$(36.2) million and \$(70.1) million for the three months ended March 31, 2025 and 2024, respectively. For additional information regarding Adjusted EBITDA, a non-GAAP financial measure, see “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Non-GAAP Financial Measures.” We expect to incur additional net losses in the near future, and our expenses will increase as we continue to invest in developing new solutions, expand our organization, and increase our marketing efforts to continue to drive market adoption of our solutions. These investments, together with general and administrative expenses, have resulted in negative cash flows from operations of \$245.2 million, \$276.1 million, \$31.3 million, and \$73.9 million for the years ended December 31, 2024 and 2023 and the three months ended March 31, 2025 and 2024, respectively. Our free cash flow was \$(253.6) million and \$(298.4) million for the years ended December 31, 2024 and 2023, respectively, and, \$(34.0) million and \$(75.7) million for the three months ended March 31, 2025 and 2024, respectively. For additional information regarding free cash flow, a non-GAAP financial measure, see “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Non-GAAP Financial Measures.” Additionally, as of March 31, 2025, we had cash, cash equivalents, and short-term marketable securities of \$33.4 million, and the aggregate principal amount of debt outstanding under our existing term loan was \$400.0 million. For additional information regarding our liquidity and capital resources, see “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources.”

Industry Overview

Addressing the complexity of cancer remains a major challenge in healthcare and a critical area of unmet medical need, despite enormous investments in research and development (“R&D”), and the introduction of new oncology therapeutics and treatments. The molecular revolution is upending the traditional paradigm of complex workflows of diagnosis, treatment, and monitoring of diseases, which largely uses a symptomatic, reactive approach to medicine. Over the last several decades, significant advances in genomics, proteomics, molecular technology, and computing power have enabled a comprehensive, multi-omic approach to the molecular profiling of diseases, both efficiently and at scale. The information provided by comprehensive molecular profiling is driving a revolution in medicine, where molecular information is used to guide individualized patient diagnoses and treatment.

Comprehensive molecular profiling entails evaluating thousands of potential biomarkers, including DNA, RNA, proteins, and other molecular and clinical information for characteristics unique to a particular patient’s disease. Given the complexity of a cancer’s origin and drivers, comprehensive molecular information incorporating DNA, RNA, and protein profiles can help provide the most robust picture of a patient’s disease and potential treatment pathways. WES/WTS streamlines the patient experience and clinical decision-making and offers increased value to patients, physicians, and payers. We believe WES/WTS

provides the most efficient and cost-effective way to obtain the maximum information on a patient's cancer at the start of the patient journey. It enables accurate identification of a greater number of actionable genomic alterations that can be leveraged to match patients to the most effective treatments, yielding a higher probability of response and providing comprehensive predictive and prognostic information.

While the molecular revolution has already changed the way cancer is being diagnosed and treated, we believe that molecular testing faces several major challenges in its current form, which have hindered broader adoption of precision oncology. These challenges include: (1) targeted panels are subject to missing information and significant variability; (2) lack of consistent RNA profiling; (3) lack of clonal hematopoiesis ("CH") derived variant subtraction technology in current blood assays, contributing to the inability to identify false positive mutations that are not tumor-derived; (4) disparate data sets collected across testing modalities; (5) logistical drawbacks and sensitivity limitations of current MRD assays; and (6) false positives and a lack of early-stage sensitivity with current multi-cancer early detection ("MCED") assays.

As a result of these challenges, clinicians may make critical treatment decisions based on incomplete and/or inaccurate information and analytics, potentially resulting in suboptimal outcomes. We believe that our comprehensive molecular profiling solutions and the data generated by our multi-omic technology platform is well-suited to address the limitations and challenges of today's molecular testing alternatives.

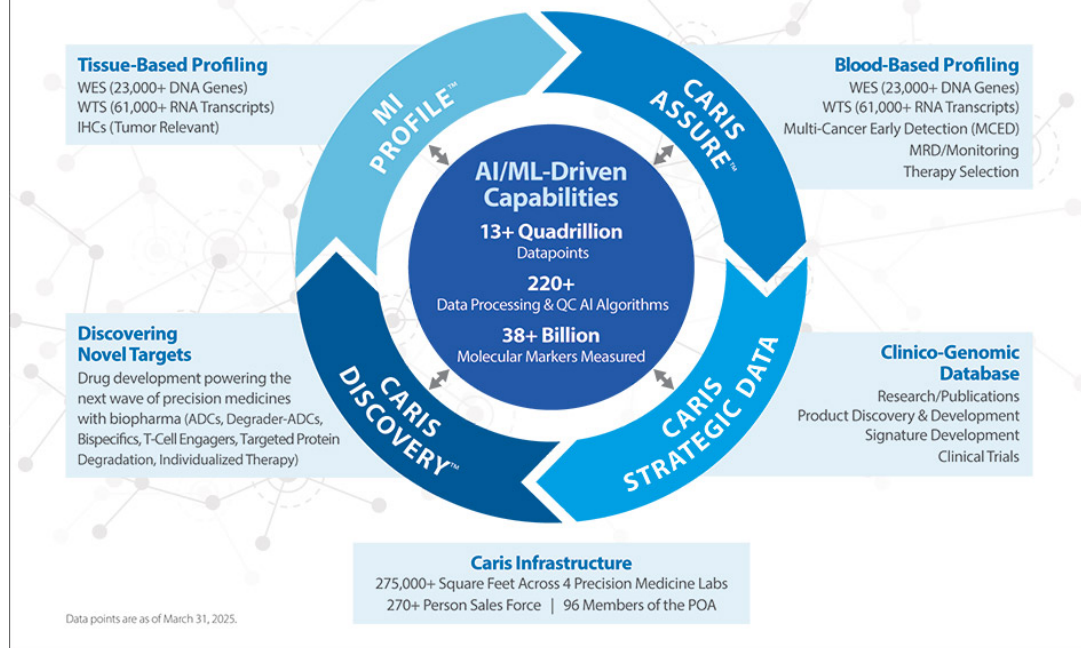
The Caris Platform

We are leading a molecular revolution and developing the latest generation of advanced precision medicine information solutions that we believe have applicability across the care continuum for a broad range of conditions. The fundamental differentiation of the Caris platform and our business model is the depth, breadth, and scale of data, including how that data is integrated vertically and horizontally across our business, as well as the resulting innovation which it fuels.

Our multi-omic technology platform is built on the following pillars: (1) Caris Assure; (2) MI Profile; (3) Caris Discovery; (4) Caris Strategic Data; and (5) Caris Infrastructure. These five pillars are designed to work together to create a virtuous cycle that can enable continued innovation and improved impact for patients and physicians. We believe our comprehensive approach to profiling will continue to drive demand for our genomic profiling capabilities, leading to further expansion of our clinico-genomic datasets, which provide additional valuable inputs to develop and enhance our solutions, with the ultimate goal of contributing to improved patient results. We believe this continuing cycle will deepen our competitive advantage and allow us to achieve meaningful innovation and business success in precision oncology, while illuminating a path to precision medicine for other chronic disease states, including cardiology, neurology, and metabolic conditions.

The Caris Platform

Harnessing the Power of AI/ML to Create Precision Medicine Solutions



We believe our growth and competitive differentiation are driven by the five pillars of our platform, each of which are both a product of the upstream data and a foundation to further innovation and data generation across the platform:

- Caris Assure.** Our universal blood-based WES/WTS profiling solution is designed to deploy a single assay across the entire continuum of cancer care, including early detection, MRD tracking, therapy selection, and treatment monitoring, and generates over 42 billion datapoints, spanning 168,000 molecular markers, per clinical case. We leveraged our experience and data from MI Profile to create Caris Assure, which enables us to understand how a patient's disease started, what therapies the tumor may be sensitive to, how the tumor is transforming to resist therapies, and how best to control or cure the disease.
- MI Profile.** Our tissue-based profiling solution for therapy selection includes MI Cancer Seek, our FDA-approved companion diagnostic WES/WTS profiling assay, and IHC protein expression testing. Our WES/WTS profiling solution generates over 28.8 billion datapoints, spanning 84,000 molecular markers, per clinical case.
- Caris Discovery.** The combination of our data and our AI enables us to discover previously unknown drug targets for antibody-directed therapies (such as antibody drug conjugates, degrader-antibody conjugates, and T-cell engagers), small molecules, targeted protein degradation, synthetic lethal interactions, and cell therapy. In addition, we believe Caris Discovery is well-positioned for neoantigen discovery for personalized therapy development given our ability to detect variants, insertions, and deletions by WES and to assess gene expression and detect fusions by WTS on every patient's tumor.
- Caris Strategic Data.** As of March 31, 2025, we have run more than 6.5 million tests that have measured over 38 billion molecular markers from over 13 quadrillion datapoints. To assist us with analyzing the data we generate, we utilize over 220 AI and AI/ML tools across our

clinical testing, R&D, and biopharma business. These tools include over 50 clinical sequencing automation and variant calling AIs, over 100 RNA expression AI signatures, approximately 20 multi-omic AI/ML therapy response predictors, two ADAPT target discovery AI/ML algorithms, 37 digital image AI/ML classifiers, and 12 AI/ML support tools. The breadth and depth of our data assets, along with our ability to create algorithms and discover signatures, represent a deep competitive moat for us.

- **Caris Infrastructure.** We have a well-developed laboratory, R&D, and sales infrastructure that we believe is foundational to our business. Our infrastructure includes substantial testing capacity and a dedicated workforce to support our R&D efforts, sales activity, and expansion.

Our Market Opportunity and Vision for Leveraging Molecular Information

We believe we are well-positioned to initially pursue a total addressable market in U.S. oncology of approximately \$150 billion through the provision of precision medicine solutions across the entire cancer care continuum, as well as offerings to support biopharma drug discovery and development. While our tissue-based molecular profiling solution for cancer therapy has generated the majority of our revenue to date, we believe the launch of our blood-based profiling offering for therapy selection, our expansion of our blood-based profiling offering beyond therapy selection in particular, and further leveraging our platform to provide solutions to biopharma companies will enable us to benefit significantly from this large market opportunity. Our estimated total addressable U.S. oncology market, which is based on a market study by Nephron Research LLC that we commissioned, is comprised of opportunities in the following areas:

- **Early detection:** approximately \$100 billion.
- **Therapy selection:** approximately \$8 billion.
- **MRD tracking and treatment monitoring:** approximately \$28 billion.
- **Core biopharma services:** approximately \$4 billion.
- **Data services for biopharma:** approximately \$10 billion.

We also believe there is a large market opportunity for our platform in other chronic disease states beyond oncology, including cardiology, neurology, and metabolic conditions, based on the fundamental premise that approaching blood-based disease detection with a comprehensive WES/WTS approach enables examination of biomarkers that go beyond oncology. For additional information, see “Business—Our Market Opportunity and Vision for Leveraging Molecular Information.”

The Caris Advantage

We believe our approach is differentiated and we have a competitive advantage because:

- *We purpose-built our Caris platform to put the patient first and make comprehensive precision medicine a reality.*
- *We are a leading provider of tissue-based molecular profiling, including through our FDA-approved companion diagnostic tissue-based profiling solution, MI Cancer Seek.*
- *Our novel, universal blood-based profiling solution, Caris Assure, is unique in the market and poised for rapid adoption.*
- *We have built what we believe to be one of the largest and most comprehensive multi-modal clinico-genomic datasets in oncology.*
- *Our first mover advantage, specialized commercial channel, robust infrastructure, and deep research collaborations enable our leadership and provide us with the ability to scale for future growth.*
- *We are led by a founder with significant experience building and scaling businesses in the healthcare industry and a management team with scientific expertise.*

Our Strategies

To achieve our goal of leading a molecular revolution and developing the next generation of precision medicine information solutions for a broad range of conditions across the care continuum, we plan to:

- *Drive the continued adoption and use of our tissue-based profiling and expand blood-based profiling offering into early detection, MRD, and monitoring.*
- *Utilize the data generated by our existing solutions to develop new solutions with additional revenue using our existing sales channel.*
- *Leverage our platform to provide solutions to biopharma companies to drive advances in personalized medicine and accelerate the development of novel therapeutics.*
- *Continue to expand and enrich our clinico-genomic datasets to drive breakthrough science and develop new solutions.*
- *Maximize market reach through our regulatory approval and reimbursement strategy.*
- *Capitalize on the ultimate potential of our novel, universal blood-based profiling solution, Caris Assure, and broader innovation platform in other chronic disease states beyond oncology, including in cardiology, neurology, and metabolic conditions.*

Caris Assure—Our Universal Blood-Based Profiling Solution

Caris Assure is our novel, universal blood-based solution that is purpose-built to extend across the entire continuum of cancer treatment, including early detection, monitoring of MRD and recurrent cancers, and precision selection of molecularly targeted therapies. Caris Assure also has applications in therapeutic discovery and development. We believe Caris Assure represents the most comprehensive blood-based solution on the market, featuring over 23,000 gene coverage at a raw average sequencing depth of coverage of 8,000 times for clinically relevant genes, as compared to other blood-based offerings in the market that only assess 500 to 1,000 genes from DNA. Caris Assure performs WES and WTS for every eligible patient blood sample. We integrate WES and WTS with sophisticated AI and ML technologies to offer diagnostic, prognostic, and predictive utility in a single test.

For therapy selection, in addition to sequencing cell-free DNA and cell-free RNA isolated from the plasma to identify somatic tumor variants, Caris Assure also sequences genomic nucleic acid (gDNA and gRNA) isolated from the white blood cells, or buffy coat, from each sample. Sequencing the buffy coat in addition to the plasma allows Caris Assure to identify incidental germline mutations as well as CH mutations. CH mutations are age-related non-malignant mutations that occur in a substantial portion of the population, are not cancer-derived and are present in both the plasma and buffy coat and cannot be identified from sequencing plasma alone. Caris Assure “subtracts” CH mutations in the reporting of somatic tumor variants. This lessens the risk of incorrectly interpreting CH or germline mutations as tumor-derived and results in fewer false positive diagnoses and more accurate and effective treatment recommendations. We believe that CH subtraction is of critical importance to ensure optimal cancer care because of the prevalence of CH mutations. By identifying and distinguishing variants that are not from the tumor itself and, therefore not relevant to therapeutic decision-making, the CH subtraction feature of Caris Assure further separates our solution from other liquid biopsy tests currently on the market that do not sequence the white blood cells and therefore cannot definitively distinguish CH mutations from tumor-derived mutations. To our knowledge, Caris Assure is the only commercially available tissue-naïve blood-based profiling assay that directly accounts for CH mutations instead of using algorithmic approximations, which we believe gives Caris Assure a differentiated ability to drive improved therapy selection.

Customers for Caris Assure include treating physicians as well as researchers and biopharma companies. The same benefits that blood-based WES, WTS, and CH subtraction bring to patients in the clinical setting also offer significant and previously unavailable advantages to biopharma companies.

We initiated a broad commercial launch of Caris Assure for therapy selection in the first quarter of 2024 and currently offer the solution as a laboratory developed test (“LDT”), which the FDA has historically considered a form of medical device, as an *in vitro* diagnostic (“IVD”) test intended for clinical use and

designed, manufactured, and used within a single laboratory. The FDA has historically exercised enforcement discretion and not required marketing authorization for certain kinds of LDTs. Accordingly, we have not obtained FDA marketing authorization for Caris Assure. We may decide to seek FDA marketing authorization for certain of our solutions in the future, including Caris Assure for therapy selection, depending in part on the ultimate outcome of litigation over the FDA's authority over LDTs. For additional information, see "Business—Government Regulation—U.S. Food and Drug Administration" and "Risk Factors—We have current solutions marketed as LDTs and plan to launch future solutions as LDTs. The regulation of LDT products in the United States remains subject to significant uncertainty, and if we fail to comply with any new or existing legal requirements governing our LDT solutions, our business, financial condition, and results of operations could be adversely affected." We have Medicare reimbursement and various levels of commercial payer adoption and/or reimbursement coverage for Caris Assure for therapy selection across the United States. The current pricing of Caris Assure for therapy selection under Medicare's Molecular Diagnostic Services Program ("MoIDX") is \$3,649.

Caris Assure for therapy selection is available in all U.S. states (other than New York, where we intend to apply in 2025 for approval from New York State's Clinical Laboratory Evaluation Program ("NY CLEP")) and in Puerto Rico. We also offer Caris Assure for therapy selection internationally through distributors and direct contracts with hospital systems, where permitted by applicable regulations.

Our Differentiated Approach to Address the Entire Cancer Care Continuum Through a Single Blood Test

Our universal approach to blood-based profiling is unique. Liquid biopsies can be used across the care continuum, including for: therapy selection in the advanced/metastatic setting; MRD and monitoring in the curative/adjuvant setting; and early detection in the diagnosis setting. Because many of our competitors' liquid biopsy assays are designed to address only a single portion of this care continuum, in order to develop products for other portions of the care continuum, our competitors must invest in the development of new wet lab assays and generate disparate datasets across the patient journey for patients, oncologists, and researchers. In contrast, Caris Assure is designed as a single test applicable across the entire patient journey. To our knowledge, there is no other assay on the market that can be applied as broadly as Caris Assure. We believe that our approach will enable us to scale our R&D infrastructure to analyze increasingly larger testing volumes, process expanding datasets, and reach economies of scale in liquid biopsy across the entire cancer care continuum.

We believe that one of the most promising uses for Caris Assure is for detection of cancer at very early stages, such as stage 1 or stage 2. Our detection of cancer at very early stages would enable clinicians to treat disease sooner, which could significantly improve patient outcomes. We believe that Caris Assure for early detection of cancers will initially be available for early detection of certain types of cancers, such as breast cancer and colon cancer, and then we intend to expand Caris Assure for full MCED indications. In an internal validation study conducted by us, the performance of our Assure Blood-based Cancer Detection ai ("ABCDai") for MCED ("ABCDai-MCED") demonstrated a high level of sensitivity at a specificity that reduces the burden of false positives. For additional information on the validation study, see "Business—Our Solutions—Caris Assure—Our Universal Blood-Based Profiling Solution—Caris Assure for Early Detection."

For MRD, our detection methodology based on ABCDai takes a tumor naïve approach, and therefore does not require a bespoke panel to be created to track the recurrence of a patient's tumor. This approach means that our MRD assay can be used without the need for a tissue sample and enables faster turn-around-time, enabling patients to be informed of additional therapy sooner to combat their disease.

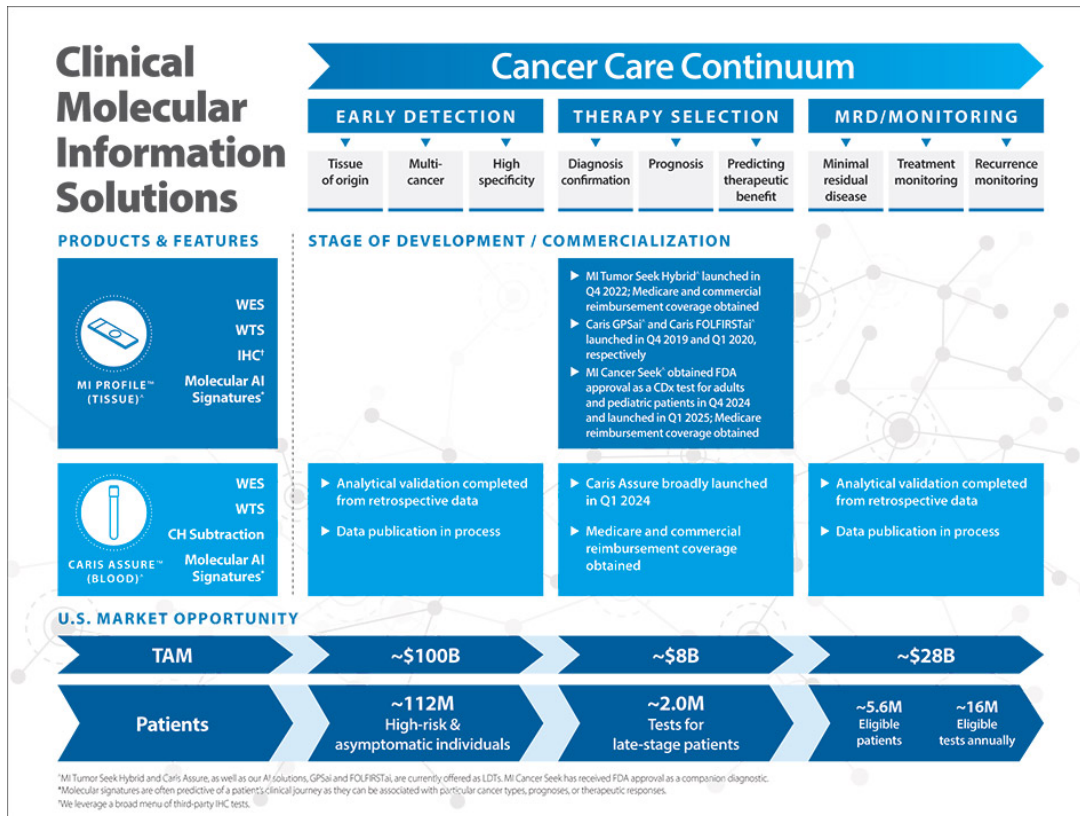
MI Profile—Our Tissue-Based Profiling Solution

MI Profile is our tissue-based molecular profiling solution for cancer therapy selection, with over one million tests performed on approximately 146,500 clinical cases in 2024 and an additional approximately 40,000 clinical cases in the three months ended March 31, 2025. As of March 31, 2025, we have performed over 6.5 million tissue-based tests on over 790,000 clinical cases since inception. MI Profile includes MI Cancer Seek, our FDA-approved companion diagnostic WES/WTS NGS assay, and IHC protein expression testing.

Customers for MI Profile include treating physicians as well as researchers and biopharma companies. The information generated from profiling the patient's tissue is used to create an interpretative report based on our bioinformatics pipeline and recommend individualized therapies for cancer patients. Our goal is to maximize the information generated and corresponding clinical utility for patients from the limited available tumor tissue. Molecular profiling also has broad applications for our biopharma partners, including prospective screening, retrospective testing and deep translational analyses, stratification of patients for existing or future trials, and treatment monitoring.

We have obtained Medicare and commercial reimbursement for MI Profile. We have also obtained a premarket approval ("PMA") from the FDA for a companion diagnostic and tumor profiling designation for MI Cancer Seek, a WES/WTS NGS assay that uses the whole exome for tumor mutational burden ("TMB") calling, and for which we have obtained a Proprietary Laboratory Analyses ("PLA") code, Current Procedural Terminology ("CPT") code 0211U, at a reimbursement rate of \$8,455. In the first quarter of 2025, we began to market MI Cancer Seek as the WES/WTS NGS component of MI Profile. We have obtained Medicare coverage for MI Cancer Seek for CPT code 0211U under the NGS NCD. We currently offer MI Tumor Seek Hybrid, which is a WES/WTS NGS LDT assay, as an alternative assay if a specimen does not meet the eligibility requirements for MI Cancer Seek.

MI Profile, including our MI Cancer Seek assay and proprietary clinical molecular signatures GPSai and FOLFIRSTai, is available in all U.S. states and in Puerto Rico. We also offer MI Profile internationally in over 40 countries through distributors and direct contracts with hospital systems, where permitted by applicable regulations.



Caris Discovery

Caris Discovery is our drug target and therapeutic discovery business. Caris Discovery leverages our profiling solutions, multi-modal clinico-genomic datasets, wet lab facilities, proprietary Adaptive

Dynamic Artificial Polyligand Targeting (“ADAPT”) platform, and AI/ML-enabled *in silico* analyses to identify potential drug targets and develop therapeutics. We launched Caris Discovery in 2022 to partner with biopharma partners to address the lack of novel cancer-specific targets and the herding of biopharma pipelines around a discrete number of lower-risk targets. Caris Discovery is disease- and modality-agnostic and can be applied to any therapeutic modality, including antibody-directed therapies (such as antibody drug conjugates, degrader-antibody conjugates, and T-cell engagers), small molecules, targeted protein degradation, synthetic lethal interactions, and cell therapy. We have achieved external validation of our Caris Discovery approach through strategic partnerships with established biopharma companies, such as Merck KGaA and Xencor, to develop therapeutics against novel targets that emanate from our molecular insights and proprietary technology. In addition, we believe Caris Discovery is well-positioned for neoantigen discovery for personalized therapy development given our ability to detect variants, insertions, and deletions by WES and to assess gene expression and detect fusions by WTS on every patient’s tumor.

Our proprietary repositories of tissue and data, each of which we believe to be at an unmatched scale, are a resource that could not have been amassed without our underlying commercial profiling business, and as such are a significant differentiator and enabler of our discovery efforts.

Caris Strategic Data

Data and molecular information are at the core of every aspect of our business. Our team of more than 60 data scientists deploy our proprietary advanced AI/ML algorithms to decipher unique features from our resulting clinico-genomic datasets, helping us decode and further unravel the molecular complexity of disease. Our 17-year history of utilizing AI and ML algorithms, together with the breadth and depth of our clinico-genomic datasets, provide us a significant advantage in sophisticated analysis of cancer, and a foundation that we believe will have applications in additional disease states.

The tremendous amount of data generated through our profiling solutions, which we have deidentified for research use, provides us a differentiated capability to advance precision oncology research through many business models. For example, we launched our data licensing business in late 2022, through which we license deidentified data that we have generated from our clinical profiling business to biopharma companies with the aim of generating insights directly responsible for superior clinical outcomes for patients. We have a rich pipeline of data opportunities that we believe will deliver new partnerships, as we continue to introduce biopharma companies to this unique data offering. Additionally, through the Caris POA, which is a growing network of leading cancer centers and research consortia across the globe, we support research partner engagement, collaboration opportunities, and the advancement of precision oncology research. Since its establishment in 2015, the Caris POA has grown to comprise 96 members as of March 31, 2025, including 45 NCI-designated comprehensive cancer centers that work collaboratively toward a common goal: to advance tumor profiling and establish and optimize standards of care for molecular testing through innovative research to improve clinical outcomes for cancer patients. We estimate that the members of the Caris POA have over 3,000 oncologists in over 650 locations that treat more than 650,000 new cancer patients annually.

Future Assays

Caris aims to develop the next generation of precision medicine tools that will allow us to transition from intuitive medicine to empirical medicine. As a leader in the transition to WES/WTS sequencing through our launch of a WTS solution in 2019 and a WES solution the following year, we believe we have more molecular data and information than any other company and are well-positioned to make precision medicine widely accessible. For example, we are developing Caris ChromoSeq, an assay to detect and analyze hematological (blood) cancers using whole genome sequencing (“WGS”) and WTS. We are internally validating this assay and developing it for commercial launch. We are also working to develop and validate the plasma portion of our Caris Assure assay for full germline testing. Additionally, we are using our molecular data to develop ESPai, an AI/ML algorithm to predict the risk of recurrence of early-stage breast cancer. We have obtained the samples and clinical data from the National Surgical Adjuvant Breast and Bowel Project and the ECOG-ACRIN Cancer Research Group. We are currently in the process of creating two AI/ML models for ESPai using these samples and are working to obtain additional samples for external

validation studies. We are initially creating a model for late recurrence (five to 15 years following diagnosis), but we are also in the beginning stages of creating a model for early recurrence (zero to five years following diagnosis).

Caris Infrastructure

We believe our well-developed laboratory, R&D, and sales infrastructure is foundational to our business. We have substantial testing capacity, including over 275,000 square feet of space across four precision medicine laboratories with throughput capabilities of over one trillion reads per day generated by 50 NovaSeq sequencing systems. We believe this capacity provides us with ample capability to manage our current operations and future growth. We also have a dedicated R&D infrastructure, including a specialized laboratory and over 200 employees dedicated to R&D efforts. In addition to our internal research, we regularly partner with outside academic centers and researchers, including through the Caris POA. Additionally, to support our sales activity and expansion, as of March 31, 2025, we have assembled a targeted sales organization in the United States of over 270 sales team members and nearly 50 highly trained Ph.D. or M.D. molecular science liaisons (“MSLs”) who focus on physician and provider education. We believe that our robust, foundational infrastructure, together with our expansive multi-modal clinico-genomic datasets, has uniquely positioned Caris to deliver transformative and advanced innovations in precision medicine and patient care into the future.

Summary Risk Factors

Participating in this offering involves substantial risk. Our ability to execute our strategy is also subject to certain risks. The risks described under the heading “Risk Factors” included elsewhere in this prospectus may cause us not to realize the full benefits of our strengths or may cause us to be unable to successfully execute all or part of our strategy. Some of the most significant challenges and risks we face include the following:

- The precision medicine industry is highly competitive and subject to rapid change.
- We have incurred significant losses since inception, expect to incur losses in the future, and may not be able to generate sufficient revenue to achieve and maintain profitability.
- Our current or future solutions may not achieve or maintain sufficient commercial market acceptance.
- Our solutions may not perform as expected, and the results of our validation studies or our clinical trials may not support the launch or use of our solutions and may not comply with the requirements, or be replicated in later trials required, for any necessary or desirable marketing authorizations. This could adversely affect our business, financial condition, results of operations, and growth prospects.
- Our current revenue is primarily generated from the continued adoption and use of our tissue-based profiling solution.
- Our future success and growth will depend in part on market acceptance and commercial success of our MI Cancer Seek and Caris Assure solutions. We may be unsuccessful in continuing the commercialization of MI Cancer Seek or Caris Assure, which would adversely affect our business, financial condition, results of operations, and growth prospects.
- If we are unable to support demand for MI Profile, Caris Assure, and any other solutions we develop, including ensuring that we have adequate capacity to meet increased demand, or if we are unable to successfully manage our anticipated growth, our business could suffer.
- Our results of operations may fluctuate significantly, which makes our future results of operations difficult to predict and could cause our results of operations to fall below expectations or any guidance we may provide.
- If our solutions, or solutions we develop in the future, do not receive adequate coverage and reimbursement from third-party payers, including government and commercial payers, our

ability to expand access to our solutions beyond our existing sales channels, and thus our overall commercial success, will be limited.

- Our billing, collections, and claims processing activities are complex and time-consuming, and any delay in transmitting and collecting claims or failure to comply with applicable billing requirements could have an adverse effect on our future revenue.
- We rely on a limited number of third-party suppliers or, in many cases, sole suppliers, for some of our next-generation sequencers, lab materials, reagents, and supplies, and we may not be able to find replacements or immediately transition to alternative suppliers if necessary.
- If we or our partners fail to comply with healthcare and other applicable laws and regulations, we could face substantial penalties and sanctions and our business, reputation, financial condition, and results of operations could be adversely affected.
- If we are unable to obtain and maintain intellectual property protection for our technology, or if the scope of the intellectual property protection we obtain is not sufficiently broad, our competitors could develop and commercialize technology and products similar or identical to our solutions, and our ability to successfully commercialize our solutions may be impaired.
- We have incurred substantial indebtedness, and we may not generate sufficient cash flow from operations to meet our debt service requirements, continue our operations, and pursue our growth strategy, and we may be unable to raise capital when needed or on acceptable terms.
- After this offering, our executive officers, directors, and principal shareholders, including, in particular, David D. Halbert, our Founder, Chairman, and Chief Executive Officer, will continue to have the ability to control or significantly influence matters submitted to shareholders for approval, which could limit the ability of our other shareholders to affect the outcome of key corporate decisions and transactions, including a change of control.

Before you invest in our common stock, you should carefully consider all the information in this prospectus, including matters set forth in the section titled “Risk Factors.”

Corporate Information

We were founded in 2008 when we entered the field of precision oncology through our acquisition of Molecular Profiling Institute, a Delaware-incorporated molecular life sciences company. We were incorporated under the laws of the Cayman Islands in October 2011 as Caris Life Sciences, Ltd. and in July 2020, we changed our name to Caris Life Sciences, Inc. and re-domiciled to be incorporated in Texas.

Our principal executive offices are located at 750 West John Carpenter Freeway, Suite 800, Irving, Texas 75039, and our telephone number is (866) 771-8946. Our website address is www.carislifesciences.com. The information on, or that can be accessed through, our website is not incorporated into this prospectus. You should not consider information contained on our website to be part of this prospectus in deciding whether to purchase shares of our common stock.

Implications of Being an Emerging Growth Company

We qualify as an “emerging growth company” as defined in the Jumpstart Our Business Startups Act of 2012, as amended (the “JOBS Act”). We will remain an emerging growth company until the earliest to occur of: (i) the last day of the fiscal year in which we have at least \$1.235 billion in total annual gross revenue; (ii) the last day of the fiscal year in which we are deemed to be a “large accelerated filer” as defined in Rule 12b-2 under the Securities Exchange Act of 1934, as amended (the “Exchange Act”), which would occur if the market value of our common stock held by non-affiliates exceeded \$700 million as of the last business day of the second fiscal quarter of such year; (iii) the date on which we have issued more than \$1.0 billion in non-convertible debt securities during the prior three-year period; and (iv) the last day of the fiscal year ending after the fifth anniversary of the date of the completion of this offering. An emerging growth company may take advantage of specified reduced reporting requirements and is relieved of certain other significant requirements that are otherwise generally applicable to public companies. As an emerging growth company:

- we will present in this prospectus only two years of audited financial statements, plus any required unaudited financial statements, and related management’s discussion and analysis of financial condition and results of operations;
- we will avail ourselves of the exemption from the requirement to obtain an attestation and report from our auditors on the assessment of our internal control over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act of 2002 (“SOX Section 404”);
- we will provide less extensive disclosure about our executive compensation arrangements; and
- we will not be required to hold shareholder non-binding advisory votes on executive compensation or golden parachute arrangements.

Accordingly, the information contained herein may be different than the information you receive from our competitors that are public companies or other public companies in which you hold stock.

In addition, the JOBS Act provides that an emerging growth company can delay the adoption of new or revised accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of this extended transition period for complying with new or revised accounting standards and, as a result, our results of operations and financial statements may not be comparable to those of companies that have adopted the new or revised accounting standards.

THE OFFERING	
Common stock offered by us	23,529,412 shares.
Option to purchase additional shares of common stock	We have granted the underwriters an option for a period of 30 days to purchase up to 3,529,411 additional shares of our common stock.
Common stock to be outstanding immediately after this offering	283,555,185 shares (or 287,084,596 shares if the underwriters exercise their option to purchase additional shares of common stock in full).
Reserved share program	At our request, the underwriters have reserved up to 5% of the shares of common stock offered by this prospectus, excluding the additional shares that the underwriters have a 30-day option to purchase, for sale, at the initial public offering price, to certain individuals identified by management, including certain of our directors, officers, employees and certain other parties related to us. If these persons purchase reserved shares it will reduce the number of shares of common stock available for sale to the general public. Any reserved shares of common stock that are not so purchased will be offered by the underwriters to the general public on the same terms as the other shares of common stock offered by this prospectus. For more information, see “Underwriting—Reserved Share Program.”
Use of proceeds	We estimate that the net proceeds from this offering will be approximately \$419.3 million (or \$483.3 million if the underwriters exercise their option to purchase additional shares of common stock in full), based on an assumed initial public offering price of \$19.50 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. We intend to use the net proceeds from this offering for general corporate purposes, including working capital, operating expenses, and capital expenditures. We also intend to use approximately \$5.8 million of the net proceeds to satisfy our anticipated tax withholding and remittance obligations related to the RSU Net Settlement (as defined below). We will have broad discretion in the way that we use the net proceeds from this offering. See the section titled “Use of Proceeds” for additional information.
Indication of interest	Neuberger Berman has indicated an interest in purchasing up to \$75.0 million of shares of our common stock being offered in this offering at the initial public offering price and on the same terms as the other purchasers in this offering. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters could determine to sell more, fewer, or no shares to Neuberger Berman, and Neuberger Berman could determine to purchase more, fewer, or no shares in this offering. The underwriters will receive the same underwriting discounts and commissions on

	any of our shares of common stock purchased by Neuberger Berman as they will from any other shares of common stock sold to the public in this offering.
Risk factors	See the section titled “Risk Factors” beginning on page 21 and the other information included in this prospectus for a discussion of factors you should consider carefully before deciding to invest in our common stock.
Proposed Nasdaq trading symbol	“CAI”
The number of shares of our common stock to be outstanding after this offering is based on 260,025,773 shares of our common stock outstanding as of March 31, 2025, after giving effect to (i) the Warrant Net Exercises, (ii) the Series E and F Issuance, (iii) the Preferred Stock Conversion, (iv) the issuance of the 2025 Convertible Notes and the related Notes Conversion, and (v) the RSU Net Settlement (each as defined below), and excludes: • 24,113,482 shares of our common stock issuable upon the exercise of options outstanding under our 2020 Incentive Plan, as amended and restated (the “2020 Plan”), as of March 31, 2025, at a weighted-average exercise price of \$10.18 per share; • 249,999 shares of our common stock issuable upon the exercise of options granted under our 2020 Plan subsequent to March 31, 2025, at an exercise price per share equal to the initial public offering price; • 236,290 shares of our common stock issuable upon the vesting and settlement of restricted stock units (“RSUs”) outstanding under our 2020 Plan as of March 31, 2025 that are subject to vesting conditions that are not satisfied in connection with this offering; • 15,406,122 shares of our common stock reserved for future issuance under our 2025 Incentive Award Plan (the “2025 Plan”), based on an assumed initial public offering price of \$19.50 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, which 2025 Plan will become effective in connection with this offering, as well as shares of our common stock that may be issued pursuant to provisions of our 2025 Plan that automatically increase the share reserve under our 2025 Plan (see the section titled “Executive Compensation” for additional information); and • 2,619,040 shares of our common stock reserved for future issuance under our 2025 Employee Stock Purchase Plan (the “ESPP”), based on an assumed initial public offering price of \$19.50 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, which ESPP will become effective in connection with this offering, as well as shares of our common stock that may be issued pursuant to provisions in our ESPP that automatically increase the share reserve under our ESPP. Unless otherwise indicated, all information in this prospectus assumes: • a one-for-four reverse stock split of our common stock effected as of June 1, 2025; • the net issuance of 16,053,866 shares of our Series C preferred stock upon the cashless exercise, based on an assumed initial public offering price of \$19.50 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, of warrants outstanding as of March 31, 2025 at a weighted-average exercise price of \$1.76 per share, which warrants are exercisable to purchase, at the holder’s election, shares of either our common stock or our Series C preferred stock and would have expired upon the completion of this offering unless earlier exercised (the “Series C Warrant Net Exercise”); • the net issuance of 844,429 shares of our common stock issuable upon the cashless exercise of warrants issued in April 2025 at an exercise price of \$0.04 per share (the “2025 Warrants”), based on an assumed initial public offering price of \$19.50 per share, which is the midpoint of the price range set forth on the cover page of this prospectus (the “2025 Warrant Net Exercise” and together with the Series C Warrant Net Exercise, the “Warrant Net Exercises”);	

- the conversion of (i) all shares of our convertible preferred stock outstanding as of March 31, 2025 (including the 16,053,866 shares of Series C preferred stock issued upon the Series C Warrant Net Exercise) and (ii) all shares of our Series E and Series F convertible preferred stock issued and sold in April 2025 (such issuance and sale, the “Series E and F Issuance”), into an aggregate of 220,956,018 shares of our common stock, based on an assumed initial public offering price of \$19.50 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, which conversion will occur immediately prior to and in connection with the completion of this offering (the “Preferred Stock Conversion”);
- the issuance of 2,236,331 shares of our common stock upon the conversion of senior convertible notes issued by us in April 2025 (the “2025 Convertible Notes”), based on an assumed initial public offering price of \$19.50 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, which conversion will occur immediately prior to and in connection with the completion of this offering (the “Notes Conversion”);
- the net issuance of 751,464 shares of our common stock underlying RSUs outstanding under our 2020 Plan that will vest in connection with this offering, after giving effect to the withholding of 296,786 shares of our common stock to satisfy the estimated tax withholding and remittance obligations (based on an assumed tax withholding rate of 28.3%) (the “RSU Net Settlement”);
- the effectiveness of our amended and restated certificate of formation and the adoption of our amended and restated bylaws, each of which will occur immediately prior to the completion of this offering;
- no exercise by the underwriters of their option to purchase additional shares of common stock; and
- no exercise of outstanding options or settlement of outstanding RSUs except as described above.

The number of shares of our common stock to be issued upon (i) the Preferred Stock Conversion, (ii) the 2025 Warrant Net Exercise, and (iii) the Notes Conversion, in each case, will vary based on the actual initial public offering price per share. In addition, the assumed 28.3% tax withholding rate applicable to the RSU Net Settlement used in this prospectus is an estimated blended withholding rate for all of the RSUs that will vest in connection with this offering. The estimates in this prospectus relating to the RSU Net Settlement and related share withholding may differ from actual results due to, among other things, the actual initial public offering price and other terms of this offering, actual forfeitures through the date of this prospectus, and actual tax withholding rates.

For illustrative purposes, the table below shows the number of shares of our common stock to be issued upon the occurrence of the foregoing transactions, based on an assumed initial public offering price of \$19.50 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and certain other prices as set forth in the table, and, in each case, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same. We will not know the actual initial public offering price and, as a result, the final number of shares of common stock to be issued in these transactions or the total number of shares of common stock to be outstanding immediately after this offering, until the determination of the initial public offering price and other terms of this offering at pricing.

<u>Initial Public Offering Price</u>	<u>Number of Shares of Common Stock to be Issued Upon the Preferred Stock Conversion, the 2025 Warrant Net Exercise, and the Notes Conversion</u>	<u>Common Stock to be Outstanding Immediately After this Offering</u>
\$19.00	226,477,763	285,996,170
\$19.50	224,036,778	283,555,185
\$20.00	221,714,820	281,233,227
\$21.00	218,414,372	277,932,779
\$22.00	215,949,252	275,467,659

SUMMARY CONSOLIDATED FINANCIAL AND OTHER DATA

The following tables set forth a summary of our historical consolidated financial and other data as of, and for the periods ended on, the dates indicated. The summary consolidated statements of operations data for the years ended December 31, 2024 and 2023 and the summary consolidated balance sheet data as of December 31, 2024 are derived from our audited consolidated financial statements and related notes included elsewhere in this prospectus. The summary consolidated statements of operations data for the three months ended March 31, 2025 and 2024 and the summary consolidated balance sheet data as of March 31, 2025 are derived from our unaudited condensed consolidated financial statements and related notes included elsewhere in this prospectus. In our opinion, the unaudited interim financial statements have been prepared on a basis consistent with our audited financial statements and contain all adjustments, consisting only of normal and recurring adjustments, necessary for a fair presentation of such interim financial statements.

Our historical results are not necessarily indicative of results that may be expected in the future. You should read these data together with our financial statements and related notes appearing elsewhere in this prospectus and the information in the section titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations.”

	Three Months Ended March 31,		Years Ended December 31,	
	2025	2024	2024	2023
	(in thousands, except share and per share data)			
Consolidated Statements of Operations Data:				
Revenue:				
Molecular profiling services	\$ 114,081	\$ 73,233	\$ 349,115	\$ 278,748
Pharma research and development services	6,834	7,444	63,145	27,380
Total revenue	120,915	80,677	412,260	306,128
Costs and operating expenses:				
Cost of services—Molecular profiling services	60,894	52,894	223,075	207,509
Cost of services—Pharma research and development services	2,958	1,669	10,403	9,309
Selling and marketing expense	39,829	39,609	152,602	142,925
General and administrative expense	52,119	44,354	169,386	149,053
Research and development expense	23,066	34,376	113,916	116,883
Total costs and operating expenses	178,867	172,902	669,382	625,679
Loss from operations	(57,952)	(92,225)	(257,122)	(319,551)
Other income (expense), net:				
Interest income	503	1,768	7,122	11,258
Interest expense	(12,782)	(9,290)	(50,025)	(31,610)
Changes in fair value of financial instruments	(32,333)	(11,064)	18,484	11,094
Other expense, net	(17)	(219)	(349)	(12,606)
Total other expense, net	(44,629)	(18,804)	(24,768)	(21,864)
Loss before income taxes and provision for income taxes	(102,581)	(111,028)	(281,890)	(341,415)
Provision for income taxes	—	—	—	—
Net loss	\$ (102,581)	\$ (111,028)	\$ (281,890)	\$ (341,415)
Adjustments of redeemable convertible preferred stock to redemption value	(24,262)	(23,113)	(96,367)	(121,112)
Net loss attributable to common shareholders	\$ (127,043)	\$ (134,141)	\$ (378,257)	\$ (462,527)
Net loss per share attributable to common shareholders, basic and diluted ⁽¹⁾	\$ (3.57)	\$ (3.80)	\$ (10.66)	\$ (13.24)

	Three Months Ended March 31,		Years Ended December 31,	
	2025	2024	2024	2023
	(in thousands, except share and per share data)			
Weighted-average shares used to compute net loss per share attributable to common shareholders, basic and diluted ⁽¹⁾	35,623,042	35,313,037	35,496,832	34,942,691
Pro forma net loss per share attributable to common shareholders, basic and diluted (unaudited) ⁽¹⁾⁽²⁾	\$ (0.39)		\$ (2.91)	
Weighted-average shares used to compute pro forma net loss per share attributable to common shareholders, basic and diluted (unaudited) ⁽¹⁾⁽²⁾	260,411,284		260,285,074	

(1) See Note 12 to our consolidated financial statements included elsewhere in this prospectus for an explanation of the method used to calculate our historical basic and diluted net loss per share attributable to common shareholders and the weighted-average number of shares of common stock used in the computation of these per share amounts.

(2) Gives effect to (i) the Warrant Net Exercises, (ii) the Series E and F Issuance, (iii) the Preferred Stock Conversion, (iv) the issuance of the 2025 Convertible Notes and the related Notes Conversion, (v) the RSU Net Settlement, and (vi) the reduction of the compound derivative liability bifurcated from the 2023 Term Loan. The following table sets forth the computation of our unaudited pro forma basic and diluted net loss per share, which does not include shares being offered in this offering:

	Three Months Ended March 31, 2025	Year Ended December 31, 2024
	(in thousands, except share and per share data)	
Numerator:		
Net loss attributable to common shareholders	\$ (127,043)	\$ (378,257)
Pro forma adjustment related to deemed dividend from Series C and Series D redeemable convertible preferred stock from the triggering of conversion price adjustments ^(a)	—	(453,102)
Pro forma adjustment to record stock-based compensation expense related to RSUs for which the performance-based vesting conditions will be satisfied in connection with this offering	—	(19,718)
Other miscellaneous pro forma adjustments ^(b)	—	(1,295)
Pro forma adjustment to record the reduction of fair value of derivative liability associated with the 2023 Term Loan ^(c)	—	17,451
Pro forma adjustment to reverse the adjustments of Series C and D redeemable convertible preferred stock to redemption value	24,462	96,367
Pro forma adjustment related to the reversal of the change in fair value of derivative liabilities	—	(11,393)
Pro forma adjustment related to the reversal of the change in fair value of warrant liabilities	—	(7,091)
Pro forma net loss	\$ (102,581)	\$ (757,037)
Denominator:		
Weighted-average shares used in computing net loss per share attributable to common shareholders, basic and diluted	35,623,042	35,496,832
Pro forma adjustment to reflect the Preferred Stock Conversion	216,766,459	216,766,459
Pro forma adjustment to reflect the Series C Warrant Net Exercise	4,189,559	4,189,559
Pro forma adjustment to reflect the 2025 Warrant Net Exercise	844,429	844,429

	Three Months Ended March 31, 2025	Year Ended December 31, 2024
	(in thousands, except share and per share data)	
Pro forma adjustment to reflect the Notes Conversion	2,236,331	2,236,331
Pro forma adjustment to reflect the RSU Net Settlement	751,464	751,464
Weighted-average shares used in computing pro forma net loss per share, basic and diluted	260,411,284	260,285,074
Pro forma net loss per share, basic and diluted ^(d)	\$ (0.39)	\$ (2.91)

- (a) Gives effect to conversion price adjustments for the Series C preferred stock and Series D preferred stock, in each case based on an assumed initial public offering price of \$19.50 per share, which is the midpoint of the price range set forth on the cover page of this prospectus. The change in the fair value of the shares of preferred stock triggered by such conversion price adjustments is considered a deemed dividend and thus excluded from the computation of pro forma net loss per share attributable to common shareholders.
- (b) Gives effect to (i) the cash bonus payable upon a successful initial public offering, as further described in the section titled “Executive Compensation,” and (ii) expenses associated with the issuance of the 2025 Warrants.
- (c) Gives effect to the reduction of the fair value of the compound derivative liability bifurcated from the 2023 Term Loan. The fair value is mainly driven by the prepayment amortization feature of the 2023 Term Loan, which, upon consummation of this offering, has a de minimis value.
- (d) Each \$1.00 increase in the assumed initial public offering price of \$19.50 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would (decrease)/increase the pro forma net loss per share for the three months ended March 31, 2025 and the year ended December 31, 2024, by approximately \$0.01 and \$(0.17), respectively. Each \$1.00 decrease in the assumed initial public offering price of \$19.50 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would (decrease)/increase the pro forma net loss per share for the three months ended March 31, 2025 and the year ended December 31, 2024, by approximately \$(0.01) and \$0.17, respectively. Pro forma adjustments in this footnote are illustrative only and will be adjusted based on the actual initial public offering price and other terms of this offering determined at pricing.

	As of March 31, 2025		
	Actual	Pro Forma ⁽¹⁾	Pro Forma As Adjusted ⁽²⁾⁽³⁾
		(in thousands)	
Consolidated Balance Sheet Data:			
Cash, cash equivalents, and restricted cash	\$ 32,704	\$185,531	\$600,227
Working capital ⁽⁴⁾	8,679	156,745	571,631
Total assets	291,583	444,410	853,284
Total liabilities	645,335	520,063	509,631
Redeemable convertible preferred stock	2,246,113	—	—
Total shareholders' (deficit) equity	(2,599,865)	(75,653)	343,653

- (1) Gives effect to (i) the Warrant Net Exercises, (ii) the Series E and F Issuance, (iii) the Preferred Stock Conversion, (iv) the issuance of the 2025 Convertible Notes and the related Notes Conversion, (v) the RSU Net Settlement, and (vi) the reduction of the compound derivative liability bifurcated from the 2023 Term Loan.
- (2) Gives effect to (i) the pro forma adjustments described in footnote (1) above, (ii) the sale by us of 23,529,412 shares of common stock in this offering at an assumed initial public offering price of \$19.50 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated

underwriting discounts and commissions and estimated offering expenses payable by us, net of \$1.4 million of offering expenses paid as of March 31, 2025 and (iii) the use of approximately \$5.8 million of the net proceeds from this offering to satisfy our anticipated tax withholding and remittance obligations related to the RSU Net Settlement.

- (3) Each \$1.00 increase (decrease) in the assumed initial public offering price of \$19.50 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash, cash equivalents, and restricted cash, working capital, total assets, and total shareholders' (deficit) equity by approximately \$21.9 million, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase (decrease) of 1,000,000 in the number of shares of common stock we are offering would increase (decrease) the pro forma as adjusted amount of each of cash, cash equivalents, and restricted cash, working capital, total assets, and total shareholders' (deficit) equity by approximately \$18.1 million, assuming the assumed initial public offering price per share remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Pro forma adjustments in this footnote and the footnotes above, as well as the related information in the balance sheet data, are illustrative only and will be adjusted based on the actual initial public offering price and other terms of this offering determined at pricing. The pro forma as adjusted cash, cash equivalents, and restricted cash amount includes the employer portion of the withholding tax obligation of approximately \$0.2 million related to the RSU Net Settlement at the assumed initial public offering price of \$19.50 per share, which is the midpoint of the price range set forth on the cover page of this prospectus.
- (4) We define working capital as current assets, less current liabilities. See our consolidated financial statements and related notes included elsewhere in this prospectus for further details regarding our current assets and current liabilities.

Non-GAAP Financial Measures

	Three Months Ended March 31,		Years Ended December 31,	
	2025	2024	2024	2023
	(in thousands)			
Adjusted EBITDA	\$(36,216)	\$(70,062)	\$(189,566)	\$(255,309)
Free cash flow	\$(34,027)	\$(75,663)	\$(253,643)	\$(298,419)

We use Adjusted EBITDA and free cash flow, financial measures not calculated in accordance with generally accepted accounting principles in the United States ("GAAP") to supplement our consolidated financial statements, which are presented in accordance with GAAP. We believe the non-GAAP financial measures we use, Adjusted EBITDA and free cash flow, are useful in evaluating our performance and liquidity. Our non-GAAP financial measures have limitations as analytical tools, however, and you should not consider them in isolation or as substitutes for analysis of our results as reported under GAAP.

We define Adjusted EBITDA as net loss, adjusted to exclude interest income, interest expense, changes in fair value of financial instruments, other expense, net, the provision for (benefit from) income taxes, depreciation and amortization, and stock-based compensation expense. We use Adjusted EBITDA in conjunction with GAAP measures as part of our overall assessment of our performance, including the preparation of our annual operating budget and quarterly forecasts, to evaluate the effectiveness of our business strategies, and to communicate with our board of directors concerning our financial performance. We believe Adjusted EBITDA provides useful information to investors and others in understanding and evaluating our operating results in the same manner as our management team and board of directors. Adjusted EBITDA provides a useful measure for period-to-period comparisons of our business, as it removes the effect of certain non-cash expenses and certain variable charges. We define free cash flow as net cash used in operating activities less purchases of property and equipment. We believe free cash flow is a useful measure of liquidity that provides an additional basis for assessing our ability to generate cash. For additional information regarding Adjusted EBITDA and free cash flow, including a reconciliation of these measures to the most directly comparable financial measure calculated in accordance with GAAP, see the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations—Non-GAAP Financial Measures."

RISK FACTORS

Investing in our common stock involves risk. You should carefully consider the risks described below, as well as the other information in this prospectus, including our financial statements and the related notes and the section titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in this prospectus, before deciding whether to invest in our common stock. This prospectus also contains forward-looking statements that involve risks and uncertainties. See the section titled “Special Note Regarding Forward-Looking Statements.” The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations, and growth prospects. In such an event, the market price of our common stock could decline, and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations.

Risks Related to Our Business and Industry

The precision medicine industry is highly competitive and subject to rapid change.

Our industry is highly competitive and characterized by rapid changes, including technological and scientific breakthroughs, frequent new product introductions and enhancements, and evolving industry standards. Our future success will depend on our ability to compete successfully and keep pace with the evolving needs of physicians, patients, and our biopharma partners on a timely and cost-effective basis and to pursue new market opportunities that develop as a result of technological and scientific advances. In recent years, there have been numerous advances in technologies relating to the diagnosis and treatment of cancer and advances in methods used to analyze large amounts of genomic information. We must continuously enhance our proprietary profiling and signature offerings and develop new solutions in a cost-effective way to achieve meaningful innovation in precision oncology and other chronic disease states. If we do not update our suite of solutions to reflect new scientific knowledge or technological advancements, including as they relate to precision medicine, therapeutic developments, or relevant validation studies or clinical trials, adoption and use of our current solutions and any new solutions we may develop could decline, which would adversely affect our business, financial condition, and results of operations.

Moreover, as an AI TechBio company that has experienced significant recent growth in the rapidly evolving field of precision medicine, our current business, our future success, and the risks and challenges we may encounter can be difficult to evaluate or accurately predict. If we fail to address the risks and difficulties that we face, including those described elsewhere in this “Risk Factors” section, our business, financial condition, and results of operations could be adversely affected. We have encountered in the past, and expect to encounter in the future, risks and difficulties frequently experienced by companies operating in rapidly evolving fields. If our assumptions regarding these risks and difficulties, which we use to plan and operate our business, are incorrect or change, or if we do not address these risks and difficulties, our results of operations could differ materially from our or your expectations, and our business, financial condition, and results of operations could be adversely affected.

We have incurred significant losses since inception, expect to incur losses in the future, and may not be able to generate sufficient revenue to achieve and maintain profitability.

We have incurred significant losses since our inception. For the years ended December 31, 2024 and 2023, we incurred net losses of \$281.9 million and \$341.4 million, respectively. For the three months ended March 31, 2025 and 2024, we incurred net losses of \$102.6 million and \$111.0 million, respectively. As of March 31, 2025, we had an accumulated deficit of \$2.6 billion. To date, we have financed our operations principally from the sale of convertible preferred stock, the incurrence of indebtedness, and revenue from molecular profiling and pharma R&D services. Over the last 17 years, we have devoted significant resources towards developing our current portfolio that consists of tissue- and blood-based profiling solutions, building our multi-modal clinico-genomic datasets, expanding our operational capacity, and strengthening our AI/ML-driven data analysis capabilities. We also devote significant resources to clinical and regulatory initiatives to obtain marketing authorization, sales and marketing activities, and R&D activities. We anticipate incurring significant costs to continue developing and commercializing our solutions.

In addition, because of the various risks and uncertainties associated with developing and commercializing our solutions, we are unable to predict the extent of future costs that may impact our prospects for profitability. Our future expenses will depend, in part, on the level of our expenditures and our ability to generate revenue at scale. We expect to continue to incur significant expenses and operating losses for the foreseeable future if and as we, among other things:

- attract, hire, and retain qualified personnel;
- continue our R&D activities and scale our R&D infrastructure;
- expand our laboratory capacity and operating capabilities, including completing the build-out of our laboratory facility in Irving, Texas;
- further build our sales, marketing, and distribution infrastructure;
- continue to invest in the expansion and enrichment of our clinico-genomic datasets and related analysis capabilities;
- seek marketing authorization that may be necessary or desired for our solutions;
- obtain, maintain, protect, and enforce our intellectual property portfolio, including intellectual property obtained through license agreements;
- meet the requirements and demands of being a public company; and
- defend against any claims or other lawsuits related to our solutions or otherwise.

Our expenses could increase beyond expectations if we are required by the FDA or other regulatory agencies to delay the launch of any new solutions, narrow or change our intended use or product claims, modify or expand our clinical trials or to perform additional clinical trials, either pre- or post-approval, in addition to those that we currently anticipate.

We will also need to generate significant additional revenue to achieve and then sustain profitability, and even if we achieve profitability, we cannot be sure that we will remain profitable for any substantial period of time. While we have commercially launched MI Cancer Seek, a new WES/WTS NGS assay, in the United States and seek to drive its increased adoption, and also plan to capitalize on the potential of Caris Assure applications for early detection, MRD tracking, and treatment monitoring and in chronic disease states beyond oncology, we cannot assure you that we will successfully be able to do so as planned, if at all, and our failure to do so may prevent us from generating increased revenue. Our failure to achieve or maintain profitability could negatively impact the value of our common stock.

Our current or future solutions may not achieve or maintain sufficient commercial market acceptance.

The commercial success of any of our solutions, including MI Profile and Caris Assure, or solutions that are marketed in the future, will depend upon the degree of commercial market acceptance, including by government payers, insurance companies, integrated health systems, healthcare providers, patients, biopharma companies and other third-party payers. The degree of market acceptance of our solutions will depend on a number of factors, including:

- the performance and clinical utility of such solutions as demonstrated in clinical trials and published in peer-reviewed journals;
- the rate of adoption and/or endorsement of our solutions by clinicians, KOLs, advocacy groups, and biopharma companies;
- the ability of our newer solutions, such as Caris Assure, and solutions that may be marketed in the future, to demonstrate the same performance in real-world intended use populations as in clinical trials or analytical or clinical validation studies;
- the willingness of medical providers to utilize our solutions as they are commercially released;
- the willingness of commercial third-party payers and government payers to cover and reimburse for our solutions;

- the development or introduction of competing products, including the expansion of the capabilities of existing products;
- the market acceptance of existing competitive products, including tests that are currently reimbursed;
- publicity concerning our solutions or competing products; and
- the strength of our marketing and sales support.

We cannot assure you that we will be successful in addressing each of these factors or other factors that might affect the market acceptance of our solutions. Failure to achieve broad market acceptance of our solutions, would harm our business, financial condition, and results of operations. For additional information, see “—Our current revenue is primarily generated from the continued adoption and use of our tissue-based profiling solution, and we are highly dependent on it for our success” and “—Our future success and growth will depend in part on market acceptance and commercial success of our MI Cancer Seek and Caris Assure solutions. We may be unsuccessful in continuing the commercialization of MI Cancer Seek or Caris Assure, which would adversely affect our business, financial condition, results of operations, and growth prospects.”

Our solutions may not perform as expected, and the results of our validation studies or our clinical trials may not support the launch or use of our solutions and may not comply with the requirements, or be replicated in later trials required, for any necessary or desirable marketing authorizations. This could adversely affect our business, financial condition, results of operations, and growth prospects.

Our success depends on the market and the medical community’s confidence that we can provide reliable, high-quality solutions, as well as our ability to complete validation studies and clinical trials and comply with applicable regulatory requirements that would allow us to commercialize our solutions. Our solutions, including MI Cancer Seek, for which we have obtained PMA approval from the FDA, MI Tumor Seek Hybrid, and Caris Assure, may not perform as expected, and the results obtained from our ongoing or future studies and trials may be inconsistent with certain results obtained from our previous studies or trials. In addition, the application of Caris Assure in early detection, MRD tracking, and treatment monitoring, for which we are still collecting preliminary data to support, may not be as effective as we anticipate. If Caris Assure or our other solutions are ineffective or do not consistently perform as expected, either before or after launch, our business, financial condition, results of operations, and growth prospects would suffer.

Our solutions require a number of complex and sophisticated biochemical and bioinformatics processes, many of which are highly sensitive to external factors. An operational or technological failure in one of these complex processes or fluctuations in external variables may result in sensitivity and specificity rates that are lower than we anticipate or that vary between test runs or in a higher than anticipated number of tests that fail to produce consistent results. In addition, we regularly evaluate and refine our AI/ML algorithms and other processes under development. These refinements may inadvertently result in unanticipated issues that may reduce our sensitivity and specificity rates or otherwise adversely affect the performance of our solutions and their results, such that supplemental submissions to the FDA may be required.

We have obtained a PMA approval from the FDA for MI Cancer Seek and may decide to seek FDA approval for Caris Assure and additional solutions, though whether we will do so and the timing thereof is uncertain. The FDA and other regulators may request additional information or require that we generate additional clinical data to support such future approval applications, which could result in delays, increased costs, or other limitations on our ability to receive such approval. Additionally, the FDA included certain conditions of approval and limitations in the PMA approval letter for MI Cancer Seek, namely that we submit data evaluating the effects of interfering substances such as necrotic tissue, melanin, and fatty acids and also conduct a study and submit data regarding formalin-fixed paraffin-embedded block and slide stability duration claims. Our failure to comply with these limitations and conditions could result in the withdrawal of the PMA approval for MI Cancer Seek.

Further, we plan to enhance, iterate, and improve our solutions, scalability, and/or reduce our cost of goods. However, we may not be successful in transitioning our solutions to new or enhanced versions or iterations, or reducing our cost of goods. The improvement of our solutions involves a lengthy and complex process, may require regulatory approval, and we may be unable to commercialize, validate, or improve performance of any of our solutions on a timely basis, or at all. Our failure to successfully develop new and/or improved solutions (including new versions of existing solutions) on a timely basis could adversely affect our business, financial conditions, and results of operation.

Finally, generating the clinical data necessary to validate and support the launch of our solutions and new versions of solutions and subsequently obtain marketing authorization or third-party reimbursement, is time-consuming and carries with it the risk of not yielding the desired results. The performance achieved in our analytical validation studies, clinical trials, or published studies may not be replicated in later studies that may be required to obtain or maintain marketing authorization. For example, limited results from earlier-stage analytical validation studies, such as our analytical validation studies on the use of Caris Assure for early detection, MRD tracking, and treatment monitoring, may not predict results from studies in larger numbers of participants drawn from more diverse populations over a longer period of time. Unfavorable results from ongoing analytical validation studies or clinical trials, or delays in publication of such results, could lead to delays, modifications, or abandonment of ongoing or future studies and trials, or abandonment of a solution development program, or may delay, limit, or prevent marketing authorizations or commercialization of our solutions. In addition, results from such studies and trials may not be consistent with the results from real-world application of our solutions, if commercialized, for a particular care setting.

Our current revenue is primarily generated from the continued adoption and use of our tissue-based profiling solution.

Our ability to execute our growth strategy and become profitable is highly dependent on the continued adoption and use of MI Profile, our tissue-based profiling solution, which accounted for 78.2% and 91.0% of our revenue in the years ended December 31, 2024 and 2023, respectively, and 83.9% and 87.9% of our revenue for the three months ended March 31, 2025 and 2024, respectively. Continued adoption and use of MI Profile will depend on several factors, including the prices we charge for our solution, the scope of coverage and amount of reimbursement available from government and third-party payers for our solution, the availability of clinical data that supports the value of MI Profile and the inclusion of MI Profile solutions in industry treatment guidelines. The commercial success of our tissue-based profiling solution depends significantly on its broad adoption and use by oncologists and other physicians. Many physicians and biopharma companies have existing relationships with companies that develop molecular diagnostic tests, including our competitors, and may continue to use their tests instead of MI Profile. Despite our business development efforts, it could be difficult, expensive, and/or time-consuming for physicians and/or biopharma companies to switch diagnostic tests for their products, and MI Profile may not be widely accepted, if at all, which could in turn hinder the rate of adoption and continued use of our solutions. We cannot assure you that MI Profile will continue to maintain or gain market acceptance, and any failure to do so would harm our business, financial condition, and results of operations. Moreover, as we have leveraged the data we have generated to date with MI Profile to develop Caris Assure and other solutions, if the adoption and use of MI Profile wanes or if reliability or other issues with the data we generate with MI Profile are discovered, the further development and future success and growth of Caris Assure and other solutions would be adversely impacted.

Our future success and growth will depend in part on market acceptance and commercial success of our MI Cancer Seek and Caris Assure solutions. We may be unsuccessful in continuing the commercialization of MI Cancer Seek or Caris Assure, which would adversely affect our business, financial condition, results of operations, and growth prospects.

MI Cancer Seek, for which we obtained a PMA approval from the FDA in November 2024 and commercially launched in January 2025, is the new WES/WTS NGS assay component of MI Profile, our tissue-based molecular profiling solution for cancer therapy that has generated the majority of our revenue to date. Driving increased adoption among physicians of, and obtaining reimbursement for, MI Cancer Seek are key expected drivers of our growth, particular in the near and medium term. The success of MI

Cancer Seek will depend upon, among other things, the extent to which our recent FDA approval drives increased adoption and use of the solution by physicians as a companion diagnostic tool.

Caris Assure, for which we initiated the broad commercial launch for therapy selection in the first quarter of 2024, ultimately aims to address the entire continuum of cancer treatment. Realizing the potential of Caris Assure across disease states is a key component of our long-term business strategy. The commercial success of Caris Assure for therapy selection and in other applications across the cancer treatment continuum will depend upon, among other things, additional analytical validation studies and clinical trials that demonstrate the effectiveness of Caris Assure, particularly for early detection, MRD tracking, and treatment monitoring, the continued adoption of Caris Assure by physicians, the medical community, patients, and third-party payers, and our ability to successfully run and market Caris Assure in substantial quantities or to manage and expand the required infrastructure to do so, including large-scale laboratory and information technology systems. Maintaining and expanding market acceptance of our solutions, marketing, and laboratory capabilities are expensive and time-consuming. If MI Cancer Seek or Caris Assure is not successfully commercialized, we will not be able to recover the significant investment we have made in developing these solutions, and our business, prospects, financial condition, and results of operations would be harmed.

If we are unable to support demand for MI Profile, Caris Assure, and any other solutions we develop, including ensuring that we have adequate capacity to meet increased demand, or if we are unable to successfully manage our anticipated growth, our business could suffer.

As and to the extent the volumes of our current and new solutions continue to grow, we will need to simultaneously increase our capacity for sample intake, storage, and processing enhance our customer service, improve our billing and general processes, expand our internal quality assurance programs, incorporate new equipment, implement new technology systems and processes, expand laboratory capacity, and otherwise extend our operational capabilities to support comprehensive genomic analyses at a larger scale while retaining expected turnaround times. We will also need additional equipment and certified and licensed laboratory personnel to process higher volumes of solutions. We may face difficulties increasing the scale of our operations, including implementing changes in infrastructure or programs or acquiring additional equipment or personnel. As we refine our solutions and develop additional solutions, we may need to bring new equipment on-line, implement new systems, technology, controls and procedures, and hire personnel with different qualifications, licenses, or certifications.

We are also in the process of constructing additional facilities in order to increase capacity, including our laboratory facility in Irving, Texas. We may not be able to complete construction of such facilities and obtain necessary certifications, permits, licenses, and accreditations in a timely or cost-effective manner, or at all. Therefore, we may be unable to support our development and commercial activities in a timely manner, if at all. There is no assurance that any of these increases in scale, expansion of personnel, equipment, software and computing capacities or process enhancements will be successfully implemented, or that we will have adequate resources and facilities to accommodate such required expansion.

The value of MI Profile, Caris Assure, and related solutions will depend, in part, on our ability to perform tests and return test results to providers on a timely basis and at an appropriate quality standard, and on our reputation for such timeliness and quality. If our business grows too quickly, our ability to meet demand for our solutions in a timely and efficient manner could be challenged, and our quality standards or turnaround time may be compromised. Failure to implement necessary procedures, to transition to new equipment or processes, or to hire the appropriate, qualified personnel could result in higher costs of processing, longer turnaround times, declining product quality, deteriorating customer service, an inability to meet market demand, or slower responses to competitive challenges, all of which could make it difficult for us to meet market expectations for our solutions and could damage our reputation and the prospects for our business. There can be no assurance that we will be able to perform tests on a timely basis at a level consistent with demand, that we will be able to maintain the quality of our test results as we scale our commercial operations, or that we will be successful in responding to the growing complexity of our laboratory operations, including the related data analysis requirements.

We expect to add new associates in our Phoenix and Tempe, Arizona and Irving, Texas facilities. We will need additional laboratory scientists, technicians, and other scientific and technical personnel with

different qualifications, licenses, or certifications. As our development plans and strategies develop, and as we transition into operating as a public company, we must add a significant number of additional managerial, operational, financial, and other personnel. Future growth will impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, retaining, and motivating employees;
- managing our internal development and commercialization efforts effectively, including creating and maintaining compliant programs and processes, such as a laboratory and manufacturing quality system, and managing the regulatory requirements for our solutions, while adhering with our contractual obligations to contractors and other third parties;
- expanding our operational, human resources, financial and management controls, reporting systems, and procedures; and
- managing the increasing complexity associated with a larger organization and expanded operations.

Our growth may place a significant strain on our management, operating and financial systems, R&D, and our sales, marketing, and administrative resources. As a result of our growth, our operating costs may escalate even faster than planned, and some of our internal systems may need to be enhanced or replaced. If we cannot effectively manage our expanding operations and our costs, we may not be able to successfully commercialize future solutions and grow successfully, and our business could be adversely affected.

Our results of operations may fluctuate significantly, which makes our future results of operations difficult to predict and could cause our results of operations to fall below expectations or any guidance we may provide.

Our quarterly and annual results of operations may fluctuate significantly, which makes it difficult for us to predict our future results of operations. These fluctuations may occur due to a variety of factors, many of which are outside of our control, including, but not limited to:

- the level of demand for our solutions, which may vary significantly;
- the timing and cost of, and level of investment in, research, development, regulatory approval, or certification and commercialization activities relating to our solutions, which may change from time to time;
- the volume and customer mix of our solutions;
- the introduction of new solutions or solution enhancements by us or others in our industry;
- coverage and reimbursement policies with respect to our solutions and products that compete with our solutions;
- expenditures that we may incur to acquire, develop, or commercialize additional solutions and technologies;
- changes in governmental regulations or in the status of our regulatory approvals or certifications or applications;
- future accounting pronouncements or changes in our accounting policies;
- developments or disruptions in the business and operations of physicians and our biopharma partners;
- the impact of natural disasters, political instability, including wars, terrorism, and political unrest, epidemics or pandemics, boycotts, and curtailment of trade and other business restrictions; and
- the effects of high inflation or other general market and economic conditions and other factors, including factors unrelated to our operating performance or the operating performance of our competitors.

Additionally, due to the inherent variability and unpredictability of the reimbursement landscape, including related to the amount that payers reimburse us for any of our solutions, when we recognize revenue we estimate the transaction price based on our historical collection experience and on the historical selling price of similar transactions, where applicable, and subsequent changes to the estimate of the transaction price are generally recorded as adjustments to revenue in the period where such changes occur. Both the estimate and any subsequent revision are uncertain and require the use of management's judgment in the estimation of the variable consideration and application of the constraint for such variable consideration. Due to this variability and unpredictability, previously recorded revenue adjustments are not indicative of future revenue adjustments from actual cash collections, which may fluctuate significantly. Moreover, we receive a substantial portion of our revenue from a limited number of third-party commercial payers. If one or more of these payers were to significantly reduce or cease to pay the amount such payer reimburses us for our solutions, or if such payer does not reach or maintain favorable coverage and reimbursement decisions for our solutions, it could have an adverse effect on our business, financial condition, and results of operations. We have experienced situations where commercial payers proactively reduced the amounts they were willing to reimburse for our solutions, and in other situations, payers have determined that the amounts they previously paid were too high and have sought to recover those perceived excess payments by deducting such amounts from payments otherwise being made. For additional information regarding risks associated with the reimbursement landscape, see "—If our solutions, or solutions we develop in the future, do not receive adequate coverage and reimbursement from third-party payers, including government and commercial payers, our ability to expand access to our solutions beyond our existing sales channels, and thus our overall commercial success, will be limited."

The cumulative effects of factors discussed above could result in large fluctuations and unpredictability in our quarterly and annual results of operations. As a result, comparing our results of operations on a period-to-period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance.

This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our results of operations fall below the expectations of analysts or investors or below any guidance we may provide, or if the guidance we provide is below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated guidance we may provide, and which could harm our business, financial condition, and results of operations.

If we do not have the support of KOLs or if clinical data using our solutions is not published in peer-reviewed journals or is otherwise not well received, it may be difficult to drive adoption and use of our solutions and establish them as a component of the standard of care for patients with cancer.

As of March 31, 2025, the Caris POA was comprised of 96 members, including 45 NCI-designated comprehensive cancer centers. If these KOLs or others within the broader precision oncology industry determine that our platform, our existing solutions, or other solutions that we develop are not clinically effective, that alternative technologies are more effective, or if they elect to use internally developed products or services, we may see lower demand for our solutions and face difficulty establishing our solutions as an integral component of the applicable standard of care, which would limit our revenue growth and our ability to achieve profitability.

The publication of clinical data using our solutions in peer-reviewed journals is also crucial to our success. We are unable to control when, if ever, results are published, which may delay or limit broad adoption and use of our solutions. Our ability to publish clinical data relating to our solutions in peer-reviewed publications may be limited by many factors, including increased difficulty in obtaining acceptance for publication from journals, conflicts of interest, lack of qualified experts willing to participate in the peer review process, delays in the completion of, poor design of, or lack of compelling data from, validation studies or clinical trials, as well as delays in the review, acceptance, and publication process. If our solutions do not receive sufficient favorable exposure in peer-reviewed publications or are not well received by clinicians, the rate of clinician adoption and use of our solutions and positive reimbursement coverage determinations for our solutions, even if approved with guideline inclusion, could be adversely affected.

If our solutions, or solutions we develop in the future, do not receive adequate coverage and reimbursement from third-party payers, including government and commercial payers, our ability to expand access to our solutions beyond our existing sales channels, and thus our overall commercial success, will be limited.

Our revenue and commercial success depend on achieving coverage and reimbursement for assays that comprise MI Profile, Caris Assure, and any solutions we may offer in the future, from third-party payers, including both government and commercial payers. Obtaining approvals from third-party payers to cover our solutions and establishing adequate coding recognition and reimbursement levels is an unpredictable, challenging, time-consuming, and costly process, and we may not always be successful. Coverage determinations from third-party payers may depend on a number of factors, including a payer's determination that a solution is appropriate, medically necessary, and cost-effective. Each payer will make its own decision as to whether to establish a policy or enter into a contract to cover our solutions and the amount it will reimburse for such solutions. In addition, determinations by a payer whether to cover and the amount it will reimburse for our solutions are often made on an indication-by-indication basis. If we are unable to provide payers with sufficient evidence of the clinical utility and validity of our solutions, they may not provide coverage, may provide limited coverage, or may terminate coverage for our solutions, which will adversely affect our revenues and our financial condition. In addition, the fact that one of our solutions has been approved for reimbursement in the past does not guarantee that such solution will remain approved for reimbursement, that the approved reimbursement amount will not be reduced in the future, or that similar or additional solutions will be approved in the future. Moreover, there can be no assurance that any new solutions we launch will be reimbursed at rates that are comparable to the rates that we historically obtained for our existing portfolio or rates that other industry participants receive. Third-party payers may not cover or provide adequate payment for our current or future molecular and other solutions to enable us to maintain past levels of revenue or profitability with respect to such solutions. Further, third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on investment in the development of our solutions.

Healthcare providers may not order our solutions unless third-party payers cover and provide reimbursement rates for a substantial portion of the price of our solutions. If we are unable to obtain adequate coverage and an acceptable level of reimbursement for our solutions from third-party payers, patients could incur a greater co-insurance, co-payment, and/or deductible obligation. Uninsured patients or patients whose insurance does not cover our solutions may also be forced to pay for our solutions out-of-pocket. Such scenarios could dissuade physicians from ordering our solutions or, if ordered, could result in delay in or decreased likelihood of our collection of payment. We thus believe our revenue and revenue growth will depend on our success in achieving broad coverage and adequate reimbursement for our solutions from third-party payers.

In addition, the coding process used by third-party payers to identify various medical procedures during the billing process is complex, may not adapt well to the types of solutions we offer, and may not enable coverage and adequate reimbursement rates. Current Procedural Terminology ("CPT") coding plays a significant role in how our solutions are reimbursed both from commercial and governmental payers. The CPT code set is maintained by the American Medical Association ("AMA") and includes the Proprietary Laboratory Analyses ("PLA") codes that are used to describe many molecular diagnostic tests. In cases where there is not a specific CPT code to describe a test, or when required by a commercial payer, we bill under an unlisted molecular pathology procedure code or through the use of a combination of single gene CPT codes, depending on the payer. In addition, the Centers for Medicare and Medicaid Services ("CMS") maintains the Healthcare Common Procedure Coding System ("HCPCS") and may assign unique Level II HCPCS code to tests that are not already described by a unique CPT code. New CPT codes are issued annually and new HCPCS codes are issued as frequently as quarterly. In addition to CPT and HCPCS codes, Z-Code Identifiers are used by certain payers, including under MolDX, to supplement CPT codes for our solutions. Our MI Tumor Seek Hybrid solution is reported to Medicare and to some commercial payers using unlisted molecular pathology CPT code 81479 and unique test-specific identifier ("a DEX Z-Code"). Our MI Cancer Seek solution is reported to Medicare and to commercial payers using the 0211U CPT code and a unique DEX Z-Code identifier. Our Caris Assure solution is reported to Medicare and to non-contracted, commercial payers using the 0485U CPT code and a unique DEX Z-Code identifier. Commercial payers sometimes require other codes to be reported for our solutions, and we will bill in accordance with

the respective contract terms. Changes to the codes used to report our solutions to payers may result in significant changes in reimbursement.

Third-party payers are increasingly attempting to contain healthcare costs by limiting both coverage of certain diagnostic tests and the amounts that they will pay for such tests. Payers may also create conditions for coverage or may contract with third-party vendors to manage laboratory benefits, in both cases creating administrative hurdles for ordering physicians and patients that may make our services more difficult to sell. U.S. and foreign governments continue to propose and pass legislation designed to reduce the cost of healthcare. In some foreign markets, the government controls the pricing of many healthcare products. In the United States, we expect that there will continue to be federal and state proposals to implement governmental controls or impose healthcare requirements, which may increase the pressure to reduce spending on genetic testing and comprehensive molecular profiling. In addition, the Medicare program and increasing emphasis on managed care in the United States will continue to put pressure on product pricing. Cost control initiatives could decrease the price that we would receive for any solutions in the future, which would limit our revenue and profitability.

Obtaining approvals from third-party payers to cover our existing and new solutions and establishing adequate coding recognition and reimbursement levels is an unpredictable, challenging, time-consuming, and costly process, and we may not always be successful. If third-party payers do not provide adequate coverage and reimbursement for our solutions, our ability to succeed commercially will be limited.

Medicare

Medicare is the single largest U.S. payer and a particularly important payer for many cancer-related laboratory services given the demographics of the Medicare population. Medicare coverage is limited to items and services that are within the scope of a Medicare benefit category that are reasonable and necessary for the diagnosis or treatment of an illness or injury. Medicare coverage criteria that define when items and services are reasonable and necessary are defined in National Coverage Determinations (“NCDs”) made by CMS through an evidence-based process, with opportunities for public participation, and Local Coverage Determinations (“LCDs”) made by Medicare Administrative Contractors (“MACs”) that apply within the specific jurisdictions. Medicare’s NCD for NGS (NCD 90.2), first established in 2018 and subsequently updated in 2020, provides national Medicare coverage for certain molecular diagnostic tests (1) performed in a laboratory certified by the Clinical Laboratory Improvement Amendments of 1988 (“CLIA”), (2) ordered by a treating physician, (3) the patient meets certain clinical and treatment criteria, including having recurrent, relapsed, refractory, metastatic, or advanced stages III or IV cancer, (4) the test is approved or cleared by the FDA as a companion IVD for an FDA-approved or -cleared therapeutic for use in that patient’s cancer, and (5) results are provided to the treating physician for management of the patient using a report template to specify treatment options. The NGS NCD also provides discretion to the MACs to provide local coverage of other NGS tests for cancer patients only when the test is performed by a CLIA-certified laboratory, ordered by a treating physician and the patient meets the same clinical and treatment criteria required of nationally covered NGS tests under the NGS NCD. Palmetto GBA is the MAC responsible for administering MoIDX, which issues coverage determinations applicable to molecular diagnostic tests within the scope of the program, including for molecular assays that are LDTs. Our MAC for the Phoenix laboratory locations is Noridian, and Noridian relies on MoIDX to make local coverage and pricing determinations relating to molecular testing. To achieve coverage under MoIDX, laboratories must apply for and obtain a DEX Z-Code that is unique to the laboratory’s specific test and must also submit a technical assessment to demonstrate analytical and clinical validity, and clinical utility at a level that meets the Medicare reasonable and necessary requirement. Analytical validity relates to technical performance, such as that an assay accurately and reliably measures a specific feature. Clinical validity means whether a test can accurately identify, measure, or predict a clinical condition or characteristic in patients.

Molecular Diagnostic Tests: Tissue- and Blood-Based Solutions

We have received DEX Z-Codes and MoIDX technical assessments for our MI Cancer Seek, Caris Assure, and MI Tumor Seek Hybrid solutions.

We received a PMA approval for MI Cancer Seek from the FDA in November 2024 and commercially launched the solution in January 2025. We have obtained Medicare coverage under the NGS NCD for MI Cancer Seek for CPT code 0211U at \$8,455 under the CLFS.

Our MI Tumor Seek Hybrid solution is covered for solid tumor testing as allowable under the NGS NCD and related LCD and are reported to Medicare with unlisted molecular pathology CPT code 81479 and the unique DEX Z-Code identifier issued by MoIDX. MI Tumor Seek Hybrid is covered by Medicare as of August 3, 2022, with current MoIDX pricing of \$3,500.

Our Caris Assure solution is currently reported to Medicare using a PLA code, CPT code 0485U, and a unique DEX Z-Code identifier issued by MoIDX. Caris Assure is covered for therapy selection by Medicare as of December 8, 2023 for Comprehensive Genomic Profiling from ctDNA of patients with recurrent, relapsed, refractory, metastatic, or advanced solid tumors who are seeking treatment, and for whom tissue-based, comprehensive genomic profiling (“CGP”) is infeasible (for example, quantity not sufficient for tissue-based CGP or invasive biopsy is medically contraindicated), with current MoIDX pricing of \$3,649. In November 2024, CMS determined to price Caris Assure for therapy selection using the “Gapfill” method. There is no certainty regarding the pricing that we will obtain for Caris Assure during the Gapfill process. For additional information, see “Business—Government Regulation—Coverage and Reimbursement—Coverage and Reimbursement in the United States.”

Immunohistochemical Tests

As part of our MI Profile solution, we perform certain third-party IHC tests. Medicare coverage and payment for these tests is under the Molecular Pathology Procedures Billing and Coding Article, with payment amounts assigned to specific HCPCS and CPT codes.

Protecting Access to Medicare Act

Medicare payment for clinical diagnostic laboratory tests (“CDLTs”) is generally made under the CLFS based on payment rates that are assigned to specific HCPCS or CPT codes. Under the Protecting Access to Medicare Act of 2014 (“PAMA”), laboratories that meet certain requirements related to volume and type of Medicare revenues are required to report to CMS, beginning in 2017 and every three years thereafter (or annually for “advanced diagnostic laboratory tests” (“ADLTs”)), their private payer payment rates and volume for each test they perform that is reported with a specific HCPCS code (defined by PAMA to exclude miscellaneous or unlisted codes). ADLTs are subject to separate reporting and payment requirements under PAMA. New ADLTs are paid at a rate equal to their actual list charge during an initial period of three calendar quarters, after which CLFS payment is based on the weighted median of private payer rates, which must be reported annually for ADLTs. We are subject to these reporting requirements under PAMA for any solution we perform that is not reported with a miscellaneous HCPCS or CPT code, including the third-party IHC tests we perform, and for any profiling solutions that commercial payers currently require us to report using a HCPCS code that has been identified by CMS as subject to PAMA reporting requirements. In addition, MI Cancer Seek, which is reported with PLA code 0211U, Caris Assure, which is reported using PLA Code 0485U, and any other solution for which we obtain a specific HCPCS or CPT code, will be subject to these reporting requirements in future PAMA reporting cycles, and that the Medicare CLFS payment rates for such solutions will be calculated in the future based on our private payer rates. While we do not currently have ADLT status for any of our solutions, we may seek ADLT status for one or more of our solutions in the future. If we are successful in obtaining such ADLT status, any solution for which we obtain ADLT status will be subject to the PAMA reporting requirements and pricing methodology as an ADLT.

Congress passed legislation that delayed data reporting requirements for CDLTs that are not ADLTs and further delayed the phase-in of payment reductions under the CLFS from private payer rate implementation. Any reductions to reimbursement rates resulting from the new methodology are limited to 0% in 2025 and 15% per test per year in each of 2026 through 2028. The subsequent data reporting periods for CDLTs that are not ADLTs will occur in three-year cycles, with the next cycle beginning in 2026. CLFS rates for CDLTs will be updated every three years, and for ADLTs will be updated annually. For many tests and/or laboratories, the result of the PAMA pricing methodology has been lower pricing and reimbursement. As a result, our Medicare CLFS pricing for any solutions that may be subject to PAMA reporting requirements in the future could be negatively impacted by PAMA. In addition, private payer payment levels have more significance in setting Medicare reimbursement and, therefore, future Medicare payments may fluctuate more often and become subject to the willingness of private payers to recognize

the value of diagnostic tests generally and any given test individually. Given the many uncertainties built into PAMA's price-setting process, we cannot predict how payments we receive under the CLFS, and thus our revenue, may change from year to year.

In addition to the reporting requirements and pricing methodology described above, PAMA codified Medicare coverage rules for laboratory tests by requiring any local coverage determination to be made following the local coverage determination process. PAMA also authorizes CMS to consolidate coverage policies for clinical laboratory tests among one to four laboratory specific MACs. These same contractors may also be designated to process claims if CMS determines that such a model is appropriate. It is unclear whether CMS will proceed with contractor consolidation under this authorization.

Molecular Signature Tests, and Screening and Early Detection Intended Uses for Our Solutions

Our proprietary molecular signature tests, GPSai and FOLFIRSTai, as well as early detection indications for our blood and tissue-based profiling solutions, are not currently covered by Medicare. Obtaining Medicare coverage for these molecular signatures would require significant investments and may ultimately be unsuccessful or may take several years to achieve.

In addition, we are developing screening capabilities for Caris Assure for MRD tracking and treatment monitoring in colorectal cancer ("CRC"), breast cancer, lung cancer, and other indications. On January 19, 2021, CMS released an NCD that covers future tests for CRC screening if and when such screening tests have FDA approval and meet pre-specified CMS criteria. In addition, MolDX LCDs provide coverage for MRD for CRC, breast cancer, lung cancer, and other indications when applicable coverage criteria are satisfied. While this NCD and applicable LCDs may provide a pathway to coverage of Caris Assure in CRC and other indications under Medicare if applicable coverage criteria are satisfied, there is no assurance that we will be successful in completing the required studies, trials, or publications or obtaining FDA approval, or obtaining Medicare coverage even if we are successful in obtaining FDA approval, and if we are not successful, our business, financial condition, and results of operations would be harmed.

Commercial Payers and Other Payers

Our commercial success also depends on achieving acceptable coverage and reimbursement for our solutions from commercial payers. When we contract with a payer as a participating provider, reimbursements by the payer are generally made pursuant to a negotiated fee schedule and are limited to only covered indications, and in many cases require prior authorization. Becoming a participating provider can result in higher reimbursement amounts for covered uses of our solutions and, potentially, no reimbursement for non-covered uses identified under the payer's medical policies or the contract. Although we are a participating provider with many commercial payers, certain payers may not cover based on existing medical policy and may treat our solutions or solutions that we develop in the future as experimental and investigational or import restrictive coverage criteria. If we are not successful in obtaining coverage from such payers, or if other payers issue non-coverage policies, our business, financial condition, and results of operations could be adversely affected.

Because current codes applicable to our solutions are not always test-specific, each insurance claim will have different submission criteria, including appending our DEX Z-Code, and typically must be examined to determine what test was provided, whether the test was appropriate and medically necessary, and whether payment should be rendered, which may require progress notes, medical records, or a letter of medical necessity from the ordering physician. This process can result in a delay in processing the claim, a lower reimbursement amount or denial of the claim. As a result, obtaining approvals from third-party payers to cover our solutions and establishing adequate reimbursement levels is an unpredictable, challenging, time-consuming, and costly process, and we may never be successful in obtaining such approvals.

Some payers have implemented, or are in the process of implementing, laboratory benefit management programs, often using third-party benefit managers to manage these programs. The stated goals of these programs are to help improve the quality of outpatient laboratory services, support evidence-based guidelines for patient care and lower costs. The impact on laboratories, such as ours, of active laboratory benefit management by third parties is unclear, and we expect that it would have a negative impact on our revenue in the short term. Payers may resist reimbursement for our solutions in favor of less

expensive tests, require pre-authorization for our solutions, or impose additional pricing pressure on and substantial administrative burden for reimbursement for our solutions. We expect to continue to focus substantial resources on increasing adoption of, and coverage and reimbursement for, our current solutions and any future solutions we may develop. We believe it may take several years to achieve broad coverage and adequate contracted reimbursement with a majority of payers for our solutions. However, we cannot predict whether, under what circumstances, or at what price levels payers will cover and reimburse our solutions. If we fail to establish and maintain broad adoption of, and coverage and reimbursement for, our solutions, our ability to generate revenue could be harmed and our business, financial condition, and results of operations could be adversely affected.

Even if we establish relationships with commercial payers to provide our future solutions at negotiated rates, such agreements would not obligate any healthcare providers to order our solutions or guarantee that we would receive reimbursement for our solutions from these or any other payers at adequate levels. Thus, these payer relationships, or any similar relationships, may not result in acceptable levels of coverage and reimbursement for our solutions, or meaningful increases in the number of billable tests we perform. We believe it may take several years to achieve coverage and adequate reimbursement for our solutions with a majority of third-party payers, including with those payers offering negotiated rates. In addition, we cannot predict whether, under what circumstances, or at what payment levels payers will cover and reimburse for our solutions. In addition to the available Medicare coverage, we plan to market Caris Assure for early detection, MRD tracking, and treatment monitoring, as well as other solutions that we are developing or may develop in the future, to large self-insured employers, commercial insurance plans, certain physician directed channels, concierge medicine and executive health programs, and innovative health systems. Additionally, a third-party payer's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Further, coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained, less favorable coverage policies and reimbursement rates may be implemented in the future. If we fail to establish and maintain broad-based coverage and reimbursement for certain solutions, our ability to expand access to our solutions, generate increased revenue, and grow our clinical case volume and customer base for such solutions will be limited and our overall commercial success may be limited.

Our billing, collections, and claims processing activities are complex and time-consuming, and any delay in transmitting and collecting claims or failure to comply with applicable billing requirements could have an adverse effect on our future revenue.

Depending on the billing arrangement and applicable law, we bill and expect to bill various payers, such as governmental payers, insurance companies, hospitals, and patients, which may each have different billing requirements. We may face increased risk in our collection efforts, including long collection cycles and the risk that we never collect at all, either of which could adversely affect our business, financial condition, and results of operations.

Our failure to timely submit claims for our solutions to payers or failure to comply with applicable billing requirements could have an adverse effect on our revenue and our business, and could result in our inability to receive payment for our services or in attempts by private payers and state and federal healthcare programs, such as Medicare and Medicaid, to recover payments already made. Submission of claims in violation of billing requirements and applicable laws and regulations can result in recoupment of payments already received, substantial civil monetary penalties, and exclusion from state and federal health care programs, and can subject us to liability under the federal False Claims Act (the "FCA") and similar laws. For example, in March 2025, we received a Civil Investigative Demand ("CID") from the DOJ in connection with an investigation under the False Claims Act regarding our compliance with Medicare's date of service rule (also referred to as the 14-day rule). For additional information, see "—We have been, are currently, and in the future may be the subject of government investigations, claims, audits, whistleblower and payer audits, overpayment and recoupment efforts and other litigation in the course of our business that could adversely affect our business and financial statements" and "Business—Legal Proceedings." The failure to report and return an overpayment to the Medicare or Medicaid program within 60 days of identifying its existence can also give rise to liability under the FCA. Further, a government agency could attempt to hold us liable for causing the improper submission of claims by another entity for services that we performed if we were found to have knowingly participated in the arrangement at issue.

In addition, our claims for reimbursement may be denied and we may have to appeal such denials in order to get paid. Such appeals may not result in payment and can be time-consuming and costly. Moreover, payers often perform audits of historically paid claims and regularly attempt to recoup funds years after the funds were initially distributed if the payers believe the funds were paid in error or determine that our solutions were medically unnecessary. If a payer's audit of our claims results in a negative finding, and we are unable to reverse the finding through appeal or subsequent litigation, any subsequent recoupment could have an adverse effect on our revenue. Additionally, in some cases commercial payers for whom we are not a participating provider may elect at any time to review claims previously paid and determine the amount they paid was excessive. In these situations, the payer typically notifies us of its decision and then offsets the amount it determines to be overpaid against amounts it owes us on current claims. We may not have a mechanism to dispute these retroactive adjustments, and we cannot predict when, or how often, a payer might engage in these reviews. We have been, are currently, and may in the future be, subject to overpayment demands, recoupment efforts, and related disputes from or with payers, managed care plans, and government healthcare programs relating to the billing and coding of our solutions.

Furthermore, we maintain financial assistance programs under which we assess patient financial need and offer to provide solutions at a discount, or at no cost, to certain eligible patients. These practices may result in scrutiny of our financial assistance programs by governmental and commercial payers and could result in recoupment actions or termination of coverage of our solutions, as well as scrutiny under health care fraud and abuse laws. For additional information, see “—We have been, are currently, and in the future may be the subject of government investigations, claims, audits, whistleblower and payer audits, overpayment and recoupment efforts and other litigation in the course of our business that could adversely affect our business and financial statements” and “Business—Legal Proceedings.”

We currently handle our own billing and coding for our solutions but have initiated the process of transitioning certain of our billing and coding software and other operations to a vendor for revenue cycle management services. Our business, financial condition, and results of operations may be affected by our ability to successfully transition these functions and the ability of our vendor to timely, accurately, and appropriately code and bill claims and collect payments in compliance with the stringent billing, coding and documentation requirements imposed by government healthcare programs and other payers. Terminating or transitioning arrangements with revenue cycle management vendors could result in additional costs and a risk of operational problems, delays in collections from payers, potential errors and possible control issues during the termination and transition processes, any of which could adversely affect our business, financial condition, and results of operations.

We rely on a limited number of third-party suppliers or, in many cases, sole suppliers, for some of our next-generation sequencers, lab materials, reagents, and supplies, and we may not be able to find replacements or immediately transition to alternative suppliers if necessary.

We rely on Illumina, Inc. (“Illumina”) as the sole supplier of NGS instruments and the associated sequencing reagent kits for our solutions. Illumina is also the sole provider of maintenance and repair services for these sequencing instruments. Without access to these sequencers, we may be unable to run our solutions and commercialize our solutions. Additionally, we rely on several sole suppliers, including, among others, Roche Diagnostics Corporation (“Roche”), Matsunami Glass USA (“Matsunami Glass”), and Agilent Technologies, Inc. (“Agilent”), for certain lab materials, reagents, and supplies. If we do not have timely access or access to sufficient quantities of these lab materials, reagents, and supplies, we may be unable to run our solutions and commercialize our solutions. We also rely on several sole suppliers, or manufacturers, for blood collection tubes, including the cfDNA PAXgene tubes for use with liquid biopsy profiling, for total nucleic acid extraction kits, and for the NGS panels and library preparation kits we use. Given the specialized function of certain instruments and reagents, suitable replacements may not be available if a product is discontinued or the product specification undergoes substantial changes due to their own external competition or otherwise. This may significantly delay our ability to continue to develop and commercialize any other future commercial products. All changes to instruments, associated software and reagents will undergo a risk evaluation to determine the level of validation required per the product regulatory status and may require supplementary submissions to, and approval of, regulatory agencies such as the FDA. Whether transitioning to a new supplier, instrument or reagent, the process is likely to be time-consuming, expensive and could affect test performance metrics.

We have obtained a PMA approval from the FDA for MI Cancer Seek and may decide to seek FDA approval for Caris Assure and additional solutions. We do not manufacture the instruments or reagents used with our solutions, nor do we control such process, and we rely on external suppliers to maintain development and commercialization activities. The molecular testing performed by us is highly complex and requires specialized instruments and reagents, some of which are considered critical and could not be substituted without significant impact to our operations. Any failures or delays in negotiating appropriate agreements with our suppliers on reasonable terms, or their inability to obtain any required marketing authorizations, may increase our costs or delay or prevent us from obtaining or maintaining FDA marketing authorization of the related solutions.

Our current suppliers may also discontinue or substantially change the specification of products that we use or intend to use in our solutions. We believe there are few other manufacturers that are currently capable of supplying and servicing the equipment and materials necessary for our laboratory operations, including certain instruments, components, consumables, and reagents. Transitioning to a new supplier for this equipment or these materials would be time-consuming and expensive, could result in interruptions in or otherwise affect the performance specifications of our laboratory operations and sample processing or could require that we revalidate our solutions and could require a new submission to the FDA and other regulatory bodies to authorize such changes for any of our solutions that have received FDA approval. We also cannot guarantee that we will appropriately prioritize or select alternative suppliers, where necessary. In addition, we do not have written supply agreements with certain of our suppliers, including Agilent, Matsunami Glass, and PAXgene, and instead purchase certain products on a purchase order basis, which exposes us to potential price increases and termination of supply without notice or recourse. We cannot guarantee a consistent source of supply and cannot assure you that any efforts to enter into written agreements with our suppliers will be successful. The use of equipment or materials provided by a replacement supplier could require us to alter our laboratory operations and sample collection and processing and related procedures. Moreover, replacement instruments and associated reagents, tubes, and panels that meet our quality control and performance requirements may not be available at all, or may not be available on reasonable terms or in a timely manner. If we encounter delays or difficulties in securing, reconfiguring, or revalidating the equipment, reagents, and other materials that we require for our solutions, laboratory operations and sample collection and processing, in particular for those products that are sole sourced, we would likely face significant disruptions or delays in commercializing our solutions and our business, financial condition, results of operations, and growth prospects would be adversely affected.

If we fail to obtain additional financing, we may be unable to execute on our business strategies and our growth prospects could be harmed.

Our operations have required substantial amounts of cash since our inception. The development of our solutions are expensive, and we expect to continue to spend substantial amounts as we continue to enhance our solutions, broaden the applications of our existing solutions, and develop new solutions. In addition, obtaining any necessary or desirable marketing authorizations for our solutions will require substantial additional funding.

We may consider raising additional capital in the future to expand our business, meet existing obligations, pursue acquisitions or strategic investments, take advantage of financing opportunities, or for other reasons, including to:

- increase our sales and marketing efforts to drive market adoption of our current solutions and address competitive developments;
- fund development and marketing efforts of new solutions or any other future solutions;
- expand our technologies into other types of cancer management and detection solutions for other chronic disease states;
- acquire, license, or invest in our existing and future technologies;
- acquire or invest in complementary businesses or assets; and
- finance capital expenditures and general and administrative expenses.

As of March 31, 2025, we had \$31.2 million of cash and cash equivalents and \$2.2 million of short-term marketable securities. We could use our available capital resources sooner than we expect, including due to changing circumstances or those beyond our control that may cause us to increase our spending significantly faster than we anticipate, requiring us to raise additional funds sooner than we anticipate.

We will require additional capital for the development and commercialization of MI Cancer Seek, Caris Assure, Caris ChromoSeq, and the development of additional solutions. Our future capital requirements depend on many additional factors, including:

- the cost of development and commercialization activities, including marketing and sales, for our solutions;
- our ability to achieve revenue growth;
- the cost related to scaling operating capabilities to support demand for our solutions, including the cost of completing the build-out of our laboratory in Irving, Texas;
- the timing of, and the costs involved in, obtaining any required or desired marketing authorizations for our solutions;
- the timing, scope, progress, results and costs of developing additional solutions, and of conducting validation studies, clinical trials, and other studies that may be required in order to market our solutions;
- the costs involved in obtaining, maintaining, protecting, and enforcing patent and other intellectual property rights and claims, including litigation costs and the outcome of such litigation;
- the timing and amount of sales of our solutions, if any, and collection of related receivables;
- the extent to which our solutions are eligible for coverage and reimbursement from third-party payers and government payers;
- the emergence of new technologies, scientific breakthroughs, or any competing tests, products, or services, and other adverse market developments; and
- other potential adverse developments.

Additional capital may not be available when we need it, on terms acceptable to us or at all. We have no committed source of additional capital, having borrowed the remaining principal amount of \$200.0 million under the delayed draw loan of the 2023 Term Loan (as defined below) in March 2024. Furthermore, any additional capital raised through the sale of equity or equity-linked securities will dilute shareholders' ownership interests in us, may require shareholder approval, may have an adverse effect on the price of our common stock, and holders of these securities may have rights, preferences, or privileges senior to those of our then-existing shareholders. Debt financing, if available, may include restrictive covenants that could limit how we conduct our business. Our ability to incur additional indebtedness also is currently restricted by the terms of our 2023 Term Loan Agreement (as defined below). If adequate capital is not available to us on a timely basis, we may be required to significantly delay, scale back, or discontinue the commercialization of our solutions or R&D programs, or be unable to continue or expand our operations or otherwise capitalize on our business opportunities, as desired, which could adversely impact our business, financial condition, and results of operations and cause the price of our common stock to decline.

If our facilities or those of our third-party collaborators are insufficient or become inoperable, our ability to provide our solutions will be significantly impaired and our business will be harmed.

We currently perform all R&D and commercial profiling in our multiple laboratories in Phoenix and Tempe, Arizona and are building out our newest facility in Irving, Texas. Any disruption to the operations of these facilities could compromise the integrity of our samples and impede our ability to accurately perform our profiling and ultimately adversely impact our reputation, business, financial condition, and results of operations. In addition, we may maintain samples for several years. It is possible that some,

if not all, of these samples may degrade over time, which could negatively impact our ability to use such samples to validate future solutions and which could adversely impact our business, financial condition, and results of operations.

One or more of our facilities may be harmed, rendered inoperable by physical damage or otherwise become partially or completely unusable due to fire, floods, earthquakes, power loss, telecommunications failures, break-ins, accidents, water shortages, floods, tornadoes, hurricanes, fires, extreme weather conditions, health epidemics, pandemics, and similar events, which may render it difficult or impossible for us to provide our solutions for some period of time. Our laboratories and the equipment we use to perform our R&D or commercialization work could be unavailable or costly and time-consuming to repair or replace. It would be difficult, time-consuming, and expensive to rebuild one of our facilities, particularly in light of the licensure, permits, and accreditation requirements for clinical laboratories like ours. Although we carry insurance for damage to our properties and the disruption of our business, this insurance may not be sufficient to cover all of our potential losses and may not continue to be available to us on acceptable terms, or at all.

We have started the process of constructing a new laboratory facility in Irving, Texas to increase product development and operational capacity. Such construction requires significant resources, and we may encounter difficulties and delays in construction, procuring laboratory equipment, obtaining necessary validation, permits, licenses, and certifications (including CLIA certification and College of American Pathologists (“CAP”) accreditation, or completing the technology implementation) for this new facility. If we are unable to complete construction and go-live in a timely and satisfactory manner, obtain the necessary permits, licenses, certificates, and accreditations within our currently anticipated timelines, or meet demand for our solutions at our Arizona facilities, on a timely basis or at all, our reputation and commercial activities would be negatively impacted. We may be unable to regain customers or repair our reputation in the future, which would negatively impact our business, financial condition, and results of operations.

We also rely on our third-party collaborators, consultants, contractors, vendors, suppliers, and service providers. The facilities of these partners could be subject to fire, floods, earthquakes, power loss, telecommunications failures, break-ins, accidents, water shortages, floods, tornadoes, hurricanes, fires, extreme weather conditions, health epidemics, pandemics and other natural or man-made disasters or business interruptions. In addition, they may be affected by government shutdowns, changes to applicable laws, regulations, and policies, or withdrawn funding. The occurrence of any of these business disruptions could seriously harm their ability to complete their contracted services to us, which may adversely impact our business, financial condition, and results of operations.

If our solutions result in direct or indirect patient harm or injury, we could be subject to significant reputational and liability risks, and our business, financial condition, and results of operations could suffer.

Our success depends on the market’s confidence that our solutions, including MI Profile, MI Cancer Seek, Caris Assure, MI Tumor Seek Hybrid, and GPSai and other solutions that we may develop in the future, can provide reliable and high-quality results. We believe that patients, physicians, and regulators are likely to be particularly sensitive to errors in the use of our solutions or failure of our solutions to perform as described, and there can be no guarantee that our solutions will meet their expectations. Performance failures could establish a negative perception of our solutions among physicians, patients, and regulators, jeopardize our ability to successfully commercialize our solutions, impair our ability to obtain marketing authorizations or secure favorable coverage and reimbursement, or otherwise result in reputational harm. The costs incurred in correcting any defects or errors may be substantial and could adversely affect our operating margins. Identifying the root cause of quality issues, particularly those affecting reagents and third-party components, may be difficult, which increases the time needed to address quality issues as they arise, and increases the risk that similar problems could recur. In addition, we may be subject to legal claims arising from any errors in the use, manufacture, design, labeling or performance of our solutions, including any false-positive or false-negative results.

Our anticipated application of Caris Assure for early detection, MRD tracking, and treatment monitoring poses additional risks. Caris Assure is currently intended to be used to detect cancers in patients. A detection of cancer by Caris Assure would need to be followed up with a cancer diagnosis by a physician. Because Caris Assure is not currently able to detect all forms of cancer, a negative test would not rule out the presence of cancer. Additionally, an individual undergoing further diagnostic procedures on

the basis of a false-positive result or an erroneous cancer lineage could expose us to significant liability and reputational risks, notwithstanding the emotional and mental health effects to which the patient may be exposed. Similarly, an individual who receives a cancer diagnosis shortly following an inaccurate result, such as a negative test or false negative result, may create adverse publicity about our solutions, which could damage our reputation and have a negative impact on our business, financial condition, and results of operations. Failure to accurately detect cancer and other performance failures could establish a negative perception of our solutions among physicians, patients, customers, and regulators, jeopardize our ability to successfully commercialize our solutions, impair our ability to obtain marketing authorizations or secure favorable coverage and reimbursement, or otherwise result in reputational harm or enforcement action or inquiry by a regulatory body. These risks may be more pronounced and could expose us to claims of injury or other adverse events under medical liability, product liability, or other liability laws if a provider uses our tests inaccurately or inappropriately for diagnosis purposes, as our solutions would be directly involved with the choice to use certain treatments. In addition, we may be subject to legal claims arising from any errors in the use, manufacture, design, labeling, marketing, or performance of our products, including from inaccurate results. If our solutions result in direct or indirect participant or patient harm or injury, we could be subject to significant reputational and liability risks, may be required to initiate corrective actions, recalls or suspend sales of our products, which may adversely impact our reputation, business, financial condition, and results of operations.

If we were to be sued for product liability or professional liability, we could face substantial liabilities that exceed our resources, including any insurance coverage.

The marketing, adoption, and use of our solutions could lead to the filing of product liability claims if someone alleges that our solutions identified inaccurate or incomplete information regarding the genomic alterations of the tumor or malignancy analyzed, reported inaccurate or incomplete information concerning the available therapies for a certain type of cancer, or otherwise failed to perform as designed. We may also be subject to professional liability for errors in, a misunderstanding of, or inappropriate reliance upon, the information we provide in the ordinary course of our business activities. A product liability or professional liability claim could result in substantial damages and be costly and time-consuming for us to defend.

We maintain product and professional liability insurance, but this insurance may not fully protect us from the financial impact of defending against product liability or professional liability claims. Any product liability or professional liability claim brought against us, with or without merit, could increase our insurance rates or prevent us from securing insurance coverage in the future. Additionally, any product liability or professional liability lawsuit could damage our reputation or cause current clinical customers to terminate existing agreements with us and potential clinical customers to seek other partners, any of which could adversely impact our business, financial condition, and results of operations.

Our business and results of operations will suffer if we fail to compete effectively.

The precision oncology industry, which is the focus of our current commercial portfolio, is intensely competitive. Our competitors include numerous companies offering or seeking to offer tissue-based molecular profiling, blood-based early detection, blood-based molecular profiling for therapy selection, MRD tracking, and/or treatment monitoring, core biopharma services, and genomic data and AI services to biopharma companies. For additional information, see “Business—Competition.” Our competitors have or may have substantially greater financial, technical, and other resources, such as larger R&D staff and more well-established marketing and sales forces. Our competitors may succeed in developing, acquiring, or licensing, on an exclusive basis or otherwise, tests or services that are more effective or less costly than our solutions. In addition, established medical technology, biotechnology, or biopharma companies, some of whom may be our customers, may invest heavily to accelerate discovery and development of tests that could make our solutions less competitive than we anticipate.

Our ability to compete successfully will depend largely on our ability to:

- successfully commercialize and expand the features of our solutions and develop new solutions to achieve meaningful innovation in precision oncology and other chronic disease states;

- demonstrate compelling advantages in the performance and convenience of our solutions, including on a cost competitive basis;
- achieve market acceptance of our solutions by patients and healthcare providers;
- the rate of adoption and/or endorsement of our solutions by clinicians, KOLs, advocacy groups, and biopharma companies;
- achieve adequate coverage and reimbursement recognition from governmental payers, health insurance organizations, and other third-party payers for our solutions;
- address any technological, scientific, and market developments to differentiate our solutions from products and services offered by current and potential competitors;
- attract qualified scientific, data science, clinical development, solution development, and commercial personnel;
- obtain, maintain, defend, and enforce patent and other proprietary protection as necessary for our solutions and platform;
- obtain and maintain any necessary or desirable marketing authorizations from regulators in the United States and other jurisdictions for any versions of our current solutions and any future solutions that we may develop;
- successfully collaborate with institutions in the discovery, development, and commercialization of our solutions;
- establish and maintain supply and manufacturing relationships with third parties that can timely and consistently provide adequate, in both amount and quality, products and services to support clinical development and the market demand for our solutions; and
- successfully expand our operations infrastructure and implement a successful sales and marketing strategy to support increased commercialization.

We may not be able to compete effectively or keep pace with the rapid rate of change in our industry if we are unable to accomplish one or more of these or similar objectives. This could render our solutions obsolete or less attractive, result in significant price reductions, or substantially limit the volume of products that we offer.

Failure of, or defects in, our AI/ML models and on-premise, co-located, and cloud-based computing infrastructure, including interruption of services through Amazon Web Services, or increased regulation in the AI/ML space, could impair our ability to process our data, develop solutions, or provide test results, and harm our business and results of operations.

The design, development, maintenance, and operation of our technology over time is expensive and complex, and may involve unforeseen difficulties including material performance problems, undetected defects, or errors. Overcoming technical obstacles and correcting defects or errors could prove to be impossible or impracticable, and the costs incurred may be substantial and adversely affect our business, financial condition, and results of operations. Additionally, regulation in the AI/ML space is constantly evolving. See “—Regulatory, social and ethical issues relating to our use of new and evolving technologies, such as AI and ML, may result in reputational harm and liability.” If our technology does not function reliably, fails to meet expectations in terms of performance, or cannot be fully utilized due to increasing regulation, including regulation by the FDA of AI or medical device software, we may be unable to provide, or our customers may stop using, our solutions.

We currently host our data on, and conduct certain data analysis through, Amazon Web Services (“AWS”) cloud-based hosting facilities as well as on our own co-located or on-premise computing infrastructure. Any technical problems or outages that may arise in connection with AWS’s or our data center hosting facilities could result in operational disruption, loss of our data or delayed or ineffective data processing. A variety of factors, including infrastructure changes, human or software errors, viruses, malware, security attacks, fraud, denial of service or technical support issues could cause interruptions in our service. Such service interruptions may reduce or inhibit our ability to provide our solutions, delay our

clinical trials, and damage our relationships with our customers. We could also be exposed to potential lawsuits, customer reputational impact, liability claims or regulatory actions, for example, if AWS or we experienced a privacy or data security breach. If we were required to transfer our data to an alternative hosting provider, the transfer and acclimation to the new provider could result in significant business delays and subject us to technological risks and require additional resources.

Regulatory, social, and ethical issues relating to our use of new and evolving technologies, such as AI and ML, may result in reputational harm, additional costs, and liability.

We utilize AI/ML algorithms for data analysis of patient information and other data. As with many cutting-edge innovations, AI and ML present new risks and challenges, including social and ethical issues and a quickly evolving legal and regulatory environment, which may cause us to incur increased compliance or R&D costs, or to divert resources from other development efforts. Regulation of AI/ML usage continues to evolve, and limitations placed on the use of data, including personal information, health data, or genetic/genomic data in such systems may make it difficult or more costly for us to continue using our ML algorithms. Existing laws and regulations may be interpreted to apply to us in new ways due to our use of AI and ML, the nature and extent of which are difficult to predict. The risks and challenges presented by AI and ML could undermine public confidence in AI and ML, which could slow its adoption, impact patients' and physicians' confidence in our solutions, and otherwise affect our business. Failure to adequately address ethical and social issues related to our use of AI/ML could adversely affect the adoption of our solutions and subject us to reputational harm, regulatory action, or legal liability, which may harm our financial condition and results of operations.

Potential government regulation related to AI ethics or usage may also increase the burden and cost of R&D in this area. Certain U.S. states have passed or are considering the passage of laws intended to regulate and/or require disclosures in connection with the usage of AI, including in interactions with customers or other market participants. For example, Colorado passed the Colorado Artificial Intelligence Act, which will require disclosures and compliance efforts associated with different uses of AI, and Utah passed the Utah Artificial Intelligence Policy Act, which requires certain disclosures to customers and confirms companies' responsibility for legal violations caused by their AI applications. It is possible that these or other states or the federal government could pass additional legislation or implement regulations impacting businesses' use of AI/ML, which could impact our operations and impose additional costs or liability on us. Additionally, employees or customers who are dissatisfied with our public statements, policies, practices, or solutions related to the development and use of AI and ML may express opinions that could introduce reputational or business harm, or legal liability.

We use AI/ML to assist us in making certain diagnostic and benefit prediction decisions, which AI/ML is regulated by certain privacy laws. Due to inaccuracies or flaws in the training, development, inputs, outputs, and logic of an AI/ML model, the model could be biased. Any bias in a model could result in limits on the applicability or accuracy of the model across patient populations or could lead us to make decisions that could disadvantage certain individuals (or classes of individuals) and adversely impact their rights, employment, and ability to obtain certain pricing, products, services, or benefits.

We are highly dependent on our key personnel, and if we lose key members of our senior management, scientific or technical teams or are not successful in attracting, motivating, and retaining highly qualified personnel, we may not be successful.

Our ability to compete in the competitive precision medicine industry depends upon our ability to attract, motivate, and retain highly qualified personnel. We are particularly dependent on key members of our senior management team, including David D. Halbert, our Founder, Chairman, and Chief Executive Officer. The loss or incapacity of existing members of our senior management team could adversely affect our operations if we experience difficulties in hiring qualified successors and could hamper or delay the development and commercialization of our solutions and harm our business, financial condition, and results of operations. We do not maintain "key person" insurance policies on the lives of these individuals or the lives of any of our other employees.

Our R&D programs and laboratory operations depend on our ability to attract and retain highly skilled scientists, technicians, and data scientists. We may not be able to attract or retain qualified scientists

and technicians in the future due to the competition for qualified personnel among life science businesses. We also face competition from universities and public and private research institutions in recruiting and retaining highly qualified scientific personnel. In addition, we may have difficulties locating, recruiting, or retaining qualified sales representatives and business development managers. Recruiting and retention difficulties can limit our ability to support our R&D and sales programs.

To induce valuable employees to remain at our company, in addition to salary and cash incentives, we provide stock option and RSU grants with vesting conditions. The value of these equity grants may be significantly affected by movements in our stock price that are beyond our control, and may at any time be insufficient to counteract more lucrative offers made to our employees from other companies. Although we have employment agreements with certain key employees, consistent with all of our employment arrangements, these employment agreements provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice. If we are unable to attract and incentivize highly qualified personnel on acceptable terms, or at all, our business, financial condition, and results of operations may suffer.

If our information technology systems or those of third parties with whom we work, or our data are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions, litigation, fines and penalties, disruptions of our business operations, reputational harm, loss of revenue or profits, and other adverse consequences.

In the ordinary course of our business, we and the third-parties with whom we work collect, store, receive, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, “Process”) personal information, including health-related information, individually identifiable health information and protected health information (“PHI”) as defined by the Health Insurance Portability and Accountability Act, as amended by the Health Information Technology for Economic and Clinical Health Act, and their implementing regulations (collectively, “HIPAA”), personally identifiable information, credit card and other financial information, and intellectual property and proprietary business information (collectively “Sensitive Information”).

As a result, we and the third parties with whom we work face numerous and evolving cybersecurity risks that threaten the confidentiality, integrity, and availability of our information technology and telecommunications systems and Sensitive Information. Such threats are prevalent and continue to rise, are increasingly difficult to detect, and come from a variety of sources, including telecommunications or network failures, malicious human acts, and natural disasters.

We and the third parties with whom we work are subject to threats from various threat actors, such as state-sponsored organizations, criminal threat actors, organized crime outfits, opportunistic hackers and “hacktivists,” as well as a variety of evolving threats, such as social engineering/phishing (including through deep fakes, which may be increasingly more difficult to identify as fake), malware (including ransomware and as a result of advanced persistent threat intrusions), network reconnaissance and intellectual property theft, use of illegitimate virtual private networks or anonymization tools, malfeasance by insiders (such as personnel misconduct or error), human or technological error, malicious code (such as viruses and worms), denial-of-service attacks, database compromises, business email compromises, credential stuffing, credential harvesting, credential theft, software “bugs,” misconfigurations, or other vulnerabilities in software that is integrated into our (or the third parties with whom we work) IT systems, misuse of company resources and software, lack of adherence to company policy, products or services, adware, attacks enhanced or facilitated by AI, physical or electronic break-ins, earthquakes, fires, floods, and similar disruptive threats.

Some actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we and the third parties with whom we work are vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks, that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our services.

Remote work has become more common and has increased risks to our information technology systems and data, as more of our employees utilize network connections, computers, and devices outside our premises or network, including working at home, while in transit and in public locations. Additionally,

future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program.

We depend on information technology and telecommunications systems, including those provided by third parties and their vendors (some of which are legacy systems developed internally and may carry additional information security vulnerabilities), for significant elements of our operations, such as our laboratory information management systems, including test validation, specimen tracking, and quality control; personal information collection, storage, maintenance, and transmission; our profiling report production systems; and our billing and reimbursement, R&D, scientific and medical data analysis, and general administrative activities that collect, store and transmit large amounts of Sensitive Information, including intellectual property, proprietary business information, PHI, and other personal information of our customers, patients, business partners, employees, and contractors on such systems. In turn, the third parties and vendors with whom we work depend upon technology and telecommunications systems provided by outside vendors.

Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If the third parties with whom we work experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if the third parties with whom we work fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. In addition, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or that of the third parties with whom we work have not been compromised.

Cyber-attacks, malicious internet-based activity, online and offline fraud, insider threats and other similar activities are increasing in their frequency, levels of persistence, sophistication, and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives and expertise. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we and the third parties with whom we work may be unable to anticipate these techniques or implement adequate preventative measures. We and the third parties with whom we work may also experience security incidents that may remain undetected for an extended period. There can also be no assurance that our cybersecurity risk management program and processes, including our policies, controls, or procedures, will be fully implemented, complied with or effective in protecting our information technology and telecommunications systems and Sensitive Information.

In addition, severe ransomware attacks are becoming increasingly prevalent and can lead to significant interruptions in our operations, ability to provide our products or services, loss of Sensitive Information and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments. Some of these attacks have also been coupled with attackers directly threatening executives with physical harm.

Applicable privacy and data security obligations may require us to notify relevant stakeholders, including affected individuals, customers, regulators, and investors, of security incidents, or to implement other requirements such as providing credit monitoring. Such disclosures and compliance with such requirements are costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences. For example, a growing number of legislative and regulatory bodies around the world have adopted breach notification and other requirements in the event that information subject to such laws is accessed by unauthorized persons and additional regulations regarding the use, access, accuracy, and security of such data are possible. In particular, we are a "Covered Entity" as defined under HIPAA, and, in the event of a breach as defined by HIPAA, we have specific reporting requirements under HIPAA regulations.

Under HIPAA, in the event of a significant breach, the reporting requirements could include notification to the general public, in addition to affected individuals and certain governmental agencies. In

addition, in the United States, we are subject to state and other laws that require notification. Complying with such numerous and complex regulations in the event of unauthorized access would be expensive and difficult, and failure to comply with these regulations could subject us to regulatory scrutiny and additional liability, could harm our reputation and our ability to compete, and could adversely affect our business, financial condition, and results of operations.

We take steps designed to detect, mitigate, and remediate vulnerabilities in our information systems (such as our hardware and/or software, including that of third parties with whom we work). We may not, however, detect or remediate all such vulnerabilities including on a timely basis. By way of example, in the spring of 2024, a security researcher informed us of a previously unknown vulnerability in one of our systems, which we have remediated. Further, we may experience delays in developing and deploying remedial measures and patches designed to address identified vulnerabilities. Vulnerabilities could be exploited and result in a security incident. If attackers are able to exploit vulnerabilities before patches are installed or mitigating measures are implemented, compromises could impact our information technology systems and Sensitive Information.

Any of the previously identified or similar threats could cause a security incident or other interruption that could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our Sensitive Information or our information technology systems, or those of the third parties with whom we work. A security incident or other interruption could disrupt our ability (and that of third parties with whom we work) to provide our services. If an attacker were to gain sufficient access to our systems, our data contained in those systems could be discovered by the attacker.

We, and the third parties with whom we work have been the target of cybersecurity attacks in the past and expect that such cybersecurity incidents will continue to occur in the future. For example, the February 2024 cybersecurity attack on Change Healthcare, who we used to process certain insurance claims, resulted in a delay in our ability to submit claims for payment and could require us to issue notifications to impacted individuals and various regulators if Change Healthcare determines that any PHI of our patients was impacted. While we may be entitled to damages as a result of this incident, any award may be insufficient to cover all such damages, or we may be unable to recover such award.

We may expend significant resources or modify our business activities to try to protect against security incidents. Additionally, certain privacy and data security obligations may require us to implement and maintain specific security measures or industry-standard or reasonable security measures to protect our information technology systems and Sensitive Information.

Despite the precautionary measures we and the third parties with whom we work have taken to detect and prevent or solve problems that could affect our information technology and telecommunications systems and Sensitive Information, there is a risk that our security measures will not be fully effective in the future. Failures or significant downtime of these systems or those used by the third parties with whom we work could prevent us from conducting tests, preparing and providing reports to future customers, billing payers, conducting R&D activities, maintaining our financial controls and other reporting functions, and managing the administrative aspects of our business. Any failure by us or the third parties with whom we work to prevent or mitigate security incidents, or other adverse impact to the availability, integrity, or confidentiality of our information technology systems or Sensitive Information, or improper access to, or use, acquisition, disclosure, alteration or destruction of, any such Sensitive Information, including loss of PHI or other data subject to privacy laws or proprietary business information, could result in operational or business delays, significant liability, regulatory action, a material loss of revenue resulting from the adverse impact on our reputation and brand, a diminished ability to retain or attract new customers, disruption to our business, and adversely affect our business, financial condition, and results of operations.

Our existing cyber liability insurance policies may not cover, or may cover only a portion of, any potential claims related to security breaches to which we are exposed or may not be adequate to indemnify us for all or any portion of liabilities that may be imposed. We also cannot be certain that our existing insurance coverage will continue to be available on acceptable terms or in amounts sufficient to cover the potentially significant losses that may result from a security incident or breach or that the insurer will not deny coverage of any future claim.

In addition to experiencing a security incident, third parties may gather, collect, or infer Sensitive Information about us from public sources, data brokers, or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position. Additionally, Sensitive Information of the Company or our customers could be leaked, disclosed, or revealed as a result of or in connection with our employees', personnel's, or vendors' use of AI/ML technologies.

We may not be successful in developing and commercializing new solutions or new applications for our current solutions.

We continue to expand our R&D efforts to use our solutions and our multi-modal clinico-genomic datasets to develop enhanced versions of our solutions and create new solutions. These initiatives include expanding the application of Caris Assure to early detection, MRD tracking, and treatment monitoring, developing Caris ChromoSeq for hematological (blood) cancers, developing additional AI signatures using NGS or image data, and additional solutions, including for chronic disease states beyond cancer. The commercialization of any new solutions or new applications for our current solutions will require the completion of certain clinical development activities, validation studies and/or clinical trials, having guidelines or recommendations for healthcare providers, administrators, payers, and patient communities relating to such solutions, and receiving favorable exposure in peer-reviewed publications and from KOLs. We cannot assure you that we can successfully complete the clinical development or applicable subsequent requirements of any such solutions in order to commercialize such solutions.

We may fail to build a sustainable data licensing business, and our data licensing efforts may result in reputational harm that has an adverse effect on our business, financial condition, and results of operations.

We and our biopharma and academic partners leverage high-powered computing and AI/ML algorithms to analyze our data to find the key molecular characteristics of a particular disease or dysfunction that drives disease. As part of these efforts, we license data to our partners, and certain of our partners license data to us. We are in the early stages of these data licensing efforts and may not be able to grow these efforts into a sustainable business.

The outbound licensing of data for research purposes is a novel business model without an established track record, which makes it difficult to evaluate our future prospects and the risks and challenges we may encounter in seeking to execute on this opportunity. Although we have negotiated data licensing agreements with several partners, these partners may have rights to terminate these agreements before the initial term has been completed, and these arrangements may not be renewed, or they may be renewed on less favorable terms. In addition, many of our data licensing agreements involve the use of third-party clinical data that is combined with our molecular data and then licensed to biopharma companies or other end users, and these third-party clinical data partners may not be willing to work with us in the future. We also depend on these third-party partners to provide access to data from their own data partners. We cannot guarantee that our third-party partners will enter into new data sharing arrangements with us, continue to provide their data, or that of their partners, to us, or include their data as part of combined data sets, and in the event that any of these arrangements terminate, we may not be able to find a replacement, or a replacement may not be available on reasonable terms or in a timely manner. Any of the foregoing could result in us losing access to real-world evidence, longitudinal patient data, and clinical outcomes that are key to maintaining, expanding, and enriching our datasets, which could have an adverse effect on our business, financial condition, and results of operations.

The commercial market for licensing this type of data may not develop or may be limited by regulation or other factors, which could diminish the value of licensing this data over time and make it challenging to secure arrangements with these partners on similar terms, or at all, with any additional licensees. While our data licensing arrangements include protections against abuse and misuse of patient data, we may be unable to adequately control how our partners, or the commercial customers that they license our data to as part of a combined data set, use the data, and any abuse or misuse could adversely impact our reputation, which could have an adverse effect on our business, financial condition, and results of operations.

If we cannot maintain our current relationships, or enter into new relationships, with biopharma companies, our development of solutions could be delayed or our business, financial condition, and results of operations could be adversely affected.

We deploy our proprietary profiling and signature offerings to analyze tissue and blood samples provided by biopharma partners.

Our success in the future depends in part on our ability to maintain and expand relationships with our biopharma partners. This can be difficult due to several factors, including internal and external constraints placed on these organizations that can limit the number and type of relationships with companies like us they can consider and consummate; that certain of our agreements governing our relationships are terminable at will by our biopharma partners; and that our biopharma partners may be dissatisfied with our services. Continued usage of our services by particular biopharma partners may also depend on whether the partner obtains positive data in its clinical trials, is able to successfully obtain regulatory approval and subsequently commercializes a therapy for which we have partnered with them to develop a companion diagnostic, or other administrative factors that are outside our control. Additionally, some of our biopharma partners have contracted with us to provide profiling for large numbers of samples, which could strain our testing capacity and restrict our ability to perform tests for other customers. If we fail to maintain these relationships or enter into new ones, our business could suffer.

From time to time, we expect to engage in discussions with biopharma companies regarding commercial opportunities. There is no assurance that any of these discussions will result in a commercial agreement, or if an agreement is reached, that the resulting engagement will be successful or that any clinical trials conducted as part of the engagement will produce successful outcomes. Speculation in the industry about our existing or potential engagements with biopharma companies can be a catalyst for adverse speculation about us, our services, and our technology, which can result in harm to our reputation and our business.

We rely on third-party services to collect, process, transport, and store our samples in a secure and cost-efficient manner. If these services were disrupted, our business would be harmed.

We rely on third-party providers to collect tissue and blood samples for our solutions. If third-party providers fail to adequately and properly obtain and collect viable blood and tissue samples from patients and to properly and timely package and ship the samples to us, our patients and their physicians may experience problems and delays in receiving test results, which could lead to dissatisfaction with our solutions, therefore harming our reputation and adversely affecting our business, financial condition, and results of operations. If our current third-party providers become unable to continue to collect samples for us or if our clients are unable to readily access a provider to collect a blood or tissue sample that we can analyze, we may be unable to compete effectively with other laboratories that have greater access to phlebotomy providers and our business, may be harmed.

In addition, we may maintain samples and extracted material for several years. It is possible that the long-term stability of these samples may not be maintained with the passage of time, which could negatively impact our ability to use such samples to validate our solutions. Further, interruptions in collection, processing, freezing, storing, or transportation of samples performed by third parties, whether due to labor disruptions, weather conditions, natural disaster, terrorist acts, threats, or for other reasons could adversely affect the samples and our ability to process the samples in a timely manner, which could negatively affect our ongoing research studies and harm our business.

The clinical trial process is lengthy and expensive with uncertain outcomes. We have encountered delays, and may encounter future substantial delays, in our clinical trials, and may therefore be unable to complete our clinical trials on the timelines we expect, if at all, which could adversely impact our ability to market our solutions or receive adequate reimbursement.

Clinical testing is expensive, time-consuming, and subject to uncertainty. Initiating and completing validation studies and clinical trials necessary to validate and market our solutions, and to support any submissions to CMS, MolDX, or other payers for reimbursement, or the FDA for marketing authorization for our solutions, will be time-consuming and expensive and the outcomes are inherently uncertain.

Validation studies and clinical trials must be conducted in accordance with the laws and regulations of the FDA and other applicable regulatory authorities' legal requirements and regulations, and are subject to oversight by these governmental agencies and institutional review boards ("IRBs").

The results of preclinical studies and clinical trials of our solutions conducted to date and ongoing or future studies and trials of our current, planned, or future solutions may not be predictive of the results of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Our interpretation of data and results from our validation studies and clinical trials do not ensure that we will achieve similar results in future validation studies or clinical trials. In addition, preclinical and clinical data are often susceptible to various interpretations and analyses, and many companies that have believed their products performed satisfactorily in validation studies, preclinical studies and earlier clinical trials have nonetheless failed to replicate results in later validation studies or clinical trials. Products in later stages of validation studies or clinical trials may fail to show the desired analytical validity and clinical validity despite having progressed through validation studies, nonclinical studies, and earlier clinical trials.

In addition, we cannot guarantee that any validation studies or clinical trials will be conducted as planned or completed on schedule, if at all. The timely completion of validation studies in accordance with their protocols depends, among other things, on our ability to locate and test a sufficient number of samples to demonstrate satisfaction of the validation study criteria. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of participants who remain in the trial until its conclusion. Many of our validation studies and clinical trials require enrolling a large number of participants without cancer who may not see value in enrollment. Additionally, we may encounter delays as a result of the administrative complexities in managing and recruiting for validation studies and trials of this scope and size. If we are unable to recruit and enroll sufficient participants for our validation studies or clinical trials, or maintain sufficient participation of enrolled participants, our product development, commercialization activities and our ability to seek marketing authorization for our solutions could be delayed, modified, or prevented.

The initiation and completion of validation studies and clinical trials may be prevented, delayed, or halted for numerous reasons, including related to the following:

- the inability to generate sufficient *in vitro* or *in vivo* data to support the initiation or continuation of clinical trials;
- the requirement to submit an IDE application to the FDA, which must become effective prior to commencing certain human clinical trials of significant risk medical devices, and which the FDA may disapprove;
- delays caused by participants withdrawing from clinical trials or failing to return for follow-up or by institutions failing to timely submit data, including follow-up data, if at all;
- delays or failure in reaching a consensus or agreement, if required, with regulatory agencies on trial design or feedback from regulatory agencies necessitating changes to ongoing or planned clinical trial design;
- delays or failure in reaching agreement on acceptable terms with prospective contract research organizations ("CROs"), service providers, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- delays or failure in obtaining any required IRB approvals or ethics committee ("EC") approvals for our clinical trial sites;
- delays in amending, or the inability to amend, our IRB-approved protocols at clinical trial sites when necessary or desired;
- difficulty or delays in collaborating with sites, institutions, and investigators;
- failure by us, investigators, sites, or participants to comply with the applicable trial protocol or applicable regulatory requirements and standards for data collection, reporting, records maintenance, or data integrity;

- failure by us, investigators, sites or any CROs or other third parties to adhere to clinical trial requirements, including the applicable protocol;
- failure to perform in accordance with good clinical practice (“GCP”) and good laboratory practice requirements, and/or other applicable regulations and requirements of the FDA or other applicable governmental authorities;
- failure to comply with applicable privacy and data security laws related to clinical trials;
- failure of our solutions to achieve acceptable performance, and safety endpoints;
- unacceptable safety findings, including findings related to the risk of the false positive tests (which could lead to unnecessary biopsy or anxiety) or false negative tests (which could lead to a delay in diagnosis or disease progression);
- termination or suspension of a trial or site by us or the data safety monitoring board, suspension or termination of a trial or site by an IRB, EC, or institution, or clinical hold or termination of a trial or site by a regulatory authority, including the FDA;
- disqualification, termination, or suspension of a clinical investigator;
- adverse inspections of our clinical trial sites or results by any applicable regulatory authority, including the FDA;
- changes in statutory or regulatory requirements or guidance, or clinical guidelines, that require amending existing or designing new clinical protocols, obtaining new IRB or EC approvals, modifying our clinical trials, modifying our consent process or obtaining additional consent from trial participants, or altering the pathway to marketing authorization of our solutions;
- changes in the standard of care on which a clinical development plan was based, which may require new or additional clinical trials;
- the cost of clinical trials of our solutions being greater than we anticipate;
- destruction or compromise of, or other inability to access or receive, clinical trial samples processed, stored, or managed at a third-party site or otherwise in the control of a third party;
- clinical trials of our solutions producing negative or inconclusive results, which may result in our deciding, or regulators requiring us, to conduct additional clinical trials or abandon development programs; and
- lack of adequate funding.

Any such delays could adversely affect the costs, timing, or successful completion of any future clinical trials. Moreover, we may depend on our collaborators and on medical institutions and CROs to conduct any future clinical trials in compliance with applicable GCP requirements, and while we may have agreements governing their committed activities, we may have limited influence over their actual performance. To the extent any future collaborators, the CROs, or clinical sites fail to enroll participants for our clinical trials, fail to conduct the trial to GCP requirements or are delayed for a significant time in the execution of trials, including achieving full enrollment, we may be affected by increased costs, program delays, and/or enforcement actions. In addition, any future clinical trials that are conducted in countries outside the United States may subject us to further delays and expenses.

Any inability to initiate or complete clinical trials successfully could result in additional costs to us, slow down or prevent our product development and receipt of positive reimbursement and coverage decisions, or impair our ability to generate revenue. Delays in initiating or completing our planned clinical trials could also allow our competitors to bring competing products to market before we do or sooner than expected, which could impair our ability to successfully commercialize our solutions, if launched, and may harm our business, financial condition, and results of operations. In addition, many of the factors that may cause, or lead to, a delay in initiation or completion of clinical trials may also ultimately lead to the delay or the narrowing or denial of any marketing authorization we may seek with respect to our solutions. Delays in the initiation or completion of any clinical trial of our solutions, such as Caris Assure for early detection, MRD tracking, or treatment monitoring, or seeking coverage and reimbursement, will increase

our costs, slow down, or jeopardize our product development and marketing authorization process, and delay or potentially jeopardize broad adoption of our solutions and their ability to generate revenue.

Risks Related to Regulation and Legal Compliance

If we or our partners fail to comply with healthcare and other applicable laws and regulations, we could face substantial penalties and sanctions and our business, reputation, financial condition, and results of operations could be adversely affected.

Our operations in the United States are subject to various U.S. federal and state laws and regulations that govern, among other things, the manner in which we provide and bill for tests and collect reimbursement from governmental programs, third-party payers and patients, our relationships with referral sources, and our marketing and advertising activities. In addition, the commercialization of our solutions outside the United States would also subject us to foreign equivalents of the healthcare laws described below, among other foreign laws. The laws that may impact our operations include:

- the federal Anti-Kickback Statute (the “AKS”), which prohibits, among other things, knowingly and willfully soliciting, receiving, offering, or paying any remuneration (including any kickback, bribe, rebate, a provision of free or discounted goods, services or items), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order, recommendation, or arrangement of any good, facility, item, or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation, and many courts have interpreted the AKS as being violated if merely one purpose of any arrangement is to induce referrals or purchases. The AKS includes statutory exceptions and regulatory safe harbors that protect certain arrangements. Failure to meet the requirements of an exception or safe harbor, however, does not render an arrangement illegal. Rather, the government may evaluate arrangements that do not fit into an exception or safe harbor on a case-by-case basis, taking into account all facts and circumstances, including the parties’ intent and the arrangement’s potential for abuse, and such arrangements may be subject to greater scrutiny by enforcement agencies;
- the Eliminating Kickbacks in Recovery Act of 2018 (“EKRA”), which establishes an all-payer anti-kickback prohibition for, among other things, knowingly and willfully paying or offering any remuneration directly or indirectly to induce a referral of an individual to or in exchange for an individual using the services of a clinical laboratory. EKRA applies to all payers including commercial payers and government payers. EKRA adopted safe harbors that are not directly analogous to the safe harbors under the AKS, and certain conduct that is permissible under the AKS may violate EKRA;
- the federal physician self-referral prohibition, commonly known as the Stark Law, which, in the absence of an applicable exception, prohibits a physician from making a referral for certain designated health services covered by the Medicare or Medicaid program if the physician or an immediate family member of the physician has a financial relationship (including an ownership interest or a compensation arrangement) with the entity providing the designated health services. The Stark Law also prohibits the entity furnishing the designated health services from billing, presenting, or causing to be presented a claim for the designated health services furnished pursuant to the prohibited referral. The term “designated health services” includes, among other things, clinical laboratory services. Unlike the AKS, the Stark Law is violated if the financial arrangement does not meet an applicable exception, regardless of any intent by the parties to induce or reward referrals or the reasons for the financial relationship and the referral;
- the FCA, which imposes civil and criminal liability on individuals or entities that knowingly submit false or fraudulent claims for payment to the government or knowingly make, or cause to be made, a false statement in order to have a false claim paid. Actions under the FCA may be brought by the government or by a private person under a qui tam, or “whistleblower,” suit. There are many potential bases for liability under the FCA. For example, the government

has used the FCA to prosecute Medicare and other government healthcare program fraud such as coding errors, coding and billing for tests not compliant with coverage and reimbursement requirements, including MoIDX reimbursement and coverage standards and requirements, waiver of patient copayments and deductibles, and performing tests that are not medically necessary or that are substandard in quality. In addition, a claim including items or services resulting from a violation of the AKS constitutes a false or fraudulent claim for purposes of the FCA, and courts have held that claims for services furnished pursuant to a referral prohibited by the Stark Law also are considered false for purposes of the FCA;

- the criminal healthcare fraud provisions of HIPAA and related rules that prohibit knowingly and willfully executing a scheme or artifice to defraud any healthcare benefit program or falsifying, concealing, or covering up a material fact or making any materially false, fictitious, or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items, or services. These criminal healthcare fraud provisions are not limited to benefits, items, or services that may be paid for by federal or state healthcare programs, and similar to the AKS, a person or entity does not need to have actual knowledge of these statutes or specific intent to violate them in order to have committed a violation;
- the federal Civil Monetary Penalties Law, which provides civil penalties for a wide variety of conduct relating to federal and state healthcare programs, including, subject to certain exceptions, prohibiting, among other things, the offer or transfer of remuneration, including free services, discounts, or waivers of copayments and deductible amounts (or any part thereof), to a Medicare or state healthcare program beneficiary if the person knows or should know it is likely to influence the beneficiary's selection of a particular provider, practitioner or supplier of services reimbursable by Medicare or a state healthcare program;
- the federal Physician Payment Sunshine Act, created under the Affordable Care Act (the "ACA"), and its implementing regulations, which require manufacturers of drugs, devices, biologicals, and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program to report annually to the U.S. Department of Health and Human Services ("HHS") under the Open Payments Program, information related to payments or other transfers of value made to physicians (as defined by statute), teaching hospitals and other healthcare practitioners such as physician assistants and nurse practitioners, as well as ownership and investment interests held by such physicians and their immediate family members and similar state laws with various reporting requirements;
- state self-referral, kickback, false claim, fraud, and abuse laws, some of which may apply to items or services reimbursed by any payer, including patients and commercial insurers, and include "whistleblower" provisions;
- federal and state "Anti-Markup" rules, which, among other things, typically prohibit a physician or supplier billing for clinical or diagnostic tests (with certain exceptions) from marking up the price of a purchased test performed by another physician or supplier that does not "share a practice" with the billing physician or supplier;
- federal and state laws applicable to test ordering, documentation of tests ordered, consent requirements, billing practices and claims payment and laws that prohibit other specified practices, such as providing tests at no or discounted cost to induce adoption, which may apply to laboratories; waiving co-insurance, deductibles or other amounts owed by patients; and billing a state healthcare program at a price that is higher than what is charged to other payers;
- the "No Surprises Act," which prohibits balance billing for certain non-emergency care, including for out-of-network clinical laboratory tests, and analogous state laws;
- state corporate practice prohibitions and professional fee-splitting laws that prohibit employing, exercising control over, or splitting fees with licensed medical professionals;
- federal and state consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and

- analogous state and foreign laws and regulations, such as state and foreign anti-kickback, self-referral, false claims, consumer protection, and unfair competition laws that may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements as well as submitting claims involving healthcare items or services reimbursed by any third-party payer, including commercial insurers; state laws that require healthcare companies to comply with the medical device industry's voluntary compliance guidelines, the relevant compliance guidance promulgated by the federal government that otherwise restricts payments that may be made to healthcare providers, and other potential referral sources or state-specific standards on financial interactions with healthcare providers; state laws that require healthcare companies to file reports with states regarding pricing and marketing information, such as the tracking and reporting of gifts, compensation, and other remuneration and items of value provided to healthcare professionals and entities; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

These laws and regulations, among other things, constrain our business and limit the types of financial arrangements we have with providers, customers, patients, vendors and third-party payers, and our billing, coding, and collection practices, including our patient financial assistance programs and our practices relating to collection of co-payments and deductibles. Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available and lack of clear guidance, our business activities could be subject to challenge under one or more of such laws. To enforce compliance, the Office of the Inspector General ("OIG") and the DOJ recently have increased their scrutiny of interactions between healthcare companies, on the one hand, and healthcare providers and patients on the other, which has led to a number of investigations, prosecutions, convictions, and settlements in the healthcare industry. These investigations often are focused on billing and coding practices as well as financial arrangements with referral sources and patients. We expect that the federal government will continue to devote substantial resources to investigating healthcare providers' compliance with the FCA and other applicable fraud and abuse laws.

We also have been, are currently, and may be in the future, subject to actions or investigations relating to our arrangements and interactions with healthcare professionals and patients. For additional information, see "—We have been, are currently, and in the future may be the subject of government investigations, claims, audits, whistleblower and payer audits, overpayment and recoupment efforts and other litigation in the course of our business that could adversely affect our business and financial statements."

Efforts to ensure that our business arrangements will comply with applicable laws, including healthcare laws and regulations, may involve substantial costs. In addition, the healthcare and other laws applicable to our business may change or be amended, and, it is possible that governmental and enforcement authorities will conclude that our business practices do not comply with current or then-existing statutes, regulations, or case law interpreting applicable fraud and abuse or other healthcare or applicable laws and regulations. We may not properly interpret certain requirements or fail to timely report activities, when required. If any such actions are instituted against us, and we are not successful in defending ourselves, those actions could have a material impact on our business, including the imposition of significant civil, criminal, and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, imposition of forward-looking compliance obligations, and curtailment of our operations, any of which could adversely affect our business, financial condition, and our results of operations.

We and the third parties with whom we work are subject to stringent and evolving U.S. and foreign privacy and data security laws, regulations, and rules, contractual obligations, industry standards, policies and other obligations related to privacy and data security. Our actual or perceived failure to comply with privacy and data security obligations (or such failure by the third parties with whom we work) could result in significant liability, administrative or governmental penalties, reputational harm and/or, other adverse business consequences.

In the ordinary course of business, we process Sensitive Information, including personal information, genetic information, and data about trial participants in connection with clinical trials. These data processing

activities subject us to numerous federal, state, and foreign privacy and data security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements, and other obligations, including AI/ML usage, relating to privacy and data security.

In the United States, numerous state and federal laws and regulations govern the privacy and security of personal information, including health-related information, such as data breach notification laws, personal information privacy laws, consumer protection laws (for example, Section 5 of the Federal Trade Commission Act), and other similar laws (e.g., wiretapping laws). HIPAA establishes a set of national privacy and security standards for the protection of individually identifiable health information, by health plans, healthcare clearinghouses and certain healthcare providers (“Covered Entities”), as well as for entities that perform certain services for or on behalf of such Covered Entities that involve creating, receiving, maintaining, or transmitting PHI (“Business Associates”), and their covered subcontractors. We are a Covered Entity when performing our healthcare services for customers, and also act as a Business Associate when performing certain services for or on behalf of Covered Entities.

When we act as a Covered Entity, for example, through services provided by Caris MPI, Inc., we are subject to certain obligations such as notice of privacy practices and secure handling of protected health information. In addition, when we act as a Business Associate of Covered Entities, for example, through services provided by our other entities, we are subject to certain provisions of HIPAA and the terms of any business associate agreements we enter into with such other Covered Entities. In addition, we may obtain health information from third parties that are subject to privacy and security requirements under HIPAA.

Under HIPAA, Covered Entities must report breaches of unsecured PHI to affected individuals without unreasonable delay, not to exceed 60 days following discovery of the breach by a Covered Entity or its agents. Notification also must be made to the HHS Office for Civil Rights and, in certain circumstances involving large breaches, to the media. Business associates must report breaches of unsecured PHI to Covered Entities during the timeframe outlined in the operative Business Associate Agreement, but in no even longer than 60 days of discovery of the breach by the Business Associate or its agents. A non-permitted use or disclosure of PHI is presumed to be a breach under HIPAA unless the Covered Entity or Business Associate establishes that there is a low probability the information has been compromised consistent with requirements enumerated in HIPAA.

Entities that are found to be in violation of HIPAA as the result of a breach of unsecured PHI, a complaint about privacy practices or an audit by HHS may be subject to significant civil, criminal, and administrative fines and penalties and/or additional reporting and oversight obligations if required to enter into a resolution agreement and corrective action plan with HHS to settle allegations of HIPAA non-compliance. HIPAA also authorizes state Attorneys General to file suit on behalf of their residents. Courts may award damages, costs and attorneys’ fees related to violations of HIPAA in such cases. While HIPAA does not create a private right of action allowing individuals to sue us in civil court for violations of HIPAA, its standards have been used as the basis for duty of care in state civil suits such as those for negligence or recklessness in the misuse or breach of PHI.

Certain states have also implemented genetic testing and privacy laws imposing specific patient consent requirements and protecting test results by strictly limiting the disclosure of those results. In addition, in the past few years, more than a dozen U.S. states have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal data; however, many of these laws have exceptions for entities subject to HIPAA or include exemptions for data subject to HIPAA, including clinical data protected under HIPAA and clinical trial data. For example, the California Consumer Privacy Act of 2018, as amended by the California Privacy Rights Act of 2020 (“CPRA”) (collectively, “CCPA”), applies to personal information of consumers, business representatives, and employees who are California residents, and gives California residents expanded rights regarding their personal information, including the right to opt out of certain personal information sharing, and receive detailed information about how their personal information is used. The CCPA provides for fines of up to \$7,500 per intentional violation, as well as a private right of action for certain data breaches. Although the CCPA exempts some data processed in the context of clinical trials and information subject to HIPAA, the CCPA increases compliance costs and potential liability with respect to other personal information we maintain about California residents.

We may also be subject to new laws governing the privacy of consumer health data, including genetic information. For example, Washington’s My Health My Data Act broadly defines consumer health data, imposes obligations and restrictions on processing consumer health data (including imposing stringent requirements for consents), provides consumers certain rights with respect to their health data, and creates a private right of action to allow individuals to sue for violations of the law. More than a dozen states have also adopted laws regarding the processing, privacy, and security of genetic information or expanded their comprehensive privacy laws to include additional restriction on companies with respect to processing of sensitive personal information, including genetic information; however, many of these laws have exceptions for entities subject to HIPAA or include exemptions for data subject to HIPAA, including clinical data protected under HIPAA and clinical trial data.

Similar laws are being considered in several other states, as well as at the federal and local levels, and we expect more states to pass similar laws in the future. While several of these laws exempt some data processed in the context of clinical trials or deidentified information under HIPAA, such laws could have potentially conflicting requirements and may increase our compliance costs and potential liability. We could be adversely affected if such laws and other state or federal legislation or regulations applicable to us require changes in our business practices (including our ability to license deidentified information to biopharma companies) or privacy policies, or if governing jurisdictions interpret or implement their legislation or regulations in ways that adversely affect our business, financial condition, and results of operations.

Furthermore, violation of consumers’ privacy rights or failure to take appropriate steps to keep consumers’ personal information secure may constitute unfair and/or deceptive acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act, including entities subject to HIPAA. The Federal Trade Commission (“FTC”) expects a company’s data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits particularly strong safeguards. We publish privacy policies, marketing materials, and other statements, such as compliance with certain certifications or self-regulatory principles, regarding privacy and data security. If these policies, materials, or statements are found to be deficient, lacking in transparency, deceptive, unfair, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators, or other adverse consequences.

In addition, we seek to utilize biological samples and data from participants in our clinical trials and validation studies in accordance with applicable law, IRB requirements, and participant permissions (through consent forms and HIPAA authorizations). If we are unable or significantly restricted in using participant samples and data for secondary research purposes, our ability to develop additional solutions and/or improve or refine existing solutions will be limited, which may impact our business and prospects.

Moreover, we are subject to laws, regulations, and standards governing certain marketing, advertising, and other communications conducted by telephone, fax, or text. In particular, sending short message service text messages to participants and prospective participants in our clinical trials is governed by the Telephone Consumer Protection Act (“TCPA”) which imposes various consumer consent requirements and other restrictions on communications with consumers. Although we may be able to rely on certain exemptions for healthcare-related purposes, any actual or perceived violations of the TCPA can result in significant financial penalties, including penalties or criminal fines imposed by the Federal Communications Commission or fines of up to \$1,500 per violation imposed through private litigation or by state authorities.

In addition, because we accept debit and credit cards payments, we are subject to the Payment Card Industry Security Standard (“PCI-DSS”), issued by the Payment Card Industry Security Standards Council; however, we rely on third-party payment processors to process such payments who are also separately subject to PCI-DSS. Noncompliance with PCI-DSS can result in penalties ranging from \$5,000 to \$100,000 per month by credit card companies, litigation, damage to our reputation, and revenue losses. If we or our third-party payment processors are unable to comply with the PCI-DSS, we may be subject to fines, restrictions, expulsion from card acceptance programs, or other consequences which could affect our business.

Moreover, it is not guaranteed that PCI-DSS compliance will prevent illegal or improper use of our third-party payment processors' payment systems or the theft, loss or misuse of payment card data or transaction information.

Our business also increasingly relies on AI to improve our services. However, the development and use of AI presents various privacy and data security risks that may impact our business and is subject to various laws. For example, several countries, states, and localities have proposed or enacted measures related to the use of AI in products and services, including the EU's AI Act, which may limit our ability to utilize AI or make utilization of such technology more expensive. The effects of these regulations are difficult to predict, and we expect other jurisdictions will adopt similar laws. Additionally, certain privacy laws extend rights to consumers (such as the right to delete certain personal information) and regulate automated decision making, which may be incompatible with our use of artificial intelligence. These obligations may make it harder for us to conduct our business using artificial intelligence, lead to regulatory fines or penalties, require us to change our business practices, retrain our artificial intelligence, or prevent or limit our use of artificial intelligence. For example, the FTC has required other companies to turn over (or disgorge) valuable insights or trainings generated through the use of AI where they allege the company has violated privacy and consumer protection laws. If we cannot use AI or that use is restricted, our business may be less efficient, or we may be at a competitive disadvantage.

Outside the United States, an increasing number of laws, regulations, and industry standards may govern privacy and data security. For example, the European Union General Data Protection Regulation (the "EU GDPR") and to the United Kingdom General Data Protection Regulation and Data Protection Act 2018 (collectively, the "UK GDPR") (the EU GDPR and UK GDPR together referred to as the "GDPR") impose strict requirements for processing personal data. The GDPR imposes stringent and comprehensive data protection requirements, and provides for greater penalties for noncompliance. The GDPR expands the rights that individuals have to request access, correction, and deletion of their personal data, although certain exceptions exist for scientific research, and makes notification of data breaches to supervisory authorities and data subjects mandatory in certain circumstances. In addition, the GDPR imposes additional compliance obligations and local law derogations in relation to the processing of special category or sensitive personal data under the GDPR (e.g., health data); we may be subject to diverging requirements under EU member state laws and the United Kingdom ("UK") laws, such as whether consent can be used as a legal basis for processing. Where we rely on consent as a legal basis for processing, the validity of informed consent from patients may be challenged, which could force us to stop offering our services, which could hinder our business and operations. In addition, as laws develop, we may need to make operational changes to adapt to diverging rules, which could increase our costs and adversely affect our business. The GDPR also regulates cross-border transfers of personal data outside of the EEA (in the case of the EU GDPR) and UK (in the case of the UK GDPR) and recent case law and regulatory guidance have increased legal complexity and uncertainty regarding international personal data transfers, which we expect to continue. In particular, we expect international transfers to the United States and to other jurisdictions more generally to continue to be subject to enhanced scrutiny by regulators. As the regulatory guidance and enforcement landscape in relation to data transfers continue to develop, we could suffer additional costs, complaints and/or regulatory investigations or fines; we may have to stop using certain tools and vendors and make other operational changes.

Penalties and fines for failure to comply with the GDPR include fines of up to 20 million euros under the EU GDPR, 17.5 million pounds sterling under the UK GDPR or, in each case, 4% of annual global revenue, whichever is greater, and since we are subject to the supervision of relevant data protection authorities under both the EU GDPR and UK GDPR, we could be fined under each of those regimes independently in respect of the same breach. In addition to fines, a breach of the EU GDPR and/or UK GDPR may result in regulatory investigations, reputational damage, orders to cease/ change our data processing activities, enforcement notices, assessment notices (for a compulsory audit) and/ or civil claims (including class actions).

In addition, we may be unable to transfer personal data from Europe and other jurisdictions to the United States or other countries due to data localization requirements or limitations on cross-border data flows. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, we expect the existing legal complexity and uncertainty

regarding international data transfers from the European Economic Area (“EEA”) and the UK to continue. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross-border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA’s standard contractual clauses, the UK’s International Data Transfer Agreement/Addendum, and the EU-U.S. Data Privacy Framework and the UK extension thereto (which allows for transfers to relevant U.S.-based organizations who self-certify compliance and participate in the Framework), these mechanisms are subject to legal challenges. As the regulatory guidance and enforcement landscape in relation to data transfers continues to develop, there is no assurance that we can continue to satisfy or rely on these measures to lawfully transfer personal data to the United States. If there is no lawful manner for us to transfer personal data from the EEA, the UK, or other jurisdictions to the United States, or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions (such as Europe) at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activist groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers of personal data out of Europe for allegedly violating the GDPR’s cross-border data transfer limitations.

We furnish to biopharma partners and academic researchers genomic information that has been de-identified in accordance with applicable laws, regulations, and the requirements governing the clinical trial. Any data transferred pursuant to international health information privacy regulations is transferred under relevant data protection agreements at the direction of the Data Controller. We may also furnish our biopharma partners and academic researchers with identifiable genomic information for research purposes, so long as such disclosure has been consented to by the patient and/or approved by an IRB or other ethical or privacy review board. The laws of certain states and countries may require specific consent from the individual either to retain or utilize certain genetic information for research or other purposes even if such information has been de-identified, or may require that we obtain a waiver of such consent from an ethical or privacy review board. Even where we furnish to biopharma partners and academic researchers genomic information that has been de-identified in accordance with applicable laws and regulations, biopharma partners or academic researchers may use technology or other methods to link that de-identified genomic information to the patient from whom it was obtained in contravention of one or more applicable laws and regulations. A finding that we have failed to comply with any such laws and any remedial activities required to ensure compliance with such laws could cause us to incur substantial costs, to be subject to unfavorable publicity or public opinion, to change our business practices, or to limit the retention or use of genetic information in a manner that, individually or collectively, could be adverse to our business.

Obligations related to privacy and data security (and consumers’ data privacy expectations) are quickly changing, becoming increasingly stringent, and creating uncertainty. For example, HHS issued a notice of proposed rulemaking on January 6, 2025, clarifying existing requirements and imposing new security requirements for entities subject to HIPAA. The agency received thousands of proposed comments, and may adjust or clarify the rule as part of the rule making process. Under President Trump’s Regulatory Freeze Pending Review executive order, HHS cannot issue a final rule until a President-appointed department head has reviewed and approved the rule. It is uncertain whether the proposed rule will move forward in its current state and what the timing of a final rule will be. If adopted in a form similar to the proposed rule, we anticipate our compliance costs could increase substantially. We would need to invest in additional cybersecurity technologies, hire specialized personnel, and potentially redesign certain aspects of our systems and processes. These investments were not contemplated in our current business plan and could impact our profitability. If we are unable to comply with new requirements by any prescribed deadlines, we could face penalties, enforcement actions, reputational damage, and potential loss of business from customers. While we have begun assessing our current security posture against the proposed requirements, the uncertainty regarding the final rule makes comprehensive preparation difficult.

Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. We also expect that there will continue to be new laws, regulations, and industry standards concerning privacy and data security proposed and enacted in various jurisdictions in which we do business. In addition to privacy and data security laws, we are also bound by other contractual obligations related to privacy and data security. Preparing for and complying with these obligations requires us to devote significant resources and may necessitate changes to our services, information technologies, systems, and practices and to those of any third parties that process personal data on our behalf.

Compliance with privacy and data security obligations could cause us to incur substantial costs or require us to change our business practices and compliance procedures in a manner adverse to our business. We strive, and contractually obligate our vendors, to comply with applicable laws, regulations, policies, and other legal obligations relating to privacy and data security. However, the various regulatory frameworks for privacy and data protection are, and are likely to remain, uncertain, and it is possible that these or other actual or alleged obligations may be interpreted and applied in a manner that is inconsistent from one jurisdiction to another and may conflict with other rules and subject our business practices to uncertainty. In addition, it is not guaranteed that regulators or consumers will agree with our interpretation of our obligations or our steps to comply with them. Any actual or perceived failure by us to comply with privacy and data security laws, rules, regulations, industry standards and other obligations could result in proceedings or actions against us by individuals, consumer rights groups, government agencies, or others, or orders to cease/ change our data processing activities. We could incur significant costs in investigating and defending such claims and, if found liable, pay significant damages or fines or be required to make changes to our business practices. Further, these proceedings and requires to any subsequent adverse outcomes may subject us to significant negative publicity and an erosion of trust. If any of these events were to occur, our business, financial condition, and results of operations could be adversely affected.

We have current solutions marketed as LDTs and plan to launch future solutions as LDTs. The regulation of LDT products in the United States remains subject to significant uncertainty, and if we fail to comply with any new or existing legal requirements with respect to our LDT solutions, our business, financial condition, and results of operations could be adversely affected.

We have obtained PMA approval from the FDA for MI Cancer Seek as a companion diagnostic device. We have also contemplated seeking FDA approval for Caris Assure and additional solutions. Except for MI Cancer Seek, we currently offer our NGS solutions, MI Tumor Seek Hybrid and Caris Assure, and our AI solutions, such as GPSai and FOLFIRSTai, as LDTs. The FDA considers LDTs to be IVD tests that are intended for clinical use and are designed, manufactured, and used within a single laboratory, and the FDA has historically viewed LDTs as medical devices subject to FDA's medical device authority. Notwithstanding this position, the FDA historically exercised enforcement discretion and did not enforce certain medical device requirements, including requirements for premarket review, with respect to LDTs, with certain exceptions.

Even under that enforcement discretion policy, the FDA has issued warning letters to, and published Medical Device Safety Communications about, manufacturers for commercializing laboratory tests that were purported to be LDTs but the FDA alleged failed to meet the definition of an LDT or that otherwise were not subject to the FDA's enforcement discretion policy. If our current solutions fail to meet the definition of an LDT, our business, financial condition, and results of operations could be adversely affected.

However, the FDA had for a number of years stated its intention to modify its enforcement discretion policy with respect to LDTs and enforce applicable medical device requirements to LDTs more broadly, and on May 6, 2024, the FDA issued a final rule in effort to clarify the FDA's historical view that LDTs are medical devices subject to the requirements applicable to IVDs (the "LDT Final Rule"), and to phase out the FDA's enforcement discretion policy over a period of four years from issuance of the LDT Final Rule.

In connection with the LDT Final Rule, the FDA sought to establish certain new and targeted enforcement discretion policies. Specifically, if the LDT Final Rule were implemented, the FDA planned to exercise enforcement discretion and not enforce certain medical device requirements (including the

requirements for marketing authorization and compliance with certain elements of the Quality System Regulation (“QSR”) with respect to LDTs that were marketed as of the date of the LDT Final Rule’s publication, although such products would still be required to comply with certain other FDA requirements, such as registration and listing, relevant portions of the QSR, medical device reporting, labeling, and corrections and removals reporting. However, where these tests are modified in certain ways from the version of the test marketed as of the LDT Final Rule’s publication date, this enforcement discretion policy, if implemented, would no longer apply and the FDA would enforce all applicable FDA requirements (including premarket review and marketing authorization requirements) consistent with the stated phase-in policy. In addition, for LDTs that receive approval from NY CLEP, FDA planned to not enforce the proposed marketing authorization requirements at either three and a half or four years following the date of publication of the LDT Final Rule. However, these tests would still be subject to the remaining medical device requirements, including registration and listing, medical device reporting, and QSR requirements, at the time that such requirements would be phased in more generally.

However, on March 31, 2025, the United States District Court for the Eastern District of Texas vacated the LDT Final Rule, reasoning that LDTs are not medical devices, and remanded the matter to the FDA for further consideration. The District Court’s decision remains subject to a potential appeal until June 30, 2025, and it remains uncertain at this time whether such appeal will be sought and if such appeal would be successful, and even if an appeal is not sought, whether the District Court’s decision has the effect of eliminating the FDA’s authority over LDTs nationwide, as the holding in the case merely vacated the LDT Final Rule, which simply clarified FDA’s longstanding position on LDTs being classified as medical devices. Accordingly, it is unclear whether or when the FDA may be able to implement the LDT Final Rule, or otherwise exercise its medical device authority with respect to LDTs. This uncertainty could adversely affect the FDA’s ability to apply and enforce its medical device requirements with respect to diagnostic tests more broadly, including any LDTs for which we have obtained or plan to obtain PMAs. Such uncertainty, the final resolution of the litigation over the LDT Final Rule, and the FDA’s actions in response could have a material adverse effect on our business and operations.

In light of the uncertainty regarding the future status and potential implementation of the LDT Final Rule, the associated planned new enforcement discretion policies, and the FDA’s actions in response the District Court’s decision as it relates to LDTs, we do not know if or when our offerings could become or will remain subject to FDA medical device requirements, including the need to seek and obtain marketing authorization (in the case of our LDTs, at the time that those medical device requirements are phased in more generally if they are phased in at all). If we were unable to comply with any medical device requirements applicable to LDTs if and when such requirements become applicable, we could be required to cease marketing any solutions that we market as LDTs. In addition, further efforts by the FDA or Congress to impose more regulation on LDTs could create a negative public perception about the validity, safety, effectiveness, or performance of LDTs, including our solutions, which could adversely affect patient, provider, and customer perception about, and confidence in, our solutions.

Moreover, the FDA may assert that we are improperly marketing our solutions as LDTs, or if FDA succeeds in maintaining asserted authority over LDTs as medical devices, the FDA may assert we do not comply with applicable requirements, and in such cases may take enforcement action against us and/or require premarket review and marketing authorization, which may require us to cease marketing any commercially marketed solutions that are marketed as LDTs until such marketing authorization is obtained or the applications are submitted. There can be no assurance that we will be able to obtain such marketing authorization or that any labeling claims would be consistent with the claims we have made or intend to make for such solutions when launched as LDTs, or that such claims will be adequate to support continued adoption of and reimbursement for our solutions. In the event we are required to seek FDA marketing authorization for any current or planned LDT solutions, the FDA may request that we provide additional analyses and information beyond that which we intend to produce based on the designs of our current and planned validation studies or clinical trials, or that we modify or narrow our intended use or product claims. It is possible that the FDA, among other things, could disagree with our interpretation of data we have relied on to support our LDT launches for our intended uses. If we are required to provide additional analyses or additional data or perform additional clinical trials beyond those we currently contemplate to support the intended uses of our solutions, our planned commercial launches may be delayed and we may be required to cease commercialization of any solutions we currently market as LDTs. Even if our solutions are allowed

to remain on the market prior to any required marketing authorization, demand or reimbursement for our solutions may decline if there is uncertainty about our solutions, if we are required by the FDA to label our solutions as RUO or IUO, or if the FDA limits the labeling claims we are permitted to make for our solutions. As a result, we could experience significantly increased development costs and a delay in generating additional revenue from our current or future solutions, which could reduce our revenues or increase our costs and adversely affect our business, financial condition, and results of operations. Additionally, an FDA enforcement action against us, a delay in the launch of our solutions, or significantly narrowing their intended uses, could negatively impact our business, financial condition, and results of operations.

In addition, Congress has, for over the past decade, considered a number of proposals, which if enacted, would subject LDTs to additional regulatory requirements. Any such legislation could substantially alter our marketing of LDTs and negatively impact our business, financial condition, and results of operations.

Our early detection and MRD tracking assays are intended to introduce new approaches to cancer detection, which present a number of novel and complex issues for FDA review. Because the FDA has never provided marketing authorization for an early detection test and has only granted marketing authorization in limited instances for MRD tests, it is difficult to predict what information we will need to submit to obtain approval of a PMA from the FDA for a proposed intended use of early detection or MRD tracking, or if we will be able to obtain such approval on a timely basis or at all.

The FDA has never granted marketing authorization for an early detection test and has only granted marketing authorization in limited instances for MRD tests. Therefore, obtaining FDA approval for Caris Assure for early detection and/or MRD tracking presents a number of novel issues. For example, in November 2023, the Molecular and Clinical Genetics Panel (the “Panel”) of the FDA’s Medical Devices Advisory Committee held a public meeting in which the Panel discussed and made recommendations on the design of MCED IVD devices as well as potential study designs and study outcomes of interest that could inform the assessment of the probable benefits and risks of MCED screening tests. The FDA may continue to modify its thinking on how to evaluate the performance of these types of tests, as well as its views around MRD tests. As such, we believe the FDA requirements that will govern any early detection or MRD tracking test we develop, as well as the breadth and nature of data we must provide the FDA, to support the proposed intended use, will remain subject to change.

Given the novel nature and complexity of our early detection and MRD tracking assays, we cannot be certain whether we will receive FDA marketing authorization for our screening tests and whether the trials we eventually conduct will be sufficient to provide the data that the FDA requires to support a proposed intended use. The FDA may require us to perform new analyses of future clinical data or perform additional clinical trials beyond any trials that we may conduct in the future. We may be required to undertake significant efforts to address the FDA requests, which could delay or prevent approval, lead to a more limited intended use statement than the broader intended use statement we plan to pursue, and/or lead to significant post-approval limitations or restrictions, if approval is obtained at all.

Our business could be adversely affected by legal challenges to our business model or by actions restricting our ability to provide the full range of our solutions.

Many states prohibit, by statute, regulation, guidance from professional licensing boards or state attorneys general or under common law, the unlicensed practice of medicine. Corporate practice restrictions are generally designed to prohibit a non-professional entity, such as us, from practicing medicine, employing physicians, or controlling or unduly influencing the professional practice and clinical decision making of physicians. The laws relating to corporate practice vary from state to state and are subject to change and to evolving interpretations by courts, state licensing boards and state attorneys general, among others. Further, changes to the membership or staff of state agencies, licensing boards or attorney general offices could lead to increased enforcement of these laws and regulations. In addition, many states also have laws that prohibit a non-professional entity or individual from sharing in or splitting profits or professional fees for patient care, often referred to as “fee-splitting.” Some states also prohibit entities from engaging in certain financial arrangements, such as fee-splitting, with physicians. The laws relating to fee-splitting also vary from state to state and are not fully developed or uniformly enforced. Generally, these laws restrict business

arrangements that involve a physician sharing professional fees with a non-professional source, but in some states, these laws have been interpreted to extend to other agreements between physicians and business entities under some circumstances.

Our test reports delivered to physicians provide information regarding solutions that oncologists and other physicians may use in making treatment decisions for their patients. We also employ pathologists and other medical professionals that interpret results of our solutions and sign our profiling results. These pathologists, physicians and other medical professionals are employed through our subsidiary non-profit corporation, Caris Molecular Pathology, which we believe complies with state corporate practice prohibitions and professional fee-splitting prohibitions. A governmental authority or other parties could allege that the business practices and services we provide constitute the practice of medicine or violate professional fee-splitting prohibitions and that our structure and arrangements are not compliant. A state may seek to have us discontinue the related services we provide, or subject us to fines, penalties, or other sanctions. Any determination that we are practicing medicine without a license may result in significant liability to us, and our business and reputation would be harmed.

Obtaining and maintaining regulatory authorization of our solutions in one jurisdiction does not mean that we will be successful in obtaining regulatory authorization of our solutions in other jurisdictions.

Obtaining and maintaining regulatory authorization of solutions in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory authorization in any other jurisdiction, but a failure or delay in obtaining regulatory authorization in one jurisdiction may have a negative effect on the regulatory authorization process in others. For example, even if the FDA or a comparable foreign regulatory authority grants marketing authorization for our solutions, comparable regulatory authorities in foreign jurisdictions may also need to authorize the solutions in those countries. Premarket authorization processes vary among jurisdictions and can involve requirements and administrative review periods different from those in the United States, including additional clinical trials, because clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions or the data may not be considered applicable to the jurisdiction's intended patient population. For example, while we have obtained a PMA approval from the FDA for MI Cancer Seek, we do not have any non-U.S. approvals for this solution, and there can be no assurance that we receive any such approvals in the future. In some cases, the price that we intend to charge for our solutions may also be subject to approval. In addition, NY CLEP approval is required in order to market LDTs in New York State. We have not received NY CLEP approval for Caris Assure.

Obtaining foreign regulatory authorization and maintaining compliance with foreign regulatory requirements could result in significant delays, difficulties, and costs for us and could delay or prevent the introduction of our solutions in certain countries. If we fail to comply with the regulatory requirements in other jurisdictions, or we fail to receive necessary or desirable marketing authorizations in other jurisdictions, our target market will be reduced and our ability to realize the full market potential of our solutions will be harmed.

Our employees, independent contractors, consultants, commercial partners, customers, and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk of fraud, misconduct, or other illegal activity by our employees, independent contractors, consultants, commercial partners, customers, and vendors. Misconduct by these parties could include intentional, reckless and negligent conduct that fails to: comply with the rules and regulations of the CMS, the FDA, and other comparable foreign regulatory authorities; provide true, complete and accurate information to such regulatory authorities; comply with manufacturing and clinical laboratory standards; comply with healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws; or report financial information or data accurately or to disclose unauthorized activities to us. Since we began commercializing MI Profile, Caris Assure and our earlier solutions in the United States, our potential exposure under such laws has increased significantly, and our costs associated with compliance with such laws have, and will likely continue to, increase. In particular, research, sales, marketing, education, and other business arrangements in the healthcare industry are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing, and other abusive practices, as well as off-label product

promotion. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, educating, marketing and promotion, sales and commission, certain customer incentive programs, and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of participant recruitment for clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. We have adopted a Corporate Compliance Program, but it is not always possible to identify and deter misconduct by employees and third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions. Even if it is later determined after an action is instituted against us that we were not in violation of these laws, we may be faced with negative publicity, incur significant expenses defending our actions, and have to divert significant management resources from other matters. We expect our exposure to and costs associated with compliance with healthcare fraud and abuse laws to increase significantly if we commercialize additional solutions in the future.

We use medical and hazardous materials that require considerable expertise and expense for handling, storage, or disposal and may result in claims against us.

We and our facilities are subject on an ongoing basis to federal, state, and local laws and regulations governing the use, storage, handling, and disposal of regulated medical waste, hazardous waste, and biohazardous waste, including chemicals, biological agents and compounds and blood and other tissue specimens. We cannot eliminate the risk of accidental contamination or injury to employees, consultants, or third parties from the use, storage, handling, or disposal of these materials. Typically, we use licensed or otherwise qualified outside vendors to dispose of this waste. However, many of these laws and regulations provide for strict liability, holding a party potentially liable without regard to fault or negligence. As a result, we could be held liable for damages and fines if our, or others', business operations or other actions result in contamination of the environment or personal injury due to exposure to hazardous materials. Our costs for complying with these laws and regulations cannot be estimated or predicted with accuracy and depends on a number of factors, including the amount and nature of waste we produce, which depends in part on the number of tests we perform, and the terms we negotiate with our waste disposal vendors.

We have been, are currently, and in the future may be the subject of government investigations, claims, audits, whistleblower and payer audits, overpayment and recoupment efforts and other litigation in the course of our business that could adversely affect our business and financial statements.

Healthcare companies are subject to various criminal, civil, and administrative investigations and audits by governmental authorities. Both federal and state government agencies have heightened civil and criminal enforcement efforts in recent years and expanded collaborative program integrity initiatives. These efforts have led to a number of investigations, prosecutions, convictions, and settlements in the healthcare industry involving federal civil and criminal false claims laws, other healthcare fraud and abuse laws, and civil monetary penalties laws, including the FCA. Further, under the FCA, private parties may bring *qui tam*, or "whistleblower," lawsuits on behalf of the government in connection with alleged false claims for payments submitted to the government or improper retention of overpayments, and these types of actions can be "under seal" for a long period of time while regulatory authorities investigate. The private parties who bring FCA lawsuits are entitled to share in any amounts recovered by the government. When an entity is determined to have violated the FCA and other criminal healthcare fraud laws, the government may impose substantial civil and criminal fines and penalties for each false claim, plus up to treble damages, and exclude the entity from participation in Medicare, Medicaid, and other federal healthcare programs. In addition, a number of states have adopted their own false claims and whistleblower provisions.

We have been, are currently, and may in the future be subject to lawsuits, *qui tam* actions, CIDs, subpoenas, investigations, audits, and other inquiries related to our operations. We have also been, are currently, and may be in the future, subject to subpoenas, CIDs, actions, or investigations relating to our arrangements and interactions with third parties such as healthcare professionals, healthcare institutions, market participants, or patients.

For example, in March 2025, we received a CID from the DOJ in connection with an investigation under the False Claims Act regarding our compliance with Medicare's date of service rule (also referred to as the 14-day rule), particularly focused on patients of certain health care providers, and our policies, procedures, and training related to compliance with the 14-day rule. The related investigation continues to evolve and is in too early a stage to assess potential outcomes. We are cooperating with the investigation. We have implemented compliance policies, procedures, and training designed to foster compliance with the 14-day rule, but there can be no certainties regarding the outcome of the CID. In June 2022, we entered into a settlement agreement with the United States in connection with a previous investigation into our compliance with the 14-day day rule. Pursuant to this settlement agreement, under which we admitted no fault or liability, we paid approximately \$2.9 million in restitution and penalties and we obtained a nationwide release from all 14-day rule claims prior to January 1, 2018. For additional information see "Business—Legal Proceedings." These interactions could result in the government or other parties pursuing legal claims against us that may result in liabilities, including damages penalties, the potential for exclusion from participation in federal healthcare programs, or the imposition of additional compliance and reporting requirements as part of a corporate integrity agreement, any of which could have an adverse effect on our business, financial condition, reputation, and results of operations.

We are subject to audits and investigations of the ordering, billing, and coding of our solutions, including whether these services were properly ordered, billed, and coded or otherwise compliant with requirements for coverage and payment. In particular, as a result of our participation in the Medicare and Medicaid programs, we face and are currently subject to various governmental reviews, audits, and investigations to verify our compliance with these program requirements and applicable laws and regulations. Government agencies and their agents, such as the MACs and Recovery Audit Contractors ("RACs"), as well as the OIG, CMS, and state Medicaid programs, conduct audits of post-payment reviews to detect and correct improper payments in the Medicare program. Private third-party payers conduct similar reviews, audits and pre-payment and post-payment audits. Government agencies and their contractors and other third-party payers regularly conduct audits and request documentation to support claims submitted for payment of services rendered and compliance with claim submission requirements. We are routinely subject to audits under various government programs and third-party payers, and any delays timely providing requested records, negative audit findings or allegations of fraud or abuse may subject us to liability, such as overpayment liability, refunds or recoupments of previously paid claims, payment suspension or the revocation of billing or payment privileges in governmental healthcare programs or other third-party payer programs. Such actions, if imposed on us or our subsidiaries, could adversely impact our business, financial condition, and results of operations. In addition, we perform internal audits and monitoring. Depending on the nature of the conduct uncovered in such audits, and whether the underlying conduct could be considered systemic, the resolution of these audits could have an adverse effect on our business, financial condition, and results of operations.

Responding to government investigations, qui tam lawsuits, payer audits, subpoenas, CIDs, or other legal and administrative proceedings can be time- and resource-consuming and can divert management's attention from the business. Even an unsuccessful challenge or investigation into our practices could cause unfavorable publicity and require us to incur significant costs, resulting in an adverse effect to our reputation and business. If our operations are found to be in violation of applicable laws or regulations, we may be subject to civil and criminal penalties, including significant fines or damages or other sanctions, including exclusion from government healthcare programs. Settlements of lawsuits involving Medicare and Medicaid issues routinely require both monetary payments and corporate integrity agreements that require the imposition of substantial compliance and reporting requirements, any of which could have an adverse effect on our business, financial condition, and results of operations.

Healthcare reform measures or changes in policy or government spending could cause significant harm to our business, financial condition, and results of operations.

Healthcare systems are subject to ongoing reform in the United States and abroad. Federal and state governments have made, and continue to make, significant modifications to the Medicare and Medicaid programs through statutory and regulatory changes, administrative rulings and other interpretations and determinations. For example, in the United States, the ACA made a number of substantial changes to the way healthcare is financed both by government and private insurers. The ACA, among other things,

included provisions governing enrollment in federal and state healthcare programs, reimbursement matters, and fraud and abuse. We expect these and other provisions will influence our industry and our operations in ways that we cannot currently predict. Since its enactment, there have been judicial and congressional challenges to certain aspects of the ACA. For example, on June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the “individual mandate” was repealed by Congress. In addition, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 (the “IRA”) into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the “donut hole” under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creating a new manufacturer discount program. It is possible that efforts to reform, modify, or repeal parts of the ACA may continue under the new presidential administration.

In recent years, legislative and regulatory changes have resulted in limitations and reductions in reimbursement levels and payments to healthcare providers for certain services under the Medicare program. For example, In April 2014, Congress passed PAMA, which included substantial changes to the way in which clinical laboratory services are paid under Medicare. In addition, Congress established automatic spending reductions under the Budget Control Act of 2011 (the “BCA”), resulting in a 2% reduction in Medicare payments that began in 2013, and due to subsequent legislative amendments, will remain in effect until 2032, unless additional Congressional action is taken. In addition, as a result of the American Rescue Plan Act of 2021 (“ARPA”), an additional Medicare payment reduction of up to 4% was required to take effect in January 2022; however, Congress has delayed implementation of this reduction until 2025. It is difficult to predict whether, when or what other deficit reduction initiatives may be proposed by Congress. We anticipate that the federal budget deficit will continue to place pressures on government healthcare programs and impose additional spending reductions.

In addition to changing federal policy and regulatory oversight, states and third-party payers may also introduce proposals and policies to reduce costs while expanding individual healthcare benefits. Certain of these proposals may limit the prices we will be able to charge for our solutions or limit coverage of or lower reimbursement for the procedures associated with the use of our solutions. Healthcare reform and pricing of prescription drugs and medical devices, including clinical laboratory tests, are and will remain a key bipartisan issue. Policies to be pursued in the future may be more aggressive, regardless of which party controls the White House or houses of Congress. Uncertainty surrounding future changes may adversely affect our operating environment and therefore our business, financial condition, results of operations, and growth prospects.

We cannot predict whether or when these or other recently enacted healthcare initiatives will be implemented at the federal or state level or in foreign jurisdictions, or the full impact of current or future healthcare reform measures on our business. For example, the payment reductions imposed by the ACA and the changes to the reimbursement amounts paid by Medicare for tests based on the procedures set forth in PAMA, could limit the prices we are able to charge or the amount, if any, of available reimbursement or coverage for our solutions, which would reduce our revenue. Additionally, these healthcare policy changes could be amended or additional healthcare initiatives could be implemented in the future.

Further, the impact on our business of the expansion of the federal and state governments’ role in the U.S. healthcare industry generally, including the social, governmental, and other pressures to reduce healthcare costs while expanding individual benefits is uncertain.

Statutory, regulatory, and policy changes, or government budget and funding levels, may also impact the ability of the FDA, the Department of Health and Human Services (including CMS) and other regulatory authorities to perform their regulatory functions. Inadequate funding or staffing for such organizations and/or potentially shifting priorities, including under the new administration, could prevent or delay regulatory reviews and approval processes on which certain of our initiatives may rely, adversely affect agencies’ ability to hire and retain key personnel, or otherwise prevent those agencies from timely performing normal business functions on which the operation of our business may rely, any of which could negatively impact our business.

The current Trump administration is pursuing policies to reduce regulations and expenditures across government including at HHS, the FDA, CMS, and related agencies. These actions, presently directed by executive orders or memoranda from the Office of Management and Budget, may propose policy changes that create additional uncertainty for our business. Further, in June 2024, the U.S. Supreme Court reversed its longstanding approach under the Chevron doctrine, which provided for judicial deference to regulatory agencies' interpretation of statutes that are silent or ambiguous, including the FDA and CMS. As a result of this decision, we cannot be sure whether there will be increased challenges to existing agency regulations or how lower courts will apply the decision in the context of other regulatory schemes without more specific guidance from the U.S. Supreme Court. For example, this decision may result in more companies bringing lawsuits against the regulatory agencies to challenge current regulations and longstanding decisions and policies of the FDA or CMS, which could lead to uncertainties in the industry. We cannot predict the full impact of this decision, future judicial challenges brought against the FDA, CMS, or other regulatory agencies, or the nature or extent of government regulation that may arise from future legislation or administrative action.

The marketing authorization processes of the FDA and comparable foreign regulatory authorities are lengthy, time-consuming, and unpredictable. If we are ultimately unable to obtain any necessary or desirable marketing authorizations, or if such marketing authorizations are significantly delayed, our business will be substantially harmed.

Except for MI Cancer Seek, for which we have obtained a PMA approval from the FDA, we currently offer our NGS solutions, MI Tumor Seek Hybrid and Caris Assure, and our AI solutions, such as GPSai and FOLFIRSTai, as LDTs. See “—We have current solutions marketed as LDTs and plan to launch future solutions as LDTs. The regulation of LDT products in the United States remains subject to significant uncertainty, and if we fail to comply with any new or existing legal requirements with respect to our LDT solutions, our business, financial condition, and results of operations could be adversely affected.” We currently anticipate eventually seeking FDA approval for Caris Assure and additional solutions. The time required and ability to obtain marketing authorization from the FDA and comparable foreign regulatory authorities is unpredictable and typically takes several years following the commencement of clinical trials, and depends upon numerous factors, including the type, complexity, and novelty of our solutions. In addition, policies, laws, regulations, or the type and amount of clinical data necessary to gain marketing authorization may change during the course of a test's clinical development and may vary among jurisdictions, which may cause delays in the marketing authorization of, or the decision not to approve, an application. Regulatory authorities have substantial discretion in the premarket review process and may refuse to accept any application, decide that our data are insufficient for marketing authorization, require additional clinical or other data, or determine that our manufacturing and quality systems are insufficient or in violation of applicable requirements. Even if we believe our data are sufficient to support marketing authorization, regulatory authorities may disagree, or may require the generation and submission of additional data or analyses, which could significantly delay or preclude marketing authorization.

Before a new medical device can be marketed in the United States, a company must first submit a premarket notification to FDA and receive clearance by FDA under Section 510(k) of the FDCA, a PMA application and receive approval by FDA under Section 515 of the FDCA, or a *de novo* classification request and receive a grant of the request from the FDA under section 513(f)(2) of the FDCA, unless an exemption applies. In the 510(k) clearance process, before a device may be marketed, the FDA must determine that a proposed device is “substantially equivalent” to a legally-marketed “predicate” device, which includes a device that has been previously cleared through the 510(k) process, a device that was legally marketed prior to May 28, 1976 (pre-amendments device), a device that was originally on the U.S. market pursuant to an approved PMA and later down-classified, a device that was classified under the *de novo* classification pathway, or a 510(k)-exempt device. To be “substantially equivalent,” the proposed device must have the same intended use as the predicate device, and either have the same technological characteristics as the predicate device or have different technological characteristics and not raise different questions of safety or effectiveness than the predicate device and performance data show that the proposed device is as safe and effective as the predicate device. Clinical data are sometimes required to support substantial equivalence. In the process of obtaining PMA approval, the FDA must determine that a proposed device is safe and effective (which means analytically valid and clinically valid in the case of tests) for its intended use based, in part, on extensive data, including, but not limited to, technical, pre-clinical, clinical trial, manufacturing and labeling data.

The PMA process is typically required for devices that are deemed to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices. In the *de novo* classification process, a manufacturer whose novel device under the FDCA would otherwise be automatically classified as Class III and require the submission and approval of a PMA prior to marketing is able to request down-classification of the device to Class I or Class II on the basis that the device presents a low or moderate risk. If Class II, new special controls will be required to provide reasonable assurance of safety and effectiveness of the device. If the FDA grants the *de novo* classification request, the applicant will receive authorization to market the device. This device type may be used subsequently as a predicate device for future 510(k) submissions.

The PMA approval, 510(k) clearance and *de novo* classification processes can be expensive, lengthy, and uncertain. The FDA's 510(k) clearance process usually takes from three to 12 months, but can take longer. The process of obtaining a PMA approval or *de novo* classification is much more costly and uncertain than the 510(k) clearance process and the FDA has 180 days from the day of filing under the FDC Act to complete its review of the PMA and FDA endeavors to review *de novo* classification requests within 150 days, although, in practice, the FDA's review often takes significantly longer. In addition, a PMA generally requires the performance of one or more clinical trials. Despite the time, effort and cost, a device may not obtain marketing authorization by the FDA. Any delay or failure to obtain necessary marketing authorizations could harm our business. Furthermore, even if we are granted such marketing authorizations, they may include significant limitations on the indicated uses for the solution, which may limit the potential commercial market for the solution.

In the United States, any modification to a product for which we receive marketing authorization may require us to submit a new 510(k) notification and obtain clearance, to submit a supplemental PMA and obtain FDA approval, or to submit a *de novo* request prior to implementing the change. For example, any modification to a 510(k)-cleared device that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, design, or manufacture, generally requires a new 510(k) clearance or other marketing authorization. The FDA requires every manufacturer to make such determinations in the first instance, but the FDA may review any manufacturer's decision. The FDA may not agree with a manufacturer's decisions regarding whether new marketing authorizations is necessary. If we obtain market authorizations from the FDA, we may make modifications or add additional features in the future that we believe do not require a new 510(k) clearance, *de novo* request or approval of a PMA or supplement. If the FDA disagrees with our determination and requires us to seek new marketing authorizations for the modifications for which we have concluded that new marketing authorizations are unnecessary, we may be required to cease marketing and/or to recall the modified product until we obtain such marketing authorization, and we may be subject to significant regulatory fines or penalties. If the FDA requires us to go through a lengthier, more rigorous examination for future solutions or modifications to existing solutions than we had expected, solution introductions or modifications could be delayed or canceled, which could adversely affect our business.

The FDA or other regulators can delay, limit, or deny marketing authorization of a product for many reasons, including but not limited to the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design, implementation, or results of, or interpretation of the data from, our clinical trials;
- the FDA or comparable foreign regulatory authorities may determine that our solution has not been shown to be safe and effective or substantially equivalent to a predicate device, or has other characteristics that preclude us from obtaining marketing authorization or prevent or limit its commercial use (for example, a narrowed indication for use claim);
- the population studied in the clinical program may not be sufficiently broad, generalizable, or representative of the intended target population of our solution to assure effectiveness and safety in the population for which we seek approval or clearance;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from clinical trials or may fail to accept data from clinical trials (or clinical sites), including if we fail to establish the integrity of our data;
- the FDA or comparable foreign regulatory authorities may determine that our clinical trials otherwise fail to comply with applicable regulations;

- serious or unexpected adverse effects or other performance issues are identified with our solutions;
- the FDA or comparable foreign regulatory authorities may determine that our manufacturing or quality system fails to comply with applicable regulations or otherwise fails to meet the standards necessary to support approval; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

There can be no assurance that our solutions for which we may seek marketing authorization will receive such marketing authorization from by the FDA or a comparable foreign regulatory authority on a timely basis, if at all, nor can there be assurance that labeling claims will be consistent with our anticipated claims or adequate to support continued adoption of, and reimbursement for, our solutions. If our solutions receive marketing authorization but there is uncertainty about such solutions among providers or payers, or if the approved or cleared indication or other labeling claims the FDA or a comparable foreign regulatory authority has authorized us to make are more limited than we expect, reimbursement may be adversely affected and we may not be able to sell our solutions. Compliance with FDA or comparable foreign regulatory authority regulations will require substantial costs, and subject us to heightened scrutiny by regulators and substantial penalties for failure to comply with such requirements or the inability to market our solutions, if authorized. The lengthy and unpredictable marketing authorization processes, as well as the unpredictability of the results of our clinical trials, may result in our failing to obtain marketing authorization to market our solutions, which would significantly harm our business, results of operations, reputation, and prospects.

Ethical, legal, and social concerns related to the use of genomic information could reduce demand for our solutions.

Genomic testing, like that conducted using our solutions, has raised ethical, legal, and social issues regarding privacy and the appropriate uses of the resulting information. Governmental authorities could, for social or other purposes, limit or regulate the use of genomic information or genomic testing or prohibit testing for genetic predisposition to certain conditions, particularly for those that have no known cure. Similarly, these concerns may lead patients to refuse to use genomic and somatic profiling tests even if permissible.

Ethical and social concerns may also influence U.S. and foreign patent offices and courts with regard to patent protection for technology relevant to our business. These and other ethical, legal, and social concerns may limit market acceptance of our solutions or reduce the potential markets for services enabled by our platform, either of which could have an adverse effect on our business, financial condition, and results of operations.

If the validity of an informed consent from patients regarding our solution was challenged and proven invalid, unlawful, or otherwise inadequate for our purposes, we could be forced to stop offering our solutions or using our resources, our business, financial condition, and results of operations will be adversely affected.

We offer our solutions to physicians and to biopharma companies in connection with clinical trials. We generally rely on treating physicians to obtain required informed consent under applicable state laws, but we have also recently implemented measures to ensure that data and biological samples that we receive have been collected from subjects who have provided appropriate informed consent. We also conduct validation studies, or act as a sponsor of clinical trials in connection with the development and validation of our solutions, which are frequently conducted in collaboration with different parties. We submit for projects that meet the definition of “human subjects research,” to the IRB, or other reviewing body for review and approval of processes for subject informed consent and authorization for use of personal information or waivers thereof. We and our biopharma partners could conduct clinical trials in a number of different countries. When we are acting as a vendor in connection with a clinical trial sponsored by our biopharma partners, we rely upon them to comply with the requirements to obtain the subject’s informed consent and to comply with applicable laws and regulations. The collection of data and samples in many different countries results in complex legal questions regarding the adequacy of informed consent and the status of genetic material under a large number of different legal systems. Those informed consents could be challenged and

proven invalid, unlawful, or otherwise inadequate for our purposes. Any such findings against us, or our biopharma partners, could force us to stop accessing or using data and samples or servicing or conducting clinical trials, which would hinder our product offerings or development. We could also become involved in legal actions, which could consume our management and financial resources.

If we fail to comply with applicable data interoperability and information blocking rules, our business, financial condition, and results of operations could be adversely affected.

The 21st Century Cures Act (the “Cures Act”), which was passed and signed into law in December 2016, includes provisions related to data interoperability, information blocking and patient access. In March 2020, the HHS Office of the National Coordinator for Health Information Technology (“ONC”) finalized and issued complementary rules that are intended to clarify provisions of the Cures Act regarding interoperability and information blocking, and include, among other things, requirements surrounding information blocking and changes to ONC’s health IT certification program. The companion rules will transform the way in which healthcare providers, health IT developers, health information exchanges/health information networks and health plans share patient information, and create significant new requirements for healthcare industry participants. For example, the ONC rule, which went into effect on April 5, 2021, prohibits healthcare providers from engaging in practices that are likely to interfere with, prevent, materially discourage, or otherwise inhibit the access, exchange, or use of electronic health information (“EHI”), also known as “information blocking.” To further support access and exchange of EHI, the ONC rule identifies eight “reasonable and necessary activities” as exceptions to information blocking activities, as long as specific conditions are met. On July 3, 2023, the HHS Office of the Inspector General (“HHS-OIG”) published its final rule implementing information blocking penalties for “actors,” which is supplemented by ONC’s January 9, 2024 final rule enhancing certain information blocking requirements, under which HHS-OIG may impose penalties for information blocking that has occurred after September 1, 2023. In addition, ONC and HHS proposed a rule on November 1, 2023, listing “appropriate disincentives” for noncompliance by healthcare providers. If we fail to comply with the requirements, it may negatively impact our business operations. The goals of increased use of electronic health data and interoperability are improved quality of care and lower healthcare costs generally. However, increased use of electronic health data and interoperability inherently magnifies the risk of security breaches involving that data and information systems used to share it. For additional information, see “—Risks Related to Our Business and Industry—If our information technology systems or those of third parties with whom we work, or our data are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse consequences.” Any failure to comply with these rules could adversely affect our business, financial condition, and results of operations.

If we or our partners fail to comply with federal, state, and foreign laboratory and other applicable licensing and registration requirements, we could be prevented from performing our solutions or experience disruptions to our business.

CLIA is a federal law that regulates clinical laboratories that perform testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention, or treatment of disease, or impairment of, or the assessment of the health of, human beings. CLIA regulations require, among other things, clinical laboratories to obtain a certificate and mandate specific standards in the areas of personnel qualifications, administration, participation in proficiency testing, test management, and quality assurance. CLIA certification is also required for us to be eligible to bill state and federal healthcare programs, if such reimbursement is otherwise available, as well as many private third-party payers, for our solutions. Certain product additions to our solution menu require notification to regulatory and accrediting bodies that regulate our laboratories. To renew these certifications, we are subject to routine surveys and inspections. Moreover, CLIA inspectors may make random or “for cause” inspections of our clinical laboratories.

We currently have two commercial clinical laboratory facilities in Phoenix, Arizona, and we are in the process of building out our newest clinical laboratory in Irving, Texas. Both of the Phoenix laboratory facilities hold independent CLIA Certificates of Accreditation. A CLIA Certificate of Accreditation is issued

to a laboratory facility that performs moderate and/or high complexity testing after an accreditation organization conducts a survey and determines that the laboratory is in compliance with the CLIA regulations. Our laboratory facility in Irving, Texas will seek a CLIA Certificate of Registration from CMS, and upon required inspection, anticipate receiving a CLIA Certificate of Accreditation. The CLIA Certificate of Registration allows the laboratory facility to begin conducting moderate and/or high complexity testing, subject to a survey to determine compliance with the CLIA regulations. After a laboratory obtains a Certificate of Registration, CLIA begins scheduling regular, routine inspections. Once the inspection process for the laboratory facility is successfully completed, the facility qualifies for a CLIA Certificate of Accreditation and thereafter is inspected every two years.

Both of our Phoenix laboratories hold CAP accreditations upon which our CLIA Certificate of Accreditation are based. CAP typically conducts biannual surveys of each facility. Any failure to pass inspections, maintain our CAP accreditation, CLIA Certificate of Registration, CLIA Certificate of Accreditation, or state licenses, or add new validated solutions to our laboratory offerings could significantly harm our business, results of operations, and prospects.

In addition to obtaining federal certification for a laboratory under CLIA, we are also required to obtain and maintain state licenses to conduct profiling in our laboratories. Neither Arizona (where we currently operate two clinical laboratories) nor Texas (where we are completing the build-out of our newest clinical laboratory) requires us to obtain and maintain state licenses to conduct profiling in our laboratories. However, some states require out-of-state licensure if we test specimens originating from those states and return patient-specific results. Our tissue-based Arizona facility has obtained licenses from California, Rhode Island, Maryland, New York, and Pennsylvania, and our blood-based Arizona facility has obtained licenses from California, Maryland, Pennsylvania, and Rhode Island. If we have a blood-based profiling solution approved by New York state, we will also obtain a New York license for our blood-based facility.

For example, to be able to receive specimens originating from New York, we must obtain and maintain a New York State Department of Health clinical laboratory permit. We have a New York State Department of Health clinical laboratory permit for our tissue-based Arizona facility, and we intend to apply for such a permit for our other commercial facilities. Research testing (which we conduct at our R&D laboratory in Tempe, Arizona), however, does not require licensure if patient-specific results are not generated and/or returned for diagnostic purposes. As our blood-based Arizona facility does not currently operate in New York, we have not sought a New York laboratory permit. We cannot guarantee that the New York State Department of Health will issue a clinical laboratory permit for our Texas facility or our blood-based Arizona facility, and if we do not receive this permit, our business may be adversely impacted. In addition, New York laws and regulations establish rigorous standards for day-to-day operation of a clinical laboratory, including training and skill levels required of laboratory personnel, physical requirements of a facility, equipment, and validation and quality control, and we are required to abide by these laws and regulations as a permit holder. Failure to comply with these laws and regulations could result in various significant penalties, including loss of our New York permit, fines and other penalties, or limitations on our potential profiling population, which could adversely impact our business. New York also requires specific reporting for companies in the oncology space. Failure to comply with any established reporting requires could negatively impact our license.

The states that require us to hold an out-of-state license may change, and we are uncertain whether states will continue to grant or may require us to hold these licenses in the future. Any failure or inability on our part to obtain required state licensure may result in substantial penalties, including prohibition from billing certain payers and thus adversely affect our business.

In connection with CLIA certification and state laboratory licensing and permitting, we remain subject to a number of risks in the event of noncompliance. Any sanction imposed under CLIA, its implementing regulations, or state or foreign laws or regulations governing licensure or permitting, or our failure to renew or maintain a CLIA certificate, a state license or permit, or accreditation (including CAP), could adversely affect our business and reputation. CMS also has the authority to impose a wide range of sanctions, including suspension, limitation, or revocation of the CLIA certification, termination of Medicare and Medicaid participation, civil money penalties, and a bar on the ownership or operation of a CLIA-certified laboratory by any owners or operators of the deficient laboratory. If we fail to obtain any required state licensure, or lose CLIA certification, CAP accreditation, or licensure once obtained, we

would not be able to operate our clinical laboratories and offer our solutions in full or in particular states, which would adversely impact our business, financial condition, and results of operations. Even if we were able to bring our laboratory back into compliance, we could incur significant expenses and potentially lose revenue in doing so.

In addition to state laboratory licensing laws, we may also be subject to foreign state registration and/or licensing requirements that apply to companies that manufacture medical devices. Certain states may require such registrations or licenses before the solutions are commercialized, including while manufacturers are evaluating the devices in clinical trials. Violations of these laws may result in a range of potential sanctions or penalties which could include the denial, suspension, limitation or revocation of the registration or license, as well as other fines and penalties, including imprisonment.

In addition, our pathologists are subject to individual medical licensure requirements and our pathologists, physicians, and geneticists could also be subject to in the future additional licensure requirements under state law. If the physicians and geneticists are not able to timely maintain, obtain or otherwise satisfy any new licensure requirements, this could have a negative impact on our operations.

Data from our clinical trials that we announce or publish from time to time before our trials are complete may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose preliminary or topline data from our validation studies and clinical trials that we conduct ourselves or in partnership with other organizations, including on the application of Caris Assure in early detection, MRD tracking, and treatment monitoring, and Caris ChromoSeq, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular trial. We also make assumptions, estimations, calculations, and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results once additional data have been received and fully evaluated. Topline and preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the topline or preliminary data we previously published. As a result, topline and preliminary data should be viewed with caution until the final data are available.

From time to time, we may also disclose interim data from our validation studies that we conduct or from our clinical trials. Interim data from these studies or trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as subject enrollment continues and more data become available. Adverse differences between interim data and top-line, preliminary, or final data could significantly harm our business prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our common stock.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions, or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, and our ability to receive coverage, marketing authorization or commercialize a particular solution and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding our business. If the data that we report differ from final results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to commercialize or obtain marketing authorization for, our solutions may be harmed, which could harm our reputation, business, financial condition, results of operations, and prospects.

Any solution for which we obtain marketing authorization will be subject to extensive ongoing regulatory requirements, and we may be subject to penalties if we or our partners fail to comply with regulatory requirements or if we experience unanticipated problems with our solutions.

Medical devices, along with the manufacturing processes, post-market surveillance, labeling, packaging, advertising, and promotion, distribution, storage, import, export, reporting, and recordkeeping

for such solutions, are subject to continued regulatory review, oversight, requirements, and periodic inspections by the FDA and comparable foreign regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports; registration and listing requirements; requirements relating to quality control, quality assurance, cyber security, and corresponding maintenance of records and documents; requirements relating to recalls, removals, and corrections; and requirements relating to product labeling, advertising and promotion, and recordkeeping. It is uncertain whether our currently-marketed LDTs will become subject to these or any other requirements. See “Risk Factors—We have current solutions marketed as LDTs and plan to launch future solutions as LDTs. The regulation of LDT products in the United States remains subject to significant uncertainty, and if we fail to comply with any new or existing legal requirements with respect to our LDT solutions, our business, financial condition, and results of operations could be adversely affected.” Regardless, the regulations to which we are subject are complex and have tended to become more stringent over time. Regulatory changes could result in restrictions on our ability to carry on or expand our operations, higher than anticipated costs or lower than anticipated sales. The FDA enforces these regulatory requirements through, among other means, periodic unannounced inspections. We do not know whether we will be found compliant in connection with any future regulatory inspections.

Marketing authorization of a test or device may be subject to limitations by the regulatory body as to the indicated uses for which the product may be marketed or to other conditions of marketing authorization. In addition, marketing authorization may contain requirements for costly post-marketing testing and surveillance to monitor the safety or effectiveness of the test or device. Discovery of problems with our solutions, suppliers, vendors, contract manufacturers, manufacturing processes (including software validation), and/or failure to comply with regulatory requirements, may result in actions such as:

- restrictions on operations of our laboratories;
- restrictions on manufacturing processes;
- restrictions on marketing of a product;
- Untitled or Warning letters;
- withdrawal or recall of the product from the market or seizure of the product;
- refusal to approve applications or supplements to approved applications that we may submit;
- fines, restitution or disgorgement of profits or revenue;
- suspension, limitation, or withdrawal of marketing authorization;
- exclusion from participation in U.S. federal or state healthcare programs, such as Medicare and Medicaid;
- safety communications;
- refusal to permit the import or export of our solution;
- injunctions; or
- imposition of civil or criminal penalties.

Any of these sanctions could result in higher than anticipated costs or lower than anticipated sales and adversely affect our reputation, business, financial condition, and results of operations.

In addition, the FDA may change its marketing authorization policies, adopt additional regulations or revise existing regulations, or take other actions. For example, in addition to the FDA’s LDT Final Rule, a few months earlier in February 2024, the FDA issued a final rule to amend and replace the QSR, which sets forth the FDA’s current good manufacturing practice requirements for medical devices, to align more closely with the International Organization for Standardization standards. Specifically, this final rule, which the FDA expects to go into effect on February 2, 2026, establishes the Quality Management System Regulation (“QMSR”), which among other things, incorporates by reference the quality management system requirements of ISO 13485:2016. Although the FDA has stated that the standards contained in ISO 13485:2016 are substantially similar to those set forth in the QSR, it is unclear the extent to which this

final rule, once effective, could impose additional or different regulatory requirements on us that could increase the costs of compliance or otherwise adversely affect our business. If we are unable to comply with the QMSR, once effective, or with any other changes in the laws or regulations enforced by the FDA or comparable regulatory authorities, we may be subject to enforcement action, which could have an adverse effect on our business, financial condition, and results of operations.

For any solution we market that is or becomes subject to the FDA's medical device authority, we are or may become subject to the FDA's requirements to report to the FDA certain information about adverse medical events or malfunctions for any of our solutions, and if we fail to do so, we would be subject to sanctions that could harm our reputation, business, financial condition, and results of operations. The discovery of serious safety issues with our solutions, or a recall of our solutions either voluntarily or at the direction of the FDA or another governmental authority, could have a negative impact on us.

Any solution we market that is or becomes subject to the FDA's medical device authority and any solution for which we obtain FDA marketing authorization, including MI Cancer Seek, is or will become subject to the FDA's medical device reporting regulations and similar foreign regulations, which require us to report to the FDA when we receive or become aware of information that reasonably suggests that one or more of these solutions may have caused or contributed to a death or serious injury or malfunctioned in a way that, if the malfunction were to recur, it could cause or contribute to a death or serious injury. Under the FDA's LDT Final Rule issued on May 6, 2024, and which was vacated by a federal District Court on March 31, 2025, any LDT that receives marketing authorization would be subject to these medical device reporting regulations, as applicable, if the rule is ultimately implemented. See "Risk Factors—"We have current solutions marketed as LDTs and plan to launch future solutions as LDTs. The regulation of LDT products in the United States remains subject to significant uncertainty, and if we fail to comply with any new or existing legal requirements with respect to our LDT solutions, our business, financial condition, and results of operations could be adversely affected." The timing of our obligation to report is triggered by the date we become aware of the adverse event as well as the nature of the event. We may fail to report adverse events of which we become aware within the prescribed timeframe. We may also fail to recognize that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of the product. If we fail to comply with our reporting obligations, the FDA could take action, including warning letters, untitled letters, administrative actions, criminal prosecution, imposition of civil monetary penalties, revocation of our device marketing authorization, withdrawal of our solutions from the market, seizure of our solutions, or delay in marketing authorization of future solutions.

The FDA and foreign regulatory bodies have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture of a product or in the event that a product poses an unacceptable risk to health. The FDA's authority to require a recall must be based on a finding that there is reasonable probability that the device could cause serious injury or death. We may also choose to voluntarily recall a product if any material deficiency is found. A government-mandated or voluntary recall by us could occur as a result of an unacceptable risk to health, component failures, malfunctions, manufacturing defects, labeling or design deficiencies, packaging defects or other deficiencies, or failures to comply with applicable regulations. Product defects or other errors may occur in the future.

Depending on the corrective action we take to redress a product's deficiencies or defects, the FDA may require, or we may decide, that we will need to obtain new marketing authorizations for the device before we may market or distribute the corrected device. Seeking such marketing authorizations may delay our ability to replace the recalled devices in a timely manner. Moreover, if we do not adequately address problems associated with our devices, we may face additional regulatory enforcement action, including FDA warning letters, product seizure, injunctions, administrative penalties or civil or criminal fines.

Companies are required to maintain certain records of recalls and corrections, even if they are not reportable to the FDA. We may initiate voluntary withdrawals or corrections for our solutions in the future that we determine do not require notification of the FDA. If the FDA disagrees with our determinations, it could require us to report those actions as recalls and we may be subject to enforcement action. A future recall announcement could harm our reputation with customers, potentially lead to product

liability claims against us and negatively affect the adoption and use of our solutions. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require the dedication of our time and capital, distract management from operating our business and may harm our reputation and financial results.

Our solutions will need to be manufactured and offered in accordance with federal and state regulations, and we could be forced to recall our devices or terminate production or offering our LDTs if we or our partners fail to comply with these regulations.

The methods used in, and the facilities used for, the manufacture of medical devices must comply with the FDA's QSR requirements, which is a complex regulatory scheme that covers the procedures and documentation of the design, testing, production, process controls, quality assurance, labeling, packaging, handling, storage, distribution, installation, servicing, and shipping of medical devices. Furthermore, we are required to verify that our suppliers maintain facilities, procedures and operations that comply with our quality standards and applicable regulatory requirements. The FDA enforces the QSR requirements through periodic announced or unannounced inspections of medical device manufacturing facilities, which may include the facilities of subcontractors. Our solutions are also subject to similar state regulations and various laws and regulations of foreign countries governing manufacturing.

Our third-party manufacturers may not take the necessary steps to comply with applicable regulations, which could cause delays in the delivery of our solutions. In addition, in February 2024, the FDA issued a final rule to amend and replace the QSR, which sets forth the FDA's current good manufacturing practice requirements for medical devices, to align more closely with the International Organization for Standardization standards. Specifically, this final rule, which the FDA expects to go into effect on February 2, 2026, establishes the QMSR, which among other things, incorporates by reference the quality management system requirements of ISO 13485:2016. Although the FDA has stated that the standards contained in ISO 13485:2106 are substantially similar to those set forth in the QSR, it is unclear the extent to which this final rule, once effective, could impose additional or different regulatory requirements on us that could increase the costs of compliance or otherwise negatively affect our business. Failure to comply with applicable FDA requirements or later discovery of previously unknown problems with our solutions or manufacturing processes could result in, among other things: warning letters or untitled letters; fines, injunctions or civil penalties; suspension or withdrawal of approvals; seizures or recalls of our solutions; total or partial suspension of production or distribution; administrative or judicially imposed sanctions; FDA's refusal to grant pending or future marketing authorizations for our solutions; clinical holds; refusal to permit the import or export of our solutions; and criminal prosecution of us, our suppliers, or our employees.

Any of these actions could significantly and negatively affect supply of our solutions. If any of these events occurs, our reputation could be harmed, we could be exposed to product liability claims and we could lose customers, experience reduced sales, and increased costs.

The misuse or off-label use of our solutions may harm our reputation in the marketplace, lead to product liability suits or result in costly investigations, fines, or sanctions by regulatory bodies if we are deemed to have engaged in the promotion of these uses, any of which could be costly to our business.

Any marketing authorization we may receive for our solutions will be limited to specified indications for use. We train our marketing personnel and direct sales force to not promote our solutions for uses outside of FDA cleared or approved indications for use, known as "off-label uses." We cannot, however, prevent a physician from using our solutions off-label, when in the physician's independent professional medical judgment, he or she deems it appropriate.

If the FDA or any foreign regulatory body determines that our promotional materials or training constitute promotion of an off-label use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance or imposition of an untitled letter, which is used for violators that do not necessitate a warning letter, injunction, seizure, civil fine or criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action under other regulatory authority, such as false claims laws, if they consider our business activities to constitute promotion of an off-label use, which could result in significant penalties, including,

but not limited to, criminal, civil and administrative penalties, damages, fines, disgorgement, exclusion from participation in government healthcare programs and the curtailment of our operations.

In addition, physicians may misuse our solutions if they are not adequately trained, potentially leading to injury and an increased risk of product liability. If our solutions are misused, we may become subject to costly litigation by our customers or their patients. As described above, product liability claims could divert management's attention from our core business, be expensive to defend and result in sizeable damage awards against us that may not be covered by insurance.

Misleading, untruthful, or unsubstantiated labeling, advertising, marketing, or promotional practices could adversely impact our business, financial condition, and results of operations. The FTC has instituted enforcement actions against certain healthcare testing companies for making false or misleading advertising claims and for failing to adequately substantiate claims made in advertising. These enforcement actions may result in warning letters, consent decrees, and the payment of civil penalties and/or restitution by the companies involved. Should the FTC determine that our claims are false or misleading or unsubstantiated, we could be subject to FTC enforcement action and may face significant penalties which may adversely impact our business, financial condition, and results of operations.

The labeling, advertising, marketing, and promotional practices related to our solutions is governed by numerous state and federal regulators, including the FDA and the FTC, as well as subject to third-party claims. Any statements related to our solutions that could be construed as misleading, untruthful, or unsubstantiated, could subject us to regulatory enforcement action, third-party lawsuits, or plaintiffs' complaints. Any of these actions could significantly and negatively affect our reputation, expose us to liability claims, and we could lose customers and experience reduced sales and increased costs.

Our "research use only" and any potential "investigational use only" products could become subject to more onerous regulation by the FDA or other regulatory authorities in the future, which could increase our costs and delay our commercialization efforts, thereby materially and adversely affecting our business, financial condition, and results of operations.

In the United States, some of our products are currently available, or may become available, for research use only ("RUO"), or for investigational use only ("IUO"), depending on the proposed application. We make our RUO and IUO products available to a variety of parties, including pharmaceutical and biotechnology companies and research institutes. Because RUO and IUO products are not intended for use in clinical practice and cannot be advertised or promoted for clinical or diagnostic claims, they are exempt from many regulatory requirements otherwise applicable to medical devices. In particular, FDA regulations require that RUO products be labeled "For Research Use Only. Not for use in diagnostic procedures," and IUO products be labeled "For Investigational Use Only. The performance characteristics of this product have not been established," and such products are not subject to the FDA's pre- and post-market controls for medical devices.

A significant change in the laws governing RUO or IUO products or how they are enforced may require us to change our business model in order to maintain compliance. In addition, even under the current law and governmental policies, there is a risk that the FDA may disagree with our characterization of whether a product is appropriately considered an "RUO" product that is not subject to FDA's premarket review or marketing authorization. For instance, in November 2013, the FDA issued a guidance document entitled "Distribution of In Vitro Diagnostic Products Labeled for Research Use Only or Investigational Use Only" (the "RUO/IUO Guidance"), which indicates that distribution of RUO or IUO products with written or verbal statements in any labeling, advertising or promotion suggesting that clinical laboratories can validate the test through their own procedures and subsequently offer it for clinical diagnostic use as an LDT would conflict with the RUO or IUO status. The RUO/IUO Guidance further indicates that any assistance offered in performing clinical validation or verification, or similar specialized technical support, to clinical laboratories, would conflict with the RUO or IUO status of the product. If we engage in any activities that the FDA deems to be in conflict with the RUO or IUO status held by any of our products so labeled, we may be subject to immediate, severe, and broad FDA enforcement action that would adversely affect our ability to continue operations. Accordingly, if the FDA finds that we are distributing our RUO or IUO products in a manner that is inconsistent with its RUO/IUO requirements and restrictions, we may

be forced to stop distribution of our RUO/IUO tests until we are in compliance, which would reduce our revenue, increase our costs, and adversely affect our business, financial condition, and results of operations.

Changes in funding or disruptions at the FDA and other government agencies caused by funding shortages, staffing limitations, or global health concerns could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could adversely impact our business.

The ability of the FDA to review and provide marketing authorization of new products or changes to existing products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, federal government shutdowns, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund R&D activities is subject to the political process, which is inherently fluid and unpredictable. Decreases in government funding of research and development, including termination of federal employees and any reductions in funding to the U.S. National Institutes of Health may impact our business, as could changes in government programs that provide funding to research institutions and companies, including changes in the amount of funds allocated to different areas of research or changes that have the effect of increasing the length of time of the funding process. Disruptions at the FDA and other government agencies may also slow the time necessary for new medical devices or modifications to FDA cleared or approved medical devices to be reviewed and/or approved by necessary government agencies, which could adversely affect our business. For example, in recent years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. In addition, the current U.S. Presidential administration has issued certain policies and Executive Orders directed towards reducing the employee headcount and costs associated with U.S. administrative agencies, including the FDA, and it remains unclear the degree to which these efforts may limit or otherwise adversely affect the FDA's ability to conduct routine activities.

In addition, during the COVID-19 pandemic, the FDA postponed most inspections of domestic and foreign manufacturing facilities at various points. If a prolonged government shutdown occurs, or if funding shortages, staffing limitations or renewed global health concerns prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other routine activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could adversely affect our business.

The Federal Policy for the Protection of Human Subjects or related state regulations may be revised or altered in a way that negatively impacts our business.

The Federal Policy for the Protection of Human Subjects (typically referred to as the Common Rule) may be altered in a way that prevents or restricts us from using patient samples or clinical trial data to further develop or validate our solutions or future AI/ML algorithms which rely upon identifiable data. The revised Common Rule, effective as of July 19, 2018, allows the use of prospective consent to unspecified future research (i.e., "broad consent") from a human subject for the storage, maintenance, and secondary use of identifiable private information and identifiable biospecimens in research activities. We obtain both identifiable and de-identified data which we use to develop our solutions through biospecimen repositories and from our biopharma partners. If regulations allowing broad consent or the regulatory definition of "research" changes in a way that excludes our research activities, our business may be negatively impacted. State laws governing clinical research may complicate our compliance efforts and add costs and delay to our R&D activities.

Our business activities are subject to the FCPA and similar anti-bribery and anti-corruption laws, as well as export and import controls and economic sanctions laws and regulations of the United States and other jurisdictions.

Our business activities are subject to the Foreign Corrupt Practices Act of 1977, as amended (the "FCPA"), and similar anti-bribery or anti-corruption laws, regulations, or rules of other countries, such as

the U.K. Bribery Act. The FCPA generally prohibits offering, promising, giving, or authorizing others to give anything of value, either directly or indirectly, to a non-U.S. government official in order to influence official action, or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. Our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non-U.S. governments. Additionally, in many countries, the healthcare providers who administer diagnostic tests are employed by their government, and the purchasers of diagnostics tests are government entities; therefore, our dealings with these providers and purchasers are subject to regulation under the FCPA. The Securities and Exchange Commission (“SEC”) and DOJ have increased their FCPA enforcement activities with respect to life sciences companies. There is no certainty that all of our employees, agents, contractors, or collaborators, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Filing of FCPA enforcement actions have been temporarily paused. Once enforcement resumes, companies may incur additional damage due to delayed prosecution.

Our business is also subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. customs regulations, and various economic and trade sanctions regulations administered by the U.S. Treasury Department’s Office of Foreign Assets Control. Export controls and trade sanctions laws and regulations may restrict or prohibit altogether the provision, sale, or supply of our products to certain governments, persons, entities, countries, and territories, including those that are the target of comprehensive sanctions or an embargo. In particular, there is currently significant uncertainty about the future relationship between the United States and various other countries, including, without limitation, China, Mexico, and Canada, with respect to trade policies, treaties, tariffs, taxes, and other limitations on cross-border operations.

Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers, or our employees, the closing down of our facilities, requirements to obtain export licenses, cessation of business activities in sanctioned countries, implementation of compliance programs, and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our solutions in one or more countries and could harm our reputation, brand, international expansion efforts, and ability to attract and retain employees, which could have an adverse effect on our business, financial condition, and results of operations.

Risks Related to Intellectual Property

If we are unable to obtain and maintain intellectual property protection for our technology, or if the scope of the intellectual property protection we obtain is not sufficiently broad, our competitors could develop and commercialize technology and products similar or identical to our solutions, and our ability to successfully commercialize our solutions may be impaired.

Our success and ability to compete successfully will depend in part on our ability to obtain, maintain, and enforce issued patents, trademarks, and other intellectual property rights and proprietary technology protection for our solutions, preserve our trade secrets, and operate without infringing the intellectual property rights of third parties. Filing, prosecuting, enforcing, and defending patents on our solutions and other technologies in all countries throughout the world would be prohibitively expensive and time-consuming, and the laws of some foreign countries may not protect our rights to the same extent as the laws of the United States. We may not, and our exclusive licensors may not, be able to file, prosecute, maintain, enforce, or license all necessary or desirable patents or patent applications at a reasonable cost or in a timely manner, or in all jurisdictions, or at all, or may choose not to do any of the foregoing. Furthermore, in some cases, we have only filed provisional patent applications on certain aspects of our products and technologies and each of these provisional patent applications, or any future provisional patent application on certain aspects of our products and technologies, is not eligible to become an issued patent until, among other things, we file a non-provisional patent application within 12 months of the filing date of the applicable provisional patent application. In cases where we have not obtained, or decided not to obtain, patent protection for certain of our inventions, we may not be able to prevent third parties from practicing our inventions or from selling or importing tests made using our inventions in and into the United States or other jurisdictions.

The patent positions of companies, including our patent position, may involve complex legal and factual questions that have been the subject of much litigation in recent years, and, therefore, the scope of any patent claims that we have or may obtain cannot be predicted with certainty. Accordingly, we cannot provide any assurances about which of our patent applications will issue, the breadth of any resulting patent, whether any of the issued patents will be found to be infringed, that any of our issued patents have, or that any of our currently pending or future patent applications that mature into issued patents will include, claims with a scope sufficient to protect our solutions and services. Our pending and future patent applications may not result in the issuance of patents or, if issued, may not issue in a form that will be advantageous to us. The coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. We cannot offer any assurances that the breadth of our granted patents will be sufficient to prevent a competitor from developing, manufacturing, and commercializing a solution or technologies in a non-infringing manner that would be competitive with one or more of our solutions or technologies, or otherwise provide us with any competitive advantage.

Moreover, although we have applied for patents covering aspects of our technology in the United States and several other countries, we cannot be certain that our owned and exclusively licensed patents will not be challenged, or that all patents for which we have applied, or that are covered by our exclusive in-licenses, will be issued on a timely basis or at all, or that such patents will protect our technology, in whole or in part, or be issued in a form that will provide us with meaningful protection, prevent competitors from competing with us, or otherwise provide us with any competitive advantage. As further described below, the enforceability of issued patents may be challenged on a number of fronts, including inventorship, scope, or validity, and certain of our owned or exclusively in-licensed patents have been, and others in the future may be, challenged in the courts or patent offices in the United States and abroad. As a result of such challenges, our issued patents may be held invalid or unenforceable and the scope of existing or future patents may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. For additional information, see “—Issued patents covering our solutions and other technologies could be found invalid or unenforceable if challenged in court or before administrative bodies in the United States and abroad.” We may fail to identify patentable technologies in a timely fashion, which could impair our ability to obtain patent protection on such technology at all. If we fail to timely file for patent protection in any jurisdiction, we may be precluded from doing so at a later date. Our competitors may be able to circumvent our owned or exclusively in-licensed patents by developing similar or alternative technologies or tests in a non-infringing manner. In addition, to the extent we have granted, or may grant in the future, licenses, or sublicenses of our intellectual property rights to third parties, we cannot be certain that such intellectual property rights will not be used by those third parties in a manner that could compete with our business or otherwise negatively impact any competitive advantage provided by such intellectual property rights.

Publications of discoveries in scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability, and commercial value of our patent rights are uncertain. Given the amount of time required for the development, testing, and regulatory review of biological tests, patents protecting or covering such tests might expire shortly after such solutions are commercialized. As a result, our owned or exclusively in-licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

If a third party obtains an issued patent on a technology we use in our solutions, that party may be able to prevent us from using those inventions, and we may not be able to design around the third party’s patents or obtain a license on commercially reasonable terms, if at all. Third-party patents or other intellectual property may exist that our current technology, manufacturing methods, solutions, platform, or future methods or tests will be alleged to infringe, which could result in litigation, the imposition of injunctions preventing our use of the foregoing, or require us to obtain licenses or pay royalties and/or other forms of compensation to third parties, which could be significant and could harm our results of operations.

Some of our patents and patent applications may in the future be co-owned with third parties. If we are unable to obtain an exclusive license to any such third-party co-owners’ interest in such patents or

patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products, services, and technology. In addition, we may need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us.

The degree of future protection for our proprietary rights is uncertain, and we cannot ensure that:

- any of our patents, or any of our pending patent applications, if issued, will include claims having a scope sufficient to protect our solutions;
- any of our pending patent applications will issue as patents;
- we will be able to successfully manufacture and commercialize our solutions on a substantial scale, if approved, before relevant patents we may have expire;
- we were the first to make the inventions covered by each of our patents and pending patent applications;
- we were the first to file patent applications for these inventions;
- others will not independently develop, manufacture and/or commercialize similar or alternative or duplicative solutions of any of our technologies or products that do not infringe our patents;
- any of our challenged patents will be found to ultimately be valid and enforceable;
- any patents issued to us will provide a basis for an exclusive market for our commercially viable solutions or technologies, and will provide us with any competitive advantages or will not be challenged by third parties;
- we will develop additional proprietary technologies or solutions that are separately patentable;
- our pending patent applications or those that we may own in the future will lead to issued patents;
- our competitors will not conduct R&D activities in countries where we do not have patent rights and then use the information learned from such activities to develop, manufacture, and commercialize competitive products for sale in our major commercial markets;
- the patents of others will not harm our business;
- a third party does not subsequently file a patent covering trade secrets or know-how that we chose not to seek patent protection; or
- our commercial activities or solutions will not infringe upon the patents of others.

Third parties may allege that we infringe, misappropriate, or violate their intellectual property rights, and if they prevail, could block sales of our solutions and force us to pay damages and/or royalties, which could adversely affect the success of our business.

Our commercial success in part depends upon our ability, and the ability of our relevant commercial partners, to market, sell, and distribute our solutions and use our proprietary technologies and platform without infringing, misappropriating, or otherwise violating the intellectual property rights of third parties. There is considerable intellectual property litigation in the medical technology, biotechnology, diagnostic, and pharmaceutical industries, and companies in these industries have used intellectual property litigation to gain a competitive advantage. In addition, there is ongoing intellectual property litigation involving the analysis of circulating nucleic acid, the outcome of which could also impact future litigation involving our intellectual property or our ability to commercialize our solutions. We may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights. Third parties may assert infringement claims against us based on existing patents or patents that issue in the future.

If we are found to infringe, misappropriate, or otherwise violate a third party's intellectual property rights, we could be required to obtain a license from such third party to continue developing, marketing, selling, and distributing our solutions or platform, or to cease using the infringing technology. However, we

may not be able to obtain any required license on commercially reasonable terms, if at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In addition, we could be found liable for monetary damages, including treble damages if we are found to have willfully infringed a patent and attorneys' fees if the court finds the case to be exceptional. A finding of infringement, misappropriation, or other violation could prevent us from commercializing our solutions or force us to cease some of our operations or develop alternate technologies, which could materially harm our business, financial condition, results of operations, and prospects. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our reputation and business.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our personnel from their normal responsibilities. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, or distribution activities. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can if they have greater financial resources and/or more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could adversely affect our ability to compete in the marketplace.

Issued patents covering our solutions and other technologies could be found invalid or unenforceable if challenged in court or before administrative bodies in the United States and abroad.

In addition to allegations of infringement of a third party's intellectual property rights, a third party may also challenge the validity or enforceability of our owned or in-licensed patents in court or before administrative bodies in the United States or abroad. If we or one of our licensors were to initiate legal proceedings against a third party to enforce a patent covering a solution or a solution candidate, the defendant could counterclaim that the asserted patent is invalid and/or unenforceable. Though an issued patent is presumed valid and enforceable, defendant counterclaims alleging invalidity or unenforceability are commonplace in patent litigation in the United States. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements for patentability, including lack of novelty, obviousness, lack of subject matter eligibility, lack of written description, and non-enablement. Non-statutory grounds for unenforceability include inequitable conduct in obtaining the patent, such as an allegation that someone connected with prosecution of the patent withheld relevant information from the United States Patent and Trademark Office (the "USPTO"), or made a material misleading statement. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to validity, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. In addition, the patent laws or interpretation thereof by the USPTO and courts could result in some of the claims of our patents to become invalidated. A court may decide that a patent or other intellectual property right of ours is invalid or unenforceable, in whole or in part, construe the patent's claims or other intellectual property narrowly or refuse to stop a third party from using the technology at issue on the grounds that our patents or other intellectual property do not cover the technology in question and is therefore not infringed upon, violated, or misappropriated. For example, certain claims of five of our U.S. patents have previously been invalidated in *inter partes* review ("IPR") proceedings, two of our European patents were challenged but ultimately upheld in their entirety in opposition proceedings, and one of our European patents was held unpatentable in an opposition that is currently under appeal. As a result of such challenges, our issued patents may be held invalid or unenforceable and the scope of existing or future patents may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

If a defendant were to prevail on its legal assertion of invalidity and/or unenforceability against our intellectual property related to a solution or a solution candidate, we could lose at least part, and perhaps all, of the patent protection on such solution or solution candidate. Such a loss of patent protection could adversely impact our business. Moreover, our competitors could counterclaim that we infringe their intellectual property, and some of our competitors have substantially greater intellectual property portfolios than we do. Even if our patents or other intellectual property rights are found to be valid and infringed, a court may refuse to grant injunctive relief against the infringer and instead grant us monetary damages and/or ongoing royalties. Such monetary compensation may be insufficient to adequately offset the damage to our

business caused by the infringer's competition in the market. An adverse result in any litigation or administrative proceeding could put one or more of our patents or other intellectual property rights at risk of being invalidated or interpreted narrowly, which could adversely affect our competitive business position, financial condition, and results of operations. Moreover, even if we are successful in any litigation, we may incur significant cost and expense in connection with such proceedings, and the amount of any monetary damages may be inadequate to compensate us for damage from the infringement and proceedings.

In addition to infringement claims against us, third parties have raised, and in the future may raise, claims challenging the validity or enforceability of our owned or in-licensed patents before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms before the USPTO include re-examination, post grant review, IPR, derivation proceedings, interference proceedings, and equivalent proceedings in foreign jurisdictions (such as opposition proceedings in Europe). Such administrative proceedings could result in the revocation of, cancellation of, or amendment to our patents in such a way that they no longer cover our technologies or solutions. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we, our patent counsel, and the patent examiner were unaware during prosecution. If a third party were to prevail on a legal assertion of invalidity and/or unenforceability, we may lose at least part, and perhaps all, of the patent protection on our solutions or technologies. Such a loss of patent protection could adversely impact our business, financial condition, and results of operations.

If we fail to comply with our obligations in the agreements under which we license or may license intellectual property rights from third parties or we otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business.

We have entered into, and may further need to enter into, certain licenses or other collaboration agreements pertaining to the in-license of intellectual property rights from others to advance our research or allow commercialization of our solutions and technologies. Some of these licenses are for a limited term and may include the right for the licensor to terminate upon notice. If any such arrangement is terminated by the licensor, or if we need to enter into any additional licensing arrangements, then we may be unable to obtain such licenses at a reasonable cost or on reasonable terms, if at all, and as a result, we may be required to expend significant time and resources to redesign our technology or to develop or license replacement technology, any of which may not be feasible on a technical or commercial basis. If we are unable to obtain or maintain applicable licenses, we may be unable to commercialize certain solutions or continue to use certain technology, which could harm our business, financial condition, and results of operations.

Our intellectual property in-licenses may impose various reporting, development, diligence, milestone payment, royalty, insurance, commercialization, and other obligations on us, and we expect that our future license or development agreements will contain similar types of obligations. If we fail to comply with any of these obligations, our licensor or collaboration partners may have the right to terminate the relevant license or collaboration agreement, in which event we would not be able to develop or market the solutions or technologies covered by such licensed intellectual property, or to pursue other reasonable or alternative arrangements. Despite our efforts, our licensors or collaborators might conclude that we have materially breached our obligations under such license agreements. If our licensors or collaborators were to terminate the license agreements or otherwise modify our rights under those agreements, our ability to develop and commercialize solutions and technology covered by these license agreements could be limited if not halted. This could adversely affect our competitive position, business, financial condition, results of operations, and prospects.

Agreements under which we license or otherwise obtain rights to intellectual property or technology from third parties may be complex, and certain provisions in such agreements may be susceptible to multiple interpretations, which could lead to disputes between us and our licensor, including:

- the scope of rights granted under the license agreement;
- the extent to which our solution and technology are alleged to infringe the licensor's intellectual property that is not subject to the license agreement;
- the right to sublicense patent and other rights under our collaborative development relationships;

- our diligence and other obligations under the license agreement;
- the priority of invention of patented technology; and
- the inventorship and ownership of inventions and know-how resulting from the collaboration with a licensor or joint invention of intellectual property by us and our licensors and our partners.

The resolution of any contract disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could adversely affect our business, financial condition, results of operations, and prospects. If we were required to engage in litigation to enforce or defend our rights under our license or development agreements, even if we were successful, such litigation could require significant financial resources, divert the attention of management, and harm our business. Moreover, if disputes over intellectual property rights that we have licensed or otherwise obtained rights to prevent or impair our ability to maintain our current arrangements on commercially acceptable terms, or at all, we may be unable to successfully commercialize the affected solution or technology, which could adversely affect our business, financial condition, results of operations, and prospects.

In addition, we may have limited control over the maintenance and prosecution of in-licensed patents and patent applications, or any other intellectual property that may be related to our in-licensed intellectual property. For example, we cannot be certain that such activities by any future licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights. If any of our current or future licensors fail to obtain and maintain patent or other protection for the proprietary intellectual property we license from them, we could lose our rights to the intellectual property, or these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business and our competitors could market competing products using the intellectual property. In the event we breach any of our obligations related to such maintenance or prosecution, we may incur significant liability to our licensing partners, including loss of our right to the licensed patent applications or early termination of the license by our licensor. We also may have limited control over the manner in which our licensors initiate an infringement proceeding against a third-party infringer of the intellectual property rights, or defend certain of the intellectual property that is licensed to us. It is possible that the licensor's infringement proceeding or defense activities may be less vigorous than had we conducted such activities ourselves. Our ability to enforce in-licensed patents may be in question if our licensors refuse to join in such activities initiated by us.

Our technology licensed from third parties may be subject to retained rights.

Any license we may enter into could provide for the retention by the licensor of certain rights under their agreements with us, including for example, the right to use the underlying technology for noncommercial academic and research use, to publish general scientific findings from research related to the technology, and to make customary scientific and scholarly disclosures of information relating to the technology. It is difficult to monitor whether any future licensors will limit their use of the technology to these uses, and we may incur substantial expenses to enforce our rights to our licensed technology in the event of misuse.

In addition, the U.S. government retains certain rights in inventions produced with its financial assistance under the Patent and Trademark Law Amendments Act (the "Bayh-Dole Act"). The U.S. government retains a "nonexclusive, nontransferable, irrevocable, paid-up license" for its own benefit. The Bayh-Dole Act also provides federal agencies with "march-in rights." March-in rights allow the government, in specified circumstances, to require the contractor or successors in title to the patent to grant a "nonexclusive, partially exclusive, or exclusive license" to a "responsible applicant or applicants." If the patent owner refuses to do so, the government may grant the license itself. The Bayh-Dole Act also imposes other obligations, including the requirement that products covered by the government funded patents be manufactured in the United States. We sometimes collaborate with academic institutions to accelerate our R&D efforts. In the future, we may own or license technology which is critical to our business that is developed in whole or in part with federal funds subject to the Bayh-Dole Act. If the federal government exercises its rights under the Bayh-Dole Act, our ability to enforce or otherwise exploit patents covering such technology may be adversely affected.

We may become involved in lawsuits to protect or enforce or defend our patents or other intellectual property rights, which could be expensive, time-consuming, and unsuccessful.

Third parties, including our competitors, may currently, or in the future, infringe, misappropriate, or otherwise violate our issued patents or other intellectual property rights, and we may file lawsuits or initiate other proceedings to protect or enforce our patents or other intellectual property rights, which could be expensive, time-consuming, and unsuccessful. We monitor for unauthorized use of our intellectual property rights and, from time to time, analyze whether to seek enforce our rights against potential infringement, misappropriation, or violation of our intellectual property rights. However, the steps we have taken, and are taking, to protect our proprietary rights may not be adequate to enforce our rights as against such infringement, misappropriation, or violation of our intellectual property rights. In certain circumstances it may not be practicable or cost-effective for us to enforce our intellectual property rights fully, for example, in certain countries or where the initiation of a claim might harm our business relationships. We may also be hindered or prevented from enforcing our rights with respect to a government entity or instrumentality because of the doctrine of sovereign immunity. Our ability to enforce our patent or other intellectual property rights can depend on our ability to detect infringement. It may be difficult to detect infringers who do not advertise the components or methods that are used in connection with their products or technologies. Moreover, it may be difficult or impossible to obtain evidence of infringement in a competitor's or potential competitor's product or technologies. Thus, we may not be able to detect unauthorized use of, or take appropriate steps to enforce, our intellectual property rights. Any inability to meaningfully enforce our intellectual property rights could harm our ability to compete and reduce demand for our solutions.

In addition, these lawsuits or other proceedings could be costly and could affect our operations and divert the attention of our managerial, legal, and scientific personnel. There is a risk that a court or administrative body would decide that our owned or in-licensed patents are invalid or not infringed by a third party's activities, or that the scope of certain claims is more limited than we believe. An adverse outcome in a litigation or other proceeding involving our owned or in-licensed patents could limit our ability to enforce our patents against competitors, affect our ability to receive royalties or other licensing consideration, and may curtail or preclude our ability to exclude third parties from making, using, and selling similar or competitive products. We may become more susceptible to these types of lawsuits and proceedings given the proliferation of organizations pursuing intellectual property protections in the biomarker testing space, particularly as relates to cell free nucleic acids. Any of these occurrences could adversely affect our business, financial condition, results of operations, and prospects.

Intellectual property litigation may lead to public disclosures and unfavorable publicity that harms our reputation and causes the market price of our common stock to decline.

Because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. Further, during the course of any intellectual property litigation, there could be public announcements of the initiation of the litigation as well as results of hearings, rulings on motions, and other interim proceedings in the litigation. If securities analysts or investors regard these announcements as negative, the perceived value of our existing solutions, programs or intellectual property could be diminished. Accordingly, the market price of shares of our common stock may decline. Such announcements could also harm our reputation or the market for our future solutions, which could adversely affect our business.

Patent terms may be inadequate to protect our competitive position on our solutions for an adequate amount of time.

Patents have a limited lifespan in all jurisdictions around the world. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the protection offered by a patent remains time limited. Once a patent covering our solutions expires, we may be subject to additional competition. Given the amount of time required for the development, testing and regulatory review of new products, patents protecting such products might expire before or shortly after such products are commercialized or receive regulatory approval. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing solutions similar or identical to ours for a meaningful

amount of time, or at all. Such an inability to exclude competitors from commercializing similar or identical products could have adversely impact our reputation, business, financial condition, results of operations, and prospects.

If we do not obtain patent term extension and data or regulatory exclusivity for any solutions we may develop, our business may be materially harmed.

Depending upon the timing, duration, and specifics of any FDA marketing approval of any therapeutic solutions we may develop, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Action of 1984 (the “Hatch-Waxman Amendments”). The Hatch-Waxman Amendments permit a patent extension term of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable legal requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we will have the right to exclusively market our solution will be shortened and our competitors may obtain approval of competing products following our patent expiration and may take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data to launch their product earlier than might otherwise be the case.

Additionally, depending upon the timing, duration, and specifics of any FDA approval of biological products we may develop as part of Caris Discovery or otherwise, such products may be eligible for a period of regulatory exclusivity under the Biologics Price Competition and Innovation Act of 2009 (“BPCIA”), a subtitle of the Patient Protection and Affordable Care Act. The BPCIA created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Under the BPCIA, an application for a highly similar or “biosimilar” product may not be submitted to the FDA until four years following the date that the reference product was first approved by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first approved. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full biologics license application for the competing product containing the sponsor’s own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of its product.

Biological products we may develop, if any and if approved, could be considered reference products entitled to 12-year exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider a product candidate to be reference products for competing products, potentially creating the opportunity for competition sooner than anticipated. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. Moreover, the extent to which a biosimilar, once approved, will be substituted for any reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing. The FDA only approved the first interchangeable biosimilar in July 2021, and the law is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty. If competitors are able to obtain marketing approval for biosimilars referencing any biological products we may develop, our products may become subject to competition from such biosimilars, which could adversely impact our competitive position.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent application process to

maintain patent applications and issued patents. In addition, periodic maintenance fees, renewal fees, annuity fees, and various other government fees on patents and applications must be paid to the USPTO and similar patent agencies outside of the United States over the lifetime of our owned and in-licensed patents and applications. In some cases, we rely on our licensing partners to pay such fees and to take the necessary actions to comply with other requirements to maintain such in-licensed patents during their term. While an unintentional lapse of a patent or patent application can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, in some cases non-compliance can result in abandonment or lapse of the patent or patent application, resulting in a partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, potential competitors might be able to enter the market with similar or identical tests or technology, which could adversely affect our competitive position.

Developments in patent law could have a negative impact on our business.

From time to time, the U.S. Supreme Court or other federal courts, the U.S. Congress, the USPTO, or similar governmental authorities in other jurisdictions may change the standards of patentability and any such changes could have a negative impact on our business.

Several decisions from the U.S. Supreme Court regarding patentable subject matter are of particular relevance in the medical diagnostics and computer-implemented applications space. The 2012 decision in *Mayo Collaborative v. Prometheus Laboratories* (“*Mayo*”) concerns patent claims directed to optimizing the amount of drug administered to a specific patient based on certain metabolite levels in blood. The Supreme Court held that the applicable patent’s claims were directed to a law of nature (i.e., a natural correlation between metabolite levels and efficacy or toxicity) and failed to incorporate a sufficiently inventive concept above and beyond routine and conventional method steps to allow the claimed methods of treatment to qualify as patent eligible. The 2014 decision in *Alice Corporation Pty. Ltd. v. CLS Bank International* (“*Alice*”) concerns a computer-implemented, electronic escrow service for facilitating financial transactions. The Supreme Court held that an abstract idea could not be patented just because it is implemented on a computer. It is generally believed that *Mayo* and *Alice*, and subsequent cases interpreting these decisions, have made it more difficult to patent medical diagnostic and computer-implemented inventions. Our efforts to seek patent protection for such technologies and solutions may be negatively impacted by this jurisprudence, or guidance or procedures issued by the USPTO or authorities in other jurisdictions.

We cannot predict the impact of the changing landscape of patent eligible subject matter on our ability, or that of our competitors, to obtain or enforce patents relating to products and services involving genomic or biomarker related discoveries, or computer-implemented technologies, such as molecular tests that implement ML. Indeed, many believe that the contours of whether claims are patent eligible, or recite laws of nature, natural phenomena, natural products, or abstract ideas remain unclear despite a decade of interpretation at the USPTO and in the courts. Third parties holding patents issued prior to *Mayo*, *Myriad* and *Alice* could allege that we infringe these patents, even if these patents are not likely enforceable under current U.S. laws. We could be forced to defend against claims of patent infringement or obtain license rights, if available on commercially reasonable terms or at all, under these patents. In jurisdictions other than the United States, gene- and computer-related patent claims may remain valid and may be enforceable against us.

The U.S. Congress has periodically sought to pass laws concerning subject matter eligibility for patent protection, aimed in large part at abrogating the holdings of *Mayo* and *Alice*. To date, these efforts have been unsuccessful, but are ongoing. We cannot fully predict the impact that such new laws may have on our ability to obtain patent protection on our solutions and technologies, and our ability to operate in view of the patents controlled by third parties.

We may not be able to enforce our intellectual property rights throughout the world.

The laws of foreign countries may not protect intellectual property rights to the same extent as the laws of the United States. In some cases, companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries,

particularly developing countries, do not favor the enforcement of patents and other intellectual property protection, especially those relating to life sciences. This could make it difficult for us to stop the infringement of our patents or the misappropriation of our other intellectual property rights. For example, some foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties.

On June 1, 2023, the European Union implemented a unitary patent system with the goal of providing a single pan-European Unitary Patent and a new European Unified Patent Court (“UPC”) for litigation involving European patents. As a result, all European patents, including those issued prior to ratification of the unitary patent system, now by default automatically fall under the jurisdiction of the UPC, although patent applicants and patent holders may elect to opt-out of the new system for a transitional period of at least seven years. It is uncertain how the UPC will impact European patents, including those in the biotechnology and pharmaceutical industries. If we do not opt-out, our European patents could be challenged in the UPC. Thus far, like many others, we have elected to opt-out of the UPC as it matures. We may continue to opt-out our future European patents, but doing so may preclude us from realizing its benefits. Moreover, if we do not meet all of the formalities and requirements for opt-out under the UPC, our future European patents could remain under the jurisdiction of the UPC. The UPC will provide our competitors with a new forum to centrally revoke our European patents, and allow for the possibility of a competitor to obtain a pan-European injunction. Such a loss of patent protection or injunction obtained by a competitor could adversely impact our business and our ability to commercialize our technology and solutions and, as a result, on our business, financial condition, prospects, and results of operations.

Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business. Furthermore, while we intend to protect our intellectual property rights in our expected significant markets, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our solutions. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate. In addition, changes in the law and legal decisions by courts in the United States and foreign countries may affect our ability to obtain and enforce adequate intellectual property protection for our solutions and technology.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position could be harmed.

In addition to seeking patents for certain of our solutions and other technologies, we rely on trade secrets and confidentiality agreements to protect our unpatented know-how, technology, data, and other proprietary information and to maintain our competitive position. Trade secrets and know-how can be difficult to protect. Our trade secrets and know-how may over time become known to others through various means such as independent development, personnel movement, collaborative efforts or other intentional or unintentional disclosure.

We seek to protect our trade secrets and other proprietary technology, in part, by entering into non-disclosure and confidentiality agreements with relevant parties, such as our employees, directors, corporate and scientific collaborators, contract research organizations, contract manufacturers, suppliers, service providers, consultants, advisors, and other third parties. We generally enter into confidentiality and invention assignment agreements with our employees and consultants upon their commencement of a relationship with us, and remind departing employees of their continuing confidentiality obligations. However, we may not be successful in entering into such agreements with all employees and consultants. Although we generally require all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information, processes, or technology to enter into confidentiality agreements, we cannot provide any assurances that we have entered into confidentiality agreements with each person or party that had or may have had access to our proprietary know-how, information, processes, or technology. In addition, monitoring unauthorized use and disclosure of our proprietary know-how, information, processes or technology by employees, consultants and other third parties who have access can be difficult, and we cannot be certain whether the steps we have taken to protect our proprietary know-how, information, processes, or technology will be adequate. Therefore, we may not be able to prevent the unauthorized disclosure or use of our technical knowledge or other trade secrets by such employees, consultants, advisors or third parties, despite the existence of confidentiality restrictions. These agreements may also not provide meaningful

protection against the unauthorized use or disclosure of our trade secrets, know-how or other proprietary information in the event the unwanted use is outside the scope of the provisions of the contracts or in the event of any unauthorized use, misappropriation, or disclosure of such trade secrets, know-how, or other proprietary information.

Despite our efforts, any of these persons or parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a person or party illegally disclosed or misappropriated a trade secret can be difficult, expensive, and time-consuming, and the outcome is unpredictable. In addition, some courts outside the United States may be less willing or unwilling to protect trade secrets. Further, agreement terms that address non-competition are difficult to enforce in many jurisdictions and might not be enforceable in certain cases. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us. We may enter into collaboration, license, contract research and/or manufacturing relationships with contract organizations that operate in certain countries that are at heightened risk of theft of technology, data, and intellectual property through direct intrusion by private parties or foreign actors, including those affiliated with or controlled by state actors. If any of our trade secrets were to be misappropriated by, disclosed to, or independently developed by a competitor or other third party, our competitive position could be adversely harmed.

In addition to contractual measures, we try to protect the confidential nature of our proprietary information by maintaining physical security of our premises and electronic security of our information technology systems. Such security measures may not be adequate for all scenarios, for example, in the case of misappropriation of a trade secret by an employee, consultant, or other third party with authorized access. An employee, consultant or other third party who misappropriates our trade secrets may provide such information to a competitor, and any recourse we take against such misconduct may not provide an adequate remedy to protect our interests fully. Unauthorized parties may also attempt to copy or reverse engineer certain aspects of our solutions, platform, or services that we consider proprietary. Although we use commonly accepted security measures, trade secret violations are a matter of both federal and state law in the United States, and the criteria for protection of trade secrets can vary among different jurisdictions. If the steps we have taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret. In addition, trade secrets may be independently developed by others in a manner that could prevent legal recourse by us. If any of our intellectual property rights or confidential or proprietary information, such as our trade secrets, were to be disclosed or misappropriated, or if any such information was independently developed by a competitor, it could adversely affect our competitive position, business, financial condition, results of operations, and prospects.

Accordingly, our efforts to protect and enforce our trade secrets, know-how and intellectual property rights around the world may be inadequate to obtain a significant commercial advantage, and we may be at heightened risk of losing our trade secrets, proprietary know-how and intellectual property rights around the world, to the extent such theft or intrusion destroys their secrecy or other proprietary nature.

We may be subject to claims by third parties asserting that we or our employees have infringed or misappropriated intellectual property rights, or to assertions by third parties or employees claiming ownership of what we regard as our own intellectual property.

Many of our former, current, and future employees, consultants and contractors have been previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors and strategic partners. Some of these employees, consultants and contractors may have executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment or engagement. We train our employees, consultants, and contractors not to bring, or use in their work proprietary information or technology from former employers. Although we intend for such training and other measures to ensure that our employees do not use the proprietary information or know-how of others in their work for us, to the extent that our employees, consultants or contractors use intellectual property rights or proprietary information owned by others in their work for us, we may be subject to claims that an employee has used or disclosed intellectual property, including trade secrets or other proprietary information, of such employee's former employer. Litigation,

which would be expensive, time-consuming, a distraction to management, and uncertain of outcome, may be necessary to defend against these claims.

In addition, we may be subject to claims from third parties challenging ownership interest in or inventorship of intellectual property rights we regard as our own, based on claims that our agreements with employees or consultants obligating them to assign their intellectual property rights to us are ineffective or in conflict with prior or competing contractual obligations to assign inventions and intellectual property rights to another employer, to a former employer, or to another person or entity. We are not aware of any threatened or pending claims related to these matters, but, in the future, litigation may be necessary to defend against such claims should they arise, and it may be necessary or we may desire to obtain a license to such third party's intellectual property rights to settle any such claim. However, there can be no assurance that we would be able to obtain such license on commercially reasonable terms, if at all. If we fail in defending any such claims, in addition to paying monetary damages or a settlement payment, we may lose valuable intellectual property rights or personnel, or access to consultants and contractors. A court could prohibit us from using technologies, features or other intellectual property rights that are essential to our solutions or technologies, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of another person or entity, including another or former employers. An inability to incorporate technologies, features or other intellectual property rights that are important or essential to our solutions or technologies could adversely affect our business, financial condition, results of operations, and competitive position, and may prevent us from developing, manufacturing and/or commercializing our solutions or technologies. In addition, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and our employees. Any litigation or the threat of litigation may adversely affect our ability to hire employees or contract with independent sales representatives. A loss of key personnel or their work product could hamper or prevent our ability to develop, manufacture and/or commercialize our solutions or services, which could adversely affect our business, financial condition, and results of operations.

In addition, we may be subject to claims that our former employees, contractors or collaborators, or other third parties have an ownership interest in our current or future patents, patent applications, or other intellectual property rights, including as an inventor or co-inventor. We may be subject to ownership or inventorship disputes in the future arising, for example, from conflicting obligations of employees, consultants or others who were or are involved in developing our solutions.

If we fail to prevail on any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, or be required to obtain a license, which may not be available to us on commercially reasonable terms or at all. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to management, which could harm our business.

If our trademarks and trade names are not adequately protected, we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

We currently hold and/or have applied for a number of trademarks, covering Caris, MI Profile, MI Tumor Seek Hybrid, MI Cancer Seek, Caris Assure, and other solutions and services in certain jurisdictions. However, our pending or future trademark applications may not be approved or our registered or unregistered trademarks or trade names may be challenged, invalidated, infringed, or declared generic or determined to be infringing on other marks. If any of the foregoing occurs, we could be forced to re-brand our solutions or technologies, and we may not be able to protect our rights to these trademarks and trade names, which we view as valuable to building name recognition among partners and customers in our markets of interest. At times, competitors or other third parties have adopted or may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion and/or litigation. In addition, there have been and could be trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. There can be no assurance that competitors will not infringe our trademarks or that we will have adequate resources to enforce our trademarks. Over the long term, if we are unable to establish name recognition based on our trademarks

and trade names, we may be unable to compete effectively and our business may be adversely affected. Our efforts to enforce, protect, or defend our trademarks may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our competitive position, business, financial condition, results of operations, and prospects.

Our use of open-source software could subject our proprietary technology to unwanted open-source license conditions that could negatively impact our business.

We use open-source software in some of our technologies and solutions, and we may incorporate open-source software into future technologies and solutions. From time to time, companies that use third-party open source software have faced claims challenging the use of such open source software and requesting compliance with the open source software license terms. Accordingly, we may be subject to suits by parties claiming ownership of what we believe to be open source software or claiming non-compliance with the applicable open source licensing terms. Some open source software licenses require end users, who use, distribute, or make available across a network software and services that include open source software, to make publicly available or to license all or part of such software (which in some circumstances could include valuable proprietary code, such as derivative works of the open source software) under the terms of the particular open source license. If a third party were to allege that we had not complied with the conditions of one or more of these licenses, we could be required to invest substantial time and resources to re-engineer some of our software or release certain portions of our proprietary source code, which could substantially help our competitors develop products that are similar to or improve upon ours and harm our business. We could also be required to incur significant legal expenses defending against such allegations. Further, the outcome of such litigation may be particularly uncertain because there are numerous open source software licenses which have not been tested in courts of law, and thus lack guidance regarding their proper legal interpretation. Any of the foregoing could disrupt and harm our business.

In addition, the use of third-party open source software typically exposes us to greater risks than the use of third-party commercial software because open source licensors generally do not provide warranties or controls on the functionality or origin of the software. Use of open source software may also present additional security risks because the public availability of such software may make it easier for hackers and other third parties to determine how to compromise platforms using such source code. Any of the foregoing could harm our business and could help our competitors develop products and services that are similar to or that improve upon ours.

The occurrence of any of these events could adversely affect our business, financial condition, results of operations, and prospects.

Risks Related to Our Indebtedness

We have incurred substantial indebtedness, and we may not generate sufficient cash flow from operations to meet our debt service requirements, continue our operations, and pursue our growth strategy, and we may be unable to raise capital when needed or on acceptable terms.

As of March 31, 2025, we and our subsidiaries had approximately \$400.0 million aggregate principal amount of debt outstanding under the 2023 Term Loan. Subsequent to March 31, 2025, we issued \$30.0 million aggregate principal amount of our 2025 Convertible Notes in April 2025, which will convert into shares of our common stock in connection with this offering, in accordance with their terms. Our substantial level of indebtedness increases the risk that we may be unable to generate cash sufficient to pay amounts due in respect of our indebtedness, pay dividends and to fund our general corporate and capital requirements. The substantial indebtedness of us and our subsidiaries could have important consequences to our shareholders, including:

- a portion of our cash flow from operations must be dedicated to the payment of principal and interest on our debt, thereby reducing the funds available to us for other purposes;
- our ability to satisfy our obligations under the 2023 Term Loan Agreement may be adversely affected;

- our ability to make loans and investments or engage in acquisitions without issuing additional equity or obtaining additional debt financing may be impaired in the future;
- our ability to obtain additional financing for working capital, capital expenditures, acquisitions, debt service requirements or general corporate purposes may be impaired in the future;
- our ability to pay dividends or engage in share repurchases may continue to be restricted;
- our flexibility may be limited in planning for, or reacting to, changes or challenges relating to the business we conduct;
- we may be more vulnerable to general adverse economic and industry conditions;
- we may be at a competitive disadvantage compared to our competitors who have less debt or comparable debt at more favorable interest rates or terms and who, as a result, may be better positioned to withstand economic downturns or to finance capital expenditures or acquisitions; our costs of borrowing may increase; and
- we may be unable to refinance our debt on terms as favorable as our existing debt or at all.

The occurrence of any one of these events could have an adverse effect on our business, financial condition, results of operations, and ability to satisfy our obligations under the 2023 Term Loan Agreement. We may not be able to access capital on acceptable terms, raise additional capital in the future, or make effective capital allocation decisions, which could result in our inability to achieve operational objectives. Any disruption in access to capital could require us to take measures to conserve cash until alternative credit arrangements or other funding for business needs can be arranged. Such measures could include deferring capital expenditures, acquisitions or other discretionary uses of cash, or revising capital allocation decisions. Any of these risks could adversely affect our business, financial condition, and results of operations.

The agreements and instruments governing our debt contain restrictions and limitations that could significantly impact our management's flexibility and our financial and operational flexibility to operate our business.

Restrictive covenants in the 2023 Term Loan Agreement place limits on our ability to conduct our business. Covenants in the 2023 Term Loan Agreement include those that, subject to certain exceptions, restrict our ability to:

- materially alter the business we conduct;
- incur certain additional indebtedness and guarantee indebtedness;
- create or incur liens;
- purchase, make, incur, assume, or permit to exist certain investments;
- make any dividends, distributions, and certain other payments to our shareholders;
- sell, transfer, or otherwise dispose of assets, including capital stock of our subsidiaries;
- modify certain agreements that have an impact on our indebtedness;
- engage in certain transactions with our affiliates;
- enter into any restrictive agreements prohibiting (i) the creation of liens to secure our obligations under the 2023 Term Loan Agreement, (ii) our or our subsidiaries' modification of the 2023 Term Loan Agreement, or (iii) our or our subsidiaries' ability to pay dividends or make any other distributions on any capital securities;
- enter into sale and leaseback transactions;
- make changes to name, location, executive office, executive management, or fiscal years without prior notice; and
- incur any actual or potential liability on benefit plans or allow any employee benefit plans to cease to be tax qualified.

The 2023 Term Loan Agreement also imposes maintenance requirements on our liquidity and revenue base and restricts our ability to engage in certain mergers or consolidations. For additional

information, see “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources—Indebtedness” and “—Risks Related to Our Business and Industry—Our business and results of operations will suffer if we fail to compete effectively.” These restrictions may prevent us from taking actions that we believe would be in the best interest of our business and may make it difficult for us to execute our business strategy successfully or compete effectively with companies that are not similarly restricted. We may also incur future debt obligations that might subject us to additional restrictive covenants that could affect our financial and operational flexibility. Our ability to comply with the covenants and restrictions contained in the 2023 Term Loan Agreement may be affected by economic, financial and industry conditions beyond our control. The breach of any of these covenants or restrictions could result in a default under the 2023 Term Loan Agreement that would permit the applicable lenders or noteholders, as the case may be, to declare all amounts outstanding thereunder to be due and payable, together with accrued and unpaid interest. In addition, such a default or acceleration may result in the acceleration of any other debt to which a cross-acceleration or cross-default provision applies. Our obligations under the 2023 Term Loan Agreement are secured by our intellectual property. If we are unable to repay debt, lenders having secured obligations under the 2023 Term Loan Agreement could proceed against the collateral securing the debt. This could have serious consequences to our business, financial condition, and results of operations and could cause us to become bankrupt or insolvent.

We rely on cash generated from our financing and operating activities as our primary source of liquidity. To support our operations, execute our growth strategy as planned and pay dividends, if declared, we will need to continue generating significant amounts of cash from operations, including funds required to pay our employees, related benefits and other operating expenses, finance future acquisitions, invest in the growth of our business and pay for the increased direct and indirect costs associated with operating as a public company. If our business does not generate sufficient cash flow from operations to fund these activities, we may need to seek additional capital, including by incurring additional debt or equity capital. Additional capital may not be available to us on acceptable terms or at all. In addition, incurring indebtedness requires that a portion of cash flow from operating activities be dedicated to interest and principal payments. Debt service requirements could reduce our ability to use our cash flow to fund operations and capital expenditures, to capitalize on future business opportunities, including additional acquisitions, or to pay dividends. Any of these risks could adversely affect our business, financial condition, and results of operations.

Our variable rate debt subjects us to interest rate risk, which could cause our debt service obligations to increase significantly and affect our operating results.

The indebtedness under the 2023 Term Loan is at variable rates of interest, which exposes us to interest rate risk. In addition, our 2023 Term Loan references the Secured Overnight Financing Rate (“SOFR”) as the primary benchmark rate for our variable rate indebtedness. If benchmark interest rates, including SOFR, were to increase, our debt service obligations on our variable rate indebtedness would increase even if the amount borrowed remains the same, and our net income and cash flows, including cash available for servicing our indebtedness, will correspondingly decrease. In addition, while our 2023 Term Loan will continue to be subject to SOFR, other factors may impact SOFR, including factors causing SOFR to cease to exist, new methods of calculating SOFR to be established, or the use of an alternative reference rate. Such circumstances are not entirely predictable, but could have an adverse impact on our financing costs and results of operations. As of March 31, 2025, we had \$400.0 million outstanding principal amount of variable rate debt subject to interest rate exposure. While we currently hedge the interest rate risk on \$200.0 million principal amount of this outstanding variable rate debt with a purchased interest rate cap derivative with a strike rate of 6.0% and a February 2026 maturity, the remainder of the outstanding amount is not similarly hedged. Accordingly, a 1% increase in interest rates would increase annual interest expense by \$4 million.

Despite our indebtedness level, we and our subsidiaries may incur substantially more debt, including secured debt. This could further exacerbate the risks associated with our substantial indebtedness.

We and our subsidiaries may incur substantial additional indebtedness in the future. Although the terms of the 2023 Term Loan Agreement contain restrictions on the incurrence of additional indebtedness, such restrictions are subject to a number of significant exceptions and qualifications and any additional indebtedness incurred in compliance with such restrictions could be substantial. These restrictions also will

not prevent us from incurring obligations that do not constitute indebtedness. If we and our subsidiaries incur significant additional indebtedness or other obligations, the related risks that we face could increase, and we may not be able to meet all our debt obligations.

Risks Related to This Offering and Ownership of Our Common Stock

An active, liquid, and orderly market for our common stock may not develop or be sustained. As a result, it may be difficult to sell shares of our common stock.

We currently expect our common stock to be listed and traded on Nasdaq. Prior to listing on Nasdaq there has been no public trading market for our common stock. If an active, liquid, and orderly trading market for our common stock does not develop or is not sustained after this offering, it may be difficult to sell shares of our common stock at an attractive price, if at all. We cannot predict the prices at which our common stock will trade. It is possible that in one or more future periods our results of operations, regulatory approval process, and/or development of our platform and solutions may not meet the expectations of securities research analysts and investors. These and other factors could also significantly depress the market price of our common stock.

The market price of our common stock may be volatile, which could result in substantial losses for investors purchasing shares in this offering.

The initial public offering price for our common stock will be determined by agreement among us and the representatives of the underwriters. This initial public offering price may differ from the market price of our common stock after this offering. As a result, if you purchase shares of our common stock in this offering, it may not be possible for you to sell those shares at or above the initial public offering price. Securities markets worldwide experience significant price and volume fluctuations. This market volatility, as well as general economic, market, or political conditions, could reduce the market price of our common stock regardless of our operating performance. Some of the factors that may cause the market price of our common stock to fluctuate include:

- the timing or success of launch of our solutions, such as Caris Assure for early detection, MRD tracking, and treatment monitoring, as well as MI Cancer Seek or other solutions;
- the degree to which the launch and commercialization of our solutions meet the expectations of securities analysts and investors;
- changes in the structure of healthcare payment systems, including changes that would affect coverage and reimbursement by third-party or government payers;
- the success of, or perception of success of, our research and development efforts and our ability to develop new solutions and enhance our existing solutions, as well as our solutions' effectiveness or perceived effectiveness compared to those of our competitors;
- the timing and results of validation studies and clinical trials for our solutions and solutions from our competitors;
- commencement or termination of collaborations for our solution development and research programs;
- failure or discontinuation of any of our solution development and research programs;
- the success of existing or new competitive tests, services, or technologies;
- results of validation studies, clinical trials, or regulatory approvals of diagnostic or other cancer-related screening tests of our competitors, or announcements about new research programs or diagnostic or other cancer-related tests of our competitors;
- regulatory or legal developments in the United States and other countries affecting our solutions or competing products;
- developments or disputes concerning patent applications, issued patents, or other proprietary rights;

- the impact of public health crises on our business and on global economic conditions;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our research programs, clinical development programs or commercialization activities;
- actual or anticipated changes in our estimates as to our financial results or development timelines;
- whether our quarterly and annual financial results, forecasts, and development timelines meet the expectations of securities analysts or investors;
- announcement or expectation of additional financing efforts;
- sales of our common stock by us, our insiders, or other shareholders;
- expiration of lock-up agreements and market stand-off provisions;
- variations in our quarterly and annual financial results or those of companies that are perceived to be similar to us;
- changes in estimates or recommendations by securities analysts, if any, that cover our stock;
- changes in accounting standards, policies, guidelines, interpretations, or principles;
- market conditions in the healthcare sector;
- general economic, industry, and market conditions; and
- the other factors described in this “Risk Factors” section.

Stock markets in general, and the market for healthcare companies in particular (including companies in the precision oncology industry and broader precision medicine industry), experience significant price and volume fluctuations that are often unrelated or disproportionate to changes in the operating performance of the companies whose stock is experiencing those price and volume fluctuations. Broad market and industry factors may significantly affect the market price of our common stock, regardless of our actual operating performance. Following periods of such volatility in the market price of a company’s securities, securities class action litigation has often been brought against that company. Because of the potential volatility of our stock price, we may become the target of securities litigation in the future. Securities litigation could result in substantial costs and divert management’s attention and resources from our business.

If securities analysts do not publish research or reports about our business or if they publish negative evaluations of our stock, the price of our stock could decline.

The trading market for our common stock will rely in part on the research and reports that industry or securities analysts publish about us or our business. We do not currently have, and may never obtain, research coverage by industry or securities analysts. If no or few analysts commence coverage of us, the trading price of our common stock could decrease. Even if we do obtain analyst coverage, if one or more of the analysts covering our business downgrade their evaluations of our stock, the price of our common stock could decline. If one or more of these analysts cease to cover our stock, we could lose visibility in the market for our common stock, which in turn could cause the price of our common stock to decline.

Sales of a substantial number of shares of our common stock following the completion of this offering could cause the price of our common stock to decline.

Sales of a substantial number of shares of our common stock in the public market following the completion of this offering, or the perception that these sales might occur, could depress the market price of our common stock, and could impair our ability to raise capital through the sale of additional equity securities. Many of our existing equity holders have substantial unrecognized gains on the value of the equity they hold based upon the price of this offering, and therefore, may take steps to sell their shares or otherwise secure the unrecognized gains on those shares. We are unable to predict the timing of or the effect that such sales may have on the prevailing market price of our common stock.

In connection with this offering, we, our directors and executive officers, and holders of substantially all of our common stock and securities exercisable for or convertible into our common stock, have entered or will enter into lock-up agreements with the underwriters that restrict our and their ability to sell or transfer shares of our common stock, and securities convertible into or exercisable or exchangeable for shares of our common stock, for a period of 180 days from the date of this prospectus, subject to certain customary exceptions and a potential earlier termination. See the sections titled “Shares Eligible for Future Sale” and “Underwriting” for a discussion of such exceptions that may allow for sales during the lock-up period. In addition, upon providing prior written notice to BofA Securities, Inc., J.P. Morgan Securities LLC, and Goldman Sachs & Co. LLC, BofA Securities, Inc. and either J.P. Morgan Securities LLC or Goldman Sachs & Co. LLC may, in their sole discretion, release certain shareholders from the lock-up agreements prior to the end of the lock-up period. Additionally, at our request, the underwriters have reserved up to 5% of the shares of our common stock offered by this prospectus, excluding the additional shares that the underwriters have a 30-day option to purchase, for sale, at the initial public offering price, to certain individuals identified by management under the reserved share program, including certain of our directors, officers, employees, and certain other parties related to us. Except for any shares acquired by our directors and officers, shares purchased pursuant to the reserved share program will not be subject to lock-up restrictions with the underwriters. If not earlier released, all of our shares of common stock, other than those sold in this offering, which are freely tradable, will become eligible for sale upon expiration of the lock-up period, except for any shares held by our affiliates as defined in Rule 144 under the Securities Act of 1933, as amended (the “Securities Act”).

In addition, after this offering, up to 24,599,771 shares of our common stock may be issued upon exercise of outstanding stock options or vesting and settlement of outstanding RSUs, and up to 18,025,162 shares of our common stock will initially be available for future issuance under our 2025 Plan and our ESPP, and will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, exercise limitations, the lock-up agreements, and Rule 144 and Rule 701 under the Securities Act. We intend to register all of the shares of common stock issuable upon exercise of outstanding options or other equity incentive awards we may grant in the future for public resale under the Securities Act. If any of these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

Further, holders of approximately 251.5 million shares as of March 31, 2025, or approximately 88.7% of our capital stock after the completion of this offering, will have rights, subject to some conditions and the lock-up agreements described above, to require us to file registration statements covering the sale of their shares or to include their shares in registration statements that we may file for ourselves or other shareholders.

Investors in our common stock will incur immediate and substantial dilution as a result of this offering.

Our common stock will incur immediate and substantial dilution of \$18.36 per share, representing the difference between the assumed initial public offering price of \$19.50 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and our pro forma as adjusted net tangible book value per share after giving effect to this offering, the Warrant Net Exercises, the Series E and F Issuance, the Preferred Stock Conversion, the issuance of the 2025 Convertible Notes and the related Notes Conversion, the RSU Net Settlement, and the reduction of the compound derivative liability bifurcated from the 2023 Term Loan. As of March 31, 2025, there were 24,113,482 shares of common stock issuable upon exercise of outstanding stock options with a weighted-average exercise price of \$10.18 per share and 1,284,540 shares of common stock issuable upon the vesting and settlement of outstanding RSUs. To the extent that these outstanding options or RSUs, or any other rights, are exercised, or we issue additional equity or convertible securities in the future, or the underwriters exercise their option to purchase additional shares of common stock, investors will incur further dilution. See the section titled “Dilution” for a further description of the dilution that will occur immediately after this offering.

Raising additional capital may cause dilution to our existing shareholders, restrict our operations, or require us to relinquish rights to our technologies or our solutions.

We may need or determine to raise additional capital through a combination of public and private equity offerings, debt financings, strategic partnerships, and alliances and licensing arrangements. We, and

indirectly, our shareholders, will bear the cost of issuing and servicing securities issued in any such transactions. Because our decision to issue debt or equity securities in any future offering will depend on market conditions and other factors beyond our control, we cannot predict or estimate the amount, timing, or nature of any future offerings. If we incur debt, debt holders would have rights senior to holders of our common stock to make claims on our assets, and any debt financing we secure would result in increased fixed payment obligations and could involve restrictive and financial covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell, or license intellectual property rights, and other operating restrictions that could adversely impact our ability to conduct our business. If we issue additional equity securities, shareholders will experience dilution, and the new equity securities could have rights senior to those of our common stock. Additionally, any future collaborations we enter into with third parties may provide capital in the near term but limit our potential cash flow and revenue in the future. If we raise additional funds through strategic partnerships, alliances, or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or our solutions, or grant licenses on terms unfavorable to us.

After this offering, our executive officers, directors, and principal shareholders, including, in particular, David D. Halbert, our Founder, Chairman, and Chief Executive Officer, will continue to have the ability to control or significantly influence matters submitted to shareholders for approval, which could limit the ability of our other shareholders to affect the outcome of key corporate decisions and transactions, including a change of control.

Following the completion of this offering, David D. Halbert, our Founder, Chairman, and Chief Executive Officer, will beneficially own approximately 43.7% of our outstanding common stock, based on an assumed initial public offering price of \$19.50 per share, which is the midpoint of the price range set forth on this cover page, and assuming no exercise by the underwriters of their option to purchase additional shares of our common stock. As a result, Mr. Halbert will be able to significantly influence all matters submitted to our shareholders for approval, including the election of directors, amendments to our certificate of formation and bylaws, and the approval of significant corporate transactions, regardless of whether others believe that any such transaction is in our best interests.

Additionally, immediately following the completion of this offering, our executive officers (including Mr. Halbert), directors, holders of more than 5% of our outstanding capital stock, and their respective affiliates will collectively beneficially own shares representing approximately 65.4% of our outstanding common stock, based on an assumed initial public offering price of \$19.50 per share, which is the midpoint of the price range set forth on this cover page, and assuming no exercise by the underwriters of their option to purchase additional shares of our common stock. If these shareholders act together, they will be able to influence our management and affairs and control all matters requiring shareholder approval, including the election of directors and approval of significant corporate transactions. This concentration of ownership may have the effect of delaying, deferring, or preventing a change in control, impeding a merger, consolidation, takeover, or other business combination involving us, or discouraging a potential acquiror from making a tender offer or otherwise attempting to obtain control of our business, even if such a transaction would benefit other shareholders. Moreover, it could deprive shareholders of an opportunity to receive a premium for their common stock as part of a sale of our company and may adversely affect the trading price for our common stock because some investors perceive disadvantages in owning shares in companies with concentrated equity ownership.

We have identified a material weakness in our internal control over financial reporting. If our remediation of such material weakness is not effective, or if we experience additional material weaknesses in the future or otherwise fail to develop and maintain effective internal control over financial reporting, our ability to produce timely and accurate financial statements or comply with applicable laws and regulations could be impaired, investors may lose confidence in our financial reporting, and the trading price of our common stock may decline.

In connection with the audit of our consolidated financial statements for the year ended December 31, 2024, we identified a material weakness in our internal control over financial reporting. A material weakness, as defined by Rule 12b-2 under the Exchange Act, is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis.

The material weakness identified pertained to a lack of sufficient qualified accounting resources, including those with technical expertise necessary to account for and disclose accounting transactions which require complex calculations or thorough evaluation of the accounting literature.

We have taken and will continue to take action to remediate the material weakness, including:

- implementation of controls to enhance our review of significant accounting transactions and other new technical accounting and financial reporting issues and the preparation and review of accounting memoranda addressing these issues;
- implementation of controls to enable an effective and timely review of account analyses and account reconciliations; and
- continued hiring of additional accounting and finance resources with public company experience and expanding the capabilities of the existing accounting and financial personnel through continuous training and education in the accounting and reporting requirements under GAAP and SEC rules and regulations.

Pursuant to SOX Section 404, our management will be required to report upon the effectiveness of our internal control over financial reporting beginning with the second annual report following the completion of this offering. When we lose our status as an “emerging growth company” and do not otherwise qualify as a “smaller reporting company” with less than \$100.0 million in annual revenue, our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting. The rules governing the standards that must be met for our management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation. To comply with the requirements of being a reporting company under the Exchange Act, we may need to upgrade our information technology systems; implement additional financial and management controls, reporting systems and procedures; and hire additional accounting and finance staff. If we or, if required, our auditors are unable to conclude that our internal control over financial reporting is effective, investors may lose confidence in our financial reporting and the trading price of our common stock may decline.

We will not be able to fully remediate the material weakness until the steps detailed above have been completed and such controls have been operating effectively for a sufficient period of time. Additionally, as stated above, we have not performed an evaluation of our internal control over financial reporting as permitted under the JOBS Act; accordingly, we cannot assure you that we have identified all, or that we will not in the future have additional, material weaknesses. Material weaknesses may still exist when we report on the effectiveness of our internal control over financial reporting as required under SOX Section 404, beginning with our second annual report after the completion of this offering.

We cannot assure you that additional material weaknesses in our internal control over financial reporting will not arise in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by Nasdaq, the SEC, or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

We are an emerging growth company and the reduced disclosure requirements applicable to emerging growth companies may make our common stock less attractive to investors.

We are an emerging growth company and, for so long as we remain an emerging growth company, we are permitted by SEC rules and plan to rely on exemptions from certain disclosure requirements that are applicable to other SEC-registered public companies that are not emerging growth companies. Under these exemptions, we are not required to comply with the auditor attestation requirements of SOX Section 404 or the auditor requirements to communicate critical audit matters in the auditor’s report on the financial statements, have reduced disclosure obligations regarding executive compensation, and have

exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. As a result, the information we provide shareholders will be different than the information that is available with respect to other public companies. We have taken advantage of reduced reporting burdens in this prospectus. In particular, in this prospectus, we have provided only two years of audited financial statements and we have not included all of the executive compensation related information that would be required if we were not an emerging growth company.

We could be an emerging growth company for up to five years following the completion of this offering. We will cease to be an emerging growth company upon the earliest of: (i) the end of the fiscal year following the fifth anniversary of this offering, (ii) the first fiscal year after our annual gross revenues are \$1.235 billion or more, (iii) the date on which we have, during the previous three-year period, issued more than \$1.0 billion in nonconvertible debt securities or (iv) the end of any fiscal year in which the market value of our common stock held by non-affiliates exceeded \$700 million as of the end of the second quarter of that fiscal year. We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock, and our stock price may be more volatile.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards, and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies, which may make comparison of our financials to those of other public companies more difficult.

We will incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives and corporate governance practices.

As a public company, and particularly after we are no longer an emerging growth company, we will incur significant legal, accounting, and other expenses that we did not incur as a private company. SOX Section 404, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of Nasdaq, and other applicable U.S. rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. We expect that we will need to hire additional accounting, finance, and other personnel in connection with our becoming, and our efforts to comply with the requirements of being, a public company, and our management and other personnel will need to devote a substantial amount of time towards maintaining compliance with these requirements. These requirements will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect that the rules and regulations applicable to us as a public company may make it more difficult and more expensive for us to obtain director and officer liability insurance, which could make it more difficult for us to attract and retain qualified members of our board of directors. We cannot predict or estimate the amount of additional costs we may incur or the timing of such costs. These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

Upon the completion of this offering, we will become subject to the periodic reporting requirements of the Exchange Act. We designed our disclosure controls and procedures to provide reasonable assurance that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the SEC. Even if we are successful in remediating our material weaknesses, we believe that any disclosure controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

If our estimates or judgments relating to our critical accounting policies are based on assumptions that change or prove to be incorrect, our results of operations could fall below our publicly announced guidance or the expectations of securities analysts and investors, resulting in a decline in the market price of our common stock.

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in our financial statements and accompanying notes. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets, liabilities, equity, revenue, and expenses that are not readily apparent from other sources. For example, as we adopted and implemented the new revenue accounting standard, management made judgments and assumptions based on our interpretation of the new standard. The new revenue standard is principle-based and interpretation of those principles may vary from company to company based on their unique circumstances. It is possible that interpretation, industry practice and guidance may evolve as we continue to use these new accounting standards. If our assumptions change or if actual circumstances differ from our assumptions, our results of operations may be adversely affected and could fall below our publicly announced guidance or the expectations of analysts and investors, resulting in a decline in the market price of our common stock.

We have broad discretion in the use of the net proceeds from this offering and may not use them effectively.

Our management will have broad discretion in the application of the net proceeds, including for any of the purposes described in the section titled “Use of Proceeds” in this prospectus. Our management may spend a portion or all of the net proceeds from this offering in ways that our shareholders may not desire or that may not yield a favorable return. The failure by our management to apply these funds effectively could harm our business, financial condition, and results of operations. Pending their use, we may invest the net proceeds from this offering in a manner that does not produce income or that loses value.

We do not intend to pay dividends for the foreseeable future. Investors in this offering may never obtain a return on their investment.

We have never declared or paid any cash dividends on our capital stock, and we do not intend to pay any cash dividends in the foreseeable future. We expect to retain all available funds and future earnings, if any, to support our operations and to finance the growth and development of our business. Any future determination to pay dividends on our capital stock will be at the discretion of our board of directors subject to applicable laws and dependent on factors our board of directors deems relevant. In addition, our ability to pay dividends on our capital stock is limited by the terms of the 2023 Term Loan Agreement and may be further restricted under the terms of any future debt or preferred securities or future credit facility. Accordingly, you must rely on the sale of your common stock after price appreciation, which may never occur, as the only way to realize any future gain on your investment.

Texas law and provisions in our amended and restated certificate of formation and bylaws that will be in effect prior to the completion of this offering might discourage, delay, or prevent a change in control of our company or changes in our management and, therefore, depress the trading price of our common stock.

Provisions in our amended and restated certificate of formation and bylaws that will be in effect prior to the completion of this offering may discourage, delay, or prevent a merger, acquisition, or other change in control that shareholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares of our common stock. These provisions may also prevent or frustrate attempts by our shareholders to replace or remove our management. Therefore, these provisions could adversely affect the price of our common stock. Among other things, our organizational documents will:

- authorize our board of directors to issue shares of preferred stock and determine the price and other terms of those shares, including preferences and voting rights, without shareholder approval;
- provide that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum, or by a sole remaining director, or by the affirmative vote of a majority of the voting power of our then-outstanding capital stock entitled to vote generally in the election of directors;
- provide that any action required or permitted to be taken at an annual or special meeting of shareholders may be taken by written consent in lieu of a meeting of shareholders only with the unanimous written consent of our shareholders entitled to vote on such action;
- provide that the written request of the holders of at least 50% of the voting power of our outstanding capital stock entitled to be voted at a special meeting is required for our shareholders to call a special meeting of shareholders; and
- require that shareholders give advance notice to nominate directors or submit proposals for consideration at shareholder meetings.

Further, as a Texas corporation, we are also subject to provisions of Texas law that may impair a takeover attempt that our shareholders may find beneficial. For additional information, see “Description of Capital Stock—Anti-Takeover Effects of Certain Provisions of Our Amended and Restated Certificate of Formation.” Any provision of our amended and restated certificate of formation, bylaws, or Texas law that has the effect of delaying or preventing a change in control could limit the opportunity for our shareholders to receive a premium for their shares of our capital stock and could also affect the price that some investors are willing to pay for our common stock.

Our amended and restated certificate of formation will provide that the Business Court in the First Business Court Division of the State of Texas will be the exclusive forum for substantially all disputes between us and our shareholders (excluding claims under the federal securities laws), which could limit our shareholders’ ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees.

Our amended and restated certificate of formation will provide that, unless we consent in writing to the selection of an alternative forum, the Business Court in the First Business Court Division of the State of Texas will be the exclusive forum for the following types of actions or proceedings under Texas statutory or common law:

- any derivative action or proceeding brought on our behalf;
- any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees, or shareholders to us or our shareholders;
- any action asserting a claim arising pursuant to any provision of the Texas Business Organizations Code (“TBOC”) or our amended and restated certificate of formation and bylaws; and
- any action asserting a claim governed by the internal affairs doctrine.

However, this provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. Furthermore, our amended and restated certificate of formation will also provide that unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. Any person purchasing or otherwise acquiring or holding any interest in shares of our capital stock is deemed to have received notice of and consented to the foregoing provisions. This choice of forum provision may limit a shareholder’s ability to bring a claim in a judicial forum that it finds more favorable for disputes with us or with our directors, officers, other employees or agents, or our other shareholders, may discourage such lawsuits against us and such other persons, and may result in increased costs for a shareholder to bring a claim. Alternatively, if a court were to find this choice of forum provision inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs

associated with resolving such matters in other jurisdictions, which could adversely affect our business, financial condition, and results of operations.

General Risk Factors

The sizes of the markets for our current and future solutions have not been established with precision, and may be smaller than we estimate.

Our estimates of the total addressable markets for our current or future solutions are based on a number of internal and third-party estimates, including, without limitation, the number of new cancer cases, the market size of oncology testing, and the number of patients with advanced stage cancer. While we believe the assumptions and the data underlying these estimates are reasonable, these assumptions and estimates may not be correct and the conditions supporting these assumptions or estimates may change at any time, thereby reducing the predictive accuracy of these underlying factors. As a result, these estimates of the total addressable market for our current or future solutions may prove to be incorrect. If the actual number of patients who would benefit from our solutions, the price at which we can sell our solutions, or the annual total addressable market for our solutions is smaller than estimated, it may impair our sales growth and have an adverse impact on our business, financial condition, and results of operations.

Adverse economic or market conditions may harm our business.

Worsening economic conditions, including heightened inflation, increasing interest rates, decreasing economic activity, volatility in equity and credit markets, or other changes in the economic environment, may adversely affect our business, financial condition, and results of operations. For example, we depend on third-party manufacturers and suppliers for some of our solutions, or components and materials used in our solutions, and the suppliers of these inputs may seek to raise prices in the current inflationary economic environment. If our costs increase and we are unable to successfully pass along those increased costs to our partners and patients, our revenue and or operating profitability may be adversely affected. In addition, we may in the future raise additional debt or refinance existing debt. Our cost of borrowing in the future may be higher than it has been to date because interest rates have risen and may continue to increase. An increased cost of borrowing may adversely affect our financial condition and results of operations.

Our business is subject to economic, political, regulatory, and other risks associated with international operations.

Some of our ordering physicians and biopharma partners are located outside of the United States. While we currently have limited international operations, international expansion could also become a key component of our future business strategy. Accordingly, our future results could be harmed by a variety of factors, including:

- challenges enforcing our contractual and intellectual property rights, especially in those foreign jurisdictions that do not respect and protect intellectual property rights to the same extent as the United States;
- trade protection measures, import or export controls and licensing requirements (including possible restrictions on licensing intellectual property to certain non-U.S. persons) or other restrictive actions by U.S. or non-U.S. governments;
- changes in non-U.S. laws, regulations and customs, tariffs, and trade barriers;
- exchange rate risk we may face from denominating a portion of our transactions in currencies other than the U.S. dollar;
- changes in a specific country's or region's political or economic environment, including inflation, including the United States;
- logistics and regulations associated with shipping samples, including infrastructure conditions and transportation delays;
- negative consequences from changes in tax laws;

- negative consequences from changes in U.S. national security laws, including those governing non-U.S. investors' ownership of U.S. biotech and other technology companies and U.S. companies' ability to enter into joint ventures with non-U.S. entities;
- compliance with tax, employment, immigration, and labor laws for employees living or traveling abroad;
- compliance challenges relating to the complexity of multiple, conflicting, and changing data protection laws and international data sharing and transfer restrictions globally. For additional information, see “—Risks Related to Regulation and Legal Compliance—We are subject to stringent and evolving U.S. and foreign privacy and data security laws, regulations, and rules, contractual obligations, industry standards, policies and other obligations related to privacy and data security. Our actual or perceived failure to comply with privacy and data security obligations could result in significant liability, administrative or governmental penalties, reputational harm and/or, other adverse business consequences”;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- adoption of new regulations, modification to existing regulations, or expiration of prior regulations that apply to the products we offer;
- difficulties associated with staffing and managing international operations, including differing labor relations;
- regulator and compliance risks that relate to maintaining and control over sales and distribution activities that may fall within the purview of the FCPA or comparable foreign laws;
- difficulties associated with the interpretation of laws and regulations in non-English speaking jurisdictions; and
- business interruptions resulting from geo-political actions, including war and terrorism, pandemics, or natural disasters, including earthquakes, typhoons, floods, and fires.

These and other risks associated with current and future international operations may adversely affect our business and prospects.

Our business is subject to risks arising from public health crises.

Widespread public health crises may pose the risk that our company, our personnel, courier delivery services, and other partners may be prevented from conducting business activities for an indefinite period of time, including due to spread of the disease within these groups or due to shutdowns that may be requested or mandated by governmental authorities. For example, the COVID-19 pandemic and mitigation measures have had an adverse impact on global economic conditions. Comparable future public health crises could have similar adverse effects on our business, financial condition, and results of operations, including impairing the ability to raise capital when needed.

Government-imposed quarantines and restrictions as a result of future public health crises may also require us to temporarily terminate our clinical sites. Furthermore, if we determine that our trial participants may suffer from exposure to such diseases as a result of their participation in our clinical trials, we may voluntarily terminate certain clinical sites as a safety measure until we reasonably believe that the likelihood of exposure has subsided. As a result, our expected regulatory submissions and development timelines for our solutions may be negatively impacted. Future public health crises may materially disrupt or delay our business operations, further divert the attention and efforts of the medical community to coping with such epidemics, reduce the number of patients getting physicals and physicians potentially ordering our solutions, disrupt the clinical sites on which we depend, and/or adversely affect our operations.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

Our ability to utilize our net operating loss (“NOL”) and R&D credit carryforwards is subject to certain conditions. For instance, we have experienced a history of losses and a lack of future taxable income

would adversely affect our ability to utilize our NOL and R&D credit carryforwards. As of March 31, 2025, we had NOL carryforwards of \$1,150.7 million for federal income tax purposes and \$985.8 million for state income tax purposes. In addition, our federal NOL carryforwards generated in taxable years beginning before January 1, 2018, are permitted to be carried forward for only 20 years. Although our federal NOL carryforwards generated in taxable years beginning after December 31, 2017, may be carried forward indefinitely, they are permitted to be used in any taxable year to offset only up to 80% of taxable income, if any, in such year. For state income tax purposes, there may be periods during which the use of NOL carryforwards is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. We also had R&D credit carryforwards of \$2.8 million that will begin to expire in 2031. Our ability to use our NOL and R&D credit carryforwards also may be subject to certain limitations due to prior or future ownership changes, if any, as defined in Section 382 of the U.S. Internal Revenue Code of 1986, as amended (the “Code”) (generally a greater than 50% change, by value, in a corporation’s equity ownership over a three-year period). Under Sections 382 and 383 of the Code, and corresponding provisions of state law, if a corporation undergoes an ownership change, the corporation’s ability to use its pre-change NOL and R&D credit carryforwards to offset the corporation’s post-change income or taxes may be limited. Although we have not experienced ownership changes in the past, we may experience ownership changes as a result of this offering or subsequent shifts in our stock ownership, some of which may be outside our control. As such, there can be no assurance that we will be able to utilize our NOL and R&D credit carryforwards, and we have established valuation allowances against our NOL and R&D credit carryforwards due to the uncertainty surrounding the realization of such assets.

Changes in tax laws or regulations may have an adverse effect on our business, financial condition, and results of operations.

New tax laws, statutes, rules, regulations, or ordinances could be enacted at any time. For example, the Tax Cuts and Jobs Act, the Coronavirus Aid, Relief, and Economic Security Act, and the Inflation Reduction Act made significant changes to U.S. tax laws. Further, existing tax laws, statutes, rules, regulations, or ordinances could be interpreted differently, changed, repealed, or modified at any time. Any such enactment, interpretation, change, repeal, or modification could adversely affect us, possibly with retroactive effect.

We may seek acquisitions or other strategic transactions from time to time that could increase our capital requirements, dilute our shareholders, cause us to incur debt or assume contingent liabilities, and subject us to other risks.

We may engage in various acquisitions and strategic partnerships in the future, including licensing or acquiring complementary intellectual property rights, technologies, or businesses. Any acquisition or strategic partnership may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of indebtedness or contingent liabilities;
- the issuance of our equity securities that would result in dilution to our shareholders;
- assimilation of operations, personnel, intellectual property, and products of an acquired company;
- failure to achieve any expected synergies;
- retention of key employees, the loss of key personnel, and uncertainties in our ability to maintain key business relationships; and
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or candidates and regulatory approvals, and the validity and enforceability of their intellectual property.

In addition, as our strategy evolves, we may opt to discontinue, deprioritize, or dispose of assets, technologies, or acquired businesses.

The increasing focus on environmental, social, and governance (“ESG”) initiatives could increase our costs, harm our reputation, and adversely impact our financial results.

There has been increasing public focus by investors, patients, environmental activists, the media, and governmental and nongovernmental organizations on a variety of environmental, social, and other sustainability matters. We may experience pressure to make commitments relating to sustainability matters, including the design and implementation of specific risk mitigation strategic initiatives relating to sustainability. While we may in the future engage in various initiatives (including but not limited to voluntary disclosures, policies, or goals) to improve our ESG profile or respond to stakeholder expectations, we cannot guarantee that these initiatives will have the desired effect. If we are not effective in addressing environmental, social, and other sustainability matters affecting our business, or setting and meeting relevant sustainability goals, our reputation and financial results may suffer. In addition, even if we are effective at addressing such concerns, we may experience increased costs as a result of executing upon our sustainability goals that may not be offset by any benefit to our reputation, which could have an adverse impact on our business and financial condition.

In addition, this emphasis on ESG matters has resulted and may result in the adoption of new laws and regulations, including new reporting requirements, including with respect to climate change. ESG and sustainability-related regulation and legislation, to the extent implemented, will require us to incur significant additional costs to comply, including the implementation of significant additional internal controls, processes and procedures regarding matters that have not been subject to such controls in the past, and impose increased oversight obligations on our management and board of directors as well as impose additional disclosure obligations on us. Additionally, our suppliers, customers or other business partners may require us to provide additional climate-related information if they are also subject to additional climate-related disclosure laws or regulations in other jurisdictions. If we fail to comply with new laws, regulations or reporting requirements, or we fail to provide complete and accurate information to our suppliers, customers or other business partners, our reputation and business could be adversely impacted.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements. All statements other than statements of historical facts contained in this prospectus, including statements regarding our future results of operations and financial condition, business strategy, information solutions, technology, R&D costs, regulatory approvals, potential market opportunity, anticipated trends in our business, timing and likelihood of success, as well as plans and objectives of management for future operations, are forward-looking statements. These statements involve known and unknown risks, uncertainties, and other important factors that are in some cases beyond our control and may cause our actual results, performance, or achievements to be materially different from any future results, performance, or achievements expressed or implied by the forward-looking statements.

The words “anticipate,” “believe,” “contemplate,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “target,” “will,” or “would,” or the negative of these terms or other similar expressions, are intended to identify forward looking statements. Forward-looking statements contained in this prospectus include, but are not limited to, statements about:

- developments in the precision oncology industry, including our biopharma partners’ use of molecular information and the market size for molecular information services;
- our expectations as to our addressable U.S. market in oncology, future financial performance, results of operations, or other operational results or metrics;
- the ability of the Caris platform to help our biopharma partners and physicians improve the efficiency and success of their therapeutic development, and clinical programs;
- our ability to scale the Caris platform and develop new solutions or enhancements to existing solutions;
- our ability to capture, aggregate, analyze, or otherwise utilize molecular information in novel ways;
- our ability to compete with companies that are currently in, or may in the future enter, the industry in which we operate;
- third-party payer reimbursement and coverage decisions;
- our ability to establish, maintain, protect, and enforce our intellectual property rights of our solutions;
- federal, state, and foreign regulatory requirements, including FDA regulation of our solutions;
- the timing, likelihood, or conditions of regulatory filings and approvals;
- our ability to hire and retain key personnel;
- our anticipated cash needs and our estimates regarding our capital requirements and our needs for additional financing;
- our estimates regarding our expenses, future revenue, and capital requirements;
- our expectations related to the use of proceeds from this offering;
- remediating the material weakness in our internal control over financial reporting; and
- the volatility of the trading price of our common stock.

These forward-looking statements are subject to a number of risks, uncertainties, and assumptions, including those described in the section titled “Risk Factors” and elsewhere in this prospectus. Moreover, we operate in a competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties, and assumptions, the forward-looking events and circumstances discussed in this prospectus may not occur, and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, advancements, discoveries, levels of activity, performance, or events and circumstances reflected in the forward-looking statements will be achieved or occur. In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this prospectus, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain, and you are cautioned not to unduly rely upon these statements. We undertake no obligation to update publicly any forward-looking statements for any reason after the date of this prospectus to conform these statements to actual results or to changes in our expectations.

You should read this prospectus and the documents that we reference in this prospectus and have filed as exhibits to the registration statement of which this prospectus is a part with the understanding that our actual future results, levels of activity, performance, and events and circumstances may be materially different from what we expect. We qualify all of the forward-looking statements in this prospectus by these cautionary statements.

MARKET AND INDUSTRY DATA

This prospectus contains estimates, projections, and other information concerning our industry, our business, and the markets for our precision medicine information solutions, including data regarding the estimated size of such markets. We obtained the industry, market, and similar data set forth in this prospectus from our internal estimates and research, including surveys and studies we have sponsored and/or conducted, and from academic and industry research, publications, surveys, and studies conducted by third parties, including governmental agencies. Information based on estimates, forecasts, projections, market research, or similar methodologies is inherently subject to uncertainties, and actual events or circumstances may differ materially from events and circumstances that are assumed in this information. Forecasts and other forward-looking information with respect to industry, business, market, and other data are subject to the same qualifications and additional uncertainties regarding the other forward-looking statements in this prospectus. See the section titled “Special Note Regarding Forward-Looking Statements.”

The sources of certain industry, business, market, and other data contained in this prospectus include:

- Nephron Research LLC, Oncology Testing TAM Analysis, March 2024, which we commissioned;
- Evaluate Pharma, World Preview 2023, Outlook to 2028, August 2023;
- The Centers for Disease Control and Prevention;
- The American Cancer Society;
- The American Lung Association;
- The International Agency for Research on Cancer;
- National Center for Biotechnology Information; and
- The American Society of Clinical Oncology.

USE OF PROCEEDS

We estimate that the net proceeds from this offering will be approximately \$419.3 million (or \$483.3 million if the underwriters exercise their option to purchase additional shares of common stock in full), based on an assumed initial public offering price of \$19.50 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

Each \$1.00 increase (decrease) in the assumed initial public offering price of \$19.50 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the net proceeds to us from this offering by approximately \$21.9 million, assuming the number of shares of common stock offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. An increase (decrease) of 1,000,000 shares in the number of shares of common stock offered by us, as set forth on the cover page of this prospectus, would increase (decrease) our net proceeds from this offering by approximately \$18.1 million, assuming no change in the assumed initial public offering price per share and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The principal purposes of this offering are to increase our capitalization and financial flexibility, create a public market for our common stock, and enable access to the public equity markets for us and our shareholders. As of the date of this prospectus, we have no specific plan for any significant portion of the net proceeds from this offering. However, we intend to use the net proceeds from this offering for general corporate purposes, including working capital, operating expenses, and capital expenditures. We also intend to use approximately \$5.8 million of the net proceeds to satisfy our anticipated tax withholding and remittance obligations related to the RSU Net Settlement, based on an assumed initial public offering price of \$19.50 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and an assumed tax withholding rate of 28.3%. We may also use a portion of our net proceeds to co-develop, acquire, or invest in products, technologies, or businesses that are complementary to our business, although we do not have agreements or commitments for any material acquisitions or investments at this time.

We will have broad discretion over the uses of the net proceeds from this offering. The expected use of net proceeds from this offering represents our intentions based upon our present plans and business conditions. We cannot predict with certainty all of the particular uses for the proceeds of this offering or the amounts that we will actually spend on the uses set forth above. The timing and amount of our actual expenditures will be based on many factors, including cash flows from operations and the anticipated growth of our business. Pending the uses described above, we plan to invest the net proceeds in a variety of capital preservation investments, including short-term interest-bearing investment-grade securities, certificates of deposit, or government securities. Investors will be relying on the judgment of our management regarding the application of the net proceeds from this offering.

DIVIDEND POLICY

We have never declared or paid any cash dividends on our capital stock, and we do not currently intend to pay any cash dividends on our capital stock for the foreseeable future. We currently intend to retain all available funds and any future earnings to support operations and to finance the growth and development of our business. Any future determination to pay dividends will be made at the discretion of our board of directors subject to applicable laws and will depend upon, among other factors, our results of operations, financial condition, contractual, legal, tax, and regulatory restrictions, capital requirements, and such other factors as our board of directors may deem relevant. In addition, our ability to pay cash dividends is currently restricted by the terms of the 2023 Term Loan Agreement. Our future ability to pay cash dividends on our capital stock may also be limited by the terms of any future debt or preferred securities or future credit facility.

CAPITALIZATION

The following table sets forth our cash, cash equivalents, and restricted cash and capitalization as of March 31, 2025, as follows:

- on an actual basis;
- on a pro forma basis to give effect to (i) the Warrant Net Exercises, (ii) the Series E and F Issuance, (iii) the Preferred Stock Conversion, (iv) the issuance of the 2025 Convertible Notes and the related Notes Conversion, (v) the RSU Net Settlement, and (vi) the reduction of the compound derivative liability bifurcated from the 2023 Term Loan; and
- on a pro forma as adjusted basis to give further effect to (i) our issuance and sale of 23,529,412 shares of common stock in this offering at an assumed initial public offering price of \$19.50 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, net of \$1.4 million of offering expenses paid as of March 31, 2025 and (ii) the use of approximately \$5.8 million of the net proceeds from this offering to satisfy our anticipated tax withholding and remittance obligations related to the RSU Net Settlement.

The pro forma and pro forma as adjusted information below is illustrative only. Our capitalization following the completion of this offering will be adjusted based on the actual initial public offering price and other terms of this offering determined at pricing. You should read this table in conjunction with the information contained in “Use of Proceeds” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” as well as the consolidated financial statements and the notes thereto included elsewhere in this prospectus.

	As of March 31, 2025		
	Actual	Pro Forma	Pro Forma As Adjusted ⁽¹⁾
	(in thousands, except share and per share data)		
Cash, cash equivalents, and restricted cash	\$ 32,704	\$ 185,531	\$ 600,227
Debt (including current portion of long-term debt) ⁽²⁾	\$ 414,183	\$ 412,841	\$ 408,421
Redeemable convertible preferred stock, par value \$0.001 per share; 787,439,505 shares authorized, 734,142,041 shares issued and outstanding, actual; and no shares authorized, issued, or outstanding, pro forma and pro forma as adjusted	2,246,113	—	—
Warrants to purchase capital stock	128,691	—	—
Shareholders’ (deficit) equity:			
Preferred stock, par value \$0.001 per share; no shares authorized, issued and outstanding, actual; 100,000,000 shares authorized, no shares issued and outstanding, pro forma and pro forma as adjusted	—	—	—
Common stock, par value \$0.001 per share; 1,173,000,000 shares authorized, 35,237,531 shares issued and outstanding, actual; 2,800,000,000 shares authorized, 260,025,773 shares issued and outstanding, pro forma; and 2,800,000,000 shares authorized, 283,555,185 shares issued and outstanding, pro forma as adjusted	38	262	286
Treasury stock—1,620,638 shares of common stock, par value \$0.001 per share	(16,917)	(16,917)	(16,917)
Additional paid-in capital	—	2,543,659	2,962,940
Accumulated deficit	(2,583,231)	(2,602,901)	(2,602,901)
Accumulated other comprehensive income	245	245	245
Total shareholders’ (deficit) equity	(2,599,865)	(75,653)	343,653
Total capitalization	\$ 189,122	\$ 337,188	\$ 752,074

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- (1) Each \$1.00 increase (decrease) in the assumed initial public offering price of \$19.50 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash, cash equivalents, and restricted cash, additional paid-in capital, total shareholders' (deficit) equity, and total capitalization by approximately \$21.9 million, assuming that the number of shares of common stock offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase (decrease) of 1,000,000 shares in the number of shares of common stock offered by us at the assumed initial public offering price of \$19.50 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash, cash equivalents, and restricted cash, additional paid-in capital, total shareholders' (deficit) equity, and total capitalization by approximately \$18.1 million, assuming the shares of our common stock offered by this prospectus are sold at the assumed initial public offering price of \$19.50 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. The pro forma as adjusted cash, cash equivalents, and restricted cash amount includes the employer portion of the withholding tax obligation of approximately \$0.2 million related to the RSU Net Settlement at the assumed initial public offering price of \$19.50 per share, which is the midpoint of the price range set forth on the cover page of this prospectus.
- (2) Represents long-term indebtedness, net of debt discounts. Total debt as of March 31, 2025 consisted of approximately \$400.0 million of borrowings outstanding under the 2023 Term Loan Agreement. In April 2025, we also issued 2025 Convertible Notes to certain investors in aggregate principal amount of \$30.0 million. The 2025 Convertible Notes mature on January 1, 2026, accrue interest at a rate of 8% per annum (payable quarterly in cash), and will, immediately prior to and in connection with the completion of this offering, convert at a conversion price equal to 70% of the initial public offering price per share, or into 2,236,331 shares of our common stock, based on an assumed initial public offering price of \$19.50 per share, which is the midpoint of the price range set forth on the cover page of this prospectus. The pro forma as adjusted debt amount reflects payment of accrued offering costs of approximately \$4.4 million. For a discussion of our long-term debt, see the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources." Also, see our consolidated financial statements and related notes thereto included elsewhere in this prospectus, which include all recorded liabilities.

The number of shares of common stock in the table above excludes:

- 24,113,482 shares of our common stock issuable upon the exercise of options outstanding under our 2020 Plan as of March 31, 2025, at a weighted-average exercise price of \$10.18 per share;
- 249,999 shares of our common stock issuable upon the exercise of options granted under our 2020 Plan subsequent to March 31, 2025, at an exercise price per share equal to the initial public offering price;
- 236,290 shares of our common stock issuable upon the vesting and settlement of RSUs outstanding under our 2020 Plan as of March 31, 2025 that are subject to vesting conditions that are not satisfied in connection with this offering;
- 15,406,122 shares of our common stock reserved for future issuance under our 2025 Plan, based on an assumed initial public offering price of \$19.50 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, which 2025 Plan will become effective in connection with this offering, as well as shares of our common stock that may be issued pursuant to provisions of our 2025 Plan that automatically increase the share reserve under our 2025 Plan; and
- 2,619,040 shares of our common stock reserved for future issuance under our ESPP, based on an assumed initial public offering price of \$19.50 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, which ESPP will become effective in connection with this offering, as well as shares of our common stock that may be issued pursuant to provisions in our ESPP that automatically increase the share reserve under the ESPP.

DILUTION

If you invest in our common stock in this offering, your ownership interest will be immediately diluted to the extent of the difference between the initial public offering price per share and the pro forma as adjusted net tangible book value per share of our common stock immediately after this offering.

Historical net tangible book value (deficit) per share represents our total tangible assets less our liabilities and preferred stock that is not included in equity divided by the total number of shares of common stock outstanding. As of March 31, 2025, our historical net tangible book value (deficit) was approximately \$(2,625.03) million, or \$(74.50) per share. Our pro forma net tangible book value (deficit) as of March 31, 2025, was approximately \$(100.82) million, or \$(0.39) per share, after giving effect to (i) the Warrant Net Exercises, (ii) the Series E and F Issuance, (iii) the Preferred Stock Conversion, (iv) the issuance of the 2025 Convertible Notes and the related Notes Conversion, (v) the RSU Net Settlement, and (vi) the reduction of the compound derivative liability bifurcated from the 2023 Term Loan.

After giving further effect to receipt of the net proceeds of our sale of 23,529,412 shares of common stock at an assumed initial public offering price of \$19.50 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and after deducting estimated underwriting discounts and commissions and estimated offering expenses, net of \$1.4 million of offering expenses paid as of March 31, 2025, our pro forma as adjusted net tangible book value as of March 31, 2025 would have been approximately \$324.3 million, or \$1.14 per share. This represents an immediate increase in pro forma as adjusted net tangible book value of \$74.11 per share to our existing shareholders and an immediate dilution of \$18.36 per share to investors purchasing common stock in this offering.

The following table illustrates this dilution to new investors on a per share basis:

Assumed initial public offering price per share	\$19.50
Historical net tangible book value (deficit) per share as of March 31, 2025	\$(74.50)
Increase per share attributable to the pro forma adjustments described above	74.11
Pro forma net tangible book value (deficit) per share as of March 31, 2025	(0.39)
Increase in pro forma net tangible book value per share attributable to new investors in this offering	1.53
Pro forma as adjusted net tangible book value per share immediately after this offering	1.14
Dilution per share to new investors purchasing shares in this offering	<u>\$18.36</u>

Each \$1.00 increase (decrease) in the assumed initial public offering price of \$19.50 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted net tangible book value, by \$0.07 per share and the dilution per share to new investors by \$0.93 per share, assuming the number of shares of common stock offered by us, as set forth on the cover page of this prospectus, remains the same, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

We may also increase or decrease the number of shares of common stock we are offering. An increase (decrease) of 1,000,000 shares in the number of shares of common stock we are offering would increase (decrease) our pro forma as adjusted net tangible book value by approximately \$18.1 million, or \$0.06 per share, and the pro forma dilution per share to investors in this offering by \$0.06 per share, assuming that the assumed initial public offering price remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

If the underwriters' option to purchase additional shares of common stock in this offering is exercised in full, the pro forma as adjusted net tangible book value would be \$1.35 per share, the increase in the pro forma net tangible book value per share for existing shareholders would be \$0.21 per share, and the dilution to new investors participating in this offering would be \$0.21 per share.

The dilution information discussed above is illustrative only and will change based on the actual initial public offering price, number of shares of common stock offered and other terms of this offering determined at pricing.

The table below summarizes, as of March 31, 2025, on the pro forma basis described above, the number of shares of our common stock, the total consideration, and the average price per share (i) paid to us by our existing shareholders and (ii) to be paid by new investors participating in this offering at an assumed initial public offering price of \$19.50 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, before deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

	Shares Purchased		Total Consideration		Weighted-Average Price Per Share
	Number	Percent	Amount	Percent	
Existing shareholders	260,025,773	91.7%	1,541,910,812	77.1%	5.93
New investors	23,529,412	8.3	458,823,534	22.9	19.50
Total	283,555,185	100%	\$2,000,734,346	100%	7.06

Each \$1.00 increase (decrease) in the assumed initial public offering price of \$19.50 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) total consideration paid by new investors by \$23.5 million and increase (decrease) the percent of total consideration paid by new investors by 0.9%, assuming the number of shares of common stock we are offering, as set forth on the cover page of this prospectus, remains the same, after deducting estimated underwriting discounts and commissions. We may also increase or decrease the number of shares of common stock we are offering. An increase (decrease) of 1,000,000 in the number of shares of common stock offered by us would increase (decrease) total consideration paid by new investors by \$19.5 million, assuming that the assumed initial price to the public remains the same, and after deducting estimated underwriting discounts and commissions.

In addition, if the underwriters' option to purchase additional shares of common stock is exercised in full, the number of shares held by existing shareholders will be reduced to 90.6% of the total number of shares of common stock to be outstanding upon the completion of this offering, and the number of shares of common stock held by new investors participating in this offering will be further increased to 9.4% of the total number of shares of common stock to be outstanding upon the completion of the offering.

The number of shares of our common stock to be outstanding after this offering is based on 260,025,773 shares of our common stock outstanding as of March 31, 2025, after giving effect to (i) the Warrant Net Exercises, (ii) the Series E and F Issuance, (iii) the Preferred Stock Conversion, (iv) the issuance of the 2025 Convertible Notes and the related Notes Conversion, and (v) the RSU Net Settlement, and excludes:

- 24,113,482 shares of our common stock issuable upon the exercise of options outstanding under our 2020 Plan as of March 31, 2025, at a weighted-average exercise price of \$10.18 per share;
- 249,999 shares of our common stock issuable upon the exercise of options granted under our 2020 Plan subsequent to March 31, 2025, at an exercise price per share equal to the initial public offering price;
- 236,290 shares of our common stock issuable upon the vesting and settlement of RSUs outstanding under our 2020 Plan as of March 31, 2025 that are subject to vesting conditions that are not satisfied in connection with this offering;
- 15,406,122 shares of our common stock reserved for future issuance under our 2025 Plan, based on an assumed initial public offering price of \$19.50 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, which 2025 Plan will become effective in connection with this offering, as well as shares of our common stock that may be issued pursuant to provisions of our 2025 Plan that automatically increase the share reserve under our 2025 Plan; and

- 2,619,040 shares of our common stock reserved for future issuance under our ESPP, based on an assumed initial public offering price of \$19.50 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, which ESPP will become effective in connection with this offering, as well as shares of our common stock that may be issued pursuant to provisions in our ESPP that automatically increase the share reserve under our ESPP.

To the extent that any outstanding options are exercised, or new awards are granted and exercised or settled under our equity compensation plans, new investors will experience further dilution.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and the related notes and other financial information included elsewhere in this prospectus. In addition to historical financial information, the following discussion and analysis contains forward-looking statements that involve risks, uncertainties, and assumptions. Our actual results and timing of selected events may differ materially from those anticipated in these forward-looking statements as a result of many factors, including those discussed under the section titled "Risk Factors" and elsewhere in this prospectus. See the section titled "Special Note Regarding Forward-Looking Statements" elsewhere in this prospectus.

Overview

We are a leading, patient-centric, next-generation AI TechBio company and precision medicine pioneer. We develop and commercialize innovative solutions to transform healthcare through the use of comprehensive molecular information and AI/ML algorithms at scale. Our entire portfolio of precision medicine solutions is designed to benefit patients, with an initial focus on oncology, and serves the clinical, academic, and biopharma markets.

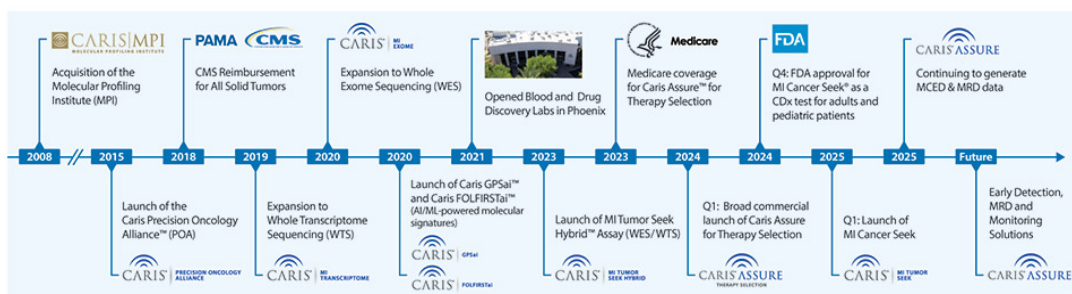
We founded Caris in 2008 with the belief and vision that combining a vast set of consistently generated molecular information with robust data-driven insights could realize the potential of precision medicine for patients. We have spent the last 17 years developing and building our portfolio of comprehensive, proprietary molecular profiling solutions and generating what we believe to be one of the largest and most comprehensive multi-modal clinico-genomic datasets in oncology based on the more than 6.5 million tests we have run on over 849,000 cases, which have generated measurements of over 38 billion molecular markers. Our platform is purpose-built to leverage the convergence of NGS, AI and ML technologies, and high-performance computing. The power of our differentiated Caris platform has enabled us to develop the latest generation of advanced precision medicine diagnostic solutions designed to address the entire cancer care continuum, including early detection, MRD tracking, therapy selection, and treatment monitoring, as well as to create molecular signatures and discover and develop novel precision medicine therapeutics.

Our current commercial product portfolio consists of MI Profile, our tissue-based molecular profiling solution that has generated the majority of our revenue to date, and Caris Assure, our novel, universal blood-based molecular profiling solution that was broadly launched in the first quarter of 2024 for therapy selection. Our purpose-built, proprietary multi-omic profiling solutions capture and analyze molecular information from tissue and blood in a comprehensive manner. We believe this approach best positions us to provide actionable treatment pathways from targeted therapies to drive superior clinical outcomes for patients while also generating a rich dataset to power insights and innovation. Our molecular profiling solutions and the data generated by our multi-omic technology platform also provide value to our more than 100 biopharma partners, such as Moderna, AbbVie, Xencor, and Merck KGaA, through partnerships that aim to increase the probability of technical and regulatory success of their therapeutic pipelines.

We believe that our early foresight to generate comprehensive data at scale over the past many years and build a robust, foundational infrastructure have uniquely positioned Caris to leverage the benefits of biological and technological advances to deliver transformative and advanced innovations in precision medicine and patient care into the future.

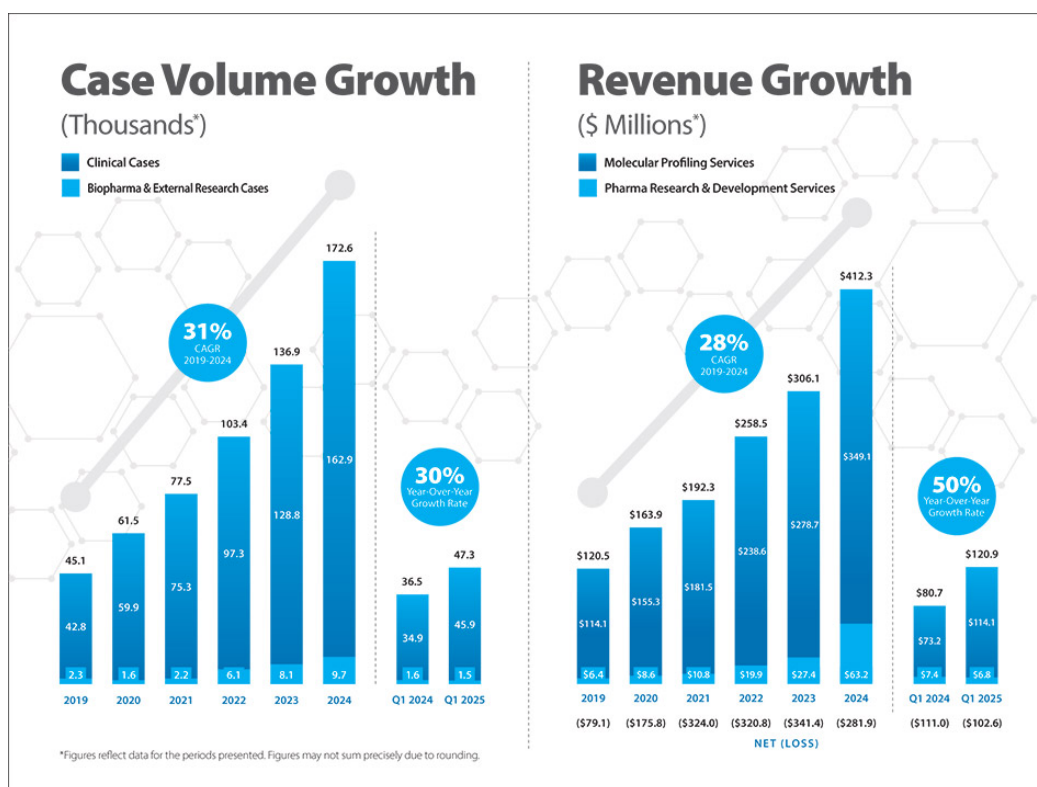
Since our founding, we have achieved the following significant milestones:

Key Development and Commercialization Milestones



To our knowledge, we remain the only genomic profiling company to consistently utilize WES and WTS as standard practice on every eligible patient sample. Our in-depth profiling of patient samples has led to the creation of what we believe to be one of the largest and most comprehensive multi-modal clinico-genomic datasets in oncology. Our ever-expanding datasets include data generated from more than 6.5 million tests that have generated measurements of over 38 billion molecular markers from over 13 quadrillion datapoints as of March 31, 2025, as well as matched clinical outcomes for many of these patients.

Our global annual clinical case volume has been growing rapidly, with year-over-year growth of 29% in 2022, 32% in 2023, 26% in 2024, and 31% in the first quarter of 2025, primarily driven by MI Profile. With our broad commercial launch of Caris Assure for therapy selection in the first quarter of 2024 and the FDA approval of MI Cancer Seek as a companion diagnostic in the fourth quarter of 2024 followed by the broad commercial launch of MI Cancer Seek in the first quarter of 2025 as the NGS component of MI Profile, we believe that increased profiling volumes will meaningfully contribute to our growth in 2025 and beyond.



Our Caris platform is designed to create a virtuous cycle that can enable continued innovation and improved impact for patients and physicians. We believe our comprehensive approach to profiling will continue to drive demand for our genomic profiling capabilities, leading to further expansion of our clinico-genomic datasets, which provide additional valuable inputs to develop and enhance our solutions, with the ultimate goal of contributing to improved patient results. This continuous feedback loop enabled us to develop Caris Assure, which utilized genomic data generated by MI Profile to inform our blood-based bioinformatics algorithms, allowing us to detect previously unknown features and signals in the blood that provide advanced insights into disease development. We believe we will be able to further leverage this process to continue meaningful innovation in precision oncology as well as other chronic disease states, including cardiology, neurology, and metabolic conditions.

We have funded our operations to date principally from the sale of our stock, convertible and senior secured notes, and revenue from our molecular profiling solutions and services with biopharma companies. For the years ended December 31, 2024 and 2023, we generated total revenue of \$412.3 million and \$306.1 million, respectively, and incurred net losses of \$281.9 million and \$341.4 million, respectively. For the three months ended March 31, 2025 and 2024, we generated total revenue of \$120.9 million and \$80.7 million, respectively, and incurred net losses of \$102.6 million and \$111.0 million, respectively. Our Adjusted EBITDA was \$(189.6) million and \$(255.3) million for the years ended December 31, 2024 and 2023, respectively. Our Adjusted EBITDA was \$(36.2) million and \$(70.1) million for the three months ended March 31, 2025 and 2024, respectively. For additional information regarding Adjusted EBITDA, a non-GAAP financial measure, see “—Non-GAAP Financial Measures.” We expect to incur additional net losses in the near future, and our expenses will increase as we continue to invest in developing new solutions, expand our organization, and increase our marketing efforts to continue to drive market adoption of our solutions. These investments, together with general and administrative expenses, have resulted in negative cash flows from operations of \$245.2 million, \$276.1 million, \$31.3 million, and \$73.9 million for the years ended December 31, 2024 and 2023 and the three months ended March 31, 2025 and 2024, respectively. Our free cash flow was \$(253.6) million and \$(298.4) million for the years ended December 31, 2024 and 2023, respectively, and \$(34.0) million and \$(75.7) million for the three months ended March 31, 2025 and 2024, respectively. For additional information regarding free cash flow, a non-GAAP financial measure, see “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Non-GAAP Financial Measures.” Additionally, as of March 31, 2025, we had cash, cash equivalents, and short-term marketable securities of \$33.4 million, and the aggregate principal amount of debt outstanding under our existing term loan was \$400.0 million. For additional information regarding our liquidity and capital resources, see “—Liquidity and Capital Resources.”

Our Business Model

We generate revenue primarily from the provision of precision oncology solutions to ordering physicians utilizing MI Profile and Caris Assure. We have obtained Medicare and commercial reimbursement for MI Profile. We also have Medicare reimbursement and various levels of commercial payer adoption and/or reimbursement coverage for Caris Assure for therapy selection across the United States (other than New York State).

We also generate revenue utilizing our Caris platform to provide R&D services for biopharma partners, who we partner with to help improve the efficiency and success of their therapeutic development and clinical programs. For our biopharma partners, our profiling solutions provide prospective and retrospective testing, companion diagnostics development, data licensing, and commercial services that include identification of patients for approved therapies. In addition, our multi-modal data creates a differentiated capability to advance precision oncology research through novel target identification and discovery, translational sciences, clinical trial design solutions and patient enrollment facilitated by our right-in-time trials network, post-market label expansion, and commercialization insights. Under the strategic partnerships, targets discovered by us using our proprietary wet lab, *in silico*, ADAPT, proximity labeling, and surfacesome analysis can be pursued by our biopharma partners to conduct their own preclinical and clinical research, as well as the eventual development and commercialization of drug candidates. Our biopharma partners select drug targets based, among other things, on their prevalence and expression across cancer types, the uniqueness of the targets and efficacy of current treatments, and their therapeutic modality. Our biopharma partners are also able to combine their relevant technology and/or drug

development capabilities, such as data analysis, *in vitro* studies, molecule design, and therapeutic modality, to design and manufacture potential therapies for the treatment of cancer.

We believe the market for our solutions is large and expanding. We have made significant investments in our scaled and state-of-the-art infrastructure to support our growth and our ability to address the needs of the U.S. oncology market through the provision of molecular information services across the full patient care continuum and to support biopharma drug development. We operate two precision medicine laboratories in Phoenix, Arizona, and one R&D laboratory in Tempe, Arizona. Our Arizona laboratories all utilize state-of-the-art genomic sequencing technology, including 50 NovaSeq sequencing systems, with capacity to perform more than one trillion “reads” daily. Our newest laboratory facility in Irving, Texas, near our headquarters, is continuing to be built-out and will bring our total operational capacity to over 275,000 square feet. To support our sales activity and expansion, as of March 31, 2025, we have assembled a targeted sales organization in the United States of over 270 sales team members and nearly 50 highly trained Ph.D. or M.D. MSLs who focus on physician and provider education and consultation. In addition, the Caris POA, which we established in 2015, is a growing network of leading cancer centers and research consortia across the globe that supports our academic partner engagement and research and collaboration opportunities.

Key Factors Affecting Our Performance

We believe that our operating performance and future success depend on a number of factors that present significant opportunities for us and may pose risks and challenges, including those discussed below and in the “Risk Factors” section of this prospectus.

- **Market acceptance and commercial success of our solutions.** Our success and future growth will depend on maintaining and expanding market acceptance of our molecular profiling solutions along with commercial success of these solutions across existing and new customers. Our MI Profile and Caris Assure case volumes have continued to increase over time. Such changes in our case volumes and the pricing of our solutions, however, are not impacted by the cancer type. For the years ended December 31, 2024 and 2023, the number of clinical cases was 162,862 and 128,831, respectively. For the three months ended March 31, 2025 and 2024, the number of clinical cases was 45,858 and 34,902, respectively. We commercially launched our MI Cancer Seek solution in January 2025 as the WES/WTS NGS component of MI Profile. We initiated the broad commercial launch of Caris Assure for therapy selection in the first quarter of 2024, and realizing the potential of Caris Assure across the cancer treatment continuum is a key component of our business strategy. The commercial success of Caris Assure will depend upon, among other things, additional clinical trials that demonstrate the effectiveness of Caris Assure, particularly for early detection, MCED, MRD tracking, and treatment monitoring, and the continued adoption of Caris Assure by patients, the medical community, and third-party payers. In addition, we expect that our ability to maintain and expand our sales, marketing, and distribution capabilities to support the increased adoption of our molecular profiling solutions will play a key factor in our success.
- **Biopharma partners.** Our revenue also depends on our ability to maintain and expand relationships with our biopharma partners and attract new biopharma partners. As we continue to develop these relationships, we expect to support a growing number of projects and continue to have opportunities to offer our platform to such customers for development and research services. For the years ended December 31, 2024 and 2023, our year-over-year growth in pharma research and development services revenue has been 131% and 37%, respectively.
- **Development and introduction of new solutions.** Our business success will also depend on our ability to develop and commercialize new solutions. We plan to continue to invest in the enhancement of our molecular profiling solutions, the development of new solutions to achieve meaningful innovation in precision oncology and other disease states, and the expansion of our clinico-genomic datasets to drive breakthrough science. We intend to expand the application of Caris Assure to early detection, MCED, MRD tracking, and treatment monitoring. Our ability to develop and commercialize new solutions and services could face many challenges and thus impact our future performance and results of operations. Such challenges include, but

are not limited to, obtaining regulatory approvals; completing certain clinical development activities, validation studies, and/or clinical trials; having guidelines or recommendations for healthcare providers, administrators, payers, and patient communities relating to such solutions; and receiving favorable exposure in peer-reviewed publications and from KOLs.

- Payer coverage and reimbursements.*** Our revenue and future revenue growth will depend on our success in achieving broad coverage and adequate reimbursement for our solutions from third-party payers. Coverage and reimbursement by third-party payers, including managed care organizations, private health insurers, and government healthcare programs for the types of solutions we offer can be limited and uncertain and may depend on a number of factors, including a payer’s determination that a product is appropriate, medically necessary, and cost-effective. Each payer will make its own decision as to whether to establish a policy or enter into a contract to cover our products and the amount it will reimburse for such products. In addition, Z-Code Identifiers are used by certain payers, including under MolDX, to supplement CPT codes for our molecular diagnostics solutions. Changes to the codes used to report to payers may result in significant changes in their reimbursement. We have obtained a PMA approval from the FDA for a companion diagnostic and tumor profiling designation for MI Cancer Seek, a WES/WTS NGS assay that uses the whole exome for tumor mutational burden (“TMB”) calling along with being designed to meet the stricter requirements applicable to companion diagnostic devices. We have obtained Medicare coverage for MI Cancer Seek for CPT code 0211U, at a reimbursement rate of \$8,455, under the NGS NCD. We currently market MI Cancer Seek as the WES/WTS NGS component of MI Profile. The current MolDX pricings of MI Tumor Seek Hybrid, and Caris Assure are \$3,500 and \$3,649, respectively. In July 2024, the AMA issued a PLA code, CPT code 0485U, for Caris Assure, with an effective date of October 1, 2024. In November 2024, CMS determined to price Caris Assure for therapy selection using the “Gapfill” method, a method used when there are no comparable existing codes available. There is no certainty regarding the pricing that we will obtain for Caris Assure during the Gapfill process. For additional information, see “—Government Regulation—Coverage and Reimbursement—Coverage and Reimbursement in the United States.” While the average selling prices (“ASPs”) for Caris Assure and MI Cancer Seek reimbursed by a particular payer are determined by our arrangements with that payer and do not materially differ by cancer type, any fluctuation or differences in coverage and reimbursement among our third-party payers may impact our ASPs and gross margins. Moreover, if we are unable to obtain and/or maintain broad coverage and adequate reimbursement for our solutions from third-party payers, we may not be able to effectively increase our clinical case volume and our revenue would be impacted.
- Scaling infrastructure to meet increasing demand.*** Our financial results are also dependent upon our ability to support current and future levels of demand for our solutions, including MI Profile and Caris Assure. As and to the extent the volumes of our current and new molecular profiling solutions continue to grow, we will need to simultaneously increase our capacity for sample intake and storage, enhance our customer service, improve our billing and general processes, expand our internal quality assurance programs, incorporate new equipment, implement new technology systems and processes, expand laboratory capacity, and otherwise extend our operational capabilities to support comprehensive genomic analyses at a larger scale while retaining expected turnaround times. This may result in us purchasing additional equipment, constructing additional facilities, hiring additional qualified labor, and implementing new systems, technology, controls, and procedures. As such, our capital expenditures and cost of services may increase as we continue our efforts to expand capacity. In addition, revenue may be impacted in the event that we are not able to meet the increase in demand.

Components of Results of Operations

Revenue

Revenue consists primarily of the following:

Molecular Profiling Services

Molecular profiling services revenue is generated from the provision of precision oncology solutions to ordering physicians utilizing MI Profile, MI Cancer Seek (NGS component of MI Profile), and Caris Assure. Revenue is recorded when performance obligations are satisfied, which is deemed to be when the results of the profiling services are provided to the ordering physicians, including certain hospitals, cancer centers, and institutions. Revenue is recorded at the amount that reflects the consideration to which we expect to be entitled from customers and third-party payers in exchange for providing such services.

Pharma Research and Development Services

Pharma research and development services revenue is generated from the provision of research and development services for biopharma partners utilizing our Caris platform. Given the nature of these services, each contract may contain multiple performance obligations, such as molecular profiling solutions, developmental services, and strategic data services. Each performance obligation is analyzed, and revenue is recognized as or when such performance obligations are satisfied. The timing and extent of revenue recognized may vary from contract to contract.

Costs and Operating Expenses

We allocate certain overhead expenses, such as rent, utilities, and depreciation to cost of services and operating expense categories based on headcount and facility usage. As a result, an overhead expense allocation is reflected in cost of services and operating expenses.

Cost of Services—Molecular Profiling Services

Cost of molecular profiling services generally consists of cost of materials, direct labor (including bonus and stock-based compensation), equipment maintenance and depreciation expenses associated with processing cases (including accessioning, sequencing, quality control analyses, and shipping charges to transport samples), and freight. Costs associated with completing the molecular profiling services are recorded as the service is performed, regardless of whether revenue is recognized with respect to the service.

Cost of Services—Pharma Research and Development Services

Cost of services for pharma research and development services generally consists of costs incurred for the performance of the services requested by our biopharma partners related to research and development services. For the development of new products, costs incurred before technological feasibility has been achieved are reported as research and development expenses, while costs incurred thereafter are reported as cost of services. Cost of services for pharma research and development services will vary depending on the nature, timing, and scope of customer projects.

We expect cost of services to increase in absolute dollars as our revenue grows. In the short term, increases to cost of services may outpace revenue growth as we invest in expanding our laboratory capacity and implementing new processes. However, over time, the cost per clinical case is expected to decrease due to economies of scale.

Selling and Marketing Expense

Our selling and marketing expense includes costs associated with our sales organization, including our direct sales force and sales management, marketing, and business development personnel. These expenses consist principally of salaries, incentive compensation, bonuses, employee benefits, travel, and stock-based compensation, as well as marketing and educational activities. We expense all selling and marketing expenses as incurred.

We believe that our marketing activities continue to drive awareness and differentiate our existing solutions and future solutions. We expect our selling and marketing expenses to continue to increase in absolute dollars as we expand our sales force and continue to grow our presence within and outside of the United States.

General and Administrative Expense

Our general and administrative expense includes costs for our executive, accounting and finance, legal, information technology, billing, and human resources functions. These expenses consist principally of salaries, bonuses, employee benefits, travel, and stock-based compensation, as well as professional services fees (such as audit and tax consulting), general corporate costs, and allocated overhead expenses. While we expect our general and administrative expenses will increase in absolute dollars as we continue to invest in our growth and operate as a public company, we expect them to decline as a percentage of revenue over time as we scale our business and leverage our investments already made.

We expect to incur additional expenses after we complete this offering, primarily due to the costs of operating as a public company, which are expected to include additional legal, accounting, corporate governance, and investor relations expenses, as well as higher directors' and officers' insurance premiums. In addition, as a public company, we also expect to incur increased stock-based compensation expense related to our long-term equity incentive plan.

Research and Development Expense

Our research and development expense consists of costs incurred in performing research and development activities. These expenses include direct costs for salaries and benefits, supplies used in research and development, contract services and other outside costs, costs to acquire in-process research and development projects and technologies that have no alternative future use, and allocated overhead expenses.

We expect that our overall research and development expenses will vary from period to period as a percentage of revenue, as projects and prospective trials are initiated and completed.

Other Income (Expense), Net

Interest Income

Interest income consists primarily of interest earned on our cash and cash equivalents and marketable securities.

Interest Expense

Interest expense consists primarily of contractual interest expense on our term loan, amortization of the debt discount related to our term loans, and interest expense on our finance leases.

Changes in Fair Value of Financial Instruments

Changes in fair value of financial instruments consists of changes in the fair value of the warrant liability and changes in the fair value of the derivative liability. Our warrants are classified as a liability on our consolidated balance sheets and re-measured to fair value at each balance sheet date with the corresponding changes in fair value recorded within changes in fair value of financial instruments, as the holders have the option to convert their warrants into shares of either our common stock or our Series C preferred stock. The warrants will expire upon the completion of this offering unless earlier exercised.

Other Expense, Net

Other expense, net consists of items related to foreign currency gains and losses, and other immaterial items.

Results of Operations

Comparison of the Three Months Ended March 31, 2025 and 2024

The following table sets forth a summary of our results of operations for the periods presented:

	Three Months Ended March 31,	
	2025	2024
	(In thousands)	
Revenue:		
Molecular profiling services	\$ 114,081	\$ 73,233
Pharma research and development services	6,834	7,444
Total revenue	120,915	80,677
Costs and operating expenses ⁽¹⁾ :		
Cost of Services – Molecular Profiling Services	60,894	52,894
Cost of Services – Pharma Research and Development Services	2,958	1,669
Selling and marketing expense	39,829	39,609
General and administrative expense	52,119	44,354
Research and development expense	23,066	34,376
Total costs and operating expenses	178,867	172,902
Loss from operations	(57,952)	(92,225)
Other income (expense), net:		
Interest income	503	1,768
Interest expense	(12,782)	(9,290)
Changes in fair value of financial instruments	(32,333)	(11,064)
Other expense, net	(17)	(219)
Total other expense, net	(44,629)	(18,804)
Loss before income taxes and provision for income taxes	(102,581)	(111,028)
Provision for (benefit from) income taxes	—	—
Net loss	<u><u>\$(102,581)</u></u>	<u><u>\$(111,028)</u></u>

(1) Costs and operating expenses contains the following stock-based compensation expense:

	Three Months Ended March 31,	
	2025	2024
	(In thousands)	
Cost of services – Molecular profiling services	\$ 466	\$ 427
Cost of services – Pharma research and development services	1	2
Selling and marketing expense	1,243	1,118
General and administrative expense	10,636	1,945
Research and development expense	2,346	966
Total	<u><u>\$14,691</u></u>	<u><u>\$4,458</u></u>

The following table sets forth our results of operations as a percentage of revenue for the periods presented:

	Three Months Ended March 31,	
	2025	2024
Revenue:		
Molecular profiling services	94%	91%
Pharma research and development services	6%	9%
Total revenue	100%	100%
Costs and operating expenses ⁽¹⁾ :		
Cost of services – Molecular profiling services	50%	66%
Cost of Services – Pharma Research and Development Services	2%	2%
Selling and marketing expense	33%	49%
General and administrative expense	43%	55%
Research and development expense	19%	43%
Total costs and operating expenses	148%	214%
Loss from operations	(48)%	(114)%
Other income (expense), net:		
Interest income	—%	2%
Interest expense	(11)%	(12)%
Changes in fair value of financial instruments	(27)%	(14)%
Other expense, net	—%	—%
Total other expense, net	(37)%	(23)%
Loss before income taxes and provision for income taxes	(85)%	(138)%
Provision for (benefit from) income taxes	—%	—%
Net loss	(85)%	(138)%

Revenue

	Three Months Ended March 31,		Change	
	2025	2024	\$	%
(Dollars in thousands)				
Molecular profiling services	\$ 114,081	\$ 73,233	\$ 40,848	55.8%
Pharma research and development services	6,834	7,444	(610)	(8.2)%
Total revenue	\$ 120,915	\$ 80,677	\$ 40,238	49.9%

Total revenue was \$120.9 million for the three months ended March 31, 2025, compared to \$80.7 million for the three months ended March 31, 2024, an increase of \$40.2 million, or 49.9%.

Molecular Profiling Services Revenue

Molecular profiling services revenue increased to \$114.1 million for the three months ended March 31, 2025, from \$73.2 million for the three months ended March 31, 2024, an increase of \$40.8 million, or 55.8%.

This increase in revenue was primarily due to the increase in clinical cases associated with MI Profile and Caris Assure for therapy selection from 33,095 and 1,807 cases, respectively, for the three months ended March 31, 2024, to 40,048 and 5,810 cases, respectively, for the three months ended March 31, 2025,

a total increase of 10,956 cases, or 31.4%. We believe the growth in MI Profile clinical case volume is driven by increased market acceptance and adoption of MI Profile by ordering physicians year over year, and increased market acceptance and adoption of Caris Assure following its broad commercial launch in the first quarter of 2024.

Revenue from clinical cases for patients covered by Medicare represented approximately 54.3% and 40.5% of our molecular profiling services revenue for the three months ended March 31, 2025 and 2024, respectively due to mix.

The following table sets forth the relative impacts of clinical volume and ASP on our increase in molecular profiling services revenue.

	(In thousands)
Molecular profiling services revenue for the three months ended March 31, 2024	\$ 73,233
MI Profile volume increase	14,894
MI Profile ASP increase due to payer mix	15,704
Caris Assure for therapy selection	10,250
Molecular profiling services revenue for the three months ended March 31, 2025	<u>\$114,081</u>

Pharma Research and Development Services Revenue

Pharma research and development services revenue decreased to \$6.8 million for the three months ended March 31, 2025, from \$7.4 million for the three months ended March 31, 2024, a decrease of \$0.6 million, or 8.2%. The decrease is mainly driven by reduced research case volume.

Cost of Services

	Three Months Ended March 31,		Change	
	2025	2024	\$	%
	(Dollars in thousands)			
Cost of services – Molecular profiling services	\$60,894	\$52,894	\$8,000	15.1%
Cost of services – Pharma research and development services	\$ 2,958	\$ 1,669	\$1,289	77.2%

Cost of Services—Molecular Profiling Services

Cost of services—Molecular profiling services was \$60.9 million for the three months ended March 31, 2025, compared to \$52.9 million for the three months ended March 31, 2024, an increase of \$8.0 million, or 15.1%.

The Caris Assure laboratory contributed to the majority of the \$8.0 million increase. The Caris Assure increase was primarily driven by an increase in materials and related testing costs of \$5.0 million, a \$1.3 million increase in utilities, rent, and allocated overhead, and an increase in labor costs of \$1.1 million, due to the increased volume from broad launch in the first quarter of 2024.

Cost of Services—Pharma Research and Development Services

Cost of services—Pharma research and development services was \$3.0 million for the three months ended March 31, 2025, compared to \$1.7 million for the three months ended March 31, 2024, an increase of \$1.3 million, or 77.2%. The increase was driven primarily by an increase within costs associated with the delivery of data licensing and target discovery services of \$2.5 million, offset by a reduction in delivering research services of \$1.2 million, driven by lower research volume.

Gross Profit

Gross profit, calculated as total revenue less cost of services, was \$57.1 million for the three months ended March 31, 2025, compared to \$26.1 million for the three months ended March 31, 2024, an increase of \$30.9 million, or 118.5%, primarily due to the increase in clinical revenue.

Selling and Marketing Expense

	Three Months Ended March 31,		Change	
	2025	2024	\$	%
	(Dollars in thousands)			
Selling and marketing expense	\$39,829	\$39,609	\$221	0.6%

Selling and marketing expenses were \$39.8 million for the three months ended March 31, 2025, compared to \$39.6 million for the three months ended March 31, 2024, an increase of \$0.2 million, or 0.6%. This increase was primarily due to a \$2.1 million increase in personnel costs to support existing solutions, offset by a \$1.9 million decrease in travel and marketing expenses.

General and Administrative Expense

	Three Months Ended March 31,		Change	
	2025	2024	\$	%
	(Dollars in thousands)			
General and administrative expense	\$52,119	\$44,354	\$7,765	17.5%

General and administrative expenses were \$52.1 million for the three months ended March 31, 2025, compared to \$44.4 million for the three months ended March 31, 2024, an increase of \$7.8 million, or 17.5%. This increase was primarily due to an increase of \$11.6 million in labor costs, benefits and stock-based compensation associated with an expansion of personnel, a \$1.3 million increase in consulting, audit and legal professional fees, a \$1.3 million increase related to utilities and cloud computing usages, offset by a \$7.2 million decrease in depreciation expense.

Research and Development Expense

	Three Months Ended March 31,		Change	
	2025	2024	\$	%
	(Dollars in thousands)			
Research and development expense	\$23,066	\$34,376	\$(11,310)	(32.9)%

Research and development expenses were \$23.1 million for the three months ended March 31, 2025, compared to \$34.4 million for the three months ended March 31, 2024, a decrease of \$11.3 million, or 32.9%. The decrease was primarily driven by a reduction of \$9.6 million in material and reference testing costs associated with the development of Caris Assure and FDA submission of MI Cancer Seek, a reduction of \$0.8 million in labor costs, benefits and stock-based compensation, and a \$0.8 million reduction in allocated overhead.

Other Income (Expense), Net

	Three Months Ended March 31,		Change	
	2025	2024	\$	%
	(Dollars in thousands)			
Interest income	\$ 503	\$ 1,768	\$ (1,265)	(71.6)%
Interest expense	(12,782)	(9,290)	(3,492)	37.6%
Changes in fair value of financial instruments	(32,333)	(11,064)	(21,269)	192.2%
Other expense, net	(17)	(219)	202	(92.2)%
Total other income (expense), net	<u>\$(44,629)</u>	<u>\$(18,804)</u>	<u>\$(25,825)</u>	<u>137.3%</u>

Interest Income

Interest income was \$0.5 million for the three months ended March 31, 2025, compared to \$1.8 million for the three months ended March 31, 2024, a decrease of \$1.3 million, or 71.6%. This decrease was primarily due to reduced investments in marketable securities.

Interest Expense

Interest expense was \$12.8 million for the three months ended March 31, 2025, compared to \$9.3 million for the three months ended March 31, 2024, an increase of \$3.5 million, or 37.6%. This increase was primarily due to increased interest expense associated with \$200.0 million of additional borrowing under the 2023 Term Loan Agreement, which was drawn on March 5, 2024.

Changes in Fair Value of Financial Instruments

Changes in fair value of financial instruments was \$32.3 million for the three months ended March 31, 2025, compared to \$11.1 million for the three months ended March 31, 2024, an increase of \$21.3 million, or 192.2%. This increase is mainly driven by the increase in warrant and derivative fair values during the three months ended March 31, 2025.

Other Expense, Net

Other expense, net was \$17 thousand for the three months ended March 31, 2025, compared to \$0.2 million for the three months ended March 31, 2024, a decrease of \$0.2 million, or 92.2%. This decrease was primarily due to the undrawn fee of the 2023 Term Loan, incurred during the three months ended March 31, 2024.

Comparison of the Years Ended December 31, 2024 and 2023

The following table sets forth a summary of our results of operations for the periods presented:

	Years Ended December 31,	
	2024	2023
	(In thousands)	
Revenue:		
Molecular profiling services	\$ 349,115	\$ 278,748
Pharma research and development services	63,145	27,380
Total revenue	412,260	306,128
Costs and operating expenses⁽¹⁾:		
Cost of services—Molecular profiling services	223,075	207,509
Cost of services—Pharma research and development services	10,403	9,309
Selling and marketing expense	152,602	142,925
General and administrative expense	169,386	149,053
Research and development expense	113,916	116,883
Total costs and operating expenses	669,382	625,679
Loss from operations	(257,122)	(319,551)
Other income (expense), net:		
Interest income	7,122	11,258
Interest expense	(50,025)	(31,610)
Changes in fair value of financial instruments	18,484	11,094
Other expense, net	(349)	(12,606)
Total other expense, net	(24,768)	(21,864)
Loss before income taxes and provision for income taxes	(281,890)	(341,415)
Provision for (benefit from) income taxes	—	—
Net loss	<u><u>\$ (281,890)</u></u>	<u><u>\$ (341,415)</u></u>

(1) Costs and operating expenses contains the following stock-based compensation expense:

	Years Ended December 31,	
	2024	2023
	(In thousands)	
Cost of services—Molecular profiling services	\$ 1,669	\$ 1,504
Cost of services—Pharma research and development services	11	10
Selling and marketing expense	4,301	3,400
General and administrative expense	8,448	6,983
Research and development expense	4,214	3,344
Total	<u><u>\$18,643</u></u>	<u><u>\$15,241</u></u>

The following table sets forth our results of operations as a percentage of revenue for the periods presented:

	Years Ended December 31,	
	2024	2023
Revenue:		
Molecular profiling services	85%	91%
Pharma research and development services	15%	9%
Total revenue	100%	100%
Costs and operating expenses ⁽¹⁾ :		
Cost of services—Molecular profiling services	54%	68%
Cost of services—Pharma research and development services	3%	3%
Selling and marketing expense	37%	47%
General and administrative expense	41%	49%
Research and development expense	28%	38%
Total costs and operating expenses	162%	204%
Loss from operations	(62)%	(104)%
Other income (expense), net:		
Interest income	2%	4%
Interest expense	(12)%	(10)%
Changes in fair value of financial instruments	4%	4%
Other expense, net	—%	(4)%
Total other expense, net	(6)%	(7)%
Loss before income taxes and provision for income taxes	(68)%	(112)%
Provision for (benefit from) income taxes	—%	—%
Net loss	(68)%	(112)%

Revenue

	Years Ended December 31,		Change	
	2024	2023	\$	%
	(Dollars in thousands)			
Molecular profiling services	\$349,115	\$278,748	\$ 70,367	25.2%
Pharma research and development services	63,145	27,380	35,765	130.6%
Total revenue	\$412,260	\$306,128	\$106,132	34.7%

Total revenue was \$412.3 million for the year ended December 31, 2024, compared to \$306.1 million for the year ended December 31, 2023, an increase of \$106.1 million, or 34.7%.

Molecular Profiling Services Revenue

Molecular profiling services revenue increased to \$349.1 million for the year ended December 31, 2024, from \$278.7 million for the year ended December 31, 2023, an increase of \$70.4 million, or 25.2%.

This increase in revenue was primarily due to the increase in clinical cases associated with MI Profile and Caris Assure for therapy selection from 128,168 and 663 cases, respectively, for the year ended December 31, 2023, to 146,580 and 16,282 cases, respectively, for the year ended December 31, 2024, a total increase of 34,031 cases, or 26.4%. We believe the growth in MI Profile clinical case volume is driven by increased market acceptance and adoption of MI Profile by ordering physicians year over year, and increased market acceptance and adoption of Caris Assure following its broad commercial launch in the first quarter of 2024.

For the year ended December 31, 2023, we recorded \$4.4 million of revenue related to the transition of payers from “non-contract basis” to “contract basis.” Revenue from clinical cases for patients covered by Medicare represented approximately 39.0% and 39.3% of our molecular profiling services revenue for the years ended December 31, 2024 and 2023, respectively.

The following table sets forth the relative impacts of clinical volume and ASP on our increase in molecular profiling services revenue from 2023 to 2024.

	(In thousands)
Molecular profiling services revenue for the year ended December 31, 2023	\$278,748
MI Profile volume increase	39,393
MI Profile ASP increase due to payer mix	8,621
Transition adjustments for MI Profile payers in 2023	(4,390)
Caris Assure for therapy selection	26,743
Molecular profiling services revenue for the year ended December 31, 2024	<u>\$349,115</u>

Pharma Research and Development Services Revenue

Pharma research and development services revenue increased to \$63.1 million for the year ended December 31, 2024, from \$27.4 million for the year ended December 31, 2023, an increase of \$35.7 million, or 130.3%. This increase was primarily due to increased activity with our biopharma partners for our data licensing business of \$35.6 million and an increase within pharma profiling services of \$1.8 million. The increases were partially offset by a reduction in research revenue of \$2.5 million.

Cost of Services

	Years Ended December 31,		Change	
	2024	2023	\$	%
	(Dollars in thousands)			
Cost of services—Molecular profiling services	\$223,075	\$207,509	\$15,566	7.5%
Cost of services—Pharma research and development services	\$ 10,403	\$ 9,309	\$ 1,094	11.8%

Cost of Services—Molecular Profiling Services

Cost of services—Molecular profiling services was \$223.1 million for the year ended December 31, 2024, compared to \$207.5 million for the year ended December 31, 2023, an increase of \$15.6 million, or 7.5%.

The Caris Assure laboratory contributed a \$20.2 million increase, which was offset by a \$4.6 million decrease within the MI Profile tissue laboratory. The Caris Assure increase was primarily driven by an increase in materials and related testing costs of \$15.7 million and an increase in labor costs of \$2.7 million, due to the increased volume from broad launch in the first quarter of 2024. The MI Profile decrease was driven primarily by a reduction in labor costs of \$2.9 million and reduced depreciation of \$5.7 million, mainly from lab equipment that has been fully depreciated, offset by an increase in materials and related testing costs of \$2.0 million, driven by increased case volume.

Cost of Services—Pharma Research and Development Services

Cost of services—Pharma research and development services was \$10.4 million for the year ended December 31, 2024, compared to \$9.3 million for the year ended December 31, 2023, an increase of \$1.1 million, or 11.8%. The increase was driven primarily by an increase within costs associated with the delivery of data licensing and target discovery services, offset by a reduction in labor and materials used in pharma profiling services.

Gross Profit

Gross profit, calculated as total revenue less cost of services, was \$178.8 million for the year ended December 31, 2024, compared to \$89.3 million for the year ended December 31, 2023, an increase of \$89.5 million, or 100.2%, primarily due to the increase in the number of clinical cases and pharma research and development services revenue.

Selling and Marketing Expense

	Years Ended December 31,		Change	
	2024	2023	\$	%
	(Dollars in thousands)			
Selling and marketing expense	\$152,602	\$142,925	\$9,677	6.8%

Selling and marketing expenses were \$152.6 million for the year ended December 31, 2024, compared to \$142.9 million for the year ended December 31, 2023, an increase of \$9.7 million, or 6.8%. This increase was primarily due to a \$5.7 million increase in personnel costs to support existing solutions, a \$1.4 million increase in professional service costs from expanded EMR integrations and consulting, and a \$2.4 million increase in travel and marketing expenses.

General and Administrative Expense

	Years Ended December 31,		Change	
	2024	2023	\$	%
	(Dollars in thousands)			
General and administrative expense	\$169,386	\$149,053	\$20,333	13.6%

General and administrative expenses were \$169.4 million for the year ended December 31, 2024, compared to \$149.1 million for the year ended December 31, 2023, an increase of \$20.3 million, or 13.6%. This increase was primarily due to an increase of \$6.9 million in labor costs, benefits and stock-based compensation associated with an expansion of personnel, a \$4.3 million increase in consulting, audit and legal professional fees, and a \$6.9 million increase related to utilities and cloud computing usages.

Research and Development Expense

	Years Ended December 31,		Change	
	2024	2023	\$	%
	(Dollars in thousands)			
Research and development expense	\$113,916	\$116,883	\$(2,967)	(2.5)%

Research and development expenses were \$113.9 million for the year ended December 31, 2024, compared to \$116.9 million for the year ended December 31, 2023, a decrease of \$3.0 million, or 2.5%. The decrease was primarily driven by a reduction of \$8.2 million in material and reference testing costs associated with the development of Caris Assure and FDA submission of MI Cancer Seek and a reduction of \$2.6 million in consulting fees, offset by an \$8.0 million increase in labor costs, benefits and stock-based compensation.

Other Income (Expense), Net

	Years Ended December 31,		Change	
	2024	2023	\$	%
	(Dollars in thousands)			
Interest income	\$ 7,122	\$ 11,258	\$ (4,136)	(36.7)%
Interest expense	(50,025)	(31,610)	(18,415)	58.3%
Changes in fair value of financial instruments	18,484	11,094	7,390	66.6%
Other expense, net	(349)	(12,606)	12,257	(97.2)%
Total other income (expense), net	<u>\$(24,768)</u>	<u>\$(21,864)</u>	<u>\$ (2,904)</u>	13.3%

Interest Income

Interest income was \$7.1 million for the year ended December 31, 2024, compared to \$11.3 million for the year ended December 31, 2023, a decrease of \$4.1 million, or 36.7%. This decrease was primarily due to reduced investments in marketable securities.

Interest Expense

Interest expense was \$50.0 million for the year ended December 31, 2024, compared to \$31.6 million for the year ended December 31, 2023, an increase of \$18.4 million, or 58.3%. This increase was primarily due to increased interest expense associated with \$200.0 million of additional borrowing under the 2023 Term Loan Agreement, which was drawn on March 5, 2024.

Changes in Fair Value of Financial Instruments

Changes in fair value of financial instruments was \$18.5 million for the year ended December 31, 2024, compared to \$11.1 million for the year ended December 31, 2023, an increase of \$7.4 million, or 66.6%. This increase is mainly driven by the decrease in warrant and derivative fair values during the year ended December 31, 2024.

Other Expense, Net

Other expense, net was \$0.3 million for the year ended December 31, 2024, compared to \$12.6 million for the year ended December 31, 2023, a net decrease of \$12.3 million, or 97.2%. This decrease was primarily due to a loss on debt extinguishment of \$10.9 million in connection with our prior term loan that was recorded in January 2023.

Non-GAAP Financial Measures

We use certain non-GAAP financial measures to supplement our consolidated financial statements, which are presented in accordance with GAAP. We believe the non-GAAP financial measures we use, Adjusted EBITDA and free cash flow, are useful in evaluating our performance and liquidity. Our non-GAAP financial measures have limitations as analytical tools, however, and you should not consider them in isolation or as substitutes for analysis of our results as reported under GAAP.

Adjusted EBITDA

We define Adjusted EBITDA as net loss, adjusted to exclude interest income, interest expense, changes in fair value of financial instruments, other expense, net, the provision for (benefit from) income taxes, depreciation and amortization, and stock-based compensation expense.

We use Adjusted EBITDA in conjunction with GAAP measures as part of our overall assessment of our performance, including the preparation of our annual operating budget and quarterly forecasts, to evaluate the effectiveness of our business strategies, and to communicate with our board of directors concerning our financial performance. We believe that Adjusted EBITDA provides useful information to

investors and others in understanding and evaluating our operating results in the same manner as our management team and board of directors. In addition, it provides a useful measure for period-to-period comparisons of our business, as it removes the effect of certain non-cash expenses and certain variable charges. Some of the limitations related to the use of Adjusted EBITDA as an analytical tool include:

- it does not reflect interest income, interest expense or other non-operating gains and losses, which may represent an increase to or reduction in cash available to us;
- it does not reflect recurring, non-cash expenses of depreciation of property and equipment and amortization of right-of-use assets and intangible assets, and although these are non-cash expenses, the assets being depreciated and amortized may have to be replaced in the future;
- it does not reflect the impact of stock-based compensation expense, which has been, and will continue to be a part of our compensation strategy; and
- it may be calculated differently than similarly titled measures used by other companies, which reduces its usefulness as a comparative measure.

Because of these limitations, you should consider Adjusted EBITDA alongside other financial performance measures, including net loss and our other GAAP results. In evaluating Adjusted EBITDA, you should be aware that in the future we may incur expenses that are the same as, or similar to, some of the adjustments in this presentation. Our presentation of Adjusted EBITDA should not be construed to imply that our future results will be unaffected by the types of items excluded from the calculation of Adjusted EBITDA.

The following table provides a reconciliation of net loss, the most directly comparable financial measure presented in accordance with GAAP, to Adjusted EBITDA for the periods presented:

	Three Months Ended March 31,		Years Ended December 31,	
	2025	2024	2024	2023
	(In thousands)			
Net loss	\$(102,581)	\$(111,028)	\$(281,890)	\$(341,415)
Interest income	(503)	(1,768)	(7,122)	(11,258)
Interest expense	12,782	9,290	50,025	31,610
Changes in fair value of financial instruments	32,333	11,064	(18,484)	(11,094)
Other expense, net	17	219	349	12,606
Depreciation and amortization expense	7,045	17,705	48,913	49,001
Stock-based compensation expense	14,691	4,458	18,643	15,241
Adjusted EBITDA	<u>\$ (36,216)</u>	<u>\$ (70,062)</u>	<u>\$(189,566)</u>	<u>\$(255,309)</u>

Free Cash Flow

We define free cash flow as net cash used in operating activities less purchases of property and equipment. We believe free cash flow is a useful measure of liquidity that provides an additional basis for assessing our ability to generate cash. Some of the limitations related to the use of free cash flow as an analytical tool include:

- it does not reflect our future contractual commitments;
- it does not represent our total residual cash flow for a given period; and
- it may be calculated differently than similarly titled measures used by other companies, which reduces its usefulness as a comparative measure.

Because of these limitations, you should consider free cash flow alongside other financial performance measures, including net cash used in operating activities, capital expenditures, and our other GAAP results.

The following table provides a reconciliation of net cash used in operating activities, the most directly comparable financial measure presented in accordance with GAAP, to free cash flow for the periods presented:

	Three Months Ended March 31,		Years Ended December 31,	
	2025	2024	2024	2023
	(In thousands)			
Net cash used in operating activities	\$(31,338)	\$(73,925)	\$(245,199)	\$(276,100)
Less: purchases of property and equipment	(2,689)	(1,738)	(8,444)	(22,319)
Free cash flow	<u><u>\$(34,027)</u></u>	<u><u>\$(75,663)</u></u>	<u><u>\$(253,643)</u></u>	<u><u>\$(298,419)</u></u>

Liquidity and Capital Resources

Sources of Liquidity

We have incurred net losses and negative cash flows from operations since inception. We expect to incur additional net losses in the near future, and our expenses will increase as we continue to invest in developing new solutions, expand our organization, and increase our marketing efforts to continue to drive market adoption of our solutions. These investments, together with general and administrative expenses, have resulted in negative cash flows from operations of \$245.2 million and \$276.1 million for the years ended December 31, 2024 and 2023, respectively, and an accumulated deficit of \$2.6 billion as of March 31, 2025.

To date, we have funded our operations principally from the issuance of stock, term loan borrowings and convertible debt, and through revenue from molecular profiling and pharma research and development services. As of March 31, 2025, we had cash and cash equivalents of \$31.2 million and short-term marketable securities of \$2.2 million. We believe our existing cash and cash equivalents and anticipated cash flows from operations, together with the net proceeds from our 2025 Private Placement and this offering, will provide sufficient capital and liquidity to fund our operating expenses and capital expenditure requirements for at least the next 12 months after the completion of this offering. We will, however, continue to require additional capital to meet our operational needs. See “—Indebtedness” and “—Cash Requirements” below for additional information regarding our cash requirements and various factors that may impact our liquidity and capital resources, including the Non-conversion Amortization Payments (as defined below) in respect of our existing indebtedness.

Cash Flows

The following table summarizes our cash flows for the periods presented:

	Three Months Ended March 31,		Years Ended December 31,	
	2025	2024	2024	2023
	(In thousands)			
Net cash used in operating activities	\$(31,338)	\$(73,925)	\$(245,199)	\$(276,100)
Net cash provided by investing activities	\$ (2,689)	\$ 59,638	\$ 52,932	\$ 214,774
Net cash provided by financing activities	\$ 1,285	\$200,107	\$ 200,292	\$ 10,132

Operating Activities

Net cash used in operating activities during the year ended December 31, 2024 was \$245.2 million, which was primarily due to a net loss of \$281.9 million and a net change in our operating assets and liabilities of \$29.1 million, and offset by non-cash charges of \$65.8 million. The net change in our operating assets and liabilities was primarily the result of a \$33.8 million increase in accounts receivable, a \$1.4 million increase in prepaid expenses and other current assets, offset by a \$5.5 million decrease in supplies and a \$0.1 million decrease in other assets. Net non-cash charges, primarily consisted of \$48.9 million of

depreciation and amortization expense, \$18.6 million of stock-based compensation expense and \$7.1 million in amortization of debt discount costs, offset by a \$18.5 million gain within changes in the fair value of financial instruments.

Net cash used in operating activities during the year ended December 31, 2023 was \$276.1 million, which was primarily due to a net loss of \$341.4 million and a net change in our operating assets and liabilities of \$7.1 million, and offset by non-cash charges, net of \$72.4 million. The net change in our operating assets and liabilities was primarily the result of a \$15.1 million increase in accounts receivable, and offset by a \$7.2 million increase in accounts payable and a \$1.3 million increase in accrued expenses and other current liabilities. Net non-cash charges primarily consisted of \$49.0 million of depreciation and amortization, \$15.2 million of stock-based compensation expense, \$10.9 million of debt extinguishment expense, offset by a \$11.1 million gain within changes in the fair value of financial instruments.

Net cash used in operating activities during the three months ended March 31, 2025 was \$31.3 million, which was primarily due to a net loss of \$102.6 million and a net change in our operating assets and liabilities of \$13.3 million, offset by non-cash charges of \$57.9 million. The net change in our operating assets and liabilities was primarily the result of a \$1.7 million decrease in accounts payable, offset by a \$7.9 million decrease in accounts receivable, a \$2.5 million decrease in prepaid expenses and other current assets, a \$2.1 million decrease in supplies, and a \$2.6 million increase in accrued expenses and other liabilities. Net non-cash charges primarily consisted of \$7.0 million of depreciation and amortization expense, \$14.7 million of stock-based compensation expense and \$1.9 million in amortization of debt discount costs, offset by a \$32.3 million loss within changes in the fair value of financial instruments.

Net cash used in operating activities during the three months ended March 31, 2024 was \$73.9 million, which was primarily due to a net loss of \$111.0 million and a net change in our operating assets and liabilities of \$1.2 million, and offset by non-cash charges of \$38.3 million. The net change in our operating assets and liabilities was primarily the result of a \$2.4 million increase in accounts receivable, a \$0.1 million increase in prepaid expenses and other current assets, a \$2.8 million decrease in accounts payable, a \$0.8 million decrease in accrued expenses and other liabilities, offset by a \$4.0 million decrease in supplies and a \$0.3 million decrease in other assets. Net non-cash charges, primarily consisted of \$17.7 million of depreciation and amortization expense, \$4.5 million of stock-based compensation expense and \$1.6 million in amortization of debt discount costs, offset by a \$11.1 million loss within changes in the fair value of financial instruments.

Investing Activities

Net cash provided by investing activities during the year ended December 31, 2024 was \$52.9 million, which was primarily due to maturities of marketable securities of \$61.4 million, offset by purchases of purchases of property and equipment of \$8.4 million.

Net cash provided by investing activities during the year ended December 31, 2023 was \$214.8 million, which was primarily due to maturities of marketable securities of \$300.5 million, offset by purchases of marketable securities of \$63.4 million and purchases of property and equipment of \$22.3 million.

Net cash used in investing activities during the three months ended March 31, 2025 was \$2.7 million, which was primarily due to purchases of property and equipment of \$2.7 million.

Net cash provided by investing activities during the three months ended March 31, 2024 was \$59.6 million, which was primarily due to maturities of marketable securities of \$61.4 million, offset by purchases of property and equipment of \$1.7 million.

Financing Activities

Net cash provided by financing activities during the year ended December 31, 2024 was \$200.3 million, which was primarily due to proceeds from issuance of additional borrowings under the 2023 Term Loan Agreement (as defined below) on March 5, 2024, net of issuance costs, of \$200.0 million.

Net cash provided by financing activities during the year ended December 31, 2023 was \$10.1 million, which was primarily due to proceeds from issuance of the initial borrowing under the 2023 Term Loan Agreement, net of issuance costs, of \$189.0 million, offset by the repayment of the prior term loans of \$180.0 million.

Net cash provided by financing activities during the three months ended March 31, 2025 was \$1.3 million, which was primarily due to proceeds from exercises of stock options of \$1.4 million, offset by the payment of deferred offering costs of \$0.1 million.

Net cash provided by financing activities during the three months ended March 31, 2024 was \$200.1 million, which was primarily due to proceeds from issuance of additional borrowings under the 2023 Term Loan Agreement on March 5, 2024, net of issuance costs, of \$200.0 million.

Indebtedness

In January 2023, we entered into a term loan agreement, as amended (the “2023 Term Loan Agreement”) with OrbiMed Royalty & Credit Opportunities III, LP, OrbiMed Royalty & Credit Opportunities IV, LP, and Braidwell Transaction Holdings LLC (the “Lenders”), pursuant to which we issued senior, secured promissory notes and the Lenders agreed to lend us up to an aggregate principal amount of \$400.0 million (the “2023 Term Loan”), \$200.0 million of which was drawn down upon issuance of the notes. Net cash proceeds to us were \$189.0 million, after deducting customary debt discounts and debt issuance costs. The net proceeds were used to repay in full our then-outstanding term loans, including an aggregate principal amount of \$175.0 million, a prepayment premium of \$5.0 million, and accrued and unpaid interest of \$1.0 million. In March 2024, we drew down the remaining \$200.0 million under the 2023 Term Loan Agreement. As of March 31, 2025, we had \$400.0 million of borrowings outstanding under the 2023 Term Loan Agreement.

The aggregate principal amount outstanding under the 2023 Term Loan Agreement is due and payable on January 18, 2028. If an event of default occurs and is continuing, the lenders may declare all amounts outstanding under the 2023 Term Loan Agreement to be immediately due and payable. A final payment exit fee equal to 2.0% of the amount funded under the 2023 Term Loan Agreement is due upon prepayment or maturity. Amounts borrowed pursuant to the 2023 Term Loan Agreement may be prepaid at any time. Upon prepayment, we may be subject to a prepayment penalty based on the timing of repayment.

Additionally, pursuant to the terms of the 2023 Term Loan Agreement, on the earlier to occur of (x) for dates prior to January 1, 2026, any date that the redemption rights in respect of our Series C preferred stock, Series D preferred stock, or Series E preferred stock are or may become exercisable within 90 days following such date, or (y) January 1, 2026 or the first date thereafter if, as of such date, the redemption rights in respect of our Series C preferred stock, Series D preferred stock, or Series E preferred stock are or may become exercisable on or prior to the date that is six months after the maturity date, we will be required to make a one-time payment in an amount equal to 15% of the outstanding principal amount under the 2023 Term Loan Agreement together with any applicable repayment premium and exit fee as described in the 2023 Term Loan Agreement and, commencing with the first full fiscal quarter following such payment, we will be required to repay 2.5% of the outstanding principal amount in equal quarterly installments each quarter thereafter (such payments, the “Non-conversion Amortization Payments”). The Series C preferred stock redemption rights may be exercised on or after March 31, 2026, and the Series D preferred stock and Series E preferred stock redemption rights may be exercised on or after May 11, 2026. All outstanding shares of our Series C preferred stock, Series D preferred stock, and Series E preferred stock will convert into shares of common stock as part of the Preferred Stock Conversion and any redemption rights thereunder will terminate in connection with the completion of this offering and consequently, the Non-conversion Amortization Payments discussed above would not be applicable following the completion of this offering.

The aggregate principal amount under the 2023 Term Loan Agreement bears interest at a rate per annum equal to a fixed margin of 6.5% plus the greater of (a) forward-looking three-month secured overnight financing rate (“SOFR”) and (b) 2.5%. In the event of default, the fixed margin shall increase by 3.0% per annum. As of December 31, 2024, the interest rate was 11.1%. Regular quarterly payments are interest-only for the 60-month term of the 2023 Term Loan Agreement, with the principal due at maturity. The effective interest rate for the term loan is 17.0%.

Our obligations under the 2023 Term Loan Agreement are secured by a first lien security interest in substantially all of our assets and our subsidiaries' assets. The 2023 Term Loan Agreement contains certain customary representations and warranties, affirmative and negative covenants, financial covenants, and events of default applicable to us and our subsidiaries. Additional covenants include those restricting dispositions, fundamental changes to its business, mergers or acquisitions, indebtedness, encumbrances, distributions, investments, transactions with affiliates, and subordinated debt. As of March 31, 2025, we were in compliance with all covenants under the 2023 Term Loan Agreement.

On April 1, 2025, we closed a private financing in which we issued a combination of senior convertible notes (the "2025 Convertible Notes"), Series E convertible preferred stock and Series F convertible preferred stock, for an aggregate of \$167.7 million. The 2025 Convertible Notes have an aggregate principal amount of \$30.0 million. The 2025 Convertible Notes accrue interest at a rate of 8% per annum, payable quarterly in cash, and mature on January 1, 2026. In connection with this financing, we also issued warrants to acquire shares of common stock to the holders of the 2025 Convertible Notes. These warrants are not initially exercisable for any shares of common stock, but such warrants become exercisable for a specified dollar value of shares on a monthly basis commencing on June 1, 2025 if we have not completed an initial public offering by such date. Any exercisable portion of the warrants will be automatically exercised prior to the closing of the initial public offering and such warrants will terminate upon the closing of the offering.

Immediately prior to and in connection with the completion of the initial public offering, the 2025 Convertible Notes, Series E convertible preferred stock and Series F convertible preferred stock (plus accrued interest in connection with the 2025 Convertible Notes and an 8% accretion in connection with the preferred stocks) will convert into common stock at a price equal to 70% of the initial public offering price per share.

Cash Requirements

Our primary use of cash is to fund operating expenses and capital expenditures (including leases of equipment and buildings), which consist of research and development expenditures, general and administrative expenditures, clinical and regulatory expenditures, purchases of testing equipment, and buildout of our laboratories. Cash used to fund such activities is impacted by the timing of when we pay or prepay these expenses.

The following table summarizes our material cash requirements as of December 31, 2024:

	Total	Due by			
		2025	2026	2027	Thereafter
		(In thousands)			
Operating leases	\$ 69,312	\$ 10,718	\$10,071	\$ 7,082	\$ 41,441
Finance leases	387	117	118	117	35
Term loans and interest ⁽¹⁾	516,813	97,360	36,819	36,819	345,816
Total material cash requirements	<u>\$586,512</u>	<u>\$108,195</u>	<u>\$47,008</u>	<u>\$44,018</u>	<u>\$387,292</u>

- (1) Excludes the Non-conversion Amortization Payments described above under "—Indebtedness," as such payment will not be required if this offering is completed prior to December 31, 2025 (the date that is 90 days prior to March 31, 2026, the first date the Series C preferred stock redemption rights may be exercised, if such rights are not earlier amended, waived, or terminated).

We will continue to require additional capital to fund our operations and to continue to fund investments in the development and marketing of our solutions for the foreseeable future. We may need or determine to raise additional capital through private or public equity or debt financings, through collaborative or other arrangements with corporate sources, or through other sources of financing. Requirements for additional capital will depend on many factors, including:

- the scope, timing, rate of progress and costs of our research efforts, preclinical development activities, laboratory testing, and clinical trials for our solutions;

- the number and scope of clinical programs we decide to pursue;
- the cost, timing, and outcome of preparing for and undergoing regulatory review of our solutions;
- the scope and costs of development and commercial manufacturing activities;
- the cost and timing associated with commercializing our solutions if they receive marketing approval;
- the extent to which we acquire or in-license other complementary solutions or technologies;
- the costs of preparing, filing, and prosecuting patent applications, maintaining and enforcing our intellectual property rights, and defending intellectual property-related claims;
- our ability to establish and maintain collaborations on favorable terms, if at all;
- our efforts to enhance operational systems and our ability to attract, hire, and retain qualified personnel;
- our success in achieving broad coverage and adequate reimbursement for our solutions from third-party payers;
- our implementation of operational, financial, and management systems; and
- the costs associated with being a public company.

A change in the outcome of any of these or other variables with respect to the development and commercialization of any of our solutions could significantly change the costs and timing associated with such development and commercialization. Furthermore, our operating plans may change in the future, and we will continue to require additional capital to meet operational needs and capital requirements associated with such operating plans.

We may experience increased costs and be required to raise additional capital much sooner than anticipated. In April 2025, we issued the 2025 Convertible Notes and shares of our convertible Series E preferred stock and convertible Series F preferred stock. Further, if the Series C preferred stock redemption rights described above have not been amended, waived, or otherwise terminated prior to December 31, 2025 (the date that is 90 days prior to March 31, 2026, the first date on which such redemption rights would become exercisable), we will be required to make the Non-conversion Amortization Payments following such date. See “—Indebtedness” above. If this offering is not completed by such date and such early repayment and the repayment on maturity of the 2025 Convertible Notes are required, based on our existing assumptions and expenditures, our existing cash resources and projected operating cash flows would not be sufficient to fund our operating expenses and capital expenditure requirements for at least the next 12 months from the date of this prospectus. These conditions indicate the existence of a material uncertainty that raises substantial doubt as to our ability to continue as a going concern. See Note 1 of our consolidated financial statements included elsewhere in this prospectus.

Critical Accounting Policies and Estimates

Our consolidated financial statements have been prepared in conformity with GAAP. Any reference in these notes to applicable guidance is meant to refer to GAAP as found in the Accounting Standards Codification (“ASC”) and Accounting Standards Updates (“ASUs”) of the Financial Accounting Standards Board (“FASB”). The preparation of the consolidated financial statements in conformity with GAAP requires the use of estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the consolidated financial statements, and the reported amounts of revenues and expenses during the reporting periods.

While our significant accounting policies are described in Note 2 to our consolidated financial statements included elsewhere in this prospectus, we believe that the following critical accounting policies are most important to understanding and evaluating our reported financial results.

Revenue

We recognize revenue in accordance with ASC Topic 606, *Revenue from Contracts with Customers* (“ASC 606”).

ASC 606 provides a five-step framework through which revenue is recognized when control of promised goods or services is transferred to a customer at an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. To determine revenue recognition for arrangements that are within the scope of ASC 606, we perform the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract(s); (iii) determine the transaction price, including whether there are any constraints on variable consideration; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) we satisfy a performance obligation. At contract inception, once a contract is determined to be within the scope of ASC 606, we assess whether individual goods or services promised within each contract are distinct and, therefore, represent separate performance obligations.

Molecular Profiling Services

We recognize revenue from our molecular profiling services at the time when the results of the profiling services are delivered to ordering physicians, including certain hospitals, cancer centers, and institutions. We identify each sale of our profiling case as a single performance obligation. We estimate the transaction price based on our historical collection experience using a portfolio approach for third-party payers and patients with similar reimbursement characteristics. This includes analysis of an average reimbursement per case per portfolio and a percentage of cases reimbursed by considering the historical reimbursement data (including any refunds and recoupments) from such third-party payers and patients, current contractual and statutory requirements, patient insurance eligibility and payer reimbursement contracts, and any known or current or anticipated reimbursement trends not reflected in the historical data. We monitor the estimated amount to be collected in the portfolio at each reporting period. Subsequent changes to the estimate of the transaction price are generally recorded as adjustments to molecular profiling services in the period of change.

Pharma Research and Development Services

Contracts with biopharma partners may include multiple distinct performance obligations, such as provision of molecular profiling services, pharma research and development services, and strategic data services. For each of our contracts with biopharma partners, we evaluate the terms and conditions to identify distinct performance obligations. For each performance obligation determined, based on when and how it is delivered, we recognize revenue either when or as such obligation is delivered. Under contracts that include a performance obligation to provide molecular profiling services, to facilitate the development and regulatory approval of drugs, or to provide target discovery services, we receive payments upon the achievement of milestones, as well as provision of on-going support. We recognize pharma research and development services revenue over the period in which pharma research and development services are provided. Depending on the nature of the service, we recognize revenue using either the output or input method to measure progress, whichever provides a more faithful depiction of the transfer of goods or services. Use of an output method or input method to depict the transfer of services generally does not result in a material difference with respect to the timing of revenue recognition because most services commence and end within the same reporting period. We determine the transaction price of each performance obligation by considering the historical selling price of similar transactions, where applicable, as well as other factors, including, but not limited to, the price that customers in the market would be willing to pay, competitive pricing of our competitors, industry publications, and current pricing practices.

Stock-Based Compensation

We have granted stock-based awards consisting primarily of stock options and RSUs to employees, consultants, and members of our board of directors. We account for stock-based compensation in accordance with ASC Topic 718, *Compensation—Stock Compensation*. Stock-based compensation expense is measured based on the fair value of the awards as of the grant date and is recognized as expense over the requisite service period, which is generally the vesting period.

The fair value of stock option awards as of the date of the grant is estimated by applying the Black-Scholes option pricing model. The Black-Scholes option pricing model requires the use of highly

subjective and complex assumptions, which determine the fair value of stock-based awards. These assumptions include the following:

- *Fair value per share of the underlying stock.* As our common stock is not publicly traded, the fair value of the common stock underlying our stock options is determined by our board of directors, with input from management and valuation reports prepared by third-party valuation specialists as described below under “—Common Stock Valuations.”
- *Expected price volatility.* As we are not a publicly traded company, the expected price volatility for our stock options is determined by using an average of historical volatilities of selected industry peers deemed to be comparable to our business and corresponding to the expected term of the awards.
- *Risk-free interest rate.* The risk-free interest rate is based on the U.S. treasury yield curve in effect at the time of grant for U.S. treasury notes with maturities corresponding to the expected term of the awards.
- *Expected term.* The expected term of stock options represents the period of time over which the options granted are expected to remain outstanding and is based on our estimate, taking into consideration vesting terms, contractual terms, and historical actual lives. Options granted have a maximum term of 10 years. Due to the lack of historical option exercise data, we utilize the simplified method for determining the expected term.
- *Expected dividend rate.* We have never declared or paid any cash dividends, and we do not intend to pay any cash dividends in the foreseeable future. Therefore, we use an expected dividend yield of zero percent.
- *Expected forfeitures.* Forfeitures are estimated at the time of grant and reduce compensation expense ratably over the vesting period. This estimate is based on historical forfeitures and is adjusted periodically based on the extent to which actual forfeitures differ, or are expected to differ, from the previous estimate.

We will continue to use judgment in evaluating the assumptions related to our stock-based compensation on a prospective basis. As we continue to accumulate additional data related to our common stock, we may refine our estimation process, which could materially impact our future stock-based compensation expense.

In connection with this offering, we expect to incur approximately \$28.9 million of stock-based compensation expense related to RSUs granted through March 31, 2025, for which the performance-based vesting condition will be satisfied in connection with this offering.

Common Stock Valuations

Prior to this offering, given the absence of a public trading market for our common stock, and in accordance with the American Institute of Certified Public Accountants Accounting and Valuation Guide, *Valuation of Privately-Held Company Equity Securities Issued as Compensation*, our board of directors exercised reasonable judgment and considered numerous objective and subjective factors to determine the best estimate of fair value of our common stock at each grant date, including:

- independent third-party valuations of our common stock;
- the prices of recent issuances of convertible preferred stock by us to investors in arm’s-length transactions;
- the rights, preferences, and privileges of our convertible preferred stock relative to our common stock;
- our performance and market position relative to comparable publicly traded companies;
- the likelihood and timing of achieving a liquidity event, such as an initial public offering or sale of our company, given prevailing market conditions;
- our developments and milestones;

- our current business conditions and projections;
- the lack of marketability inherent in our common stock; and
- the general economic outlook and global economic trends.

In valuing our common stock, the fair value of our business, or enterprise value, was determined using the market approach and/or income approach. The market approach estimates value based on a comparison of the subject company to comparable public companies in a similar line of business. From the comparable companies, a representative market value multiple is determined and then applied to the subject company's financial results to estimate the value of the subject company. The precedent transaction method, a form of the market approach that derives the implied equity value from the recent issuance of stock by the subject company, was also utilized when appropriate. The income approach estimates value based on the expectation of future cash flows, which are then discounted to present value.

For each valuation, the equity value, which is calculated as the enterprise value, adjusted for cash and debt, was then allocated to the common stock using the option pricing method ("OPM") and/or the probability-weighted expected return method ("PWERM"). The OPM allocates the equity value to the various share classes based on differences in liquidation preferences, participation rights, dividend policy, and conversion rights, using a series of call options. The call right is valued using a Black-Scholes option pricing model. The PWERM employs additional information not used in the OPM, including the likelihood and potential timing of various discrete future liquidity scenarios, such as an initial public offering.

Application of these approaches involves the use of estimates, judgment, and assumptions that are highly complex and subjective, such as those regarding our expected future revenues, expenses, cash flows, discount rates and market multiples, the selection of comparable companies, and the probability of possible future events. Changes in any or all of these estimates and assumptions, or the relationships between those assumptions, impact our valuations as of each valuation date and may have a material impact on the valuation of our common stock.

Following this offering, it will not be necessary to estimate the fair value of our common stock, as our shares of common stock will be traded in the public market, and the fair value of our common stock will be based on the closing price of our common stock as reported by Nasdaq.

Emerging Growth Company Status

The JOBS Act permits an "emerging growth company" such as us to delay the adoption of new or revised accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of this extended transition period for complying with new or revised accounting standards and, as a result, our results of operations and financial statements may not be comparable to those of companies that have adopted the new or revised accounting standards. We will remain an emerging growth company until the earliest to occur of: (1) the last day of the fiscal year in which we have at least \$1.235 billion in total annual gross revenue; (2) the last day of the fiscal year in which we are deemed to be a "large accelerated filer" as defined in Rule 12b-2 under the Exchange Act, which would occur if the market value of our common stock held by non-affiliates exceeded \$700 million as of the last business day of the second fiscal quarter of such year; (3) the date on which we have issued more than \$1.0 billion in non-convertible debt securities during the prior three-year period; and (4) the last day of the fiscal year ending after the fifth anniversary of the date of the completion of this offering.

Recent Accounting Pronouncements

See Note 2 of our consolidated financial statements included elsewhere in this prospectus for more information regarding recently issued accounting pronouncements.

Quantitative and Qualitative Disclosures about Market Risk

Interest Rate Risk

The market risk inherent in our financial instruments and in our financial position represents the potential loss arising from adverse changes in interest rates. As of March 31, 2025, we had cash, cash

equivalents, and restricted cash of \$35.3 million, and short-term marketable securities of \$2.2 million, consisting of interest-bearing money market accounts, for which the fair market value would be affected by changes in the general level of United States interest rates. However, due to the short-term maturities and the low risk profile of our investments, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our cash and investments.

Our borrowings under the 2023 Term Loan Agreement also subject us to market risk associated with movements in interest rates associated with forward-looking three-month SOFR. We had \$400.0 million in variable rate debt outstanding as of March 31, 2025. A hypothetical 100 basis point adverse movement in the interest rate would increase our annual interest expense by \$4.0 million. We hedge interest rate risk on \$200.0 million of this variable rate debt with a purchased interest rate cap derivative that has a strike rate of 6.0%. We did not receive any settlement payments from the counterparty to the interest rate cap for the year ended December 31, 2024 or the three months ended March 31, 2025.

Foreign Currency Risk

Substantially all of our revenue is generated in the United States, and we do not believe we are currently subject to significant foreign currency risk. To date, foreign currency transaction gains and losses have not had a material impact on our operations, and we have not engaged in any foreign currency hedging transactions. As we expand our presence in the international market, our results of operations and cash flows are expected to increasingly be subject to fluctuations due to changes in foreign currency exchange rates and may be adversely affected in the future due to changes in foreign exchange rates. We will continue to reassess our approach to manage risk relating to fluctuations in currency rates as our international operations grow.

BUSINESS

Overview

We are a leading, patient-centric, next-generation AI TechBio company and precision medicine pioneer. We develop and commercialize innovative solutions to transform healthcare through the use of comprehensive molecular information and artificial intelligence/machine learning algorithms at scale. Our entire portfolio of precision medicine solutions is designed to benefit patients, with an initial focus on oncology, and serves the clinical, academic, and biopharma markets.

We founded Caris in 2008 with the belief and vision that combining a vast set of consistently generated molecular information with robust data-driven insights could realize the potential of precision medicine for patients. We have spent the last 17 years developing and building our portfolio of comprehensive, proprietary molecular profiling solutions and generating what we believe to be one of the largest and most comprehensive multi-modal clinico-genomic datasets in oncology based on the more than 6.5 million tests we have run on over 849,000 cases, which have generated measurements of over 38 billion molecular markers. Our platform is purpose-built to leverage the convergence of next-generation sequencing (“NGS”), artificial intelligence (“AI”) and machine learning (“ML”) technologies, and high-performance computing. The power of our differentiated Caris platform has enabled us to develop the latest generation of advanced precision medicine diagnostic solutions designed to address the entire cancer care continuum, including early detection, minimal residual disease (“MRD”) tracking, therapy selection, and treatment monitoring, as well as to create molecular signatures and discover and develop novel precision medicine therapeutics. Our current commercial product portfolio is focused on oncology and consists of MI Profile, our tissue-based molecular profiling solution that has generated the majority of our revenue to date, and Caris Assure, our novel, universal blood-based molecular profiling solution that was broadly launched in the first quarter of 2024 for therapy selection.

Dysfunctionality at the molecular level underlies every chronic disease, and this dysfunction is now measurable using techniques such as NGS. Cells are embedded within highly complex biological networks that govern all aspects of life, including how these cells grow, divide, interact, and die. These biological networks and their inherent functions, as well as dysfunctions, are controlled and directed at the molecular level. The precise molecular origins or contributors to a given biological dysfunction, however, are often unknown, and a comprehensive molecular profile is necessary to determine these origins. The central dogma of molecular biology states that genetic information flows in one direction, from DNA, to RNA, to proteins. Our approach is designed to accurately capture the full breadth of the DNA and RNA coding information in cells as well as protein expression through immunohistochemical (“IHC”) tests, constructing a fulsome mosaic of disease, and ultimately unlocking the potential for precision medicine therapeutics to guide individualized patient diagnoses and treatment.

We believe we are well-positioned to realize the full potential of our vision and optimally leverage our vast datasets due to the recent convergence of several advancements in biology, medicine, and technology: (1) the medical community’s understanding and appreciation of the molecular nature of cancer has accelerated in recent years, resulting in a continued increase in molecular profiling of different cancer types and stages; (2) NGS costs have declined, making NGS more accessible to the healthcare ecosystem; (3) cloud-computing architecture has enabled massive scalability, distributed real-time collaboration, and greater cost efficiency for the analysis of previously unmanageable amounts of data; and (4) AI and ML computational capabilities have advanced to allow more effective interrogation of large biological datasets. We believe that our early foresight to generate comprehensive data at scale over the past many years and build a robust, foundational infrastructure have uniquely positioned Caris to leverage the benefits of these biological and technological advances to deliver transformative and advanced innovations in precision medicine and patient care into the future.

Our purpose-built, proprietary multi-omic profiling solutions capture and analyze molecular information from tissue and blood in a comprehensive manner. We provide whole exome sequencing (“WES”) (all 23,000 encoding DNA genes) and whole transcriptome sequencing (“WTS”) (all 61,000 RNA transcripts that encode proteins) on every eligible patient sample (a sample provided by ordering physicians that contains sufficient genetic material for profiling). Since launching our WTS solution in 2019 and WES solution in 2020, we have performed over 500,000 WES and WTS cases through May 2025, which we

believe is more than any other company. We sequence at a sector-leading depth of coverage, which directly correlates with increased accuracy and detection of low frequency molecular markers of relevance. MI Cancer Seek, our FDA-approved companion diagnostic assay to identify cancer patients who may benefit from treatment with targeted therapies (a component of MI Profile), consistently reaches 1,500 times depth of coverage for clinically relevant DNA genes, which is a higher sequencing depth than other assays available in the marketplace based on reported depths of coverage, and 300 times depth of coverage for the whole exome. Caris Assure features a raw average sequencing depth of 8,000 times for clinically relevant genes, similarly a higher sequencing depth than other assays available in the marketplace based on reported depths of coverage. We generate tens of billions of datapoints per clinical case to reveal an individualized molecular blueprint of the patient's disease. We believe this approach best positions us to provide actionable treatment pathways from targeted therapies to drive superior clinical outcomes for patients while also generating a rich dataset to power insights and innovation. To our knowledge, we remain the only genomic profiling company to consistently utilize WES and WTS as standard practice on every eligible patient sample. We also evaluate protein molecular markers through an extensive menu of IHC tests performed in a tumor-type specific manner, which in combination with WES and WTS, provide a comprehensive view of a patient's disease.

Our in-depth profiling of patient samples has led to the creation of what we believe to be one of the largest and most comprehensive multi-modal clinico-genomic datasets in oncology, including genomic data, clinical data, digitized slide images, and remnant tissue. As of March 31, 2025, we have run more than 6.5 million tests on over 849,000 cases, which have generated measurements of over 38 billion molecular markers. Leveraging high-powered computing and AI/ML algorithms, we, and our biopharma and research partners who use our data and bioinformatics services, analyze our datasets to determine the key molecular characteristics of a particular disease or dysfunction that drives disease, enabling signature identification and drug target discovery. As a leader in the transition to WES/WTS sequencing through our launch of a WTS solution in 2019 and a WES solution the following year, we believe we have more molecular data and information than any other company and are well-positioned to make precision medicine widely accessible. In 2018, our clinical case volume was approximately 29,000 cases, increasing to approximately 43,000 cases in 2019, approximately 60,000 cases in 2020, approximately 75,000 cases in 2021, approximately 97,000 cases in 2022, approximately 129,000 cases in 2023 and approximately 163,000 cases in 2024. Our clinical case volume for the first quarter of 2025 was approximately 45,900 cases, representing 31% year-over-year growth from approximately 34,900 clinical cases in the first quarter of 2024.

Our molecular profiling solutions and the data generated by our multi-omic technology platform provide value to our more than 100 biopharma partners, such as Moderna, AbbVie, Xencor, and Merck KGaA, through partnerships that aim to increase the probability of technical and regulatory success of their therapeutic pipelines. In addition to biopharma, we leverage our datasets to partner with outside academic centers and researchers to further advance precision oncology research. The Caris Precision Oncology Alliance ("Caris POA"), which we established in 2015, is a growing network of leading cancer centers and research consortia across the globe that collaborate to advance precision oncology and biomarker-driven research, with its members working together to establish and optimize standards of care for molecular testing through innovative research to improve clinical outcomes for cancer patients. As of March 31, 2025, the Caris POA was comprised of 96 members, including 45 National Cancer Institute ("NCI")-designated comprehensive cancer centers. This academic-industry collaborative network has been exceptionally productive with over 145 peer-reviewed manuscripts published since the beginning of 2022. Close connectivity with this vast network of key opinion leaders ("KOLs") in oncology clinical care, research, and drug development has enabled us to remain at the forefront of precision oncology and closely attuned to the key needs of the most sophisticated researchers.

Our Caris platform is designed to create a virtuous cycle that can enable continued innovation and improved impact for patients and physicians. We believe our comprehensive approach to profiling will continue to drive demand for our genomic profiling capabilities, leading to further expansion of our clinico-genomic datasets, which provide additional valuable inputs to develop and enhance our solutions, with the ultimate goal of contributing to improved patient results. This continuous feedback loop enabled us to develop Caris Assure, which utilized genomic data generated by MI Profile to inform our blood-based bioinformatics algorithms, allowing us to detect previously unknown features and signals in the blood that provide advanced insights into disease development. We believe we will be able to further leverage this process to

continue meaningful innovation in precision oncology as well as other chronic disease states, including cardiology, neurology, and metabolic conditions.

Our global annual clinical case volume has been growing rapidly, with year-over-year growth of 29% in 2022, 32% in 2023, 26% in 2024, and 31% in the first quarter of 2025, primarily driven by MI Profile. With our broad commercial launch of Caris Assure for therapy selection in the first quarter of 2024 and the FDA approval of MI Cancer Seek as a companion diagnostic in the fourth quarter of 2024 followed by the broad commercial launch of MI Cancer Seek in the first quarter of 2025 as the NGS component of MI Profile, we believe that increased profiling volumes will meaningfully contribute to our growth in 2025 and beyond. For the years ended December 31, 2024 and 2023, we generated total revenue of \$412.3 million and \$306.1 million, respectively. For the three months ended March 31, 2025 and 2024, we generated total revenue of \$120.9 million and \$80.7 million, respectively. We have incurred net losses and negative cash flows from operations since inception. For the years ended December 31, 2024 and 2023, we incurred net losses of \$257.1 million and \$341.4 million, respectively. For the three months ended March 31, 2025 and 2024, we incurred net losses of \$102.6 million and \$111.0 million, respectively. Our Adjusted EBITDA was \$(189.6) million and \$(255.3) million for the years ended December 31, 2024 and 2023, respectively. Our Adjusted EBITDA was \$(36.2) million and \$(70.1) million for the three months ended March 31, 2025 and 2024, respectively. For additional information regarding Adjusted EBITDA, a non-GAAP financial measure, see “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Non-GAAP Financial Measures.” We expect to incur additional net losses in the near future, and our expenses will increase as we continue to invest in developing new solutions, expand our organization, and increase our marketing efforts to continue to drive market adoption of our solutions. These investments, together with general and administrative expenses, have resulted in negative cash flows from operations of \$245.2 million, \$276.1 million, \$31.3 million, and \$73.9 million for the years ended December 31, 2024 and 2023 and the three months ended March 31, 2025 and 2024, respectively. Our free cash flow was \$(253.6) million and \$(298.4) million for the years ended December 31, 2024 and 2023, respectively, and \$(34.0) million and \$(75.7) million for the three months ended March 31, 2025 and 2024, respectively. For additional information regarding free cash flow, a non-GAAP financial measure, see “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Non-GAAP Financial Measures.” Additionally, as of March 31, 2025, we had cash, cash equivalents, and short-term marketable securities of \$33.4 million, and the aggregate principal amount of debt outstanding under our existing term loan was \$400.0 million. For additional information regarding our liquidity and capital resources, see “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources.”

Our Industry

Cancer is a Large and Growing Disease State with a Significant Human Cost and Economic Burden on Society

Addressing the complexity of cancer remains a major challenge in healthcare and a critical area of unmet medical need, despite enormous investments in research and development (“R&D”), and the introduction of new oncology therapeutics and treatments. According to the Centers for Disease Control and Prevention, cancer is the second leading cause of death in the United States, exceeded only by heart disease. The American Cancer Society (the “ACS”) reports that in January 2022, there were more than 18 million Americans with a history of cancer and that approximately two million new cancer cases will be diagnosed in 2024 in the United States. Furthermore, approximately 611,720 Americans are expected to die of cancer in 2024. The International Agency for Research on Cancer predicts that the annual global burden of cancer will reach 35 million new cases and 18.5 million cancer deaths by 2050.

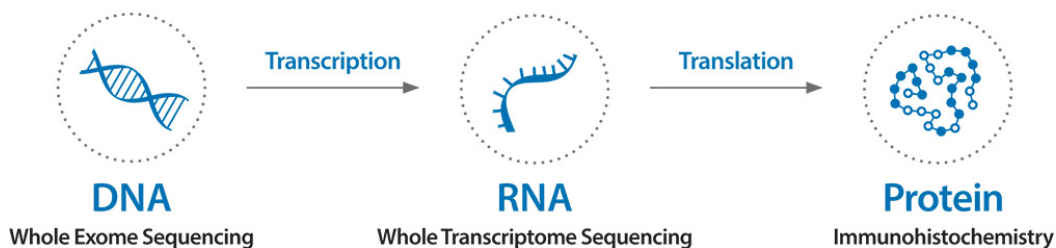
The annual burden of cancer care in the United States was more than \$200 billion in 2020 and is expected to increase over the coming decades. According to an article published in JAMA Oncology, a peer-reviewed medical journal published by the American Medical Association (the “AMA”), it is estimated that the total cumulative global economic cost of cancer from 2020 to 2050 will be approximately \$25 trillion. Better information and solutions are needed to detect and treat cancer earlier and more effectively to improve lives and manage healthcare costs.

The Central Dogma of Biology Drives the Fundamental Need for Comprehensive Molecular Information

At its core, cancer represents the uncontrolled division and growth of the body's cells. There are numerous biological processes in place for preventing the proliferation of cancerous cells. However, the failure of one or multiple genetic processes can lead to cancer. A cell is considered cancerous when it no longer responds to the body's attempts to control its growth, function, and location due to abnormalities in its DNA. The central dogma of biology states that genetic information flows in one direction, from DNA, to RNA, to proteins. Thus, when present, DNA abnormalities in the exome, also referred to as genomic mutations, are transcribed into defective RNA in the transcriptome. This defective RNA, in turn, is translated into defective proteins, ultimately causing a cell to replicate uncontrollably or become cancerous.

The behavior of a specific cancer cell depends on which processes are not functioning properly. Oncogenes are genes that, when aberrantly active, cause a normal cell to become cancerous. Tumor suppressor genes must remain activated to prevent cancer; if deactivated, the cell proliferates uncontrollably. Many cancers begin with a few discreet genomic mutations, but additional mutations accumulate as the cells divide. In addition, chemical modifications to proteins post-production, known as post-translational modifications, can impact structure and function and may also result in uncontrollable cell growth. This dynamic range of potential mutations results in varying cancer types. For example, some cancer cells may simply divide and produce more cancer cells locally, while other cancer cells may invade normal tissue, enter the bloodstream, and metastasize to a remote site in the body. Given the complexity of a cancer's origin and drivers, we believe comprehensive molecular information incorporating DNA, RNA, and protein profiles provides the most robust picture of a patient's disease and potential treatment pathways. The below graphic depicts the central dogma of molecular biology and the profiling technology that can be used to capture the relevant molecular information at each step.

Central Dogma of Molecular Biology



Technological Advancements have Ushered in a Molecular Revolution in Precision Oncology

The molecular revolution is upending the traditional paradigm of complex workflows of diagnosis, treatment, and monitoring of diseases, which largely uses a symptomatic, reactive approach to medicine. For example, early detection of cancer has traditionally been performed using a myriad of different non-molecular tests, including mammograms for breast cancer, colonoscopy and fecal immunochemical test for colorectal cancer, pap test for cervical cancer, and low-dose computed tomography ("CT") scan for lung cancer. Despite these techniques, cancers can still go undetected as many of these tests can be subject to interpretative bias or risk of inaccurate results. Further, prior to the use of genetic biomarkers for the treatment of cancers, all cancer patients were treated with generic chemotherapies with a broad applicability, often resulting in lower efficacy. Comprehensive molecular profiling is augmenting these different testing modalities by introducing streamlined workflows and replacing the patchwork of tests currently in use, using a small sample of the patient's tissue or blood.

Molecular profiling in oncology began with single-gene testing focused on individual genes in an attempt to match patients with effective targeted therapies. With the declining cost of sequencing and growing number of targeted therapies, profiling evolved to include targeted testing focused on a small number of identified gene alterations correlated with effective targeted therapies and further expanded to include profiling using 500 to 1,000 gene panels. These targeted profiling methods are now acknowledged as being inefficient in the use of limited tumor tissue, as they generate a sub-optimal and incomplete amount of

molecular information. For example, a study titled “Mutational Landscape of Metastatic Cancer Revealed from Prospective Clinical Sequencing of 10,000 Patients” published by authors associated with Memorial Sloan Kettering Cancer Center in New York in June 2017 in the scientific journal, *Nature Medicine*, found that “hotspot” panels can miss 81% of actionable mutations in refractory cancers.

Over the last several decades, significant advances in genomics, proteomics, molecular technology, and computing power have enabled a comprehensive, multi-omic approach to the molecular profiling of diseases, both efficiently and at scale. Innovations in genomic sequencing and computing power have revealed deep insights into the cellular pathways and molecular nature of all types of cancer, heralding a new era of precision oncology. For example, a 2004 study published in *Nature Reviews Cancer* identified approximately 300 genes as being linked to cancer; a 2022 *Genome Biology* study identified approximately 3,350 genes were well-known or predictive drivers of cancer; and a 2022 *Trends in Genetics* analysis showed that of the approximately 17,300 human genes with at least one paper in PubMed, approximately 15,200 have at least one paper mentioning cancer. Precision oncology is defined as the use of molecular profiling—including analysis of DNA, RNA, and proteins—to identify a cancer’s alterations that can be targeted with specific therapies. NGS, the most advanced high-throughput sequencing method, has far surpassed other techniques used to analyze tumors and has become a cornerstone of precision oncology. This is due in large part to the genomically-driven nature of cancer, as well as the continued ongoing steep declines in the cost of sequencing over the last 30 years and technology advances in speed and accuracy, which have made NGS far more available in the clinical setting.

The treatment paradigm for oncology continues to evolve with molecular medicine practiced across the entire continuum of the disease course: from using blood-based testing to detect cancers at its earliest stages; to the determination of whether a patient is at a high-risk of relapse after completing therapy; to the advanced/metastatic setting where molecular profiling is used to guide therapy interventions. Large scale studies interrogating cancers using NGS have led to the identification of thousands of biomarkers. Oncology therapeutics are now increasingly biomarker-driven targeted therapies. Over 100 biomarker-assisted therapeutics have been approved in the United States, and numerous clinical trials are currently in progress. In addition to being predictive markers for patients likely to benefit from certain treatments, biomarkers may also be used as diagnostic indicators of the presence or type of cancer, as prognostic indicators for patient outcomes, or as tools to monitor therapy response, residual disease, or recurrence.

The information provided by comprehensive molecular profiling is driving a revolution in medicine, where molecular information is used to guide individualized patient diagnoses and treatment. Beyond oncology, this precision medicine approach has applications across a wide range of broad disease areas including cardiology, neurology, and metabolic conditions, among other chronic diseases.

The Importance of Comprehensive Molecular Profiling

Comprehensive molecular profiling provides greater clinical and economic value than traditional targeted panel testing approaches. Comprehensive molecular profiling entails evaluating thousands of potential biomarkers, including DNA, RNA, proteins, and other molecular and clinical information for characteristics unique to a particular patient’s disease.

Case Study: Advancing Cancer Treatment with Caris Molecular Profiling

Caris was presented with the case of a female patient in her early 50's with a history of Stage I endometrial cancer. Her oncologist discovered a softball-sized tumor in her ovary. After undergoing a biopsy, it was determined to be late-stage ovarian cancer, which had metastasized into surrounding tissues and her bowels. She underwent immediate surgery to remove her ovaries and 18 inches of her sigmoid colon and began a standard chemotherapy regimen.

Despite the surgery and three rounds of chemotherapy, the cancer grew back within three months, now spreading into the patient's lymph nodes. Her oncologist recognized the urgency of her situation and sent the patient's tumor biopsy to Caris for molecular testing, noting additional rounds of chemotherapy would not be beneficial. The profiling using our MI Profile solution revealed the tumor was microsatellite instability-high, indicating responsiveness to immunotherapy and supporting her oncologists' prior suspicion of Lynch Syndrome, also known as hereditary nonpolyposis colorectal cancer ("HNPCC").

HNPCC is caused by mutations in genes responsible for DNA mismatch repair ("MMR"), leading to an accumulation of errors in DNA replication and an increased risk of cancer development. Individuals with HNPCC have a higher lifetime risk of developing various cancers, particularly colorectal and endometrial. Identifying it in patients can help guide screening and surveillance efforts to detect cancers at an early, more treatable stage, as well as inform preventive measures to reduce cancer risk for their families.

With the guidance of molecular profiling results, the patient commenced immunotherapy treatment, leading to remarkable results. Within three months, her tumor disappeared, and the cancer in her lymph nodes significantly regressed. The patient went from having no real treatment options to having multiple with the use of comprehensive profiling, and to our knowledge remains cancer-free. Additionally, the identification of Lynch Syndrome is invaluable in guiding screening and surveillance for her children and grandchildren.

This transformative outcome underscores the importance of comprehensive profiling in tailoring treatment strategies based on individual genetic profiles.

*The Importance of WES/WTS**DNA*

Mutations and copy number alterations (variations) can be detected using the polymerase chain reaction ("PCR") or NGS, while DNA methylation is analyzed using PCR or pyrosequencing, which is a method for sequencing short stretches of DNA on the basis of the detection of pyrophosphate. DNA sequencing can be performed for an entire genome, exome, or, as in the case of targeted panels, within specific regions containing common cancer-associated alterations. NGS-based targeted panels are currently FDA-approved for several tumor types. These targeted panels identify known alterations in key cancer genes but do not provide a comprehensive overview of a tumor's molecular makeup.

RNA

While mutations detected in DNA may be silent (not expressed) and therefore of little clinical relevance, those in RNA are one step closer to producing an abnormal protein. RNA is also needed to understand gene expression and splice variants through *in situ* hybridization and RNA sequencing. RNA sequencing provides information that DNA cannot and is superior for detecting expressed fusions.

As with DNA, RNA sequencing can be performed for one, multiple, or all transcribed genes, in either targeted areas or the full transcriptome. Transcriptome analysis using NGS generates information on splice variants and gene fusions, including fusions not previously described. This information can help define molecular signatures, stratify risk, and guide targeted therapy use. In combination with WES, WTS provides information on all expressed genes, thereby detecting alterations that can be targeted with FDA-approved therapies, standard-of-care treatments, and investigational therapies in clinical trials.

Case Study: The Importance of RNA Profiling

Caris was presented with the case of a teenaged boy diagnosed with high-grade astrocytoma, a type of brain tumor. Two years prior, the patient's oncologist had ordered DNA-only profiling from another provider who did not identify any actionable mutations in the patient's DNA. As a result, the patient was placed on a standard chemotherapy regimen.

Upon recurrence of the tumor two years later, the oncologist ordered genomic testing from the same provider, who again did not identify any actionable mutations in the DNA. The patient began radiation therapy. Despite the initial profiling attempt and results, the tumor's recurrence necessitated further investigation, leading the patient's healthcare team to seek out more comprehensive testing with Caris.

The Caris WES/WTS report revealed a significant finding: an FGFR fusion, which is a genetic alteration that can disrupt normal cell signaling and lead to cancerous cell growth, found in the patient's RNA. Despite the challenges posed by the tumor's recurrence, Caris' ability to detect this actionable variant offered hope for potential targeted therapies, including the National Cancer Institute-Children's Oncology Group Pediatric MATCH trial* for pediatric patients with advanced, recurrent solid tumors.

This case demonstrated the critical role of comprehensive molecular profiling of both the DNA and RNA. By leveraging advanced testing methodologies such as WES and WTS, the provider was able to uncover potentially life-saving treatment options for this patient facing a challenging diagnosis, high-grade astrocytoma.

Molecular Signatures

In addition to individual gene alterations, profiling can provide information on specific patterns or combinations of molecular features that might otherwise be challenging to detect. These molecular signatures may be associated with particular cancer types, prognoses, or therapeutic responses. Examples of molecular signatures include:

- **TMB:** TMB is a measurement of the number of somatic mutations per megabase of DNA sequenced. A high TMB is used as a biomarker for the selection of certain checkpoint inhibitors to treat solid tumors. WES is the gold standard for measuring TMB as it covers the entire coding region of the genome. Measurements derived from targeted panels or comprehensive genomic profiling, on the other hand, vary significantly from panel to panel due to variable and incomplete coverage.
- **Microsatellite instability ("MSI"):** MSI testing measures the ability of a cell to repair mistakes in DNA replication. Defective mismatch repair caused by alterations in mismatch repair genes is associated with elevated mutation rates in areas where short DNA sequences of base pairs are repeated. These areas are referred to as microsatellites. MSI analysis can identify candidates for immunotherapy or MSI-indicated clinical trials and diagnose Lynch Syndrome in colon and endometrial cancers.
- **Genomic loss of heterozygosity ("gLOH"):** Loss of one copy of a genomic region, known as gLOH, may cause tumor suppressor gene inactivation, thereby promoting cancer development. gLOH is indicative of a form of defective DNA repair called homologous recombination deficiency. When a tumor exhibits DNA repair mechanism impairment, drugs targeting a secondary repair pathway can kill tumor cells without harming normal cells, a phenomenon called synthetic lethality. Thus, gLOH is a biomarker for therapeutic response to poly adenosine diphosphate-ribose polymerase ("PARP") inhibitors which target the single-strand break DNA repair pathway.
- **Homologous recombination deficiency ("HRD"):** Related to gLOH, inefficient repair of damaged DNA via homologous recombination can contribute to the development of cancer. HRD often results from aberrations in key DNA repair genes, including BRCA1 and BRCA2 genes, ataxia telangiectasia mutated ("ATM"), PALB2, and CHEK2, and is associated with increased sensitivity to PARP inhibitors, as above.

* <https://www.cancer.gov/about-cancer/treatment/nci-supported/pediatric-match>

WES/WTS Offers a Complete Molecular Blueprint from the Beginning and Provides Value across the Patient Journey

WES/WTS streamlines the patient experience and clinical decision-making and offers increased value to patients, physicians, and payers. We believe WES/WTS provides the most efficient and cost-effective way to obtain the maximum information on a patient's cancer at the start of the patient journey, potentially identifying additional mutations and expanding treatment options compared to sequential targeted panels. Through the use of WES/WTS, we believe we have significantly reduced the need for a trade-off between time and information, two valuable resources in oncology that have historically come at the expense of one another, particularly when relying on sequential targeted panels, due to cancer's rapidly progressive nature. In a single test, we believe WES/WTS provides substantially all the relevant information needed for physicians to make the best-informed clinical decisions for their patients and does so in less time than running multiple DNA or RNA single or targeted panels sequentially. While using comparable tissue, WES/WTS enables accurate identification of a greater number of actionable genomic alterations that can be leveraged to match patients to the most effective treatments, yielding a higher probability of response and providing comprehensive predictive and prognostic information. Furthermore, the benefits conferred by WES/WTS have the potential to extend across the healthcare ecosystem, beyond patients and their clinicians. By supporting WES/WTS, payers can reduce waste and harm from suboptimal treatment selection and resulting over-treatment and/or misdiagnosis.

WES/WTS can also inform on acquired resistance to treatments and suggest potential synergistic therapy combinations, as well as providing substantial clinical benefit to patients with cancer of unknown origin or rare cancers. Additionally, by taking a tumor-agnostic approach compared to using tumor-specific panels, WES/WTS can detect biomarkers that have targeted therapies in other cancer types, indicating the potential to apply those drugs more broadly. Armed with these molecular insights, clinicians can identify the most suitable therapies and trials available to their patients today. Having a full molecular blueprint *in silico* also facilitates future use of newly approved biomarkers and therapies.

We also operate a Look Back Program that leverages our comprehensive WES/WTS to provide long-term clinical insights that help oncologists optimize patient care and identify patients that may be eligible for newly approved biomarker-driven therapies without the need for additional testing. When a novel therapy receives approval, our team reviews all of our recent clinical sequencing results to identify previously tested patients whose sequencing results match the new therapy's criteria. Through our molecular science liaisons ("MSLs"), we then contact treating physicians to ensure they are aware of these newly approved treatment options for their patients. Many clinicians may not be aware of evolving biomarker-driven therapies, and our Look Back Program bridges this gap by providing updated insights. By conducting comprehensive molecular testing upfront, the need for repeat testing is significantly reduced when new drug approvals or indications arise. This ensures timely treatment decisions, increasing the likelihood of patients receiving effective, biomarker-driven therapies. Through the Look Back Program, Caris empowers oncologists with continuous, data-driven insights that enhance patient outcomes and drive precision oncology forward. Since 2023, we have used this program to identify 556 patients that may benefit from Trastuzumab and Teucatinib for HER2+/KRAS wildtype colorectal cancer, 134 patients that may benefit from Talazoparib + Enzalutamide HRR deficient prostate cancer, 233 patients that may benefit from Reptrectinib for cancers with NTRK gene fusions, 1,737 patients that may benefit from Capivasertib for PIK3CA, AKT1 or PTEN-mutated HR+/HER2- breast cancer and 78 patients that may benefit from Zenocutuzumab for cancers with NRG1 fusions and 1,847 patients that may benefit from Trastuzumab Deruxtecan for Her2 Score 0 HR+ breast cancer. We have not broadly marketed our Look Back Program, but we use it in payer-facing materials to highlight the advantages of our WES/WTS platform.

Aside from its clinical benefits, WES/WTS is also a powerful research tool for identifying new predictive biomarkers. For example, pancreatic ductal carcinoma currently has the worst prognosis among common cancers—a situation compounded by a scarcity of predictive biomarkers and therapeutic targets. In a recent study, a comprehensive profiling approach involving WES and WTS sequencing was used to identify novel potential markers and targets for this cancer.

The table below compares targeted panels with WES/WTS.

Targeted Panels vs. Comprehensive (WES/WTS)	
TARGETED PANELS (50 - 1,000 GENES)	WES / WTS
 Less information Analyze specific genes, meaning that alterations outside of these genes are missed	 More information Analyze all known 23,000+ coding genes, resulting in unbiased detection of all alterations
 Slower time to actionable results Longer total run time when multiple sequential panels are needed to reach an actionable result	 Faster time to actionable results Comparable time to a single panel but offers a complete blueprint from the start
 Increased sample requirement Each sequential panel requires additional tissue. Tumor samples can become exhausted, necessitating further biopsy or cessation of testing	 Smaller sample requirement Uses a similar amount of tissue to a single panel and less overall material than multiple sequential panels
 Increased cost Although panels are individually cheaper than WES/WTS, cost adds up when running multiple panels	 Decreased cost Compared to running multiple panels, a single WES/WTS run comes at a similar cost and avoids unnecessary downstream costs
 Increased administrative burden Each panel requires ordering, separate billing, and reporting. Running multiple panels sequentially multiplies this effort	 Reduced administrative burden Single WES/WTS test requires ordering, one bill, and reporting only once
 Multiple partial reports Results of each panel are presented in a separate report, requiring additional time to consolidate, interpret, and prioritize results	 Single comprehensive report Results are presented, interpreted, and prioritized in a single report, thereby streamlining the clinical decision-making process

The Convergence of NGS, AI/ML Technologies, and High-Performance Cloud Computing

NGS can generate vast amounts of genomic data. The availability of large libraries of molecular data for each individual patient is creating exciting opportunities for research in the diagnosis, treatment, and early detection of cancer, especially when paired with a patient's clinical data.

AI can be used to mine these large volumes of data to address complex biological questions and has the potential to deliver new insights and bring precision medicine into mainstream clinical care. ML is an AI approach that focuses on applications that learn from experience and large amounts of data to improve decision-making and predictive accuracy over time. While this is a promising field of research and clinical activity, there are significant challenges to achieving the promise of AI in cancer—specifically, generating accurate and broad molecular information to underpin algorithms.

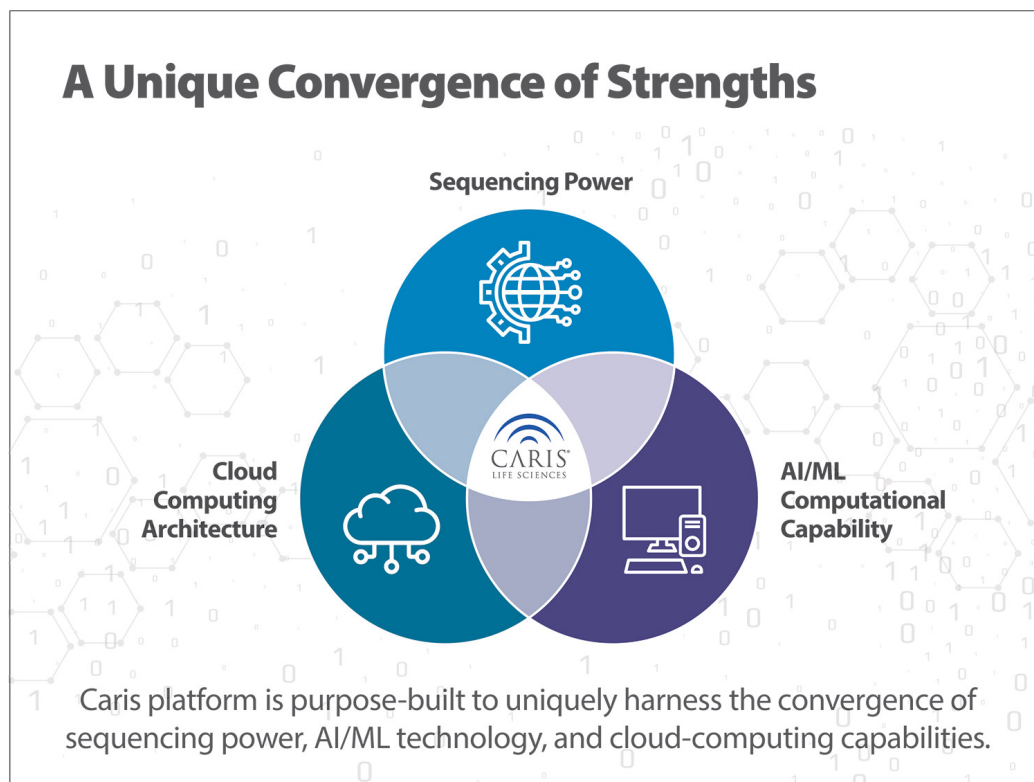
The accuracy of predictions made by AI/ML algorithms is highly dependent upon the accuracy and breadth of the underlying data used for training the AI/ML algorithms, analytically validating those algorithms, and applying the algorithms on real world data to make predictions. The accuracy of NGS-based genomic data is highly correlated to the depth of coverage of sequencing of the samples. Depth of coverage refers to the number of times a nucleotide is sequenced. A greater depth of coverage increases the confidence in the final results and allows for differentiation between sequencing errors and single nucleotide polymorphisms. A high depth of coverage is especially useful when a tumor is heterogeneous for specific mutations.

The ability to conduct research on genomic data using AI is also highly dependent on the number of genes being tested. Complex diseases are the result of multiple genomic alterations including point mutations, translocations, amplifications, and/or deletions. Cancers with more malignant properties and

poorer prognosis are generally associated with larger numbers of genomic alterations. To accurately conduct research using AI, a large number of genes need to be tested and included in a given data set.

Cloud-computing architecture has enabled massive scalability and distributed real-time collaboration across industries. In addition, it has created opportunities for greater cost efficiency for the storage, processing, and analysis of previously unmanageable amounts of data.

Our Caris platform was purpose-built to leverage the convergence of NGS, AI and ML technologies, and high-performance computing.



Limitations of Molecular Testing Today

While the molecular revolution has already changed the way cancer is being diagnosed and treated, we believe that molecular testing faces several major challenges in its current form, which have hindered broader adoption of precision oncology. These challenges include:

- **Targeted panels are subject to missing information and significant variability.** Targeted panels test for only a small portion of all cancer-associated genomic alterations. As a result, they can miss critical clinically actionable information. This information deficit can lead to suboptimal treatment decisions and/or the need for further testing, requiring increased patient sample, time, and expense. Further, the treatment landscape in oncology continues to rapidly evolve, with new agents and their cognate predictive biomarkers entering clinical trials and achieving regulatory approval. This renders targeted panels insufficient to account for newly implicated cancer genes absent re-development and validation of such panels. Using broad sequencing approaches with WES and WTS enables comprehensive identification of information to effectively treat a patient.
- **Lack of consistent RNA profiling.** RNA, which is transcribed from DNA, can better represent which genes are actively involved in cancer. By including both DNA and RNA

coverage, we believe Caris captures more tumor-informed information than others in the market, leading to more accurate and comprehensive molecular profiling results for the physician and patient. This approach includes enhanced sensitivity for gene fusions with the incorporation of RNA, as well as the deployment of multi-gene signatures that use RNA to support predictive and prognostic endpoints.

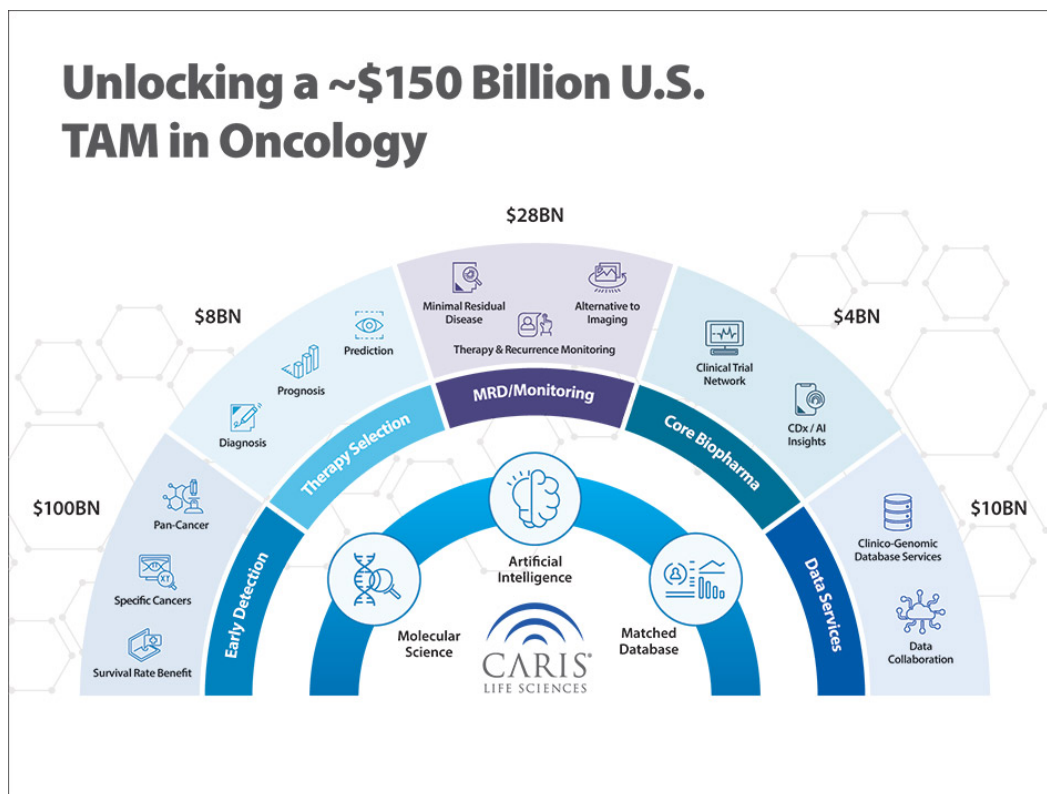
- **Lack of clonal hematopoiesis derived variant subtraction technology in current blood assays.** Blood is comprised of two major components that are pertinent to patient testing: plasma and the buffy coat (a concentration of white blood cells). Most liquid biopsy providers analyze only the plasma. This is suboptimal as a plasma-only approach is unable to identify false positive mutations derived from clonal hematopoiesis (“CH”) variants and that are not tumor-derived. CH mutations are common aging-related non-malignant mutations that occur in a substantial portion of the population and are not drivers of solid tumors but contribute to the formation of a genetically distinct subpopulation of blood cells. If CH mutations are not distinguished from tumor-derived mutations, it can lead to therapy selection targeted at a mutation that is present in the white blood cells instead of in the tumor, which is not beneficial for the cancer patient. Because of the prevalence of CH mutations, we believe that CH subtraction is of critical importance to optimal cancer care. Other liquid biopsy tests currently on the market cannot definitively distinguish CH mutations from tumor-derived mutations because they do not sequence the white blood cells. Caris Assure incorporates CH subtraction, resulting in fewer false positives and representing a differentiated ability to drive improved and more effectively targeted therapy selection.
- **Disparate data sets collected across testing modalities.** Currently, liquid biopsy providers do not offer a single blood-based testing solution across the continuum of cancer care. Instead, the use of different assay technologies across different applications and settings results in the accumulation of non-uniform data sets, which are difficult to leverage and interpret across a patient’s comprehensive care journey. We utilize a novel approach consisting of a single wet-lab test across the cancer treatment continuum, with consistently-generated uniform datasets. The elegant simplicity of a single test paired with a comprehensive assessment of the patient’s DNA and RNA allows Caris Assure to be this integrated diagnostic solution. This approach allows many more datapoints to be assessed, enabling us to select those markers that we believe provide the greatest potential for sensitivity, specificity, and overall accuracy of our test and capture the dynamic nature of biological processes.
- **Logistical drawbacks and sensitivity limitations of current MRD assays.** There are several limitations with current MRD approaches. Traditional tumor-informed approaches struggle with logistical drawbacks, which include needing to sequence primary tumor tissue first and experiencing long turn-around times due to the creation of a bespoke panel. Further, current tumor-informed MRD tests also limit their sensitivity by the small number of tracker mutations utilized. Because sensitivity is proportional to the numbers of tumor-derived alterations that are tracked over time, limiting to a small number of mutations artificially limits sensitivity. Currently deployed tumor-naïve approaches, while logistically superior, also limit their sensitivity by using a targeted panel of genes and do not encompass the myriad of tumor-derived signals present in the circulation.
- **False positives and a lack of early-stage sensitivity with current multi-cancer early detection assays.** Multi-cancer early detection (“MCED”) testing holds significant promise to make improvements in overall survival by detecting cancers at their earliest stages when they are most treatable. However, significant limitations exist with current assays. Their high rate of false positives when used in an average-risk population is notable. This leads to unneeded and costly diagnostics, such as imaging and biopsies. Also, a lack of early-stage sensitivity for many tumor types inhibits current MCED testing assays’ clinical utility. As seen in our data, the use of Caris Assure and our Assure Blood-based Cancer Detection ai (“ABCDai”) algorithm leverages detection of a wide swath of cancer-derived analytes, resulting in significantly higher Stage I/II sensitivity while mitigating false positives by maintaining high specificity.

As a result of these challenges, clinicians may make critical treatment decisions based on incomplete and/or inaccurate information and analytics, potentially resulting in suboptimal outcomes. We believe that

our comprehensive molecular profiling solutions and the data generated by our multi-omic technology platform is well-suited to address the limitations and challenges of today's molecular testing alternatives.

Our Market Opportunity and Vision for Leveraging Molecular Information

We believe we are well-positioned to pursue a very large market opportunity through the provision of precision medicine solutions across the entire cancer care continuum, as well as offerings to support biopharma drug discovery and development. Broad, deep, and consistent molecular information is expected to drive better clinical outcomes for patients and more efficient and effective drug discovery and development for biopharma companies. We believe our expansive multi-omic technology platform has application across multiple clinical and biopharma settings that collectively represent an estimated total addressable U.S. market of approximately \$150 billion in oncology, according to a market study by Nephron Research LLC ("Nephron Research") that we commissioned.



Early Detection of Cancer in the Asymptomatic Population

The availability of an MCED blood-based profiling solution offers the potential to augment and disrupt the standard of care in preventative cancer screening. Preventative cancer screening today is limited to a small group of high prevalence cancers, including cervical, breast, colon, lung, and prostate cancers. Low adherence rates are common among patients with several of these cancers due to challenges related to socioeconomic status, age, personal attitudes and beliefs, awareness gaps, and lack of access to healthcare facilities and social support, among other factors. For example, the American Lung Association estimates that in 2021, there were approximately 14 million high-risk individuals in the United States who were eligible for lung cancer screening using low-dose CT scans yet only approximately 0.6 million screenings were completed, representing a dismal screening recommendation adherence rate of 4.5%. An MCED blood-based profiling solution that entails a minimally invasive blood draw could expand the reach of testing to more cancers and drive higher adoption in this market.

We believe screening offers the greatest benefit for individuals aged 45 to 75 years given the prevalence of cancer and potential for improved outcomes and reduction in cancer mortality within the U.S. population. Based on U.S. Census Bureau data, the 45 to 75 years-old cohort who would benefit from screening for cervical, breast, colon, lung, and prostate cancers based on the recommendations of the U.S. Preventive Services Task Force (“USPSTF”), an independent body of experts that makes evidence-based recommendations for cancer screening, represents approximately 112 million people in the United States. Clinical unmet needs in this population include low patient adherence, poor performance, and lack of screening options for a majority of cancer types. Access to liquid biopsies that are reliable and can detect multiple cancer types should drive greater access and penetration of the early detection market, with early detection liquid biopsy solutions supplementing or in certain instances replacing existing screening modalities. Based on the estimated size of the cohort of individuals aged 45 to 75 years who would benefit from cancer screening per the above-referenced guidelines, and assuming pricing of at least \$900 for a high-quality MCD liquid biopsy solution (based on cash pay pricing for existing available liquid biopsies), the estimated total addressable U.S. market for early detection of cancer using liquid biopsy is approximately \$100 billion.

Therapy Selection for Cancer Patients

Patients with advanced and metastatic solid tumors are recommended to undergo molecular profiling to identify predictive markers for patients likely to benefit from certain approved biomarker-linked therapies. Molecular profiling of patients through either tissue biopsy or blood-based liquid biopsy allows physicians to identify a cancer’s targetable alterations. These molecular insights, particularly when generated through comprehensive molecular profiling, enable the tailoring of therapy to patients likely to benefit, while sparing exposure, toxicity, and cost for those who will not.

According to the ACS, approximately 780,000 of the two million patients in the United States who are newly diagnosed with cancer each year are found to have advanced-stage solid tumor cancers at initial diagnosis. The ACS also estimates that there are 16.5 million cancer survivors in the United States, approximately 4.3%, or 710,000, of whom are expected to relapse annually. Based on National Comprehensive Cancer Network (“NCCN”) guidelines suggesting that breast and lung cancer patients would benefit from at least two tests during therapy, and assuming that these benefits would apply to other types of solid tumors, Nephron Research estimates that approximately 520,000 newly-diagnosed advanced stage and recurrent cancer patients in the United States would benefit from repeat testing. Additionally, turnaround time for a blood test is typically shorter, but tissue tests are often more comprehensive so physicians will often order both a tissue test and a blood test. Accordingly, based on the newly-diagnosed patient, recurrent patient, and repeat testing patient cohorts described above, Nephron Research estimates that the total addressable U.S. market for therapy selection is comprised of approximately two million unique patient profiles annually and, assuming an average reimbursement of approximately \$4,000 based on blended Medicare, commercial payer, and Medicaid coverage rates for various genomic profiling tests, amounts to approximately \$8 billion.

According to the Nephron Research analysis, the number of annual unique patient profiles is expected to increase with clinical and payer adoption of broad molecular testing in earlier stages for newly-diagnosed cancer patients. The study also suggests that a majority of the market is currently being tested by either single gene tests or targeted testing for a low number of biomarkers recommended under NCCN guidelines and is currently approximately 30% penetrated by broad molecular testing (both tissue and blood) using broad panels (50 or more genes).

Minimal Residual Disease Tracking and Treatment Monitoring for Cancer Patients and Survivors

According to the ACS, approximately 1.3 million of the 2 million patients in the United States who are newly diagnosed with cancer each year are found to have non-metastatic cancer. We believe MRD tracking and recurrence testing is most applicable to patients within this cohort. Patients in the non-metastatic cancer cohort are expected to be monitored during their treatment journey and beyond for up to five years for recurrence, including MRD testing for patients who underwent surgery for their cancer. In addition, patients with metastatic cancer are expected to receive treatment monitoring tests during their treatment journey. According to the Nephron Research analysis, these result in a cohort of approximately 5.6 million patients being monitored at various points in their treatment journey. Assuming a range of two to

three tests annually for each patient, consistent with MolDX coverage policy for MRD, pricing of \$2,500 per reference test and \$1,650 per follow-up blood test, in each case based on pricing for other tests available on the market, Nephron Research estimates that the total addressable U.S. market for MRD tracking tests represents approximately 16 million tests annually and amounts to approximately \$28 billion.

Core Biopharma: Profiling Services for Biopharma Drug Development and Commercial Testing

Key services relevant for biopharma companies include prospective and retrospective profiling services, companion diagnostics development, and commercial services that include identification of patients for approved therapies.

According to the Nephron Research analysis, oncology testing associated with clinical trials includes approximately 250,000 cancer patients in targeted therapy clinical trials. Assuming five tests (one therapy selection test to establish cancer type and determine the therapeutic intervention(s) and four monitoring tests for follow-up consistent with typical trial designs) for each trial participant and pricing of \$5,000 per therapy selection test and \$1,950 per monitoring test, based on existing reimbursement rates for other tests available on the market, Nephron Research estimates that the addressable U.S. market for oncology testing in clinical trials is approximately \$3.2 billion. The development of companion diagnostics tests and the identification of patients for commercial targeted therapies are both attractive opportunities for molecular information-based services. Assuming approximately 25 Phase 1b trials progress to Phase 2 each year based on recent historical data from ClinicalTrials.gov, with each trial having two partners per customary industry practice (a specialty lab and a distributable kit) and an average contract price of \$10 million based on Nephron Research's market analysis, the addressable U.S. market for the development of companion diagnostics tests is estimated to be approximately \$500 million. For rare biomarkers, biopharma sponsors generally will reimburse laboratories that can help identify patients as candidates for their therapeutics. Assuming a rate of rare mutation of 4.0% within the population of newly-diagnosed cancer patients in the United States with advanced-stage solid tumor cancers, based on data from the National Institutes of Health, and an average reimbursement per patient of \$10,000 based on Nephron Research's market analysis, the addressable U.S. market for commercial services that include identification of patients for approved therapies is estimated to be approximately \$300 million. Accordingly, the estimated total addressable U.S. market for core biopharma services is approximately \$4.0 billion.

Data Services for Biopharma Research and Development

Matched genomic data has demonstrated use cases for biopharma applications across discovery, drug development, and clinical trial execution. Biopharma companies leverage multi-modal genomic data, including data they license, to identify key molecular characteristics of a particular disease or dysfunction that drives disease, enabling signature identification and drug target discovery. The valuable insights provided by multi-modal genomic datasets help biopharma companies identify optimal patient populations for therapeutic development and also help inform trial design, validate biomarker strategies, and assess execution feasibility of oncology clinical trials.

According to Evaluate Pharma, global spending on pharmaceutical R&D by biopharma companies grew from an estimated \$145 billion in 2014 to an estimated \$262 billion in 2023. According to the Nephron Research analysis, it is estimated that approximately \$70 billion of the \$262 billion spent in 2023 represented R&D investments in discovery, pre-trial costs, and real-world evidence, areas where matched genomic data has demonstrated use cases for biopharma applications. We expect biopharma companies to continue increasing the allocation of their total R&D investment towards multi-modal genomic data and bioinformatics services to increase efficiency and development success rates. Based on Nephron Research's market analysis, approximately 14% of the estimated \$70 billion in R&D investments in 2023 was allocated towards such data and services, resulting in an estimated total addressable U.S. market for this opportunity of approximately \$10 billion.

Other Disease States Beyond Oncology

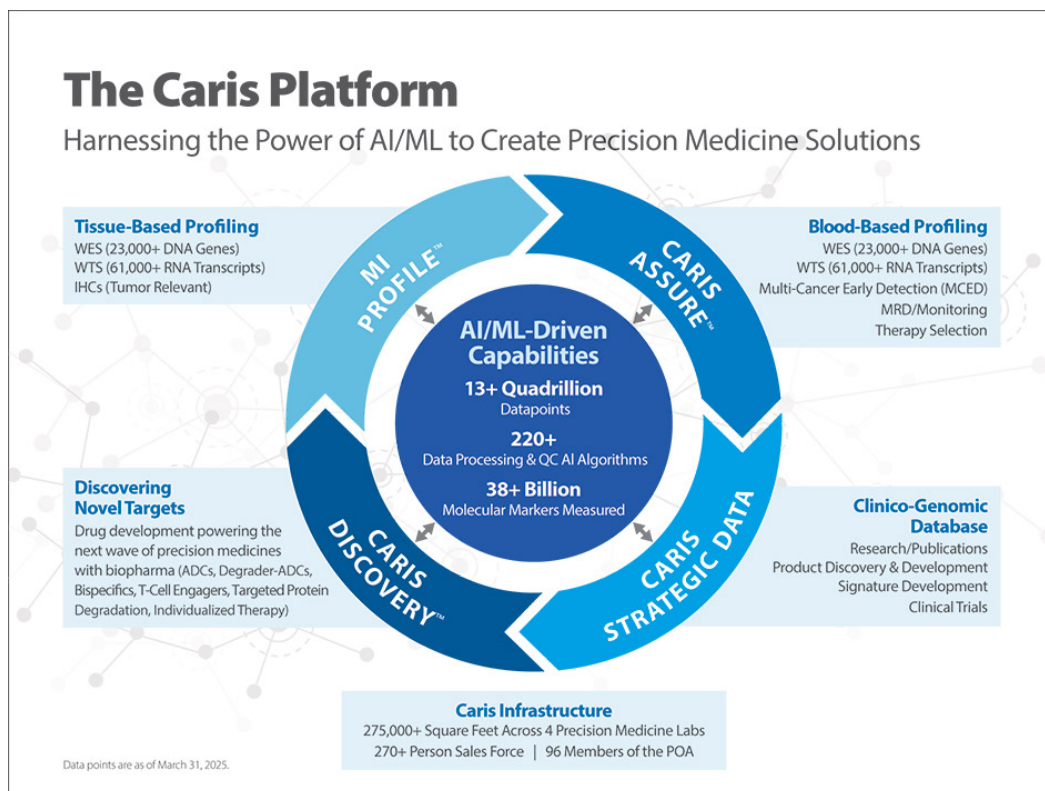
We believe there is a large market opportunity for our platform in other chronic disease states beyond oncology, including cardiology, neurology, and metabolic conditions. This begins with a fundamental premise that approaching blood-based disease detection with a comprehensive WES/WTS approach

enables examination of biomarkers that go beyond oncology. It is already well known that other disease states have blood-based genomic markers that can be used for diagnostic assessment. The increasing role of CH in cardiovascular disease and neurology further buttress this approach. In cardiology, the first natural bridge exists in the field of cardio-oncology where, for example, biomarkers to predict cardiotoxicity to commonly used therapies could be implemented to help mitigate adverse events. In addition, the deployment of cardiovascular disease risk based on CH mutations could be used to augment early detection efforts. In neurology, disorders such as Alzheimer's or Parkinson's disease are difficult to diagnose, as the same symptoms manifest in different combinations across different disorders. Symptoms of one condition may often be similar to that of another, leading patients down the path of a "diagnostic odyssey." The diagnosis involves tests such as CT scan, electroencephalogram, magnetic resonance imaging, electromyography, nerve conduction velocity, positron emission tomography, angiogram, spinal tap, myelogram, neurosonography, and ultrasound, among others. Personalized medicine and targeted therapies do not exist today for CNS disorders, however there is general consensus that detecting symptoms early and intervening can slow the development of disease.

The Caris Platform

We are leading a molecular revolution and developing the latest generation of advanced precision medicine information solutions that we believe have applicability across the care continuum for a broad range of conditions. The fundamental differentiation of the Caris platform and our business model is the depth, breadth, and scale of data, including how that data is integrated vertically and horizontally across our business, as well as the resulting innovation which it fuels.

Our multi-omic technology platform is built on the following pillars: (1) Caris Assure; (2) MI Profile; (3) Caris Discovery; (4) Caris Strategic Data; and (5) Caris Infrastructure. These five pillars are designed to work together to create a virtuous cycle that can enable continued innovation and improved impact for patients and physicians. We believe our comprehensive approach to profiling will continue to drive demand for our genomic profiling capabilities, leading to further expansion of our clinico-genomic datasets, which provide additional valuable inputs to develop and enhance our solutions, with the ultimate goal of contributing to improved patient results. We believe this continuing cycle will deepen our competitive advantage and allow us to achieve meaningful innovation and business success in precision oncology, while illuminating a path to precision medicine for other chronic disease states, including cardiology, neurology, and metabolic conditions.



We believe our growth and competitive differentiation are driven by the five pillars of our platform, each of which are both a product of the upstream data and a foundation to further innovation and data generation across the platform:

- Caris Assure:** Our universal blood-based WES/WTS profiling solution is designed to deploy a single assay across the entire continuum of cancer care, including early detection, MRD tracking, therapy selection, and treatment monitoring, and generates over 42 billion datapoints, spanning 168,000 molecular markers, per clinical case. We leveraged our experience and data from MI Profile to create Caris Assure, which enables us to understand how a patient's disease started, what therapies the tumor may be sensitive to, how the tumor is transforming to resist therapies, and how best to control or cure the disease.
- MI Profile:** Our tissue-based profiling solution for therapy selection includes our comprehensive WES/WTS profiling assay and IHC protein expression testing. Our WES/WTS profiling solution generates over 28.8 billion datapoints, spanning 84,000 molecular markers, per clinical case.
- Caris Discovery:** The combination of our data and our AI enables us to discover previously unknown drug targets for antibody-directed therapies (such as antibody drug conjugates, degrader-antibody conjugates, and T-cell engagers), small molecules, targeted protein degradation, synthetic lethal interactions, and cell therapy. In addition, we believe Caris Discovery is well-positioned for neoantigen discovery for personalized therapy development given our ability to detect variants, insertions, and deletions by WES and to assess gene expression and detect fusions by WTS on every patient's tumor.
- Caris Strategic Data:** As of March 31, 2025, we have run more than 6.5 million tests that have measured over 38 billion molecular markers from over 13 quadrillion datapoints. To assist us with analyzing the data we generate, we utilize over 220 AI and AI/ML tools across our clinical testing, R&D, and biopharma business. These tools include over 50 clinical sequencing

automation and variant calling AIs, over 100 RNA expression AI signatures, approximately 20 multi-omic AI/ML therapy response predictors, two ADAPT target discovery AI/ML algorithms, 37 digital image AI/ML classifiers, and 12 AI/ML support tools. We have used our datasets to create many of these algorithms and signatures. The breadth and depth of our data assets, together with our demonstrated ability to use them to create algorithms and discover signatures, represent a deep competitive moat for us.

- **Caris Infrastructure:** We have a well-developed laboratory, R&D, and sales infrastructure that we believe is foundational to our business.
 - *Operational Capacity.* We have substantial testing capacity, including over 275,000 square feet of space across four precision medicine laboratories with throughput capabilities of over one trillion reads per day generated by 50 NovaSeq sequencing systems. We believe this capacity provides us with ample capability to manage our current operations and future growth.
 - *Research and Development.* We have a dedicated R&D infrastructure, including a specialized laboratory and over 200 employees dedicated to R&D efforts. In addition to our internal research, we regularly partner with outside academic centers and researchers. The Caris POA, which we established in 2015, is a growing network of leading cancer centers and research consortia across the globe that supports research partner engagement, collaboration opportunities, and the advancement of precision oncology research.
 - *Commercial Channel.* To support our sales activity and expansion, as of March 31, 2025, we have assembled a targeted sales organization in the United States of over 270 sales team members and nearly 50 highly trained Ph.D. or M.D. MSLs who focus on physician and provider education.

The Caris Advantage

We believe our approach is differentiated and we have a competitive advantage because:

- **We purpose-built our Caris platform to put the patient first and make comprehensive precision medicine a reality.** Our patient-centric ethos has guided us since inception. This guiding principle underpins our belief and vision that combining a vast set of consistently generated molecular information with robust data-driven insights would realize the potential of precision medicine, driving superior patient outcomes. Our approach, which includes deep sequencing all DNA encoding genes and RNA transcripts, maximizes the molecular information generated for each clinical case and enables us to analyze and provide patients and physicians with industry-leading breadth, depth, and accuracy of multi-omic information. By providing a high-quality, individualized molecular blueprint of a patient's disease, our platform is designed to enable the discovery, development, and application of cutting-edge precision medicine that pushes the boundaries of current science. This differentiated approach has made Caris a destination for KOLs and clinicians seeking the most complete and accurate information available for treating their patients.
- **We are a leading provider of tissue-based molecular profiling, including through our FDA-approved companion diagnostic tissue-based profiling solution, MI Cancer Seek.** MI Profile is a leading tissue-based molecular profiling solution for therapy selection, with over one million tests performed on approximately 146,500 clinical cases in 2024, which represents a 31.2% compound annual growth rate in clinical tissue case volume since 2018. MI Profile consists of a WES and WTS NGS component, IHC analysis, and AI/ML analysis to identify the origin of a tumor for 90 unique cancer types with approximately 95% accuracy. This comprehensive solution assists clinicians in identifying patients who may benefit from treatment with specific targeted therapies.
- **Our novel, universal blood-based profiling solution, Caris Assure, is unique in the market and poised for rapid adoption.** We believe our leadership in tissue molecular profiling uniquely positions us to capitalize on the increased use of blood-based profiling and adoption into

clinical practice with Caris Assure, our novel, universal blood-based solution that is purpose-built to extend across the entire cancer care continuum and to therapeutic development by generating over 42 billion datapoints per clinical case. We built upon the data we have generated to date with MI Profile and believe our data is a significant competitive advantage in the development and clinical utility of Caris Assure. Caris Assure naturally enriches our AI/ML algorithms and transfers learning across the care continuum, yielding greater sensitivity and specificity, while continuously expanding our longitudinal patient datasets. Moreover, we believe that our single-test approach will enable us to scale our R&D infrastructure to analyze increasingly large testing volumes, process expanding datasets, and reach economies of scale in liquid biopsy. To our knowledge, we have developed and launched the most informationally rich blood-based solution in the market. We have Medicare reimbursement and various levels of commercial payer adoption and/or reimbursement coverage for Caris Assure for therapy selection across the United States (other than New York State).

- **We have built what we believe to be one of the largest and most comprehensive multi-modal clinico-genomic datasets in oncology.** Our proprietary oncology clinico-genomics datasets provide insights into the fundamental building blocks of disease, potentially enabling breakthroughs from targeted therapies to truly personalized medicine. Our ever-expanding datasets include data generated from more than 6.5 million tests that have generated measurements of over 38 billion molecular markers from over 13 quadrillion datapoints as of March 31, 2025, as well as matched clinical outcomes for many of these patients. Our platform generates over 111 million reads per clinical case, and each new case further expands our datasets allowing us and our biopharma partners to generate even more clinically relevant insights. We also expand and enrich our datasets through partnerships that add real-world evidence, longitudinal patient data, and clinical outcomes. The breadth and depth of our large and growing data assets represents a deep competitive moat for us, overcoming which requires significant capital investment, scaled sequencing capacity, acquisition of patient samples, and generation of corresponding clinical outcomes data. These significant data assets enable us to effectively deploy our proprietary AI/ML algorithms to analyze patient information and empower our customers to make better informed diagnoses and treatment decisions.

Our Caris platform is designed to create a virtuous cycle that can enable continued innovation and improved impact for patients and physicians. We believe our comprehensive approach to profiling will continue to drive demand for our genomic profiling capabilities, leading to further expansion of our clinico-genomic datasets, which provide additional valuable inputs to develop and enhance our solutions, with the ultimate goal of contributing to improved patient results. We believe this continuous feedback loop will allow us to achieve meaningful next-generation innovation in precision oncology as well as other chronic disease states.

- **Our first mover advantage, specialized commercial channel, robust infrastructure, and deep research collaborations enable our leadership and provide us with the ability to scale for future growth.** We believe we will be the first provider to achieve leadership in both solid tumor and liquid biopsy profiling solutions across the entire precision oncology care continuum. To support our sales activity and expansion, we have built a commercial organization specialized in precision oncology consisting of approximately 270 team members as of March 31, 2025, plus nearly 50 highly trained Ph.D. or M.D. MSLs, serving over 5,600 physicians in the United States across all major health systems, academic cancer institutions, and community settings. Due to the increased market acceptance of our solutions, we have achieved revenue growth and case volume growth without growing the aggregate sales headcount over the last three years.

Our robust infrastructure includes a team of over 60 Caris data scientists to decipher unique features from our datasets generated from millions of tests. We operate two precision medicine laboratories in Phoenix, Arizona, and one R&D laboratory in Tempe, Arizona. Our Arizona laboratories all utilize state-of-the-art genomic sequencing technology, including 50 NovaSeq sequencing systems, with capacity to perform more than one trillion “reads” daily. Our newest laboratory facility in Irving, Texas, near our headquarters, is continuing to be built-out and will bring our total operational capacity to over 275,000 square feet.

Since its establishment in 2015, the Caris POA, whose members work together to establish and optimize standards of care for molecular testing through innovative research to improve clinical outcomes for cancer patients, has grown to comprise 96 members as of March 31, 2025, including 45 NCI-designated comprehensive cancer centers. This academic-industry collaborative network has been exceptionally productive with over 145 peer-reviewed manuscripts published since the beginning of 2022. Close connectivity with this vast network of KOLs in oncology clinical care, research, and drug development has enabled us to remain at the forefront of precision oncology and closely attuned to the key needs of the most sophisticated researchers.

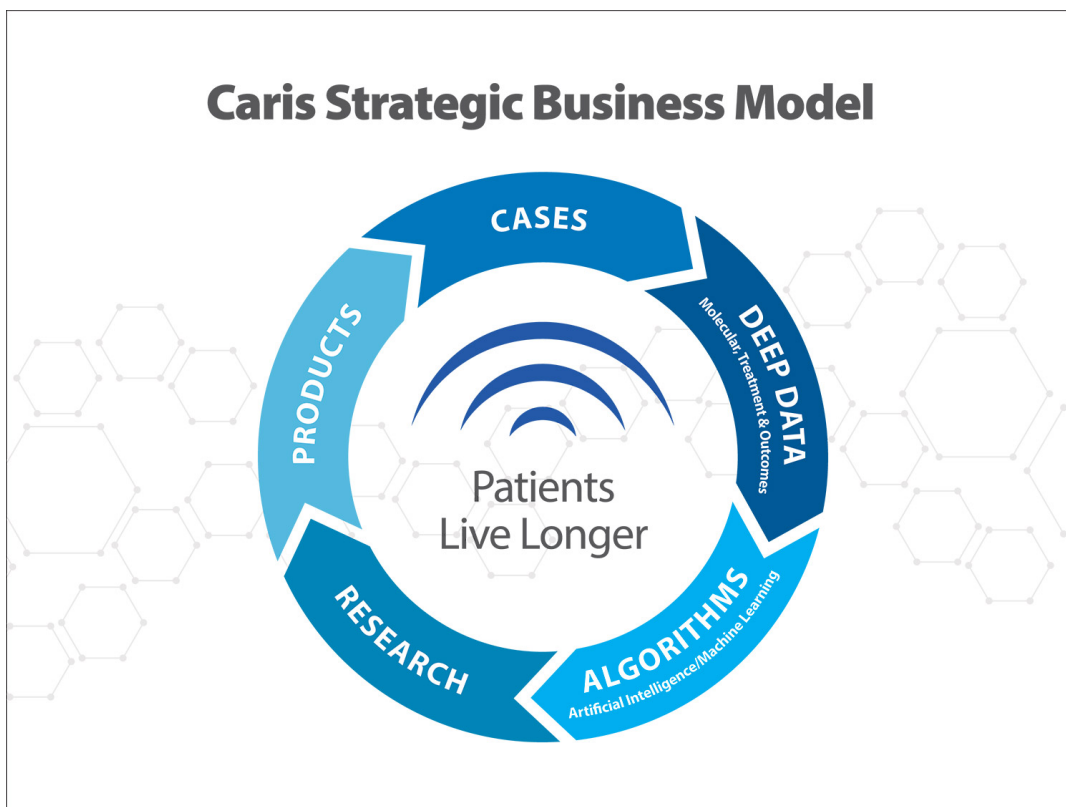
- **We are led by a founder with significant experience building and scaling businesses in the healthcare industry and a management team with scientific expertise.** Our management team has deep domain expertise in molecular biology, oncology, artificial intelligence, data science, medicine, and genomics and have a track record of delivering innovative, high clinical utility solutions to the market. Our management team is highly entrepreneurial and has significant experience leading and operating large multi-national organizations and building innovative healthcare companies. In particular, our Founder, Chairman, and Chief Executive Officer, David D. Halbert, has successfully built and scaled profitable enterprises for approximately 40 years, including AdvancePCS Inc. (acquired by CareMark in 2004 for \$7.5 billion), and Caris Diagnostics (acquired by Miraca Life Sciences in 2011 for \$725 million), among others.

Our Strategies

As we execute on our vision, we will continue to put the patient first. Our solutions provide physicians and individual patients with actionable information throughout the disease journey, while contemporaneously generating data that can be aggregated and leveraged to unlock academic and biopharma scientific breakthroughs, which may lead to curative therapies for future generations. To achieve our goal of leading a molecular revolution and developing the next generation of precision medicine information solutions for a broad range of conditions across the care continuum, we plan to:

- **Drive the continued adoption and use of our tissue-based profiling and expand our blood-based profiling offering into early detection, MRD, and monitoring.** MI Profile continues to be one of the most comprehensive tissue-based molecular profiling solutions available. We plan to leverage our leadership with MI Profile and our proprietary clinico-genomics datasets, to drive the adoption of blood-based profiling with Caris Assure, our highly differentiated, comprehensive multi-omic liquid biopsy solution. We believe Caris Assure will address the significant unmet need across the entire cancer care continuum, with solutions for early detection, MRD tracking, therapy selection, and treatment monitoring. Broadly launched in the first quarter of 2024 for therapy selection, we have seen over 3,400 physicians from over 480 institutions order Caris Assure for therapy selection through March 31, 2025. We intend to leverage our existing commercial infrastructure, including our substantial testing capacity across two precision medicine labs and our specialized commercial channel, to support the continued launch and commercialization of Caris Assure.
- **Utilize the data generated by our existing solutions to develop new solutions with additional revenue using our existing sales channel.** We will leverage our clinico-genomic datasets to identify novel AI-based molecular signatures that are predictive of a patient's clinical journey. This will allow us to reach new patient populations at earlier stages of cancer, who may not be eligible for our current solutions. We are currently using an AI/ML approach driven by H&E slide images and clinical results data from more than 10,000 breast cancer patients to develop ESPai, a new algorithm to predict the risk of disease recurrence for early-stage breast cancer patients. We have obtained the samples and clinical data from the National Surgical Adjuvant Breast and Bowel Project and the ECOG-ACRIN Cancer Research Group. We are currently in the process of creating two AI/ML models for ESPai using these samples and are working to obtain additional samples for external validation studies. We are initially creating a model for late recurrence (five to 15 years following diagnosis), but we are also in the beginning stages of creating a model for early recurrence (zero to five years following diagnosis). The ability to deliver results to patients who would otherwise require multiple tests, or for whom testing would

not be a possibility, further differentiates us and provides significant value to patients and their physicians. This business model, possible only through our testing platform and the comprehensiveness of our underlying data, has created a new category of operational efficiency centered around patient care as shown below:



- Leverage our platform to provide solutions to biopharma companies to drive advances in personalized medicine and accelerate the development of novel therapeutics.** We partner with biopharma companies to improve the efficiency and success of their therapeutic development and clinical programs by leveraging our platform. We provide prospective and retrospective profiling services, companion diagnostics development, data licensing, and commercial services that include identification of patients for approved therapies. Our biopharma business continues to gain significant momentum, with \$63.1 million of revenue generated in 2024, representing a 130.3% increase compared to the prior year. A key strategy for future growth is continued pursuit of opportunities to partner with biopharma institutions to accelerate scientific breakthroughs through access to our datasets. These arrangements, such as our partnerships with Moderna, AbbVie, Xencor, and Merck KGaA include research into molecular markers and tumor-associated antigens, characterization of resistance mechanisms, and the development of personalized therapies. We believe the future of therapeutics will become more and more personalized, requiring the information that we produce to create individually tailored therapies that will have the greatest likelihood of controlling and/or curing patients of disease. Recent advances of personalized therapies that are specifically created for patients demonstrate the value of this approach.
- Continue to expand and enrich our clinico-genomic datasets to drive breakthrough science and develop new solutions.** Our continued comprehensive sequencing for patients, together with our leadership in tissue-based profiling and expansion into blood-based profiling, will enable continued rapid expansion of our datasets, both with new profiling data as well as with longitudinal insights as we follow patients over time. We plan to accelerate the enrichment of

our datasets through continuous R&D at our own laboratories, third party partnerships, and collaborative research with Caris POA members to remain at the cutting-edge of precision oncology and stay attuned to the key needs of our researchers.

- Maximize market reach through our regulatory approval and reimbursement strategy.** A key aspect of our commercial strategy is to obtain regulatory approval and reimbursement for our solutions. In November 2024, we obtained a premarket approval (“PMA”) from the U.S. Food and Drug Administration (the “FDA”) for a companion diagnostic and tumor profiling designation for MI Cancer Seek, a WES/WTS NGS assay that uses the whole exome for TMB calling and has been designed to meet the stricter requirements applicable to companion diagnostic devices. We currently market MI Cancer Seek as the WES/WTS NGS component of MI Profile. We have secured a PLA code of 0211U from the AMA and pricing from CMS for this PLA code. We have obtained Medicare coverage for MI Cancer Seek for CPT code 0211U under the NGS NCD. For MI Tumor Seek Hybrid, we have Medicare and commercial reimbursement. For Caris Assure, we received Medicare coverage in late 2023, have secured various levels of payer adoption and/or reimbursement coverage, and will continue working to expand coverage. In July 2024, the AMA issued a PLA code, CPT code 0485U, for Caris Assure, with an effective date of October 1, 2024. In November 2024, CMS determined to price Caris Assure for therapy selection using the “Gapfill” method, a method used when there are no comparable existing codes available. There is no certainty regarding the pricing that we will obtain for Caris Assure during the Gapfill process. For additional information, see “—Government Regulation—Coverage and Reimbursement—Coverage and Reimbursement in the United States.” We plan to work closely with Medicare and private payers to continue to demonstrate the economic benefit of our platform and secure reimbursement coverage for our future offerings by leveraging our proprietary clinico-genomic datasets that contains a growing volume of corresponding clinical outcomes data. We believe this approach will lead to a differentiated reimbursement profile relative to our peers.
- Capitalize on the ultimate potential of our novel, universal blood-based profiling solution, Caris Assure, and broader innovation platform in other chronic disease states beyond oncology, including in cardiology, neurology, and metabolic conditions.** We believe there is a large market opportunity to diagnose and treat chronic conditions beyond oncology through molecular information-based approaches. Beyond oncology, researchers are actively exploring the genetic and biological connections between patients and other disease states, including cardiology, neurology, and metabolic conditions. These diseases are frequently multifactorial in nature and are characterized by significant individual variability. Accordingly, a comprehensive understanding of the underlying biological pathway dysfunction is critical if we want to understand the molecular origins of disease and generate insights to bring new therapeutics to patients. As we continue to scale, we believe our solutions will drive superior clinical outcomes, leading to additional demand for our profiling solutions and further expansion of our clinico-genomic datasets, allowing us to achieve meaningful innovation in other disease states beyond oncology.

Our Solutions

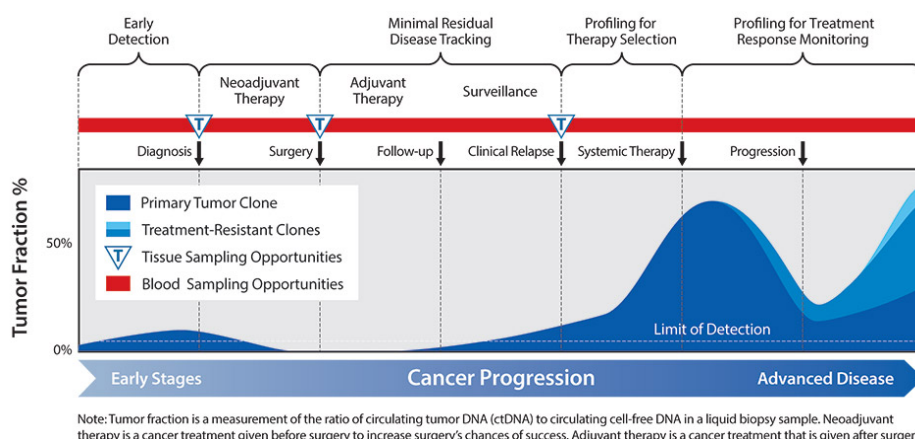
Caris Assure—Our Universal Blood-Based Profiling Solution

Caris Assure is our novel, universal blood-based solution that is purpose-built to extend across the entire continuum of cancer treatment, including early detection, monitoring of MRD and recurrent cancers, and precision selection of molecularly targeted therapies. Caris Assure also has applications in therapeutic discovery and development. Customers for Caris Assure include treating physicians as well as researchers and biopharma companies.

Our universal approach to blood-based profiling is unique. While Caris Assure is a single wet lab test, the backend bioinformatics pipeline and analyses are adapted to where the patient may be in their cancer journey. For example, the genes, molecular alterations, and features in late-stage metastatic cancer for therapy selection will be interpreted differently than in early detection. The elegant simplicity of a single test paired with a comprehensive assessment of the patient’s DNA and RNA allows Caris Assure to be

this universal diagnostic. This approach also allows many more datapoints to be assessed, enabling us to select those markers that provide the greatest potential for sensitivity, specificity, and overall accuracy of our test.

Liquid biopsies can be used across the care continuum, including for: therapy selection in the advanced/metastatic setting; MRD and monitoring in the curative/adjuvant setting; and early detection in the diagnosis setting. Because many of our competitors' liquid biopsy assays are designed to address only a single portion of this care continuum, in order to develop products for other portions of the care continuum, our competitors must invest in the development of new wet lab assays and generate disparate datasets across the patient journey for patients, oncologists, and researchers. In contrast, Caris Assure is designed as a single test applicable across the entire patient journey. To our knowledge, there is no other assay on the market that can be applied as broadly as Caris Assure. We believe that our single-test approach will enable us to scale our R&D infrastructure to analyze increasingly larger testing volumes, process expanding datasets, and reach economies of scale in liquid biopsy across the entire cancer care continuum. The figure below shows the opportunities for blood and tissue sampling and treatment therapies within stages of the cancer care continuum. As a blood-based profiling solution designed for the entire cancer care continuum, Caris Assure has many more opportunities for testing relative to tissue-based profiling, as can be seen on the chart below.



Caris Assure is currently being offered for therapy selection as a laboratory developed test (“LDT”), and we have Medicare reimbursement and various levels of commercial payer adoption and/or reimbursement coverage for Caris Assure for therapy selection across the United States (other than New York State), at current pricing under MolDX of \$3,649. We are in the process of conducting studies and analysis to internally validate and refine the assay for application to early detection, MCED, MRD tracking, and treatment monitoring, with certain validation processes and results to date described below. The commercial application of Caris Assure as an LDT to the cancer care continuum beyond therapy selection is subject to further assay development, validation, and reimbursement coverage. Further, depending on the ultimate outcome of the litigation over FDA’s final rule to subject LDTs to its medical device authorities through a phase out of its historical enforcement discretion policy with respect to LDTs (the “LDT Final Rule”), the marketing of Caris Assure for these applications may require us to seek marketing authorization from the FDA. Because many of these factors are outside of our control, we are not certain regarding the timing of the availability of Caris Assure for the early detection, MCED, MRD tracking, and treatment monitoring markets.

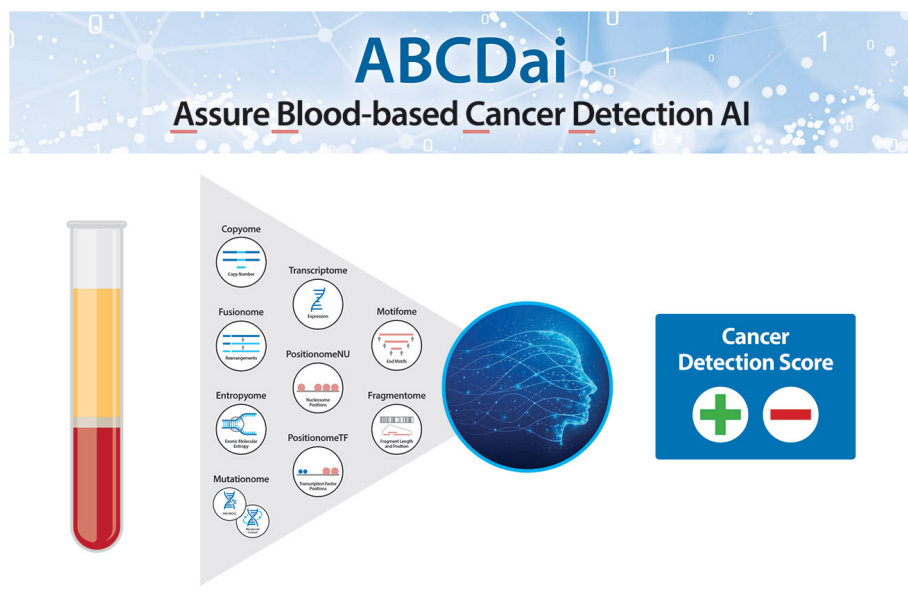
Drawing blood is a routine medical procedure that is much less invasive than a tissue biopsy. Processing of a blood specimen, from collection to isolation, analysis, and reporting, enables faster time to results and potentially earlier start of treatment. Clinical guidelines for molecular profiling in cancer have focused on tissue as the gold standard, but with recent advances in blood-based profiling demonstrating its clinical utility, we believe that evidence and clinical guidelines support complementary usage of both tissue- and blood-based profiling across many major cancer types. We believe that one example of the benefits of blood-based profiling is that cancers frequently become resistant to new targeted therapies by developing genetic mutations that can make drugs less effective and lead to cancer recurrence. When resistance develops,

clinicians need an updated molecular profile of the cancer to guide subsequent treatment strategies. At this stage in cancer progression, it is often not feasible to acquire additional tumor tissue to build the updated profile, or the amount or quality of accessible tissue is low. Small quantities or low quality of tissue from an inaccessible biopsy site can lead to a Quantity Not Sufficient (QNS) result when NGS fails for lack of input material. Without another way to generate an updated molecular profile of the patient's tumor, the tools of precision oncology cannot be deployed. Conducting additional tissue biopsies also carries its own health risks, such as tumor seeding, which can occur when cancer cells are unintentionally deposited elsewhere in the body during the biopsy process, and infection. Liquid biopsy is a potential solution to the challenges and risks of tissue biopsies. A sample eligible for Caris Assure analysis consists of two 10 milliliter tubes of whole blood, gently inverted 10 times as is common practice in blood collection, shipped at room temperature.

Nonetheless, we believe that tissue-based profiling generally remains the gold standard for cancer therapy selection primarily because it is the most mature technology and is broadly supported by analytical validation studies. Microscopic examination of the tumor tissue is necessary for characterization of tumor type and stage and to confirm the presence of key proteins via IHCs. In blood, the variant allele frequencies of tumor biomarkers can be so low that negative results must be confirmed by tissue analysis. However, the tide is turning in clinical guidelines toward acceptance that tissue and liquid biopsy, used in combination, can improve clinical outcomes for patients. For example, the 2024 version of one of the prominent clinical guidelines for non-small cell lung cancer states that: (1) concurrent testing can improve time to test results and should be considered in the appropriate clinical situation, and (2) negative results (meaning absence of definitive driver mutation) by one method suggests the use of a complementary method.

We believe Caris Assure represents the most comprehensive blood-based solution on the market, featuring over 23,000 gene coverage at a raw average sequencing depth of coverage of 8,000 times for clinically relevant genes, as compared to other blood-based offerings in the market that only assess 500 to 1,000 genes from DNA. Caris Assure performs WES and WTS for every eligible patient blood sample. We couple this WES and WTS with advanced AI and ML technologies to offer diagnostic, prognostic, and predictive utility in a single test. Additionally, Caris Assure generates sequencing results from both the plasma and the white blood cells, or buffy coat, from each sample. This gives Caris Assure a differentiated ability to distinguish tumor variants, which are relevant for therapy selection, from both incidental germline variants and common age-related mutations that are not related to the tumor and which can confound analysis and therapy selection if not properly distinguished. For additional information regarding this capability, see “—Benefits of CH Subtraction with Caris Assure.”

Molecular features we identify using Caris Assure's WES and WTS data include single nucleotide variants (“SNVs”), insertions/deletions (“INDELs”), structural variants, gene expression, copy number alterations (“CNAs”), TMB, and MSI. In addition, we deploy our ABCDai algorithm on Caris Assure's WES and WTS data to address important clinical needs in early detection and monitoring of MRD and recurrent cancers. We trained ABCDai using data for over 375,000 tissue profiles and over 7,000 paired blood and tissue profiles. In a first phase, separate AI models were trained on nine feature sets representative of cancer-related and cell-free nucleic acids. In a second phase, the 500 most important features determined by us from each feature set were used to train a final ABCDai model. We engineered three ABCDai models to work in concert with Caris Assure: (i) MCED; (ii) diagnostic pathway; and (iii) MRD and monitoring.



Caris Assure for Early Detection

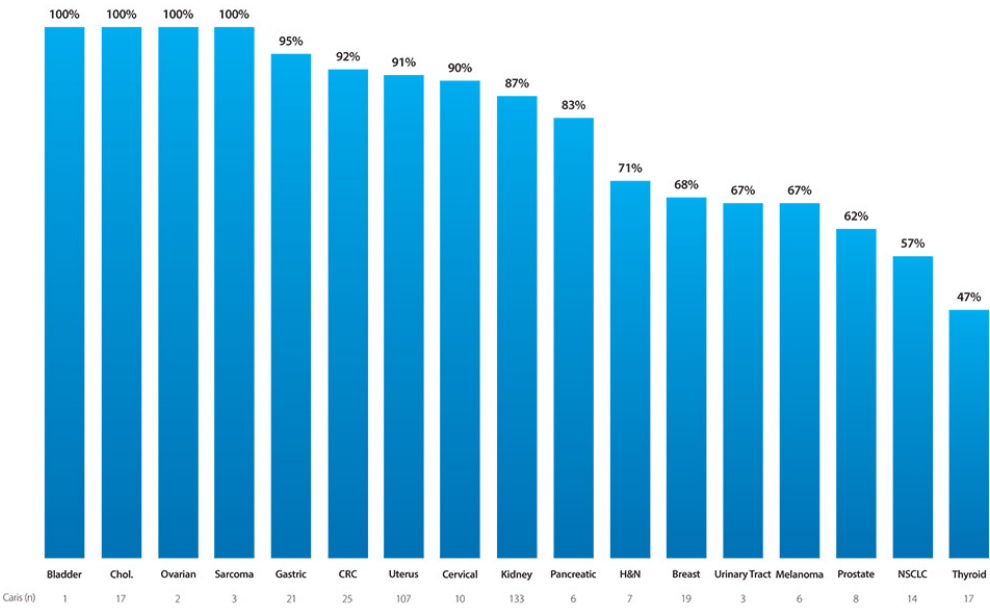
We believe that one of the most promising uses for Caris Assure is for early detection, including both cancer-type-specific early detection and MCED. Our detection of cancer at very early stages would enable clinicians to treat disease sooner, which could significantly improve patient outcomes.

We trained ABCDai for MCED (“ABCDai-MCED”) using the aforementioned features on samples from 1,013 patients (507 patients with cancer and 506 individuals with no reported cancer). Performance was assessed on an independent set of 2,675 patients (526 patients with cancer and 2,149 samples from individuals with no reported cancer). ABCDai-MCED’s performance on the stratification of blood samples from the independent cohort of patients with cancer versus those with no reported cancer resulted in sensitivities for stages I-IV ($n=284, 129, 90,$ and 23 , respectively) of 83.1% (stage I), 86.0% (stage II), 84.4% (stage III), and 95.7% (stage IV) at 99.6% specificity ($n=2,149$).

The chart below illustrates ABCDai-MCED’s sensitivity in detecting a range of cancer types at stages I and II, at a specificity of 99.5%

Sensitivity In Stage I & II Cancers

(At 99.5% Specificity)



The MCED model was trained on 1,013 patients and validated on an independent set of 2,675 patients. The tissue of origin for MCED model was trained on 1,166 samples and validated using 5-fold cross validation.

ABCDai-MCED has been shown to be useful in detecting the presence of cancer in an asymptomatic individual. Additionally, the molecular information provided by Caris Assure can assist in predicting the diagnostic pathway that can confirm the presence and tissue of origin of cancer, which knowledge is needed for proper intervention. We focused diagnostic pathway prediction on those tumor types that are most common and thus provide the most clinical utility: colonoscopy, abdominal/chest CT, endoscopy, liver ultrasound, mammograph with MRI, neck ultrasound, pelvic ultrasound, and prostate-specific antigen (“PSA”). A model to predict diagnostic pathway, ABCDai-GPS, was trained by us using the feature sets described above obtained for treatment-naïve samples from 660 patients with stage I and II cancers and 506 individuals with no reported cancer. Using 5-fold cross validation, we observed that ABCDai-GPS predicted the diagnostic pathway for 100% of the ABCDai-MCED positive calls with a top-3 accuracy of 85% for stage I and II cancers. The relationship between the proposed diagnostic pathways and tissue of origin of the cancer is shown in the following table.

Diagnostic Pathway	Cancer Types
Colonoscopy	Colorectal
CT Abdomen/Chest	Pancreatic, Kidney, Bladder, Urinary tract, Lung
Endoscopy	Esophageal, GIST, Gastric, Small Intestine
Liver ultrasound	Cholangiocarcinoma, Liver
Mammograph with MRI	Breast
Neck ultrasound	Head and Neck, Thyroid
Pelvic ultrasound	Uterus, Cervical, Ovarian, Female Genital Tract Malignancy
PSA	Prostate

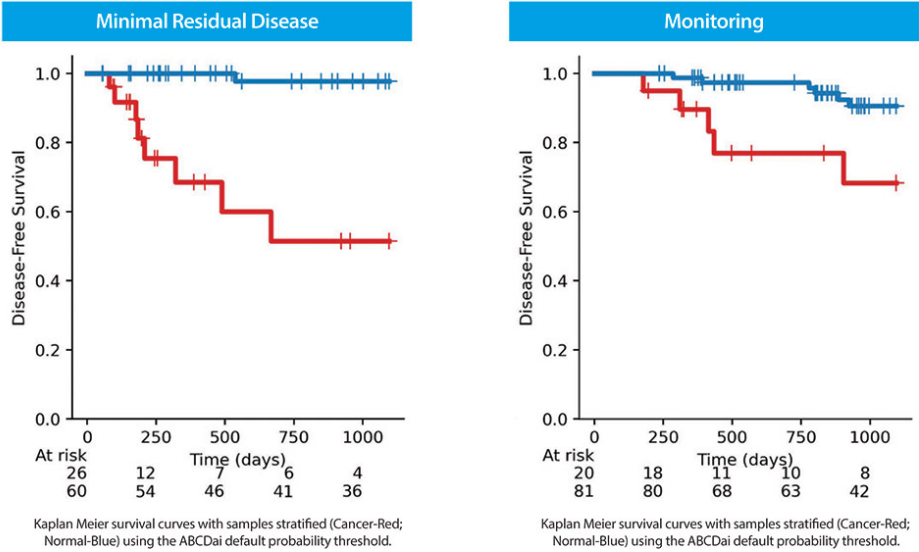
We are also in the early stages of developing a version of ABCDai to be used with Caris Assure for early detection of specific types of cancer. We are currently developing cancer-type-specific early detection for breast and colorectal cancers. We believe that cancer-specific early detection assays will benefit patients by providing them with clear treatment pathways. We currently intend to launch Caris Assure for early

detection of breast cancer and intend to do so in a capital efficient manner, with the expectation that we will leverage either a commercial partner or our existing sales channels, however, our plans and intentions may change.

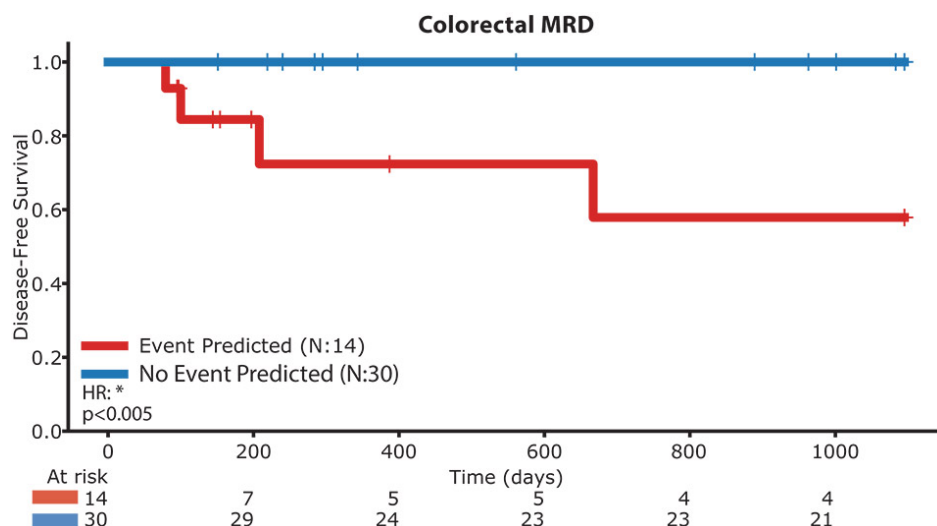
Caris Assure for Minimal Residual Disease Tracking and Treatment Monitoring

A third model was trained by us using the feature sets described above for deployment in the settings of MRD and recurrence monitoring. This model, ABCDai-M&M, was trained using samples from 3,439 patients (1,290 patients with cancer and 2,149 individuals with no reported cancer) and performance was assessed on two independent validation cohorts: 86 patients in the MRD study and 101 patients in the recurrence monitoring study. The disease-free survival of patients whose cancers were predicted by ABCDai-M&M to have an event was significantly shorter than those predicted not to have an event using a tumor naïve approach (HR=33.4, $p<0.005$, HR=4.39, $p=.008$, respectively). The ABCDai-M&M model captured 89% of MRD recurrence events with 98% NPV and 76% specificity, and 45% of recurrence monitoring events with 92.6% NPV and 83% specificity.

Caris Assure Detects MRD in Plasma & Functions as a Monitoring Tool



The following graphic illustrates the performance of Caris Assure for CRC in the MRD setting, in our clinical validation performed on 44 patient samples.



Our MRD detection methodology based on ABCDai takes a tumor naive approach, and therefore does not require a bespoke panel to be created to track the recurrence of a patient’s tumor. This bespoke-free approach enables faster turn-around-time, enabling patients to be informed of additional therapy sooner to combat their disease. Additionally, because Caris Assure analyzes the entire exome, any tumor-derived alterations including those that may derive from subclones not included in the original tissue biopsy, are also detectable, thus accounting for tumor heterogeneity to help contribute to sensitivity of detection.

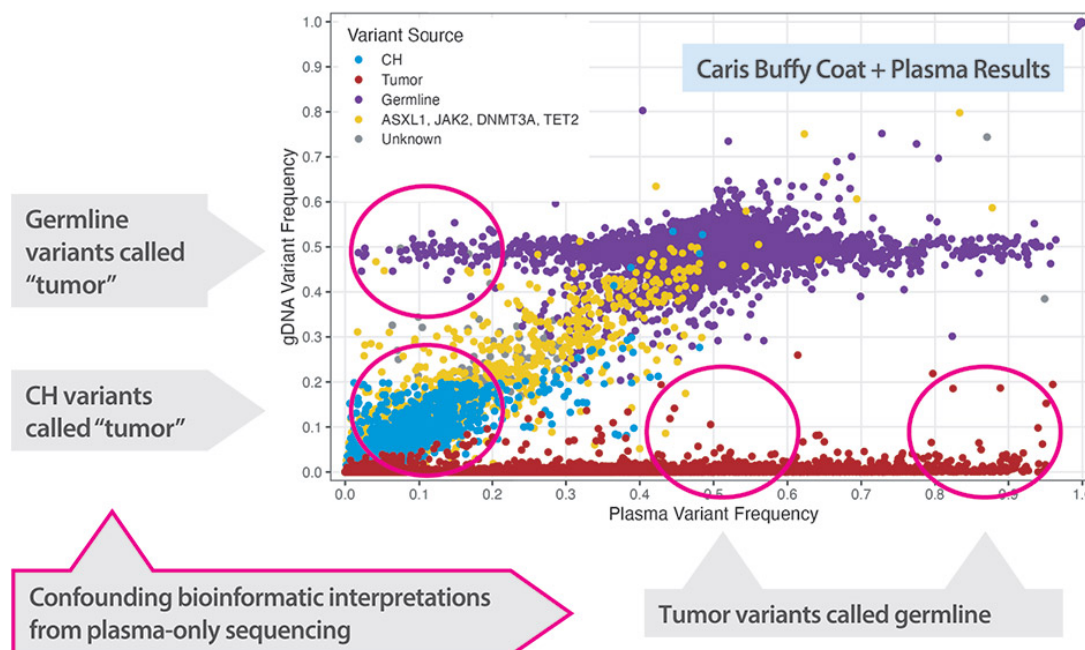
Benefits of CH Subtraction with Caris Assure

For therapy selection, in addition to sequencing cell-free DNA and cell-free RNA isolated from the plasma to identify somatic tumor variants, we also sequence genomic nucleic acid (gDNA and gRNA) isolated from the white blood cells, or buffy coat, from each sample. Plasma contains a mixture of cell-free variants derived from tumor, blood and other cells. These variants cannot be separated based on plasma sequencing alone. Sequencing the buffy coat separately from the plasma allows Caris Assure to identify incidental germline (inherited) mutations as well as CH mutations. CH mutations are somatic mutations that accumulate in the blood with age, occur in a substantial portion of the population, and are not cancer-derived. Caris Assure “subtracts” CH mutations in the reporting of somatic tumor variants. If CH mutations are not distinguished from tumor-derived mutations, it can confound liquid biopsy results and lead to selection of a therapy targeted at a mutation that is present in the white blood cells instead of in the tumor, which is not beneficial for the patient with cancer. Because of this, the College of American Pathologists (“CAP”) and Association for Molecular Pathology recommend that cfDNA assays should incorporate whole blood controls to differentiate CH from tumor-derived variants. Caris Assure sequencing follows this approach, thus lessening the risk of incorrectly interpreting CH or germline mutations as tumor-derived and thus result in fewer false positive diagnoses and more accurate and effective treatment recommendations.

In February 2025, we published in *Clinical Cancer Research*, a peer-reviewed medical journal on oncology, our validation study conducted in collaboration with leading cancer centers such as Rocky Mountain Cancer Centers, OU Health University of Oklahoma Medical Center, Hope Cancer Center of Nevada, and Texas Oncology. The study analyzed over 16,800 patients with advanced cancer across 49 cancer types and found that nearly more than four of 10 patients had at least one CH variant among reportable clinical genes. The study also found a median rate of CH variant classification of 20% for patients ranged from 65 to 69, 33% for patients aged 70 to 74, 33% for patients aged 75 to 79, and 50% for patients 80 years of age and older. High CH rates were notably detected in BRCA2, BRCA1, CHEK2, ATM and NRAS.

The following graphic illustrates the study's findings on variant classification by gDNA and plasma variant frequency, and illustrates the types of diagnostic errors that can occur when variants are not properly characterized as tumor, germline or CH mutations.

Plasma and Buffy Coat Sequencing Provides a More Complete Molecular Profile



Because of the prevalence of CH mutations, we believe that CH subtraction is critical to optimal cancer care. As noted above, the identification of CH mutations by an assay can lead to improper therapy selection if such mutations are not shown to be from the white blood cells. By identifying and distinguishing variants that are not from the tumor itself and, therefore not relevant to therapeutic decision-making, the CH subtraction feature of Caris Assure further separates our solution from other liquid biopsy tests currently on the market that do not sequence the white blood cells and therefore cannot definitively distinguish CH mutations from tumor-derived mutations. To our knowledge, Caris Assure is the only commercially available tissue-naïve blood-based profiling assay that directly accounts for CH mutations instead of using algorithmic approximations, which we believe gives Caris Assure a differentiated ability to drive improved therapy selection.

By leveraging CH subtraction, somatic mutation detection from blood collected within 30 days of matched tumor tissue showed high concordance to our tissue-based assays, with a positive percent agreement ("PPA") of 93.8% and a positive predictive value ("PPV") of 96.8% PPA and PPV are terms commonly used in the context of diagnostic tests and medical studies and are helpful for evaluating assay performance. PPA stands for positive percent agreement and is a measure of the agreement between a test's positive result and the true positive status as determined by a reference standard. PPV stands for positive predictive value, which is a measure of the probability of a positive result correctly identifying a disease or condition.

Case Study: The Benefits of CH Subtraction in Therapy Selection

A male patient in his 80's with a history of renal cell carcinoma presented with a large osseous (bone) metastasis involving the thoracic and lumbar spine, ribs, and pelvis. Pathology was consistent with an origin in the prostate. Immunohistochemical studies performed by the outside pathology team was consistent with this diagnosis, and a liquid biopsy performed outside of Caris revealed a mutation in the ATM gene, which helps repair damaged DNA that was potentially actionable as supported by a specific FDA-approval for PARP inhibitors for patients with this mutation. This outside liquid biopsy did not specify whether the detected ATM mutation was derived from the tumor or potentially from clonal hematopoiesis.

A tissue biopsy was sent to Caris for molecular profiling. Tissue molecular profiling done at Caris confirmed the diagnosis of metastatic prostate cancer with mutations in FOXA1 and MEK1, genes that play roles in regulating cell growth and behavior.

The patient received palliative radiation therapy and began androgen deprivation therapy ("ADT"). The ATM mutation detected by the outside liquid biopsy also indicated potential benefit from the PARP inhibitor olaparib. After an increase in the patient's prostate-specific antigen levels led the clinician to consider new therapy options, a blood sample was sent for Caris Assure molecular profiling.

Caris Assure confirmed the previously-identified FOXA1 and MEK1 mutations, MSS, and low blood TMB consistent with low tissue TMB, but showed that the ATM mutation was CH-derived rather than tumor-derived. Therefore, ADT could continue while the patient is responsive and tolerant, but the clinician could avoid prescribing the PARP inhibitor olaparib, knowing that the ATM mutation targeted by that therapy is a false positive from CH and not a tumor biomarker.

The CH subtraction capability of Caris Assure in this case provided the patient and his clinicians more accurate information about potential future treatment options, and helped the patient avoid the potential harmful side effects, time and financial cost of therapies that would likely have been ineffective.

Caris Assure for Therapy Selection

We initiated a broad commercial launch of Caris Assure for therapy selection in the first quarter of 2024 and currently offer the solution as an LDT, which the FDA has historically considered to be a category of *in vitro* diagnostic ("IVD") test intended for clinical use and designed, manufactured, and used within a single laboratory. The FDA has historically exercised enforcement discretion and not required marketing authorization for LDTs. Accordingly, we have not yet obtained FDA marketing authorization for Caris Assure. However, the FDA recently issued the LDT Final rule, which if implemented, would have imposed medical device requirements on many types of LDTs that were previously subject to enforcement discretion. This rule was set to go into effect in May 2025. However, on March 31, 2025, a federal district court set aside and vacated the LDT Final Rule on the basis that LDTs are not medical devices. It remains unclear at this time what impact this court decision will have on the FDA's oversight over LDTs moving forward, including which of our offerings may be eligible for or otherwise require FDA marketing authorization. We have anticipated seeking FDA marketing authorization for certain of our solutions in the future, including Caris Assure for therapy selection. Additionally, while we currently market Caris Assure for therapy selection as an LDT, it remains possible that marketing authorization would be required in order for us to market Caris Assure as a companion diagnostic device for therapy selection. We do not yet have specific plans regarding the timing of a PMA or other submission, if any, for Caris Assure for therapy selection or any other indication. For additional information, see "Business—Government Regulation—U.S. Food and Drug Administration." We have Medicare reimbursement and various levels of commercial payer adoption and/or reimbursement coverage for Caris Assure for therapy selection across the United States. The current pricing of Caris Assure for therapy selection under MolDX is \$3,649.

Caris Assure for therapy selection is available in all U.S. states (other than New York, where we intend to apply in 2025 for approval from New York State's Clinical Laboratory Evaluation Program ("NY CLEP")) and in Puerto Rico. We also offer Caris Assure for therapy selection internationally through distributors and direct contracts with hospital systems, where permitted by applicable regulations.

Caris Assure Profile Report

Caris Assure for therapy selection generates a personalized report that provides oncologists with the information to tailor each patient's treatment plan. This report is built to maximize clinical utility in an

easy-to interpret format. Our technology enables us to report our results for blood-based profiling even quicker than tissue-based profiling, as Caris Assure results are typically reported in approximately seven calendar days from “activation,” the time at which we receive the patient’s samples and required paperwork. A sample Caris Assure profile report is depicted below.

Blood Report

Treatment Planning:

- Navigate among FDA-approved drugs and therapies with potential benefit or lack of benefit
- Identify therapies that may not have been considered
- Match patient to clinical trials based on tumor biology

Evidence-guided:

- Drug associations based on peer-reviewed literature and clinical treatment guidelines
- Testing methodologies consistent with industry guidelines

EHR Compatible:

- HITECH compliant
- Easy installation
- Secure encryption
- Real-time sync

CARIS

ASSURE

Final Report

Patient

Name: TEST, TM

Date of Birth: 01/01/1960

Sex: Male

Case Number: TH23-777635

Diagnosis: NSCLC

Specimen Information

Primary Tumor Site: Overlapping lesion of lung

Specimen Site: Specimen ID: 777635

Specimen Collected: 02-Oct-2023

Test Report Date:

Ordered By

Test Test Physician 2

Test Account 1

1234 Test Avenue

Test, AZ 00000

(000) 000-0000

Results with Therapy Associations

Biomarker	Results	Therapy Association	Biomarker Level*
EGFR	Pathogenic Variant Exon 20 p.L858R	BENEFIT afatinib; dacomitinib; erlotinib [†] ; gefitinib; osimertinib	Level 2

*Level 1: Companion diagnostic (CDx); Level 2: Strong evidence of clinical significance or endorsed by clinical guidelines; Level 3: Potential clinical significance.

IMPORTANT NOTE: Osimertinib is the NCCN preferred agent for first-line setting of advanced or metastatic NSCLC patients harboring sensitizing EGFR mutations.
[†]erlotinib combinations with VEGF receptor (VEGFR) inhibitors utilized in the first-line setting for metastatic NSCLC include:
- erlotinib + ramucicromab (FDA-approved, Nakagawa, et al., 2019)
- erlotinib + bevacizumab (NCCN guidelines, Saito, et al., 2019)
Osimertinib and VEGFR inhibitor combinations have not been evaluated.

Tumor Associated Findings

Biomarker	Protein Change	DNA Change	Variant Frequency	Interpretation
CDKN2A	R58*	c.172C>T	3.4%	Pathogenic Variant
EGFR	L858R	c.2573T>G	2.5%	Pathogenic Variant
TP53	R342*	c.1024C>T	7.2%	Pathogenic Variant

Other Results
TUMOR FRACTION: 10.5%
BLOOD TMB (mut/Mb): 18
MICROSATELLITE INSTABILITY: Not Detected

Incidental Findings* (Pathogenic & Likely Pathogenic Variants)

Incidental Germline Variants

Biomarker	Protein Change	DNA Change	Variant Frequency	Interpretation
None Detected	—	—	—	—

Clonal Hematopoiesis (CH)

Biomarker	Protein Change	DNA Change	Variant Frequency	Interpretation
ASXL1	G645f*	c.1934delG	1.2%	Pathogenic Variant

*Incidental findings section reports variants characterized as non-tumor derived. These results are not replacement for comprehensive germline testing. Incidental germline pathogenic alterations in ACAG-recognized 5 additional selected cancer genes are reported (see reportable gene list). Negative results do not imply the patient does not harbor a germline mutation. Clonal mutations in cancer-associated genes in white blood cells (WBCs) and not of solid tumor origin (Incidental CH variants) are reported but may not comprehensively detect all CH variants. These mutations occur naturally and increase with age or may be smoking- or therapy-related. Although CH is considered a benign state, there is a link of progression to hematological malignancy and thus appropriate clinical correlation is recommended. Variants characterized as indeterminate origin, if reported, are likely characterized as high-level CH variants or potential mosaic. Categorization of incidental pathogenic and likely pathogenic variants are based on the observed allele frequency in the buffy coat, such that, for the majority of cases: 1. 30% is germline; 20% is indeterminate origin; 50% is clonal hematopoiesis, though some rare exceptions may exist.

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Technical Specifications and Analytical Validation

Caris Assure analyzes all coding genes through WES (cell-free DNA) and WTS (cell-free RNA), and categorizes variants found in plasma as either tumor-derived or CH-derived and either somatic or germline. Caris Assure clinically reports SNVs, INDELs, and select fusions, as well as MSI, TMB, human leukocyte antigens, and select amplifications.

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Technical Specifications: Caris Assure for Therapy Selection

Technology

Circulating Total Nucleic Acids (cTNA)

Application

Biomarker Analysis (including resistance mutations)

Biological Coverage

Plasma: cfDNA, cfRNA White Blood Cells: gDNA, mRNA

Variant Coverage

Tumor-Derived Incidental Germline[†] Incidental CH

Genes & Depth

23,000+ 8,000x (raw average for clinically relevant genes)

Next-Generation Sequencing

Whole Exome Whole Transcriptome

Alterations

SNV INDEL CNA Fusions/Rearrangements

Genomic Signatures / Other

bTMB HLA Genotype MSI

Sample Quantity

2 Tubes Whole Blood (10 mL PAXgene® Blood ccfDNA tubes)

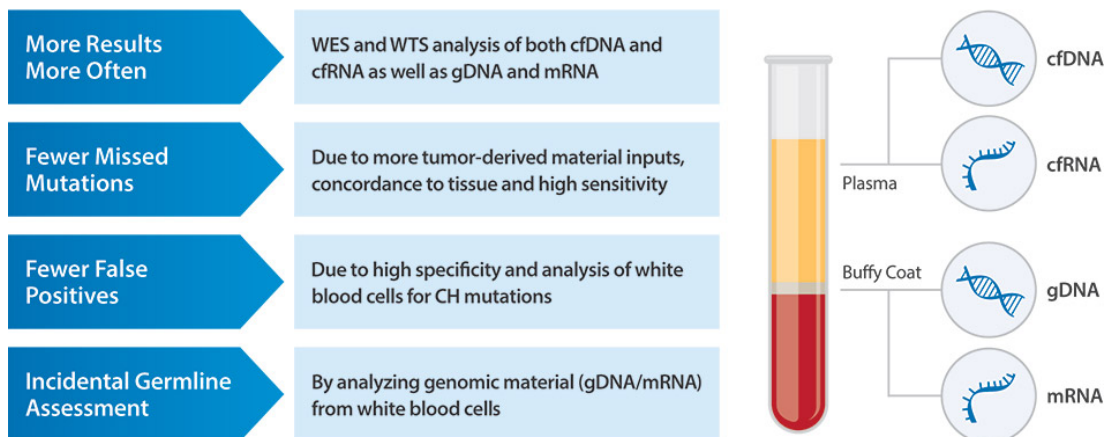
Assay Performance Specifications

Performance in advanced/metastatic patients compared to matched tissue collected within 30 days; based on ≥ 5 ng of cNAS (circulating nucleic acid sequencing) input. **Clinically actionable SNVs and indels demonstrated 93.8% sensitivity and 96.8% PPV, with >99.99% specificity. Incidental germline reported >99% for sensitivity, PPV and specificity.**

Alteration	Limit of Detection at 95% Sensitivity	Specificity	Threshold for Positivity
SNVs	Min: 0.05% Mode (most common value): 0.15%	>99.99%	>0% VF > 2 reads
Indels	Min: 0.1% Mode (most common value): 0.45%	>99.99%	>0% VF > 2 reads
CNAs	3.83 copies	>99.99%	3.36 copies
Fusions/Rearrangements	Min: 0.15% Mode (most common value): 0.22%	>99.99%	>0% VF > 1 read
MSI-High	Calculated from Frameshifts	-	-
bTMB	Calculated from SNVs	-	-

Variant Frequency ("VF") represents the proportion of sequencing reads that carry a specific variant in the sample sequenced (mutated reads/mutated + wildtype reads).

Novel Circulating Nucleic Acids Sequencing



Caris Assure for Biopharma

The same benefits that blood-based WES, WTS, and CH subtraction bring to patients in the clinical setting also offer significant and previously unavailable advantages to biopharma companies across the drug development continuum. Caris Assure allows biopharma companies to conduct exploration into biology and address elusive questions around response and resistance with repeat and/or longitudinal biopsies, without the restriction of earlier generation liquid biopsies. This enables biopharma companies to understand the molecular alterations responsible for resistance. In a drug development setting, the only way to get this understanding is through the WES/WTS sequencing technology underlying Caris Assure. With a typical results turn-around-time of approximately seven calendar days from activation, Caris Assure can be used in early-stage trials to identify and enroll eligible patients that meet inclusion and exclusion criteria, or more broadly to leverage this comprehensive molecular profile of patients for exploratory analyses.

Caris Assure is designed to be particularly valuable when used serially for time point studies, real-time monitoring of disease progression and treatment response, and post-treatment monitoring for recurrence. Caris Assure offers the biopharma industry the opportunity, for the first time, to incorporate complete WES and WTS interrogation at multiple timepoints throughout clinical trials in a non-invasive and easy-to-implement modality. This would enable biopharma companies to not only track changes in the mutation profile of a tumor in response to treatment, but also to assess changes in gene expression over time. Until now, different assays and analysis methods were required at different time points. Caris Assure offers biopharma companies the ability to use the same, consistent, and uniform assay across their full development program, allowing for more consistent, complete, and inter-comparable datasets across drug studies and time points. With Caris Assure, we believe biopharma companies would be able to generate more NGS data on individual clinical trial patients than has ever been possible using a blood-based assay in the history of cancer research and clinical trials.

MI Profile—Our Tissue-Based Profiling Solution

MI Profile is our tissue-based molecular profiling solution for cancer therapy selection, with over one million tests performed on approximately 146,500 clinical cases in 2024 and an additional approximately 40,000 clinical cases in the three months ended March 31, 2025. As of March 31, 2025, we have performed over 6.5 million tissue-based tests on over 790,000 clinical cases since inception. MI Profile includes our comprehensive WES/WTS NGS assay and IHC protein expression testing. Our tissue microdissection process has, to date, resulted in a high success rate in identifying actionable biomarkers in 95% of patients profiled. Eligibility of tissue samples for our MI Profile tissue profiling requires a presence of at least 20% tumor nuclei and at least 50 ng of DNA for MI Cancer Seek, and at least 25 ng for MI Tumor Seek Hybrid, and the sample must meet other requirements detailed in our requisition form used by ordering physicians. MI Cancer Seek requires formalin-fixed paraffin embedded tissue samples, but we can accept samples in different forms for MI Tumor Seek Hybrid as detailed in our requisition form.

The information generated from profiling the patient's tissue is used to create an interpretative report based on our bioinformatics pipeline and recommend individualized therapies for cancer patients. Our goal is to maximize the information generated and corresponding clinical utility for patients from the limited available tumor tissue. The information generated, which further expands our multi-modal datasets, also provides valuable insights to aid drug discovery and development efforts. Customers for MI Profile include treating physicians as well as researchers and biopharma companies.

We have obtained Medicare and commercial reimbursement for MI Profile. MI Profile, including our MI Cancer Seek assay and our proprietary clinical molecular signatures GPSai and FOLFIRSTai are available in all U.S. states and in Puerto Rico. We also offer MI Profile internationally in over 40 countries through distributors and direct contracts with hospital systems, where permitted by applicable regulations.

We have obtained a PMA approval from the FDA for a companion diagnostic and tumor profiling designation for MI Cancer Seek, a WES/WTS NGS assay that uses the whole exome for TMB calling and for which we have obtained a Proprietary Laboratory Analyses ("PLA") code, Current Procedural Terminology ("CPT") code 0211U, at a reimbursement rate of \$8,455. Our MI Cancer Seek solution was commercially launched in January 2025, and we currently market it as the WES/WTS NGS component of MI Profile. We have obtained Medicare coverage for MI Cancer Seek for CPT code 0211U under the NGS

NCD. MI Tumor Seek Hybrid, which is a WES/WTS NGS LDT assay that we currently offer as an alternative assay in the event a specimen does not meet the requirements for MI Cancer Seek, is currently priced by MolDX at \$3,500.

MI Profile Report

MI Profile generates a personalized report that provides oncologists with the information to tailor each patient’s treatment plan. The MI Profile report was built by oncologists for oncologists and is designed to maximize clinical utility in an easy-to interpret format. We generally report our results for tissue-based profiling approximately 10 calendar days from activation. A sample MI Profile report is depicted below.

Tissue Report

Treatment Planning:

- Navigate among FDA-approved drugs and therapies with potential benefit or lack of benefit
- Identify therapies that may not have been considered
- Match patient to clinical trials based on tumor biology

Evidence-guided:

- Drug associations based on peer-reviewed literature and clinical treatment guidelines
- Testing methodologies consistent with industry guidelines

EHR Compatible:

- HITECH compliant
- Easy installation
- Secure encryption
- Real-time sync

ADDITIONAL SERVICES SECTION

Final Report

CARIS
LIFE SCIENCE

Patient

Specimen Information

Ordered By

Name:
Date of Birth:
Sex:
Case Number: T21216
Diagnosis: Adenocarcinoma, metastatic, N22

Primary Tumor Site: Lower lobe, lung

Specimen Site:
Specimen ID:
Specimen Collected:
Test Report Date:

Results with Therapy Associations

BIOMARKER	METHOD	ANALYTE	RESULT	THERAPY ASSOCIATION	BIOMARKER LEVEL
	Seq	ChkA-Tumor	Pathogenic Variant: Exon 19 (pL2746_A750del)	afatinib, docetaxel, erlotinib, gefitinib, osimertinib	Level 1
PD-L1 (22C3)	IHC	Protein	Positive, TPS, 1%	atezolizumab, nivolumab, pembrolizumab	Level 2
RET	Seq	RNA-Tumor	Pathogenic Fusion	pralsetinib, selpercatinib	Level 2
HER	IHC	Protein	Negative (0)	capecitabine	Level 3
HER	Seq	RNA-Tumor	Fusion Not Detected	lapatinib, tofacitinib	Level 2
BRCA	Seq	ChkA-Tumor	Mutation Not Detected	abiraterone, abiraterone + tamsulosin, enzalutamide, sipuleucel-S	Level 2
BRCA	Seq	ChkA-Tumor	Mutation Not Detected	olaparib, talazoparib	Level 2
BRCA	Seq	ChkA-Tumor	Mutation Not Detected	enzalutamide, sipuleucel-S	Level 2
BRCA	Seq	ChkA-Tumor	Mutation Not Detected	enzalutamide, sipuleucel-S	Level 2
BRCA	Seq	ChkA-Tumor	Mutation Not Detected	enzalutamide, sipuleucel-S	Level 2
BRCA	Seq	ChkA-Tumor	Mutation Not Detected	enzalutamide, sipuleucel-S	Level 2

CDx Associated Findings

Genomic Findings Detected

FDA-approved Therapeutic Options

EGFR E746_A750del

GIOTRE* (afatinib), IRESSA* (gefitinib), TAGRESSO* (osimertinib), TARCENAV* (erlotinib), VIZIMPRO* (dacomitinib)

EGFR L858R

Not Detected

Microsatellite Instability (MSI)

Stable

Tumor Profiling Results

MI Cancer Seek is FDA-approved to provide tumor mutation profiling results for previously diagnosed oncology patients v

Other Alterations and Biomarkers Identified

Results reported in this section are not prescriptive or conclusive for labeled use of any specific therapeutic product. Confirmation of tumor mutation status using an FDA-approved CDx test is needed for therapeutic use.

Tumor Mutational Burden (TMB)

6 mut/Mb

BRCA2

W2626R

CDx RESULTS SECTION

CARIS[®] GPSai

Most Likely Tumor Type: Cholangiocarcinoma

94%

Caris GPSai™

Cancer type similarity assessment intended to help identify the tumor of origin by comparing molecular characteristics of the patient's tumor against 90 tumor categories in the Caris database.

CARIS[®] FOLFIRSTai

INCREASED BENEFIT to FOLFOX + bevacizumab in first-line metastatic CRC

Caris FOLFIRSTai™

Chemotherapy response predictor intended to gauge a mCRC patient's likelihood of benefit from first-line FOLFOX+ BV followed by FOLFIRI+ BV, versus FOLFIRI+BV followed by FOLFOX+BV treatment.

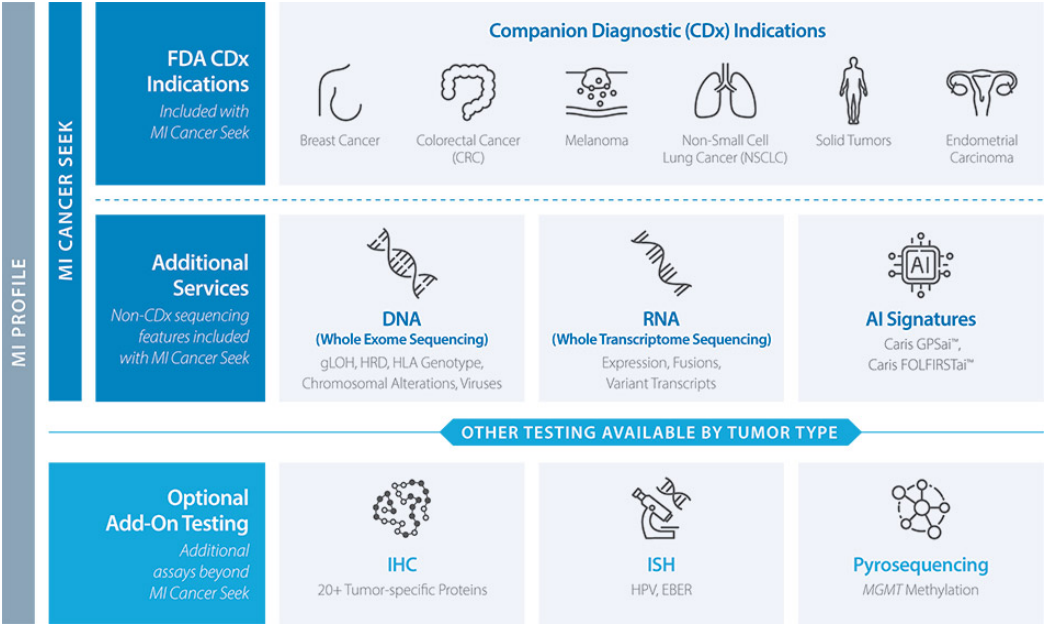
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Technical Specifications and Validation

MI Cancer Seek

The current WES/WTS NGS component of MI Profile is MI Cancer Seek, for which we have received FDA approval for use as a companion diagnostic device to identify cancer patients who may benefit from treatment with targeted therapies. The assay includes one pan-cancer and five tumor-specific indications for numerous FDA-approved therapies. To our knowledge, MI Cancer Seek is the first and only simultaneous WES and WTS-based assay with FDA-approved companion diagnostic indications for molecular profiling of solid tumors. MI Cancer Seek is available for adults and pediatric patients between the ages of one and 22.

MI Cancer Seek is a NGS-based in vitro diagnostic device using total nucleic acid isolated from formalin-fixed paraffin embedded tumor tissue specimens for the detection of SNVs, InDels, MSI, TMB in patients with previously diagnosed solid tumors, and CNA in one gene in patients with breast cancer. MI Cancer Seek is intended as a companion diagnostic to identify patients who may benefit from treatment with the targeted therapies listed in the Companion Diagnostic Indications table below, in accordance with the approved therapeutic product labeling.



MI Cancer Seek Companion Diagnostic Indications

Indication	Biomarker	Therapy
Breast Cancer	<i>PIK3CA</i> (C420R; E542K; E545A, E545D [1635G>T only], E545G, E545K, Q546E, Q546R; and H1047L, H1047R, H1047Y)	PIQRAY® (alpelisib)
Colorectal Cancer (CRC)	<i>KRAS</i> wild-type (absence of mutations in exons 2, 3, and 4) and <i>NRAS</i> wild-type (absence of mutations in exons 2, 3, and 4) <i>BRAF</i> V600E	VECTIBIX® (panitumumab) BRAFTOVI® (encorafenib) in combination with ERBITUX® (cetuximab)
Melanoma	<i>BRAF</i> V600E <i>BRAF</i> V600E or V600K	<i>BRAF</i> inhibitors approved by FDA MEKINIST® (trametinib) or <i>BRAF</i> / <i>MEK</i> inhibitor combinations approved by FDA
Non-Small Cell Lung Cancer (NSCLC)	<i>EGFR</i> exon 19 deletions and exon 21 L858R alterations	<i>EGFR</i> Tyrosine Kinase Inhibitors approved by FDA
Solid Tumors	MSI-H	KEYTRUDA® (pembrolizumab), JEMPERLI® (dostarlimab-gxly)
Endometrial Carcinoma	Not MSI-H	KEYTRUDA® (pembrolizumab) in combination with LENVIMA® (lenvatinib)

As of March 31, 2025, MI Cancer Seek had 20 FDA-approved therapies and therapy combinations associated with its companion diagnostic indications.

Beyond the MI Cancer Seek FDA-approved indications, MI Cancer Seek reports additional sequencing-based features from DNA such as gLOH, HRD, HLA genotype, chromosomal alterations, viruses, and additional sequencing-based features from RNA such as gene expression, fusions, and variant transcripts.

MI Cancer Seek Technical Specifications and Performance

Technology Next-generation sequencing of total nucleic acids	Breast	<i>PIK3CA</i>	PPA: 99.4% NPA: 100%
	CRC	<i>KRAS</i> & <i>NRAS</i> Wild-type	PPA: 100% NPA: 97.2%
		<i>BRAF</i> V600E	PPA: 99.4% NPA: 100%
Variant Coverage Somatic Tumor: SNVs InDels CNAs	Melanoma	<i>BRAF</i> V600E	PPA: 98.7% NPA: 99.4%
		<i>BRAF</i> V600E/K	PPA: 98.9% NPA: 99.3%
Genomic Signatures MSI TMB	NSCLC	<i>EGFR</i> exon 19 deletions and exon 21 L858R alterations	PPA: 98.1% NPA: 99.4%
	Solid Tumors	MSI-H	PPA: 97.5% NPA: 98.5%
Specimen Quantity[†] TNA extraction with ≥50 ng of DNA (~10 slides at 20% tumor nuclei)	Endometrial	Not MSI-H	PPA: 98.4% NPA: 97.6%

PPA and NPA are terms commonly used in the context of diagnostic tests and medical studies and are helpful for evaluating the performance of diagnostic tests:

- **PPA** stands for Positive Percent Agreement. Similar to NPA, it is a measure of the agreement between a test's positive results and the true positive status as determined by a reference standard. It reflects the test's ability to correctly identify positive results.
- **NPA** stands for Negative Percent Agreement. It is a measure of the agreement between a test's negative results and the true negative status as determined by a reference standard. It reflects the test's ability to correctly identify negative results.

MI Tumor Seek Hybrid

Our legacy MI Tumor Seek Hybrid profiling solution combines WES analysis of DNA for mutations, CNAs, INDELs, and genomic signatures (TMB, MSI, gLOH, and HRD) with WTS analysis for RNA fusions and variant transcripts. We have also analytically validated MI Tumor Seek Hybrid for viral detection and report HPV, MCV, and EBV presence from the WES data in the appropriate tumor context. MI Tumor Seek Hybrid achieves accurate results through high coverage depths for DNA and RNA sequencing. MI Tumor Seek Hybrid consistently reaches 1,500 times depth of coverage for clinically relevant DNA genes and 300 times depth of coverage for the whole exome. Our WTS technology allows for fusion detection, variant transcript analysis, and gene expression profiling.

AI Signatures

Our WES/WTS profiling solutions generate over 28.8 billion datapoints, spanning 84,000 molecular markers, per clinical case. To interpret this data, MI Profile utilizes an advanced, AI-powered bioinformatics pipeline. This bioinformatics pipeline includes a sophisticated rules engine, variant calling, fusion calling, copy number prediction, and expression analysis. We use over 220 AI algorithms in connection with the

bioinformatic pipeline of our tissue-based sequencing. These AI algorithms assist in sample processing, quality control, biological processing, and biological interpretation. Collectively, these AI algorithms generate data on 84,000 molecular markers for each WES/WTS run.

MI Profile can also include our proprietary clinical molecular signatures, GPSai and FOLFIRSTai, which were developed by training and clinically validating AI/ML algorithms with our extensive multi-modal clinico-genomic datasets. These molecular signatures, which we currently offer as LDTs, provide clinical utility for molecular diagnosis of cancer and prediction of patient response to treatment.

- **GPSai.** Our GPSai signature is a molecular disease classifier that utilizes multiple deep neural networks and hundreds of thousands of molecular features to predict a histologic diagnosis and tumor origin directly from the DNA and RNA sequencing data. The result is a probability of the most likely diagnosis, which is then reviewed by a Caris Board-Certified Pathologist in the context of all available clinicopathologic information before report release. The primary indication for GPSai is to determine if the initial diagnosis is correct and serves as a quality control for all patients. In addition, it can be used to help identify the tissue of origin for Cancers of Unknown Primary (“CUP”), cases where the starting point of the cancer is not yet clear, which is a major unmet need in clinical oncology. This tissue of origin prediction is provided along with the comprehensive biomarker data without the need for additional specimen utilization; this tool runs on the MI Profile exome and transcriptome sequencing results. GPSai is also utilized as a quality control metric where it is run on every clinical case and the results reviewed by a pathologist. If the GPSai results do not match the outside pathologic diagnosis of the specimen, our pathologists will do additional work-up, including IHC testing, to support a new diagnosis to provide the best overall service and patient care.

GPSai was trained and clinically validated by us through retrospective profiling data from over 250,000 clinical cases using the outside pathologist diagnosis as the baseline. In a prospectively run clinical validation study that we conducted, GPSai demonstrated overall accuracy of 94.8% and an overall call rate of 95.1%. This clinical validation of GPSai enabled us to offer the solution as an LDT in accordance with the Clinical Laboratory Improvement Amendments of 1988’s (“CLIA”) requirement of clinical validation of a variety of performance characteristics, including accuracy, precision, specificity, sensitivity, reportable range, and reference interval before an LDT is used in clinical testing.

- **FOLFIRSTai.** Our FOLFIRSTai signature is our first clinically validated, AI-powered molecular predictor of efficacy of oxaliplatin-based chemotherapy combined with bevacizumab in patients with metastatic colorectal cancer (“mCRC”). According to estimates by the ACS, one in 23 men and one in 25 women in the United States will be diagnosed with colorectal cancer in their lifetime. FOLFOX, FOLFIRI, or FOLFOXIRI chemotherapy with bevacizumab is considered standard first-line treatment option for patients with mCRC. Some mCRC patients benefit from one combination chemotherapy regimen over the others, and identifying which patients would benefit from which regimen is a challenge for physicians. FOLFIRSTai is included for all clinical cases with completed WES results and a diagnosis of advanced stage colorectal adenocarcinoma. The FOLFIRSTai results appear in the MI Profile report as “Increased Benefit” or “Decreased Benefit” with additional detail provided about the results in the report. FOLFIRSTai is broadly accessible to patients and is covered by almost all insurance companies.

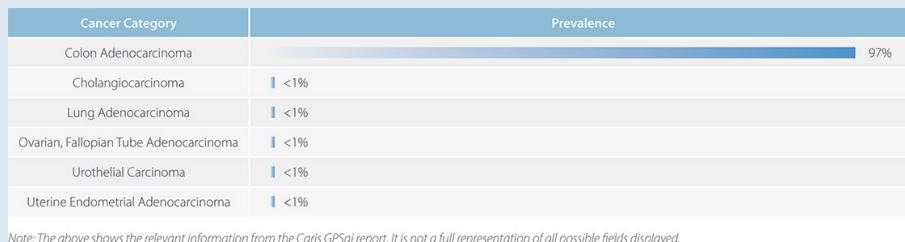
We clinically validated FOLFIRSTai using a real-world evidence dataset collected from the Caris POA registry, insurance claims data and samples from the TRIBE2 Phase 3 clinical trial, which compared first-line use of FOLFOXIRI and FOLFOX. In a clinical validation study that we conducted, FOLFIRSTai demonstrated that the overall survival of patients treated in a manner consistent with the FOLFIRSTai prediction was 17.5 months longer than the overall survival of patients treated counter to the prediction (representing a 71% difference). This clinical validation of FOLFIRSTai enabled us to offer the solution as an LDT in accordance with CLIA’s requirement of analytical validation of a variety of performance characteristics, including

accuracy, precision, specificity, sensitivity, reportable range, and reference interval before an LDT is used in clinical testing.

Case Study: The Power of Caris' AI Signatures to Inform Diagnosis and Treatment

Caris was presented with the case of a female patient in her early 50's with bilateral adnexal masses (growth occurring in or near the uterus, ovaries, fallopian tubes and connecting tissues), the largest of which measured 22 cm in greatest dimension. The patient's pathological diagnosis was ovarian adenocarcinoma based on a morphological examination under a microscope. The patient underwent total abdominal hysterectomy (surgical removal of the uterus), bilateral salpingo-oophorectomy (removal of both ovaries and fallopian tubes) with pelvic debulking of tumor (removal of as much cancerous tissue in the abdomen as possible).

A representative post-surgery tissue specimen of the patient's right adnexal lesion was sent to Caris, to help her oncologist decide the best options for therapy. Based on the patient's comprehensive sequencing results using WES and WTS, a GPSai™ score was generated highly suggesting the colon as the malignant tissue of origin, as shown in the excerpt below:



To help further validate the GPSai™ finding, a panel of diagnostic IHCs (protein analysis) was performed that showed the tumor to be positive for colon-specific protein expression further pointing toward a diagnosis of colorectal cancer.

As a result of these findings, the patient underwent colonoscopy that showed large nearly obstructive colonic lesion. This case was reviewed at the hospital tumor board and there was consensus that this patient would be best managed as metastatic colonic adenocarcinoma. As a result of the Caris GPSai™ finding, the patient's diagnosis and course of treatment was altered based on a detailed discussion of the results with the ordering physician. Caris also provided the FOLFIRSTai result for therapy sequencing and, through NGS, generated a targeted therapy recommendation for the treating physician.

This was an example of a use of Caris' collective sequencing and proprietary AI signatures to help a patient obtain a targeted therapy recommendation and avoid the potential cost, time and side effects of ineffective therapy.

QuantumAI Report

We also use the in-depth sequencing data generated by MI Profile to produce the QuantumAI report, a research use only description of the patient's molecular tumor biology and characterization of their phenotype using whole exome and whole transcriptome sequencing. The QuantumAI report, which we have analytically validated but not yet clinically validated, contains various biological signatures such as DNA variants counted towards TMB across the whole exome, the Catalogue of Somatic Mutations in Cancer (COSMIC) signatures resulting from a subset of TMB variants, genomic loss of heterozygosity, genomic scar score, and copy number alterations at the chromosome band level as well as exon-level copy number alterations on over 700 genes. An enhanced eKaryotype shows copy number alterations per chromosomal band along with associated confidence intervals to highlight areas of strong or likely amplifications and deletions. RNA gene expression signatures include consensus molecular subtypes (colorectal cancer), PAM50 (breast), and purIST (pancreatic). The report also includes measurements of tumor infiltrating lymphocytes and RNA heatmap expression for hundreds of genes relative to nearly 90 distinct cancer types. An additional RNA component is a circos diagram representing all RNA fusions observed across the whole transcriptome, to help oncologists and researchers understand relationships between genetic variations, mutations, and other molecular features and to help tailor precision medicine approaches. The report also

features MGMTai, an AI signature that uses both DNA and RNA features to predict response to temozolomide in glioblastoma. Anticipated future additions to the report include pancreatic, lung, and breast cancer drug therapy response predictors using AI signatures, a brain metastasis predictor using AI signatures, an image of the H&E stain used for sequencing, raw depth of coverage per genes/exons, gene expression interpretation and genetic predispositions.

IHC Testing

We leverage a broad menu of third-party IHC tests to create a customized set of tests for each patient to reveal a more complete molecular blueprint of the patient's disease. We use IHC testing to complement our WES/WTS profiling both to inform decisions regarding therapy selection as well as to act as confirmatory testing in circumstances where our GPSai algorithm indicates a different diagnosis than that indicated in the patient record prior to our profiling or in CUP cases. We believe we have one of the broadest IHC testing menus available to patients and physicians to provide the most appropriate therapy results and diagnosis.

Testing patient specimens for protein-based biomarkers by IHC is the standard of care for both predictive and diagnostic purposes. For predictive IHCs, we run third-party companion diagnostic IHCs when available to provide therapy associations that cannot be identified through NGS testing. For example, checkpoint inhibitor therapies require IHC testing for PD-L1. We also utilize a number of third-party diagnostic IHCs to help with refining or changing a diagnosis. Most samples come to us for molecular profiling with a diagnosis in hand. However, WES and WTS provide a broad and deep data set that can help alter or refine a diagnosis. In some cases, we receive patient sample labeled as 'Cancer of Unknown Primary,' where it is hoped that molecular profiling will allow a more specific diagnosis to be applied. Once we evaluate the molecular data, including the results of GPSai if applicable, our pathology team will often order diagnostic IHC testing to provide additional support for a specific diagnosis.

Case Study: Caris GPSai™ Helps Diagnose Origin of Metastatic Malignancy

A woman in her early 30's presented to her primary care physician with symptoms of abdominal distension and gastrointestinal discomfort. Imaging revealed widespread metastatic disease, including pleural effusions (excess fluid in the space between the lungs and the chest wall), pulmonary nodules (small growths in the lung), and extensive lymphadenopathy (swelling of the lymph nodes). A biopsy of a soft tissue mass in the right abdominal wall was preliminarily thought to represent carcinoma.

IHC testing showed certain positive and negative markers that together led to a diagnosis by the patient's physician of metastatic cancer of unknown primary (CUP). Seeking further clarity, the patient's tissue sample was sent to Caris for molecular profiling and GPSai™ analysis.

The GPSai™ result returned with a 99% probability of mesothelioma, suggesting the cancer originated from mesothelial cells, such as those lining the lungs and abdomen, rather than being a metastatic adenocarcinoma from another primary site.

The integration of Caris GPSai™ into the patient's care pathway facilitated a more precise understanding of her tumor's origin and molecular characteristics, guiding personalized treatment decisions tailored specifically to mesothelioma. By pinpointing the precise nature of the cancer, Caris GPSai™ enabled a more targeted and effective approach to treatment, with the goal of ultimately optimizing treatment and outcomes.

MI Profile for Biopharma

Maximizing knowledge and extracting the most information out of every patient sample on a clinical trial reduces the risk of researchers missing potential efficacy or safety signals. Sequencing the whole exome and the whole transcriptome not only yields far more biomarker data from limited specimens, but also allows for the power of such comprehensive information to be aggregated and deployed to improve patient outcomes in the future via real-world data analyses. The breadth and depth of data make our methodology fundamentally different from the currently available DNA panels, which are limited by only looking at known biomarkers. We believe that a non-comprehensive, subset panel of genes or DNA-only assay that ignores RNA is an inadequate solution for efficient and successful drug development, and represents

the central underpinning for why we believe we are uniquely positioned in the marketplace to be the industry leading innovator and strategic partner of choice for biopharma companies, to jointly bring forward the next generation of novel therapies for patients with cancer. Oncology therapeutics are inevitably shifting from single driver alterations with single biomarkers to more sophisticated and complex biomarkers that can stratify patients such as novel signatures for DNA damage response repair targeting molecules and RNA-based expression for immunotherapies. Our comprehensive WES/WTS NGS assay is optimally positioned to seamlessly validate these novel biomarkers that are already included in our assay.

Molecular profiling has broad applications for our biopharma partners, including prospective screening, retrospective testing and deep translational analyses, stratification of patients for existing or future trials, and treatment monitoring. When our tissue WES/WTS assay is deployed as an integrated component of early development programs and clinical trials, that same assay can be leveraged for companion diagnostics development and commercial services that we deliver for our partners. Commitment to Caris as registration partner allows early regulatory interactions while minimizing pharma sponsor costs, maintaining flexibility to changing timelines and evolving biomarker strategies. We have obtained a PMA approval from the FDA for MI Cancer Seek as a companion diagnostic device, and we believe approval by the FDA will serve as another important inflection point for our biopharma business. Furthermore, the comprehensiveness of our WES/WTS approach creates a deep competitive moat for us.

In addition to testing of both DNA and RNA, we offer companion diagnostic partners opportunities to use samples sourced from our vast biobank of clinical specimens. This offers partners access to a large selection of fully characterized specimens of known positive and negative biomarker status. This can alleviate one of the most difficult hurdles of companion diagnostic development, namely access to enough biomarker-positive specimens across the minimum number of cancer types required to conduct FDA validation studies. For companion diagnostic projects involving a biomarker with low incidence, we offer partners a significant advantage. Beyond companion diagnostics, our biobank carries significant value for exploratory translational studies. When novel discoveries are made *in silico*, or based on DNA or RNA, the path to validate these findings requires tissue for proteomic assessments or targets or biomarkers. Having any tissue is valuable however, our tissue biobank is unique because of the scale due to the number of cases and tests we have completed to date, the heterogeneity of tissue types which reflects cancer prevalence, and most importantly because of the amount of WES and WTS information we have generated. In aggregate, our biobank with accompanying data and digital images provides biopharma companies with a unique and highly valuable set of research tools to help validate and derisk the next wave of oncology therapeutics.

Caris ChromoSeq

Through an exclusive license arrangement with Washington University in St. Louis (“WashU”) that we entered into in October 2024, we are developing Caris ChromoSeq, an assay that detects and analyzes hematological (blood) cancers using whole genome sequencing (“WGS”) and WTS for commercial launch. We are internally validating this assay, which is based upon the licensed assay and also includes our WTS technology, and developing it for commercial launch subject to successful validation and a successful application for reimbursement from MolDX. If successful, we believe this assay designed for genomic evaluation of patients with blood cancers would serve as a valuable complement to our existing tissue and liquid assay solutions, which are oriented towards identifying and profiling cancers of solid tumor origin, and enhance our position as a provider of choice for molecular profiling solutions. If we determine to commercialize this assay, we anticipate initially doing so as an LDT.

The licensed assay is a high coverage WGS assay currently designed and initially validated for the comprehensive genomic evaluation of patients diagnosed with acute myeloid leukemia (“AML”) or myelodysplastic syndromes (“MDS”). The licensed assay requires only 50 ng of tumor DNA (blood or bone marrow) for sequencing and is designed to identify over 600 clinically relevant chromosomal rearrangements known to be recurrent in myeloid malignancies. The licensed assay is an alternative to existing conventional diagnostic and risk assessment tools for AML and MDS, which are primarily cytogenetic testing (karyotyping, or visual analysis of chromosomes), fluorescence *in situ* hybridization (“FISH”), or sequencing assays targeting specific genes or RNA transcripts, each of which conventional methods may provide incomplete information, have limited sensitivity, or present challenges in obtaining viable samples for testing. In a study published by WashU in 2021, the licensed assay was used to obtain genomic profiles for

263 patients with myeloid cancers, including a 146 patient retrospective cohort and a 117 patient prospective cohort. Overall, the licensed assay identified 100% of the clinically significant abnormalities that had been identified by conventional cytogenetic analysis and identified new clinically reportable genetic information not detected by conventional methods in 17% of the patients tested. Additionally, for 19 of the 117 patients in the prospective cohort (16%), analysis performed by the licensed assay changed their risk categorization on the basis of standard risk categories promulgated by the European Leukemia Network and the International Prognostic Scoring System—Revised. The licensed assay displayed similar performance as conventional cytogenetic analysis when predicting clinical outcomes using existing genetic risk groups (adjusted $p=0.09$ by log-rank test in groups identified by conventional testing; adjusted $p=0.01$ by log-rank test in groups identified by the licensed assay). The licensed assay was also found to stratify patients who had inconclusive results by cytogenetic analysis into risk groups in which clinical outcomes were measurably different (adjusted $p=0.03$ by log-rank test).

WashU has obtained Medicare coverage for patients diagnosed with AML and MDS. We believe the methods used by the licensed assay, to be modified by us, can be applied to, and we are working to expand and validate the assay's capabilities for, hematological cancers beyond AML and MDS. In order to obtain MolDX coverage for Caris ChromoSeq, we will need to submit, and MolDX will need to approve, a technical assessment for Caris ChromoSeq.

Caris Discovery

Caris Discovery is our drug target and therapeutic discovery business. Caris Discovery leverages our profiling solutions, multi-modal clinico-genomic datasets, wet lab facilities, proprietary Adaptive Dynamic Artificial Polyligand Targeting ("ADAPT") platform, and AI/ML-enabled *in silico* analyses to identify potential drug targets and develop therapeutics. We launched Caris Discovery in 2022 to partner with biopharma partners to address the lack of novel cancer-specific targets and the herding of biopharma pipelines around a discrete number of lower-risk targets. Caris Discovery is disease- and modality-agnostic and can be applied to any therapeutic modality, including antibody-directed therapies (such as antibody drug conjugates, degrader-antibody conjugates, and T-cell engagers), small molecules, targeted protein degradation, synthetic lethal interactions, cell therapy, and neoantigen discovery for personalized therapy development, among others. In addition to working with biopharma partners, Caris Discovery is developing a wholly-owned pipeline of biologics based on our platform.

An antibody-drug conjugate is a targeted cancer therapy that combines an antibody with a cytotoxic drug. The antibody specifically targets cancer cells, delivering the drug directly to them, which helps minimize the impact on healthy cells. This approach aims to increase the effectiveness of the drug while reducing side effects.

Degrader-antibody conjugates ("DACs") are an emerging class of therapeutic agents that combine the targeting ability of antibodies with the protein degradation mechanism of degraders. DACs are designed to bind to specific proteins on the surface of cancer cells through the antibody component and then recruit the cell's degradation machinery to eliminate the target protein inside the cell. This dual action allows for precise targeting and removal of disease-causing proteins, potentially leading to more effective treatments with fewer side effects.

T-cell engagers are a class of artificial engagers that are designed to specifically direct the body's immune system to target cancer cells. They function by simultaneously binding to CD3 on T cells and to a specific antigen on the tumor cell, thereby bringing the T cells into close proximity with the tumor cells, which can result in the T cells attacking and killing the tumor cells.

A small molecule refers to a low molecular weight organic compound that can regulate a biological process, with a size on the order of 1 nm. In the pharmaceutical industry, small molecules can include drugs that can be orally or intravenously administered and are often used to regulate biological processes. The term contrasts with larger molecules, such as biologics.

Targeted protein degradation is a therapeutic strategy that aims to eliminate disease-causing proteins from cells. It involves the use of small molecules, known as proteolysis-targeting chimeras, or

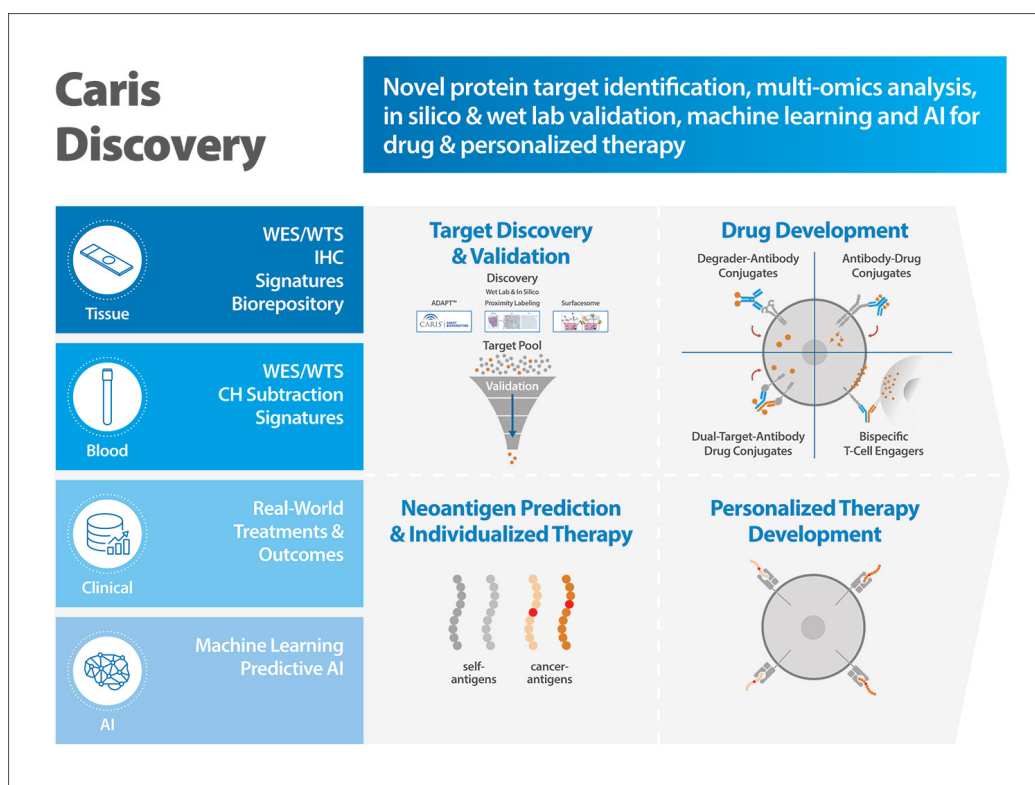
molecular glues, that can bind to specific proteins and tag them for destruction by the cell. This approach is particularly useful for targeting proteins that are difficult to inhibit with traditional drugs or for which no inhibitors exist.

Synthetic lethal interactions in drug discovery refer to a relationship between two genes where the loss of function of either gene alone is survivable by the cell, but the simultaneous loss of both is lethal. This concept is utilized in drug discovery to target cancer cells with specific genetic mutations. By inhibiting the function of a gene that is synthetically lethal to a mutated gene already present in the cancer cell, the cell can be selectively killed without harming normal cells.

Cell therapy is a form of treatment where living cells are injected into a patient to help cure a disease. In the context of cancer treatment, cell therapy can involve the use of immune cells that are either taken from the patient or from a donor, modified in a lab to enhance their ability to fight cancer, and then injected back into the patient. This approach is part of a broader category known as immunotherapy, which aims to harness the body's immune system to combat cancer.

In addition, we believe Caris Discovery can be leveraged to discover personalized therapies for cancer. A major paradigm-shift in cancer therapy in recent years has focused on harnessing the immune system's ability to recognize and eliminate cancer cells. One promising approach involves using personalized therapies to stimulate the immune system against tumor-specific antigens also known as neoantigens. Those neoantigens are proteins that are produced by mutations in the DNA of cancer cells and are not present in normal cells. We believe Caris Discovery is well-positioned to be able to discover personalized neoantigens for cancer therapies given our ability to detect variants and INDELs by WES and to assess gene expression and detect fusions by WTS on every patient's tumor. We also leverage our deep proteomics expertise utilizing mass spectrometry to validate neoantigens using our biorepository of contemporaneous molecular profiled remnant patient tissue that can be predicted by deep ML from our Caris Assure blood and MI Profile tissue sequencing. Furthermore, we can predict who may or may not respond to personalized therapies and who should be excluded from personalized therapy trials due to defects in antigen presentation machinery, such as loss of major histocompatibility complex genes due to mutations or downregulation. We are working with multiple partners that have a personalized therapy in clinical development or clinical trials.

Our proprietary repositories of tissue and data, each of which we believe to be at an unmatched scale, are a resource that could not have been amassed without our underlying commercial profiling business, and as such are a significant differentiator and enabler of our discovery efforts.



We have achieved external validation of our Caris Discovery approach through strategic partnerships with established biopharma companies, such as Merck KGaA and Xencor, to develop therapeutics against novel targets that emanate from our molecular insights and proprietary technology. Our Caris Discovery partnerships are designed to emphasize both near term revenue and the potential upside of successful therapeutics developed against novel targets identified by us, thus aligning our partners' financial interests with our own. Our proprietary discovery proteomics and downstream target validation work is performed, by over 50 Caris scientists, in our R&D laboratory in Tempe, Arizona, a 59,000 square foot facility that includes a cell culture laboratory and state-of-the-art instrumentation dedicated to drug target discovery.

In Silico Target Discovery Leveraging the Caris Clinico-genomic Dataset

Caris Discovery leverages our multi-modal clinico-genomic datasets to define clinically relevant cohorts of unmet need for drug target discovery. Stratifying cases by molecular profile, histology, and/or clinical features *in silico* prior to performing our proprietary proteomic work on the profiled cases in our tissue repository is extremely powerful to identify drug targets in highly relevant therapeutic areas. Once potential targets are identified, the clinico-genomic data can be integrated with our proteomics data and can be utilized to filter the initial target pool down to the targets with the highest potential value for further downstream wet-lab validation.

The proteomics work leveraging our *in silico* discovery work is driven by three complimentary components: (1) our ADAPT Biotargeting, (2) Proximity Labeling, and (3) the Caris Surfacesome.

- **ADAPT Biotargeting—Aptamer-Based Proteomics Discovery System.** Our ADAPT system uses a broad library of synthetically manufactured molecules called aptamers that bind to a wide range of biological targets and characterize complex biological systems, enabling the profiling

of biological samples at a systems-wide scale coupled with affinity purification-mass spectrometry to identify the underlying target proteins. ADAPT is able to simultaneously measure millions of molecular interactions within complex biological systems in their natural states and directly from patient tissue. ADAPT is powered by real world contemporaneous patient samples, including our combined clinico-genomic datasets, thus overcoming the limitations of traditional target discovery approaches, such as comparative genetics, molecular pharmacology of variants, analysis of molecular signaling pathways, cell-based and *in vivo* disease models, limited panel based proteomics with a defined set of target proteins and traditional proteomics, which result in a high degree of off-target activity, false positives and bias, and lack enrichment of patient enriched cancer proteins. ADAPT allows us to make unbiased identification of unique features of disease state and allows for elucidation of novel biological mechanisms. Actionable drug targets (or molecular markers) include proteins that are present in diseased tissue but low to no detection in normal tissue. Traditional biomarker discovery tools suffer from a signal to noise challenge and require a hypothesis of where to look before being deployed. ADAPT can filter out features shared by both cancer and normal cells and enriches for features specific to cancer cells.

- **Proximity Labeling—Antibody-based Proteomics Discovery System.** We also apply proximity labeling on molecularly profiled remnant patient tissue to examine protein-protein interactions as well as to identify components that localize to discrete subcellular compartments. This approach enables us to identify actionable drug targets in patient tissue and permits the systemic analysis of spatially restricted proteomes. Applying proximity labeling on our proprietary tissue profiling data has resulted in the discovery of numerous novel drug targets potentially actionable for bispecific antibodies, dual targeting antibody modalities, and cell therapies.
- **Caris Surfaceome.** Cell-surface proteins are key to antibody-based therapeutics, and we have developed our own cell surfaceome comprising a database of cell surface proteins detected by mass spectrometry. This in-house database comprises genomic, transcriptomic, and proteomic data for multi-omic data analysis in addition to prepared cytosections and live cells instrumental for antibody quality control and wet-lab validation of drug targets discovered from our Aptamer and Antibody-based discovery systems.

Caris Strategic Data

Data and molecular information are at the core of every aspect of our business. Our team of more than 60 data scientists deploy our proprietary advanced AI/ML algorithms to decipher unique features from our resulting clinico-genomic datasets, helping us decode and further unravel the molecular complexity of disease. Our 17-year history of utilizing AI and ML algorithms, together with the breadth and depth of our clinico-genomic datasets, provide us a significant advantage in sophisticated analysis of cancer, and a foundation that we believe will have applications in additional disease states.

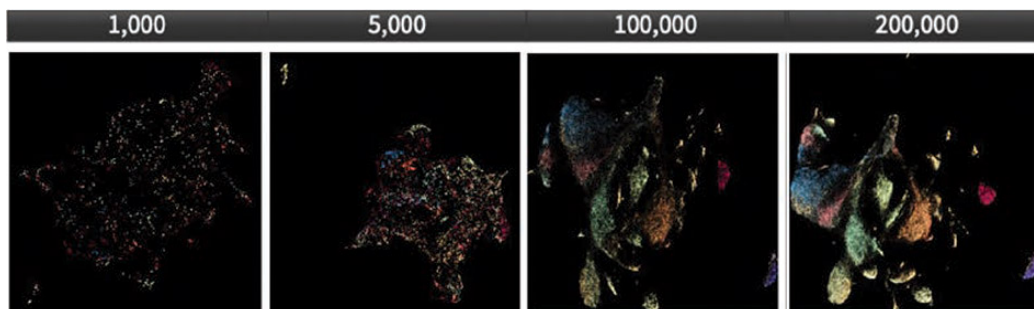
As of March 31, 2025, we have run more than 6.5 million tests that have measured over 38 billion molecular markers from over 13 quadrillion datapoints. To assist us with analyzing the data we generate, we utilize over 220 AI and AI/ML tools across our clinical testing, R&D, and biopharma business. These tools include over 50 clinical sequencing automation and variant calling AIs, over 100 RNA expression AI signatures, approximately 20 multi-omic AI/ML therapy response predictors, two ADAPT target discovery AI/ML algorithms, 37 digital image AI/ML classifiers, and 12 AI/ML support tools. This tremendous amount of data, which we have deidentified for research use, provides us a differentiated capability to advance precision oncology research through many business models, including training new profiling solutions and signature development, therapy development, and research into new ways to treat and cure disease, including personalized treatments.

Our goal is to develop the next generation of precision medicine tools that will allow us to transition from intuitive medicine to empirical medicine. As a leader in the transition to WES/WTS sequencing through our launch of a WTS solution in 2019 and a WES solution the following year, we believe we have more molecular data and information than any other company and are well-positioned to make precision medicine widely accessible.

The Power of Big Data

With a dataset as large as ours, a key task is to reduce the dimensionality of data to those key features that are useful to understanding the systems biology while avoiding any preconceived bias in how we might expect the features to be related. We accomplish this through mathematical embedding, which we use to reduce the dimensionality of the datasets to provide powerful insights into the underlying relationships within the data. This massive amount of information, across the whole transcriptome and multiplied across hundreds of thousands of patients, then undergoes a process where features that tend to occur together more often (or clusters) are associated into a multidimensional vector space.

One example of this methodology, and how additional data drives better predictions, can be seen in the pictures below, which show the clustering of a single gene set enrichment analysis (GSEA) across increasingly large datasets, from our research into a predictive algorithm for brain metastasis. This clustering, which reflects screening through AI to reduce dimensionality and identify underlying clusters, shows that meaningful clustering groups can only be seen with larger amounts of data. The clusters become increasingly visible as the datasets grow from 1,000 to 200,000 cases.



In this study, once we identified the relevant clusters, we then used the coordinates of the clusters as inputs into a separate AI/ML model that would predict the likely outcome—in this case, whether a patient was more or less likely to develop a brain metastasis.

Our in-depth profiling of patient samples has led to the creation of what we believe to be one of the largest and most comprehensive multi-modal clinico-genomic datasets in oncology based on the more than 6.5 million tests we have run on over 849,000 cases, which have generated measurements of over 38 billion molecular markers. Leveraging high-powered computing and AI/ML algorithms, we, and our biopharma and research partners who use our data and bioinformatics services, analyze our datasets to determine the key molecular characteristics of a particular disease or dysfunction that drives disease, enabling signature identification and drug target discovery. We believe this wealth of data and processing power, together with whole-slide imaging, our tissue and slide repository, can help our researchers and external partners gain previously unattainable insights about specific patient populations.

A study that we recently published in *Nature Communications*, a peer-reviewed scientific journal, demonstrated the power of our real-world clinical and genomic dataset, augmented through agreements with external providers of clinical outcomes data, to drive clinical insights. This study evaluated real-world outcomes for patients eligible for available tissue-agnostic therapies, which are powerful “pan-cancer” therapies that target specific molecular alterations across multiple cancer types and of which several have FDA approval. The study, using the largest real-world clinical and genomic dataset of tissue-agnostic indications reported to date across more than 295,000 de-identified patients and over 50 tumor types, demonstrated that over 20% of cancer patients are candidates for a tissue-agnostic therapies based on current FDA-approved indications. Additionally, the study found that over 5% of patients lacking any tumor-specific indication were found to carry a tissue-agnostic indication and thus to be candidates for a tissue-agnostic therapy. The study also generated insights into the different outcomes produced by tissue-agnostic therapies in different tissues. We believe the datasets built by our profiling solutions help enable further development of clinical insights with therapeutic and economic implications.

This study was conducted in 2024 by our researchers using data from all patients who had undergone comprehensive tissue sequencing at our Phoenix tissue laboratory between 2015 and 2023, who had successful

sequencing results, and for whom claims data was available. The study primarily measured time-on-treatment (“TOT”), determined as the interval from the initiation to the conclusion of treatment with an indicated therapy, and overall survival (“OS”), defined as the period from treatment initiation to the date of the patient’s last known clinical activity. Kaplan-Meier survival estimates were generated for patient cohorts defined by molecular characteristics. Significant p-values (generally $p < .05$) were seen for the following major analyses of highly clinically relevant indications: (a) poor clinical uptake of therapies targeting NTRK gene fusions, which are rare but potent drivers of tumor growth that promote cancer cell survival and proliferations; (b) differences in tissue specific outcomes in TMB-high and MSI-high settings, as well as in BRAF V600E-mutant cancers; and (c) differences in TOT and OS outcomes for non-trial patients receiving pembrolizumab and similar TOT benefit of pembrolizumab and nivolumab, two widely-used PD-1 inhibitor therapies, for patients with TMB-high tumors across various cancer types. Collectively, these analyses test the assumption that FDA-approved tissue-agnostic therapies are truly tissue-agnostic in the sense of having similar benefits across all tumor types, and demonstrate the power of large real-world datasets combining clinical data with NGS data, such as the comprehensive data generated by our solutions, to further the medical community’s understanding of cancer.

Data for Biopharma

We launched our data licensing business in late 2022. We license deidentified multi-modal datasets, components of which were generated from our clinical profiling business to external researchers, including those with biopharma companies, with the aim of generating insights directly responsible for superior clinical outcomes for patients. As the adoption of our tissue and blood-based profiling solutions continue to grow, this will result in further expansion of our multi-modal datasets, which can provide additional valuable insights to aid biopharma companies’ drug discovery and development efforts to bring innovative therapies to market. We utilize a third-party tokenization process to match deidentified data from various sources to create the multi-modal product. The linked data is then provided to the external researcher. Prior to the tokenization process, we run a series of software solutions through standardized data fields designed to remove and replace any PHI with a randomly-generated string of letters and numbers. We then use a third-party expert to certify that the data is deidentified pursuant to 45 CFR §164.514(b)(1) under HIPAA. We contractually require recipients of the data to maintain compliance with laws and regulations. The end customer takes on the contractual responsibility to properly maintain the data, not to attempt to reidentify any patient from the deidentified data set, and to obtain its own expert certification before combining the Caris data with any other data.

To further broaden the applicability and usefulness of our multi-modal datasets for biopharma companies, we have entered into agreements with clinical data partners, such as ConcertAI, Flatiron and COTA, to enable the creation of matched clinico-genomic datasets that can be licensed to biopharma companies for their use in drug discovery. These datasets generally consist of Caris molecular profiling data (and in some cases claims data), together with matched clinical data from our partners. We and our partners have entered into agreements with AbbVie, Moderna, and others to license our datasets for use in drug discovery. Together, our combined multi-modal data create a differentiated capability to advance precision oncology research through novel target identification and discovery, translational sciences, clinical trial design solutions and patient enrollment facilitated by our right-in-time trials network, post-market label expansion, and commercialization insights.

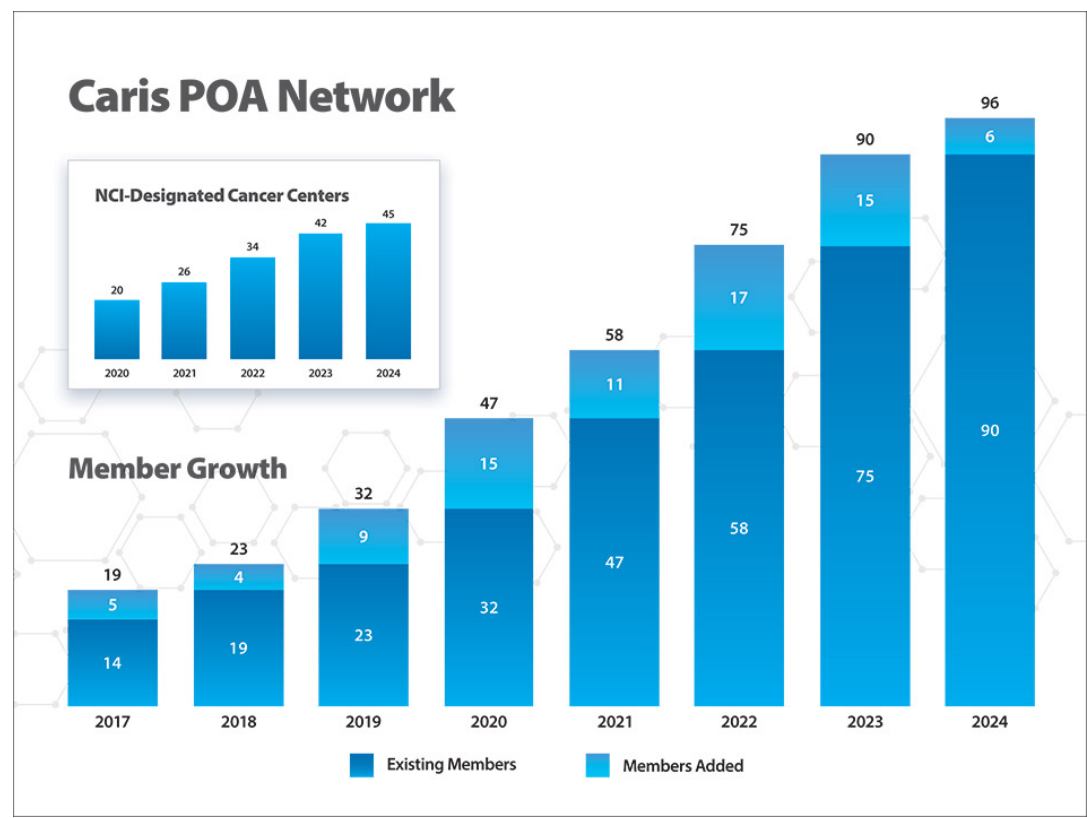
We have a rich pipeline of data opportunities that we believe will deliver new partnerships, as we continue to introduce biopharma companies to this unique data offering. In addition, many of our biopharma-related data initiatives and data partnerships allow for the flow of multi-modal data to our internal research teams, providing further synergies and enabling AI/ML powered research across the broader Caris enterprise.

Data for Clinical Research: The Caris Precision Oncology Alliance

We established the Caris POA in 2015. The Caris POA is a growing network of leading cancer centers and research consortia across the globe that supports research partner engagement, collaboration opportunities, and the advancement of precision oncology research. It consists of members that demonstrate a commitment to precision medicine and work collaboratively toward a common goal: to advance tumor

profiling and establish and optimize standards of care for molecular testing through innovative research to improve clinical outcomes for cancer patients.

As of March 31, 2025, the Caris POA was comprised of 96 members. This represents a five-fold growth in total membership since 2017. Additionally, since 2020, we have more than doubled the number of NCI-designated comprehensive cancer centers in the Caris POA, from 20 in 2020 to 45 as of March 31, 2025.



We estimate that the members of the Caris POA have over 3,000 oncologists in over 650 locations that treat more than 650,000 new cancer patients annually. Members participate in the various activities of the Caris POA through the following:

- profiling cancer patients using our comprehensive profiling solutions;
- establishing guidelines to integrate molecular testing into cancer care and patient treatment management;
- participating in research studies and clinical trials, both prospective and retrospective;
- collaborating in molecular tumor boards to advance the institution and industry’s understanding of cancer and the clinical utility of profiling in clinical care;
- tracking longitudinal outcomes and contribute data to the Caris POA; and
- publishing novel research and clinical data.

As part of the Caris POA collaboration, we contribute de-identified molecular data obtained from tumor profiling of cancer patient samples, and our partners have an opportunity to contribute outcome or clinical data for use in joint research projects. Physicians and researchers across the Caris POA network are provided with information from our datasets as part of our mission to give greater access to and disseminate

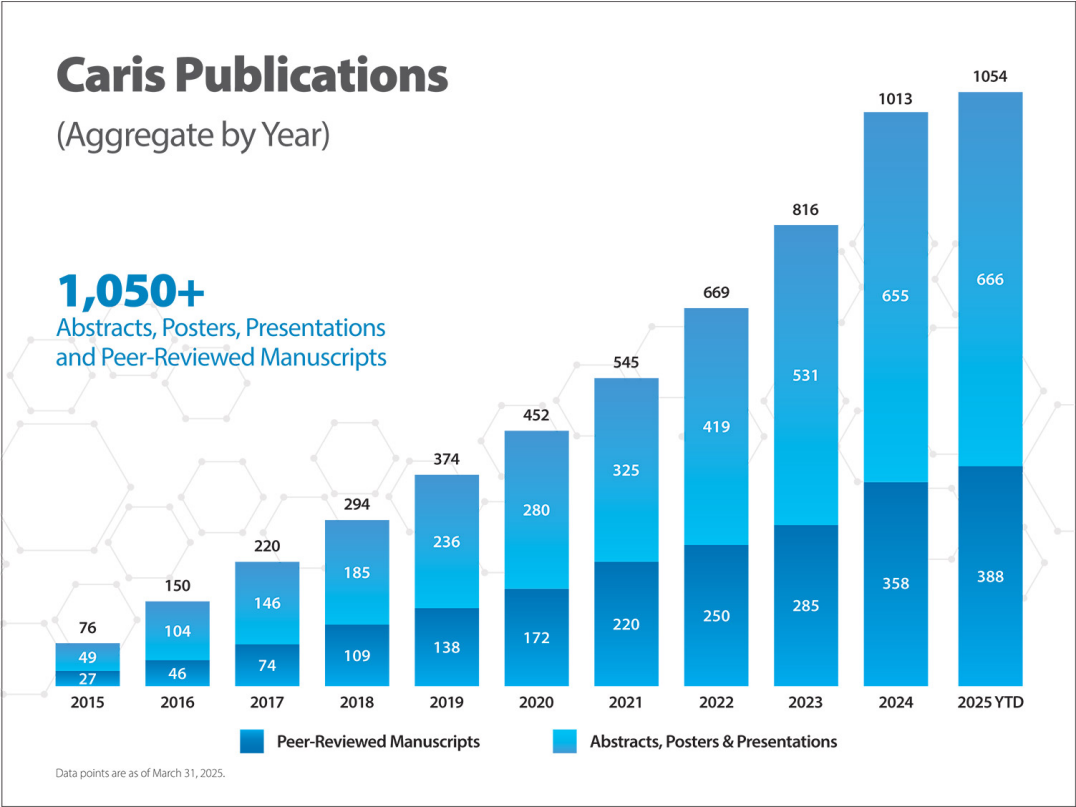
this data in furtherance of creating solutions for oncology. Caris POA members access our datasets through CODEai, a custom interface for our multi-modal clinico-genomic datasets that we launched in 2020. CODEai allows users to explore a cohort of over 295,000 matched datasets and clinical outcomes. CODEai users can define patient cohorts of interest and direct the underlying AI to mine the data, extract cogent information such as molecular markers that correlate with defined patient cohorts, and perform various analyses. Working with leading oncologists at Caris POA member sites, we have established a number of tumor-specific working groups comprised of key academic thought leaders and subject matter expertise to assist us in ensuring our profiling components remain clinically up-to-date with the latest important molecular markers and testing threshold criteria.

Selected Caris POA Members



We also contribute to academic research to advance the understanding of molecular science and further enable the delivery of precision medicines through our collaborations with member institutions within the Caris POA. We routinely collaborate with leading cancer centers to publish and present new learnings with immediate implications on the clinical use and utility of comprehensive molecular profiling.

Together with collaborators, our medical and scientific experts have authored over 380 manuscripts in peer-reviewed medical and scientific journals, and more than 660 abstracts, posters and presentations at leading industry conferences and symposiums that expound on our innovative platforms and technologies.

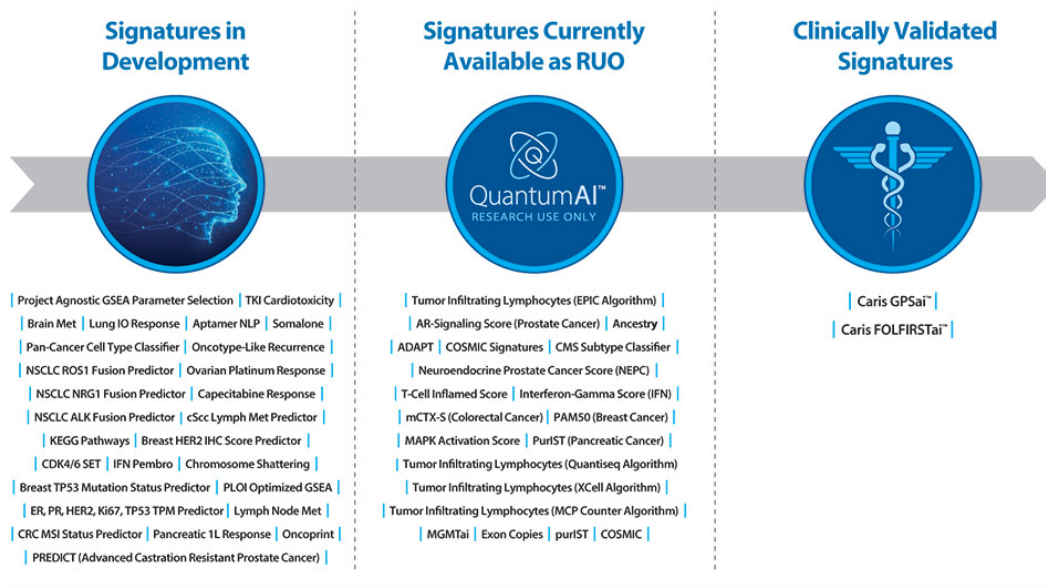


Data Driving Development of New Clinical Solutions

A significant benefit of generating WES and WTS results for every eligible patient is that the resulting dataset becomes a unique and proprietary resource to fuel the development of new molecular-driven signatures, products, and profiling solution enhancements that are only possible due to the availability of large datasets. Our datasets have also been augmented through agreements with external data providers. We have leveraged our vast datasets to drive the development of AI-based signatures and other enhancements, including our ABCDai algorithm and hundreds of other AI algorithms that are used in our bioinformatics pipelines for our profiling solutions. These solutions are designed to allow us to better leverage our data to improve patient outcomes and significantly differentiate us from our competitors.

We plan to utilize our datasets and molecular profiling knowledge to continue to create proprietary molecular signatures that leverage NGS-based testing results and to utilize digital scans of tissue slides to predict the presence of certain molecular markers without the need for NGS profiling. In addition, we plan to establish patient-level prognosis and prediction of therapeutic benefit, with an initial focus on breast cancer, but that we believe will have therapeutic benefits across all cancer types.

Robust AI Signature Portfolio & Pipeline



Caris Proprietary Molecular AI/ML Driven Signatures

We plan to utilize our datasets to continue to create proprietary molecular signatures and potentially establish patient-level prognosis and prediction of therapeutic benefit, with an initial focus on breast cancer.

In addition to our two clinically validated proprietary molecular signatures, GPSai and FOLFIRSTai, which can be ordered as part of MI Profile, we have a pipeline of proprietary molecular signatures that we are in the process of refining and validating. For example, we are developing MGMTai, a predictive signature that will help oncologists assess a patient's risk of developing brain metastases, and other signatures in development include pancreatic cancer response predictors, a predictor of response to checkpoint inhibitor therapy for lung cancer patients, and a predictor of response to platinum-based therapies for ovarian cancer patients. Similar to our FOLFIRSTai signature, we believe these types of multi-omic, ML-driven signatures will add significant and differentiating clinical value to our solutions, positioning our profiling solutions as the most complete and comprehensive for late-stage cancer available.

We believe that whole exome and whole transcriptome data is critical to develop robust AI signatures. For example, we are using whole exome and whole transcriptome data to train two AI signatures that predict therapeutic responses, which are in the early stages of development. The first AI signature that we are training predicts the response of lung cancer patients to immunotherapy and chemotherapy. This model demonstrated the capability to identify, at a p-value of less than 1%, patients that would benefit from immunotherapy along with chemotherapy, versus patients for whom chemotherapy would not be expected to have a benefit, with a sample size of 94 patients across both patient groups. Over 60% of several hundred genes and transcripts that this model identified as the most significant features are not included in a commercially available 700-gene panel. The second AI signature that we are training predicts response of pancreatic cancer patients to FOLFIRINOX and Gemcitabine + Abraxane®. This model was shown to identify, at a p-value of less than 1%, Stage IV pancreatic patients who would have a survival benefit from FOLFIRINOX treatment but not Gemcitabine + Abraxane®, and vice versa, with a sample size of 112 patients across both patient groups. Of the dozens of molecular features that feed into this model, nearly half are not analyzed in a commercially available 700-gene panel. Thus, we do not believe these types of models could be replicated without whole exome and whole transcriptome data like that produced by our sequencing solutions.

Our basic strategy for molecular signature development is to utilize our proprietary WES/WTS and claims data clinical databases for initial signature creation, with validation in external datasets (when advisable), including datasets that have been developed in other prospective clinical trials. These external datasets will, in many cases, be derived from active and ongoing collaborations with cooperative oncology groups or single academic institutions, many of which are active members of the Caris POA.

Digital Pathology Innovation

We are also utilizing our datasets and AI/ML analysis to develop the ability to use digital scans of tissue slides to predict the presence of certain biomarkers without the need for NGS profiling.

We have captured more than 4.4 million images of patient tumor tissue as of March 31, 2025, including approximately 3.1 million digitized IHC images and approximately 1.4 million digitized hematoxylin and eosin (“H&E”) images, and each image is associated with the patient’s full WES/WTS profile and clinical information. The workflow for WES and WTS sequencing of patient tumor tissue requires the sectioning of a Formalin Fixed Paraffin Embedded tissue specimen, leading to the creation of a set of unstained slides containing the patient’s tumor material. We stain two slides with traditional H&E reagents, others with antibodies for downstream IHC testing, and others with Nuclear Fast Red stain to facilitate microdissection and DNA/RNA extraction for sequencing. We have implemented a fleet of seven Pramana SpectralHT next generation, robot-controlled digital slide systems (each with four scanners for 28 total scanners) to capture ultra high-definition images of all H&E and IHC slides. The images are used to drive efficient and rapid analysis and processing during the testing workflow and also provide a unique and previously unavailable rich resource to fuel new assay development and innovation based on image-driven AI.

Our data scientists are using this powerful combination of molecular and visual data together to fuel the development of new image-driven AI signatures. The goal is to use the molecular data to validate AI signatures that can predict molecular status based on the digital slide image alone. The applications of this new approach include rapid image-based diagnosis, biomarker status determination, and prognostic determinations rapidly and cost-effectively, using just the slide image.

We are currently using an AI/ML approach driven by H&E slide images and clinical results data from more than 10,000 breast cancer patients to develop ESPai, a new algorithm to predict the risk of disease recurrence for early-stage breast cancer patients. We have obtained the samples and clinical data from the National Surgical Adjuvant Breast and Bowel Project and the ECOG-ACRIN Cancer Research Group. We are currently in the process of creating two AI/ML models for ESPai using these samples and are working to obtain additional samples for external validation studies. We are initially creating a model for late recurrence (five to 15 years following diagnosis), but we are also in the beginning stages of creating a model for early recurrence (zero to five years following diagnosis).

As an additional example, we have developed an AI tool that uses the digital image of a slide that has been stained with traditional H&E reagents to predict whether a patient has an increased likelihood for being positive for a ROS1 fusion, which is a particular type of gene fusion that is associated with non-small cell lung cancer. Biopharma companies developing new ROS1-targeted therapies typically must use NGS or FISH testing to screen more than 100 patients to identify one or two positive patients, resulting in very high cost and long timelines for clinical trials. The Caris ROS1 AI signature can be used on the slide alone and identify patients who are 33 times more likely to be ROS1 positive, thereby reducing the number of patients who need to be screened by more expensive and precise methods by more than 97%. Imaged-based, low-cost AI signatures like this might also be useful in the future in countries with limited access to sequencing technology. We expect to develop more of such image-based AI signatures using the power of ML on the combined image and molecular datasets.

Our Laboratory Infrastructure

We have built substantial testing capacity with throughput capabilities of over one trillion “reads” per day. We operate two precision medicine laboratories in Phoenix, Arizona, and one R&D laboratory in Tempe, Arizona. Our Arizona laboratories all utilize state-of-the-art genomic sequencing technology, including 50 NovaSeq sequencing systems. Our newest laboratory facility in Irving, Texas, near our

headquarters, is continuing to be built-out and will bring our total operational capacity to over 275,000 square feet. We believe this operational capacity provides us with ample capability to manage future growth.

Our solid tissue clinical laboratory in Phoenix, Arizona is an approximately 66,000 square foot, state-of-the-art laboratory. We provide high quality, reliable molecular testing services for all stages of the drug development cycle and routine clinical use. From pre-clinical research for compound development efforts to established, commercially available therapies, we provide robust genomic and proteomic testing capabilities across a variety of specimen types and high-throughput technologies. This laboratory has the following certifications: ISO 15189, ISO 13485, CLIA: CMI 03D1019490, College of American Pathologists (“CAP”): 7195577, and New York State Department of Health.

Our blood-based clinical laboratory in Phoenix, Arizona is approximately 35,500 square feet. This laboratory started testing operations in February 2022 following the installation of liquid-handling robots and NovaSeq sequencing systems. This laboratory has the following certifications: ISO 15189, CLIA: CMI 03D2210981 and CAP: 9536852.

We also have an approximately 59,000 square foot R&D laboratory in Tempe, Arizona that is utilized for R&D and therapeutic discovery work. This laboratory has ISO 13485 certification.

We have leased an approximately 114,500 square foot facility in Irving, Texas, close to our corporate headquarters, which includes office space and will house a clinical laboratory. We expect to build out the clinical laboratory in phases in the future to coincide with product launches and provide us with additional profiling capacity as we continue to grow our business.

We test patient samples on the most powerful sequencing systems available, which are built for high throughput sequencing, scalability, and speed and allow for high throughput more economically than prior platforms. Our use of high performance NGS sequencing systems improves our throughput efficiencies and lowers our cost of sequencing. We have an installation of 50 NovaSeq sequencing systems as of March 31, 2025. In addition to NGS, we employ other technologies in our operations, including 33 liquid handling robotic systems, ultra HD digital image scanning, dynamic light scattering, flow cytometry, fragment analysis, IHC, *in situ* hybridization, laser capture microdissection, mass spectrometry, Sanger sequencing, pyro sequencing, quantitative polymerase chain reaction, RT-PCR, and surface plasma resonance.

Our Commercialization Strategy

The precision medicine industry is characterized by rapid changes, including technological and scientific breakthroughs, frequent new product introductions and enhancements, and evolving industry standards. Education of customers, both physicians and biopharma companies, remains one of the key barriers to higher adoption of molecular profiling. More than ever, oncologists need a trusted profiling partner to provide reliable, high-quality molecular profiling information to guide precise and individualized treatment decisions. Our relationships across key oncology stakeholders include more than 5,600 physicians and partnerships with more than 100 biopharma companies. Additionally, we have executed agreements with or recently engaged in commercial discussions with all of the top 30 pharmaceutical companies measured by market capitalization. We have optimized our systems to provide industry-leading reports, service, and turn-around-time, helping oncologists (1) navigate among therapies with potential benefit, (2) identify therapies that may not have been considered, (3) determine drugs with potential lack of benefit (avoiding unnecessary toxicities and costs), and (4) match patients to clinical trials.

In the United States, we market our solutions to clinical customers through our marketing and commercial sales organizations. Our commercial footprint consisted of nearly 300 sales team members at the end of 2021 compared to approximately 275 sales team members and approximately 25 marketing team members at the end of 2024. Since the end of 2021, the size of our sales organization has generally remained constant, though the team has grown slightly during certain periods and contracted slightly in others. Our sales team members cover the entire U.S. market, focusing on the community setting where the majority of cancer patients are treated.

In addition, as of March 31, 2025, we had nearly 50 highly trained Ph.D. or M.D. MSLs who focus on physician and provider education and consultation, enabling us to provide a personalized consultation experience for oncologists. MSLs are responsible for communicating the value of Caris to external

stakeholders, such as physicians, nurses, scientists, and other interested parties. This communication primarily involves face-to-face discussions with customers. The MSLs use a variety of opportunities such as molecular tumor boards, educational seminars, and conference participation to act as a conduit of information and feedback between the medical community and us.

Decisions about which profiling services to use have become increasingly “institutionalized,” where cancer center directors and other medical leaders are adopting the approach of designating a “preferred partner” that is a technology and service leader for molecular profiling services. We believe that the Caris POA and our deep, high-quality institutional relationships provide us with an advantage in being selected as a preferred partner, and we expect this trend to continue to accelerate to further drive growth in ordering of our profiling solutions.

We market our solutions to biopharma companies through a separate Biopharma Business Development team. This team is differentiated from traditional sales organizations by recruiting professionals with a diversity of direct biopharma experience and strong scientific backgrounds and business acumen. We believe the credibility that our partnering team brings to discussions with biopharma companies has been well-received, and when combined with our profiling solutions and molecular datasets, has created a strong competitive edge.

We estimate that approximately two-thirds of our top 200 customers based on case volume were either academic medical centers or corporate physician practices.

International Distribution

Globally, we market our solutions through distributors and direct contracts with hospital systems, where permitted by the applicable regulations. Our distributors are generally obligated to obtain required in-country regulatory approvals and comply with in-country regulations. We have performed our clinical solutions to patients in over 50 countries since 2022 and are considering filing for regulatory approvals in Japan and the European Union.

EHR Integration and Electronic Ordering

We have established bi-directional electronic healthcare record (“EHR”) interfaces with individual institutions and/or specific provider locations. Test ordering can be done within the local EHR, and discrete test results can be returned to the ordering site automatically. We have integrated connections with every major EHR vendor. In addition to EHR integrations, we have a physician portal in which physicians can order testing and receive clinical reports electronically. Together, our EHR and portal ordering constituted approximately 47% of our clinical volume during 2024, and approximately 58% of our clinical volume during the three months ended March 31, 2025.

Competition

The precision oncology industry is highly competitive and subject to rapid change. An increasing awareness of the importance of genetic information to accurately understand cancer and deliver solutions for early detection, MRD tracking, therapy selection, and treatment monitoring is leading to more companies offering services in genomic profiling and sequencing.

Our competitors in tissue-based molecular profiling include Foundation Medicine (Roche) and Tempus. In addition, some academic centers, such as Memorial Sloan Kettering Cancer Center and New York Presbyterian — Weil Cornell, offer profiling to patients in their networks. Our competitors in blood-based early detection include Grail, Freenome, Guardant Health, Exact Sciences, and Delfi Diagnostics, among numerous other companies pursuing the early detection market. Our competitors in blood-based molecular profiling for therapy selection include Guardant Health and Foundation Medicine (Roche). Our competitors in blood-based molecular profiling for MRD tracking and treatment monitoring include Natera, Guardant Health, and Adaptive Biotechnologies. Our competitors in core biopharma services include Foundation Medicine (Roche), Guardant Health, Tempus, Natera, and Personalis, among others. Our competitors in offering genomic data and AI services include Tempus and Foundation Medicine (Roche).

Other companies offering testing in the precision oncology industry include Illumina, NeoGenomics, Myriad Genetics, Laboratory Corporation of America, Quest Diagnostics, and BostonGene.

Some of these companies may have substantially greater financial and other resources than we have, such as larger R&D staff and more established marketing and sales forces, or may operate in jurisdictions where lower standards of evidence are required to bring products to market. In addition, other established diagnostic, medical technology, biotechnology, or pharmaceutical companies may decide in the future to invest heavily to accelerate discovery and development of similar services that could make our solutions less competitive.

We believe that we compete favorably based on the following competitive factors: our patient-first approach that includes deep sequencing all DNA encoding genes and RNA transcripts utilizing comprehensive WES and WTS, enabling us to provide patients and physicians with industry-leading breadth, depth, and accuracy of multi-omic information; our tissue-based molecular profiling solution; our novel, universal blood-based profiling solution; our large and comprehensive multi-modal clinco-genomic dataset; our specialized commercial channel, robust infrastructure, and deep research collaborations; and our highly experienced management team.

Intellectual Property

Protection of our intellectual property is fundamental to the long-term success of our business. We seek to ensure that investments made into the development of our solutions to transform healthcare through the use of comprehensive molecular information, AI/ML algorithms, and proprietary molecular technologies are protected by a combination of patents, trademarks, copyrights, trade secrets, license agreements, confidentiality agreements and procedures, employee agreements (such as proprietary information, intellectual property, restrictive covenant, and arbitration agreements), and other legal and contractual rights.

Patents

We seek patent coverage for our foundational multi-cancer, multi-purpose molecular profiling solutions for tissue and blood and for our R&D activities, including biomarker discovery using our expansive molecular profiling datasets and tumor tissue archive. Our policy is to enter into invention or patent assignment agreements with our employees and consultants that obligate these employees and consultants to assign to us any inventions they develop while working for us.

Our company-owned and in-licensed patents and applications generally fall into the following categories:

- *Patents and applications related to our molecular profiling services.* As of March 31, 2025, we owned 79 patents (including three allowances) and 75 pending applications, and had an exclusive license to one patent application, which collectively relate to our molecular profiling solutions, including claims directed to early detection of cancer, monitoring disease recurrence, identifying treatments of likely benefit or lack of benefit for cancer patients, and the use of AI and ML for prediction of response to various cancer therapies, prediction of tumor origin, and to assess other characteristics of cancers based on NGS data and/or digital pathology. The Caris-owned patents and applications are assigned to our subsidiary Caris MPI, Inc. and include 17 issued U.S. patents, 16 pending U.S. applications, 62 foreign patents (including three allowances), and 59 pending foreign applications. The in-licensed patent application is a U.S. application and is exclusively licensed to Caris MPI, Inc.
- *Patents and applications related to our pharma research and development services.* As of March 31, 2025, we owned 103 patents (including four allowances), and 24 pending applications, and had exclusive licenses to 43 patents and applications, which collectively relate to aptamer library screening and uses thereof, including uses in biomarker discovery, as well as cell targeting constructs and therapeutic applications thereof. The Caris-owned patents and applications are assigned to our subsidiary Caris Science, Inc. and include 16 issued U.S. patents, six pending U.S. applications, 87 foreign patents (including four allowances), and 18 pending foreign applications. The in-licensed patents and applications are exclusively licensed to Caris Science,

Inc. and include two issued U.S. patents, one pending U.S. application, 36 foreign patents, and four pending foreign applications.

Patents and applications of particular importance within our portfolio that relate to our commercial molecular profiling services include:

- 63 patents and ten pending applications directed to systems and methods for comprehensive molecular profiling for cancer patients independent of cancer type. These include 14 issued U.S. patents and one pending U.S. application, and 49 foreign patents (including two allowances) and nine pending foreign applications between Australia, Austria, Belgium, Canada, China, Denmark, Europe, Finland, France, Germany, Iceland, India, Ireland, Israel, Italy, Japan, Mexico, Luxembourg, the Netherlands, Norway, Portugal, Singapore, South Africa, South Korea, Spain, Sweden, Switzerland, and the United Kingdom. These patents and applications are Caris-owned and assigned to our subsidiary Caris MPI, Inc., and are expected to expire between 2027 and 2033;
- One issued patent in Japan and 17 additional pending applications directed to AI/ML systems and methods for predicting cancer type. These include two pending U.S. applications, one PCT application, and 14 pending foreign applications between Australia, Canada, Europe, Israel, Japan, South Korea, and Mexico. These patents and applications are Caris-owned and assigned to our subsidiary Caris MPI, Inc., and are expected to expire between 2040 and 2044; and
- 14 patents (including one allowance) and 16 pending applications directed to AI/ML systems and methods for predicting response to platinum compounds, including FOLFOX regimens. These include three issued U.S. patents and two pending U.S. applications, and 11 foreign patents (including one allowance) and 14 pending foreign applications between Australia, Canada, Europe, France, Germany, Ireland, Israel, Japan, South Korea, Mexico, Netherlands, Switzerland, and the United Kingdom. These patents and applications are Caris-owned and assigned to our subsidiary Caris MPI, Inc., and are expected to expire between 2039 and 2040.

Additional patents and applications with varying levels of importance within our portfolio that relate to our commercial molecular profiling services include:

- 16 pending applications directed to AI/ML systems and methods for predicting response to various chemotherapies. These applications are Caris-owned and are expected to expire in 2041;
- Six pending applications directed to AI/ML systems and methods for predicting likelihood of metastasis. These applications are Caris-owned and are expected to expire between 2041 and 2045; and
- One pending application directed to profiling hematological malignancies using whole genome sequencing. This application is exclusively in-licensed and is expected to expire in 2042.

Additional patents and applications with varying levels of importance within our portfolio that relate to our pharma research and development services include:

- 38 patents directed to methods for use of microvesicles and microRNA as cancer biomarkers. These patents are exclusively in-licensed and are expected to expire in 2028;
- 47 patents and six pending applications directed to methods of sequencing aptamer libraries to detect targets of interest. These patents and applications are Caris-owned and expected to expire between 2028 and 2033;
- 47 patents (including two allowances) and nine pending applications directed to methods for aptamer library enrichment. These patents and applications are Caris-owned and are expected to expire between 2028 and 2038; and
- Nine patents (including two allowances) and 14 pending applications directed to compositions and methods related to cell-targeting technologies. These patents and applications are either Caris-owned or exclusively in-licensed and are expected to expire between 2036 and 2044.

The expiration dates described above are subject to, in the case of pending applications, our continued prosecution to allowance at the applicable patent offices, and in the case of allowed, issued and granted patents, our payment of applicable issue fees, maintenance fees and annuities. Patent expiration dates are estimates and may be subject to terminal disclaimers and patent term adjustments.

In some instances, we have acquired or in-licensed patent rights developed by third parties to enhance our patent portfolio and competitive advantage. For example, we have acquired patent families related to aptamer technologies and in-licensed patent applications related to cell targeting and hematological cancer assay technologies that are currently under development. Under such license agreements, we would be obligated to pay royalties for future sales in which the patents are used in the product or service sold.

Trade Secrets

In addition to patent protection, we have determined that certain technologies are better kept as trade secrets, such as aspects of our NGS methodology, bioinformatic analysis techniques, and identity of cancer biomarkers under development. We have a policy to restrict access to our trade secrets to a need-to-know basis. To further mitigate the chance of trade secret misappropriation, we enter into confidentiality agreements with parties who have access to trade secrets, such as our employees, collaborators, outside scientific collaborators, consultants, advisors, and other third parties.

Brand Protection

Our customers and partners recognize us as a leader in the molecular profiling field. Thus, just as patent and trade secret protection is essential to protecting our technology, we believe that it is equally as important for us to protect our brand and identity. We have obtained, and will continue to obtain, trademark protection for our name, logo, and solutions in countries where we operate, including our MI Profile and Caris Assure branding.

Additional Information

We will continue to pursue intellectual property protection, whether developed in-house or via third parties, that we believe will advance our business objectives. Despite our efforts and vigorous defense, our intellectual property rights in the United States and abroad may be invalidated, circumvented, or challenged in the future. In addition, the laws of various countries where our solutions are distributed may not protect our intellectual property rights to the same extent as the laws in other countries. For additional information, see the section titled “Risk Factors—Risks Related to Intellectual Property.”

Regulatory Strategy

Our regulatory strategy aligns with our overall business objectives. We believe that receiving FDA approval of our diagnostic solutions would positively impact our ability to sell our solutions and enhance our reimbursement efforts with payers, including Medicare. The current marketing status and relevant regulatory approvals obtained, planned, and/or potentially required for each of our solutions is summarized in the table below. We currently market all of our existing solutions, including Caris Assure for therapy selection, MI Tumor Seek Hybrid, GPSai, and FOLFIRSTai, as LDTs and, as required under CLIA, continue to analytically validate such solutions across a variety of performance characteristics, including accuracy, precision, specificity, sensitivity, reportable range, and reference interval. We have obtained an FDA marketing authorization for MI Cancer Seek, and it is possible that we may seek FDA marketing authorization for Caris Assure for therapy selection and additional solutions in the future. Additionally, while we currently market Caris Assure for therapy selection as an LDT, it is possible that marketing authorization from the FDA would be required in order for us to market Caris Assure as a companion diagnostic device for therapy selection. We do not yet have specific plans regarding the timing of a PMA or other submission, if any, for Caris Assure for therapy selection or any other indication. For additional information, see “—Government Regulation— U.S. Food and Drug Administration—Laboratory Developed Tests.”

Solution Name	Marketing Status	NY CLEP Approval	Anticipated FDA Approval/Requirements
MI Cancer Seek	Marketed since January 2025	Not applicable	PMA approval obtained in November 2024
MI Tumor Seek Hybrid	Marketed as an LDT since 2022	Approved in 2024	None planned*
Caris Assure for Therapy Selection	Marketed as an LDT since 2024	Plan to submit for NY CLEP in 2025	Potential to submit PMA application, a <i>de novo</i> request or 510(k) notification
FOLFIRSTai	Marketed as an LDT since 2020	Approved in 2024	None planned*
GPSai	Marketed as an LDT since 2019	Approved in 2024	None planned*

* *Pending resolution of litigation over the LDT Final Rule. If the LDT Final Rule is implemented or the FDA otherwise accepts applications for LDTs, we plan to seek FDA marketing authorization for each applicable LDT solution.*

The FDA premarket review process can be long and requires significant resources to complete all of the regulatory requirements necessary for market launch of an FDA-approved prescription medical device or diagnostic product. As we work with the FDA to seek marketing authorization for our diagnostic solutions, we must accurately describe the solution in terms of its intended use, indications for use, target population of patients, functional and/or performance characteristics, labeling, and anticipated marketing claims for the device, among other things. These factors, when combined with the result of the device classification, applicable product code for the device, and whether a predicate device exists, will allow us to plan the most appropriate submission type and regulatory pathway. Determining the appropriate pathway early is crucial to setting milestones, planning necessary preclinical and clinical trials, estimating cost requirements, and creating a timeline for when the product may reach the market.

The FDA encourages participation in the FDA’s Pre-Submission Program, which allows manufacturers to seek the FDA’s feedback prior to an intended premarket submission. We have had formal pre-submission meetings with the FDA Center for Devices and Radiological Health (“CDRH”) and anticipate several more in the future to seek additional feedback from the FDA on solutions that we intend to submit for premarket review. Feedback from these meetings are critical for our team to be able to put together the appropriate study designs to support a premarket submission. Though the FDA provides non-binding feedback within these discussions, obtaining this early input from CDRH can allow for necessary changes or modifications to the regulatory strategy and potentially provide long-term savings in cost and time.

We have obtained a PMA approval from the FDA for a companion diagnostic and tumor profiling designation for MI Cancer Seek, a WES/WTS NGS assay that has been designed to meet the stricter requirements applicable to companion diagnostic devices. We currently market MI Cancer Seek as the WES/WTS NGS component of MI Profile. For additional information, see “Risk Factors—Risks Related to Regulation and Legal Compliance—The marketing authorization processes of the FDA and comparable foreign regulatory authorities are lengthy, time-consuming, and unpredictable. If we are ultimately unable to obtain any necessary or desirable marketing authorizations, or if such marketing authorizations are significantly delayed, our business will be substantially harmed.”

Government Regulation

We are subject to complex and frequently changing national, state, and local laws and regulations that govern various aspects of our business. In many jurisdictions, including the United States, the clinical laboratory and medical device industries must operate in accordance with extensive and complex legal standards, including laws and regulations related to certification, licensing, development, research, testing, manufacturing, laboratory operations, distribution, ordering and billing practices, advertising, promotion,

marketing, sales and pricing practices, anti-markup practices, health information privacy and security, and consumer protection and unfair trade practices.

In the United States, the laws and regulations governing the marketing of diagnostic products are evolving, extremely complex, and in some instances, there are no significant regulatory or judicial interpretations of these laws and regulations. Clinical LDTs are regulated by the CLIA, described below, as well as by applicable state laws. In addition, the Federal Food, Drug and Cosmetic Act (“FDC Act”) defines a medical device to include any instrument, apparatus, implement, machine, contrivance, implant, *in vitro* reagent, or other similar or related article, including a component part, or accessory, intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals. Among other things, pursuant to the FDC Act and its implementing regulations, the FDA regulates the research, testing, manufacturing, safety, labeling, storage, recordkeeping, premarket clearance or approval, marketing and promotion, and sales and distribution of medical devices in the United States to ensure that medical products distributed domestically are safe and effective for their intended uses. The FDA has statutory authority to assure that medical devices are safe and effective for their intended uses.

For information on the risks we face related to the regulatory environment and other legal matters, see the section titled “Risk Factors—Risks Related to Regulation and Legal Compliance.”

Clinical Laboratory Improvement Amendments of 1988

Congress passed CLIA to establish rigorous quality standards for laboratories in the United States. Under CLIA, a laboratory is any facility that performs laboratory testing on specimens derived from human beings for the purpose of providing information for the diagnosis, prevention, or treatment of disease or the impairment or assessment of health. Such testing may also include procedures to determine, measure, or otherwise describe the presence or absence of various substances or organisms in the body.

CLIA requires that such laboratories obtain certification from the federal government and maintain compliance with various operational, personnel qualification, facilities administration, quality control and assurance, and proficiency testing requirements intended to ensure the accuracy, reliability, and timeliness of patient test results. The CMS, part of the U.S. Department of Health and Human Services (“HHS”), administers the CLIA certification program. CLIA requires that we hold a certificate that specifies the categories of testing we perform and that we comply with certain standards applicable to such tests. For every LDT used in clinical testing, CLIA requires analytical validation of a variety of performance characteristics, including accuracy, precision, specificity, sensitivity, reportable range, and reference interval. In addition, CLIA specifies certain testing categories requiring periodic proficiency testing, and certified laboratories performing these tests must enroll in an approved proficiency testing program. To demonstrate proficiency, such laboratories must test specimens received from an outside proficiency testing organization, such as CAP, and then submit the results back to that organization for evaluation. Failing to achieve a passing score on a proficiency test may lead to loss of certification to perform testing in the corresponding category. Furthermore, failure to comply with other proficiency testing regulations can result in revocation of the laboratory’s CLIA certificate, among other penalties.

We currently have two clinical laboratory facilities in Phoenix, Arizona, and we are in the process of building a laboratory in Irving, Texas. Both of the Phoenix laboratory facilities hold CAP and CLIA Accreditations. A CLIA Certificate of Accreditation is issued to a laboratory facility that performs moderate and/or high complexity testing after an accreditation organization conducts a survey and determines that the laboratory is in compliance with the CLIA regulations. Our newest laboratory facility in Irving, Texas, near our headquarters, is continuing to be built-out and will seek a CLIA Certificate of Registration from CMS, and upon required inspection, a CLIA Certificate of Accreditation. The CLIA Certificate of Registration allows the laboratory facility to begin conducting moderate and/or high complexity testing, subject to a survey to determine compliance with the CLIA regulations. After a laboratory obtains a Certificate of Registration, CLIA begins scheduling regular, routine inspections. Once the inspection process for the laboratory facility is successfully completed, the facility qualifies for a CLIA Certificate of Accreditation and thereafter is inspected every two years.

Prior to offering a new solution at our laboratories, we must also satisfy certain notification requirements to change our solution menu, such as notifications to regulatory and accrediting bodies. At their discretion, these entities may inspect our clinical laboratories at any time. CLIA accredited laboratories are subject to be required to be reviewed biannually by a CMS-approved accreditation organization (for example, CAP) and may be subject to additional random or “for cause” inspections.

If our laboratories are determined to be out of compliance with CLIA requirements at any inspection or otherwise, we may be subject to a wide range of enforcement actions and sanctions, including suspension, limitation, or revocation of the laboratory’s CLIA certificate, as well as directed plan of correction, on-site monitoring, civil monetary penalties, civil injunctive suit, or criminal penalties, as well as significant adverse publicity, all of which could have a materially adverse impact on our business.

State Laboratory Licensure Laws

In addition to the federal certification requirements for laboratories, certain states, including Maryland, Pennsylvania, New York, California, and Rhode Island require state laboratory licenses. The state laboratory licensure requirements establish standards for the day-to-day operation of a clinical laboratory, including the training and qualifications required of personnel, quality control, and proficiency testing. CLIA provides that a state may adopt laboratory regulations that are more stringent than those under federal law. A number of states have implemented their own more stringent laboratory regulatory requirements, and those states may conduct their own inspections. These states may also include reporting requirements that we must comply with in order to maintain licensure. Moreover, certain states, including New York, require approval of certain tests, including certain tests that have not been cleared or approved by the FDA (such as LDTs), through a premarket submission containing, among other information, documentation relating to device analytical and clinical performance data.

Several states require licensure of out-of-state laboratories that accept specimens from those states and/or receive specimens from laboratories in those states. Our Arizona solid tissue laboratory and our Arizona blood-based testing laboratory have obtained out-of-state licenses in states where we believe they are required, and we will file applications in additional states as applicable when we offer solutions in those states.

If a laboratory is deemed to be out of compliance with state licensing laws or regulations governing laboratories, penalties may include suspension, limitation, or revocation of the license issued by that state, disapproval of a licensure application, assessment of substantial financial penalties or fines, onsite monitoring requirements, or imposition of corrective action plans. Certain statutory or regulatory noncompliance may also result in misdemeanor charges under state law. Loss of a laboratory’s state license may also result in the inability to compliantly perform laboratory testing and receive payments from third-party payers, all of which may have a materially adverse impact on our business.

In addition to laboratory licensing, certain states, including New York and California, impose registration and/or licensing requirements on companies that manufacture medical devices. These laws can apply to a manufacturer before its products are commercialized, including when a company is evaluating its product candidates in clinical trials. Violations of these laws may result in the denial, suspension, or revocation of the registration or license, as well as other fines and penalties, including imprisonment.

Other states may adopt licensure requirements in the future, which could require us to modify, delay, or discontinue our operations in such jurisdictions. If we identify any state with such requirements or if we are contacted by a state advising us of such requirements, we intend to follow such instructions from the state regulators as to how to comply with such requirements.

U.S. Food and Drug Administration

In the United States, laboratory tests are subject to regulation by the FDA under the FDC Act and its implementing regulations, and other federal and state statutes and regulations. The laws and regulations govern, among other things, medical device development, testing, manufacture, labeling, storage, premarket clearance or approval, advertising and promotion, export, import, and product sales and distribution.

Laboratory Developed Tests

Under the FDA’s regulatory framework, IVDs are a type of medical device that can be used in the diagnosis or detection of diseases, such as cancer, or other conditions. The FDA considers LDTs to be a subset of IVDs that are intended for clinical use and are designed, manufactured, and used within a single laboratory. Until recently, the FDA has historically exercised its enforcement discretion and not enforced certain otherwise potentially applicable provisions of the FDC Act and regulations with respect to LDTs, with certain exceptions. Even under that enforcement discretion policy, the FDA has issued warning letters to, and published Medical Device Safety Communications about, manufacturers for commercializing laboratory tests that were purported to be LDTs but that the FDA alleged failed to meet the definition of an LDT or that otherwise were not subject to the FDA’s enforcement discretion policy.

The FDA has for a number of years stated its intention to modify its enforcement discretion policy with respect to LDTs and impose applicable medical device requirements to LDTs more broadly. On May 6, 2024, the FDA issued the LDT Final Rule in an effort to clarify the FDA’s historical view that LDTs are medical devices subject to the requirements applicable to IVDs, and to phase out the FDA’s enforcement discretion policy over a period of four years from issuance of the final rule, which would involve a phase-in of medical device requirements to these products over this time period.

In connection with the LDT Final Rule, the FDA established certain targeted enforcement discretion policies. Specifically, the FDA intended to exercise enforcement discretion and not enforce certain medical device requirements (including the requirements for marketing authorization and compliance with certain elements of the Quality System Regulation (“QSR”) with respect to LDTs that were marketed as of the date of the LDT Final Rule’s publication, although such products would still be required to comply with certain other FDA requirements, including registration and listing, portions of the QSR, medical device reporting, labeling, and corrections and removals reporting. However, where these tests are modified in certain ways from the version of the test marketed as of the final rule’s publication date, this enforcement discretion policy would no longer apply and the FDA would then enforce all applicable FDA requirements (including premarket review and marketing authorization requirements) consistent with the phase-in policy. In addition, for LDTs that receive approval from NY CLEP, FDA did not intend to enforce marketing authorization requirements when these requirements would become phased in more generally at either three and a half or four years following the date of publication of the LDT Final Rule. However, these tests would still be subject to the remaining medical device requirements, including registration and listing, medical device reporting, and quality system requirements, at the time that such requirements become phased in more generally.

However, on March 31, 2025, the United States District Court for the Eastern District of Texas vacated the LDT Final Rule and remanded the matter to the FDA for further consideration. The U.S. government decided not to appeal the District Court’s decision by the formal May 30, 2025 deadline. The District Court’s decision currently remains subject to appeal procedures until June 30, 2025, and at this time it remains uncertain whether such appeal will be sought by then and if such appeal would be successful. Accordingly, it remains unclear whether or when the FDA may be able to implement the LDT Final Rule, or otherwise exercise its medical device requirements with respect to these diagnostic tests, including any LDTs for which we have obtained or plan to obtain PMAs. In addition, Congress has, for over the past decade, considered a number of proposals, which if enacted, could subject LDTs to additional regulatory requirements. As a result, the FDA’s oversight with respect to LDT products remains subject to significant uncertainty.

FDA Classification and Premarket Review of Medical Devices

PMA Pathway. The FDA categorizes medical devices into one of three classes—class I, II, or III—based on the risks presented by the device and the regulatory controls necessary to provide a reasonable assurance of the device’s safety and effectiveness. Class I includes devices with the lowest risk to the patient and are those for which safety and effectiveness can be assured by adherence to the FDA’s General Controls for medical devices, which include compliance with the applicable portions of the QSR, facility registration and product listing, reporting of adverse medical events, and truthful and non-misleading labeling, advertising, and promotional materials. Class II devices are subject to the FDA’s General Controls, and special controls as deemed necessary by the FDA to ensure the safety and effectiveness of the device. Special

controls are established by the FDA for a specific device type and often include specific labeling provisions, performance metrics, and other types of controls that mitigate risks of the device (usually incorrect results for an IVD). Devices deemed by the FDA to pose the greatest risks, such as life sustaining, life supporting or some implantable devices, or devices that have a new intended use, or use advanced technology that is not substantially equivalent to that of a legally marketed device, are placed in Class III, requiring approval of a PMA. Some pre-amendment devices are unclassified, but are subject to the FDA's premarket notification and clearance process in order to be commercially distributed.

Class III devices require PMA approval before they can be marketed. Obtaining PMA approval requires the submission of "valid scientific evidence" to FDA to support a finding of a reasonable assurance of the safety and effectiveness of the device. A PMA must provide complete analytical and clinical performance data and also information about the device and its components regarding, among other things, device design, manufacturing, and labeling. Following receipt of a PMA, the FDA determines whether the application is sufficiently complete to permit a substantive review. If the FDA accepts the application for review, it has 180 days from the day of filing under the FDC Act to complete its review of a PMA, although in practice, the FDA's review often takes significantly longer. An advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. The FDA may or may not accept the panel's recommendation. As part of the FDA's review of a PMA, the FDA will typically inspect the manufacturer's facilities for compliance with QSR requirements, which impose requirements related to design controls, manufacturing controls, documentation, and other quality assurance procedures. The user fee costs and the length of the FDA review time for obtaining PMA approval are significantly higher than for a 510(k) notification or a *de novo* classification. In addition, the FDA collects user fees for certain medical device submissions and annual fees and for medical device establishments under the Medical Device User Fee Amendments to the FDC Act, which is subject to reauthorization by Congress every five years following extensive agency and industry negotiations.

FDA will approve the new device for commercial distribution if it determines that the data and information in the PMA constitute valid scientific evidence and that there is reasonable assurance that the device is safe and effective for its intended use(s). FDA may approve a PMA with post-approval conditions intended to ensure the safety and effectiveness of the device, including, among other things, restrictions on labeling, promotion, sale and distribution, and collection of long-term follow-up data from patients in the clinical study that supported PMA approval or requirements to conduct additional clinical studies post-approval. FDA may condition PMA approval on some form of post-market surveillance when deemed necessary to protect the public health or to provide additional safety and efficacy data for the device in a larger population or for a longer period of use. In such cases, the manufacturer might be required to follow certain patient groups for a number of years and to make periodic reports to FDA on the clinical status of those patients. Failure to comply with the conditions of approval can result in material adverse enforcement action, including withdrawal of the approval.

Certain changes to an approved device, such as changes in manufacturing facilities, methods, or quality control procedures, or changes in the design performance specifications, which affect the safety or effectiveness of the device, require submission of a PMA supplement. PMA supplements often require submission of the same type of information as a PMA, except that the supplement is limited to information needed to support any changes from the device covered by the original PMA and may not require as extensive clinical data or the convening of an advisory panel. Certain other changes to an approved device require the submission of a new PMA, such as when the design change causes a different intended use, mode of operation, and technical basis of operation, or when the design change is so significant that a new generation of the device will be developed, and the data that were submitted with the original PMA are not applicable for the change in demonstrating a reasonable assurance of safety and effectiveness.

510(k) Notification Pathway. To obtain 510(k) clearance, a manufacturer must submit a premarket notification demonstrating to the FDA's satisfaction that the proposed device is "substantially equivalent" to another legally marketed device that itself does not require PMA approval (a predicate device). A predicate device is a legally marketed device that is not subject to premarket approval, i.e., a device that was legally marketed prior to May 28, 1976 (pre-amendments device) and for which a PMA is not required, a device that has been reclassified from Class III to Class II or I, or a device that was found substantially equivalent

through the 510(k) process. The FDA's 510(k) clearance process usually takes from three to 12 months, but often takes longer. The FDA may require additional information, including clinical data, to make a determination regarding substantial equivalence. In addition, the FDA collects user fees for certain medical device submissions and annual fees for medical device establishments.

If the FDA agrees that the device is substantially equivalent to a lawfully marketed predicate device, it will grant 510(k) clearance to authorize the device for commercialization. If the FDA determines that the device is "not substantially equivalent" to a previously cleared device, the device is automatically designated as a Class III device. The device sponsor must then fulfill more rigorous PMA requirements, or can request a risk-based classification determination for the device in accordance with the *de novo* process, which is a route to market for novel medical devices that are low to moderate risk and are not substantially equivalent to a predicate device. Once a *de novo* classification request is reviewed and granted, it results in the device having a Class I or II classification and future devices from the company or a competitor may use the company *de novo*-classified device as a 510(k) predicate.

After a device receives 510(k) clearance or *de novo* classification, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change or modification in its intended use, will require a new 510(k) clearance or, depending on the modification, PMA approval or new *de novo* classification. The FDA requires each manufacturer to determine whether the proposed change requires submission of a 510(k) or a PMA in the first instance, but the FDA can review any such decision and disagree with a manufacturer's determination. Modifications that do not rise to the level of requiring a new 510(k) are accomplished through a "letter to file" in which the company documents the rationale for the change and why a new 510(k) is not required. However, if the FDA disagrees with a manufacturer's determination, the FDA can require the manufacturer to cease marketing and/or request the recall of the modified device until new marketing authorization for the change is obtained. Also, in these circumstances, the manufacturer may be subject to significant regulatory fines or penalties.

De Novo Classification Pathway. If no legally marketed predicate can be identified for a new device to enable use of the 510(k) pathway, the device is automatically classified under the FDC Act into Class III, which generally requires PMA approval. However, the FDA can reclassify or use "*de novo* classification" for a device that meets the FDC Act standards for a class I or class II device, which in turn permit the device to be marketed without PMA approval. To grant such a reclassification, the FDA must determine that the FDC Act's general controls alone, or general controls and special controls together, are sufficient to provide a reasonable assurance of the device's safety and effectiveness. If the manufacturer seeks reclassification into Class II, the classification request must include a draft proposal for special controls that are necessary to provide a reasonable assurance of the safety and effectiveness of the medical device. The FDA may reject the classification request if it identifies a legally marketed predicate device that would be appropriate for a 510(k) notification or determines that the device is not low to moderate risk or that general controls would be inadequate to control the risks and special controls cannot be developed. The *de novo* classification route is generally less burdensome than the PMA approval process.

Investigational Device Exemption Process. Clinical trials are almost always required to support a PMA and are sometimes required to support a 510(k) submission. All clinical investigations of investigational devices to determine safety and effectiveness must be conducted in accordance with the FDA's investigational device exemption ("IDE") regulations which govern investigational device labeling, prohibit promotion of the investigational device, and specify an array of recordkeeping, reporting and monitoring responsibilities of study sponsors and study investigators. If the device presents a "significant risk" to human health, as defined by the FDA, the FDA requires the device sponsor to submit an IDE application to the FDA, which must become effective prior to commencing human clinical trials. A significant risk device is one that presents a potential for serious risk to the health, safety, or welfare of a patient and either is implanted, used in supporting or sustaining human life, substantially important in diagnosing, curing, mitigating or treating disease or otherwise preventing impairment of human health, or otherwise presents a potential for serious risk to a subject. An IDE application must be supported by appropriate data, such as animal and laboratory test results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE will automatically become effective 30 days after receipt by the FDA unless the FDA notifies the company that the investigation may not begin. If the FDA determines that there are deficiencies or other concerns with an IDE for which it requires modification, the FDA may permit a clinical trial to proceed under a conditional approval.

In addition, the study must be approved by, and conducted under the oversight of, an Institutional Review Board (“IRB”) for each clinical site. The IRB is responsible for the initial and continuing review of the IDE and may pose additional requirements for the conduct of the study. If an IDE application is approved by the FDA and the study protocol is approved by one or more IRBs, human clinical trials may begin at a specific number of investigational sites with a specific number of patients, as approved by the FDA. IDE reporting to all reviewing IRBs regarding study progress is required at regular intervals and at least annually for ongoing IDE approved studies. For a significant risk device, the progress reports must also be submitted to FDA. If the device presents a non-significant risk to the patient, a sponsor may begin the clinical trial after obtaining approval for the trial by one or more IRBs without separate approval from the FDA, but must still follow abbreviated IDE requirements, such as monitoring the investigation, ensuring that the investigators obtain informed consent, and labeling and record-keeping requirements. Acceptance of an IDE application for review does not guarantee that the FDA will allow the IDE to become effective and, if it does become effective, the FDA may or may not determine that the data derived from the trials support the safety and effectiveness of the device or warrant the continuation of clinical trials. An IDE supplement must be submitted to, and approved by, the FDA before a sponsor or investigator may make a change to the investigational plan that may affect its scientific soundness, study plan or the rights, safety, or welfare of human subjects.

During a study, the sponsor is required to comply with the applicable FDA requirements, including, for example, trial monitoring, selecting clinical investigators and providing them with the investigational plan, ensuring IRB review, adverse event reporting, record keeping, and prohibitions on the promotion of investigational devices or on making safety or effectiveness claims for them. The clinical investigators in the clinical study are also subject to FDA regulations and must obtain patient informed consent, rigorously follow the investigational plan and study protocol, control the disposition of the investigational device, and comply with all reporting and recordkeeping requirements. Additionally, after a trial begins, we, the FDA or the IRB could suspend or terminate a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the anticipated benefits.

Expedited Development and Review Programs. The FDA has established programs to support and expedite the development of devices that meet criteria for Breakthrough Device designation, which can be voluntarily requested by sponsors. The program offers manufacturers of certain devices an opportunity to interact with the FDA more frequently and efficiently as they develop their products with the goal of expediting commercialization of such products to help patients have more timely access, as well as use of postmarket data collection, when scientifically appropriate, to facilitate expedited and efficient development and review of the device, opportunities for efficient and flexible clinical study design, and priority review of premarket submissions. The program is available to medical devices that meet certain eligibility criteria, including that the device provides more effective treatment or diagnosis of life threatening or irreversibly debilitating diseases or conditions, and constitutes a device (i) that represents a breakthrough technology, (ii) for which no approved or cleared alternatives exist, (iii) that offer significant advantages over existing approved or cleared alternatives, or (iv) the availability of which is in the best interest of patients.

Postmarket Regulation. After a device is cleared or approved by the FDA for marketing, numerous and pervasive regulatory requirements continue to apply. These include:

- establishment registration and device listing with the FDA;
- compliance with the QSR, which requires manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation, and other quality assurance procedures during all aspects of the design and manufacturing process;
- labeling regulations and FDA prohibitions against the promotion of “off-label” uses of cleared or approved products;
- requirements related to promotional activities;
- clearance or approval of product modifications to 510(k)-cleared devices that could significantly affect safety or effectiveness or that would constitute a major change in intended use of one of our cleared devices, or approval of certain modifications to PMA-approved devices;
- Medical Device Reporting, which requires that a manufacturer report to the FDA if a device it markets may have caused or contributed to a death or serious injury, or has malfunctioned

and the device or a similar device that it markets would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur;

- correction, removal, and recall reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDC Act that may present a risk to health;
- the FDA's recall authority, whereby the agency can order device manufacturers to recall from the market a product that is in violation of governing laws and regulations;
- post-market surveillance activities and regulations, which apply to certain Class II or III devices when deemed by the FDA to be necessary to protect the public health or to provide additional safety and effectiveness data for the device; and
- complying with the laws and regulations requiring Unique Device Identifiers on devices and also requiring the submission of certain information about each device to the FDA's Global Unique Device Identification Database.

Device manufacturing processes subject to the FDA oversight are required to comply with the applicable portions of the QSR, which currently cover the methods and the facilities and controls for the design, manufacture, testing, production, processes, controls, quality assurance, labeling, packaging, distribution, installation, and servicing of finished devices intended for human use. The QSR also requires, among other things, maintenance of a device master file, device history file, and complaint files. Manufacturers are subject to periodic scheduled or unscheduled inspections by the FDA. A failure to maintain compliance with the QSR requirements could result in the shut-down of, or restrictions on, manufacturing operations and the recall or seizure of products. The discovery of previously unknown problems with products, including unanticipated adverse events or adverse events of increasing severity or frequency, whether resulting from the use of the device within the scope of its clearance or off-label by a physician in the practice of medicine, could result in restrictions on the device, including the removal of the product from the market or voluntary or mandatory device recalls.

FDA Enforcement Powers

The FDA has broad regulatory compliance and enforcement powers. If the FDA determines that a manufacturer has failed to comply with applicable regulatory requirements, it can take a variety of compliance or enforcement actions, including the following:

- issuance of warning letters, untitled letters, fines, injunctions, consent decrees and civil penalties;
- requesting or requiring recalls, withdrawals, or administrative detention or seizure of products;
- imposing operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying requests for 510(k) marketing clearance, or PMA approvals of new products or modified products;
- withdrawing 510(k) clearances or PMA approvals that have already been granted;
- refusal to grant export approvals for products; or
- criminal prosecution.

Healthcare Fraud and Abuse Oversight

A variety of federal and state laws prohibit fraud and abuse involving federal and state healthcare programs, as well as private insurers. These laws are interpreted broadly and actively enforced by various state and federal agencies, including CMS, the Department of Justice ("DOJ"), and the Office of Inspector General for HHS ("OIG"). While we seek to conduct our business in compliance with all federal and state fraud and abuse laws, we are unable to predict how these laws will be applied in the future or whether our arrangements will be subject to scrutiny under them by federal or state enforcement agencies. Violations

of such laws may result in a range of penalties, including but not limited to significant administrative and civil fines and penalties, criminal fines and penalties, loss of licensure, disgorgement, imprisonment, exclusion from federal healthcare programs, additional reporting obligations, and oversight or other agreement to resolve allegations of non-compliance with these laws.

Federal and State Physician Self-Referral Prohibitions

We are subject to a set of federal laws aimed at preventing physician self-referral, including the federal anti self-referral law commonly known as the Stark Law. The Stark Law generally prohibits entities from billing, presenting, or causing to be presented a claim for designated health services, including laboratory services, payable by the Medicare or Medicaid programs when the physician ordering the service, or any member of such physician's immediate family, has an ownership interest in, or compensation arrangement with, that entity, unless the arrangement meets certain delineated exceptions to the prohibition. We rely on certain exceptions to the Stark Law, and if those exceptions were to change, we could face penalties for violations. Notably, the Stark Law is a strict liability statute, which means that no proof of scienter is required to demonstrate a violation.

Sanctions for a violation of the Stark Law, among other things, include denial of payment for the services provided in violation of the prohibition, refunds of amounts collected by the entity in violation of the Stark Law, monetary penalties, and exclusion from federal healthcare program participation. In addition, violations of the Stark Law may also serve as the basis for liability under the federal False Claims Act (the "FCA"), which prohibits knowingly presenting, or causing to be presented, a false or fraudulent claim for payment to the federal government.

Many states also have their own self-referral bans, which may extend to all self-referrals regardless of payer, with which we may have to comply unless an exception applies.

The Anti-Kickback Statute

The federal Anti-Kickback Statute ("AKS") prohibits any person or entity, including a laboratory, from knowingly and willfully offering, paying, soliciting, or receiving remuneration, directly or indirectly, in order to induce either the referral of an individual, or the furnishing, arranging for or recommending of an item or service that is reimbursable, in whole or in part, by any federal healthcare program, including the Medicare and Medicaid programs. "Remuneration" is broadly defined to include anything of value, which can include (but is not limited to) cash payments, gifts or gift cards, discounts, research opportunities, co-payment waivers or patient financial assistance, or the furnishing of services, supplies, or equipment. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. The AKS can be interpreted broadly to prohibit many arrangements and practices that are lawful in businesses outside of the healthcare industry or which are innocuous or beneficial. The AKS contains statutory exceptions and regulatory safe harbors that protect certain interactions if specific requirements are met. If an arrangement meets all of the requirements of a safe harbor, it is deemed not to violate the AKS. An arrangement must fully comply with each element of an applicable safe harbor in order to qualify for protection. The failure of a transaction or arrangement to fit within a specific safe harbor, however, does not necessarily mean that the transaction or arrangement violates the statute. A violation of the AKS may result in significant penalties, including imprisonment, fines, and possible exclusion from Medicare, Medicaid, and other federal healthcare programs. Actions that violate the AKS or any similar laws may also incur liability under the FCA. Some states also have their own AKS laws and they may apply to all payers, instead of just a state healthcare program. These statutes also typically have their own safe harbor provisions, or they may cross-reference the federal AKS safe harbors.

Federal and state law enforcement authorities scrutinize arrangements between healthcare providers and potential referral sources to determine whether the arrangements were intended to induce referrals or the purchase, prescribing or ordering of products or services reimbursable by federal healthcare programs. Law enforcement authorities and the courts have also demonstrated a willingness to look behind the formalities of a transaction to determine the underlying purpose of any remuneration exchanged between healthcare providers and actual or potential referral sources. Generally, courts and federal agencies have taken the position that the AKS may be violated if even one purpose of an arrangement is to induce referrals. We rely on safe harbors to the AKS statutes in certain arrangements with potential referral sources, and those safe

harbors could be revised or eliminated. In addition, the OIG periodically issues Special Fraud Alerts setting forth the agency's view of how certain arrangements between laboratories and referring physicians implicate and potentially violate the AKS.

The penalties for violating the federal or state AKS provisions can be severe. Consequences include, among others, criminal and civil penalties, imprisonment, and possible exclusion from federal healthcare programs, among others. Moreover, claims submitted to federal healthcare programs for items or services that were the result of a violation of the AKS are deemed to be "false" for purposes of the FCA.

Eliminating Kickbacks in Recovery Act

In October 2018, Congress enacted the Eliminating Kickbacks in Recovery Act of 2018 ("EKRA"), as part of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act ("SUPPORT Act"). EKRA is an all-payer anti-kickback law that criminalizes paying or offering any remuneration directly or indirectly to induce referrals to, or in exchange for, patients using the services of a recovery home, a substance use clinical treatment facility, or laboratory.

Although it appears that EKRA was intended to reach patient brokering and similar arrangements in the context of substance use recovery and treatment, the language in EKRA is broad. Moreover, although there is some overlap between EKRA's exceptions and the AKS safe harbors, certain arrangements that are expressly protected under the AKS do not expressly receive protection under EKRA. As such, compliance with a federal AKS safe harbor does not guarantee protection under EKRA. EKRA thus potentially expands the universe of arrangements that could be subject to enforcement under federal fraud and abuse laws, as well as substantial penalties.

EKRA permits DOJ to issue regulations clarifying or expanding the statute's exceptions, but such regulations have not yet been issued and thus there is little guidance to indicate how and to what extent it will be applied and enforced by government agencies. The relationships between laboratories and physicians, sales representatives, hospitals, and customers may be subject to scrutiny under this statute. Sanctions under the EKRA could have a negative effect on our business, if imposed.

False Claims Act

The FCA prohibits, among other things, a person from knowingly submitting (or causing to be submitted) a false claim, making a false record or statement in order to secure payment, or knowingly retaining an overpayment by the federal government. The government may assert that a claim including items and services resulting from a violation of the AKS constitutes a false or fraudulent claim for purposes of the FCA. Moreover, overpayments from certain payers must be repaid within 60 days of identification unless a favorable decision is obtained on appeal, or they may be subject to reverse false claims liability. Penalties for violating the FCA include payment, among other things, of up to three times the actual damages sustained by the government, plus substantial per-claim civil penalties, as well as possible exclusion from federal healthcare programs.

Another notable feature of the FCA is that its *qui tam* provisions allow a private individual to bring an action on behalf of the federal government and to share in any amounts paid by the defendant to the government in connection with the action. Because the *qui tam* whistleblowers initially file their complaints under seal, the action may be pending for some time before the defendant is even aware of it. If the government is ultimately successful in obtaining redress in the matter or if the plaintiff succeeds in obtaining redress without the government's involvement, then the plaintiff will receive a percentage of the recovery. It is not uncommon for *qui tam* lawsuits to be filed by current and former employees, as well as competitors or consultants of healthcare providers, including clinical laboratories. Several states have enacted similar laws modeled after the FCA that apply to items and services reimbursed under Medicaid and other state healthcare programs, and, in several states, such laws apply to claims submitted to any payer, including private insurers.

For a discussion of such a proceeding in which we are currently involved, please see "—Legal Proceedings."

Healthcare Fraud and False Statements

The federal healthcare fraud statute criminalizes knowingly and willfully defrauding any healthcare benefit program. A violation of this statute may result in fines, imprisonment, or exclusion from government healthcare programs. Exclusion from governmental healthcare programs also impacts the ability of the company to contract with private insurers. The false statements statute prohibits knowingly and willfully falsifying, concealing, or covering up a material fact or making a materially false, fictitious, or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items, or services. A violation of this statute may result in fines or imprisonment. Conduct that could be considered a violation of the other healthcare related laws described herein could also form the basis of a claim under this statute.

Civil Monetary Penalties Law

The federal Civil Monetary Penalties (“CMP”) law prohibits, among other things, (i) offering or transferring remuneration to a federal healthcare program beneficiary that a person knows or should know is likely to influence the beneficiary’s decision to order or receive items or services reimbursable by a federal healthcare program from a particular provider or supplier; (ii) employing or contracting with an individual or entity that the provider knows or should know is excluded from participation in a federal healthcare program; (iii) billing for services requested by an unlicensed physician or an excluded provider; and (iv) billing for medically unnecessary services. Conduct that could be considered a violation of the FCA or the AKS can also form the basis of a CMP complaint. Penalties for violating the CMP may include exclusion from federal healthcare programs and substantial fines.

Physician Payments Sunshine Act

The federal Physician Payments Sunshine Act (“Sunshine Act”) was enacted by Congress in 2010 as part of the Affordable Care Act (“ACA”) and was amended in 2018 by the SUPPORT Act. The Sunshine Act requires certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid, or the Children’s Health Insurance Program, with specific exceptions, to collect and report annually to CMS certain data on payments and other transfers of value by those manufacturers (and in some cases their distributors) to U.S. licensed physicians, teaching hospitals, and certain advanced non-physician healthcare practitioners, including physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, and certified nurse-midwives. The reporting program (known as the Open Payments program) is administered by CMS. Several states have enacted similar reporting requirements. The sale of covered medical devices triggers reporting obligations under the Sunshine Act as well as the similar state counterpart requirements.

While we intend fully to comply with applicable federal and state fraud and abuse laws, and similar laws of other states and countries as we commercialize solutions, it is possible that some of our arrangements or arrangements we may enter into in the future could become subject to regulatory scrutiny, and we cannot be certain that we will be found to be in compliance with these laws following any such regulatory review.

Other Potentially Applicable State Laws

In addition to the laws described above, states may have other fraud and abuse laws that apply to our business practices. Such laws include fee-splitting restrictions, insurance fraud laws, anti-markup laws, certain direct billing requirements, prohibitions on waiving coinsurance, copayments, deductibles, and other amounts owed by patients, and prohibitions on the provision of solutions at no or discounted cost to induce physician adoption. Other potentially applicable state laws prohibit the corporate practice of medicine, and are designed to prevent interference in the medical decision-making process by anyone who is not a licensed professional. Violation of these laws may result in a range of penalties, including civil or criminal penalties, as well as sanctions imposed against the business corporation and the professional through licensure proceedings and criminal penalties.

Additional International Regulation and Product Approval

We may have to obtain or submit approvals, markings, notifications, or satisfy other premarket requirements from regulatory authorities in non-U.S. jurisdictions prior to marketing our solutions in those

countries and territories. The laws and regulations in other jurisdictions vary from those in the United States and may be more difficult to satisfy, and they are subject to change, in some cases frequently. Certain regulatory authorities regulate LDTs and IVDs differently than the United States, and our solutions may need to satisfy additional requirements to be offered commercially within the jurisdictions.

European Union

In May 2017, the European Union adopted a new *In Vitro* Diagnostic Medical Devices Regulation 2017/746 (“IVDR”), which replaced the IVD Directive in May 2022. Under the IVDR, many more IVDs will require the involvement of a notified body in their conformity assessment procedure. Under transitional provisions, IVDs with notified body certificates issued under the IVD Directive prior to May 2022 may continue to be placed on the market for the remaining validity of the certificate, until May 2024 at the latest. After the expiry of any applicable transitional period, only IVDs that have been CE marked under the IVDR may be placed on the market in the European Union.

Other Jurisdictions

In the event we expand our business into other countries or jurisdictions around the world, we will be required to comply with such countries’ and jurisdictions’ healthcare and other laws and regulations covering comparable subject matter to that discussed in the foregoing paragraphs and that do not currently apply to us. Such laws and regulations are complex, change frequently, and vary among jurisdictions.

Coverage and Reimbursement

Reimbursement and billing for clinical laboratory services is highly complex. Laboratories must bill various payers, which may include federal healthcare programs (such as Medicare, Medicaid, and TRICARE), as well as Medicare Advantage plans, private insurers, and managed care organizations. Submitting claims to various payers is complicated because each payer may have different billing requirements. Additionally, the audit requirements laboratories must meet to ensure compliance with applicable laws and regulations, as well as internal compliance policies and procedures, add further complexity to the billing process.

We are currently pursuing and will continue to pursue payment for our solutions through a diverse and broad range of channels, including coverage and reimbursement by government healthcare programs and commercial third-party payers.

General Coverage and Reimbursement Considerations

Across jurisdictions, a decision by a payer (regardless of whether it is a governmental or private payer) to cover a solution does not guarantee that those payers will provide adequate reimbursement for that solution. Moreover, third-party payers are increasingly examining the medical necessity and cost-effectiveness of medical products and services, including clinical laboratory tests, in addition to their safety and efficacy. Furthermore, coverage and reimbursement for products, and services that utilize such products, can differ significantly from payer to payer. As a result, the coverage determination process is often time-consuming and costly and requires us to provide scientific and clinical support for the use of our products to each payer separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained at all.

In certain foreign markets, the government controls the coverage and pricing of many healthcare products, including clinical laboratory tests. In order to obtain coverage and reimbursement for any product that might be cleared or approved by regulators for sale, or for any procedure that utilizes such product, it may be necessary to conduct health economic studies in order to demonstrate the medical necessity and cost-effectiveness of the products. The cost of such studies would be in addition to the costs required to obtain regulatory approvals. If third-party payers do not consider a product to be cost-effective compared to other available products, they may not cover the product after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow a company to sell its products at a profit.

The marketability of our solutions may suffer if governmental and third-party payers fail to provide adequate coverage and reimbursement. In addition, emphasis on managed care in the United States

has increased, and we expect will continue to increase the pressure on medical products and services pricing. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for our solutions, less favorable coverage policies and reimbursement rates may be implemented in the future.

Coverage and Reimbursement in the United States

In the United States, there is no uniform coverage for clinical laboratory tests. The extent of coverage and rate of payment for covered services varies from payer to payer. Obtaining coverage for solutions like ours that involve genomic sequencing can be particularly challenging. Medicare is the single largest healthcare payer in the United States, and a particularly significant payer for many cancer-related laboratory services given the demographics of the Medicare population, a large portion of which includes elderly individuals. Many other U.S. payers look to the Medicare policies as a benchmark and model for their own coverage and reimbursement decisions. Medicare provides two main forms of insurance coverage: traditional Medicare fee-for-service, administered by the federal government and its contractors, and Medicare Advantage, administered by private insurers that must generally follow traditional Medicare rules and guidelines.

Medicare coverage is limited to items and services that are within the scope of a Medicare benefit category that are reasonable and necessary for the diagnosis or treatment of an illness or injury. National coverage determinations are made through an evidence-based process by the CMS, with opportunities for public participation. Medicare's National Coverage Determination ("NCD") for NGS, first established in 2018 and subsequently updated in 2020, provides national Medicare coverage for certain molecular diagnostic tests when: (1) performed in a CLIA-certified laboratory, (2) ordered by a treating physician, (3) the patient meets certain clinical and treatment criteria, including having recurrent, relapsed, refractory, metastatic, or advanced stages III or IV cancer, (4) the test is approved or cleared by the FDA as a companion IVD for an FDA approved or cleared indication for use in that patient's cancer, and (5) results are provided to the treating physician for management of the patient using a report template to specify treatment options. The NGS NCD also states that each Medicare Administrative Contractor ("MAC") may provide local coverage of other NGS tests for cancer patients only when the test is performed by a CLIA-certified laboratory, ordered by a treating physician and the patient meets the same clinical and treatment criteria required of nationally covered NGS tests under the NGS NCD. Palmetto GBA is the MAC responsible for administering Medicare's MoIDX, which issues local coverage determinations ("LCDs") for molecular diagnostic tests that are not approved or cleared by the FDA. Our MAC for the Phoenix laboratory locations is Noridian, and Noridian relies on MoIDX to make coverage and pricing determinations relating to molecular profiling. To achieve coverage under MoIDX's LCDs for molecular profiling, a test must demonstrate analytical and clinical validity, and clinical utility at a level that meets the Medicare reasonable and necessary requirement. Our MI Cancer Seek solution has Medicare coverage under the NGS NCD. Our MI Tumor Seek Hybrid solution and our Caris Assure solution for therapy selection are currently covered by Medicare under the MoIDX Program.

On January 19, 2021, CMS released an NCD that covers future tests for colorectal cancer ("CRC") screening if and when such screening tests have FDA approval and meet pre-specified CMS criteria. In addition, MoIDX LCDs provide coverage for MRD for CRC, breast cancer, lung cancer, and other indications when applicable coverage criteria are satisfied. Amongst other items, this coverage criteria includes published literature showing the clinical validity of an assay for the intended use of the assay in the intended population. While we have had preliminary discussions with MoIDX regarding coverage for Caris Assure for MRD for CRC, it is possible that MoIDX will require us to complete additional publications or validation studies and timing for MoIDX coverage, if any, is uncertain.

MoIDX has also issued an LCD for coverage of NGS assays for myeloid malignancies where applicable coverage criteria are satisfied. Among other items, this coverage criteria includes that the assay has completed a technical assessment by MoIDX for the assay's stated indications. In order to obtain MoIDX coverage for Caris ChromoSeq, we will need to submit, and MoIDX will need to approve, a technical assessment for Caris ChromoSeq.

Coding plays a significant role in how our solutions are reimbursed both from commercial and governmental payers. The CPT codes, which are maintained by the AMA, are a set of codes for medical

services, including profiling services. In addition to CPT codes, there are PLA codes, also maintained by the AMA, that are a set of billing codes for laboratory services that are more specific than CPT codes. New In addition to CPT and PLA codes, Z-Code Identifiers are used by certain payers, including under Medicare's MolDX, to supplement CPT codes for molecular diagnostics tests.

A laboratory launching a new advanced diagnostic laboratory test ("ADLT") or clinical diagnostic laboratory test ("CDLT") can apply for a PLA code with the AMA. This process requires the laboratory to submit an application to the AMA. The AMA then makes coding methodology recommendations to CMS that could include "Crosswalk" or "Gapfill." A Crosswalk is used if it is determined that there is an existing similar code, set of codes, or portion of a code that could be used to describe the new test. In this case, pricing would be the equivalent of the existing comparable code, the sum of multiple comparable codes, or a fraction of the comparable code. Gapfill is used when there are no comparable existing codes available. In this case, pricing is based on historical payments from other payers and/or resources required to complete the test. CMS will review the recommendation made by the AMA but will ultimately decide upon the coding methodology independently. This initial decision will be posted for public comment, and pricing will be published at the end of the public comment period. After pricing and coding is published, a request is then submitted to CMS for coverage under an existing NCD, or a request is made to create a new NCD.

In July 2020, the AMA issued a PLA code, CPT code 0211U, for our MI Cancer Seek solution with effective date October 1, 2020. CMS subsequently established national pricing for CPT code 0211U under the CLFS at \$8,455. We have obtained Medicare coverage for MI Cancer Seek for CPT code 0211U under the NGS NCD. Our MI Tumor Seek Hybrid solution is reported to Medicare and to some commercial payers using unlisted molecular pathology CPT code 81479 and unique Z-Code Identifiers. In July 2024, the AMA issued a PLA code, CPT code 0485U, for Caris Assure for therapy selection, with an effective date of October 1, 2024. In November 2024, CMS determined to price Caris Assure for therapy selection using the "Gapfill" method. There is no certainty regarding the pricing that we will obtain for Caris Assure during the Gapfill process. Changes to these coverage policies or to the codes used to report to payers may result in significant changes in reimbursement.

Our early detection solution could be considered a screening test by Medicare and is not currently covered by Medicare. Medicare coverage for preventive services such as screening tests must be expressly authorized by statute or by CMS under an applicable NCD. Under CMS regulations, additional preventive services covered under an NCD must be (a) reasonable and necessary for the prevention or early detection of an illness or disability, (b) recommended with a grade of A or B by the USPSTF, which is an independent, volunteer panel of experts in the field of prevention, evidence-based medicine and primary care, and (c) appropriate for Medicare beneficiaries under Part A or Part B. None of our solutions have received such a grade or determination from USPSTF, which generally waits for FDA authorization before undertaking review of novel technology. In addition, the NCD process may take multiple years to complete, and currently, coverage decisions for preventive services are not made prior to FDA authorization. Even if we go through the lengthy NCD process, it is possible that the early detection solution will never become eligible for Medicare coverage and reimbursement.

We are evaluating opportunities for nearer-term coverage and reimbursement through Medicare Advantage plans as a supplemental benefit while generating evidence to meet the requirements of the traditional Medicare path. Medicare Advantage plans generally must cover all of the services that traditional Medicare covers (except hospice care), but they have the discretion to offer their enrollees additional, or supplemental, benefits not otherwise covered under traditional Medicare, including those benefits referred to as optional supplemental benefits, for which enrollees may elect to pay extra to receive coverage. Obtaining such coverage may, however, involve lengthy negotiations with individual Medicare Advantage plans, and there is no guarantee that we will receive such coverage.

We also intend to pursue coverage and reimbursement from private payers for our solutions. Many of these private payers must cover certain services required by federal and state laws, such as preventive health services that have received a rating of A or B by the USPSTF. Like Medicare Advantage plans, private payers have discretion to extend greater coverage than recognized under traditional Medicare but obtaining coverage from such payers may involve lengthy negotiations and there is no guarantee that we will receive such coverage. Even if we are successful in receiving coverage, the reimbursement amounts may not meet expected levels. State Medicaid programs make individual coverage decisions for diagnostic tests and have

taken steps to control the cost, utilization and delivery of healthcare services meaning that, even if we receive coverage through private payers, there is no guarantee that our solutions will be covered by individual state Medicaid programs.

With respect to private health plans, the ACA mandates that such plans cover evidence-based items or services recommended by USPSTF with a grade of A or B, with certain prohibitions on cost-sharing requirements. Accordingly, if the USPSTF does not recommend use of Caris Assure or other solutions we are developing or requires a substantial amount of time to review such solutions, our business, financial condition, and results of our operations would be harmed.

The Protecting Access to Medicare Act of 2014

In April 2014, Congress passed the Protecting Access to Medicare Act of 2014 (“PAMA”), which included substantial changes to the way in which certain clinical laboratory services are paid under Medicare’s CLFS. Under PAMA (as amended by the Further Consolidated Appropriations Act in 2020 and Further Continuing Appropriations and Other Extensions Act of 2024), laboratories that receive the majority of their Medicare revenue from payments made under the CLFS and Physician Fee Schedule and receive at least \$12,500 in Medicare revenues for CLFS services during a data collection period are subject to certain reporting requirements. CMS uses the data reported, including certain private payer payment rates, the volume of tests paid at each rate, and the HCPCS code associated with the test, to calculate a weighted median payment rate for each test, which is used to establish revised Medicare CLFS reimbursement rates for tests that are considered to be CDLTs. If the test falls into the category of new ADLT instead of CDLT, the test will be paid based on an actual list charge for an initial period of three quarters before being shifted to the weighted median private payer rate reported by the laboratory performing the ADLT. Laboratories offering ADLTs are subject to recoupment if the actual list charge exceeds the weighted median private payer rate by a certain amount. Accordingly, if newly developed tests receive Medicare coverage in the future, the reimbursement rate we receive for such tests may be affected by payment rates made by private payers for such tests. In addition, PAMA codified Medicare coverage rules for laboratory tests by requiring any local coverage determination to be made following the local coverage determination process. PAMA also authorizes CMS to consolidate coverage policies for clinical laboratory tests among one to four laboratory-specific MACs. These same contractors may also be designated to process claims if CMS determines that such a model is appropriate. It is unclear whether CMS will proceed with contractor consolidation under this authorization.

Congress passed legislation that delayed data reporting requirements for CDLTs that are not ADLTs, and delayed the phase-in of payment reductions under the CLFS from private payer rate implementation. The revised reimbursement methodology described above generally results in relatively lower reimbursement amounts under Medicare for clinical laboratory services than has been historically reimbursed. Any reductions to reimbursement rates resulting from the new methodology are limited to 0% in 2025 and 15% per test per year in each of 2026 through 2028.

The subsequent data reporting period for CDLTs that are not ADLTs will occur in three-year cycles, with the next cycle beginning in 2026. The pricing for our solutions may be negatively impacted by the PAMA reporting process. Given the many uncertainties built into PAMA’s price-setting process, we cannot predict how payments we receive under the CLFS, and thus our revenue, may change from year to year.

Healthcare Reform

In the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory changes to the healthcare system. Changes in healthcare policy could increase our costs and subject us to additional regulatory requirements that may interrupt commercialization of our solutions, decrease our revenue and adversely impact sales of, and pricing of and reimbursement for, our solutions. For example, in March 2010, the ACA was signed into law, which substantially changed the way healthcare is financed by both governmental and private insurers in the United States. The ACA contains a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement adjustments, and fraud and abuse changes.

The implementation of the ACA in the United States, for example, has changed healthcare financing and delivery by both governmental and private insurers substantially, and affected medical device manufacturers significantly. The ACA included, among other things, provisions governing enrollment in federal and state healthcare programs, reimbursement matters, and fraud and abuse. Since its enactment, there have been judicial, U.S. Congressional and executive branch challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the “individual mandate” was repealed by Congress. In addition, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 (the “IRA”) into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the “donut hole” under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creating a new manufacturer discount program. It is unclear how other healthcare reform measures, if any, will impact our business.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. For example, the Budget Control Act of 2011, among other things, resulted in reductions in payments to Medicare providers, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2032, unless additional Congressional action is taken. In addition, as a result of the American Rescue Plan Act of 2021 (“ARPA”), an additional Medicare payment reduction of up to 4% was required to take effect in January 2022; however, Congress has delayed implementation of this reduction until 2025. Additionally, the American Taxpayer Relief Act of 2012, among other things, reduced CMS payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover Medicare overpayments to providers from three to five years.

We believe that there will continue to be proposals by legislators at both the federal and state levels, regulators, and third-party payers to reduce costs while expanding individual healthcare benefits. Certain of these proposals to further reform healthcare or reduce healthcare costs may limit coverage of or lower reimbursement for the procedures associated with the use of our solutions. Changes in healthcare policy could increase our costs, decrease our revenue, and impact sales of and reimbursement for our solutions.

Privacy Regulation

Data Privacy and Security Regulation

Numerous state, federal, and foreign laws, including consumer protection laws and regulations, govern the collection, dissemination, use, access to, confidentiality, and security of personal information, including health-related information. In the United States, numerous federal and state laws and regulations, including data breach notification laws, health information privacy and security laws, including HIPAA or HITECH, and federal and state consumer protection laws and regulations (for example, Section 5 of the Federal Trade Commission Act) that govern the collection, use, disclosure, and protection of health-related and other personal information could apply to our operations or the operations of our partners. In particular, we are a “Covered Entity” as defined under HIPAA when performing our healthcare services for customers, and also act as a “Business Associate” when performing certain services for or on behalf of Covered Entities, which requires us to develop and maintain policies with respect to the protection of, use, and disclosure of PHI, including the adoption of administrative, physical and technical safeguards to protect such information, and to provide notifications in the event of a breach of unsecured PHI. In addition, many states have also implemented healthcare privacy and genetic testing and privacy laws imposing specific patient consent requirements and protecting test results by limiting the disclosure of those results. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties and private litigation. Privacy and security laws, regulations, and other obligations are constantly evolving, may conflict with each other to make compliance efforts more challenging, and can result in investigations, proceedings, or actions that lead to significant penalties and restrictions on data processing.

As a healthcare provider, we are also subject to Section 4004 of the 21st Century Cures Act, and regulations promulgated by HHS related to patient access to electronic PHI (“EHI”), to promote interoperability and to ensure the access, exchange, or use of EHI.

Other International Privacy and Security Regulations

Our business is subject to a complex and evolving global web of laws and regulations governing data privacy, data security, cross-border data transfers, and data localization. Local, state, federal, and foreign governments are increasingly implementing or expanding their data protection regimes, resulting in additional compliance costs and risks. Many of these laws and regulations are subject to change and uncertain interpretation and could result in regulatory or litigation claims or actions, changes to our business practices, monetary penalties, increased cost of operations, declines in clinical study participation or engagement, or otherwise harm our business.

We rely on information technology systems, including third-party hosted services, to support our business processes and activities and to store personal data (including employee and patient data). Consequently, we are at risk of a cybersecurity-related attack, intrusion, or disruption, including by criminal organizations, hackers, foreign governments, and terrorists. A cybersecurity incident could result in some or all of our systems being unavailable, the loss, misuse, or unauthorized disclosure of genetic information or other personal data, negative publicity and reputational damage, exposure to risk of loss, and litigation and regulatory investigations. In the event we are a victim of a cyberattack, data breach notification laws may require us to notify regulators, affected individuals, and potentially other third parties in multiple jurisdictions. Cyber threats are constantly evolving, increasing the difficulty of detecting and successfully defending against them. Despite our security measures, we cannot guarantee that these measures will prevent all possible security breaches or attacks.

Employees and Human Capital Resources

As of March 31, 2025, we had 1,769 full-time employees. Of these employees, nearly 50 have Ph.D. or M.D. degrees and over 200 are engaged in R&D activities. None of our employees are represented by a labor union or party to a collective bargaining agreement.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing, and integrating our existing and new employees, advisors, and consultants. We believe our success depends on our ability to attract, retain, develop, and motivate diverse highly skilled personnel. In particular, we depend upon the personal efforts and abilities of the principal members of our senior management to partner effectively as a team and to provide strategic direction, develop our business, manage our operations, and maintain a cohesive and stable work environment. We also rely on qualified managers and skilled employees, such as scientists, engineers, and laboratory technicians, with technical expertise in operations, scientific knowledge, engineering skills, and quality management experience in order to operate our business successfully.

Our compensation program is designed to retain, motivate, and attract highly qualified personnel, including through the granting of stock-based and cash-based compensation awards, in order to increase shareholder value and the success of our Company by motivating such individuals to perform to the best of their abilities and achieve our business objectives.

Key Relationships***Supply Agreement with Illumina***

In November 2022, we entered into Illumina, Inc.'s ("Illumina") "open offer" supply agreement wherein Illumina provides products and services that we use in our laboratory operations for certain research and clinical activities, including certain sequencers, equipment, and other materials (the "Illumina Agreement").

Under the Illumina Agreement, Illumina grants non-exclusive, non-transferable, personal, non-sublicensable rights to use certain Illumina know-how and technology with Illumina products purchased under the agreement, and we granted Illumina an irrevocable, perpetual, worldwide, fully paid-up, and royalty-free license covering improvements to certain Illumina know-how and technology. The Illumina Agreement does not contain any minimum purchase requirements but provides for volume discounts and other

promotions. The Illumina Agreement also contains use limitations, representations and warranties, indemnification, limitations of liability, change notification, audit rights, and other provisions.

The Illumina Agreement is irrevocable by Illumina until its expiration in August 2033. We have a unilateral right to terminate our supply relationship with Illumina at any time and for any reason without termination liability upon 90 days' prior written notice to Illumina.

Master Supply Agreement with Roche

In July 2024, we entered into a master supply agreement with Roche Diagnostics Corporation ("Roche"), for Roche to provide sequencing probes and other testing supplies and equipment for clinical and research uses in our laboratory operations (the "Roche Agreement"). Under the Roche Agreement, we receive certain pricing levels if we purchase a specified minimum annual quantity of supplies. Under the terms of the Roche Agreement, we also agreed to make rolling forecasts of our expected needs, which forecasts currently become three- and six-month binding purchase commitments for catalog and custom products, respectively. The pricing is fixed for the initial 12 months of the agreement term described below, and subject to increase thereafter. The Roche Agreement also contains negotiated use limitations, representations and warranties, indemnification, limitations of liability, and other provisions.

The Roche Agreement has an initial term through April 2027 and will automatically renew with successive one-year terms unless either party provides 90-day advance notice of non-renewal. The agreement also provides for other customary termination rights, including in the case of material breach by, or insolvency of, either party.

Facilities

Our corporate headquarters are located in Irving, Texas, where we lease approximately 30,500 square feet pursuant to a lease expiring in 2028. We also lease office space in Arizona, Massachusetts, and New York, and in Switzerland and Japan for our international offices.

We lease an approximately 66,000 square foot solid tissue clinical laboratory facility and an approximately 35,500 square foot blood-based clinical laboratory facility in Phoenix, Arizona, with leases expiring in 2030 and 2026, respectively. We also lease an approximately 59,000 square foot R&D laboratory facility in Tempe, Arizona and an approximately 114,500 square foot laboratory facility in Irving Texas, with leases expiring in 2026 and 2035, respectively. The laboratory facility in Irving, Texas is continuing to be built-out and will bring our total operational capacity to over 275,000 square feet.

We lease an approximately 54,500 square foot customer service office and an approximately 22,550 square foot warehouse facility in Phoenix, Arizona, with leases expiring in 2030 and 2031, respectively. We also lease an approximately 23,400 square foot warehouse facility in Irving, Texas, with a lease expiring in 2032.

We do not own any real property. We believe that our facilities are adequate to meet our needs for the immediate future, and that, should it be needed, suitable additional space will be available to accommodate any such expansion of our operations.

Legal Proceedings

In March 2025, we received a Civil Investigative Demand ("CID") from the DOJ in connection with an investigation under the FCA regarding our compliance with Medicare's date of service rule (also referred to as the 14-day rule), particularly focused on patients of certain health care providers, and our policies, procedures, and training related to compliance with the 14-day rule. The related investigation continues to evolve and is in too early a stage to assess potential outcomes. We are cooperating with the investigation. We have implemented compliance policies, procedures, and training designed to foster compliance with the 14-day rule, but there can be no certainties regarding the outcome of the CID. In June 2022, we entered into a settlement agreement with the United States in connection with a previous investigation into our compliance with the 14-day day rule. Pursuant to this settlement agreement, under which we admitted no fault or liability, we paid approximately \$2.9 million in restitution and penalties and we obtained a nationwide release from all 14-day rule claims prior to January 1, 2018.

In addition to the matter described above, we are, from time to time, party to various claims and legal proceedings arising out of our ordinary course of business, including claims or proceedings relating to, among other things, regulatory matters, intellectual property, competition, tax, and employment matters, medical malpractice, product or professional liability or other tort claims. We cannot predict with certainty the results of any claims or proceedings. We may receive unfavorable preliminary or interim rulings in the course of litigation, and there can be no assurances that favorable final outcomes will be obtained. Moreover, the existence of any claim or legal proceeding, regardless of the outcome, may adversely impact us because of diversion of management time and attention as well as the financial costs related to resolving such disputes. For additional information, see “Risk Factors—Risks Related to Regulation and Legal Compliance—We have been, are currently, and in the future may be the subject of government investigations, claims, audits, whistleblower and payer audits, overpayment and recoupment efforts and other litigation in the course of our business that could adversely affect our business and financial statements.”

MANAGEMENT

Executive Officers and Directors

Set forth below are the names, ages, and positions of our executive officers and directors as of the date of this prospectus.

<u>Name</u>	<u>Age</u>	<u>Position(s)</u>
<i>Executive Officers</i>		
David D. Halbert, D.Sc. (h.c.)	69	Founder, Chairman, and Chief Executive Officer
Brian J. Brille	64	Vice Chairman and Executive Vice President
David Spetzler, M.S., Ph.D., M.B.A.	49	President
Luke Power	44	Senior Vice President, Chief Financial Officer, and Chief Accounting Officer
J. Russel Denton	42	Senior Vice President, General Counsel, and Secretary
<i>Non-Employee Directors</i>		
George H. Poste, D.V.M., Ph.D., D.Sc., F.R.S.	81	Vice Chairman
Jonathan Knowles, Ph.D.	77	Vice Chairman
Nathan Burns ⁽³⁾	43	Director
Peter M. Castleman ⁽¹⁾⁽²⁾	69	Director
David Fredrickson	50	Director
Joseph E. Gilliam ⁽¹⁾⁽²⁾	49	Director
Jon S. Halbert	65	Director
Laura I. Johansen ⁽²⁾	60	Director
Lloyd B. Minor, M.D.	68	Director
Vijay Mohan ⁽³⁾	45	Director
Danny Phillips ⁽¹⁾	65	Director
Jeffrey Vacirca, M.D., F.A.C.P.	56	Director

(1) Member of the audit committee of our board of directors.

(2) Member of the compensation committee of our board of directors.

(3) Messrs. Burns and Mohan have notified us that they each intend to resign from our board of directors effective as of immediately prior to the effectiveness of the registration statement of which this prospectus forms a part.

Executive Officers

David D. Halbert, D.Sc. (h.c.) founded our Company in 2008 and has served as our Chief Executive Officer and the Chairman of our board of directors since our inception. Mr. Halbert and his family also created and solely support the Caris Foundation, a non-profit, private foundation formed in 2002 that aids impoverished people by helping to provide for their basic needs. From 2005 to 2011, Mr. Halbert served as Chairman and Chief Executive Officer of Caris Diagnostics, a Texas-based pathology company specializing in gastrointestinal pathology, which was sold to Miraca Life Sciences in 2011. Prior to Caris Diagnostics, Mr. Halbert served as Chairman and Chief Executive Officer of AdvancePCS Inc. (“AdvancePCS”), a prescription benefit plan administrator that he founded in 1987. Mr. Halbert holds a Bachelor of Business Administration from Abilene Christian University and an honorary Doctor of Science from Abilene Christian University for his contributions to precision medicine and his global philanthropic work. We believe Mr. Halbert’s extensive knowledge of the healthcare industry, business experience, and 20 years of leadership as Caris’ Founder, Chairman, and Chief Executive Officer make him well-qualified to serve as a member of our board of directors.

Brian J. Brille has served as our Vice Chairman and Executive Vice President and as a member of our board of directors since January 2018. Mr. Brille currently serves as a member of the board of trustees at the Cancer Research Institute, a non-profit organization funding cancer research. Since 2022, Mr. Brille has also served as member of the board of directors at the International Biomedical Research Alliance, a non-profit organization with a mission to support the NIH Oxford-Cambridge Scholars Program. Prior to joining Caris, Mr. Brille served in various finance-related roles for Bank of America Merrill Lynch (now BofA Securities, Inc.), a multinational investment bank and financial services company, from 1999 to 2013, including most recently as Chairman & President of Asia Pacific from 2009 to 2013, as Head of Corporate and Investment Banking from 2005 to 2008, and as Head of Healthcare Investment Banking from 1999 to 2004. Mr. Brille began his career in 1987 at Morgan Stanley & Co. LLC (“Morgan Stanley”), a multinational investment bank and financial services company, and founded Morgan Stanley’s Healthcare Services Investment Banking Group. Mr. Brille holds a Juris Doctor from Stanford Law School, a Master in Public Policy from the Harvard Kennedy School, and a Bachelor of Science in Accounting from the University of Illinois. We believe Mr. Brille’s extensive experience in the investment industry and knowledge of healthcare and technology companies make him well-qualified to serve as a member of our board of directors.

David Spetzler, M.S., Ph.D. has served as our President since November 2016. Dr. Spetzler has also served as an adjunct faculty member of the molecular cellular biology program at Arizona State University since 2007. Dr. Spetzler joined Caris in August 2009 as a Senior Scientist and has served in a variety of roles of increasing seniority during his tenure. Before Caris, Dr. Spetzler served in various research faculty roles at Arizona State University from January 2003 to August 2009. Dr. Spetzler holds a Master of Science, a Doctor of Philosophy in Molecular & Cellular Biology, and a Master of Business Administration from Arizona State University.

Luke Power has served as our Senior Vice President, Chief Financial Officer, and Chief Accounting Officer since February 2023. Mr. Power joined Caris in December 2011 as a Financial Reporting and Accounting Manager and has served in a variety of roles of increasing seniority during his tenure, including as Chief Accounting Officer from April 2017 to February 2023, Senior Director of Accounting from May 2016 to September 2016, and Director of Accounting from August 2013 to May 2016. Prior to joining Caris, Mr. Power worked as a Manager in the international assurance practice at PricewaterhouseCoopers LLP, a provider of business advisory services, from November 2002 to October 2011. Mr. Power is a certified public accountant and a fellow of Chartered Accountants Ireland. Mr. Power holds a degree in finance and accounting from Waterford Institute of Technology in Ireland.

J. Russel Denton has served as our Senior Vice President, General Counsel, and Secretary since September 2022. Prior to joining Caris, Mr. Denton served as a partner at Shearman & Sterling LLP, an international law firm, representing clients in mergers and acquisitions and equity financing transactions from March 2018 to September 2022. Prior to Shearman & Sterling LLP, Mr. Denton served as a partner at Andrews Kurth Kenyon LLP from May 2012 to February 2018. Mr. Denton began his career in September 2008 as an associate at Skadden, Arps, Slate, Meagher and Flom LLP. Mr. Denton holds a Juris Doctor from Stanford Law School and a Bachelor of Science from Duke University.

Non-Employee Directors

George H. Poste, D.V.M., Ph.D., D.Sc., F.R.S. has served as our Vice Chairman since our founding in 2008. Since February 2009, Dr. Poste has served as the Chief Scientist of the Complex Adaptive Systems Initiative at Arizona State University, a program that links expertise across the university in research on synthetic biology, ubiquitous sensing, and healthcare informatics for personalized medicine, and as the Del E. Webb Professor of Health Innovation. From May 2003 to February 2009, Dr. Poste served as Director of The Biodesign Institute at Arizona State University. Since January 2000, Dr. Poste has served as the Chief Executive Officer of Health Technology Networks, a consulting company that specializes in the application of genomic technologies and computing in healthcare. From July 1992 to December 1999, Dr. Poste was the Chief Science and Technology Officer and President, R&D, of SmithKline Beecham Corporation, a pharmaceutical company. Dr. Poste served on the Defense Science Board of the U.S. Department of Defense from January 2000 to December 2009 and is a member of the Bipartisan Commission on Biodefense as well as other U.S. government organizations to advise on national security policy on advancing defenses against bioweapons and biowarfare. Dr. Poste has served as a member of the board of directors of Exelixis,

Inc., a genomics-based drug discovery company, since 2004. Previously, Dr. Poste served as a member of the board of directors of Monsanto Company, a provider of agricultural products and solutions, from 2003 to 2018, Orchid Cellmark, Inc., a DNA forensics company, from 2002 to 2009, AdvancePCS, from 2002 to 2005, Structural GenomiX, a biotechnology company, from 2000 to 2003, and Illumina, from 2000 to 2003. Dr. Poste also serves on several scientific advisory boards, including Synthetic Genomics Inc., VirBiotech, the University of Michigan Taubman Institute, and MIDAS Advanced Computing Initiative. Dr. Poste is a Fellow of the UK Royal Society, the UK Academy of Medical Sciences, American Institute for Medical and Biological Engineering. Dr. Poste is also a member of the Council for Foreign Relations and previously served as a member of the Hoover Institution, Stanford University, and has received several honorary doctorates from several universities. Dr. Poste holds a Doctor of Veterinary Medicine and a Doctor of Philosophy in Virology from the University of Bristol, England and Board Certification in Pathology from the Royal College of Pathologists. We believe Dr. Poste's training as a scientist, knowledge of the life sciences, healthcare, and biopharma industries, and extensive service on multiple boards make him well-qualified to serve as a member of our board of directors.

Jonathan Knowles, Ph.D. has served as our Vice Chairman since 2010. Dr. Knowles served as the President of Group Research at Roche Holding AG ("Roche"), a Swiss multinational healthcare company, from September 1998 to January 2010 and as a member of its Corporate Executive Committee from January 1998 to January 2010. From January 1998 to January 2010, Dr. Knowles served as a member of the board of directors and as Chairman of the Corporate Governance Committee of Genentech, Inc., a biotechnology corporation that later became a subsidiary of Roche. From January 2007 to January 2010, Dr. Knowles served as the Chairman of the Research Directors' Group of the European Federation of Pharmaceutical Industry Associations. He has also served on the boards of directors of various pharmaceutical companies. Dr. Knowles is a Professor Emeritus at the École Polytechnique Fédérale de Lausanne, a Distinguished Professor in Personalized Medicine at the University of Helsinki, Finland, and a visiting Professor at the University of Oxford. Dr. Knowles holds a Bachelor of Science in Molecular Genetics from the University of East Anglia and a Doctor of Philosophy in Genetics of Mitochondria from the University of Edinburgh. We believe Dr. Knowles' extensive experience in the pharmaceutical industry and years of experience in his leadership roles as a director and executive officer make him well-qualified to serve as a member of our board of directors.

Nathan Burns has served as a member of our board of directors since August 2022. Mr. Burns is currently a Managing Director & Healthcare Portfolio Manager at Highland Capital Management, L.P., a global alternative investment manager based in Dallas, Texas. Mr. Burns joined Highland Capital Management, L.P. in July 2014 as a Director of Healthcare Absolute Return Investments. Prior to joining Highland Capital Management, L.P., Mr. Burns was a Private Equity Associate at Ripplewood Holdings, a global private equity firm, from September 2007 to December 2013. Mr. Burns began his career as an Investment Banking Analyst in the Global Technology Mergers & Acquisitions Group at Lehman Brothers, a global financial services firm, from June 2004 to June 2007. Mr. Burns holds a Bachelor of Science in Analytical Finance and Economics from Wake Forest University and Master of Business Administration from Columbia Business School. He also is a CFA charterholder. We believe Mr. Burns' extensive experience in the investment industry and knowledge of healthcare companies make him well-qualified to serve as a member of our board of directors.

Peter M. Castleman has served as a member of our board of directors since 2008. Mr. Castleman is a private company investor and entrepreneur. Mr. Castleman is actively involved with about a dozen private companies where he is a significant owner through his family office, which he established in December 2006. Prior to establishing his family office, Mr. Castleman was the Chairman and Managing Partner of J. H. Whitney & Co., LLC, a private equity firm, from December 1992 to December 2006, where he oversaw all the firm's activities, including the private equity investing business. Prior to joining J. H. Whitney & Co., LLC in May 1987, Mr. Castleman was with Morgan Stanley & Co. LLC in their leveraged buyout investment group. Mr. Castleman started his career at J.P. Morgan Securities LLC, where he was an international banking officer. Mr. Castleman holds a Master of Business Administration from Harvard Business School and a Bachelor of Arts from Duke University. We believe Mr. Castleman's extensive experience in the investment industry and years of experience in his leadership roles as a director and executive officer make him well-qualified to serve as a member of our board of directors.

David Fredrickson has served as a member of our board of directors since August 2024. Mr. Fredrickson currently serves as Executive Vice-President, Oncology Business Unit of AstraZeneca PLC, a position that he has held since October 2017. Previously, Mr. Fredrickson served as President of AstraZeneca K.K. in Japan, and Vice-President, Specialty Care of AstraZeneca in the United States. While in Japan, Mr. Fredrickson also served as Vice Chairman of the European Federation of Pharmaceutical Industries and Associations Japan and was a Director of the Japan Pharmaceutical Manufacturers Association. Before joining AstraZeneca, Mr. Fredrickson worked at Genentech, Inc., a biotechnology corporation that later became a subsidiary of Roche, where he served in several functions and leadership positions, including as Oncology Business Unit Manager in Spain, and in strategy, marketing, and sales roles in the United States. Prior to this, Mr. Fredrickson worked at the Monitor Group, LLC (now Monitor Deloitte Group, LLC), a global strategy consultancy firm. Mr. Fredrickson holds a Bachelor of Arts in Government from Georgetown University. We believe Mr. Fredrickson's extensive experience in the pharmaceutical and oncology industries and years of experience in his leadership roles as a director and executive officer make him well-qualified to serve as a member of our board of directors.

Joseph E. Gilliam has served as a member of our board of directors since April 2021. Mr. Gilliam is currently the President and Chief Operating Officer at Glaukos Corporation, an ophthalmic pharmaceutical and medical device company, a position he has held since April 2022. From May 2017 to April 2022, Mr. Gilliam was Chief Financial Officer and Senior Vice President, Corporate Development at Glaukos Corporation. Prior to Glaukos Corporation, Mr. Gilliam served as a Managing Director in the Healthcare Investment Banking group at J.P. Morgan Securities LLC from 2013 to May 2017, where he led the initial public offering for Glaukos Corporation. From 2000 to 2013, Mr. Gilliam held positions of increasing responsibility at J.P. Morgan Securities LLC and its predecessor organizations, The Beacon Group and Chase Manhattan, with experience spanning mergers and acquisitions, primary and secondary public equity offerings, bank lending, bond offerings and other transactions. Mr. Gilliam started his career at PricewaterhouseCoopers LLP as an Auditor. Mr. Gilliam holds a Bachelor of Science in accounting from the Kelly School of Business at Indiana University. We believe Mr. Gilliam's extensive experience in the investment and healthcare industries and knowledge of healthcare companies make him well-qualified to serve as a member of our board of directors.

Jon S. Halbert has served as a member of our board of directors since May 2014. Mr. Halbert currently serves as a member of the board of directors at Allegiance Group, a leading provider of fundraising services to nonprofit organizations in the United States, a position he has held since January 2023. Since August 2007, Mr. Halbert has also served as a member of the board of directors of the Pursuant Group, a nonprofit-focused marketing and fundraising organization that merged with the Allegiance Group in April 2023. Mr. Halbert also currently serves on the boards of directors of CitiSquare and Forest Forward, Dallas-based nonprofit organizations that focus on poverty and the revitalization of South Dallas, respectively. Mr. Halbert served as the Chairman of Phytel, Inc., a technology driven provider-led population health improvement company, until its merger with the International Business Machines Corporation in 2015. Prior to Phytel, Inc., Mr. Halbert co-founded and served as Vice Chairman of AdvancePCS from 1987 until its merger with CVS Caremark Corporation in 2004. Mr. Halbert holds a Bachelor of Accounting from Abilene Christian University. We believe Mr. Halbert's extensive experience in the healthcare and technology industries and years of experience in his leadership roles as a director and executive officer make him well-qualified to serve as a member of our board of directors.

Laura I. Johansen has served as a member of our board of directors since our founding in 2008. Ms. Johansen served as our Vice Chairman until February 2012. In 2015, Ms. Johansen founded and currently serves as the President of Pence Management, a family office focused on real estate and equity investments. Ms. Johansen previously served as the President of Halbert & Associates, LLC ("Halbert & Associates"), the family office of Mr. Halbert, from 2004 to 2010. Ms. Johansen began her career at AdvancePCS as General Counsel in 1996 and served as the Senior Vice President and Corporate Secretary from 2001 until its merger with CVS Caremark Corporation in 2004. Before joining AdvancePCS, Ms. Johansen served as an Associate in the Corporate and Securities Group of Akin, Gump, Strauss, Hauer and Feld, an international law firm. Ms. Johansen holds a Bachelor of Business Administration in Marketing and a Juris Doctor from the University of Texas. We believe Ms. Johansen's extensive experience in the healthcare industry and years of leadership experience as our Vice Chairman make her well-qualified to serve as a member of our board of directors.

Lloyd B. Minor, M.D. has served as a member of our board of directors since August 2021. Dr. Minor is currently the Carl and Elizabeth Naumann Dean of the Stanford University School of Medicine, a position he has held since 2012. In addition to being the Dean of the School of Medicine, he became the Vice President for Medical Affairs at Stanford University in August 2023. Dr. Minor has also been a professor of Otolaryngology—Head and Neck Surgery and a professor of Neurobiology and Bioengineering, by courtesy, since 2012. Prior to 2012, Dr. Minor served as the Provost and Senior Vice President for Academic Affairs at Johns Hopkins University from 2009 to 2012. Dr. Minor began his career at Johns Hopkins School of Medicine in the Department of Otolaryngology—Head and Neck Surgery as a Professor from 1993 to 2003, before serving as department’s Andelot Professor and Director (Chair) from 2003 to 2009. Dr. Minor has served as a member of the board of directors of Biogen, a global pharmaceutical company, since 2024. Dr. Minor holds a Bachelor of Science in Biology and a Doctor of Medicine from Brown University. In 2012, Dr. Minor was elected to the National Academy of Medicine, formerly the Institute of Medicine. We believe Dr. Minor’s experience as a professor and knowledge of the medical and healthcare industries make him well-qualified to serve as a member of our board of directors.

Vijay Mohan has served as a member of our board of directors since August 2020. Mr. Mohan is currently a Co-Founder and Partner at Sixth Street Partners, a San Francisco-based investment firm, a position he has held since its founding in May 2009. Prior to Sixth Street Partners, Mr. Mohan was a Managing Principal at Bardin Hill Investment Partners L.P., a New York investment firm. Mr. Mohan began his career in the Technology, Media, and Telecom Group of the Investment Banking Division of Goldman Sachs & Co. LLC, a global investment banking, securities, and investment management firm. Mr. Mohan currently serves as a member of the Board of Visitors for Columbia College. He holds a Bachelor of Arts in Economics from Columbia University. We believe Mr. Mohan’s extensive experience in the investment industry and years of experience as the co-founder of Sixth Street Partners make him well-qualified to serve as a member of our board of directors.

Danny Phillips has served as a member of our board of directors since August 2015. Mr. Phillips is currently the owner of the Diamond P Longhorn Ranch in Lindale, Texas, and manages his own financial investments. Mr. Phillips currently serves as a member of the board of directors of Fortress Youth Development Center, a non-profit organization that aids the homeless community and low-income families in Fort Worth, Texas, and served as its Chairperson from 2007 to 2015. In addition, Mr. Phillips currently serves as a member of the board of directors of Mission Increase Fort Worth, a non-profit organization that offers teaching, coaching, consulting, and fundraising tools to help other non-profits grow and be successful. He also currently serves as a member of the board of directors of Texas Mutual Insurance Company, a workers’ compensation provider in Texas, a position he has held since 2012. Mr. Phillips has also previously served as a member of the board of directors of various academic organizations, such as on the board of regents at Pepperdine University and the investment board of Abilene Christian University. Mr. Phillips served in various finance-related roles at AdvancePCS for over 11 years, including as its Chief Financial Officer and Senior Executive Vice President until its sale to CVS Caremark Corporation in 2004. Prior to AdvancePCS, Mr. Phillips served various senior financial roles at Harken Energy Corporation (now HKN Inc.), a company engaged in hydrocarbon exploration in Texas, and Aloha Petroleum, Ltd., a gasoline marketer and convenience store operator in Hawaii. Mr. Phillips holds a Bachelor of Arts in Accounting from Abilene Christian University. We believe Mr. Phillips’ extensive experience in the pharmaceutical and investment industries and years of experience as a director and executive officer make him well-qualified to serve as a member of our board of directors.

Jeffrey Vacirca, M.D., F.A.C.P. has served as a member of our board of directors since November 2024. Since 2008, Dr. Vacirca has served as Chief Executive Officer and Chairman of the Board of New York Cancer & Blood Specialists, a cancer care center specializing in hematology/oncology and medical oncology. Since 2011, he has served as President and Co-Founder of National Translational Research Group, a group focusing on non-clinical research, and, from 2012 to 2023, he served as a Medical Director and Strategic Advisor for the International Oncology Network specialty group at Amerisource Bergen, a pharmaceutical products company. Since 2018, Dr. Vacirca has served as the Medical Director of the Oncology Network Development at Mount Sinai Health Network and as an associate clinical professor at Icahn School of Medicine at Mount Sinai, New York. He served as Medical Director for the Long Island Association for AIDS Care from 2008 to 2024. Dr. Vacirca also serves on the boards of directors of privately held companies Annexus Health, OneOncology (where he was a co-founder) and PatientPoint.

Dr. Vacirca served as a director of Assertio Holdings, a publicly-traded pharmaceutical company, from July 2023 to November 2024, Spectrum Pharmaceuticals, a publicly-traded pharmaceutical company, from November 2018 to its July 2023 acquisition by Assertio, and BeyondSpring Inc., a publicly-traded biopharmaceutical company, from December 2020 to April 2022. Dr. Vacirca is the past president of the Community Oncology Alliance and continues to be a member of its executive committee. Dr. Vacirca also served on our Scientific Advisory Board from 2014 to 2020 and was a consultant for us from February 2022 through his election as a director. He has also been part of early funding for various companies including Cedar, Thyme Care, and Sherpa Health. Dr. Vacirca co-founded Odonate Therapeutics, a publicly held pharmaceutical company, in 2016 and served as a director until September 2019. Dr. Vacirca is the founder and Chairman of the Board of Directors of the New York Cancer Foundation, which provides financial assistance to patients undergoing treatment for cancer. Dr. Vacirca holds a Bachelor of Arts in Human Biology from the University at Albany and a Doctor of Medicine from St. George's University. We believe that Dr. Vacirca's extensive clinical expertise in oncology, experience in the healthcare and pharmaceutical industries, and leadership roles in cancer-focused organizations make him well-qualified to serve as a member of our board of directors.

Family Relationships

David D. Halbert, our Founder, Chairman, and Chief Executive Officer, is the brother of Jon S. Halbert, a member of our board of directors. Aside from the foregoing relationship, there are no family relationships among any of our executive officers or directors.

Composition of Our Board of Directors

Our business and affairs are managed under the direction of our board of directors. Messrs. Burns and Mohan have notified us that they each intend to resign from our board of directors effective as of immediately prior to the effectiveness of the registration statement of which this prospectus forms a part. There have been no disagreements between us and the resigning directors on any matter relating to our operations, policies, or practices. Our board of directors upon the completion of this offering will consist of 12 members, eight of whom qualify as "independent" under the listing standards of Nasdaq. Our amended and restated certificate of formation and amended and restated bylaws, each of which will become effective immediately prior to the completion of this offering, will provide that the number of directors on our board of directors will be fixed from time to time by resolution of the board of directors.

When considering whether directors have the experience, qualifications, attributes, or skills, taken as a whole, to enable our board of directors to satisfy its oversight responsibilities effectively in light of our business and structure, the board of directors focuses primarily on each person's background and experience as reflected in the information discussed in each of the directors' individual biographies set forth above. We believe that our directors provide an appropriate mix of experience and skills relevant to the size and nature of our business.

Director Independence

Prior to the completion of this offering, our board of directors undertook a review of the independence of each director who is not an employee of Caris. Based on information provided by each such director concerning his or her background, employment, and affiliations, our board of directors has affirmatively determined that each of our directors, other than David D. Halbert, Brian J. Brille, George H. Poste, and Jon S. Halbert, do not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that each of these directors is "independent" as that term is defined under the listing standards of Nasdaq. In making these determinations, our board of directors considered the current and prior relationships that each non-employee director has with our Company and all other facts and circumstances our board of directors deemed relevant in determining their independence, including the beneficial ownership of our capital stock by each non-employee director, and the transactions involving them, if any, described in the section titled "Certain Relationships and Related Party Transactions."

Lead Independent Director

David D. Halbert serves as both our Chief Executive Officer and as Chairman of our board of directors. Our board of directors has appointed Peter M. Castleman to serve as our lead independent director. As lead independent director, Mr. Castleman will preside over all meetings of the board of directors at which the Chairman of the board or directors is not present, including any executive sessions of the independent directors; call meetings or separate sessions of the independent directors; approve meeting schedules and agendas for the board of directors; approving information sent to the board of directors; acting as the liaison between the independent directors and the Chief Executive Officer and Chairman of the board of directors; and when appropriate, meeting or otherwise communicating with major shareholders or other constituencies.

Committees of the Board of Directors

Our board of directors has established an audit committee and a compensation committee, each of which will have the composition and responsibilities described below upon the completion of this offering. Members will serve on these committees until their resignation or until as otherwise determined by our board of directors. Each committee will operate under a written charter approved by our board of directors that satisfies the applicable rules of the SEC and the listing standards of Nasdaq. Upon the completion of this offering, copies of each committee's charter will be made available on our website.

We do not intend to have a standing nominating committee. In accordance with Rule 5605 of the Nasdaq rules, a majority of the independent directors may recommend a director nominee for selection by the board of directors. The board of directors believes that the independent directors can satisfactorily carry out the responsibility of properly selecting or approving director nominees without the formation of a standing nominating committee.

Audit Committee

Upon the completion of this offering, we expect our audit committee will consist of Danny Phillips, Peter M. Castleman, and Joseph E. Gilliam, with Mr. Phillips serving as Chair, and each of whom meet the requirements for independence under the listing standards of Nasdaq and SEC rules and regulations. Each member of our audit committee also meets the financial literacy and sophistication requirements of the listing standards of Nasdaq. In addition, our board of directors has determined that each member of our audit committee is an audit committee financial expert within the meaning of Item 407(d) of Regulation S-K under the Securities Act. We intend to comply with the listing requirements of Nasdaq regarding the composition of our audit committee within the transition period for newly public companies. Following the completion of this offering, our audit committee will be responsible for, among other things:

- the appointment, compensation, retention, and oversight of our independent registered public accounting firm;
- reviewing and discussing with management and the independent registered public accounting firm our annual and quarterly financial statements and related disclosures;
- reviewing and discussing with management and the independent registered public accounting firm the adequacy of our internal control over financial reporting;
- establishing procedures for employees to submit concerns anonymously about questionable accounting or audit matters;
- discussing our policies on risk assessment and risk management;
- reviewing and, if appropriate, approving related party transactions; and
- pre-approving, all audit and all permissible non-audit services to be performed by the independent registered public accounting firm.

Compensation Committee

Upon the completion of this offering, we expect our compensation committee will consist of Peter M. Castleman, Joseph E. Gilliam, and Laura I. Johansen, with Mr. Castleman serving as Chair. Following the completion of this offering, our compensation committee will be responsible for, among other things:

- reviewing, approving and determining, or making recommendations to our board of directors regarding, the compensation of our executive officers;
- recommending compensation for non-employee directors;
- administering our equity compensation plans;
- reviewing and approving, or making recommendations to our board of directors, regarding incentive compensation and equity compensation plans; and
- establishing and reviewing general policies relating to compensation and benefits of our employees.

Subject to the terms of our compensation plans, our compensation committee will have discretion to determine the amount, form, structure and implementation of compensation payable to our employees and executive officers, including, where appropriate, discretion to increase or decrease awards or to award compensation absent the attainment of performance goals and to award discretionary cash compensation outside of the parameters of our compensation plans.

Role of the Board in Risk Oversight

Our board of directors is responsible for overseeing our risk management process. Our board of directors focuses on our general risk management policies and strategy, the most significant risks facing us, and oversees the implementation of risk mitigation strategies by management. Our board of directors is also apprised of particular risk management matters in connection with its general oversight and approval of corporate matters and significant transactions.

Our board of directors does not have a standing risk management committee but intends to administer its oversight function through our audit committee, which will be responsible for overseeing enterprise risk management, including the management of financial risks and cybersecurity risks, reviewing and discussing our guidelines and policies with respect to risk assessment and risk management, and discussing with management the steps management has taken to monitor and control these exposures. In addition, the standing committees of our board of directors will address risks inherent in their respective areas of oversight. Our compensation committee will oversee risks related to our executive compensation, equity incentive plans, and other compensatory arrangements, and our will oversee risks associated with our corporate governance framework. Our board of directors intends to implement its risk oversight function both as a whole and through delegation to its committees, which will meet regularly and report back to the board of directors.

Compensation Committee Interlocks and Insider Participation

None of our executive officers currently serves, or in the past year has served, as a member of the board of directors or compensation committee (or other board committee performing equivalent functions) of any entity that has one or more of its executive officers serving on our board of directors or compensation committee.

Code of Business Conduct and Ethics

Our board of directors has adopted a written code of business conduct and ethics that will apply to all of our employees, officers, and directors, including our principal executive officer, principal financial officer, principal accounting officer or controller, and persons performing similar functions. Upon the completion of this offering, the full text of our code of business conduct and ethics will be posted on our website, www.carislifesciences.com. In addition, we intend to post on our website all disclosures that are

required by law or the Nasdaq rules concerning any amendments to, or waivers from, any provision of the code of business conduct and ethics. The information on our website is deemed not to be incorporated in this prospectus or to be part of this prospectus.

Director Compensation

For 2024, we provided a \$50,000 cash retainer, paid in quarterly installments, to certain non-employee directors for their service on our board of directors. We also provided additional cash retainers to committee chairs and members as follows: audit committee chair (\$24,000); audit committee members (\$10,000); compensation committee chair (\$17,750); compensation committee members (\$8,000); governance and nominating committee chair (\$10,000) and governance and nominating committee members (\$5,000). Dr. Minor did not receive an annual retainer but instead received a fee of \$40,000 for every meeting he attended. We also reimbursed all of our directors for their out-of-pocket expenses in connection with attending board of directors and committee meetings, and our directors are eligible to obtain our solutions on the same terms and conditions available to our employees. We did not provide compensation for 2024 to our investor designee directors, Messrs. Burns and Mohan, for their services on our board of directors. David D. Halbert and Brian J. Brille, who are employees of the Company, did not receive any additional compensation for their services on our board of directors. See the section titled “Executive Compensation—Summary Compensation Table” for the compensation received by Mr. Halbert and Mr. Brille for 2024.

The following table sets forth information regarding compensation paid to our non-employee directors for the fiscal year ended December 31, 2024.

Name	Fees Earned or Paid in Cash (\$)	Stock Awards (\$) ⁽¹⁾	Option Awards (\$) ⁽¹⁾⁽²⁾	All Other Compensation (\$)	Total (\$)
George H. Poste	55,000	— ⁽³⁾	—	107,500 ⁽⁴⁾	162,500
Jonathan Knowles	50,000	—	—	—	50,000
Nathan Burns ⁽⁵⁾	—	—	—	—	—
Peter M. Castleman	77,750	—	—	—	77,750
David Fredrickson	25,000	—	963,000	—	988,000
Joseph E. Gilliam	60,000	—	—	—	60,000
Jon S. Halbert	50,000	—	—	—	50,000
Laura I. Johansen	63,000	—	—	—	63,000
Lloyd B. Minor	160,000	—	—	—	160,000
Vijay Mohan ⁽⁵⁾	—	—	—	—	—
Danny Phillips	74,000	—	—	—	74,000
Jeffrey Vacirca	12,500	—	972,000	—	984,500

- (1) As of December 31, 2024, certain of our non-employee directors held outstanding options to purchase a number of shares of our common stock, as follows: Dr. Poste—175,000 shares; Dr. Knowles—2,500 shares; Mr. Fredrickson—75,000 shares; Mr. Gilliam—75,000 shares; Mr. Phillips—100,000 shares; and Dr. Vacirca—100,000 shares. Additionally, as of December 31, 2024, Dr. Poste held a total of 218,625 restricted stock units (“RSUs”), which RSUs fully vest only upon the occurrence of an initial public offering or a change in control of the Company.
- (2) The amounts in this column reflect the aggregate grant date fair value of stock options granted under our 2020 Plan in 2024, as calculated in accordance with FASB ASC Topic 718 (without any reduction for risk of forfeiture) as determined based on applying the assumptions used in Note 7 to our consolidated financial statements for 2024 included elsewhere in this prospectus. Options were granted to each of Mr. Fredrickson and Dr. Vacirca in connection with their election to our board of directors.
- (3) Reflects the aggregate grant date fair value of RSUs granted under the 2020 Plan in 2024, as calculated in accordance with FASB ASC 718 (without any reduction for risk of forfeiture) as determined based on applying the assumptions used in Note 7 to our consolidated financial statements for 2024 included elsewhere in this prospectus. The RSUs will fully vest only upon the occurrence of a specific performance milestone (either an initial public offering or a change in control of the Company). Assuming the maximum performance levels are achieved, the maximum value of the RSUs would be \$4,250,070. This amount may not reflect the actual value realized upon vesting or settlement, if any.

- (4) The amounts reported reflect fees received for consulting services provided to the Company and for service on the Company's Scientific Advisory Board.
- (5) Messrs. Burns and Mohan have notified us that they each intend to resign from our board of directors effective as of immediately prior to the effectiveness of the registration statement of which this prospectus forms a part.

Compensation Paid to Employee Directors for 2024

David D. Halbert is the Chairman of our board of directors, our Founder and also serves as our Chief Executive Officer. Brian J. Brille is the Vice Chairman of our board of directors and also serves as Executive Vice President. Mr. Halbert and Mr. Brille do not receive any additional compensation for their services on our board of directors. For the compensation received by Mr. Halbert and Mr. Brille for the fiscal year ended December 31, 2024 and a description of the elements of their compensation, see the section titled "Executive Compensation."

Non-Employee Director Compensation Policy

Effective January 1, 2025, our compensation committee adopted a Non-Employee Director Compensation Policy, pursuant to which our non-employee directors are compensated effective January 2025. Under the policy, each non-employee director will receive an annual cash retainer equal to \$50,000 and an annual equity retainer consisting of time-vested RSUs with a grant date fair value equal to \$300,000. The non-employee director, if any, who serves as a lead independent director will additionally receive an annual cash retainer equal to \$30,000. The committee chairs of the audit committee and compensation committee, will receive annual cash retainers equal to \$25,000 and \$18,000, respectively. The committee members will receive the following annual cash retainers: \$12,500 for service on the audit committee and \$9,000 for service on the compensation committee. A non-employee director may elect to receive any cash retainer or specified portion thereof in shares of our common stock. Upon election to our board of directors, a non-employee director will receive an initial grant of RSUs with an aggregate grant date fair value of \$500,000, which will vest ratably in three equal installments on the first three anniversaries of the grant date.

EXECUTIVE COMPENSATION

This section sets forth the compensation of our named executive officers (“NEOs”) for the fiscal year ended December 31, 2024. Our NEOs are our Chief Executive Officer and our two other most highly compensated executive officers (as determined in accordance with SEC rules) for the fiscal year ended December 31, 2024:

- David D. Halbert, Founder, Chairman, and Chief Executive Officer
- Brian J. Brille, Vice Chairman and Executive Vice President
- David Spetzler, President

As an emerging growth company, we have elected to take advantage of exemptions from various reporting requirements that are applicable to public companies that are not emerging growth companies, including reduced disclosure obligations regarding executive compensation in this prospectus and, while an emerging growth company, our future periodic reports and proxy statements, as well as exemptions from the requirements of holding nonbinding advisory votes on executive compensation.

Summary Compensation Table

The following table shows the total compensation paid to or earned by each of our NEOs for the fiscal year ended December 31, 2024.

Name and Principal Position	Year	Salary (\$)	Bonus \$(⁽¹⁾)	Stock Awards (\$)	Option Awards (\$)	All Other Compensation \$(⁽³⁾)	Total (\$)
David D. Halbert <i>Chief Executive Officer</i>	2024	750,000	1,500,000	—	—	—	2,250,000
Brian J. Brille <i>Vice Chairman and Executive Vice President</i>	2024	600,000	600,000	—	—	—	1,200,000
David Spetzler <i>President</i>	2024	600,000	600,000	— ⁽²⁾	—	13,800	1,213,800

- (1) The amounts shown in this column are the annual bonus amounts payable in respect of fiscal year 2024 to each of our NEOs. See “—Narrative to Summary Compensation Table—Annual Bonus” for a description of the terms of these bonuses.
- (2) Reflects the aggregate grant date fair value of RSUs granted under the 2020 Plan in 2024, as calculated in accordance with FASB ASC 718 (without any reduction for risk of forfeiture) as determined based on applying the assumptions used in Note 7 to our consolidated financial statements for 2024 included elsewhere in this prospectus. These RSUs will fully vest only upon the occurrence of a specific performance milestone (either an initial public offering or a change in control of the Company). Assuming the maximum performance levels are achieved, the value for the RSUs granted in 2024 would be \$2,123,820. This amount may not reflect the actual value realized upon vesting or settlement, if any.
- (3) The amounts in this column represent matching contributions to the Company’s 401(k) plan.

Narrative Disclosure to Summary Compensation Table

Base Salary

Our NEOs each receive a base salary to compensate them for services rendered to our Company. The base salary payable to each NEO is intended to provide a fixed component of compensation reflecting the executive’s skill set, experience, role, and responsibilities. For 2024, the NEOs’ annual base salaries were as follows: Mr. Halbert—\$750,000, Mr. Brille—\$600,000, and Dr. Spetzler—\$600,000.

Annual Bonus

We maintain an annual cash bonus program in which each of our NEOs participated for 2024. Each NEO’s target bonus is expressed as a percentage of his annual base salary. Bonuses for our NEOs are

determined by the compensation committee based on a rigorous assessment of Company performance. The 2024 annual bonus targets were 200% of base salary for Mr. Halbert and 100% of base salary for each of Mr. Brille and Dr. Spetzler. In February 2025, the compensation committee determined to award two separate bonuses to Mr. Halbert: one bonus of \$750,000, with respect to the first half of 2024, and another bonus of \$750,000, with respect to the second half of 2024. In certain instances, we may also provide other cash bonus opportunities to our employees, including our NEOs, to incentivize or reward work with respect to specific business goals. In 2025, the compensation committee approved a special cash bonus of \$750,000 to Mr. Halbert to be paid upon the completion of this offering. This bonus does not appear in the Summary Compensation Table for 2024 included in this prospectus but will appear in the Summary Compensation Table for 2025.

Equity and Long-Term Incentives

We believe that equity awards provide our executive officers with a strong link to our long-term performance, create an ownership culture and help to align the interests of our executive officers and our shareholders. To date, we have used stock option and RSU grants for this purpose because we believe they are effective means by which to align the long-term interests of our executive officers with those of our shareholders. The use of stock options also can provide tax and other advantages to our executive officers relative to other forms of equity compensation. We believe that our equity awards are an important retention tool for our executive officers, as well as for our other employees.

We award stock options broadly to our employees. Grants to our executive officers and other employees are made at the discretion of our compensation committee and are not made at any specific time period during a year. In 2024, all of our equity incentive awards grants were made under the terms of the Caris Life Sciences, Inc. 2020 Incentive Plan, as amended and restated (the “2020 Plan”). See “—Equity Incentive Plans” for additional information on our equity plans.

In August 2024, the compensation committee approved a grant of 360,750 RSUs to Mr. Halbert, subject to shareholder approval that was obtained in March 2025. Such RSUs were granted in March 2025 following such approval and will fully vest upon the completion of this offering. In March 2025, the compensation committee approved a stock option grant to Dr. Spetzler with respect to 750,000 shares at a strike price of \$18.60 in order to further align his interests with those of our shareholders.

Approximately 29% of the share reserve of the 2025 Plan will be utilized shortly following the effectiveness of the registration statement of which this prospectus forms a part for compensatory grants to our employees, including 445,673 RSUs to Mr. Halbert and 142,615 RSUs to each of Dr. Spetzler and Mr. Brille, our NEOs, based on an assumed initial public offering price of \$19.50 per share, which is the midpoint of the price range set forth on the cover page of this prospectus. These awards will consist of RSUs that will vest over four years, subject to the grantee’s continued employment through each vesting date.

Other Benefits

Certain of our NEOs (and their guests) may use aircraft or private travel service arrangements or programs (such as car services) that we have access to for reasonable personal use and for which they bear the cost. In addition, Mr. Brille and Dr. Spetzler have certain severance rights. For further information, on Mr. Brille and Dr. Spetzler’s severance rights, see “Narrative Disclosure to Summary Compensation Table—Employment Agreements”.

Employment Agreements

Employment Agreement with Brian Brille

We entered into an employment agreement with Mr. Brille, dated as of May 31, 2018 (the “Brille Agreement”) in connection with Mr. Brille’s “at-will” employment with us.

Pursuant to the Brille Agreement, Mr. Brille is entitled to an annual base salary of \$500,000 and eligible to receive an annual target bonus equal to 100% of his salary. For the fiscal year ended December 31, 2024, Mr. Brille’s base salary was \$600,000 and his annual bonus target was equal to 100% of his salary.

The Brille Agreement provides that Mr. Brille is eligible to participate in the Company's employee benefit plans and includes certain vesting rights applicable to his equity awards. Upon the termination of Mr. Brille's employment by the Company without cause or by Mr. Brille for good reason, Mr. Brille would be entitled to the following payments and benefits, in addition to any accrued obligations: (1) a lump sum payment equal to six months of his then-current annual base salary; (2) six months of company-paid COBRA benefits; and (3) continued eligibility for consideration for any annual bonus that would otherwise be due to him with respect to the fiscal year of termination, prorated based on the number of days during the fiscal year that he was employed and payable at the same time as the bonus would have otherwise been paid had his employment not been terminated (a "Prorata Bonus"). Upon Mr. Brille's termination of employment due to death or disability, Mr. Brille or his estate, as applicable, will be eligible to receive a Prorata Bonus, as well as any accrued obligations, and in the case of his disability, any disability benefits he is entitled to under any applicable Company plans. The Brille Agreement also includes an indefinite confidentiality covenant, as well as non-competition, customer non-solicitation and employee non-solicitation covenants that each apply for one year following Mr. Brille's termination date and a non-interference with vendors and suppliers covenant that applies for two years following his termination date.

Employment Agreement with Dr. David Spetzler

We entered into an employment agreement with Dr. Spetzler, dated as of February 1, 2010, and an amendment to this employment agreement on July 27, 2015 (as amended, the "Spetzler Agreement") in connection with Dr. Spetzler's "at-will" employment with us.

Pursuant to the Spetzler Agreement, Dr. Spetzler is entitled to an annual base salary of \$320,000 and eligible to receive an annual target bonus equal to 50% of his salary. For the fiscal year ended December 31, 2024, Dr. Spetzler's base salary was \$600,000 and his annual bonus target was equal to 100% of his salary. The Spetzler Agreement provides that Dr. Spetzler is eligible to participate in the Company's employee benefit plans and, upon Dr. Spetzler's termination of employment by the Company without cause or by Dr. Spetzler for good reason, Dr. Spetzler would be entitled to the following payments and benefits, in addition to any accrued obligations: (1) a lump sum payment equal to six months of his then-current annual base salary; (2) six months of company-paid COBRA benefits; and (3) continued eligibility for consideration for a Prorata Bonus. Upon Dr. Spetzler's termination of employment due to death or disability, Dr. Spetzler or his estate, as applicable, will be eligible to receive a Prorata Bonus, as well as any accrued obligations, and in the case of his disability, any disability benefits he is entitled to under any applicable Company plans.

Proprietary Information, Intellectual Property, Restrictive Covenant and Arbitration Agreement

Dr. Spetzler is also party to the Company's Proprietary Information, Intellectual Property, Restrictive Covenant and Arbitration Agreement (the "PIIA"). Under the PIIA, Dr. Spetzler is subject to an indefinite confidentiality covenant, as well as non-competition, customer non-solicitation, employee non-solicitation, non-interference with vendors and suppliers, and non-disparagement covenants that each apply for one year following Dr. Spetzler's termination date.

Invention Assignment Agreement

Messrs. Halbert and Brille are also each party to an Inventions Assignment Agreement with us, under which they agreed to assign their right, title, and interest to any inventions and related intellectual property that they may develop in the course of their employment, and are subject to confidentiality restrictions related thereto.

Outstanding Equity Awards at Fiscal Year 2024

The following table sets forth information regarding outstanding equity awards held by our NEOs as of December 31, 2024. The awards shown in this table were granted pursuant to the 2020 Plan.

Name	Grant Date	Option Awards ⁽¹⁾				Stock Awards			
		Number of Securities Underlying Options Exercisable (#)	Number of Securities Underlying Options Unexercisable (#)	Option Exercise Price (\$)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares of Units of Stock That Have Not Vested (\$) ⁽²⁾	Equity Incentive Plan Awards: Number of Unearned Shares, Units or Other Rights That Have Not Vested (#)	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units or Other Rights That Have Not Vested (\$) ⁽²⁾
David D. Halbert	11/15/2018	2,000,000	—	\$ 2.44	11/14/2028				
Brian J. Brille ⁽³⁾	1/15/2018	2,000,000	—	\$ 2.44	1/14/2028				
	2/27/2020	800,000	200,000	\$ 8.00	2/26/2030				
	8/11/2022	437,500 ⁽⁴⁾	—	\$16.20	8/11/2032				
David Spetzler ⁽³⁾	6/24/2015	75,000	—	\$ 2.44	6/23/2025				
	9/12/2016	1,250,000	—	\$ 2.44	9/12/2026				
	4/1/2020	800,000	200,000	\$ 8.00	4/1/2030				
	8/11/2022					300,000 ⁽⁵⁾	\$5,580,000		
	5/17/2023							42,500 ⁽⁶⁾	\$ 790,500
	8/14/2024							109,250 ⁽⁶⁾	\$2,032,050

- (1) Except where otherwise described in these footnotes, stock option awards vest over five years, with one-fifth of the shares subject to the stock option vesting annually on each of the first five anniversaries of the grant date.
- (2) The market value of the restricted stock and RSUs as of December 31, 2024 is calculated by multiplying the number of unvested shares or units outstanding under the award by \$18.60 per share, which our board of directors determined equaled the fair market value of a share of our common stock as of December 31, 2024.
- (4) The shares of common stock subject to this option are immediately issuable pursuant to Mr. Brille's right to early exercise this option. As of December 31, 2024, Mr. Brille had not early exercised this option. The shares underlying this option vested 20% on the date of the option grant with the remainder vesting in equal 20% installments over four years on the anniversaries of the grant date, subject to Mr. Brille's continued services to us on each vesting date. As of December 31, 2024, 262,500 shares of common stock underlying this option had vested, with an unvested balance of 175,000 shares.
- (5) Represents shares of restricted stock acquired pursuant to Dr. Spetzler's early exercise of an option to purchase 750,000 shares of common stock. The shares vested 20% on the date of the option grant with the remainder vesting in equal 20% installments over four years on the anniversaries of the grant date, subject to Dr. Spetzler's continued services to us on each vesting date. As of December 31, 2024, 450,000 shares of common stock underlying this option had vested, and the remaining 300,000 shares were unvested.
- (6) Represents RSUs that will vest in full in connection with this offering, subject to the RSU holders' continuous service through the completion of the initial public offering.

Policies and Practices for Granting Option Awards

The Company has not granted any option awards as a reporting company. The Company does not plan to time the disclosure of material non-public information for purposes of affecting the exercise price of the options or the value of executive compensation or grant options during the four business days prior to or the one business day following the filing of a periodic report on Form 10-Q or Form 10-K, or the filing or furnishing of a Form 8-K that discloses material non-public information.

Long-Term Incentive Plans

The purpose of our equity compensation plans is to attract, retain, and motivate our employees, officers, and directors, by providing them with the opportunity to acquire a proprietary interest in the Company and to align their interests and efforts with the long-term interests of our shareholders. In connection with this offering, our board of directors has adopted, and our shareholders have approved, the 2025 Plan. Under the 2025 Plan, we will have 15,406,122 shares of our common stock reserved for issuance (plus any shares underlying outstanding stock awards granted under our 2020 Plan that expire or are repurchased, forfeited, canceled, or withheld), as further increased as described below.

The Caris Life Science, Inc. 2012 Incentive Plan was initially adopted by our board of directors in May 2012 and, in August 2020, was amended and restated to become the 2020 Plan. The 2020 Plan was further amended and restated in connection with this offering in order to reflect certain changes applicable in light of the Company becoming a publicly traded company. Following completion of this offering, we will not make any additional grants under the 2020 Plan. Grants, including to our NEOs, have been and may continue to be made under the 2020 Plan prior to this offering. The material terms of the 2020 Plan are substantially similar to the 2025 Plan, except with respect to the number of authorized shares, as described below. For additional information on the equity awards held by our NEOs and outstanding as of December 31, 2024 see “—Outstanding Equity Awards at Fiscal Year End 2024.”

2025 Incentive Plan

Types of Awards

Our 2025 Plan provides for the grant of incentive stock options (“ISOs”), nonstatutory stock options (“NSOs”), stock appreciation rights, restricted stock awards, RSU awards, performance-based awards, and other awards.

Plan Administration

Our board of directors, or a duly authorized committee of our board of directors, may administer our 2025 Plan. Our board of directors has delegated concurrent authority to administer our 2025 Plan to the compensation committee under the terms of the compensation committee’s charter. We sometimes refer to the board of directors, or the applicable committee with the power to administer our equity incentive plans, as the administrator. The administrator may also delegate to one or more of our officers the authority to (1) designate employees (other than officers) to receive specified awards and (2) determine the number of shares subject to such awards. The administrator has the authority to determine the terms of awards, including recipients, the exercise, purchase or strike price of awards, if any, the number of shares subject to each award, the fair market value of a share of common stock, the vesting schedule applicable to the awards, together with any vesting acceleration, and the form of consideration, if any, payable upon exercise or settlement of the award and the terms of the award agreements for use under our 2025 Plan. In addition, subject to the terms of the 2025 Plan, the administrator also has the power to modify outstanding awards under our 2025 Plan, including the authority to reprice any outstanding option or stock appreciation right, cancel and re-grant any outstanding option or stock appreciation right in exchange for new stock awards, cash or other consideration, or take any other action that is treated as a repricing under generally accepted accounting principles, with the consent of any materially adversely affected participant.

Authorized Shares

The maximum number of shares of common stock that may be issued under our 2025 Plan is equal to (a) 5% of our common stock on a fully diluted basis after giving effect to this offering (including, but not

limited to, all shares in respect of the Warrant Net Exercises, the Preferred Stock Conversion, and the Notes Conversion, shares subject to outstanding awards under the 2020 Plan, and the issuance of the common stock to be sold in this offering), plus (b) the number of shares that would have returned to the share reserve of the 2020 Plan following the effectiveness of the registration statement of which this prospectus forms a part, all of which may be issued as ISOs. The 2025 Plan's share reserve will increase on January 1 of each calendar year during the term of the 2025 Plan, beginning in 2026, by a number of shares as determined by the administrator of the 2025 Plan and in consultation with the Company, provided, that such increase (if any) will be no greater than the amount by which (y) 4% of the aggregate number of outstanding shares of our common stock as of the last day of the immediately preceding fiscal year exceeds (z) the aggregate number of shares remaining available for grant under the 2025 Plan on the last day of the immediately preceding fiscal year. Shares issued under our 2025 Plan will be authorized but unissued or reacquired shares of common stock. Shares issued pursuant to awards under our 2025 Plan that we repurchase or that are forfeited, as well as shares used to pay the exercise price of an award or to satisfy the tax withholding obligations to an award, will become available for future grant under our 2025 Plan.

Eligibility

Awards under our 2025 Plan may be granted to our employees, including our officers, our non-employee directors and consultants, and the employees and consultants of our affiliates. ISOs may be granted only to our employees, including our officers, and the employees of our affiliates.

Stock Options

ISOs and NSOs are granted pursuant to stock option agreements adopted by the administrator. The administrator determines the exercise price for a stock option, within the terms and conditions of the 2025 Plan, provided that the exercise price of a stock option generally cannot be less than 100% of the fair market value of our common stock on the date of grant. Options granted under the 2025 Plan vest at the rate specified in the stock option agreement as specified in the stock option agreement by the administrator. The administrator determines the term of stock options granted under the 2025 Plan, up to a maximum of 10 years. Acceptable consideration for the purchase of common stock issued upon the exercise of a stock option will be determined by the administrator and may include (1) cash, check, bank draft, or money order, (2) a broker-assisted cashless exercise, (3) the tender of shares of common stock previously owned by the optionholder, (4) a net exercise of the option, and (5) other legal consideration approved by the administrator.

Unless the terms of an optionholder's stock option agreement provide otherwise, if an optionholder's service relationship with us, or any of our affiliates, ceases for any reason other than disability or death, the optionholder may generally exercise any vested options until the earlier of (i) the date 90 days following the termination of the optionholder's service and (ii) the expiration of the term of the option. If an optionholder's service relationship with us or any of our affiliates ceases due to disability or death, or an optionholder dies within a certain period following cessation of service, the optionholder or a beneficiary may generally exercise any vested options until the earlier of (x) 12 months following the termination and (y) the expiration of the term of the options. In the event of a termination for cause, options generally terminate immediately upon the termination of the individual for cause. In no event may an option be exercised beyond the expiration of its term.

Tax Limitations on ISOs

The aggregate fair market value, determined at the time of grant, of common stock with respect to ISOs that are exercisable for the first time by an option holder during any calendar year under all of our stock plans may not exceed \$100,000. Options or portions thereof that exceed such limit will be treated as NSOs. No ISOs may be granted to any person who, at the time of the grant, owns or is deemed to own stock possessing more than 10% of our total combined voting power or that of any of our parent or subsidiary corporations, unless (1) the option exercise price is at least 110% of the fair market value of the stock subject to the option on the date of grant and (2) the term of the ISO does not exceed five years from the date of grant.

Restricted Shares

Restricted shares may be granted to any eligible individual and made subject to such restrictions as may be determined by the administrator. Restricted shares may generally not be sold, or otherwise transferred or hypothecated, until vesting conditions are removed or expire. Except as otherwise provided in the applicable award agreement, restricted shares that remain subject to vesting conditions that have not been satisfied will not vest.

Restricted Stock Units

RSUs may be awarded to any eligible individual, typically without payment of consideration, but subject to vesting conditions based on continued employment or service or on performance criteria established by the administrator. RSUs may not typically be sold, or otherwise transferred or hypothecated, until vesting conditions are removed or expire. Stock underlying RSUs will not be issued until the RSUs have vested, and recipients of RSUs generally will have no voting or dividend rights prior to the time when vesting conditions are satisfied. Except as otherwise provided in the applicable award agreement, RSUs that remain subject to vesting conditions that have not been satisfied will not vest and will be canceled without payment to the participant therefor.

Stock Appreciation Rights

Stock appreciation rights are granted pursuant to stock appreciation right grant agreements adopted by the administrator. The administrator determines the strike price for a stock appreciation right, which generally cannot be less than 100% of the fair market value of common stock on the date of grant. Upon the exercise of a stock appreciation right, we will pay the participant an amount equal to the product of (1) the excess of the per share fair market value of common stock on the date of exercise over the strike price, multiplied by (2) the number of shares of common stock with respect to which the stock appreciation right is exercised. A stock appreciation right granted under the 2025 Plan vests at the rate specified in the stock appreciation right agreement as determined by the administrator. The administrator determines the term of stock appreciation rights granted under the 2025 Plan, up to a maximum of 10 years.

Unless the terms of a participant's stock appreciation right agreement provide otherwise, if a participant's service relationship with us or any of our affiliates ceases for any reason other than disability or death, the participant may generally exercise any vested stock appreciation right until the earlier of (i) the date 90 days following the termination of service and (ii) the expiration of the term of the stock appreciation right. If a participant's service relationship with us, or any of our affiliates, ceases due to disability or death, or a participant dies within a certain period following cessation of service, the participant or a beneficiary may generally exercise any vested stock appreciation right until the earlier of (x) 12 months following the termination and (y) the expiration of the term of the stock appreciation right. In no event may a stock appreciation right be exercised beyond the expiration of its term.

Performance Awards

Our 2025 Plan permits the grant of performance-based stock and cash awards. The compensation committee can structure such awards so that the stock or cash will be issued or paid pursuant to such award only following the achievement of certain pre-established performance goals during a designated performance period.

Changes to Capital Structure

In the event there is a specified type of change in our capital structure, such as a stock split, reverse stock split or recapitalization, appropriate adjustments will be made to (1) the class and maximum number of shares reserved for issuance under the 2025 Plan, (2) the class and maximum number of shares by which the share reserve may increase automatically each year, (3) the class and maximum number of shares that may be issued upon the exercise of ISOs, and (4) the class and number of shares and exercise price, strike price, or purchase price, if applicable, of all outstanding awards.

Corporate Transactions

Under the 2025 Plan, a corporate transaction is generally the consummation of (1) a sale or other disposition of all or substantially all of our assets, (2) a sale or other disposition of at least 50% of our outstanding securities, (3) a merger, consolidation, or similar transaction following which we are not the surviving corporation, or (4) a merger, consolidation, or similar transaction following which we are the surviving corporation but the shares of common stock outstanding immediately prior to such transaction are converted or exchanged into other property by virtue of the transaction. In the event of a corporate transaction, unless otherwise provided in a participant's award agreement or other written agreement with us or one of our affiliates or otherwise expressly provided by the administrator at the time of grant, any stock awards outstanding under the 2025 Plan may be assumed, continued, or substituted for by any surviving or acquiring corporation (or its parent company), accelerated in full or in part or canceled for or without consideration, as determined by the administrator.

Transferability

A participant may not transfer awards under our 2025 Plan other than by will, the laws of descent and distribution, or as otherwise provided under our 2025 Plan.

Plan Amendment or Termination

Our board of directors has the authority to amend, suspend, or terminate our 2025 Plan, provided that such action does not materially impair the existing rights of any participant without such participant's written consent. The 2025 Plan will continue in effect for a term of 10 years commencing on the effective date of the 2025 Plan. Certain material amendments also require the approval of our shareholders. No ISOs may be granted after the tenth anniversary of the date our board of directors adopted our 2025 Plan. No awards may be granted under our 2025 Plan while it is suspended or after it is terminated.

2025 Employee Stock Purchase Plan

In connection with this offering, our board of directors has adopted, and our shareholders have approved, the ESPP, which will be effective following the offering. The ESPP is designed to allow our eligible employees to purchase shares of our common stock, at periodic intervals, with their accumulated payroll deductions. The ESPP is intended to qualify under Section 423 of the Code. The material terms of the ESPP, as it is currently contemplated, are summarized below.

Plan Administration

Subject to the terms and conditions of the ESPP, our board of directors, or a duly authorized committee of our board of directors, may administer the ESPP. The administrator will have the authority to administer and interpret the ESPP. All decisions made by the administrator pursuant to the ESPP will be final, binding, and conclusive on us and all participants. We will bear all expenses of administering the ESPP.

Authorized Shares

The maximum number of our shares of our common stock which will be authorized for sale under the ESPP is equal to 0.85% of the fully diluted shares of our common stock after giving effect to the offering (including, but not limited to, all shares in respect of the Warrant Net Exercises, the Preferred Stock Conversion, and the Notes Conversion, shares subject to outstanding awards under the 2020 Plan, and the issuance of the common stock to be sold in this offering). The ESPP's share reserve will automatically increase on January 1 of each calendar year during the term of the ESPP, beginning in 2026, by a number of shares equal to 1% of our common stock outstanding on the last day of the immediately preceding fiscal year, unless the administrator should decide to increase the number of shares available under the ESPP by a lesser amount. The shares reserved for issuance under the ESPP may be authorized but unissued shares or reacquired shares.

Eligibility

Employees eligible to participate in the ESPP for a given offering period generally include employees who are employed by us or one of our subsidiaries on the enrollment date of an offering period. Our employees (and, if applicable, any employees of our subsidiaries) who customarily work less than five months in a calendar year or are customarily scheduled to work less than 20 hours per week will not be eligible to participate in the ESPP. Finally, an employee who owns (directly or through attribution) 5% or more of the combined voting power or value of all our classes of stock or of one of our subsidiaries will not be allowed to participate in the ESPP.

Participation

Employees will enroll under the ESPP by completing a subscription agreement designating the percentage of their compensation to be withheld as payroll deductions during the offering period (of at least 1% of their compensation but not more than 15% of their base compensation). Such payroll deductions may be expressed as either a whole number percentage or a fixed dollar amount, and the accumulated deductions will be applied to the purchase of shares on each purchase date. However, a participant may not accrue the right to purchase shares of common stock at a rate that exceeds \$25,000 in fair market value of shares of our common stock (determined at the time the option is granted) for each calendar year the option is outstanding (as determined in accordance with Section 423 of the Code).

Offering

Under the ESPP, participants are offered the option to purchase shares of our common stock at a discount during a series of successive offering periods, the duration and timing of which will be determined by the ESPP administrator. However, in no event may an offering period be longer than 27 months in length.

The option purchase price designated by the ESPP administrator will be no less than the lower of 85% of the closing trading price per share of our common stock on the first trading date of an offering period in which a participant is enrolled or 85% of the closing trading price per share on the purchase date, which will occur on the last trading day of each purchase period within an offering period.

A participant may withdraw all (but not less than all) of the payroll deductions credited to the participant's account and not yet used to exercise the participant's rights under the ESPP at any time by giving us written notice no later than 30 days prior to the end of the offering period. All of the participant's payroll deductions credited to the participant's account during an offering period will be paid to the participant as soon as reasonably practicable after receipt of notice of withdrawal. As a result, the participant's rights for the offering period will be automatically terminated, and no further payroll deductions for the purchase of shares will be made for such offering period. If a participant withdraws from an offering period, payroll deductions will not resume at the beginning of the next offering period unless the participant timely delivers to us a new subscription agreement.

A right granted under the ESPP to a participant will not be transferable other than by will or the applicable laws of descent and distribution and is exercisable during the participant's lifetime only by the participant. Except in the case of a participant's death, a right under the ESPP may not be exercised to any extent except by the participant.

Changes to Capital Structure

Upon any reclassification, recapitalization, share split, or reverse share split; any merger, combination, consolidation, or other reorganization; any split-up, spin-off, or similar extraordinary dividend distribution in respect of the common stock; or any exchange of our common stock or other securities, or any similar, unusual or extraordinary corporate transaction in respect of the common stock; then, subject to any required action by the shareholders under applicable law, the ESPP administrator will equitably and proportionately adjust (i) the ESPP share reserve, (ii) the classes and number of shares and price per share subject to outstanding rights; and (iii) the purchase price with respect to any outstanding rights. In the event of any of the above described transactions or any unusual or nonrecurring transactions or events

affecting us or our subsidiaries or our financial statements, the ESPP administrator, in its discretion, will be authorized to provide either: (i) the termination of any outstanding right in exchange for an amount of cash equal to the amount that would have been obtained upon the exercise of such right had such right been currently exercisable or the replacement of such outstanding right with other rights or property selected by the ESPP administrator in its sole discretion; (ii) to provide that outstanding rights under the ESPP will be assumed by the successor or survivor corporation or a parent or subsidiary thereof, with appropriate adjustments to the number and kind of stock and prices; (iii) to make adjustments in the number and type of shares (or other securities or property) subject to outstanding rights under the ESPP; (iv) to provide that participants' accumulated payroll deductions may be used to purchase shares prior to the next occurring purchase date, following which the participants' rights under the ongoing offering period will be terminated; or (v) to provide that all outstanding rights will terminate without being exercised.

Plan Amendment and Termination

The ESPP administrator may amend, suspend, or terminate the ESPP at any time. However, no amendment will be effective unless approved by the shareholders to the extent required by applicable laws. The ESPP will continue in effect for a term of ten years commencing on the effective date of the ESPP.

Additional Narrative Disclosure

Retirement and Employee Benefits Plans

All of our current NEOs are eligible to participate in our employee benefit plans, including our medical, dental, vision, life, and disability insurance plans, and may obtain our solutions, in each case on the same basis as all of our other employees. We maintain a 401(k) plan for employees. The 401(k) plan is intended to qualify under Section 401(k) of the Code so that contributions to the 401(k) plan by employees or by us, and the investment earnings thereon, are not taxable to the employees until withdrawn from the 401(k) plan, and so that contributions by us, if any, will be deductible by us when made. Under the 401(k) plan, we make a matching contribution of 100% of the first 3% of salary contributed and 50% on the next 2% of salary. The maximum match is 4% up to the IRS limit.

Change-in-Control Plan

Certain of our senior executives (including Mr. Brille and Dr. Spetzler but excluding Mr. Halbert) and non-employee directors participate in the Caris Life Sciences, Inc. Executive and Director Change in Control Plan (the "Change in Control Plan"), which is administered by our compensation committee. Under the Change in Control Plan, upon a "Change in Control" (as defined in the 2020 Plan) and subject to the execution of a general release of claims in our favor, all outstanding and unvested equity awards granted to a participant will automatically vest in full immediately prior to the consummation of the Change in Control. The Change in Control Plan does not contain excise tax gross-up provisions and, instead, employs a "best-net" approach under which payments and benefits are either reduced to avoid the excise tax on excess parachute payments within the meaning of Section 280G of the Code or not reduced, depending on which approach would result in the greatest after-tax amount being retained. At any time prior to a Change in Control, the Change in Control Plan may be modified, amended, or terminated by the compensation committee without notice to participants.

Clawback Policy

We have adopted a compensation recovery policy that is compliant with the listing rules of Nasdaq, as required by the Dodd-Frank Act, to be effective upon the completion of this offering.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

The following is a description of transactions since January 1, 2022 and each currently proposed transaction in which we have been or are to be a participant and:

- the amounts involved exceeded or will exceed \$120,000; and
- any of our directors, executive officers, or holders of more than 5% of our outstanding capital stock, or any immediate family member of or person sharing the household with, any of these individuals, had or will have a direct or indirect material interest.

Transactions with Our Founder

Guarantee of Office Lease

We lease approximately 30,500 square feet of office space in Irving, Texas for our principal executive offices pursuant to a lease expiring in April 2028. Our complete and timely performance of each obligation under the lease agreement is unconditionally and irrevocably guaranteed by David D. Halbert, the Chairman of our board of directors and our Chief Executive Officer, and his spouse, in their personal capacities. During each of the years ended December 31, 2024, 2023, and 2022, we recorded rental expense of \$0.9 million in connection with this guaranteed lease.

Aircraft Charter Arrangements

In September 2017, we entered into an intercompany consulting agreement (the “Caris Air Consulting Agreement”) with Halbert & Associates and Caris Air Services, LLC (“Caris Air”), each of which is affiliated with Mr. Halbert. Pursuant to the Caris Air Consulting Agreement, we have the right to use, from time to time, an aircraft owned by Halbert & Associates and operated by Caris Air. The Caris Air Consulting Agreement has an initial term of one year and automatically renews for subsequent one-year terms on an annual basis. We only use the aircraft for business purposes and reimburse Caris Air for our usage of the aircraft based on hours of use, operating costs, and related expenses.

In September 2021, we also entered into an aircraft charter lease and services agreement (the “Aircraft Agreement”) with Caris Air, pursuant to which Caris Air dry leases from us an aircraft we own and provides chartered aircraft services, as operator of the aircraft. The Aircraft Agreement has an initial term of one year and automatically renews for subsequent one-year terms on an annual basis. Under the Aircraft Agreement, we are entitled to receive payment from Caris Air for rental of our aircraft, and we reimburse Caris Air for the chartered aircraft services it provides to us. Mr. Halbert and his family members also use our aircraft from time to time for personal use and reimburse us based on hours of use, operating costs, and related expenses.

Under the foregoing aircraft charter arrangements, we generally credit amounts owed to us by Caris Air and Mr. Halbert and his family members for rental and use of our aircraft against any amounts owed by us to Caris Air for the chartered aircraft services it provides under either the Caris Air Consulting Agreement or the Aircraft Agreement. During the years ended December 31, 2024, 2023, and 2022, we paid Caris Air aggregate net amounts of \$1.6 million, \$1.8 million, and \$1.6 million, respectively, pursuant to these arrangements.

Convertible Loan Agreement with Sixth Street

In September 2023, pursuant to a convertible loan agreement, dated as of September 21, 2018, between us, as borrower, certain of our subsidiaries, as guarantors, and entities affiliated with Sixth Street, as lenders (as amended, the “Convertible Loan Agreement”), we issued an aggregate of 31,055,901 shares of our Series C preferred stock to the Sixth Street-affiliated lenders, TOP III Barnett Investments, LLC, TAO Barnett Investments, LLC, and Sixth Street Specialty Lending, Inc., at a conversion price of \$1.61 per share, in connection with the conversion of the original aggregate principal amount of \$50.0 million outstanding under the Convertible Loan Agreement. Entities affiliated with Sixth Street collectively hold more than 5% of our outstanding capital stock, and Vijay Mohan, a member of our board of directors, is a Co-Founding Partner of Sixth Street.

The loans under the Convertible Loan Agreement had an interest rate of 8.0% per annum, payable in kind (“PIK”) and accretive as additional principal. Upon the issuance of shares of our Series C preferred stock and following our September 2023 cash payment of \$3.0 million in respect of accrued and unpaid PIK interest under the Convertible Loan Agreement, all of our obligations under the Convertible Loan Agreement were deemed satisfied in full, and the Convertible Loan Agreement was irrevocably terminated.

Term Loan Refinancing with Sixth Street

In September 2018, we entered into a secured term loan agreement (the “Original Term Loan Agreement”) with Sixth Street Specialty Lending, Inc. and Barnett Debt Holdings, LLC, which provided us with an initial term loan of \$50.0 million (the “2018 Term Loan”) and a delayed term loan draw option of \$50.0 million, which we drew down in full on October 4, 2019 (the “2019 Term Loan”). In April 2020, we amended the Original Term Loan Agreement (the “Amended Term Loan Agreement”) to obtain additional term loan proceeds of \$75.0 million (the “2020 Term Loan” and collectively with the 2018 Term Loan and the 2019 Term Loan, the “Original Term Loans”).

In January 2023, we entered into the 2023 Term Loan Agreement. The net cash proceeds from the 2023 Term Loan were used to repay in full the Original Term Loans (with an aggregate principal amount of \$175.0 million), including a prepayment premium of \$5.0 million and accrued and unpaid interest of \$1.0 million. As of December 31, 2023, we have no continuing obligations associated with the Original Term Loans.

Executive Officer Promissory Notes

On September 30, 2022, David Spetzler, our President, and J. Russel Denton, our Senior Vice President, General Counsel, and Secretary, exercised their options to purchase 750,000 shares and 255,000 shares, respectively, of our common stock at an exercise price of \$16.20 per share through the tender of promissory notes, each with an interest rate of 2.93% per annum. As of December 31, 2024, no principal or interest payments had been made with respect to these promissory notes. In March 2025, the full outstanding principal amount of, and accrued and unpaid interest on, each of the promissory notes was repaid by each of the executive officers in the form of stock.

Investors’ Rights Agreement

We are party to an amended and restated investors’ rights agreement (the “Investors’ Rights Agreement”), dated as of April 1, 2025, with certain holders of our capital stock, including David D. Halbert, the Chairman of our board of directors and our Chief Executive Officer, entities affiliated with Mr. Halbert, and entities affiliated with Sixth Street, J.H. Whitney VI, L.P., and Highland Capital Management, L.P., each of which are holders of more than 5% of our outstanding capital stock and/or entities with which certain of our directors are affiliated. Under the Investors’ Rights Agreement, certain holders of our capital stock have registration rights, including the right to demand that we file a registration statement or request that their shares be covered by a registration statement that we are otherwise filing. The Investors’ Rights Agreement also provides certain of these shareholders with information and observer rights, which will terminate immediately prior to the completion of this offering, and a right of first offer with regard to certain issuances of our capital stock, which right will terminate immediately following the completion of this offering. For a description of the registration rights that will continue to apply following this offering, see the section titled “Description of Capital Stock—Registration Rights.”

Voting Agreement

We are party to an amended and restated voting agreement (the “Voting Agreement”), dated as of April 1, 2025, under which certain holders of our capital stock, including David D. Halbert, the Chairman of our board of directors and our Chief Executive Officer, entities affiliated with Mr. Halbert, and entities affiliated with Sixth Street, J.H. Whitney VI, L.P., and Highland Capital Management, L.P., each of which are holders of more than 5% of our outstanding capital stock and/or entities with which certain of our directors are affiliated, have agreed as to the manner in which they will vote their shares of our capital stock on certain matters, including with respect to the election of directors. The Voting Agreement will terminate in its entirety upon the completion of this offering.

Right of First Refusal and Co-Sale Agreement

We are party to an amended and restated right of first refusal and co-sale agreement (the “ROFR and Co-Sale Agreement”), dated as of April 1, 2025, with certain holders of our capital stock, including David D. Halbert, the Chairman of our board of directors and our Chief Executive Officer, entities affiliated with Mr. Halbert, and entities affiliated with Sixth Street, J.H. Whitney VI, L.P., and Highland Capital Management, L.P., each of which are holders of more than 5% of our outstanding capital stock and/or entities with which certain of our directors are affiliated. Under the ROFR and Co-Sale Agreement, we and certain holders of our capital stock have a right to purchase shares of our capital stock that shareholders propose to sell in certain circumstances to other parties. The ROFR and Co-Sale Agreement will terminate in its entirety immediately prior to the completion of this offering.

Consulting and Expert Advisory Agreements

We previously entered into consulting and expert advisory agreements with George H. Poste and Jonathan Knowles, members of our board of directors, pursuant to which Dr. Poste and Dr. Knowles have provided certain consulting services to us as independent contractors and have served on our Scientific Advisory Board, a team comprised of leading scientists and clinical experts who advise us on research, development, and strategy matters pertaining to precision medicine. All such agreements were terminated in December 2024. We also entered into a consulting agreement with Jeffrey Vacirca in February 2022 pursuant to which he provided consulting services to us, which agreement was terminated upon Dr. Vacirca’s election to our board of directors in November 2024. During the years ended December 31, 2024, 2023, and 2022, we paid Dr. Poste \$107,500, \$137,917, and \$147,083, respectively, for consulting services provided to us and for his service on our Scientific Advisory Board. During each of the years ended December 31, 2024, 2023, and 2022, we paid Dr. Knowles amounts not exceeding \$120,000 for consulting services provided to us and for his service on our Scientific Advisory Board. In February 2022, we granted Dr. Vacirca an option to purchase 25,000 shares of common stock at an exercise price of \$17.16 per share pursuant to his consulting agreement, and we have not paid any additional amounts under such consulting agreement. For additional information, see the section titled “Management—Director Compensation.”

Employment Agreements and Family Relationships

We are party to employment agreements with certain of our executive officers. For additional information regarding agreements with our named executive officers, see the section titled “Executive Compensation.”

In addition, Michael Halbert, our Senior Vice President, Human Resources, is the son of David D. Halbert, our Founder, Chairman, and Chief Executive Officer, and has been employed by us in various capacities since June 2011. Michael Halbert does not reside with David D. Halbert and is not one of our executive officers.

Equity Awards to Directors and Executive Officers

We have granted stock options and other equity awards to our directors and executive officers as more fully described in the sections titled “Management—Director Compensation” and “Executive Compensation.”

Director and Officer Indemnification Agreements and Insurance

Our amended and restated certificate of formation and amended and restated bylaws will provide indemnification and advancement of expenses for our directors and executive officers to the fullest extent permitted by the Texas law, subject to limited exceptions. We also have entered into separate indemnification agreements with each of our directors and executive officers, which require us to indemnify them in certain circumstances, and have purchased directors’ and officers’ liability insurance for each of our directors and executive officers. For further information, see the section titled “Description of Capital Stock—Limitations on Liability and Indemnification of Officers and Directors.”

Reserved Share Program

At our request, the underwriters have reserved up to 5% of the shares of common stock offered by this prospectus, excluding the additional shares that the underwriters have a 30-day option to purchase, for sale, at the initial public offering price, to certain individuals identified by management, including certain of our directors, officers, employees, and certain other parties related to us. See the section titled “Underwriting—Reserved Share Program.”

Policies and Procedures for Related Person Transactions

Our board of directors recognizes the fact that transactions with related persons present a heightened risk of conflicts of interests or the perception thereof. Our board of directors has adopted a written related person transaction policy setting forth the policies and procedures for the review and approval or ratification of related person transactions. This policy will cover, with certain exceptions set forth in Item 404 of Regulation S-K under the Securities Act, any transaction, arrangement, or relationship, or any series of similar transactions, arrangements, or relationships, in which we were or are to be a participant, where the amount involved exceeds \$120,000 in any fiscal year, and a related person had, has, or will have a direct or indirect material interest, including without limitation, purchases of goods or services by or from the related person or entities in which the related person has a material interest, indebtedness, guarantees of indebtedness, and employment by us of a related person. In reviewing and approving any such transactions, our audit committee will be tasked to consider all relevant facts and circumstances, including, but not limited to, whether the transaction is on terms comparable to those that could be obtained in an arm’s length transaction and the extent of the related person’s interest in the transaction. All of the transactions described in this section occurred prior to the adoption of this policy.

PRINCIPAL SHAREHOLDERS

The following table contains information about the beneficial ownership of our common stock as of May 31, 2025 (i) immediately prior to the completion of this offering and (ii) as adjusted to reflect the sale of shares of our common stock offered by this prospectus by:

- each individual or entity known by us to beneficially own more than 5% of our outstanding shares of common stock;
- each of our named executive officers;
- each of our directors; and
- all of our directors and executive officers as a group.

Our calculation of the percentage of beneficial ownership prior to and after this offering is based on 260,197,597 shares of our common stock outstanding as of May 31, 2025, after giving effect to (i) the Warrant Net Exercises, (ii) the Preferred Stock Conversion, (iii) the Notes Conversion, and (iv) the RSU Net Settlement. The number of shares of our common stock to be issued upon (i) the Preferred Stock Conversion, (ii) the 2025 Warrant Net Exercise, and (iii) the Notes Conversion, in each case, will vary based on the actual initial public offering price per share, and the exact number of shares of our common stock that will be withheld from any shareholder in connection with the RSU Net Settlement may differ based on such shareholder's personal tax rates. For further information, see the section titled "Prospectus Summary — The Offering."

Beneficial ownership and percentage ownership are determined in accordance with the rules and regulations of the SEC. Under SEC rules, a person is deemed to be a "beneficial owner" of a security if that person has or shares voting power or investment power, which includes the power to dispose of or to direct the disposition of such security. A person is also deemed to be a beneficial owner of any securities of which that person has a right to acquire beneficial ownership within 60 days. Securities that can be so acquired are deemed to be outstanding for purposes of computing such person's ownership percentage, but not for purposes of computing any other person's percentage. Under these rules, more than one person may be deemed to be a beneficial owner of the same securities and a person may be deemed to be a beneficial owner of securities as to which such person has no economic interest. Except as indicated in the footnotes to the following table or pursuant to applicable community property laws, we believe, based on information furnished to us, that each shareholder named in the table has sole voting and investment power with respect to the shares set forth opposite such shareholder's name.

The table below does not reflect any shares of our common stock that our directors, executive officers, or other shareholders may purchase in this offering, including through the reserved share program described under "Underwriting — Reserved Share Program."

For further information regarding material transactions between us and certain of our shareholders, see the section titled "Certain Relationships and Related Party Transactions."

Unless otherwise indicated in the footnotes, the address of each of the individuals named below is: c/o 750 W. John Carpenter Freeway, Suite 800, Irving, Texas 75039.

Name of Beneficial Owner	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned	
		Before this Offering	After this Offering
Greater than 5% Shareholders:			
Entities affiliated with David D. Halbert ⁽¹⁾	124,906,296	55.3%	43.7%
Entities affiliated with Sixth Street ⁽²⁾	25,638,248	11.4%	9.0%
J.H. Whitney VI L.P. ⁽³⁾	20,256,615	9.0%	7.1%
Named Executive Officers and Directors:			
David D. Halbert ⁽¹⁾	124,906,296	55.3%	43.7%
David Spetzler ⁽⁴⁾	2,987,732	1.3%	1.0%
Brian J. Brille ⁽⁵⁾	3,762,500	1.7%	1.3%
George H. Poste ⁽⁶⁾	701,219	*	*
Jonathan Knowles ⁽⁷⁾	291,750	*	*
Nathan Burns	—	—	—
David Fredrickson ⁽⁸⁾	2,500	*	*
Peter M. Castleman ⁽⁹⁾	10,373,406	4.6%	3.7%
Joseph E. Gilliam ⁽¹⁰⁾	77,500	*	*
Jon S. Halbert ⁽¹¹⁾	1,350,000	*	*
Laura I. Johansen ⁽¹²⁾	314,576	*	*
Lloyd B. Minor	—	—	—
Vijay Mohan	—	—	—
Danny Phillips ⁽¹³⁾	102,500	*	*
Jeffrey Vacirca ⁽¹⁴⁾	15,000	*	*
All executive officers and directors as a group (17 individuals) ⁽¹⁵⁾	145,312,767	62.4%	49.7%

* Represents beneficial ownership of less than 1%.

- (1) Consists of (i) 1,881,294 shares of common stock held by David D. Halbert, of which 1,662,500 shares of common stock are pledged as collateral to secure certain personal indebtedness of Mr. Halbert, (ii) 2,000,000 shares of common stock underlying options to purchase common stock held by Mr. Halbert that are currently exercisable or would be exercisable within 60 days of May 31, 2025, (iii) 101,261,532 shares of common stock held by Caris Halbert, L.P., (iv) 8,528,805 shares of common stock held by ADAPT I Ltd., (v) 8,414,427 shares of common stock held by Carisome I, L.P., (vi) 645,149 shares of common stock held by Caris Investment II Ltd., and (vii) 2,175,089 shares of common stock held by Caris Investment III Ltd. (collectively with Caris Halbert, L.P., ADAPT I Ltd., Carisome I, L.P., and Caris Investment III Ltd., the “DDH Entities”). Caris Investment Management, LLC is the general partner of each of Caris Halbert, L.P., Caris Investment II Ltd., and Caris Investment III Ltd. Two family trusts are separately the general partner of ADAPT I Ltd. and the managing general partner of Carisome I, L.P., respectively. David D. Halbert, our Founder, Chairman, and Chief Executive Officer, is the managing member of Caris Investment Management, LLC and the trustee of each of the two family trusts, and in such capacities, has voting and investment power with respect to the shares held by each of the DDH Entities.
- (2) Consists of (i) 5,776,604 shares of common stock held by Barnett Equity Holdings, LLC (“Barnett Equity Holdings”), (ii) 10,880,343 shares of common stock held by Barnett Equity Holdings II, LLC (“Barnett Equity Holdings II”), (iii) 4,052,309 shares of common stock held by TOP III Barnett Investments, LLC (“TOP III Barnett”), (iv) 3,647,078 shares of common stock held by TAO Barnett Investments, LLC (“TAO Barnett” and, together with Barnett Equity Holdings, Barnett Equity Holdings II, and TOP III Barnett, the “Barnett Holders”), and (v) 1,281,914 shares of common stock held by Sixth Street Specialty Lending, Inc. (“SLX”). TSSP Sub-Fund Holdco, LLC, a Delaware limited liability company (“Sub-Fund HoldCo”), is the sole member of each of TAO SPV GP, LLC, a Delaware limited liability company (“TAO SPV”), and Empire SPV GP, LLC, a Delaware limited liability company (“Empire SPV”). TAO SPV is the managing member of each of (i) Barnett Equity Holdings; (ii) Barnett Equity Holdings II; and (iii) TAO Barnett. Empire SPV is the managing member of TOP III Barnett.
- TSSP Holdco Management, LLC, a Delaware limited liability company (“Holdco Management”), manages Sixth Street Specialty Lending Advisers Holdings, LLC, a Delaware limited liability company (“Adviser

Holdings”). The business and affairs of Sixth Street Specialty Lending Advisers, LLC, a Delaware limited liability company (“Adviser”), are managed by Adviser Holdings, the sole member of Adviser. SLX is managed by Adviser.

Sub-Fund HoldCo is managed by its sole member, whose managing member is Alan Waxman (“Mr. Waxman”). Holdco Management is managed by a board of directors, which is currently comprised of Mr. Waxman. Mr. Waxman is the CEO and Managing Partner of Holdco Management.

Because (i) of Sub-Fund HoldCo’s relationship with the Barnett Holders, Sub-Fund HoldCo may be deemed to beneficially own the shares of common stock owned by the Barnett Holders; (ii) of the relationship between Mr. Waxman and the Barnett Holders, Mr. Waxman may be deemed to beneficially own the shares of common stock owned by the Barnett Holders; and (iii) Mr. Waxman is a member of the board of directors of Holdco Management, he may be deemed to beneficially own the shares of common stock owned by SLX. Each of Sub-Fund HoldCo and Mr. Waxman disclaims beneficial ownership of the shares of common stock except to the extent of their pecuniary interest therein.

The address for each of the foregoing entities is 2100 McKinney Avenue, Suite 1500, Dallas, Texas 75201. The principal business address for Mr. Waxman is c/o Sixth Street Partners, LLC, 1 Letterman Drive, Building B, Suite B6-100, San Francisco, California 94129.

- (3) Consists of 20,256,615 shares of common stock held by J.H. Whitney VI L.P. J.H. Whitney Equity Partners VI, L.P. is the sole general partner of J.H. Whitney VI L.P. Paul R. Vigano and Robert M. Williams, Jr., as the managing members of J.H. Whitney Equity Partners VI, L.P., share voting and investment power with respect to the shares held by J.H. Whitney VI L.P. The address for each of the foregoing entities is 212 Elm Street, Suite 1, New Canaan, Connecticut 06840.
- (4) Consists of (i) 199,490 shares of common stock held by David Spetzler, of which 150,000 shares of common stock are pledged as collateral to secure certain personal indebtedness of Dr. Spetzler, and (ii) 2,700,000 shares of common stock underlying options to purchase common stock held by Dr. Spetzler that are currently exercisable or would be exercisable within 60 days of May 31, 2025.
- (5) Consists of (i) 3,262,500 shares of common stock underlying options to purchase common stock held by Brian J. Brille that are currently exercisable or would be exercisable within 60 days of May 31, 2025, and (ii) an aggregate of 500,000 shares of common stock held by five family trusts, each of which Mr. Brille serves as trustee.
- (6) Consists of (i) 218,625 shares of common stock held by George H. Poste, (ii) 175,000 shares of common stock underlying options to purchase common stock held by Dr. Poste that are currently exercisable or would be exercisable within 60 days of May 31, 2025, and (iii) 307,594 shares of common stock held by a family trust, of which Dr. Poste serves as trustee.
- (7) Consists of (i) 291,250 shares of common stock held by Jonathan Knowles and (ii) 500 shares of common stock underlying options to purchase common stock held by Dr. Knowles that are currently exercisable or would be exercisable within 60 days of May 31, 2025.
- (8) Consists of 2,500 shares of common stock underlying options to purchase common stock held by David Fredrickson that are currently exercisable or would be exercisable within 60 days of May 31, 2025.
- (9) Consists of (i) 2,500 shares of common stock underlying options to purchase common stock held by Peter M. Castleman that are currently exercisable or would be exercisable within 60 days of May 31, 2025, (ii) 100,000 shares of common stock held by a family trust of which Mr. Castleman serves as a trustee, and (iii) 10,270,906 shares of common stock held by CLS-PF-SPE, LLC (“CLS-PF-SPE”). CLS-PF-SPE Manager, LLC is the manager of CLS-PF-SPE. Mr. Castleman is a manager of CLS-PF-SPE Manager, LLC and in such capacity has voting and investment power with respect to the shares held by CLS-PF-SPE.
- (10) Consists of 77,500 shares of common stock underlying options to purchase common stock held by Joseph E. Gilliam that are currently exercisable or would be exercisable within 60 days of May 31, 2025.
- (11) Consists of (i) 100,000 shares of common stock held by Jon S. Halbert and (ii) 1,250,000 shares of common stock held by Ke’Ohana Ventures, LLC, of which Mr. Halbert serves as the manager.
- (12) Consists of 314,576 shares of common stock held by Laura I. Johansen.
- (13) Consists of 102,500 shares of common stock underlying options to purchase common stock held by Danny Phillips that are currently exercisable or would be exercisable within 60 days of May 31, 2025.
- (14) Consists of 15,000 shares of common stock underlying options to purchase common stock held by Jeffrey Vacirca that are currently exercisable or would be exercisable within 60 days of May 31, 2025.
- (15) Consists of (i) 136,568,999 shares of common stock held by our executive officers and directors and (ii) 8,743,768 shares of common stock underlying options to purchase common stock held by our executive officers and directors that are currently exercisable or would be exercisable within 60 days of May 31, 2025.

DESCRIPTION OF CAPITAL STOCK

The following summary describes the material provisions of our capital stock and certain provisions of our amended and restated certificate of formation and our amended and restated bylaws, each of which will become effective immediately prior to the completion of this offering, and the Texas Business Organizations Code (the “TBOC”), and is qualified by reference to the amended and restated certificate of formation, the amended and restated bylaws, and the TBOC. We urge you to read our amended and restated certificate of formation and our amended and restated bylaws, which are included as exhibits to the registration statement of which this prospectus forms a part.

General

Upon the completion of this offering, our authorized capital stock will consist of 2,800,000,000 shares of common stock, par value \$0.001 per share, and 100,000,000 shares of undesignated preferred stock, par value \$0.001 per share.

As of March 31, 2025, after giving effect to (i) the Warrant Net Exercises, (ii) the Series E and F Issuance, (iii) the Preferred Stock Conversion, (iv) the issuance of the 2025 Convertible Notes and the related Notes Conversion, and (v) the RSU Net Settlement, there were 260,025,773 shares of our common stock outstanding, held of record by 524 shareholders. No shares of preferred stock will be issued and outstanding immediately after completion of this offering.

Common Stock

Holders of our common stock will be entitled to one vote for each share held of record on all matters on which shareholders are entitled to vote generally, including the election or removal of directors, unless otherwise provided in our amended and restated certificate of formation or required by a non-waivable provision of the TBOC. Subject to preferences that may be applicable to any then outstanding preferred stock, the holders of our common stock will be entitled to receive dividends, if any, as may be declared from time to time by our board of directors out of legally available funds. The holders of our common stock will not have cumulative voting rights in the election of directors. Upon our liquidation, dissolution, or winding up and after payment in full of all amounts required to be paid to creditors and to the holders of preferred stock having liquidation preferences, if any, the holders of our common stock will be entitled to receive pro rata our remaining assets available for distribution on a pro rata basis. Holders of our common stock will not be entitled to preemptive rights, and will not be subject to conversion, redemption, or sinking fund provisions. The common stock will not be subject to further calls or assessment by us. All shares of our common stock that will be outstanding at the time of the completion of the offering will be fully paid and non-assessable. The rights, powers, preferences, and privileges of holders of our common stock will be subject to those of the holders of any shares of our preferred stock we may authorize and issue in the future.

Preferred Stock

Our amended and restated certificate of formation will authorize our board of directors to establish one or more series of preferred stock (including convertible preferred stock). Unless required by law or by the TBOC, the authorized shares of preferred stock will be available for issuance without further action by our shareholders.

Our board of directors will be able to determine, with respect to any series of preferred stock, the voting powers (full or limited, or no voting powers), designations, preferences and relative, participating, optional or other special rights, and the qualifications, limitations, or restrictions thereof, of that series, including, without limitation:

- the designation of the series;
- the number of shares of the series, which our board of directors may, except where otherwise provided in the preferred stock designation, increase (but not above the total number of authorized shares of the class) or decrease (but not below the number of shares then outstanding);

- whether dividends, if any, will be cumulative or non-cumulative and the dividend rate of the series;
- the dates at which dividends, if any, will be payable;
- the redemption rights and price or prices, if any, for shares of the series;
- the terms and amounts of any sinking fund provided for the purchase or redemption of shares of the series;
- the amounts payable on shares of the series in the event of any voluntary or involuntary liquidation, dissolution, or winding-up of the affairs of the Company;
- whether the shares of the series will be convertible into shares of any other class or series, or any other security, of the Company or any other corporation and, if so, the specification of the other class or series or other security, the conversion price or prices or rate or rates, any rate adjustments, the date or dates as of which the shares will be convertible, and all other terms and conditions upon which the conversion may be made;
- restrictions on the issuance of shares of the same series or of any other class or series; and
- the voting rights, if any, of the holders of the series.

We will be able to issue a series of preferred stock that could, depending on the terms of the series, impede or discourage an acquisition attempt or other transaction that some, or a majority, of the holders of our common stock might believe to be in their best interests or in which the holders of our common stock might receive a premium for their common stock over the market price of the common stock. In addition, the issuance of preferred stock may adversely affect the rights of holders of our common stock by restricting dividends on the common stock, diluting the voting power of the common stock, or subordinating the liquidation rights of the common stock. As a result of these or other factors, the issuance of preferred stock may have an adverse impact on the market price of our common stock.

Dividends

As a Texas corporation, we are subject to certain restrictions on dividends under the TBOC. Generally, a Texas corporation may pay dividends to its shareholders out of its surplus (the excess of its assets over its liabilities and stated capital) unless the dividend would render the corporation insolvent.

The declaration, amount, and payment of any future dividends will be at the sole discretion of our board of directors, subject to restrictions under the 2023 Term Loan Agreement, and the holders of our preferred stock we may at the time have outstanding. Our board of directors may take into account general and economic conditions, our financial condition and results of operations, our available cash and current and anticipated cash needs, capital requirements, contractual, legal, tax, and regulatory restrictions and implications on the payment of dividends by us to our shareholders or by our subsidiaries to us, including restrictions under the 2023 Term Loan Agreement and other indebtedness we may incur, and such other factors as our board of directors may deem relevant. See the section titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources.”

We currently expect to retain all future earnings for use in the operation and expansion of our business and have no current plans to pay dividends. See the sections titled “Dividend Policy” and “Risk Factors—Risks Related to This Offering and Ownership of Our Common Stock—We do not intend to pay dividends for the foreseeable future. Investors in this offering may never obtain a return on their investment.”

Options and RSUs

As of March 31, 2025, we had outstanding under our 2020 Plan options to purchase an aggregate of 24,113,482 shares of our common stock, with a weighted-average exercise price of approximately \$10.18 per share.

As of March 31, 2025, we had outstanding under our 2020 Plan RSUs that may be settled once vested for an aggregate of 1,284,540 shares of our common stock. 1,048,250 of these RSUs will vest in full

in connection with this offering, subject to the RSU holders' continuous service through the date of this prospectus, and will be settled in the RSU Net Settlement, where we will issue 751,464 shares of our common stock, after withholding an aggregate of 296,786 shares of common stock to satisfy associated estimated tax withholding and remittance obligations (based on an assumed tax withholding rate of 28.3%).

Warrants

As of March 31, 2025, we had outstanding warrants to purchase an aggregate of up to 25,094,437 shares of our Series C Preferred Stock at a weighted-average exercise price of \$1.76 per share, or, at the holder's election, a split-adjusted equivalent number of shares of common stock. In connection with this offering, these warrants, which, in each case, would have expired upon the completion of this offering unless earlier exercised, will be exercised in full, on a cashless basis, for 16,053,866 shares of our Series C preferred stock, based on an assumed initial public offering price of \$19.50 per share, which is the midpoint of the price range set forth on the cover page of this prospectus. The 16,053,866 shares of our Series C preferred stock issued upon the exercise of the warrants will convert into 4,189,559 shares of our common stock in the Preferred Stock Conversion, based on an assumed initial public offering price of \$19.50 per share, which is the midpoint of the price range set forth on the cover page of this prospectus.

In April 2025, we issued warrants to purchase shares of our common stock, at an exercise price of \$0.04 per share, if exercised on or before June 30, 2025. In connection with this offering, these warrants will be exercised in full, on a cashless basis, for 844,429 shares of our common stock, based on an assumed initial public offering price of \$19.50 per share, which is the midpoint of the price range set forth on the cover page of this prospectus.

Convertible Notes

In April 2025, we issued the 2025 Convertible Notes to certain investors in aggregate principal amount of \$30.0 million. The 2025 Convertible Notes mature on January 1, 2026 and accrue interest at a rate of 8% per annum, payable quarterly in cash. Immediately prior to and in connection with the completion of this offering, the 2025 Convertible Notes plus accrued interest will convert at a conversion price equal to 70% of the initial public offering price per share, or into 2,236,331 shares of our common stock, based on an assumed initial public offering price of \$19.50 per share, which is the midpoint of the price range set forth on the cover page of this prospectus.

Registration Rights

Under the Investors' Rights Agreement, following the completion of this offering, certain holders of our common stock, including, but not limited to, certain holders of more than 5% of our outstanding capital stock and entities affiliated with certain of our officers and directors, will have certain registration rights, as set forth below. Such registration rights will terminate upon the earliest of (i) the fourth anniversary of the completion of this offering and (ii) the completion of certain liquidation events. Under the Investors' Rights Agreement, we will generally be required to pay all expenses (other than underwriting discounts and commissions and certain other expenses) related to any registration effected pursuant to the exercise of such registration rights. The Form S-1 and Form S-3 demand registration rights described below are subject to specified conditions and limitations, including the right of the underwriters to limit the number of shares of common stock included in any such registration under specified circumstances.

Form S-1 Demand Registration Rights

After the completion of this offering, the holders of up to approximately 218.1 million shares of our common stock will be entitled to certain Form S-1 demand registration rights. At any time beginning 180 days after the effective date of this registration statement, the holders of at least 20% of the shares having these rights then outstanding may request that we file a registration statement on Form S-1 to register the offer and sale of their shares. We will generally only be obligated to effect up to two such registrations. Each such request for registration must cover securities the anticipated aggregate offering price of which, net of underwriting discounts and commissions, is at least \$10.0 million. If our board of directors determines that

it would be materially detrimental to us and our shareholders to effect such a demand registration, we will have the right to defer such registration, not more than once in any 12-month period, for a period of up to 30 days.

Form S-3 Demand Registration Rights

After the completion of this offering, holders of up to approximately 218.1 million shares of our common stock will be entitled to certain Form S-3 demand registration rights. At any time when we are eligible to file a registration statement on Form S-3, the holders of at least 20% of the shares having these rights then outstanding will be able to request that we register the offer and sale of their shares on a registration statement on Form S-3 so long as the request covers securities the anticipated aggregate public offering price of which, net of any underwriting discounts or commissions, is at least \$3.0 million. These holders may make an unlimited number of requests for registration on a registration statement on Form S-3. However, we will not be required to effect a registration on Form S-3 if we have effected three such registrations within the 12-month period preceding the date of the request. If our board of directors determines that it would be materially detrimental to us and our shareholders to effect such a demand registration, we will have the right to defer such registration, not more than once in any 12-month period, for a period of up to 30 days.

Piggyback Registration Rights

After the completion of this offering, the holders of up to approximately 251.5 million shares of our common stock will be entitled to certain “piggyback” registration rights. If we propose to register shares of our common stock or other securities under the Securities Act, either for our own account or for the account of our shareholders, in connection with such offering, all holders of these shares then outstanding will be able to request that we include their shares in such registration, subject to certain marketing and other limitations. As a result, whenever we propose to file a registration statement under the Securities Act, other than with respect to (i) a registration relating solely to our stock plans, (ii) a registration relating to a corporate reorganization or other transaction covered by Rule 145 promulgated under the Securities Act, (iii) a registration on any form that does not include substantially the same information as would be required to be included in a registration statement covering the sale of the shares having registration rights, or (iv) a registration relating to the offer and sale of debt securities, the holders of these shares will be entitled to notice of the registration and have the right, subject to certain limitations, to include their shares in the registration.

Anti-Takeover Effects of Certain Provisions of Our Amended and Restated Certificate of Formation, Amended and Restated Bylaws, and Texas Law

Our amended and restated certificate of formation and amended and restated bylaws will contain and the TBOC contains provisions, which are summarized in the following paragraphs, that are intended to enhance the likelihood of continuity and stability in the composition of our board of directors. These provisions are intended to avoid costly takeover battles, reduce our vulnerability to a hostile change of control, and enhance the ability of our board of directors to maximize shareholder value in connection with any unsolicited offer to acquire us. However, these provisions may have an anti-takeover effect and may delay, deter, or prevent a merger or acquisition of us by means of a tender offer, a proxy contest, or other takeover attempt that a shareholder might consider in its best interest, including those attempts that might result in a premium over the prevailing market price for the shares of common stock held by shareholders.

Authorized but Unissued Capital Stock

Texas law does not require shareholder approval for any issuance of authorized shares. Accordingly, the authorized but unissued shares of our common stock and our preferred stock are available for future issuance without shareholder approval, subject to any limitations imposed by the listing standards of Nasdaq and restrictions under the 2023 Term Loan Agreement and other indebtedness we may incur. The listing standards of Nasdaq, which would apply if and so long as our common stock remains listed on Nasdaq, require shareholder approval of certain issuances equal to or exceeding 20% of the then outstanding voting power or then outstanding number of shares of common stock. These additional shares may be issued in the future for a variety of corporate finance transactions, acquisitions, and employee benefit plans. The

existence of authorized but unissued and unreserved common stock and preferred stock could make more difficult or discourage an attempt to obtain control of us by means of a proxy contest, tender offer, merger, or otherwise.

Business Combinations

We are subject to the affiliated business combinations provisions of Title 2, Chapter 21, Subchapter M of the TBOC (Sections 21.601 through 21.610), which provides that a Texas corporation may not engage in specified types of business combinations, including mergers, consolidations, and asset sales, with a person, or an affiliate or associate of that person, who is an “affiliated shareholder.” For purposes of this law, an “affiliated shareholder” is generally defined as the holder of 20% or more of the corporation’s voting shares, for a period of three years from the date that person became an affiliated shareholder. The law’s prohibitions do not apply if:

- the business combination or the acquisition of shares by the affiliated shareholder was approved by the board of directors of the corporation before the affiliated shareholder became an affiliated shareholder; or
- the business combination was approved by the affirmative vote of the holders of at least two-thirds of the outstanding voting shares of the corporation not beneficially owned by the affiliated shareholder, at a meeting of shareholders called for that purpose, not less than six months after the affiliated shareholder became an affiliated shareholder.

We have more than 100 shareholders and are considered to be an “issuing public corporation” for purposes of this law. The affiliated business combinations provisions of the TBOC do not apply to the following:

- the business combination of an issuing public corporation where: (a) the corporation’s original certificate of formation or bylaws contain a provision expressly electing not to be governed by the affiliated business combinations provisions of the TBOC; or (b) the corporation adopts an amendment to its certificate of formation or bylaws, by the affirmative vote of the holders, other than affiliated shareholders, of at least two-thirds of the outstanding voting shares of the corporation, expressly electing not to be governed by the affiliated business combinations provisions of the TBOC, so long as the amendment does not take effect for 18 months following the date of the vote and does not apply to a business combination with an affiliated shareholder who became affiliated on or before the effective date of the amendment;
- a business combination of an issuing public corporation with an affiliated shareholder that became an affiliated shareholder inadvertently, if the affiliated shareholder: (a) divests itself, as soon as possible, of enough shares to no longer be an affiliated shareholder; and (b) would not at any time within the three-year period preceding the announcement of the business combination have been an affiliated shareholder but for the inadvertent acquisition;
- a business combination with an affiliated shareholder who became an affiliated shareholder through a transfer of shares by will or intestacy and continuously was an affiliated shareholder until the announcement date of the business combination; and
- a business combination of a corporation with its wholly owned Texas subsidiary if the subsidiary is not an affiliate or associate of the affiliated shareholder other than by reason of the affiliated shareholder’s beneficial ownership of voting shares of the corporation.

Neither our amended and restated certificate of formation nor our amended and restated bylaws contain any provision expressly providing that we will not be subject to the affiliated business combinations provisions of the TBOC. The affiliated business combinations provisions of the TBOC may have the effect of inhibiting a non-negotiated merger or other business combination involving us, even if that event would be beneficial to our shareholders.

Vacancies

Our amended and restated certificate of formation will provide that, subject to the rights granted to one or more series of preferred stock then outstanding, and except as otherwise provided in the TBOC,

any vacancies on our board of directors may only be filled by a majority of the directors then in office, although less than a quorum, or by a sole remaining director, or by the affirmative vote of a majority of the voting power of our then-outstanding capital stock entitled to vote generally in the election of directors.

No Cumulative Voting

Under Texas law, the right to vote cumulatively does not exist unless the certificate of formation specifically authorizes cumulative voting. Our amended and restated certificate of formation will not authorize cumulative voting. Therefore, shareholders holding a majority in voting power of the shares of our capital stock entitled to vote generally in the election of directors will be able to elect all of our directors.

Special Shareholder Meetings

Our amended and restated certificate of formation will provide that special meetings of our shareholders may be called at any time only by or at the direction of the board of directors, the Chairman of the board of directors, our President, our Chief Executive Officer, or by our Secretary at the written request of holders of at least 50% of the voting power of our outstanding capital stock entitled to be voted at the special meeting. Our amended and restated bylaws will prohibit the conduct of any business at a special meeting other than procedural matters or as specified in the notice for such meeting. These provisions may have the effect of deferring, delaying, or discouraging hostile takeovers, or changes in control or management of the Company.

Requirements for Advance Notification of Director Nominations and Shareholder Proposals

Our amended and restated bylaws will establish advance notice procedures with respect to shareholder proposals and the nomination of candidates for election as directors, other than nominations made by or at the direction of the board of directors or a committee of the board of directors. In order for any matter to be “properly brought” before a meeting, a shareholder will have to comply with advance notice requirements and provide us with certain information. Generally, to be timely, a shareholder’s notice must be received at our principal executive offices not less than 90 days nor more than 120 days prior to the first anniversary date of the immediately preceding annual meeting of shareholders. Our amended and restated bylaws will also specify requirements as to the form and content of a shareholder’s notice. Our amended and restated bylaws will allow the chair of the meeting at a meeting of the shareholders to adopt rules and regulations for the conduct of meetings which may have the effect of precluding the conduct of certain business at a meeting if the rules and regulations are not followed. These provisions may also defer, delay, or discourage a potential acquiror from conducting a solicitation of proxies to elect the acquiror’s own slate of directors or otherwise attempting to influence or obtain control of us.

Shareholder Action by Written Consent

Our amended and restated certificate of formation will provide that any action required or permitted to be taken at an annual or special meeting of shareholders may be taken by written consent in lieu of a meeting of shareholders only with the unanimous written consent of all holders of shares entitled to vote on such action.

Amendment of Bylaws and Certificate of Formation Provisions

Our amended and restated certificate of formation and amended and restated bylaws will provide that our board of directors is expressly authorized to adopt, amend, alter, or repeal, in whole or in part, our amended and restated bylaws without a shareholder vote in any manner not inconsistent with the laws of the State of Texas and our amended and restated certificate of formation. The shareholders may not adopt, amend, alter, or repeal our amended and restated bylaws unless such action is approved, in addition to any other vote required by our amended and restated certificate of formation, by the affirmative vote of the holders of at least a majority of the voting power of all the then-outstanding shares of our capital stock entitled to vote thereon, voting together as a single class.

Our amended and restated certificate of formation will provide that the affirmative vote of the holders of at least a majority of the voting power of all the then-outstanding shares of our capital stock entitled to vote thereon, voting together as a single class will be required to amend or repeal any provision of our amended and restated certificate of formation.

The lack of cumulative voting will make it more difficult for shareholders to replace our board of directors as well as for another party to obtain control of us by replacing our board of directors. Because our board of directors has the power to retain and discharge our officers, these provisions could also make it more difficult for existing shareholders or another party to effect a change in management.

These provisions may have the effect of deterring hostile takeovers or delaying or preventing changes in control of our management or of us, such as a merger, reorganization, or tender offer. These provisions are intended to enhance the likelihood of continued stability in the composition of our board of directors and its policies and to discourage certain types of transactions that may involve an actual or threatened acquisition of our Company. These provisions are designed to reduce our vulnerability to an unsolicited acquisition proposal. The provisions are also intended to discourage certain tactics that may be used in proxy fights. However, such provisions could have the effect of discouraging others from making tender offers for our shares and, as a consequence, they also may inhibit fluctuations in the market price of our shares that could result from actual or rumored takeover attempts. Such provisions may also have the effect of preventing changes in management.

Exclusive Forum

Our amended and restated organizational documents will provide that the Business Court in the First Business Court Division of the State of Texas shall be the sole and exclusive forum for certain shareholder litigation matters, unless we consent in writing to the selection of an alternative forum or if the Business Court in the First Business Court Division of the State of Texas is not accepting filings or determines that it lacks jurisdiction, the exclusive forum will be the federal district courts in the Northern District of Texas or, if such federal district courts do not have jurisdiction, the State District Court in Dallas County, Texas; provided, however, that the federal district courts of the United States shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act and provided, further, that the foregoing choice of forum provision shall not apply to claims seeking to enforce any liability or duty created by the Securities Act, the Exchange Act, or any other claim for which the U.S. federal courts have exclusive jurisdiction. Although we believe this provision benefits us by providing increased consistency in the application of Texas law in the types of lawsuits to which it applies and in limiting our litigation costs, the provision may have the effect of discouraging lawsuits against our directors and officers, may result in increased costs for our shareholders to bring claims, and may limit our shareholders' ability to obtain a favorable judicial forum for disputes with us. However, it is possible that a court could rule that this provision is unenforceable or inapplicable to a particular dispute.

Conflicts of Interest

Texas law permits corporations to adopt provisions renouncing any interest or expectancy in certain opportunities that are presented to the corporation or its officers, directors, or shareholders. Our amended and restated certificate of formation will, to the maximum extent permitted from time to time by Texas law, renounce any interest or expectancy that we have in, or right to be offered an opportunity to participate in, specified business opportunities that are from time to time presented to our officers, directors, or shareholders or their respective affiliates, other than those officers, directors, shareholders, or affiliates who are our or our subsidiaries' employees. Our amended and restated certificate of formation will provide that, to the fullest extent permitted by law, no director (or his or her affiliates) who is not employed by us will have any duty to refrain from (i) engaging in a corporate opportunity in the same or similar lines of business in which we or our subsidiaries from time to time are engaged or propose to engage or (ii) otherwise competing, directly or indirectly, with us or any of our subsidiaries. In addition, to the fullest extent permitted by law, in the event that any non-employee director acquires knowledge of a potential transaction or other business opportunity that may be a corporate opportunity for himself or herself or his or her affiliates or for us or our affiliates, such person will have no duty to communicate or offer such transaction or business opportunity to us or any of our subsidiaries, and they may take any such opportunity for themselves or offer it to another person or entity. Our amended and restated certificate of formation will not renounce our interest in any business opportunity that is expressly offered to a non-employee director solely in his or her capacity as a director or officer of our Company. To the fullest extent permitted by law, no business opportunity will be deemed to be a potential corporate opportunity for us unless we would be permitted to undertake the

opportunity under our amended and restated certificate of formation, we have sufficient financial resources to undertake the opportunity, and the opportunity would be in line with our business.

Limitations on Liability and Indemnification of Officers and Directors

The TBOC authorizes corporations to limit or eliminate the personal liability of directors and officers to corporations and their shareholders for monetary damages for breaches of directors' and officers' fiduciary duties (other than breaches of such person's duty of loyalty to corporations or their shareholders), subject to certain exceptions. Our amended and restated certificate of formation will include a provision that eliminates the personal liability of directors and officers for monetary damages for any breach of fiduciary duty as a director or officer, except to the extent such exemption from liability or limitation thereof is not permitted under the TBOC. The effect of these provisions will be to eliminate, other than limited exceptions, the rights of us and our shareholders, through shareholders' derivative suits on our behalf, to recover monetary damages from a director for breach of fiduciary duty as a director or officer, including breaches resulting from grossly negligent behavior. However, exculpation will not apply to any director or officer if such person has acted in bad faith, engaged in intentional misconduct, knowingly violated the law, authorized illegal dividends or redemptions, derived an improper benefit from his or her actions as a director or officer, or engaged in an act or omission for which the liability of the director or officer is expressly provided by an applicable statute.

Our amended and restated bylaws will provide generally that we must indemnify and advance expenses to our directors and officers to the fullest extent authorized by the TBOC. We also have entered into separate indemnification agreements with each of our directors and executive officers and will be expressly authorized to carry directors' and officers' liability insurance providing indemnification for our directors, officers, and certain employees for some liabilities. We believe that these indemnification and advancement provisions and insurance will be useful to attract and retain qualified directors and officers.

These limitation of liability, indemnification, and advancement provisions may discourage shareholders from bringing a lawsuit against directors for breach of their fiduciary duty. These provisions also may have the effect of reducing the likelihood of derivative litigation against directors and officers, even though such an action, if successful, might otherwise benefit us and our shareholders. In addition, your investment may be adversely affected to the extent we pay the costs of settlement and damage awards against directors and officers pursuant to these indemnification provisions.

There is currently no pending material litigation or proceeding involving any of our directors, officers, or employees for which indemnification is sought.

Dissenters' Rights of Appraisal and Payment

Under the TBOC, with certain exceptions, our shareholders will have appraisal rights in connection with a merger, a sale of all or substantially all of our assets, an interest exchange, or a conversion. Pursuant to the TBOC, shareholders who properly request and perfect appraisal rights in connection with such merger, sale of all or substantially all of our assets, interest exchange, or conversion will have the right to receive payment of the fair value of their shares as agreed to between the shareholder and us or, if unable to reach agreement, as determined by the State District Court in Dallas County, Texas.

Shareholders' Derivative Actions

Under the TBOC, any of our shareholders may bring an action in our name to procure a judgment in our favor, also known as a derivative action, provided that the shareholder bringing the action (i) is a holder of our shares at the time of the transaction to which the action relates or such shareholder became a shareholder by operation of law from a person that was a shareholder at the time of the transaction to which the action relates and (ii) fairly and adequately represents the interests of the Company in enforcing the right of the Company.

Listing

We have applied to list our common stock on the Nasdaq Global Select Market ("Nasdaq") under the symbol "CAI."

Transfer Agent and Registrar

The transfer agent and registrar for our common stock will be Equiniti Trust Company, LLC. The transfer agent and registrar's address is 48 Wall Street, 22nd Floor, New York, New York 10005.

SHARES ELIGIBLE FOR FUTURE SALE

Before this offering, there has not been a public market for shares of our common stock. As described below, only a limited number of shares will be available for sale shortly after this offering due to contractual and legal restrictions on resale. Nevertheless, future sales of substantial amounts of shares of our common stock, including shares issued upon the exercise of outstanding options, in the public market following this offering or the possibility of these sales occurring, could cause the prevailing market price for our common stock to fall or impair our ability to raise equity capital in the future.

Following this offering, we will have outstanding 283,555,185 shares of our common stock, based on the number of shares of common stock outstanding as of March 31, 2025, after giving effect to (i) the Warrant Net Exercises, (ii) the Series E and F Issuance, (iii) the Preferred Stock Conversion, (iv) the issuance of the 2025 Convertible Notes and the related Notes Conversion, and (v) the RSU Net Settlement. This includes 23,529,412 shares of common stock that we are selling in this offering, which shares may be resold in the public market immediately unless purchased by our affiliates and assumes no additional exercise of outstanding options other than as described elsewhere in this prospectus.

The remaining 260,025,773 shares of common stock that are not sold in this offering will be “restricted securities,” as that term is defined in Rule 144 under the Securities Act (“Rule 144”). These restricted securities are eligible for public sale only if they are registered under the Securities Act or if they qualify for an exemption from registration under Rule 144 or Rule 701 under the Securities Act (“Rule 701”), which are summarized below.

As a result of the lock-up agreements and market stand-off provisions described below, and subject to the provisions of Rule 144 or Rule 701, the earliest these restricted securities may generally be available for sale in the public market is as follows:

Earliest Date Available for Sale in the Public Market	Number of Shares of Common Stock
December 1, 2025, which is 10 trading days prior to the commencement of the quarterly blackout period under our insider trading policy that begins on December 15, 2025.	All remaining shares held by our shareholders not previously eligible for sale, subject to volume limitations applicable to “affiliates” under Rule 144 as described below.

In addition, pursuant to certain exceptions to the lock-up agreements, shares of our common stock will be eligible for sale in the open market during the Lock-Up Period (as defined below) in sell-to-cover transactions in order to satisfy tax withholding obligations.

We expect each sell-to-cover transaction to extend over a multi-day period based on trading volumes. Because the purpose of sell-to-cover transactions is to generate proceeds sufficient to satisfy tax withholding obligations or remittance payments due as a result of the vesting or settlement of RSUs or the exercise of options that are expiring during the Lock-Up Period, the exact number of shares sold will depend on the sale prices of the common stock in such transactions and our shareholders’ personal tax rates. In addition, if net settlement transactions occur on or prior to the dates set forth above, the number of shares of common stock to be sold in each sell-to-cover transaction will be reduced proportionally.

Rule 144

In general, under Rule 144 as currently in effect, a person who has beneficially owned shares of our restricted common stock for at least six months would be entitled to sell their securities provided that such person is not deemed to have been one of our affiliates at the time of, or at any time during the 90 days preceding, a sale, and we are subject to the periodic reporting requirements of the Exchange Act, for at least 90 days before the sale. In addition, under Rule 144, any person who is not an affiliate of ours and has held their shares of common stock for at least one year, including the holding period of any prior owner other than one of our affiliates, would be entitled to sell an unlimited number of shares of common stock immediately upon the completion of this offering without regard to whether current public information about us is available. Persons who have beneficially owned shares of our restricted common stock for at least six months but who are our affiliates at the time of, or any time during the 90 days preceding, a sale, would

be subject to additional restrictions, by which such person would be entitled to sell within any three-month period only a number of securities that does not exceed the greater of either of the following:

- 1% of the number of shares of our capital stock then outstanding, which will equal 2,835,552 shares immediately after the completion of this offering, assuming no exercise by the underwriters of their option to purchase additional shares of common stock; or
- the average weekly trading volume of our common stock during the four calendar weeks preceding the filing of a notice on Form 144 with respect to such sale,

provided, in each case, that we have been subject to the Exchange Act periodic reporting requirements for at least 90 days before the sale. Such sales both by affiliates and by non-affiliates must also comply with the manner of sale, current public information and notice provisions of Rule 144.

Rule 701

Any of our service providers who purchased shares under a written compensatory plan or contract prior to this offering may be entitled to rely on the resale provisions of Rule 701. Rule 701, as currently in effect, permits resales of shares, including by affiliates, in reliance upon Rule 144 but without compliance with certain restrictions, including the holding period requirement, of Rule 144. Rule 701 further provides that non-affiliates may sell such shares in reliance on Rule 144 without having to comply with the public information, volume limitation or notice provisions of Rule 144. All holders of Rule 701 shares are required to wait until 90 days after the date of this prospectus before selling such shares if such resale is pursuant to Rule 701. All Rule 701 shares are, however, subject to lock-up agreements and will only become eligible for sale upon the expiration of these lock-up agreements.

Lock-Up Agreements and Market Stand-off Provisions

In connection with this offering, our executive officers, directors, and other existing security holders have agreed not to sell or transfer any common stock or securities convertible into, exchangeable for, exercisable for, or repayable with common stock, for 180 days after the date of this prospectus (the “Lock-Up Period”) without first (a) providing prior written notice to BofA Securities, Inc., J.P. Morgan Securities LLC, and Goldman Sachs & Co. LLC and (b) obtaining the written consent of BofA Securities, Inc. and either J.P. Morgan Securities LLC or Goldman Sachs & Co. LLC, who may release the securities subject to any of the lock-up agreements in whole or in part at any time. Specifically, we and these other persons have agreed, with certain limited exceptions, not to directly or indirectly

- offer, pledge, sell, or contract to sell any common stock,
- sell any option or contract to purchase any common stock,
- purchase any option or contract to sell any common stock,
- grant any option, right, or warrant for the sale of any common stock,
- lend or otherwise dispose of or transfer any common stock,
- request or demand that we file or make a confidential submission of a registration statement related to the common stock, or
- enter into any hedging, swap, loan, or any other agreement or transaction that transfers, in whole or in part, the economic consequence of ownership of any common stock whether any such hedging, swap, loan, or transaction is to be settled by delivery of shares or other securities, in cash or otherwise.

If any director, officer or shareholder is granted an early release from its obligations under any lock-up restrictions with respect to our securities in an aggregate amount in excess of one percent of our outstanding common stock, then every other lock-up party automatically will be granted an equivalent early release from its obligations under their respective lock-up agreement on a pro rata basis, provided that such release shall not apply (i) if it is effected solely to permit a transfer not for consideration and the transferee has agreed in writing to be bound by the same terms described in the lock-up agreement to the extent and for the duration that such terms remain in effect at the time of the transfer and (ii) in the event of

an underwritten public offering, except with respect to the lock-up party's participation in such underwritten public offering, provided that the lock-up party shall be offered the opportunity to participate in such underwritten public offering in accordance with, and subject to, the terms of any rights agreement (including the Investors' Rights Agreement).

The agreements of our executive officers, directors, and other existing security holders do not apply to transfers, sales or dispositions: (i) as a bona fide gift or gifts, including, without limitation, to a charitable organization or educational institution, or for bona fide estate planning purposes; (ii) by will, testamentary document or intestate succession to the legal representative, heir, beneficiary or a member of the immediate family of the lock-up party; (iii) (A) if the lock-up party is an individual, by operation of law, such as pursuant to a qualified domestic order, divorce settlement, divorce decree or separation agreement or (B) if the lock-up party is a corporation, partnership, limited liability company or other business entity, pursuant to a merger or reorganization with or into another entity; (iv) pursuant to an order of a court or regulatory agency having jurisdiction over the lock-up party; (v) to any corporation, partnership, limited liability company or other entity controlled or managed, or under common control or management by, the lock-up party or the immediate family of the lock-up party; (vi) to a nominee or custodian of a person or entity to whom a disposition or transfer would be permissible under clauses (i) through (v) above; (vii) to any immediate family member or any trust, partnership, limited liability company or other entity for the direct or indirect benefit of the lock-up party or one or more immediate family members of the lock-up party, or if the lock-up party is a trust, to a trust or beneficiary of the trust or to the estate of a beneficiary of such trust; (viii) if the lock-up party is a corporation, partnership, limited liability company, trust or other business entity, (A) to another corporation, partnership, limited liability company, trust or other business entity that is an affiliate (as defined in Rule 405 promulgated under the Securities Act) of the lock-up party, or to any investment fund or other entity controlling, controlled by, managing or managed by or under common control or common investment management with the lock-up party or affiliates of the lock-up party (including, for the avoidance of doubt, pursuant to a merger, acquisition or reorganization of the lock-up party and, further, where the lock-up party is a partnership, to its general partner or a successor partnership or fund, or any other funds managed by such partnership), or (B) as part of a distribution to partners (general or limited partners), limited liability company members, shareholders or other equityholders of the lock-up party or holders of similar equity interests in the lock-up party; (ix) to us upon the lock-up party's death, disability or termination of employment or other service relationship with us; provided that such common stock were issued to the lock-up party pursuant to an agreement or equity award granted pursuant to an employee benefit plan, option, warrant or other right disclosed in this prospectus; (x) pursuant to a bona fide third-party tender offer, or in connection with a merger, consolidation or other similar transaction, that is approved by the our board of directors, made to all holders of our capital stock involving a change of control of us (including, without limitation, entering into any lock-up, voting or similar agreement pursuant to which the lock-up party may agree to transfer, sell, tender or otherwise dispose of lock-up securities in connection with such transaction, or vote any common stock or other securities in favor of any such transaction); provided that, in the event that such tender offer, merger, consolidation or other transaction is not completed, the lock-up party's lock-up securities shall remain subject to the restrictions set forth in this lock-up agreement; provided further that any shares of common stock not transferred, sold or otherwise disposed of in such third-party tender offer, merger, consolidation, or other similar transaction shall remain subject to the restrictions set forth in this lock-up agreement (for purposes hereof, "change of control" shall mean the transfer, sale or other disposition (whether by tender offer, merger, consolidation or other similar transaction), in one transaction or a series of related transactions, to a person or group of affiliated persons, of shares of our capital stock if, after such transaction or transactions, such person or group of affiliated persons would hold more than 50% of our outstanding voting securities (or the surviving entity)); to us in connection with the conversion or exercise of any of our outstanding equity securities into shares of common stock or in connection with the reclassification or exchange of shares of common stock, in each case as described and as contemplated in this prospectus; provided that any shares of common stock received by the lock-up party upon such conversion, exercise, reclassification, reclassification or exchange shall be subject to the restrictions set forth in this lock-up agreement; (xii) in connection with the vesting or settlement of restricted stock units or the exercise of options or other rights to purchase the shares of common stock (including, in each case, by way of "net" or "cashless" exercise), including (A) any transfer, sale or other disposition to us for the payment of exercise price, tax withholdings or remittance payments due as a result of the vesting, settlement or exercise of such restricted stock units, options or rights,

and (B) any transfer, sale or other disposition of shares of common stock necessary to generate such amount of cash needed to satisfy tax withholdings or remittance payments due as a result of the vesting or settlement of restricted stock units or the exercise of options, which are expiring during the lock-up period, to purchase the shares of common stock; provided that, in each case, any such restricted stock units and options to purchase shares of common stock were granted under an equity incentive plan or other equity award plan that is described in this prospectus and provided, further, that, in each case, any such shares of common stock received by the lock-up party upon such vesting, settlement or exercise that are not so transferred, sold or otherwise disposed shall be subject to the restrictions set forth in this lock-up agreement; (xiii) up to 15% of the lock-up party's lock-up securities, to any third-party pledgee in a bona fide transaction as collateral to secure obligations pursuant to lending or other arrangements between such third parties (or their affiliates or designees) and the lock-up party and/or its affiliates or any similar arrangement relating to a financing arrangement for the benefit of the lock-up party and/or its affiliates; and upon foreclosure of any such lending or other arrangements; (xiv) if the lock-up party is not our officer or director, in connection with a sale of the lock-up party's shares of common stock acquired (A) from the underwriters in this offering or (B) on the open market or in other transactions following this offering; or (xv) to the underwriters pursuant to the underwriting agreement.

In addition, notwithstanding the restrictions in the lock-up agreement, the lock-up party may make any demand or requests for, exercise any right with respect to, or take any action in preparation of, the registration by us under the Securities Act of the lock-up party's lock-up securities or other securities; *provided that* (i) no public filing with the Securities and Exchange Commission or any other public announcement may be made during the lock-up period in relation to such registration, (ii) the representatives must have received prior written notice from us and/or the lock-up party of a confidential submission of a registration statement with the Securities and Exchange Commission during the lock-up period at least five (5) business days prior to such submission and (iii) no lock-up securities or other securities of us may be sold, distributed or exchanged during the lock-up period. Notwithstanding the foregoing, the lock-up party also may establish trading plans pursuant to Rule 10b5-1 under the Exchange Act for the transfer, sale or other disposition of lock-up securities, *provided that* (1) none of the securities subject to such plan may be transferred, sold or otherwise disposed of until after the expiration of the lock-up period and (2) no public announcement, report or filing under the Exchange Act, or any other public filing, report or announcement, shall be voluntarily made regarding the establishment of such plan during the lock-up period, and if any such filing, report or announcement shall be legally required during the lock-up period, such filing, report or announcement shall clearly indicate therein that none of the securities subject to such plan may be transferred, sold, or otherwise disposed pursuant to such plan until after the expiration of the lock-up period.

In the event that (i) at least 150 days have elapsed since the date of this prospectus and (ii) the end of the restricted period would fall during one of our quarterly blackout periods during which trading by certain of our employees in our securities would not be permitted under our insider trading policy then in effect (a "Blackout Period"), or within 10 trading days prior to such Blackout Period the restricted period shall end on the date that is the later of (a) 10 trading days prior to the commencement of a Blackout Period and (b) the 150th day after the date of this prospectus. For a further description of these lock-up agreements, please see "Underwriting."

In addition to the restrictions contained in the lock-up agreements described above, the holders of outstanding equity awards and holders of outstanding common stock issued pursuant to the vesting, settlement, or exercise of equity awards, are subject to market stand-off provisions in agreements with us that impose similar restrictions on the ability of such security holders to offer, sell, or transfer our equity securities during the Lock-Up Period.

Registration Rights

After the completion of this offering, the holders of up to approximately 251.5 million shares of our common stock will, subject to the lock-up agreements referred to above, be entitled to certain rights with respect to the registration of such shares under the Securities Act. The registration of these shares of our common stock under the Securities Act would result in these shares becoming eligible for sale in the public market without restriction under the Securities Act immediately upon the effectiveness of such registration, subject to the Rule 144 limitations applicable to affiliates. See the section titled "Description of Capital Stock—Registration Rights" for a description of these registration rights.

Equity Plans

We intend to file a registration statement on Form S-8 under the Securities Act covering all of the shares of our common stock subject to options outstanding or reserved for issuance under our equity plans. We expect to file this registration statement as soon as practicable after the completion of this offering. This registration statement will become effective immediately upon filing, and shares covered by this registration statement will thereupon be eligible for sale in the public markets, subject to vesting restrictions, the lock-up agreements described above and Rule 144 limitations applicable to affiliates. For a more complete discussion of our stock plans, see the section titled “Executive Compensation—Long-Term Incentive Plans.”

MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES TO NON-U.S. HOLDERS OF OUR COMMON STOCK

The following discussion is a summary of the material U.S. federal income tax consequences to Non-U.S. Holders (as defined below) of the purchase, ownership, and disposition of our common stock issued pursuant to this offering, but does not purport to be a complete analysis of all potential tax effects. The effects of other U.S. federal tax laws, such as estate and gift tax laws, and any applicable state, local, or non-U.S. tax laws are not discussed. This discussion is based on the U.S. Internal Revenue Code of 1986, as amended (the “Code”), Treasury Regulations promulgated thereunder, judicial decisions, and published rulings and administrative pronouncements of the U.S. Internal Revenue Service (the “IRS”), in each case in effect as of the date hereof. These authorities may change or be subject to differing interpretations. Any such change or differing interpretation may be applied retroactively in a manner that could adversely affect a Non-U.S. Holder. We have not sought and will not seek any rulings from the IRS regarding the matters discussed below. There can be no assurance the IRS or a court will not take a contrary position to that discussed below regarding the tax consequences of the purchase, ownership, and disposition of our common stock.

This discussion is limited to Non-U.S. Holders that hold our common stock as a “capital asset” within the meaning of Section 1221 of the Code (generally, property held for investment). This discussion does not address all U.S. federal income tax consequences relevant to a Non-U.S. Holder’s particular circumstances, including the impact of the Medicare contribution tax on net investment income, the special tax accounting rules under Section 451(b) of the Code, and the alternative minimum tax. In addition, it does not address consequences relevant to Non-U.S. Holders subject to special rules, including, without limitation:

- U.S. expatriates and former citizens or long-term residents of the United States;
- persons holding our common stock as part of a hedge, straddle, or other risk reduction strategy or as part of a conversion transaction or other integrated investment;
- banks, insurance companies, and other financial institutions;
- brokers, dealers, or traders in securities;
- “controlled foreign corporations,” “passive foreign investment companies,” and corporations that accumulate earnings to avoid U.S. federal income tax;
- partnerships or other entities or arrangements treated as partnerships for U.S. federal income tax purposes (and investors therein);
- tax-exempt organizations or governmental organizations;
- persons deemed to sell our common stock under the constructive sale provisions of the Code;
- persons who hold or receive our common stock pursuant to the exercise of any employee stock option or otherwise as compensation;
- tax-qualified retirement plans; and
- “qualified foreign pension funds” as defined in Section 897(l)(2) of the Code and entities all of the interests of which are held by qualified foreign pension funds.

If an entity treated as a partnership for U.S. federal income tax purposes holds our common stock, the tax treatment of a partner in the partnership will depend on the status of the partner, the activities of the partnership, and certain determinations made at the partner level. Accordingly, partnerships holding our common stock and the partners in such partnerships should consult their tax advisors regarding the U.S. federal income tax consequences to them.

THIS DISCUSSION IS FOR INFORMATIONAL PURPOSES ONLY AND IS NOT TAX ADVICE. INVESTORS SHOULD CONSULT THEIR TAX ADVISORS WITH RESPECT TO THE APPLICATION OF THE U.S. FEDERAL INCOME TAX LAWS TO THEIR PARTICULAR SITUATIONS AS WELL AS ANY TAX CONSEQUENCES OF THE PURCHASE, OWNERSHIP, AND DISPOSITION OF OUR COMMON STOCK ARISING UNDER THE U.S. FEDERAL ESTATE

OR GIFT TAX LAWS OR UNDER THE LAWS OF ANY STATE, LOCAL, OR NON-U.S. TAXING JURISDICTION OR UNDER ANY APPLICABLE INCOME TAX TREATY.

Definition of a Non-U.S. Holder

For purposes of this discussion, a “Non-U.S. Holder” is any beneficial owner of our common stock that is neither a “U.S. person” nor an entity treated as a partnership for U.S. federal income tax purposes. A U.S. person is any person that, for U.S. federal income tax purposes, is or is treated as any of the following:

- an individual who is a citizen or resident of the United States;
- a corporation created or organized under the laws of the United States, any state thereof, or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or
- a trust that (1) is subject to the primary supervision of a U.S. court and the control of one or more “United States persons” (within the meaning of Section 7701(a)(30) of the Code), or (2) has a valid election in effect to be treated as a United States person for U.S. federal income tax purposes.

Distributions

As described in the section titled “Dividend Policy,” we do not anticipate declaring or paying dividends to holders of our common stock in the foreseeable future. However, if we do make distributions of cash or property on our common stock, such distributions will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Amounts not treated as dividends for U.S. federal income tax purposes will constitute a return of capital and first be applied against and reduce a Non-U.S. Holder’s adjusted tax basis in its common stock, but not below zero. Any excess will be treated as capital gain and will be treated as described below under “—Sale or Other Taxable Disposition.”

Subject to the discussions below on effectively connected income, backup withholding, and FATCA (as defined below) dividends paid to a Non-U.S. Holder will be subject to U.S. federal withholding tax at a rate of 30% of the gross amount of the dividends (or such lower rate specified by an applicable income tax treaty, provided the Non-U.S. Holder furnishes a valid IRS Form W-8BEN or W-8BEN-E (or other applicable documentation) certifying qualification for the lower treaty rate). A Non-U.S. Holder that does not timely furnish the required documentation, but that qualifies for a reduced treaty rate, may obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS. Non-U.S. Holders should consult their tax advisors regarding their entitlement to benefits under any applicable income tax treaty.

If dividends paid to a Non-U.S. Holder are effectively connected with the Non-U.S. Holder’s conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, the Non-U.S. Holder maintains a permanent establishment in the United States to which such dividends are attributable), the Non-U.S. Holder will be exempt from the U.S. federal withholding tax described above. To claim the exemption, the Non-U.S. Holder must furnish to the applicable withholding agent a valid IRS Form W-8ECI, certifying that the dividends are effectively connected with the Non-U.S. Holder’s conduct of a trade or business within the United States.

Any such effectively connected dividends will be subject to U.S. federal income tax on a net income basis at the regular rates in the same manner as if the Non-U.S. Holder were a resident of the United States. A Non-U.S. Holder that is a corporation also may be subject to a branch profits tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on such effectively connected dividends, as adjusted for certain items. Non-U.S. Holders should consult their tax advisors regarding any applicable tax treaties that may provide for different rules.

Sale or Other Taxable Disposition

Subject to the discussions below on backup withholding and FATCA (as defined below), a Non-U.S. Holder will not be subject to U.S. federal income tax on any gain realized upon the sale or other taxable disposition of our common stock unless:

- the gain is effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, the Non-U.S. Holder maintains a permanent establishment in the United States to which such gain is attributable);
- the Non-U.S. Holder is a nonresident alien individual present in the United States for 183 days or more during the taxable year of the disposition and certain other requirements are met; or
- our common stock constitutes a U.S. real property interest ("USRPI") by reason of our status as a U.S. real property holding corporation ("USRPHC") for U.S. federal income tax purposes at any time within the shorter of the five-year period preceding the disposition or the Non-U.S. Holder's holding period for our common stock.

Gain described in the first bullet point above generally will be subject to U.S. federal income tax on a net income basis at the regular rates in the same manner as if the Non-U.S. Holder were a resident of the United States. A Non-U.S. Holder that is a corporation also may be subject to a branch profits tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on such effectively connected gain, as adjusted for certain items.

A Non-U.S. Holder described in the second bullet point above will be subject to U.S. federal income tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on gain realized upon the sale or other taxable disposition of our common stock, which may be offset by U.S. source capital losses of the Non-U.S. Holder (even though the individual is not considered a resident of the United States), provided the Non-U.S. Holder has timely filed U.S. federal income tax returns with respect to such losses.

With respect to the third bullet point above, we believe we currently are not, and do not anticipate becoming, a USRPHC. Because the determination of whether we are a USRPHC depends, however, on the fair market value of our USRPIs relative to the fair market value of our non-U.S. real property interests and our other business assets, there can be no assurance we currently are not a USRPHC or will not become one in the future. Even if we are or were to become a USRPHC, gain arising from the sale or other taxable disposition of our common stock by a Non-U.S. Holder will not be subject to U.S. federal income tax if our common stock is "regularly traded," as defined by applicable Treasury Regulations, on an established securities market and such Non-U.S. Holder owned, actually and constructively, 5% or less of our common stock throughout the shorter of the five-year period ending on the date of the sale or other taxable disposition or the Non-U.S. Holder's holding period.

Non-U.S. Holders should consult their tax advisors regarding potentially applicable income tax treaties that may provide for different rules.

Information Reporting and Backup Withholding

Payments of dividends on our common stock will not be subject to backup withholding, provided the applicable withholding agent does not have actual knowledge or reason to know the holder is a United States person and the holder either certifies its non-U.S. status, such as by furnishing a valid IRS Form W-8BEN, W-8BEN-E, or W-8ECI, or otherwise establishes an exemption. However, information returns are required to be filed with the IRS in connection with any distributions on our common stock paid to the Non-U.S. Holder, regardless of whether such distributions constitute dividends or whether any tax was actually withheld. In addition, proceeds of the sale or other taxable disposition of our common stock within the United States or conducted through certain U.S.-related brokers generally will not be subject to backup withholding or information reporting if the applicable withholding agent receives the certification described above and does not have actual knowledge or reason to know that such holder is a United States person or the holder otherwise establishes an exemption. Proceeds of a disposition of our common stock conducted through a non-U.S. office of a non-U.S. broker generally will not be subject to backup withholding or information reporting.

Copies of information returns that are filed with the IRS may also be made available under the provisions of an applicable treaty or agreement to the tax authorities of the country in which the Non-U.S. Holder resides or is established.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules may be allowed as a refund or a credit against a Non-U.S. Holder's U.S. federal income tax liability, provided the required information is timely furnished to the IRS.

Additional Withholding Tax on Payments Made to Foreign Accounts

Withholding taxes may be imposed under Sections 1471 to 1474 of the Code (such Sections commonly referred to as the Foreign Account Tax Compliance Act, or "FATCA") on certain types of payments made to non-U.S. financial institutions and certain other non-U.S. entities. Specifically, a 30% withholding tax may be imposed on dividends on, or (subject to the proposed Treasury Regulations discussed below) gross proceeds from the sale or other disposition of, our common stock paid to a "foreign financial institution" or a "non-financial foreign entity" (each as defined in the Code), unless (1) the foreign financial institution undertakes certain diligence and reporting obligations, (2) the non-financial foreign entity either certifies it does not have any "substantial United States owners" (as defined in the Code) or furnishes identifying information regarding each substantial United States owner, or (3) the foreign financial institution or non-financial foreign entity otherwise qualifies for an exemption from these rules. If the payee is a foreign financial institution and is subject to the diligence and reporting requirements in clause (1) above, it must enter into an agreement with the U.S. Department of the Treasury requiring, among other things, that it undertake to identify accounts held by certain "specified United States persons" or "United States owned foreign entities" (each as defined in the Code), annually report certain information about such accounts, and withhold 30% on certain payments to non-compliant foreign financial institutions and certain other account holders. Foreign financial institutions located in jurisdictions that have an intergovernmental agreement with the United States governing FATCA may be subject to different rules.

Under the applicable Treasury Regulations and administrative guidance, withholding under FATCA generally applies to payments of dividends on our common stock. While withholding under FATCA would have applied also to payments of gross proceeds from the sale or other disposition of stock on or after January 1, 2019, proposed Treasury Regulations eliminate FATCA withholding on payments of gross proceeds entirely. Taxpayers generally may rely on these proposed Treasury Regulations until final Treasury Regulations are issued.

Prospective investors should consult their tax advisors regarding the potential application of withholding under FATCA to their investment in our common stock.

UNDERWRITING

BofA Securities, Inc., J.P. Morgan Securities LLC, Goldman Sachs & Co. LLC, and Citigroup Global Markets Inc. are acting as representatives of each of the underwriters named below. Subject to the terms and conditions set forth in an underwriting agreement among us and the underwriters, we have agreed to sell to the underwriters, and each of the underwriters has agreed, severally and not jointly, to purchase from us, the number of shares of common stock set forth opposite its name below.

Underwriter	Number of Shares
BofA Securities, Inc.	
J.P. Morgan Securities LLC	
Goldman Sachs & Co. LLC	
Citigroup Global Markets Inc.	
TD Securities (USA) LLC	
Evercore Group L.L.C.	
Guggenheim Securities, LLC	
BTIG, LLC	
Nomura Securities International, Inc.	
WR Securities, LLC	
Total	<u>23,529,412</u>

Subject to the terms and conditions set forth in the underwriting agreement, the underwriters have agreed, severally and not jointly, to purchase all of the shares of common stock sold under the underwriting agreement if any of these shares are purchased. If an underwriter defaults, the underwriting agreement provides that the purchase commitments of the nondefaulting underwriters may be increased or the underwriting agreement may be terminated.

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act, or to contribute to payments the underwriters may be required to make in respect of those liabilities.

The underwriters are offering the shares, subject to prior sale, when, as and if issued to and accepted by them, subject to approval of legal matters by their counsel, including the validity of the shares, and other conditions contained in the underwriting agreement, such as the receipt by the underwriters of officer's certificates and legal opinions. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part. Sales of shares made outside of the United States may be made by affiliates of the underwriters.

Commissions and Discounts

The representatives have advised us that the underwriters propose initially to offer the shares to the public at the public offering price set forth on the cover page of this prospectus and to dealers at that price less a concession not in excess of \$ per share. After the initial offering, the public offering price, concession, or any other term of the offering may be changed.

The following table shows the public offering price, underwriting discount, and proceeds before expenses to us. The information assumes either no exercise or full exercise by the underwriters of their option to purchase additional shares of common stock.

	Per Share	Without Option	With Option
Public offering price	\$	\$	\$
Underwriting discount	\$	\$	\$
Proceeds, before expenses, to us	\$	\$	\$

The expenses of the offering, not including the underwriting discount, are estimated at \$7,400,000 and are payable by us. We have also agreed to reimburse the underwriters for their expenses relating to clearance of this offering with the Financial Industry Regulatory Authority in an amount up to \$40,000.

We have engaged NCMG LLC to provide certain financial advisory services in connection with this offering. The underwriters have agreed to reimburse us for such financial advisory services provided by NCMG LLC in connection with this offering.

Option to Purchase Additional Shares

We have granted an option to the underwriters, exercisable for 30 days after the date of this prospectus, to purchase up to 3,529,411 additional shares of common stock at the public offering price, less the underwriting discount. If the underwriters exercise this option, each will be obligated, subject to conditions contained in the underwriting agreement, to purchase a number of additional shares of common stock proportionate to that underwriter's initial amount reflected in the above table.

No Sales of Similar Securities

We, our executive officers and directors and our other existing security holders have agreed not to sell or transfer any common stock or securities convertible into, exchangeable for, exercisable for, or repayable with common stock, for 180 days (the "Lock-Up Period") after the date of this prospectus without (a) providing prior written notice to BofA Securities, Inc., J.P. Morgan Securities LLC, and Goldman Sachs & Co. LLC and (b) first obtaining the written consent of BofA Securities, Inc. and either J.P. Morgan Securities LLC or Goldman Sachs & Co. LLC, who may release the securities subject to any of the lock-up agreements in whole or in part at any time. Specifically, we and these other persons have agreed, with certain limited exceptions, not to directly or indirectly

- offer, pledge, sell, or contract to sell any common stock,
- sell any option or contract to purchase any common stock,
- purchase any option or contract to sell any common stock,
- grant any option, right, or warrant for the sale of any common stock,
- lend or otherwise dispose of or transfer any common stock,
- request or demand that we file or make a confidential submission of a registration statement related to the common stock, or
- enter into any hedging, swap, loan, or any other agreement or transaction that transfers, in whole or in part, the economic consequence of ownership of any common stock whether any such hedging, swap, loan or transaction is to be settled by delivery of shares or other securities, in cash or otherwise.

This lock-up provision applies to common stock and to securities convertible into or exchangeable or exercisable for or repayable with common stock (collectively, the "lock-up securities"). It also applies to common stock owned now or acquired later by the person executing the agreement or for which the person executing the agreement later acquires the power of disposition.

The agreements of our executive officers, directors, and other existing security holders do not apply to transfers, sales or dispositions: (i) as a bona fide gift or gifts, including, without limitation, to a charitable organization or educational institution, or for bona fide estate planning purposes; (ii) by will, testamentary document or intestate succession to the legal representative, heir, beneficiary or a member of the immediate family of the lock-up party; (iii) (A) if the lock-up party is an individual, by operation of law, such as pursuant to a qualified domestic order, divorce settlement, divorce decree or separation agreement or (B) if the lock-up party is a corporation, partnership, limited liability company or other business entity, pursuant to a merger or reorganization with or into another entity; (iv) pursuant to an order of a court or regulatory agency having jurisdiction over the lock-up party; (v) to any corporation, partnership, limited liability company or other entity controlled or managed, or under common control or management by, the lock-up party or the immediate family of the lock-up party; (vi) to a nominee or custodian of a person or entity to

whom a disposition or transfer would be permissible under clauses (i) through (v) above; (vii) to any immediate family member or any trust, partnership, limited liability company or other entity for the direct or indirect benefit of the lock-up party or one or more immediate family members of the lock-up party, or if the lock-up party is a trust, to a trustor or beneficiary of the trust or to the estate of a beneficiary of such trust; (viii) if the lock-up party is a corporation, partnership, limited liability company, trust or other business entity, (A) to another corporation, partnership, limited liability company, trust or other business entity that is an affiliate (as defined in Rule 405 promulgated under the Securities Act) of the lock-up party, or to any investment fund or other entity controlling, controlled by, managing or managed by or under common control or common investment management with the lock-up party or affiliates of the lock-up party (including, for the avoidance of doubt, pursuant to a merger, acquisition or reorganization of the lock-up party and, further, where the lock-up party is a partnership, to its general partner or a successor partnership or fund, or any other funds managed by such partnership), or (B) as part of a distribution to partners (general or limited partners), limited liability company members, shareholders or other equityholders of the lock-up party or holders of similar equity interests in the lock-up party; (ix) to us upon the lock-up party's death, disability or termination of employment or other service relationship with us; provided that such common stock were issued to the lock-up party pursuant to an agreement or equity award granted pursuant to an employee benefit plan, option, warrant or other right disclosed in this prospectus; (x) pursuant to a bona fide third-party tender offer, or in connection with a merger, consolidation or other similar transaction, that is approved by the our board of directors, made to all holders of our capital stock involving a change of control of us (including, without limitation, entering into any lock-up, voting or similar agreement pursuant to which the lock-up party may agree to transfer, sell, tender or otherwise dispose of lock-up securities in connection with such transaction, or vote any common stock or other securities in favor of any such transaction); provided that, in the event that such tender offer, merger, consolidation or other transaction is not completed, the lock-up party's lock-up securities shall remain subject to the restrictions set forth in this lock-up agreement; provided further that any shares of common stock not transferred, sold or otherwise disposed of in such third-party tender offer, merger, consolidation, or other similar transaction shall remain subject to the restrictions set forth in this lock-up agreement (for purposes hereof, "change of control" shall mean the transfer, sale or other disposition (whether by tender offer, merger, consolidation or other similar transaction), in one transaction or a series of related transactions, to a person or group of affiliated persons, of shares of our capital stock if, after such transaction or transactions, such person or group of affiliated persons would hold more than 50% of our outstanding voting securities (or the surviving entity)); to us in connection with the conversion or exercise of any of our outstanding equity securities into shares of common stock or in connection with the reclassification or exchange of shares of common stock, in each case as described and as contemplated in this prospectus; provided that any shares of common stock received by the lock-up party upon such conversion, exercise, reclassification, reclassification or exchange shall be subject to the restrictions set forth in this lock-up agreement; (xii) in connection with the vesting or settlement of restricted stock units or the exercise of options or other rights to purchase the shares of common stock (including, in each case, by way of "net" or "cashless" exercise), including (A) any transfer, sale or other disposition to us for the payment of exercise price, tax withholdings or remittance payments due as a result of the vesting, settlement or exercise of such restricted stock units, options or rights, and (B) any transfer, sale or other disposition of shares of common stock necessary to generate such amount of cash needed to satisfy tax withholdings or remittance payments due as a result of the vesting or settlement of restricted stock units or the exercise of options, which are expiring during the lock-up period, to purchase the shares of common stock; provided that, in each case, any such restricted stock units and options to purchase shares of common stock were granted under an equity incentive plan or other equity award plan that is described in this prospectus and provided, further, that, in each case, any such shares of common stock received by the lock-up party upon such vesting, settlement or exercise that are not so transferred, sold or otherwise disposed shall be subject to the restrictions set forth in this lock-up agreement; (xiii) up to 15% of the lock-up party's lock-up securities, to any third-party pledgee in a bona fide transaction as collateral to secure obligations pursuant to lending or other arrangements between such third parties (or their affiliates or designees) and the lock-up party and/or its affiliates or any similar arrangement relating to a financing arrangement for the benefit of the lock-up party and/or its affiliates; and upon foreclosure of any such lending or other arrangements; (xiv) if the lock-up party is not our officer or director, in connection with a sale of the lock-up party's shares of common stock acquired (A) from the underwriters in this offering or (B) on the open market or in other transactions following this offering; or (xv) to the underwriters pursuant to the underwriting agreement.

In addition, notwithstanding the restrictions in the lock-up agreement, the lock-up party may make any demand or requests for, exercise any right with respect to, or take any action in preparation of, the registration by us under the Securities Act of the lock-up party's lock-up securities or other securities; *provided* that (i) no public filing with the Securities and Exchange Commission or any other public announcement may be made during the lock-up period in relation to such registration, (ii) the representatives must have received prior written notice from us and/or the lock-up party of a confidential submission of a registration statement with the Securities and Exchange Commission during the lock-up period at least five (5) business days prior to such submission and (iii) no lock-up securities or other securities of us may be sold, distributed or exchanged during the lock-up period. Notwithstanding the foregoing, the lock-up party also may establish trading plans pursuant to Rule 10b5-1 under the Exchange Act for the transfer, sale or other disposition of lock-up securities, *provided* that (1) none of the securities subject to such plan may be transferred, sold or otherwise disposed of until after the expiration of the lock-up period and (2) no public announcement, report or filing under the Exchange Act, or any other public filing, report or announcement, shall be voluntarily made regarding the establishment of such plan during the lock-up period, and if any such filing, report or announcement shall be legally required during the lock-up period, such filing, report or announcement shall clearly indicate therein that none of the securities subject to such plan may be transferred, sold, or otherwise disposed pursuant to such plan until after the expiration of the lock-up period.

If any director, officer, or shareholder of the Company is granted an early release from its obligations under any lock-up restrictions with respect to our securities in an aggregate amount in excess of one percent of our outstanding common stock, then every other lock-up party automatically will be granted an equivalent early release from its obligations under their respective lock-up agreement on a pro rata basis, provided that such release shall not apply (i) if it is effected solely to permit a transfer not for consideration and the transferee has agreed in writing to be bound by the same terms described in the lock-up agreement to the extent and for the duration that such terms remain in effect at the time of the transfer and (ii) in the event of an underwritten public offering, except with respect to the lock-up party's participation in such underwritten public offering, provided that the lock-up party shall be offered the opportunity to participate in such underwritten public offering in accordance with, and subject to, the terms of any rights agreement (including the Investors' Rights Agreement).

In the event that (i) at least 150 days have elapsed since the date of this prospectus and (ii) the end of the restricted period would fall during one of our quarterly blackout periods during which trading by certain of our employees in our securities would not be permitted under our insider trading policy then in effect (a "Blackout Period"), or within 10 trading days prior to such Blackout Period the restricted period shall end on the date that is the later of (a) 10 trading days prior to the commencement of a Blackout Period and (b) the 150th day after the date of this prospectus.

Listing

We have applied to list our common stock on the Nasdaq under the symbol "CAI." In order to meet the requirements for listing on that exchange, the underwriters have undertaken to sell a minimum number of shares to a minimum number of beneficial owners as required by that exchange.

Before this offering, there has been no public market for our common stock. The initial public offering price will be determined through negotiations between us and the representatives. In addition to prevailing market conditions, the factors to be considered in determining the initial public offering price are:

- the valuation multiples of publicly traded companies that the representatives believe to be comparable to us,
- our financial information,
- the history of, and the prospects for, our company and the industry in which we compete,
- an assessment of our management, its past and present operations, and the prospects for, and timing of, our future revenues,
- the present state of our development, and
- the above factors in relation to market values and various valuation measures of other companies engaged in activities similar to ours.

An active trading market for the shares may not develop. It is also possible that after the offering the shares will not trade in the public market at or above the initial public offering price.

The underwriters do not expect to sell more than 5% of the shares in the aggregate to accounts over which they exercise discretionary authority.

Price Stabilization, Short Positions and Penalty Bids

Until the distribution of the shares is completed, SEC rules may limit underwriters and selling group members from bidding for and purchasing our common stock. However, the representatives may engage in transactions that stabilize the price of the common stock, such as bids or purchases to peg, fix, or maintain that price.

In connection with the offering, the underwriters may purchase and sell our common stock in the open market. These transactions may include short sales, purchases on the open market to cover positions created by short sales and stabilizing transactions. Short sales involve the sale by the underwriters of a greater number of shares than they are required to purchase in the offering. “Covered” short sales are sales made in an amount not greater than the underwriters’ option to purchase additional shares of common stock described above. The underwriters may close out any covered short position by either exercising their option to purchase additional shares of common stock or purchasing shares of common stock in the open market. In determining the source of shares to close out the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the option granted to them. “Naked” short sales are sales in excess of such option. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of our common stock in the open market after pricing that could adversely affect investors who purchase in the offering. Stabilizing transactions consist of various bids for or purchases of shares of common stock made by the underwriters in the open market prior to the completion of the offering.

The underwriters may also impose a penalty bid. This occurs when a particular underwriter repays to the underwriters a portion of the underwriting discount received by it because the representatives have repurchased shares sold by or for the account of such underwriter in stabilizing or short covering transactions.

Similar to other purchase transactions, the underwriters’ purchases to cover the syndicate short sales may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of our common stock. As a result, the price of our common stock may be higher than the price that might otherwise exist in the open market. The underwriters may conduct these transactions on Nasdaq, in the over-the-counter market or otherwise.

Neither we nor any of the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our common stock. In addition, neither we nor any of the underwriters make any representation that the representatives will engage in these transactions or that these transactions, once commenced, will not be discontinued without notice.

Electronic Distribution

In connection with the offering, certain of the underwriters or securities dealers may distribute prospectuses by electronic means, such as e-mail.

Other Relationships

Some of the underwriters and their affiliates have engaged in, and may in the future engage in, investment banking and other commercial dealings in the ordinary course of business with us or our affiliates. They have received, or may in the future receive, customary fees and commissions for these transactions.

In addition, in the ordinary course of their business activities, the underwriters and their affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related

derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers. Such investments and securities activities may involve securities and/or instruments of ours or our affiliates. The underwriters and their affiliates may also make investment recommendations and/or publish or express independent research views in respect of such securities or financial instruments and may hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

“Wolfe | Nomura Alliance” is the marketing name used by Wolfe Research Securities and Nomura Securities International, Inc. in connection with certain equity capital markets activities conducted jointly by the firms. Both Nomura Securities International, Inc. and WR Securities, LLC are serving as underwriters in the offering described herein. In addition, WR Securities, LLC and certain of its affiliates may provide sales support services, investor feedback, investor education, and/or other independent equity research services in connection with this offering.

Reserved Share Program

At our request, the underwriters have reserved up to 5% of the shares of common stock offered by this prospectus, excluding the additional shares that the underwriters have a 30-day option to purchase, for sale, at the initial public offering price, to certain individuals identified by management. If these persons purchase reserved shares it will reduce the number of shares of common stock available for sale to the general public. Any reserved shares of common stock that are not so purchased will be offered by the underwriters to the general public on the same terms as the other shares of common stock offered by this prospectus.

Management will provide the list of potential participants to Merrill Lynch, Pierce, Fenner & Smith Incorporated, which is an affiliate of BofA Securities, Inc., a participating underwriter, and which will administer the reserved shares program. At this time, no indications of interest will be taken. Once the preliminary prospectus has been filed, an invitation package will be made available or sent to each person identified by management, which will include the preliminary prospectus and other reserved share program documentation. An invitation to participate in the reserved share program does not guarantee that the participant will receive an allocation of common stock. Accordingly, we cannot provide any assurance that any director, officer, employee, or participant will receive an invitation or an allocation in the reserved share program. If a potential participant is interested in participating, that participant will be required to complete the required documentation and will be required to return such documentation to the program administrator. The program administrator will not accept funds from any participant until after the registration statement for this offering is declared effective, this offering is priced, and the participants are notified of their final allocation and given an opportunity to confirm that they wish to purchase the shares of common stock allocated to them. After the registration statement has been declared effective and this offering is priced, we and the program administrator will prepare a final approved list of allocations. The program administrator will notify each participant who has been allocated reserved shares of the number of shares of common stock that have been allocated to them and the total purchase price due upon confirmation of their participation. Thereafter, participants will be required to wire or transfer their funds to the program administrator. The shares of common stock under the reserved shares program will be allocated following pricing and settle in the same manner as the shares sold to the general public. If purchased by directors, officers or employees, these shares will be subject to a 180-day lock-up restriction described in this prospectus. If any potential participants purchase reserved shares, it will reduce the number of shares available for sale to the general public. Any reserved shares that are not so purchased will be offered by the underwriters to the general public on the same terms as the other shares of common stock offered hereby.

Participation in Our Initial Public Offering

Neuberger Berman has indicated an interest in purchasing up to \$75.0 million of shares of our common stock being offered in this offering at the initial public offering price and on the same terms as the other purchasers in this offering. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters could determine to sell more, fewer, or no shares to Neuberger Berman, and Neuberger Berman could determine to purchase more, fewer, or no shares in this offering. The

underwriters will receive the same underwriting discounts and commissions on any of our shares of common stock purchased by Neuberger Berman as they will from any other shares of common stock sold to the public in this offering.

European Economic Area

In relation to each Member State of the European Economic Area (each a “Relevant State”), no shares have been offered or will be offered pursuant to the public in that Relevant State prior to the publication of a prospectus in relation to the shares which has been approved by the competent authority in that Relevant State or, where appropriate, approved in another Relevant State and notified to the competent authority in that Relevant State, all in accordance with the Prospectus Regulation, except that offers of shares may be made to the public in that Relevant State at any time under the following exemptions under the Prospectus Regulation:

- a. to any legal entity which is a qualified investor as defined under the Prospectus Regulation;
- b. to fewer than 150 natural or legal persons (other than qualified investors as defined under the Prospectus Regulation), subject to obtaining the prior consent for any such offer; or
- c. in any other circumstances falling within Article 1(4) of the Prospectus Regulation,

provided that no such offer of shares shall require the Company or any underwriter to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the Prospectus Regulation.

Each person in a Relevant State who initially acquires any shares or to whom any offer is made will be deemed to have represented, acknowledged, and agreed to and with the Company and the underwriters that it is a qualified investor within the meaning of the Prospectus Regulation.

In the case of any shares being offered to a financial intermediary as that term is used in Article 5(1) of the Prospectus Regulation, each such financial intermediary will be deemed to have represented, acknowledged and agreed that the shares acquired by it in the offer have not been acquired on a non-discretionary basis on behalf of, nor have they been acquired with a view to their offer or resale to, persons in circumstances which may give rise to an offer to the public other than their offer or resale in a Relevant State to qualified investors, in circumstances in which the prior consent of the underwriters has been obtained to each such proposed offer or resale.

The Company, the underwriters and their affiliates will rely upon the truth and accuracy of the foregoing representations, acknowledgements, and agreements.

For the purposes of this provision, the expression an “offer to the public” in relation to any shares in any Relevant State means the communication in any form and by any means of sufficient information on the terms of the offer and any shares to be offered so as to enable an investor to decide to purchase or subscribe for any shares, and the expression “Prospectus Regulation” means Regulation (EU) 2017/1129.

The above selling restriction is in addition to any other selling restrictions set out below.

Notice to Prospective Investors in the United Kingdom

In relation to the United Kingdom (“UK”), no shares have been offered or will be offered pursuant to the public in the UK prior to the publication of a prospectus in relation to the shares which has been approved by the Financial Conduct Authority in the UK in accordance with the UK Prospectus Regulation and the FSMA, except that offers of shares may be made to the public in the UK at any time under the following exemptions under the UK Prospectus Regulation and the FSMA:

- a. to any legal entity which is a qualified investor as defined under the UK Prospectus Regulation;
- b. to fewer than 150 natural or legal persons (other than qualified investors as defined under the UK Prospectus Regulation), subject to obtaining the prior consent for any such offer; or
- c. at any time in other circumstances falling within section 86 of the FSMA,

provided that no such offer of shares shall require the Company or any underwriter to publish a prospectus pursuant to Section 85 of the FSMA or Article 3 of the UK Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the UK Prospectus Regulation.

Each person in the UK who initially acquires any shares or to whom any offer is made will be deemed to have represented, acknowledged, and agreed to and with the Company and the underwriters that it is a qualified investor within the meaning of the UK Prospectus Regulation.

In the case of any shares being offered to a financial intermediary as that term is used in Article 5(1) of the UK Prospectus Regulation, each such financial intermediary will be deemed to have represented, acknowledged and agreed that the shares acquired by it in the offer have not been acquired on a non-discretionary basis on behalf of, nor have they been acquired with a view to their offer or resale to, persons in circumstances which may give rise to an offer to the public other than their offer or resale in the UK to qualified investors, in circumstances in which the prior consent of the underwriters has been obtained to each such proposed offer or resale.

The Company, the underwriters and their affiliates will rely upon the truth and accuracy of the foregoing representations, acknowledgements, and agreements.

For the purposes of this provision, the expression an “offer to the public” in relation to any shares in the UK means the communication in any form and by any means of sufficient information on the terms of the offer and any shares to be offered so as to enable an investor to decide to purchase or subscribe for any shares, the expression “UK Prospectus Regulation” means Regulation (EU) 2017/1129 as it forms part of domestic law by virtue of the European Union (Withdrawal) Act 2018, and the expression “FSMA” means the Financial Services and Markets Act 2000.

This document is for distribution only to persons who (i) have professional experience in matters relating to investments and who qualify as investment professionals within the meaning of Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005 (as amended, the “Financial Promotion Order”), (ii) are persons falling within Article 49(2)(a) to (d) (“high net worth companies, unincorporated associations etc.”) of the Financial Promotion Order, (iii) are outside the United Kingdom, or (iv) are persons to whom an invitation or inducement to engage in investment activity (within the meaning of Section 21 of the FSMA) in connection with the issue or sale of any securities may otherwise lawfully be communicated or caused to be communicated (all such persons together being referred to as “relevant persons”). This document is directed only at relevant persons and must not be acted on or relied on by persons who are not relevant persons. Any investment or investment activity to which this document relates is available only to relevant persons and will be engaged in only with relevant persons.

Notice to Prospective Investors in Switzerland

The shares may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange (“SIX”) or on any other stock exchange or regulated trading facility in Switzerland. This document has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this document nor any other offering or marketing material relating to the shares or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering or marketing material relating to the offering, the Company, the shares have been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with, and the offer of shares will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA (FINMA), and the offer of shares has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes (“CISA”). The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of shares.

Notice to Prospective Investors in the Dubai International Financial Centre

This prospectus relates to an Exempt Offer in accordance with the Offered Securities Rules of the Dubai Financial Services Authority (“DFSA”). This prospectus is intended for distribution only to persons

of a type specified in the Offered Securities Rules of the DFSA. It must not be delivered to, or relied on by, any other person. The DFSA has no responsibility for reviewing or verifying any documents in connection with Exempt Offers. The DFSA has not approved this prospectus nor taken steps to verify the information set forth herein and has no responsibility for the prospectus. The shares to which this prospectus relates may be illiquid and/or subject to restrictions on their resale. Prospective purchasers of the shares offered should conduct their own due diligence on the shares. If you do not understand the contents of this prospectus you should consult an authorized financial advisor.

Notice to Prospective Investors in Australia

No placement document, prospectus, product disclosure statement or other disclosure document has been lodged with the Australian Securities and Investments Commission (“ASIC”), in relation to the offering. This prospectus does not constitute a prospectus, product disclosure statement or other disclosure document under the Corporations Act 2001 (the “Corporations Act”), and does not purport to include the information required for a prospectus, product disclosure statement or other disclosure document under the Corporations Act.

Any offer in Australia of the shares may only be made to persons (the “Exempt Investors”) who are “sophisticated investors” (within the meaning of section 708(8) of the Corporations Act), “professional investors” (within the meaning of section 708(11) of the Corporations Act) or otherwise pursuant to one or more exemptions contained in section 708 of the Corporations Act so that it is lawful to offer the shares without disclosure to investors under Chapter 6D of the Corporations Act.

The shares applied for by Exempt Investors in Australia must not be offered for sale in Australia in the period of 12 months after the date of allotment under the offering, except in circumstances where disclosure to investors under Chapter 6D of the Corporations Act would not be required pursuant to an exemption under section 708 of the Corporations Act or otherwise or where the offer is pursuant to a disclosure document which complies with Chapter 6D of the Corporations Act. Any person acquiring shares must observe such Australian on-sale restrictions.

This prospectus contains general information only and does not take account of the investment objectives, financial situation, or particular needs of any particular person. It does not contain any securities recommendations or financial product advice. Before making an investment decision, investors need to consider whether the information in this prospectus is appropriate to their needs, objectives, and circumstances, and, if necessary, seek expert advice on those matters.

Notice to Prospective Investors in Hong Kong

The shares have not been offered or sold and will not be offered or sold in Hong Kong, by means of any document, other than (a) to “professional investors” as defined in the Securities and Futures Ordinance (Cap. 571) of Hong Kong and any rules made under that Ordinance; or (b) in other circumstances which do not result in the document being a “prospectus” as defined in the Companies Ordinance (Cap. 32) of Hong Kong or which do not constitute an offer to the public within the meaning of that Ordinance. No advertisement, invitation or document relating to the shares has been or may be issued or has been or may be in the possession of any person for the purposes of issue, whether in Hong Kong or elsewhere, which is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to the shares which are or are intended to be disposed of only to persons outside Hong Kong or only to “professional investors” as defined in the Securities and Futures Ordinance and any rules made under that Ordinance.

Notice to Prospective Investors in Japan

The shares have not been and will not be registered under the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948, as amended) and, accordingly, will not be offered or sold, directly or indirectly, in Japan, or for the benefit of any Japanese Person or to others for re-offering or resale, directly or indirectly, in Japan or to any Japanese Person, except in compliance with all applicable laws, regulations and ministerial guidelines promulgated by relevant Japanese governmental or regulatory authorities in

effect at the relevant time. For the purposes of this paragraph, “Japanese Person” shall mean any person resident in Japan, including any corporation or other entity organized under the laws of Japan.

Notice to Prospective Investors in Singapore

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, the shares were not offered or sold or caused to be made the subject of an invitation for subscription or purchase, and this prospectus or any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the shares, has not been circulated or distributed, nor will it be circulated or distributed, whether directly or indirectly, to any person in Singapore other than (i) to an institutional investor (as defined in Section 4A of the Securities and Futures Act (Chapter 289) of Singapore, as modified or amended from time to time (the “SFA”)) pursuant to Section 274 of the SFA, (ii) to a relevant person (as defined in Section 275(2) of the SFA) pursuant to Section 275(1) of the SFA, or any person pursuant to Section 275(1A) of the SFA, and in accordance with the conditions specified in Section 275 of the SFA, or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Where the shares are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

- (a) a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or
- (b) a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor,

securities or securities-based derivatives contracts (each term as defined in Section 2(1) of the SFA) of that corporation or the beneficiaries’ rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the shares pursuant to an offer made under Section 275 of the SFA except:

- (a) to an institutional investor or to a relevant person, or to any person arising from an offer referred to in Section 275(1A) or Section 276(4)(i)(B) of the SFA;
- (b) where no consideration is or will be given for the transfer;
- (c) where the transfer is by operation of law; or
- (d) as specified in Section 276(7) of the SFA.

Notice to Prospective Investors in Canada

The shares may be sold only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 *Prospectus Exemptions* or subsection 73.3(1) of the *Securities Act* (Ontario), and are permitted clients, as defined in National Instrument 31-103 *Registration Requirements, Exemptions and Ongoing Registrant Obligations*. Any resale of the shares must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser’s province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser’s province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 (or, in the case of securities issued or guaranteed by the government of a non-Canadian jurisdiction, section 3A.4) of National Instrument 33-105 *Underwriting Conflicts* (NI 33-105),

the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

Notice to Prospective Investors in Brazil

The offer and sale of the securities have not been and will not be registered with the Brazilian securities commission (Comissão de Valores Mobiliários, or “CVM”) and, therefore, will not be carried out by any means that would constitute a public offering in Brazil under CVM resolution no 160, dated 13 July 2022, as amended (“CVM Resolution 160”) or unauthorized distribution under Brazilian laws and regulations. The securities may only be offered to Brazilian professional investors (as defined by applicable CVM regulation), who may only acquire the securities through a non-Brazilian account, with settlement outside Brazil in non-Brazilian currency. The trading of these securities on regulated securities markets in Brazil is prohibited.

LEGAL MATTERS

The validity of the issuance of our common stock offered in this prospectus will be passed upon for us by Latham & Watkins LLP, New York, New York. Cooley LLP, New York, New York is representing the underwriters in this offering.

EXPERTS

The consolidated financial statements as of and for the year ended December 31, 2024, included in this prospectus and elsewhere in the registration statement, have been audited by Deloitte & Touche LLP, an independent registered public accounting firm, as stated in their report. Such financial statements are included in reliance upon the report of such firm given their authority as experts in accounting and auditing.

Ernst & Young LLP, an independent registered public accounting firm, has audited our consolidated financial statements at December 31, 2023 and for the year then ended as set forth in their report. We have included our financial statements in the prospectus and elsewhere in the registration statement in reliance on Ernst & Young LLP's report, given on their authority as experts in accounting and auditing.

CHANGE IN INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

On July 17, 2024, we notified Ernst & Young LLP (“EY”), which had served as our prior independent registered public accounting firm, of our intention to obtain proposals from other accounting firms to perform the audit of our consolidated financial statements as of and for the year ending December 31, 2024 (our “2024 Audit”). On July 24, 2024, EY notified the Company of its decision to decline to stand for re-election as our independent registered public accounting firm for our 2024 Audit. On September 9, 2024, the audit committee of our board of directors approved the engagement of Deloitte & Touche LLP (“Deloitte”) as our independent registered public accounting firm for our 2024 Audit, effective immediately.

The reports of EY on our consolidated financial statements as of December 31, 2023 and 2022, and for the years then ended, did not contain adverse opinions or disclaimers of opinion and were not qualified or modified as to uncertainty, audit scope, or accounting principles.

During the years ended December 31, 2023 and 2022 and the subsequent interim period through July 24, 2024, there were:

- no “disagreements” (as defined in Item 304(a)(1)(iv) of Regulation S-K and the related instructions thereto) with EY on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedure, which disagreements, if not resolved to the satisfaction of EY, would have caused EY to make reference to the subject matter of the disagreements in its report on our financial statements as of December 31, 2023 and 2022, and for the years then ended, and
- no “reportable events” (as defined in Item 304(a)(1)(v) of Regulation S-K and the related instructions thereto), other than the material weakness identified in our internal control over financial reporting, which pertained to the aggregation of several deficiencies reflecting ineffective control activities related to the incorrect application of generally accepted accounting principles. The audit committee of our board of directors discussed the above material weakness with EY. We have also authorized EY to respond fully to the inquiries of Deloitte concerning the subject matter of the material weakness.

We provided EY with a copy of the disclosure set forth in this section and requested that EY furnish us with a letter addressed to the SEC stating whether EY agrees with the statements made herein, each as required by applicable SEC rules. A copy of the letter, dated September 12, 2024, furnished by EY in response to that request, is filed as Exhibit 16.1 to the registration statement of which this prospectus is a part.

During the years ended December 31, 2023 and 2022 and the subsequent interim period through September 9, 2024, when we engaged Deloitte, we did not consult with Deloitte with respect to (i) the application of accounting principles to a specified transaction, either completed or proposed, the type of audit opinion that might be rendered on our financial statements, and neither a written report nor oral advice was provided to us that Deloitte concluded was an important factor considered by us in reaching a decision as to any accounting, auditing, or financial reporting issue, or (ii) any matter that was the subject of a “disagreement” or a “reportable event” (each as defined above).

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act, with respect to the shares of common stock offered by this prospectus. This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement or the exhibits and schedules to the registration statement. Please refer to the registration statement and exhibits for further information with respect to the common stock offered by this prospectus. Statements contained in this prospectus regarding the contents of any contract or other document are only summaries. With respect to any contract or document that is filed as an exhibit to the registration statement, you should refer to the exhibit for a copy of the contract or document, and each statement in this prospectus regarding that contract or document is qualified by reference to the exhibit. The SEC maintains an internet website that contains the registration statement of which this prospectus forms a part, as well as the exhibits thereto. These documents, along with future reports, proxy statements and other information about us, are available at the SEC's website, www.sec.gov. The information on the SEC's web site is not part of this prospectus, and any references to this web site or any other web site are inactive textual references only.

Upon the completion of this offering, we will become subject to the information and reporting requirements of the Exchange Act, and, in accordance with this law, will be required to file periodic reports, proxy statements and other information with the SEC. These periodic reports, proxy statements and other information will be available on the website of the SEC referred to above. We also maintain a website at carislifesciences.com, at which you may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. The information contained on, or that can be accessed through, our website is not a part of this prospectus. Investors should not rely on any such information in deciding whether to purchase our common stock. We have included our website address in this prospectus solely as an inactive textual reference.

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Caris Life Sciences, Inc. and Subsidiaries

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the shareholders and the Board of Directors of Caris Life Sciences, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of Caris Life Sciences, Inc. and subsidiaries (the “Company”) as of December 31, 2024, the related consolidated statements of operations and comprehensive loss, redeemable convertible preferred stock and shareholders’ deficit, and cash flows, for the year ended December 31, 2024, and the related notes (collectively referred to as the “financial statements”). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2024, and the results of its operations and its cash flows for the year ended December 31, 2024, in conformity with accounting principles generally accepted in the United States of America.

Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has redemptions in connection with the Series C preferred stock and debt payments in connection with the 2023 term loan and the 2025 convertible notes which raises substantial doubt about its ability to continue as a going concern. Management’s evaluation of the events and conditions and management’s plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty. Our opinion is not modified with respect to this matter.

Basis for Opinion

These financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the Company’s financial statements based on our audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company’s internal control over financial reporting. Accordingly, we express no such opinion.

Our audit included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audit provides a reasonable basis for our opinion.

/s/ Deloitte & Touche LLP

San Jose, California

April 4, 2025 (June 9, 2025 as to the effects of the reverse stock split described in Note 2)

We have served as the Company’s auditor since 2024.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and Board of Directors of Caris Life Sciences, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of Caris Life Sciences, Inc. (the Company) as of December 31, 2023, the related consolidated statements of operations and comprehensive loss, changes in redeemable convertible preferred stock and shareholders' deficit and cash flows for the year then ended, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2023, and the results of its operations and its cash flows for the year then ended in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audit included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audit provides a reasonable basis for our opinion.

/s/ Ernst & Young LLP

We served as the Company's auditor from 2020 to 2024.

Dallas, Texas

March 18, 2024, except for the third paragraph of Note 2, as to which the date is June 9, 2025

CONSOLIDATED BALANCE SHEETS

(amounts in thousands, except share data)	As of December 31,	
	2024	2023
Assets		
Current assets:		
Cash, cash equivalents, and restricted cash	\$ 65,442	\$ 60,007
Short-term marketable securities	2,201	65,184
Accounts receivable	88,244	55,299
Supplies	39,572	48,998
Prepaid expenses and other current assets	20,270	13,124
Total current assets	215,729	242,612
Property and equipment, net	67,817	107,088
Goodwill	19,344	19,344
Other assets	40,844	43,856
Total assets	\$ 343,734	\$ 412,900
Liabilities, Redeemable Convertible Preferred Stock, and Shareholders' Deficit		
Current liabilities:		
Accounts payable	\$ 27,791	\$ 26,680
Accrued expenses and other current liabilities	77,542	68,291
Current portion of indebtedness	60,090	167
Total current liabilities	165,423	95,138
Long-term indebtedness, net of debt discounts	319,438	166,421
Warrant and derivative liabilities	91,642	116,184
Other long-term liabilities	44,418	54,823
Total liabilities	620,921	432,566
Commitments and contingencies (see note 10)		
Redeemable convertible preferred stock:		
Series A preferred stock, par value \$0.001: 490,000,000 shares authorized as of December 31, 2024 and December 31, 2023; 485,795,293 shares issued and outstanding as of December 31, 2024 and December 31, 2023; and \$296,335 aggregate liquidation preference as of December 31, 2024 and December 31, 2023	709,261	709,261
Series B preferred stock, par value \$0.001: 30,000,000 shares authorized as of December 31, 2024 and December 31, 2023; 29,629,630 shares issued and outstanding as of December 31, 2024 and December 31, 2023; and \$16,000 aggregate liquidation preference as of December 31, 2024 and December 31, 2023	42,963	42,963
Series C preferred stock, par value \$0.001: 142,000,000 shares authorized as of December 31, 2024 and December 31, 2023; 116,200,835 shares issued and outstanding as of December 31, 2024 and December 31, 2023; and \$408,715 and \$381,908 aggregate liquidation preference as of December 31, 2024 and December 31, 2023, respectively	408,715	381,908
Series D preferred stock, par value \$0.001: 102,600,000 shares authorized as of December 31, 2024 and December 31, 2023; 102,516,283 shares issued and outstanding as of December 31, 2024 and December 31, 2023; and \$1,060,712 and \$996,458 aggregate liquidation preference as of December 31, 2024 and December 31, 2023, respectively	1,060,712	991,152
Total redeemable convertible preferred stock	2,221,651	2,125,284
Shareholders' deficit:		
Common stock \$0.001 par value; 1,150,000,000 shares authorized as of December 31, 2024 and December 31, 2023; 36,686,819 and 36,447,778 shares issued as of December 31, 2024 and December 31, 2023, respectively; 36,504,319 and 36,265,278 shares outstanding as of December 31, 2024 and December 31, 2023, respectively; shares issued and outstanding include 662,000 and 968,000 unvested shares subject to repurchase as of December 31, 2024 and December 31, 2023, respectively	38	38
Treasury stock at cost, 182,500 shares of common stock as of December 31, 2024 and December 31, 2023	(330)	(330)
Additional paid-in capital	—	—
Related party promissory note receivable (see note 7)	(26,456)	(25,701)
Accumulated deficit	(2,472,300)	(2,119,175)
Accumulated other comprehensive income	210	218
Total shareholders' deficit	(2,498,838)	(2,144,950)
Total liabilities, redeemable convertible preferred stock, and shareholders' deficit	\$ 343,734	\$ 412,900

The accompanying notes are an integral part of these consolidated financial statements

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(amounts in thousands, except share and per share data)	Years Ended December 31,	
	2024	2023
Revenue:		
Molecular profiling services	\$ 349,115	\$ 278,748
Pharma research and development services	63,145	27,380
Total revenue	412,260	306,128
Costs and operating expenses:		
Cost of services—Molecular profiling services	223,075	207,509
Cost of services—Pharma research and development services	10,403	9,309
Selling and marketing expense	152,602	142,925
General and administrative expense (includes related party amounts of \$1,869 and \$2,061, for the years ended December 31, 2024 and 2023, respectively)	169,386	149,053
Research and development expense	113,916	116,883
Total costs and operating expenses	669,382	625,679
Loss from operations	(257,122)	(319,551)
Other income (expense), net:		
Interest income	7,122	11,258
Interest expense	(50,025)	(31,610)
Changes in fair value of financial instruments	18,484	11,094
Other expense, net	(349)	(12,606)
Total other expense, net	(24,768)	(21,864)
Loss before income taxes and provision for income taxes	(281,890)	(341,415)
Provision for income taxes	—	—
Net loss	(281,890)	(341,415)
Other comprehensive (loss) income, net of tax:		
Unrealized (loss) gain on available-for-sale securities	7	(1,660)
Foreign currency translation adjustments	(15)	180
Comprehensive loss	(281,898)	(342,895)
Net loss attributable to common shareholders:		
Net loss	(281,890)	(341,415)
Adjustments of redeemable convertible preferred stock to redemption value	(96,367)	(121,112)
Net loss attributable to common shareholders	\$ (378,257)	\$ (462,527)
Net loss per share attributable to common shareholders, basic and diluted	\$ (10.66)	\$ (13.24)
Weighted-average shares used in computing net loss per share attributable to common shareholders, basic and diluted	35,496,832	34,942,691

The accompanying notes are an integral part of these consolidated financial statements

**CONSOLIDATED STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED STOCK AND
SHAREHOLDERS' DEFICIT**

(amounts in thousands, except share data)	Redeemable Convertible Preferred Stock		Common Stock		Treasury Stock		Additional Paid-In Capital	Related Party Promissory Note Receivable	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Shareholders' Deficit
	Shares	Amount	Shares	Amount	Shares	Amount					
Balances at December 31, 2022	<u>703,086,140</u>	<u>\$1,954,172</u>	<u>34,376,983</u>	<u>\$37</u>	<u>182,500</u>	<u>\$(330)</u>	<u>\$ —</u>	<u>\$(24,969)</u>	<u>\$(1,678,549)</u>	<u>\$ 1,698</u>	<u>\$(1,702,113)</u>
Stock-based compensation	—	—	—	—	—	—	15,241	—	—	—	15,241
Issuance of common stock upon exercise of stock options	—	—	614,295	1	—	—	1,864	—	—	—	1,865
Interest income from related party promissory notes	—	—	—	—	—	—	—	(732)	—	—	(732)
Vesting of shares from early exercised stock options	—	—	306,000	—	—	—	4,958	—	—	—	4,958
Adjustment of redeemable convertible preferred Series C and Series D to redemption value	—	121,112	—	—	—	—	(21,901)	—	(99,211)	—	(121,112)
Conversion of convertible note into Series C preferred stock	31,055,901	50,000	—	—	—	—	—	—	—	—	—
Other comprehensive loss	—	—	—	—	—	—	—	—	—	(1,480)	(1,480)
Net loss	—	—	—	—	—	—	—	—	(341,415)	—	(341,415)
Foreign exchange gain	—	—	—	—	—	—	(162)	—	—	—	(162)
Balances at December 31, 2023	<u>734,142,041</u>	<u>\$2,125,284</u>	<u>35,297,278</u>	<u>\$38</u>	<u>182,500</u>	<u>\$(330)</u>	<u>\$ —</u>	<u>\$(25,701)</u>	<u>\$(2,119,175)</u>	<u>\$ 218</u>	<u>\$(2,144,950)</u>
Stock-based compensation	—	—	—	—	—	—	18,643	—	—	—	18,643
Issuance of common stock upon exercise of stock options	—	—	239,041	—	—	—	1,530	—	—	—	1,530
Interest income from related party promissory notes	—	—	—	—	—	—	—	(755)	—	—	(755)
Vesting of shares from early exercised stock options	—	—	306,000	—	—	—	4,960	—	—	—	4,960
Adjustment of redeemable convertible preferred Series C and Series D to redemption value	—	96,367	—	—	—	—	(25,133)	—	(71,234)	—	(96,367)
Other comprehensive loss	—	—	—	—	—	—	—	—	—	(8)	(8)
Net loss	—	—	—	—	—	—	—	—	(281,890)	—	(281,890)
Balances at December 31, 2024	<u>734,142,041</u>	<u>\$2,221,651</u>	<u>35,842,319</u>	<u>\$38</u>	<u>182,500</u>	<u>\$(330)</u>	<u>\$ —</u>	<u>\$(26,456)</u>	<u>\$(2,472,299)</u>	<u>\$ 210</u>	<u>\$(2,498,837)</u>

The accompanying notes are an integral part of these consolidated financial statements

CONSOLIDATED STATEMENTS OF CASH FLOWS

(amounts in thousands)	Years Ended December 31,	
	2024	2023
Cash flows from operating activities		
Net loss	\$(281,890)	\$(341,415)
<i>Adjustments to reconcile net loss to net cash used in operating activities:</i>		
Depreciation and amortization	48,913	49,001
Stock-based compensation expense	18,643	15,241
Non-cash operating lease expense	5,601	4,332
Amortization of debt discounts	7,054	5,378
Changes in fair value of financial instruments	(18,484)	(11,094)
Loss on debt extinguishment	—	10,915
Others	4,031	(1,329)
<i>Changes in operating assets and liabilities:</i>		
Accounts receivable	(33,816)	(15,081)
Supplies	5,459	(4,435)
Prepaid expenses and other current assets	(1,408)	4,544
Other assets	121	(588)
Accounts payable	(226)	7,171
Accrued expenses and other liabilities	803	1,260
Net cash used in operating activities	<u>\$(245,199)</u>	<u>\$(276,100)</u>
Cash flows from investing activities		
Maturities of marketable securities	61,376	300,488
Purchases of marketable securities	—	(63,395)
Purchases of property and equipment	(8,444)	(22,319)
Net cash provided by investing activities	<u>\$ 52,932</u>	<u>\$ 214,774</u>
Cash flows from financing activities		
Payments made on finance lease obligations	(157)	(743)
Proceeds from exercise of stock options	1,530	1,865
Payment of deferred offering costs	(1,059)	—
Proceeds from the 2023 term loan, net of issuance costs	199,978	191,310
Payment of third-party debt issuance costs	—	(2,300)
Repayment of the Original Term Loans	—	(180,000)
Net cash provided by financing activities	<u>\$ 200,292</u>	<u>\$ 10,132</u>
Effect of exchange rate changes on cash, cash equivalents, and restricted cash	(4)	62
Net decrease in cash, cash equivalents, and restricted cash	8,021	(51,132)
Cash, cash equivalents, and restricted cash at beginning of year	60,007	111,139
Cash, cash equivalents, and restricted cash at end of year	<u>\$ 68,028</u>	<u>\$ 60,007</u>
Supplemental disclosure of cash flow information		
Interest paid	\$ 49,017	\$ 15,776
Supplemental disclosure of non-cash activity		
Cash paid for amounts included in the measurement of lease liabilities		
Operating cash flow used for operating leases	\$ 11,297	\$ 12,062
Operating cash flow used for finance leases	\$ 36	\$ 78
Financing cash flow used for finance leases	\$ 157	\$ 743
Property and equipment included in accounts payable and accrued liabilities	\$ 2,052	\$ 894
Deferred offering costs, accrued but not yet paid	\$ 3,266	\$ 254
Conversion of convertible debt to Series C Preferred Stock	\$ —	\$ 50,000
Lease liabilities arising from obtained right-of-use-assets		
Operating leases	\$ 725	\$ 4,782
Finance leases	\$ 42	\$ —

The accompanying notes are an integral part of these consolidated financial statements

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 1. Nature of the Business

Caris Life Sciences, Inc. (the “Company” or “Caris”) is a patient-centric, next-generation artificial intelligence (“AI”) TechBio company and precision medicine pioneer. The Company commercializes and develops innovative solutions to transform healthcare through the use of comprehensive molecular information, and machine learning (“ML”) algorithms.

The Company’s current molecular profiling services portfolio is focused on oncology and consists of MI Profile, a tissue-based molecular profiling solution, and Caris Assure, a novel, universal blood-based molecular profiling solution, with the aim to address the entire continuum of cancer treatment.

The Company also collaborates with biopharmaceutical companies to provide commercial services and prospective and retrospective testing, along with data and bioinformatics collaborations and novel target identification and discovery solutions.

The Company was incorporated under the laws of the Cayman Islands in November 2011 (Caris Life Sciences, Ltd.) and re-domiciled to be incorporated in Texas in July 2020 (Caris Life Sciences, Inc.) and is headquartered in Irving, Texas. The Company also has locations in Phoenix, Arizona; New York, New York; Cambridge, Massachusetts; Basel, Switzerland; and Tokyo, Japan.

Liquidity and Going Concern

As of December 31, 2024, the Company’s cash balance was approximately \$64.0 million, and the short-term investments balance was \$2.2 million, and the Company has a 2023 Term Loan (see Note 8) outstanding with a balance of \$400.0 million.

In 2025, the Company issued the 2025 Convertible Notes (see Note 15), in the amount of \$30.0 million. In connection with the Company’s Series C redeemable convertible preferred stock, the 2023 Term Loan and the 2025 Convertible Notes, the following payments may become due within 12 months of the date of the issuance of the consolidated financial statements if, the Company has not completed an initial public offering raising at least \$100.0 million in gross proceeds prior to such date:

1. The Series C redemption rights will become exercisable on March 31, 2026;
2. The Company will be required to make a one-time acceleration payment on December 31, 2025 (see Note 15) in an amount equal to 15% of the outstanding principal amount under the 2023 Term Loan (or \$60.0 million based on the principal amount currently outstanding) together with any applicable repayment premium and exit fee as described in the Term Loan agreement on such date; and
3. The 2025 Convertible Notes of \$30.0 million will come due on January 1, 2026.

If these payments become due, the Company’s existing cash resources and projected operating cash flows may not be sufficient to repay these amounts and continue to fund operating activities for at least the next 12 months from the issuance of the consolidated financial statements. These conditions raise substantial doubt as to the Company’s ability to continue as a going concern.

Management intends to raise additional funding through an initial public offering raising at least \$100.0 million in gross proceeds which would eliminate the requirement to make the one-time acceleration payment related to the 2023 Term Loan. Further, the initial public offering would cause the Series C redeemable convertible preferred stock and the 2025 Convertible Note to convert to common stock and thereby not be subject to redemption and repayment upon maturity on March 31, 2026 and January 1, 2026, respectively. Management may seek alternative private financing through additional debt or equity offerings that will fulfill its operating, capital and debt requirements for at least 12 months from the date of the issuance of the consolidated financial statements. However, the Company may not be able to complete such an initial public offering or otherwise secure such financing in a timely manner or on favorable terms, if at all.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 2. Summary of Significant Accounting Policies and Estimates

Basis of Financial Statement Presentation

The consolidated financial statements include the accounts of Caris and its wholly owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

The Company's consolidated financial statements have been prepared in conformity with generally accepted accounting principles in the United States ("GAAP"). Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASUs") of the Financial Accounting Standards Board ("FASB").

Reverse Stock Split

Effective June 1, 2025, the Company's Board approved a one-for-four reverse stock split of the Company's common stock. This also resulted in an adjustment to the conversion price for each series of the Company's convertible preferred stock, to the underlying number of shares outstanding with respect to the restricted stock units, and to the exercise prices and number of shares of common stock underlying the outstanding stock options. Accordingly, all share and per share information relating to common stock for all periods presented in the accompanying consolidated financial statements and notes thereto have been retroactively adjusted. The shares of common stock retain a par value of \$0.001 per share. Accordingly, an amount equal to the excess was reclassified from common stock to additional paid-in capital or, in the absence of additional paid-in-capital, accumulated deficit.

Use of Estimates

The preparation of the consolidated financial statements in conformity with GAAP in the United States requires the use of estimates and assumptions about future events that affect the amounts reported in the Company's consolidated financial statements and related notes, including the amounts of assets and liabilities, the disclosure of contingent liabilities at the date of the consolidated financial statements, and the reported amounts of revenues and expenses during the periods reported.

Significant estimates and assumptions are used for, but not limited to:

- revenue recognition
- fair value of stock-based awards and common stock
- fair value of financial assets and liabilities

Future events and their effects cannot be predicted with certainty. Accordingly, the accounting estimates require the exercise of judgment. These estimates and assumptions are based on current facts, historical experience and various other factors believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities and the recording of expenses that are not readily apparent from other sources. The accounting estimates used in the preparation of the Company's consolidated financial statements may change as new events occur, additional information is obtained, and the operating environment changes. The Company will evaluate and update the assumptions and estimates on an ongoing basis and may employ outside experts to assist in its evaluation, as considered necessary. Actual results could materially differ from those estimates.

Reclassifications

In the preparation of the financial statements for the year ended December 31, 2024, a reclassification was made to the prior period's financial statements to conform to the current period's presentation. This reclassification has no impact on previously reported net income attributable to common shareholders, total assets, or total liabilities. The details of the reclassifications is as follows:

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Cost of services was previously included under the caption “Cost of services” in the Consolidated Statement of Operations and Comprehensive Loss. Cost of services is now presented separately as Cost of services—Molecular profiling services and Cost of services—Pharma research and development services. The reason for the reclassification is to provide a clearer presentation of the Company’s operating expenses and enhance comparability with industry peers.

Cash, Cash Equivalents, and Restricted Cash

The Company considers all highly liquid investments with original maturities of three months or less from date of acquisition to be cash equivalents. Refer to Note 4 for information on the Company’s restricted cash.

Marketable Securities

The Company classifies its marketable securities, which mainly consist of high-grade U.S. treasury bills, as available-for-sale. High-grade U.S. Treasury Bills with original maturities from date of acquisition between three and twelve months from the balance sheet dates are classified as short-term marketable securities, while those with maturities over twelve months from the balance sheet dates are classified as long-term marketable securities. The Company records all marketable securities at fair value, with changes reflected within unrealized gain or loss on available-for-sale securities on the consolidated statements of operations and comprehensive loss. The cost of short-term investments is adjusted for amortization of premiums or accretion of discounts to maturity, and such amortization or accretion is included in interest income.

Foreign Currency Transactions and Translation

The Company’s operating international subsidiaries, Caris Life Sciences Switzerland Holdings GmbH and Caris K.K., use their respective local currencies as their functional currencies. Assets and liabilities for operations in local currency environments are translated to U.S. dollars at exchange rates on the last day of the reporting period. Income and expense items are translated at average rates of exchange prevailing during the reporting period. Transactions denominated in currencies other than the functional currency are remeasured based on the exchange rates at the time of the transaction. Cumulative translation adjustments are recorded as a component of accumulated other comprehensive loss. Transaction and translation gains and losses arising from intercompany balances are reported as a component of net loss and presented within the consolidated statements of operations and comprehensive loss.

Revenue Recognition

The Company recognizes revenue under ASC Topic 606, Revenue from Contracts with Customers (“ASC 606”). Revenue is recognized when control of goods and services are transferred to customers, in an amount that reflects the consideration the Company expects to be entitled to in exchange for those services.

ASC 606 provides for a five-step model that includes:

- Step 1: Identify the contract(s) with a customer.
- Step 2: Identify performance obligations in the contract.
- Step 3: Determine the transaction price.
- Step 4: Allocate the transaction price to the performance obligations in the contract.
- Step 5: Recognize revenue when (or as) the entity satisfies a performance obligation.

The Company derives revenue from two distinct channels:

- Molecular profiling services involving the provision of precision oncology solutions utilizing MI Profile and Caris Assure.
- Pharma research and development services involving delivery of laboratory, strategic data, and research services to biopharmaceutical customers.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Molecular Profiling Services

For the majority of its molecular profiling services, the Company recognizes revenue from the sale of its precision oncology solutions, provided to customers, including certain hospitals, institutions and patients, at the point in time when the results of the profiling services are delivered to ordering physicians. Most cases requested on behalf of customers are provided without a written agreement; however, the Company determines that an implied contract exists with its customers for whom a physician orders the case. Results from molecular profiling services are delivered via fax, electronically, or in hard copy. Shipping and handling activities are considered fulfillment activities and as such, amounts incurred are recorded within Cost of services—Molecular profiling services on the consolidated statements of operations and comprehensive loss. The Company identifies each sale of the Company’s profiling service as a distinct performance obligation (“contract basis”). Payment terms are a function of a patient’s existing insurance benefits and applicable reimbursement contracts established between the Company and payers. Collection of consideration the Company expects to receive typically occurs within 90 to 120 days of billing. Occasionally, payers may recoup or we may refund consideration, mainly as a result of claim processing.

The total consideration to which the Company expects to be entitled in exchange for the Company’s services may be fixed or variable. Consideration includes reimbursement from patients, hospitals, and third-party commercial and governmental payers, such as insurance companies, adjusted for variable consideration related to implicit price concessions that the Company may grant. The Company estimates the variable consideration under a portfolio approach for third-party payers, hospitals and patients with similar reimbursement characteristics. This includes analysis of an average reimbursement per case per portfolio and a percentage of cases reimbursed by considering the historical reimbursement data (including any refunds and recoupments) from such third-party payers, hospitals and patients. Specifically, the Company calculates the historical average reimbursement rates for each portfolio and applies an estimated reimbursement rate, based on historical trends, to the number of cases delivered each period. The period for which historical data is drawn upon is determined on a by- portfolio basis for each payer group, taking into consideration the average collection period. Additionally, the estimate also considers current contractual and statutory requirements, patient insurance eligibility and payer reimbursement contracts, and any known current or anticipated reimbursement trends not reflected in the historical data and only recognizes revenue for variable consideration that the Company determines is probable will not result in a significant reversal in the future. The Company monitors the estimated amount to be collected at each reporting period based on actual cash collections in order to assess whether a revision to the estimate is required. Subsequent changes to the estimate of the transaction price are recorded as adjustments to molecular profiling services revenue in the period where such changes occur. Both the estimate and any subsequent revision are uncertain and require the use of management’s judgment in the estimation of the variable consideration and application of the constraint for such variable consideration.

For the remaining portion of its molecular profiling services, the Company has determined that collectability of the consideration to which it expects to be entitled is not probable, and thus does not recognize revenue for such services until it has provided the services to the customer and received nonrefundable consideration from the customer in exchange for the services (“non-contract basis”). The Company continually reassesses the likelihood of collection for these types of services. If collectability is deemed probable prior to receipt of consideration, then the Company recognizes revenue at the point in time that collection is deemed probable. For the year ended December 31, 2023, the Company recorded \$4.4 million of revenue related to the transition of payers from non-contract basis to contract basis.

As of December 31, 2024, all payers were on the contract basis. Molecular profiling services revenue recognized by contract type for the years ended December 31, 2024 and 2023 was as follows:

	Year Ended December 31,	
	2024	2023
	(amounts in thousands)	
Molecular profiling services—contract basis	\$349,115	\$240,119
Molecular profiling services—non-contract basis	—	38,629
Total molecular profiling services revenue	<u>\$349,115</u>	<u>\$278,748</u>

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Pharma Research and Development Services

The Company collaborates with biopharmaceutical companies to provide commercial services and prospective and retrospective testing, along with data and bioinformatics collaborations and novel target identification and discovery solutions.

Contracts with biopharmaceutical customers may include multiple distinct performance obligations, such as molecular profiling services, pharma research and development services, and strategic data services. The Company evaluates the terms and conditions included within its contracts with biopharmaceutical customers for proper revenue recognition, including whether services are capable of being distinct and considered distinct within the context of the contract. The performance obligations for biopharmaceutical customers vary by contract. Such contracts may include a performance obligation to provide molecular profiling services, to facilitate the development and regulatory approval of drugs, or to provide target discovery services. Under those contracts, the Company receives payments upon the achievement of milestones, as well as provision of on-going support. The transaction price of the development services contracts may include variable consideration, due to the uncertainty associated with the achievement of the milestones. In making the assessment of whether variable consideration should be included in the transaction price, the Company considers its historical experience with similar milestones, the degree of complexity and uncertainty associated with each milestone, and whether achievement of the milestone is dependent on parties other than the Company. The Company recognizes pharma research and development services revenue over the period in which biopharmaceutical research and development services are provided. Depending on the nature of the service, the Company recognizes revenue using either the output or input method to measure progress, whichever provides a more faithful depiction of the transfer of goods or services. Use of an output method or input method to depict the transfer of services generally does not result in a material difference with respect to the timing of revenue recognition because most services commence and end within the same reporting period. A constraint for variable consideration is applied such that it is probable a significant reversal of revenue will not occur when the uncertainty associated with the contingency is resolved. Application of the constraint for variable consideration is updated at each reporting period as a revision to the estimated transaction price.

Standalone Selling Price

The Company determines standalone selling prices by considering the historical selling prices of its performance obligations in similar transactions, where applicable, as well as other factors, including, but not limited to, the price that customers in the market would be willing to pay, competitive pricing from other vendors, industry publications, current pricing practices and management estimates.

Contract Balances

The timing of revenue recognition may differ from the timing of invoicing to customers. Accounts receivable are recorded at the invoiced amount, net of an allowance for credit losses. A receivable is recognized in the period the Company delivers goods or provides services, or when the right to consideration is unconditional. In situations where revenue recognition occurs before invoicing, an unbilled receivable is created, which represents a contract asset. As of December 31, 2024 and 2023, the unbilled receivable balance was \$4.6 million and \$6.6 million, respectively, which is included in accounts receivable on the consolidated balance sheets.

The Company recognizes contract liabilities primarily related to payments received in advance of satisfaction of performance obligations from contracts with customers. Contract liabilities are relieved as the Company fulfills its obligations under the contract and revenue is recognized. As of December 31, 2024 and 2023, the contract liability balance was \$7.5 million and \$6.2 million, respectively, which is included in accrued expenses and other current liabilities on the consolidated balance sheets.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The following table shows the changes in the contract liabilities during the period:

	(amounts in thousands)
Balance at December 31, 2023	\$ 6,190
Increase in contract liabilities	12,816
Revenue recognized during the period that was included in deferred revenues at the beginning of the period	(5,406)
Revenue recognized from performance obligations satisfied within the same period	(6,130)
Balance at December 31, 2024	<u>\$ 7,470</u>

The amount of revenue recognized during the year ended December 31, 2023 pertaining to amounts deferred as of December 31, 2022 was \$0.7 million.

Transaction Price Allocated to Remaining Performance Obligations

The transaction price allocated to remaining performance obligations represents contracted revenue that has not yet been recognized, which includes contract liabilities and non-cancelable amounts that will be invoiced and recognized as revenue in future periods and excludes performance obligations that are subject to cancellation terms. The Company has elected not to disclose information regarding the transaction price allocated to the remaining performance obligations for which the original expected duration of the contract is one year or less. The amount of transaction price allocated to the remaining performance obligations for contracts with original expected duration over one year as of December 31, 2024 and 2023 was \$5.8 million and \$5.6 million, respectively. The Company expects to recognize the amounts within twelve months from the respective balance sheet dates.

Additionally, for the years ended December 31, 2024 and 2023, the Company recorded \$3.9 million and \$(1.9) million of adjustments to revenue related to services delivered in prior periods, which is based on variability that was subsequently resolved.

Practical Expedients and Contract Costs

Payment terms and conditions vary by contract and customer. In instances where the timing of the Company's revenue recognition differs from the timing of its invoicing, the Company does not assess whether a contract has a significant financing component if the expectation at contract inception is such that the period between payment by the customer and the transfer of the promised services to the customer will be one year or less.

As a practical expedient, the Company recognizes the incremental costs of obtaining contracts, such as sales commissions, as expenses when incurred, if the amortization period of the asset that the Company otherwise would have recognized for the capitalized costs is one year or less. Sales commissions are recorded within selling and marketing expense on the consolidated statements of operations and comprehensive loss. The Company did not capitalize any sales commissions or contract fulfillment costs for the years ended December 31, 2024 and 2023.

Collaboration agreements

The Company is party to various collaboration and licensing agreements under which the Company out-licenses certain know-how and molecular data. The collaboration arrangements are intended to solidify the Company's third-party partnerships to align oncology capabilities and create industry-leading molecular oncology research platforms to accelerate drug development and novel research. Under these collaboration arrangements, the Company generally receives a split of fees from its collaborative partners that are earned pursuant to statements of work ("SOWs") executed with end users of the Company's licensed molecular data.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The Company's collaboration and licensing agreements are within the scope of ASC Topic 808, Collaborative Arrangements ("ASC 808") and ASC 606 because the counterparty to these agreements meets the definition of a customer. As such, the Company recognizes revenue earned from the licenses of molecular data granted to the Company's collaborative partners in accordance with ASC 606. Each license of molecular data granted by the Company to a collaborative partner represents a distinct performance obligation in the contract. The transaction price for a given arrangement is entirely variable and depends on the SOWs executed by the counterparty with end users. The amount of revenue allocated to each license is equal to the amount of revenue to which the Company expects to be entitled. The Company recognizes revenue at the point in time that it delivers the molecular data to the third-party collaborative partner. For the years ended December 31, 2024 and 2023, the Company recognized collaboration revenue of \$16.2 million and \$5.8 million, respectively, which is included in revenue from pharma research and development services on the consolidated statements of operations and comprehensive loss.

Cost of services—Molecular profiling services

Cost of services for molecular profiling services generally consists of cost of materials, direct labor including bonus and stock-based compensation, and equipment maintenance and depreciation expenses associated with processing cases (including accessioning, sequencing, quality control analyses and shipping charges to transport tissue samples), freight and profile results for ordering physicians. Costs associated with completing the molecular profiling services are recorded as the service is performed, regardless of when revenue is recognized with respect to the service.

Cost of services—Pharma research and development services

Cost of services for pharma research and development services generally consists of cost incurred for the performance of the services requested by the Company's biopharmaceutical customers related to the delivery of laboratory, strategic data and research services, and will vary depending on the nature, timing, and scope of customer projects. Costs associated with delivery pharma research and development services are recorded as incurred.

Concentration of Credit Risk

Financial instruments that potentially expose the Company to concentration of credit risk consist primarily of cash, cash equivalents, marketable securities, and accounts receivable. The Company maintains its cash primarily with domestic financial institutions of high credit quality, with balances that exceed amounts insured by the Federal Deposit Insurance Corporation as of December 31, 2024 and 2023, respectively.

The Company invests in treasury bills issued by the U.S. Government. U.S. treasury bills with original maturities of three months or less are classified within cash equivalents. Short-term marketable securities are comprised of U.S. treasury bills with original maturities between three and twelve months. The Company believes it is not exposed to any significant credit risk on cash, cash equivalents, and marketable securities and performs periodic evaluations of the credit standing of such institutions. The goal of the Company's investment policy is to ensure safety and preservation of the principal balance, and diversification of risk over cash balances held on deposit.

The Company is subject to credit risk from its accounts receivable. The majority of the Company's accounts receivable arise from the provision of molecular profiling services and pharma research and development services and other, primarily with biopharmaceutical companies, all of which have high credit ratings. The Company has not experienced any material losses related to receivables from individual customers, or groups of customers. The Company does not require collateral. Accounts receivable are recorded net of allowance for credit losses, if any. Concentrations of credit risk are limited due to the number of payers and their dispersion across multiple geographic regions.

For the years ended December 31, 2024 and 2023, the Company's revenues were primarily derived from the sale of the Caris molecular profiling services. As discussed above, payment terms of the services

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

are a function of a patient's existing insurance benefits and applicable reimbursement contracts established between the Company and payers. Revenue associated with each payer, including its affiliated entities, as a percentage of the Company's total revenue for the respective period, and accounts receivable balance attributable to each payer, including its affiliated entities, as a percentage of the Company's total accounts receivable balance at the respective consolidated balance sheet date, are as follows:

Major Payer	% Revenue for the years ended December 31,		% Accounts receivable as of December 31,	
	2024	2023	2024	2023
Payer 1	33.1%	35.8%	16.1%	18.6%
Payer 2	*	11.0%	*	20.6%
Payer 3	14.0%	14.0%	19.3%	*

* Represents major payers below 10.0%.

In addition, as of December 31, 2024, one biopharmaceutical customer represented 22.3% of total accounts receivable.

Accounts Receivable

Accounts receivable includes billed and unbilled receivables, net of an allowance for expected credit losses. Accounts receivable primarily represent receivables from biopharmaceutical customers and third-party payers. Accounts receivable for pharmaceutical services are established based on the amounts outstanding per the contractual arrangements with biopharmaceutical customers. The Company applies the current expected credit loss standard in ASC Subtopic 326-20, *Financial Instruments—Credit Losses* ("ASC 326-20") and reserves a portion of the accounts receivable based on assessment of the collectability of customer accounts at the time of revenue recognition. The Company regularly reviews the reserve by considering factors such as historical experience, credit quality, the age of the accounts receivable balances, and current economic conditions that may affect a customer's ability to pay.

Receivables deemed to be uncollectible are written-off against the allowance for credit losses at the time such receivables are deemed to be uncollectible under a specific identification or estimated method. Recoveries of accounts receivable previously written off are recorded when received. As of December 31, 2024 and 2023, the Company had an immaterial allowance for credit losses related to its accounts receivable.

Supplies

Supplies consist primarily of laboratory items and reagents used by the Company in providing services. All supplies are raw materials and are stated at the lower of cost or net realizable value on a first-in, first-out basis. The Company periodically reviews its supplies for excess or obsolescence and writes down obsolete or otherwise unmarketable supplies to their estimated net realizable value. For the years ended December 31, 2024 and 2023, the amount of write downs associated with the Company's supplies was immaterial.

Deferred Offering Costs

Deferred offering costs consist primarily of accounting, legal, and other fees related to the Company's proposed initial public offering ("IPO"). These costs are recorded as prepaid expenses and other current assets on the consolidated balance sheets. The deferred offering costs will be recorded against IPO proceeds upon the consummation of the IPO. In the event the planned IPO is terminated, the deferred offering costs will be expensed. The Company had \$4.5 million of deferred offering costs as of December 31, 2024. Deferred offering costs were not material as of December 31, 2023.

Property and Equipment, Net

The Company reports property and equipment at cost, net of accumulated depreciation, amortization, and any asset impairments. The cost of properties held under finance leases is equal to the

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

present value of lease payments not yet paid, adjusted for initial direct costs, prepaid lease payments and lease incentives received. Major improvements which add to productive capacity or extend the life of an asset are capitalized. Normal repairs and maintenance are expensed as incurred. When assets are retired or otherwise disposed of, the cost and related accumulated depreciation and amortization are removed from the accounts, and any resulting gain or loss is reflected in the accompanying consolidated statements of operations and comprehensive loss for the period.

Depreciation and amortization expenses are calculated on a straight-line basis and applied to asset classes based upon the Company's estimate of the asset class's useful life, as summarized below:

	Estimated Useful Life
Laboratory equipment	3 years
Computer equipment and software	3 years
Furniture and fixtures	5 years
Aircraft	7 years
Leasehold improvements/leased buildings	Lesser of remaining lease term or useful life
Leased equipment	Lesser of initial lease term or 5 years

Computer equipment and software includes the purchases of hardware, software and capitalized labor costs associated with internally developed software.

The Company capitalizes purchased software which is ready-for-service and capitalizes qualifying internal software development costs incurred on significant projects. Capitalization of costs begins when two criteria are met: (1) the preliminary project stage is completed, management with relevant authority authorizes and commits to funding the software project, and (2) it is probable that the software will be completed and used for its intended function. Capitalization ceases when the software is substantially complete and ready for its intended use, including the completion of all significant testing. Costs related to preliminary project activities and post-implementation operating activities are expensed as incurred.

Research and development costs and other computer software maintenance costs related to software development are expensed as incurred.

Capitalized software costs are included in property and equipment, net. These costs are amortized using the straight-line method over the estimated useful life of the underlying software, which is three years. The Company capitalized \$1.1 million and \$3.3 million in development costs for internal use software for the years ended December 31, 2024 and 2023, respectively.

Leases

The Company is a lessee for various types of property and equipment. The Company determines if an arrangement is or contains a lease at inception by evaluating whether the contract contains an identified asset that the Company has the right to control the use of throughout the contract term. Lease classification as either an operating or finance lease is determined at the lease commencement date when the leased assets are made available for use.

Upon lease commencement, the Company recognizes a lease liability and right-of-use ("ROU") asset. ROU assets represent the right to use an underlying asset for the lease term and lease liabilities represent the Company's obligation to make payments arising from the lease. Lease liabilities are recognized at the lease commencement date based on the present value of lease payments over the lease term, regardless of whether the lease is an operating or finance lease. Lease payments consist primarily of fixed payments under the arrangement, less tenant incentives, if any. For each lease, the Company first assesses whether the rate implicit in the lease is readily determinable. When the rate implicit in the lease is not readily determinable, the Company uses an estimate of its incremental borrowing rate ("IBR") based on the information available at the lease commencement date in determining the present value of lease payments. In determining the appropriate IBR, the Company considers information including, but not limited to, its

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

credit rating, the lease term, collateral and the currency in which the arrangement is denominated. ROU assets are measured based on the corresponding lease liability adjusted for (i) prepayments made to the lessor at or before the commencement date, (ii) initial direct costs the Company incurs, and (iii) tenant incentives under the lease. Certain of the Company's leases include options to extend or terminate the lease. An option to extend the lease is considered in connection with recognizing and measuring the ROU asset and lease liability when it is reasonably certain the Company will exercise that option.

Lease expense for operating lease payments is recognized on a straight-line basis over the lease term. Amortization expense for finance leases is recognized on a straight-line basis over the lease term, and interest expense for finance leases is recognized using the effective interest method. The Company presents operating lease payments within cash flows from operating activities on the consolidated statements of cash flows. The Company presents finance lease payments related to principal amounts within cash flows from financing activities and finance lease payments related to the interest on the lease liability within cash flows from operating activities on the consolidated statements of cash flows.

The presentation of the Company's leases on the consolidated balance sheets depends on whether the lease is classified as an operating or finance lease. Operating lease ROU assets are included within other assets, the current portion of operating lease liabilities are included within accrued expenses and other current liabilities, and the long-term operating lease liabilities are included within other long-term liabilities. Finance lease ROU assets are included in property and equipment, net, the current portion of finance lease liabilities are included within current portion of notes payable, and long-term finance lease liabilities are included within long-term indebtedness, net of discounts.

The Company elected the practical expedient to not separate lease and non-lease components for its leases. The Company does not record leases on the consolidated balance sheet that have a lease term of twelve months or less at the lease commencement date. Refer to Note 9 for additional disclosures related to the Company's lease arrangements.

Warrant Liability

In 2020, the Company issued warrants and amended its outstanding warrants to include a provision to allow the purchase of either common stock or its Series C redeemable convertible preferred stock upon exercise. Because the warrants may be exercised for shares of the Company's Series C redeemable convertible preferred stock, the warrants are classified as a liability pursuant to the guidance in ASC Topic 480, *Distinguishing Liabilities from Equity*. The Company recognizes the liability associated with outstanding warrants within warrant and derivative liabilities on the consolidated balance sheets. The warrant liability is adjusted to fair value until such time as the warrants are no longer outstanding or the underlying securities are no longer redeemable outside the control of the Company. Changes in fair value of the warrant liability are reported within changes in fair value of financial instruments on the consolidated statements of operations and comprehensive loss. Refer to Note 8 for additional information about the warrant liability.

Fair Value Measurements

Fair value is defined as the exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions market participants would use in pricing an asset or liability.

The basis for these assumptions establishes a three-level fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

- *Level 1*—Observable inputs such as quoted prices in active markets for identical assets and liabilities;
- *Level 2*—Inputs, other than quoted prices in active markets, that are observable either directly or indirectly; and

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

- *Level 3*—Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions.

Assets and liabilities measured at fair value are based on one or more of three valuation techniques. The three valuation techniques are as follows:

- *Market approach*—Prices and other relevant information generated by market transactions involving identical or comparable assets or liabilities;
- *Cost approach*—Amount that would be required to replace the service capacity of an asset (i.e., replacement cost); and
- *Income approach*—Techniques to convert future amounts to a single present amount based on market expectations (including present value techniques, option-pricing models, and lattice models).

Financial instruments consist of cash, cash equivalents, restricted cash, short-term marketable securities, accounts receivable, prepaid expenses and other current assets, accounts payable, accrued expenses and other current liabilities, debt (see Note 8), warrants, and derivative instruments.

As of December 31, 2024 and 2023, the carrying amounts of the Company's cash equivalents, restricted cash, accounts receivable, prepaid expenses and other current assets, accounts payable, accrued expenses and other current liabilities approximate their fair value based on the short-term nature of these items. There were no transfers between Levels 1, 2 or 3 for the years ended December 31, 2024 and 2023.

The Company's financial assets and liabilities subject to fair value measurements on a recurring basis and the level of inputs used in such measurements were as follows:

		As of December 31, 2024			
		Fair Value	Level 1	Level 2	Level 3
		(amounts in thousands)			
Financial assets					
Short-term marketable securities		\$ 2,201	\$2,201	\$—	\$ —
Financial liabilities					
Warrant liability		\$91,642	\$ —	\$—	\$91,642
Derivative liability		\$ 6,058	\$ —	\$—	\$ 6,058
		As of December 31, 2023			
		Fair Value	Level 1	Level 2	Level 3
		(amounts in thousands)			
Financial assets					
Short-term marketable securities		\$65,184	\$65,184	\$—	\$ —
Financial liabilities					
Warrant liability		\$98,733	\$ —	\$—	\$98,733
Derivative liability		\$17,451	\$ —	\$—	\$17,451

Short-term marketable securities

The Company's short-term marketable securities, which have maturities of less than one year, are mainly comprised of U.S. treasury bills which have observable quoted prices. There were no outstanding U.S. Treasury Bills as of December 31, 2024. The following is a summary of the Company's available-for-sale securities as of December 31, 2023:

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

	As of December 31, 2023			
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized (Loss)	Estimated Fair Value
	(amounts in thousands)			
U.S. treasury bills	\$63,099	\$5	\$(12)	\$63,092

Warrant liability

The Company utilized a probability-weighted scenario approach factoring in various exit strategies and the related timing of such to estimate the fair value of its warrant liability. For each scenario, the Company utilized a Black-Scholes option pricing model with the following assumptions:

- *Fair value per share of the underlying stock*—The fair value of the underlying stock represents the fair value of the Company’s Series C preferred stock that the warrants are convertible into.
- *Volatility*—The volatility is derived from historical volatilities of several unrelated publicly-listed peer companies, since the Company has no trading history. When making the selections of industry peer companies to be used in the volatility calculation, the Company considers the size, operational and economic similarities to the Company’s principal business operations.
- *Risk-free interest rate*—The risk-free interest rate is based on U.S. treasury yield as of the measurement dates interpolated to match the maturity equal to the respective term to exit.
- *Dividend yield*—The expected dividend assumption is based on the Company’s current expectations about the Company’s anticipated dividend policy.
- *Expected term (years)*—Based on expected term under various exit strategies.

The below table summarizes the significant unobservable inputs used in the fair value measurement of the warrant liability as of December 31, 2024 and 2023:

	As of December 31,			
	2024		2023	
	2018 Warrants	2020 Warrants	2018 Warrants	2020 Warrants
Fair value per share of the underlying stock	\$3.66–\$5.65	\$3.66–\$5.65	\$2.97–\$8.14	\$2.97–\$8.14
Expected volatility	47.6%–63.0%	61.2%–63.0%	43.0%–55.0%	50.0%–55.0%
Risk-free interest rate	4.2%–4.3%	4.3%	4.4%–5.3%	4.0%–5.3%
Expected dividend yield	—%	—%	—%	—%
Expected term (years)	0.29–0.75	0.29–2.25	0.5–1.72	0.5–3.25

Derivative liability

On January 18, 2023, the Company entered into a credit agreement (the “New Term Loan Agreement”) under which the Company issued senior, secured promissory notes (the “2023 Term Loan”) by which the New Term Loan lenders agreed to lend the Company up to an aggregate principal amount of \$400.0 million, \$200.0 million of which was received by the Company upon issuance. The Company identified certain embedded features in the 2023 Term Loan, including various contingent prepayment, compensatory payment, and default interest rate features, that are required to be bifurcated from the 2023 Term Loan and separately accounted for in the consolidated financial statements as a compound derivative liability.

Fair value of the derivative liability was estimated using the discounted cash flow method under the income approach. This approach involves significant Level 3 inputs and assumptions including an estimated probability and timing of certain contingent events, such as events of default, change of control, sale of assets, etc. The analysis also required the selection of a discount rate representative of the Company’s credit risk. The discount rate used for the initial fair value was calibrated to the transaction.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The initial fair value of the derivative liability was \$28.3 million at the inception date of January 18, 2023. As of December 31, 2023, the fair value of the embedded derivative liability was \$17.5 million, resulting in a remeasurement gain of \$10.8 million reported within changes in fair value of financial instruments in the consolidated statements of operations and comprehensive loss.

Refer to Note 8 for additional information about the compound embedded derivative liability.

Debt

As of December 31, 2024, the estimated fair value of the 2023 Term Loan, excluding the bifurcated embedded derivative, was \$380.9 million, compared to a carrying value of \$373.1 million. As of December 31, 2023, the estimated fair value of the 2023 Term Loan, excluding the bifurcated embedded derivative, was \$176.1 million, compared to a carrying value of \$166.1 million. The Company estimated the fair value of the 2023 Term Loan as of December 31, 2024 based on a discounted cash flow analysis, and an income approach, which represented the use of Level 3 inputs in the fair value hierarchy.

Goodwill

Goodwill represents the excess of the purchase price over the fair value of net identifiable assets and liabilities acquired through a business combination. The Company evaluates goodwill for impairment in accordance with ASC Topic 350, *Intangibles—Goodwill and Other* on an annual basis on October 1, or more frequently if events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. The Company first assesses qualitative factors to determine whether it is more likely than not that the fair value of a reporting unit is less than its carrying amount, or the Company may determine to proceed directly to the quantitative impairment test.

If the Company assesses qualitative factors and concludes that it is more likely than not that the fair value of a reporting unit is less than its carrying amount or if the Company determines not to use the qualitative assessment, then a quantitative impairment test is performed. The factors utilized in the qualitative assessment include macroeconomic conditions, industry and market considerations, cost factors, overall financial performance, and Company-specific events. The quantitative impairment test requires comparing the fair value of the reporting unit to its carrying value, including goodwill. The fair value of the reporting unit is determined based on the present value of estimated cash flows using available information regarding expected cash flows of each reporting unit, discount rates, and the expected long-term cash flow growth rates.

The Company has identified that its business operates as a single operating segment which is also a single reporting unit for purposes of testing goodwill for impairment. An impairment exists if the fair value of the reporting unit is lower than its carrying value. If the fair value of the reporting unit is lower than its carrying value, the Company would record an impairment loss equal to the excess of the reporting unit's carrying value over its fair value.

There were no impairment losses for the years ended December 31, 2024 and 2023.

Research and Development Costs

Research and development costs are expensed as incurred. Research and development expenses consist of costs incurred in performing research and development activities. The costs include direct costs for salaries and benefits, materials, contract services and other outside costs, and costs to acquire in-process research and development projects and technologies that have no alternative future use.

Advertising

The Company expenses advertising costs as incurred. The Company incurred advertising costs of \$1.2 million and \$0.6 million for the years ended December 31, 2024 and 2023, respectively.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Self-Insurance

The Company offers medical insurance coverage to eligible employees under a self-insured program managed by a third-party administrator, leveraging stop-loss insurance policies to mitigate risk. The Company records an estimate of its liability for medical claims, which includes the incurred claims amount plus an estimate of incurred, but not reported claims. Self-insurance liability of \$1.9 million and \$1.8 million for the years ended December 31, 2024 and 2023, respectively, is included within accrued expenses and other current liabilities on the consolidated balance sheets.

Comprehensive Loss

Comprehensive loss consists of net loss, unrealized gains on available-for-sale securities, foreign currency translation adjustments and gains affecting shareholders' deficit that under GAAP are excluded from net income or loss.

Stock-Based Compensation

The Company accounts for stock-based compensation awards in accordance with ASC Topic 718, *Compensation—Stock Compensation* ("ASC 718"). Stock-based compensation expense is measured based on the fair value of the stock-based awards at the grant date for all stock-based awards to employees and non-employees and is recognized as expense over the requisite service period on a straight-line basis, which is generally the vesting period. Forfeitures are estimated using historical trends. Refer to Note 7 for additional information on the Company's stock-based compensation.

Compensated Absences

When the Company's obligation relating to employees' rights to receive compensation for future absences is attributable to employees' services rendered, the obligation relates to rights that vest or accumulate, payment is probable and amount can be reasonably estimated, a liability is recorded.

Loss Contingencies

The Company accounts for liabilities for loss contingencies arising from claims, assessments, litigation, fines, and penalties and other sources when it is probable that a liability has been incurred and the amount can be reasonably estimated. Legal costs incurred in connection with loss contingencies are expensed as incurred. Refer to Note 10 for additional information on the Company's loss contingencies.

Redeemable Convertible Preferred Stock

The Company's redeemable convertible preferred stock is recorded outside of permanent equity because, while it is not mandatorily redeemable, it is redeemable at the option of the holders for cash upon the passage of time or the occurrence of certain events considered not solely within the Company's control, such as a merger, acquisition, and sale of all or substantially all of the Company's assets (each, a "deemed liquidation event"). The redeemable convertible preferred stock classified in mezzanine equity is subject to subsequent measurement under the guidance provided in the SEC Staff Announcement: Classification and Measurement of Redeemable Securities. In accordance with that guidance, the Company has elected to recognize changes in redemption value immediately as they occur through adjustments to the carrying amounts of the instruments at the end of the reporting period with the corresponding amount recorded to additional paid-in capital or, in the absence of additional paid-in-capital, accumulated deficit.

Treasury Stock

The Company records treasury stock purchases under the cost method by recording the entire cost of the acquired shares of common stock as treasury stock. In the case of re-issuance of treasury stock, amounts that exceed the acquisition cost will be recorded in additional paid-in capital. If the re-issuance

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

price is below the treasury stock's acquisition cost and additional paid-in capital is insufficient to cover the difference between the acquisition cost and the re-issuance price, the shortfall will be recorded in accumulated deficit.

If the Company decides to retire treasury stock, the Company will deduct the par value from common stock and reduce additional paid-in capital for any excess of cost over par value. If additional paid-in capital is insufficient, the Company reflects the shortfall in accumulated deficit.

Net Loss per Share Attributable to Common Shareholders

The Company calculates its basic and diluted net loss per share attributable to common shareholders in conformity with the two-class method required for companies with participating securities. Each series of the Company's redeemable convertible preferred stock is considered to be a participating security because the preferred shareholders have a right to receive dividends on a pari passu basis with the Company's common shareholders. The two-class method determines net income (loss) per share for each class of common stock and participating security according to dividends declared or accumulated and participating rights in undistributed earnings. The two-class method requires income (loss) available to common shareholders for the period to be allocated between common and participating securities based upon the respective rights of each to share in earnings as if all income (loss) for the period had been distributed. The participating securities are not required to participate in the losses of the Company, and therefore during periods of loss there is no allocation required under the two-class method between common and participating securities.

Because the Company has reported a net loss for the years ended December 31, 2024 and 2023, basic net loss per share attributable to common shareholders is calculated by dividing net loss attributable to common shareholders by the weighted-average common stock outstanding during the period, without consideration for potential common stock equivalents. Net loss attributable to common shareholders is equal to net loss, less accretion on preferred securities to their redemption value to the extent such securities are outstanding. Diluted net loss per share attributable to common shareholders is calculated by adjusting the weighted-average stock outstanding for the dilutive effect of potential common stock equivalents outstanding. For purposes of calculating the diluted net loss per share attributable to common shareholders, convertible preferred stock, convertible promissory notes, warrants, and stock options are considered to be potential common stock equivalents but are excluded from the calculation of diluted net loss per share attributable to common shareholders because their effect would be anti-dilutive. Therefore, basic and diluted net loss per share attributable to common shareholders was the same for all periods presented.

Income Taxes

The Company accounts for income taxes under the asset and liability method as set forth in ASC 740 "Income Taxes" ("ASC 740"). Under this method, deferred tax assets and liabilities are determined based on the differences between the financial statement and tax bases of assets and liabilities by using enacted tax rates in effect for the year in which the differences are expected to reverse. Valuation allowances are established when necessary to reduce deferred tax assets to the amounts expected to be realized. The calculation of the Company's tax liabilities involves dealing with uncertainties in the application of complex tax laws and regulations in a multitude of jurisdictions across its global operations. The Company records uncertain tax positions in accordance with ASC 740 on the basis of a two-step process in which (1) we determine whether it is more likely than not that the tax positions will be sustained on the basis of the technical merits of the position and (2) for those tax positions that meet the more-likely-than-not recognition threshold, we recognize the largest amount of tax benefit that is more than 50% likely to be realized upon ultimate settlement with the related taxing authority. For tax positions not meeting the more likely than not test, no tax benefit is recorded.

At December 31, 2024 and 2023, the Company has accumulated net operating loss carryforwards in both the U.S. and foreign jurisdictions, and no provision for income taxes is required. The Company's deferred tax assets are subject to a full valuation allowance.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Recently Adopted Accounting Pronouncements

In November 2023, the FASB issued ASU No. 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*. This ASU requires disclosure of incremental segment information on an annual and interim basis for all public entities to enable investors to develop more decision-useful financial analyses. The amendments require disclosure of significant segment expenses that are regularly provided to the CODM and included within each reported measure of segment profit or loss, an amount and description of the composition for other segment items to reconcile to segment profit or loss, and the title and position of the Company's CODM. The ASU also extends certain annual disclosures to interim periods. The Company elected to early adopt this ASU for its annual reporting period ending December 31, 2023. There was no impact on the Company's reportable segments identified and additional required disclosures have been included in Note 13.

Recently Issued Accounting Pronouncements Not Yet Adopted

In December 2023, the FASB issued ASU No. 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures* which requires presentation of specific categories of reconciling items, as well as reconciling items that meet a quantitative threshold, in the reconciliation between the income tax provision and the income tax provision using statutory tax rates. The standard also requires disclosure of income taxes paid disaggregated by jurisdiction with separate disclosure of income taxes paid to individual jurisdictions that meet a quantitative threshold. For public business entities, the ASU is effective for annual periods beginning after December 15, 2024, with early adoption permitted. For entities other than public business entities, the ASU is effective for annual periods beginning after December 15, 2025. The amendments of the ASU should be applied on a prospective basis; however, entities have the option to apply retrospectively for each period presented. The Company does not expect the adoption of this new standard in 2026 to have an impact on its consolidated financial position, results of operations, or cash flow.

In November 2024, the FASB issued ASU No. 2024-03, *Income Statement- Reporting Comprehensive Income-Expense disaggregation disclosures (Subtopic 220-40) Disaggregation of Income Statement Expenses*. This ASU requires disclosure of specified information about certain costs and expenses in the notes to financial statements. This ASU is effective for annual periods beginning after December 15, 2026, and interim periods within fiscal years beginning after December 15, 2027. Adoption of this ASU should be applied on a prospective basis. Early adoption is permitted. We are currently evaluating the impact that this guidance will have on the disclosures within our financial statements, and expect to adopt this ASU for the year ending December 31, 2027.

Note 3. Consolidated Balance Sheet and Statement of Operations and Comprehensive Loss Components**Prepaid Expenses and Other Current Assets**

Prepaid expenses and other current assets consist of the following:

	As of December 31,	
	2024	2023
	(amounts in thousands)	
Prepaid expenses	\$13,562	\$11,766
Other current assets	6,708	1,358
Total prepaid expenses and other current assets	<u>\$20,270</u>	<u>\$13,124</u>

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Property and Equipment, Net

Property and equipment, net consist of the following:

	As of December 31,	
	2024	2023
	(amounts in thousands)	
Computer equipment and software	\$ 99,233	\$ 95,573
Laboratory equipment	103,795	98,985
Furniture and fixtures	9,110	8,883
Leasehold improvements/Leased buildings	63,039	66,579
Aircraft and leased equipment	21,249	21,204
Total property and equipment	296,426	291,224
Less: accumulated depreciation and amortization	(228,609)	(184,136)
Property and equipment, net	<u>\$ 67,817</u>	<u>\$ 107,088</u>

Total depreciation and amortization expense was \$48.9 million and \$49.0 million for the years ended December 31, 2024 and 2023, respectively. Out of the total depreciation expense, amortization associated with finance leases was \$0.1 million and \$0.5 million for the years ended December 31, 2024 and 2023, respectively.

Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consist of the following:

	As of December 31,	
	2024	2023
	(amounts in thousands)	
Trade accruals	\$ 7,131	\$ 7,680
Accrued payroll and employee medical	17,882	16,049
Accrued bonus	25,736	16,824
Current portion of early exercise stock option liability	4,957	4,957
Contract liability	7,470	5,676
Current portion of operating lease liabilities	6,080	6,420
Accrued interest on current portion of notes payable and convertible loan	—	6,332
Other accrued expenses	8,286	3,839
Total accrued expenses and other current liabilities	<u>\$77,542</u>	<u>\$67,777</u>

Other Long-Term Liabilities

Other long-term liabilities consist of the following:

	As of December 31,	
	2024	2023
	(amounts in thousands)	
Long-term operating lease liabilities, net of current portion	\$38,651	\$44,099
Long-term portion of early exercise stock option liability	5,767	10,724
Total other long-term liabilities	<u>\$44,418</u>	<u>\$54,823</u>

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Other Expense, Net

Other expense, net consists of the following:

	As of December 31,	
	2024	2023
	(amounts in thousands)	
Loss on debt extinguishment	\$ —	\$(10,915)
Other	(349)	(1,691)
Total other expense, net	<u>\$(349)</u>	<u>\$(12,606)</u>

Note 4. Guaranty Agreement and Restricted Cash

The Company entered into a Master Continuing Guaranty Agreement with Bank of America in 2011 to provide a guarantee for credit exposure related to the Company's commercial bank accounts with Bank of America. The agreement was guaranteed through collateral accounts of \$0.3 million as of December 31, 2024 and 2023. The agreement contains various customary affirmative and financial reporting obligations and is considered to be restricted cash, as the account is under a security deposit agreement. All obligations are in compliance with the terms of the agreement.

The Company entered into a lease agreement with KCP NNN II Leasehold 4, LLC on July 25, 2019 to lease 114,500 square feet of space in Irving, Texas. As part of the lease agreement, the Company delivered an unconditional, irrevocable letter of credit for \$3.4 million from a nationally recognized bank. The Company obtained this letter of credit and placed \$3.4 million in a security deposit account. As of December 31, 2024 and 2023, amounts outstanding are \$2.7 million and \$3.1 million, respectively, and are included within cash, cash equivalents, and restricted cash and other assets on the consolidated balance sheets.

The remaining restricted cash amounts are not material individually.

The following table provides a reconciliation of cash, cash equivalents, and restricted cash reported within the consolidated balance sheet that sum to the total of the amounts shown in the consolidated statements of cash flows. Restricted cash is presented within cash, cash equivalents, and restricted cash and other assets on the consolidated balance sheets.

	Consolidated balance sheet line item	As of December 31,	
		2024	2023
		(amounts in thousands)	
Cash and cash equivalents	Cash, cash equivalents, and restricted cash	\$63,950	\$56,402
Restricted cash – short term	Cash, cash equivalents, and restricted cash	1,492	3,605
Restricted cash – long term	Other assets	2,586	—
Total		<u>\$68,028</u>	<u>\$60,007</u>

Note 5. Income Taxes

For financial reporting purposes, income before income taxes includes the following components:

	Years Ended December 31,	
	2024	2023
	(amounts in thousands)	
United States	\$(283,720)	\$(339,724)
Foreign	\$ 1,830	\$ (1,691)
Total	<u>\$(281,890)</u>	<u>\$(341,415)</u>

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The Company had no income tax expense or benefit for the years ended December 31, 2024 or 2023.

The difference between income taxes expected at the U.S. federal statutory income tax rate of 21% and the reported income tax benefit are summarized as follows:

	Years Ended December 31,	
	2024	2023
	(amounts in thousands)	
Computed statutory benefit	\$(59,197)	\$(71,697)
Change in valuation allowance	67,333	85,643
State taxes, net of federal benefit	(10,173)	(15,342)
Permanent differences	2,946	1,231
Permanent difference—warrant fair value adjustment	(1,489)	(55)
Foreign rate differential	(267)	(5)
Adjustments to foreign NOL's	117	174
Adjustments to state NOL's	(114)	(522)
Adjustments to stock-based compensation	137	671
Rate change	(68)	(40)
Other	775	(58)
Income tax benefit	<u>\$ —</u>	<u>\$ —</u>

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's deferred tax assets and liabilities are as follows:

	Years Ended December 31,	
	2024	2023
	(amounts in thousands)	
Deferred tax assets		
Net operating loss carryforward	\$ 290,514	\$ 249,229
Accrued liabilities	8,449	5,854
Stock-based compensation	5,993	4,346
Interest limitation	35,614	26,727
Research and development credits	2,842	2,842
Intangibles	3,557	3,286
Lease obligation	11,601	13,038
Contractual allowances	16,867	17,543
Research and development costs	52,140	40,911
Property and equipment basis difference	4,796	1,249
Others	1,956	1,621
Total deferred tax assets	<u>\$ 434,329</u>	<u>\$ 366,646</u>
Deferred tax liabilities		
Right of use assets	(9,033)	(10,401)
Excess tax goodwill amortization	(262)	(240)
Derivative liability fair value adjustment	(3,456)	(1,736)
Others	—	(24)
Total deferred tax liabilities	<u>(12,751)</u>	<u>(12,401)</u>
Valuation allowance	<u>\$(421,578)</u>	<u>\$(354,245)</u>
Net deferred tax asset (liability)	<u>\$ —</u>	<u>\$ —</u>

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Management assesses the available positive and negative evidence to estimate whether sufficient future taxable income will be generated to permit the use of the existing deferred tax assets. A significant piece of objective negative evidence evaluated was the cumulative loss over the three-year period ended December 31, 2024. Such objective evidence limits the ability to consider other subjective evidence, such as the Company's projections for future growth. On the basis of this evaluation, as of December 31, 2024, a valuation allowance of \$421.6 million has been recorded to recognize only the portion of the deferred tax assets that is more likely than not to be realized. The amount of the deferred tax assets considered realizable, however, could be adjusted if additional objectively verifiable positive evidence materializes in future reporting periods, such as a demonstrated operating profitability.

The valuation allowances increased \$67.3 million and \$85.6 million during the fiscal years ended December 31, 2024 and 2023, respectively, primarily due to increased U.S. federal and state net operating loss carryforwards.

The Company has gross federal, state, and foreign net operating loss carryforwards of approximately \$2,152 million which expire as follows:

(amounts in thousands)				
Expiration Year	Federal	State	Foreign	Total
2024–2030	6,338	11,630	13,736	31,704
2031–2040	209,538	289,839	1,913	501,290
2041–2045	—	516,068	—	516,068
Indefinite	\$ 934,839	\$ 168,226	\$ —	\$ 1,103,065
Total	<u>\$1,150,715</u>	<u>\$985,763</u>	<u>\$15,649</u>	<u>\$2,152,127</u>

The 2018 through 2024 net operating losses do not expire under the Tax Cuts and Jobs Act of 2017, and are subject to the 80% of taxable income limitation.

Federal tax laws impose substantial restrictions on the utilization of net operating loss and credit carryforwards in the event of an ownership change, as defined in Section 382 of the Internal Revenue Code of 1986. Accordingly, the Company's ability to utilize these carryforwards may be limited in the event of any such ownership change. We have completed a Section 382 analysis for changes in ownership through December 31, 2023 and continue to monitor for changes that could trigger a limitation. Based on this analysis, we do not expect to have any permanent limitations on the utilization of its federal net operating losses.

The Company has U.S. federal and state tax research and development credit carryforwards of \$2.8 million as of December 31, 2024 and 2023, with expiration dates through 2031 and 2026, respectively. The Company has recorded a full valuation allowance related to the credit carryforwards as of December 31, 2024.

The Company is subject to taxation in the United States and various states and foreign jurisdictions. As of December 31, 2024, all loss years remain open to examination by the taxing authorities.

The recognition and measurement of certain tax benefits includes estimates and judgment by management that inherently involve subjectivity. Changes in estimates may create volatility in the Company's effective tax rate in future periods and may be due to the expiration of various statutes of limitations, settlements with tax authorities, or acquisition of new information about particular tax positions that may require management to change its estimates.

On December 22, 2017, the Tax Cuts and Jobs Act (TCJA) created new taxes on certain foreign earnings. Namely, U.S. shareholders are now subject to current tax on global intangible low-taxed income ("GILTI") earned by specified foreign subsidiaries. Available guidance related to GILTI provides for an accounting policy election to either recognize deferred taxes for temporary basis differences expected to reverse as GILTI in future years or provide for the tax expense related to GILTI in the year the tax is incurred as a period expense. The Company has elected to recognize the current tax on GILTI as an expense in the period the tax is incurred. As of December 31, 2024, the Company has a GILTI tax inclusion of \$2.3 million. As

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

of December 31, 2023, there is no GILTI tax inclusion. As of December 31, 2024 and 2023, the Company had no undistributed earnings from its foreign subsidiaries due to losses generated since inception.

Additionally, TCJA includes a requirement to capitalize and amortize research and experimental expenditures beginning in 2022. Prior to 2022, the Company expensed these costs as incurred for tax purposes. The capitalization of the research and experimental expenditures resulted in a deferred tax asset of \$52.1 million and \$41.9 million as of December 31, 2024 and 2023, respectively, which was offset by a valuation allowance, resulting in no significant impact to income tax expense for the years ended December 31, 2024 and 2023. This deferred tax asset will be amortized over five years for the domestic costs and fifteen years for the foreign incurred costs.

The Company accounts for uncertainty in income taxes in accordance with ASC Topic 740, *Income Taxes* (“ASC 740”). Through December 31, 2024, the Company has evaluated all tax positions for which the statute of limitations remained open, and the Company has not recognized any reserve for uncertain tax positions or any penalties or interest through the income statement or balance sheet as of December 31, 2024. The Company has not recorded and does not expect any material changes to the liability for uncertain tax positions during the next 12 months.

Note 6. Redeemable Convertible Preferred Stock

Redeemable convertible preferred stock as of December 31, 2024 and 2023, consisted of the following:

(amounts in thousands, except share and per share amounts)	As of December 31, 2024				
	Shares Authorized	Shares Issued and Outstanding	Original Issue Price Per Share	Aggregate Liquidation Preference	Net Carrying Value
Series A Preferred Stock	490,000,000	485,795,293	\$0.61	\$ 296,335	\$ 709,261
Series B Preferred Stock	30,000,000	29,629,630	\$0.54	16,000	42,963
Series C Preferred Stock	142,000,000	116,200,835	\$2.76	408,715	408,715
Series D Preferred Stock	102,600,000	102,516,283	\$8.10	1,060,712	1,060,712
Total redeemable convertible preferred stock	<u>764,600,000</u>	<u>734,142,041</u>		<u>\$1,781,762</u>	<u>\$2,221,651</u>

(amounts in thousands, except share and per share amounts)	As of December 31, 2023				
	Shares Authorized	Shares Issued and Outstanding	Original Issue Price Per Share	Aggregate Liquidation Preference	Net Carrying Value
Series A Preferred Stock	490,000,000	485,795,293	\$0.61	\$ 296,335	\$ 709,261
Series B Preferred Stock	30,000,000	29,629,630	\$0.54	16,000	42,963
Series C Preferred Stock	142,000,000	116,200,835	\$2.76	381,908	381,908
Series D Preferred Stock	102,600,000	102,516,283	\$8.10	996,458	991,152
Total redeemable convertible preferred stock	<u>764,600,000</u>	<u>734,142,041</u>		<u>\$1,690,701</u>	<u>\$2,125,284</u>

The rights, preferences, and privileges of the redeemable convertible preferred stock are as follows:

Voting Rights

On any matter presented to the shareholders of the Company for their action or consideration at any meeting of shareholders of the Company (or by written consent of shareholders in lieu of meeting), each holder of outstanding shares of preferred stock will be entitled to cast the number of votes equal to the number of whole shares of common stock into which the shares of preferred stock held by such holder are convertible as of the record date for determining shareholders entitled to vote on such matter.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Dividends

All classes of preferred stock are entitled to receive dividends out of any assets legally available only when, as, and if declared by the Company's board of directors, prior to and in preference to any declaration or payment of any dividend on the common stock.

Liquidation Preference

In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Company, the holders of shares of Series C and Series D preferred stock then outstanding will be entitled to be paid out of the assets of the Company available for distribution to its shareholders at an amount per share equal to the greater of (i) the Series C and Series D original issue price, plus (A) any dividends declared but unpaid thereon and (B) a 7.0% cumulative accruing dividend, compounding annually from the date of issuance of such share of Series C and Series D preferred stock, (ii) the amount that the holder of a share of Series C and Series D preferred stock would have received upon conversion to common stock, or (iii) solely with respect to the Series D preferred stock, 1.2 times the Series D original issue price. The Series A and Series B preferred stock are then paid on a pro rata, pari passu basis an amount equal to the greater of (i) the respective original issue price plus any dividends declared but unpaid thereon, and (ii) the amount that the holder of a share of Series A or Series B preferred stock, respectively, would receive upon conversion to common stock. The remaining proceeds will be distributed to the holders of common stock.

Conversion Rights

The holders of the Company's Series A, Series B, Series C and Series D preferred stock have the right to convert their shares into a number of fully paid and nonassessable shares of common stock as determined by dividing the respective Series A, Series B, Series C and Series D preferred stock original issue price by the conversion price in effect at the time. The initial conversion price of the Series A, Series B, Series C and Series D preferred stock was \$0.61, \$0.54, \$2.76 and \$8.10, respectively, and is subject to adjustment in accordance with anti-dilution provisions provided for in the Company's Certificate of Formation. As of December 31, 2024, each share of Series A, Series B, Series C and Series D preferred stock was convertible into 0.25 share of common stock.

Redemption Rights

At any time on or after the fifth anniversary of the Series C and Series D original issue date, which will begin for Series C in August 2025 and for Series D in May 2026, upon written notice from the applicable shareholders, the Series C and Series D shares shall be redeemed by the Company at a price per share equal to the greater of (i) the original issue price plus (a) all declared but unpaid dividends thereon and (b) a 7.0% cumulative accruing dividend, compounding annually, or (ii) the fair market value as determined by an independent appraiser.

Anti-dilution

Subject to certain exceptions, the conversion price of the Series A and Series B preferred stock is subject to broad-based weighted average adjustment to prevent dilution in the event that the Company issues additional shares at a purchase price less than the then-applicable conversion price of the Series A and Series B preferred stock, respectively. Subject to certain exceptions, in the event the Company sells additional shares of stock at a price per share less than the Series C and Series D original issue price, the conversion price of the Series C preferred stock is adjusted to the lower price that the Company sells shares in such offering, and the conversion price of the Series D preferred stock is adjusted based on a broad-based weighted average anti-dilution formula. In the event the Company sells shares in an initial public offering, for less than 110.0% of the applicable Series C and Series D conversion price, then the Series C and Series D conversion price will be reduced (but never increased), concurrently with such issuance or deemed issuance, to 90.0% of the purchase price in such initial public offering.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 7. Shareholders' Equity

Common Stock

As of December 31, 2024 and 2023, 1,150,000,000 shares of common stock with a \$0.001 par value were authorized. There were 35,842,319 and 35,297,278 shares outstanding at December 31, 2024 and 2023, respectively.

Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company's shareholders. Common shareholders are entitled to receive dividends if and when declared by the Company's board of directors, subject to the preferential dividend rights of any preferred stock then outstanding. No dividends have been declared or paid by the Company since its inception.

Treasury Stock

During the years ended December 31, 2024 and 2023, the Company did not repurchase any shares of common stock. Previously repurchased common stock is shown on the consolidated balance sheets and consolidated statements of redeemable convertible preferred stock and shareholders' deficit as treasury stock. The Company had 182,500 shares of treasury stock as of December 31, 2024 and 2023. These shares have not been retired. The Company has not reissued any shares of treasury stock as of December 31, 2024 and 2023.

2020 Incentive Plan

Pursuant to the 2020 Incentive Plan (the "Plan"), the Company may grant awards of options, restricted awards, performance awards or share appreciation rights to employees, consultants, and directors of the Company. A total of 24,824,360 shares of common stock are reserved for issuance upon the exercise of all awards granted or available to be granted under the Plan as of December 31, 2024.

To the extent permitted by applicable laws or any exchange rule, any shares of common stock issued under this Plan that are issued (a) in connection with the Company's acquisition of an unaffiliated business entity, (b) to the employees of such entity, and (c) in substitution of equity incentive awards previously issued to such employees by such entity shall not reduce the number of shares of common stock available for issuance under the Plan.

The Plan provides for a repurchase feature for vested stock-based awards at the option of the Company if the employee's continuous service terminates for any reason, with or without cause, including death or disability. The repurchase shall be exercisable at a price equal to the fair market value of vested shares or, in the case of exercisable options, the fair market value of the common stock underlying such unexercised options less the aggregate exercise price of such options. The Company's repurchase lapses when the Company's common stock becomes publicly traded.

Option Activity

Under the Plan, the Company has granted incentive stock options and non-qualified stock options to its employees and other service providers (non-employees). Most of the Company's stock options vest incrementally over five years, subject to the grantee's continuous employment with the Company ("time-vesting options"). The Company recognizes compensation cost on a straight-line basis over the requisite service period for its time-vesting options. In addition to its time-vesting options, the Company has also granted stock options to certain non-employees for which vesting is tied to the grantee's performance ("performance-vesting options"). The Company evaluates whether it is probable that the performance metric will be achieved for its performance-vesting options and recognizes compensation cost on a straight-line basis over the implied service period if achievement of the performance metric is deemed probable. No option shall be exercisable after the expiration of 10 years from the date it was granted. The exercise price of each option shall be not less than 100.0% of the fair market value of the common stock subject to the option on the date the option is granted.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The following table summarizes the Company's stock option activity during the year ended December 31, 2024:

	Options Outstanding			
	Number of Options	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contract Term (in years)	Aggregate Intrinsic Value (in thousands)
Total outstanding as of December 31, 2023:	21,762,226	\$ 7.98	5.78	\$167,491
Granted	1,981,946	19.01		—
Exercised	(239,041)	6.42		2,808
Cancelled/forfeited	(720,730)	13.88		3,030
Expired	(1,014,200)	2.44		16,316
Total outstanding as of December 31, 2024	21,770,201	\$ 9.06	5.40	\$226,117
Total exercisable as of December 31, 2024	15,809,404	\$ 6.55	4.37	\$203,971
Total vested or expected to vest as of December 31, 2024	21,338,341	\$ 8.88	5.31	\$225,511

	Unvested/Vested Activity			
	Options	Weighted Average Exercise Price	Weighted Average Grant Date Fair Value	Average Remaining Life (in years)
Unvested outstanding, as of December 31, 2023	7,553,377	\$13.75	\$ 7.48	3.54
Granted	1,981,946	19.01	12.37	
Cancelled/forfeited	(574,050)	14.71	8.59	
Vested, outstanding shares	(2,302,952)	12.14	5.90	
Unvested outstanding, as of December 31, 2024	6,658,321	15.79	9.39	3.30
Early exercised unvested, end of period	662,000	\$16.20	\$10.37	

Aggregate intrinsic value represents the difference between the estimated fair value of the underlying common stock and the exercise price of outstanding, in-the-money options.

The weighted average grant date fair value of options granted during the years ended December 31, 2024 and 2023 was \$12.37 and \$9.52 per option, respectively. The total grant date fair value of options vested during the years ended December 31, 2024 and 2023 was \$13.5 million and \$10.4 million, respectively. The total intrinsic value of options exercised during the years ended December 31, 2024 and 2023 was \$2.8 million and \$6.8 million, respectively.

Cash received for exercises of stock options during the years ended December 31, 2024 and 2023 was \$1.5 million and \$1.9 million, respectively.

As of December 31, 2024, total unrecognized compensation cost related to unvested stock options was \$49.0 million. This amount is expected to be recognized as stock-based compensation expense in the consolidated statements of operations and comprehensive loss over a weighted average period of 3.3 years.

Modification to stock options

On November 9, 2021 and February 23, 2022, the Company granted stock options to certain executives that are exercisable upon vesting for 331,250 shares and 2,000,000 shares of the Company's common stock, respectively (the "Prior Stock Options"). The Prior Stock Options vested over five years. On August 11, 2022, the Company's Compensation Committee approved a modification to the Prior Stock Options, which was communicated to holders of the Prior Stock Options on September 1, 2022. The

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

modification reduced the exercise price to \$16.20 and modified the vesting conditions such that 20.0% vest upon grant, while the remainder vest over the following four years. The total number of grantees affected by this modification was twelve. The modification was not mandatory, but rather could be elected by holders of the Prior Stock Options on an individual holder basis. If the holder elected to participate, the holder's Prior Stock Options were immediately canceled, and the Company issued the holder an equivalent number of new stock options in exchange (the "New Stock Options") which could be early exercised prior to vesting. All of the holders elected to participate in the modification and exchanged their Prior Stock Options for New Stock Options. In addition, as an alternative to paying cash, holders of the New Stock Options that elected to exercise their options were able to pay for the exercise price by executing a full recourse promissory note with the Company that is secured by the holder's restricted shares that are issued upon early exercise. Five grantees elected to early exercise utilizing the promissory note.

The principal of each note is equal to the exercise price of the New Stock Options. Interest on the unpaid balance will compound annually and accrue at a fixed rate per annum equal to the mid-term applicable federal rate in effect on the issuance of the note. The maturity date of the notes is the earlier of (1) December 31, 2030 or (2) the occurrence of a change in control event, unless an acceleration event occurs sooner. An acceleration event would generally occur if required to ensure compliance with Section 402 of the Sarbanes-Oxley Act of 2002, the termination of the holder's employment, the insolvency of the holder or the breach of any warranty of the holder. The holder may elect to prepay the outstanding principal and accrued interest balance of the promissory note at any time without penalty.

In addition to the outstanding balance of the note becoming due and payable immediately, upon the occurrence of an acceleration event, if the holder defaults on payment of the note, then interest will accrue at the maximum rate permitted by applicable law. The Company will have full recourse against the holder for failure to pay the note as and when due. Such promissory notes will be secured by the restricted shares issued to the holder that are underlying the note. If the note is not repaid upon an event of default or acceleration event, the Company has the right to repurchase the restricted shares issued upon the exercise of the note for fair market value, which proceeds will apply to repayment of the note (with any remaining balance remaining due).

The Company accounted for the modification as a Type I (Probable to Probable) modification under ASC 718 that does not change the classification of the award (i.e., the New Stock Options continue to be classified within equity). The Company calculated the fair value of the Prior Stock Options and New Stock Options immediately prior to and after the modification using the Black-Scholes option pricing model. The incremental fair value was added to the original unrecognized compensation cost to arrive at the new unrecognized compensation cost, to be recognized over the remaining requisite service period.

Unvested stock received from early exercises of the New Stock Options are subject to a right of repurchase at the lesser of (i) original issuance price or (ii) then-current fair market value in the event of the employee's termination, either voluntary, or involuntary. The Company's repurchase right with respect to these shares typically lapse over four years as the shares become vested. Early exercises of stock options are not deemed to be substantive exercises for accounting purposes and accordingly, consideration received for exercises of unvested stock options is initially recorded as a liability and subsequently reclassified into shareholders' deficit as the related shares vest. As of December 31, 2024 and 2023, 662,000 and 968,000 shares from options exercised to date were subject to repurchase at a price of \$16.20 per share. Of the amount subject to repurchase for the year ended December 31, 2024 and 2023, \$5.0 million was recorded within other accrued expenses and current liabilities, respectively, and \$5.8 million and \$10.7 million was recorded within other long-term liabilities on the consolidated balance sheets, respectively. In addition, as the early exercise was performed via issuance of a promissory note, a corresponding debt amount, plus related interest income was recorded as contra-equity. The total amount presented as contra-equity as of December 31, 2024 and 2023 was \$26.5 million and \$25.7 million, respectively, which includes interest income and the impact from exercises of both the vested portion of the New Stock Options and early exercises.

Restricted Awards Activity

During the year ended December 31, 2024, the Company granted to certain of its employees restricted stock units that will be settled in shares of the Company's common stock upon vesting.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Vesting of the restricted stock units is contingent upon the Company completing either an initial public offering of its common stock or a change of control. The Company has determined that these performance conditions are not probable of being achieved, and thus has not recognized any compensation expense associated with its restricted stock units.

The following table summarizes the Company's restricted stock unit activity during the year ended December 31, 2024:

	Number of Restricted Stock Units	Weighted Average Grant Date Fair Value
Unvested as of December 31, 2023	180,125	\$14.04
Granted	590,500	\$19.44
Vested	—	\$ —
Cancelled/forfeited	(8,125)	\$19.11
Unvested as of December 31, 2024	762,500	\$18.19

The total unrecognized compensation expense related to unvested restricted stock units as of December 31, 2024 was \$13.9 million, which will be recognized upon the occurrence of an initial public offering or a change of control.

Stock-Based Compensation Expense

The Company recorded stock-based compensation expense in the consolidated statements of operations and comprehensive loss as follows:

	Years Ended December 31,	
	2024	2023
	(amounts in thousands)	
Cost of services—Molecular profiling services	\$ 1,669	\$ 1,504
Cost of services—Pharma research and development services	11	10
Selling and marketing expense	4,301	3,400
General and administrative expense	8,448	6,983
Research and development expense	4,214	3,344
Total	<u>\$18,643</u>	<u>\$15,240</u>

There was no tax benefit associated with the above stock-based compensation expense.

Valuation of Stock-Based Awards to Employees

The Company records stock-based compensation expense for stock-based awards based on the estimated fair value of the awards on the date of the grant. The fair value of the Company's restricted stock units is based on the fair value of the Company's common stock at the date of grant.

The Company estimates the fair value of stock options using a Black-Scholes option pricing model. The absence of a public market for the Company's common stock requires the Company's board of directors to estimate the fair value of its common stock for purposes of granting options and for determining stock-based compensation expense by considering several objective and subjective factors, including contemporaneous third-party valuations, actual and forecasted operating and financial results, market conditions and performance of comparable publicly traded companies, developments and milestones in the Company, the rights and preferences of common and convertible preferred stock, transactions involving the Company's common stock, and assumptions for a discount for lack of marketability. The fair value of the Company's common stock was determined in accordance with the applicable elements of the American

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Institute of Certified Public Accountants Accounting and Valuations Guide, *Valuation of Privately Held Company Equity Securities Issued as Compensation*.

The key assumptions used in determining the fair value of options granted and a summary of the methodology applied to develop each assumption are as follows:

	Years Ended December 31,	
	2024	2023
Expected volatility	62.5%–68.4%	64.3%–77.2%
Risk-free interest rate	3.7%–4.6%	3.5%–4.4%
Expected term (years)	5.97–6.60	5.90–7.50
Expected dividend rate	—%	—%
Expected forfeiture rate	8.3%–8.5%	8.4%–8.6%

Expected volatility. This is a measure of the amount by which the share price has fluctuated or is expected to fluctuate. An increase in the expected price volatility will increase the fair value of the option granted and the related compensation expense. As the Company is not publicly traded, the expected price volatility for the Company's options was determined by using an average of historical volatilities of selected industry peers deemed to be comparable to the business corresponding to the expected term of the awards.

Risk-free interest rate. The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the time of grant for U.S. Treasury notes with maturities corresponding to the expected term of the awards.

Expected term. This is the period of time over which the options granted are expected to remain outstanding and is based on the Company's estimate, taking into consideration vesting term, contractual term and historical actual lives. Options granted have a maximum term of ten years. An increase in the expected life will increase the fair value of the option granted and the related compensation expense. Due to the lack of historical share option exercise data, the Company utilizes the simplified method for determining the expected term.

Dividend rate. The Company has not made any dividend payments, nor does it have plans to pay dividends in the foreseeable future. Therefore, an expected dividend yield of zero is utilized.

Forfeitures. Forfeitures are estimated at the time of grant and reduce compensation expense ratably over the vesting period. This estimate is adjusted periodically based on the extent to which actual forfeitures differ, or are expected to differ, from the previous estimate.

Note 8. Long-Term Debt

The carrying value of debt presented within current portion of notes payable and long-term indebtedness, net of debt discounts on the consolidated balance sheets as of December 31, 2024 and 2023 includes the following components:

	As of December 31,	
	2024	2023
	(amounts in thousands)	
Term loan Initial Draw—January 18, 2023	\$200,000	\$200,000
Exit fee on term loan—January 18, 2023	2,000	2,000
Term loan Subsequent Draw—March 5, 2024	200,000	—
Exit fee on term loan—March 5, 2024	2,000	—
Less: Amortized debt discounts and financing costs ⁽¹⁾	(30,863)	(35,893)
Net debt	\$373,137	\$166,107
Compound bifurcated derivative liability	\$ 6,058	\$ 17,451

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

- (1) Includes debt discounts of \$28.3 million associated with the initial carrying value of compound bifurcated derivative liability.

Maturities of the Company's debt are expected to be as follows as of December 31, 2024:

	Amount
Years Ending December 31,	
2025 ⁽¹⁾	\$ 60,000
2026	—
2027	—
2028	340,000
2029	—

- (1) Represents 15% of the outstanding principal amount under the 2023 Term Loan Agreement, which is due on the earlier of (x) for dates prior to January 1, 2026, any date that the redemption rights in respect of our Series C preferred stock or Series D preferred stock are or may become exercisable within 90 days following such date, or (y) January 1, 2026 or the first date thereafter if, as of such date, the redemption rights in respect of our Series C preferred stock or Series D preferred stock are or may become exercisable on or prior to the date that is six months after the maturity date. The Series C preferred stock redemption rights may be exercised on or after August 14, 2025. All outstanding shares of our Series C preferred stock and Series D preferred stock will convert into shares of common stock as part of the Preferred Stock Conversion and any redemption rights thereunder will terminate in connection with the completion of this offering and consequently, the payments disclosed herein would not be applicable.

Term Loan Refinancing

On September 21, 2018, the Company entered into a secured term loan agreement (the "Original Term Loan Agreement") with Sixth Street Specialty Lending, Inc. and Barnett Debt Holdings, LLC (collectively, the "Original Term Loan Lenders"), which provided the Company with an initial term loan of \$50.0 million (the "2018 Term Loan") and a delayed term loan draw option of \$50.0 million, which the Company drew down in full on October 4, 2019 (the "2019 Term Loan"). On April 2, 2020, the Company amended the Original Term Loan Agreement (the "Amended Term Loan Agreement") to obtain additional term loan proceeds of \$75.0 million (the "2020 Term Loan" and collectively with the 2018 Term Loan and the 2019 Term Loan, the "Original Term Loans").

On January 18, 2023, the Company entered into the New Term Loan Agreement with OrbiMed Royalty & Credit Opportunities III, LP, OrbiMed Royalty & Credit Opportunities IV, LP (collectively, "OrbiMed"), and Braidwell Transaction Holdings LLC ("Braidwell", and collectively with OrbiMed, the "New Term Loan Lenders"). Pursuant to the New Term Loan Agreement, the Company issued senior, secured promissory notes by which the New Term Loan Lenders agree to lend the Company up to an aggregate principal amount of \$400.0 million, \$200.0 million of which was received by the Company upon issuance (the "Initial Draw"), and the remaining \$200.0 million was received by the Company in March 2024 (the "Delayed Draw"). Net cash proceeds from the 2023 Term Loan were \$200.0 million and \$187.0 million after deducting customary debt discounts and debt issuance costs for the years ended December 31, 2024 and 2023, respectively. The net cash proceeds in 2023 from the 2023 Term Loan were used to repay in full the Original Term Loans (with an aggregate principal amount of \$175.0 million), including a prepayment premium of \$5.0 million and accrued and unpaid interest of \$1.0 million. A loss on debt extinguishment of \$10.9 million, reflecting the difference between the cash paid to settle the Original Term Loans and the net carrying amounts of the Original Term Loans, was recognized in other expense, net on the consolidated statements of operations and comprehensive loss for the year ended December 31, 2023. As of December 31, 2023 and onwards, the Company has no continuing obligations associated with the Original Term Loans.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Until the earlier of December 31, 2024 or the date on which the 2024 Term Loan amount was fully drawn, which occurred on March 5, 2024, the undrawn balance of the New Term Loan Commitment was subject to a fee of 0.5% per annum. The outstanding principal amount of the 2023 Term Loan is due and payable on January 18, 2028. If an event of default occurs and is continuing, the New Term Loan Lenders may declare all amounts outstanding under the New Term Loan Agreement to be immediately due and payable. A final payment exit fee equal to 1.0% of the amount funded under the New Term Loan Agreement is due upon prepayment or maturity. Amounts borrowed pursuant to the New Term Loan Agreement may be prepaid at any time. Upon prepayment, the Company is subject to a prepayment penalty based on the timing of repayment.

The 2023 Term Loan bears interest at a rate per annum equal to a fixed margin of 6.5% plus the greater of (a) forward-looking three-month secured overnight financing rate ("SOFR") and (b) 2.5%. In the event of default, the fixed margin shall increase by 3.0% per annum. As of December 31, 2024, the interest rate was 11.1%. Regular quarterly payments are interest-only for the 60-month term of the New Term Loan Agreement, with the principal due at maturity. The effective interest rate for the Initial Draw of the 2023 Term Loan is 17.0%, and the effective interest rate for the Delayed Draw of the 2023 Term Loan is 12.0%.

The Company's obligations under the New Term Loan Agreement are secured by a first lien security interest in substantially all of the assets of the Company and its subsidiaries. The New Term Loan Agreement contains certain customary representations and warranties, affirmative and negative covenants, financial covenants, and events of default applicable to the Company and its subsidiaries. Additional covenants include those restricting dispositions, fundamental changes to its business, mergers or acquisitions, indebtedness, encumbrances, distributions, investments, transactions with affiliates and subordinated debt. At December 31, 2024, the Company is in compliance with all covenants.

The Company identified multiple embedded derivatives that require bifurcation from the 2023 Term Loan. They are separately accounted for in the consolidated financial statements as one compound derivative liability. Those embedded features include various contingent prepayment and compensatory payment features as well as interest rate increases upon an event of default.

Convertible Loan Conversion

In connection with the Original Term Loan Agreement dated September 21, 2018, the Company issued \$50.0 million of convertible notes to the Original Term Loan Lenders pursuant to a convertible loan agreement (the "Convertible Loan Agreement") with interest accruing at a rate of 8.0% per annum (the "2018 Convertible Loan"). The Original Term Loan Lenders had the option on each interest payment date to receive interest in cash or in kind in the form of additional term loan principal issued pursuant to the terms of the Convertible Loan Agreement. As of December 31, 2022, the effective interest rate on the 2018 Convertible Loan was 9.4%. Following the amendment to the Convertible Loan Agreement in 2020, the Original Term Loan Lenders obtained the right to convert all or a portion of the principal amount of the 2018 Convertible Loan and any accrued but unpaid interest thereon (the "Convertible Amount") into either Series C preferred stock or common stock at a conversion price of \$1.61 or \$6.44 per share (subject to certain anti-dilution adjustments), respectively. However, the maximum aggregate Convertible Amount that the Original Term Loan Lenders may convert without the Company's consent is \$50.0 million.

On September 20, 2023, the Original Term Loan Lenders exercised the conversion right and converted the maximum \$50.0 million Convertible Amount into 31,055,901 shares of Series C preferred stock. In connection with the conversion of the 2018 Convertible Loan, the Company also paid cash of \$3.0 million to the Original Term Loan Lenders in settlement of accrued but unpaid interest on the Convertible Loan.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Interest Expense

The components of interest expense associated with the Company's long-term indebtedness, excluding finance leases, are as follows:

	Years Ended December 31,	
	2024	2023
	(amounts in thousands)	
Debt discount amortization	\$ 7,052	\$ 5,378
Interest expense	42,938	26,157
Interest expense on long-term indebtedness, excluding finance leases	<u>\$49,990</u>	<u>\$31,535</u>

Warrant Liability

As part of the Original Term Loan Agreement, the Company issued 13,694,623 warrants (the "2018 Warrants"). In connection with the amendment to the Original Term Loan Agreement in 2020, the Company issued an additional 11,399,814 warrants (the "2020 Warrants") and amended the 2018 Warrants. Furthermore, these amendments also permit the exercise of both the 2018 Warrants and 2020 Warrants into Series C preferred stock or common stock at the option of the holder. The 2018 Warrants are exercisable into Series C preferred stock at a price of \$1.61 and into common stock at a price of \$6.44. The 2020 Warrants are exercisable into Series C preferred stock at a price of \$1.93 and into common stock at a price of \$7.73. As a result of the amendment to permit exercise of the warrants into redeemable preferred stock, the warrants are classified as a liability pursuant to the guidance in ASC 480. Therefore, the warrants are reported at fair value within warrant and derivative liabilities on the consolidated balance sheets, with changes in fair value reported within changes in fair value of financial instruments on the consolidated statements of operations and comprehensive loss.

The following table reflects the changes in fair values associated with these warrants.

	2018 Warrants	2020 Warrants
Warrants granted	13,694,623	11,399,814
Exercise price	\$1.61	\$1.93
Exercise period	Earlier of 7 years from the date of issuance, or immediately after closing IPO	
Fair value at date of issuance	\$0.8 million	\$7.9 million
	(amounts in thousands)	
Fair value at December 31, 2022	\$54,498	\$44,498
Increase / (decrease) in fair value	42	(305)
Fair value at December 31, 2023	\$54,540	\$44,193
Decrease in fair value	(2,911)	(4,180)
Fair value at December 31, 2024	<u>\$51,629</u>	<u>\$40,013</u>

Note 9. Leases

The Company enters into various building leases for office, lab and other uses. Additionally, certain of the Company's arrangements to utilize data centers represent a lease. These leases are generally considered operating leases. The Company is obligated to make total fixed payments over the lease terms. Some of these arrangements include options to extend the leases. The Company determined that given the length of time between lease commencement and the renewal period, and the uncertainty of business and market conditions in the future, it is not reasonably certain that the renewal options will be exercised.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The Company has also entered into various information technology equipment leases. Certain of these leases are classified as operating leases and others are classified as finance leases, based on the terms of each lease arrangement.

Lease assets and liabilities are reflected in the Company's consolidated balance sheets as follows:

Leases	Consolidated balance sheet line item	As of December 31,	
		2024	2023
		(amounts in thousands)	
Assets			
Operating leases	Other assets	\$34,950	\$40,426
Finance leases	Property and equipment, net	40	123
Total lease assets		<u>\$34,990</u>	<u>\$40,549</u>
Liabilities			
Current			
Operating leases	Accrued expenses and other current liabilities	\$ 6,080	\$ 6,420
Finance leases	Current portion of notes payable	90	167
Total current lease liabilities		<u>\$ 6,170</u>	<u>\$ 6,587</u>
Non-current			
Operating leases	Other long-term liabilities	<u>\$38,651</u>	<u>\$44,099</u>
Finance leases	Long-term indebtedness, net of debt discounts	243	315
Total non-current lease liabilities		<u>38,894</u>	<u>44,414</u>
Total lease liabilities		<u>\$45,064</u>	<u>\$51,001</u>

Total lease cost reflected in the consolidated statements of operations and other comprehensive loss were as follows:

Lease cost	Consolidated statement of operations and comprehensive loss line item	As of December 31,	
		2024	2023
		(amounts in thousands)	
Operating lease cost	Cost of services—Molecular profiling services	\$ 1,607	\$1,935
Operating lease cost	Cost of services—Pharma research and development services	40	13
Operating lease cost	General and administrative expense	6,738	8,037
Operating lease cost	Research and development expense	2,416	2,116
Finance lease cost:			
Amortization of ROU assets	General and administrative expense	128	500
Interest on lease liabilities	Interest expense	37	78
Total finance lease cost		165.22463	578

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The table below presents additional information related to the Company's leases.

	As of December 31,	
	2024	2023
Weighted average remaining lease terms		
Operating leases	8.04 years	8.43 years
Finance leases	3.28 years	3.49 years
Weighted average discount rate		
Operating leases	11.3%	11.3%
Finance leases	10.0%	10.1%

The Company was not party to any short-term leases, and variable lease costs were immaterial for the years ended December 31, 2024 and 2023. As of December 31, 2024 and 2023, the Company does not have any additional operating and finance leases that have not yet commenced.

The following table sets forth by year, maturities of operating and finance lease liabilities as of December 31, 2024:

(amounts in thousands)	Operating Leases	Finance Leases	Total
Years Ending December 31,			
2025	\$ 10,718	\$ 117	\$ 10,835
2026	10,071	118	10,189
2027	7,082	117	7,199
2028	6,461	35	6,496
2029	6,309	—	6,309
Thereafter	28,671	—	28,671
Total lease payments	69,312	388	69,699
Less imputed interest	(24,581)	(55)	(24,635)
Present value of lease liabilities	<u>\$ 44,731</u>	<u>\$ 333</u>	<u>\$ 45,064</u>

Note 10. Commitments and Contingencies**Purchase Obligations**

The Company enters into various supply agreements that contains purchase commitments. Most of the commitments are based on a binding forecast for an agreed-upon period, which is 12-month or less. Future minimum purchase commitments under such agreements amount to \$7.7 million, of which all are due in 2025. The total amount of supplies purchased during 2024 under such agreements was \$32.3 million.

Additionally, in 2022, the Company entered into an arrangement for cloud computing services with non-cancellable purchase commitments for three years. The agreement was subsequently amended in 2024. For the years ended December 31, 2024 and 2023, the Company purchased cloud computing services of \$9.9 million and \$3.0 million, respectively, related to non-cancelable arrangements. Under the agreement, the Company has purchase obligations of \$11.3 million, \$12.4 million and \$13.7 million for years ending December 31, 2025, 2026 and 2027.

Corporate Liability and Insurance

The Company maintains professional liability, general liability, and other customary insurance on a claims-made basis in amounts deemed appropriate by the Company's management based upon historical

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

claims and the nature and risks of the Company. The Company's business may subject the Company to litigation and liability for damages. The Company believes that current insurance protection is adequate for present business operations, but there can be no assurance that the Company will be able to maintain professional and general liability insurance coverage in the future or that such insurance coverage will be available on acceptable terms or adequate to cover any or all potential product or professional liability claims. A successful liability claim in excess of insurance coverage could have a material adverse effect on the Company.

Litigation

During the ordinary course of business, the Company has become and may in the future become subject to pending and threatened legal and regulatory actions and proceedings. While it is not feasible to predict or determine the ultimate outcome of these matters, the Company believes that none of its current legal proceedings will have a material adverse effect on its financial position, results of operations, or cash flows for years ended December 31, 2024 and 2023.

Note 11. Related Parties

The Company's officers and directors have ownership interests in certain vendors providing services to the Company. During the years ended December 31, 2024 and 2023, the Company made payments to these entities for services and expenses for \$1.8 million and \$2.1 million, respectively.

Note 12. Net Loss Per Share Attributable to Common shareholders

The following table sets forth the computation of the basic and diluted net loss per share attributable to common shareholders:

(amounts in thousands, except share and per share data)	Years Ended December 31,	
	2024	2023
Net loss	\$ (281,890)	\$ (341,415)
Adjustments of redeemable convertible preferred stock to redemption value	(96,367)	(121,112)
Net loss attributable to common shareholders	<u>\$ (378,257)</u>	<u>\$ (462,527)</u>
Net loss per share attributable to common shareholders, basic and diluted	\$ (10.66)	\$ (13.24)
Weighted-average shares used in computing net loss per share attributable to common shareholders, basic and diluted	35,496,832	34,942,691

The following common stock equivalents were excluded from the calculation of diluted net loss per share attributable to common shareholders for the periods presented as they had an anti-dilutive effect:

	Years Ended December 31,	
	2024	2023
Series A preferred stock	121,448,823	121,448,823
Series B preferred stock	7,407,408	7,407,408
Series C preferred stock	29,050,209	29,050,209
Series D preferred stock	25,629,071	25,629,071
Outstanding warrants	6,273,609	6,273,609
Outstanding stock options	21,770,201	21,762,226
Unvested shares subject to repurchase	662,000	968,000
Total	<u>212,421,321</u>	<u>212,539,346</u>

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 13. Segment and Geographic Information

The Company operates as a single operating segment. An operating segment is defined as a component of an entity for which discrete financial information is available and regularly reviewed by the entity's chief operating decision maker ("CODM") in deciding how to allocate resources and in assessing performance. The Company's CODM, its Chairman and Chief Executive Officer, manages the Company's operations on a consolidated basis for the purposes of allocating resources, making operating decisions and evaluating financial performance.

Net loss as reported on the consolidated statements of operations and comprehensive loss is used by the CODM to assess segment performance against management budgets and prior period operating results for the purpose of making results-driven decisions about organizational resource allocation.

Segment revenues are derived from molecular profiling, strategic data, and research services that are delivered to the Company's biopharmaceutical and clinical customers, who are predominantly located in the United States. The Company provides these services primarily by leveraging the Company's proprietary technologies and clinico-genomic database, which are core to the Company's operations and are deployed similarly across the service offerings.

The table below is a summary of the segment profit or loss, including significant segment expenses:

	Years Ended December 31,	
	2024	2023
	(amounts in thousands)	
Revenue	\$ 412,260	\$ 306,128
Less:		
Cost of services—Molecular profiling services	223,075	207,509
Cost of services—Pharma research and development services	10,403	9,309
Selling and marketing expense	152,602	142,925
General and administrative expense	169,386	149,053
Research and development expense	113,916	116,883
Interest income	7,122	11,258
Interest expense	(50,025)	(31,610)
Changes in fair value of financial instruments	18,484	11,094
Other expense, net	(349)	(12,606)
Segment and consolidated net loss	<u><u>\$ (281,890)</u></u>	<u><u>\$ (341,415)</u></u>

The following table sets forth the Company's revenue by geographic areas based on the customer's location:

	Years Ended December 31,	
	2024	2023
	(amounts in thousands)	
United States	\$401,836	\$293,408
International	10,424	12,720
Total revenue	<u><u>\$412,260</u></u>	<u><u>\$306,128</u></u>

No single country outside of the United States accounted for more than 10.0% of total revenue during each of the years ended December 31, 2024 and 2023. As of December 31, 2024 and 2023, approximately 99.0% of the Company's total assets are located in the United States.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 14. Employee Benefit Plan

The Company sponsors a 401(k) plan, and pursuant to its terms, eligible employees can elect to contribute to the 401(k) plan, subject to certain limitations, up to the lesser of the statutory maximum or 100.0% of eligible compensation on a pre-tax basis. For the years ended December 31, 2024 and 2023, the Company contributed \$8.0 million and \$6.8 million, respectively, to match employee contributions as permitted by the plan. The Company pays the administrative costs for the plan.

Note 15. Subsequent Events

On March 3, 2025, five grantees of the New Stock Options (see Note 7), who had previously elected to early exercise utilizing the promissory note, signed agreements to repay their notes, plus accrued interest in the form of shares of our common stock. The number of shares of common stock used in the payoff was determined using the fair value of the Company's common stock at the time of the repayment.

On March 25, 2025, in connection with the financing described above, the Company amended the terms of its certificate of formation to provide that the Series C redemption rights would not be exercisable until March 31, 2026 (from August 2025) and increased the original issue price and conversion price of its Series C convertible preferred stock used to calculate the conversion ratio of Series C preferred stock into common stock in connection with the initial public offering from \$11.04 to \$18.32 per share.

On April 1, 2025, the Company closed a private financing in which it issued a combination of senior convertible notes (the "2025 Convertible Notes"), Series E convertible preferred stock and Series F convertible preferred stock, for an aggregate of \$167.7 million. The 2025 Convertible Notes have an aggregate principal amount of \$30.0 million. The 2025 Convertible Notes accrue interest at a rate of 8% per annum, payable quarterly in cash, and mature on January 1, 2026. The Company issued 12,345,674 shares of Series E convertible preferred stock with a purchase price of \$8.10 per share, for aggregate proceeds of \$100.0 million. The Company also issued 4,657,401 shares of Series F convertible preferred stock with a purchase price of \$8.10 per share, for aggregate proceeds of \$37.7 million. In connection with this financing, the Company also issued warrants to acquire shares of common stock to the holders of the 2025 Convertible Notes. These warrants are not initially exercisable for any shares of common stock, but such warrants become exercisable for a specified dollar value of shares on a monthly basis commencing on June 1, 2025 if we have not completed an initial public offering by such date. Any exercisable portion of the warrants will be automatically exercised prior to the closing of the initial public offering and such warrants will terminate upon the closing of the offering.

Immediately prior to and in connection with the completion of the initial public offering, the 2025 Convertible Notes, Series E convertible preferred stock and Series F convertible preferred stock (plus an 8% accretion in connection with the preferred stocks) will convert into common stock at a price equal to 70% of the initial public offering price per share.

As further disclosed in Note 2, the Company effected a one-for-four reverse stock split of its common stock. The reverse stock split was effective June 1, 2025.

There were no other significant subsequent events identified through the date that the consolidated financial statements were issued, that could impact the financial statements.

CONDENSED CONSOLIDATED BALANCE SHEETS (UNAUDITED)

(amounts in thousands, except share data)	As of March 31, 2025	As of December 31, 2024
Assets		
Current assets:		
Cash, cash equivalents, and restricted cash	\$ 32,704	\$ 65,442
Short-term marketable securities	2,225	2,201
Accounts receivable	80,174	88,244
Supplies	36,552	39,572
Prepaid expenses and other current assets	19,578	20,270
Total current assets	171,233	215,729
Property and equipment, net	61,651	67,817
Goodwill	19,344	19,344
Other assets	39,355	40,844
Total assets	\$ 291,583	\$ 343,734
Liabilities, Redeemable Convertible Preferred Stock, and Shareholders' Deficit		
Current liabilities:		
Accounts payable	\$ 24,226	\$ 27,791
Accrued expenses and other current liabilities	78,235	77,542
Current portion of indebtedness	60,093	60,090
Total current liabilities	162,554	165,423
Long-term indebtedness, net of debt discounts	316,643	319,438
Warrant liabilities	128,691	91,642
Other long-term liabilities	37,447	44,418
Total liabilities	645,335	620,921
Commitments and contingencies (see note 9)		
Redeemable convertible preferred stock:		
Series A preferred stock, par value \$0.001: 490,000,000 shares authorized as of March 31, 2025 and December 31, 2024; 485,795,293 shares issued and outstanding as of March 31, 2025 and December 31, 2024; and \$296,335 aggregate liquidation preference as of March 31, 2025 and December 31, 2024	709,261	709,261
Series B preferred stock, par value \$0.001: 30,000,000 shares authorized as of March 31, 2025 and December 31, 2024; 29,629,630 shares issued and outstanding as of March 31, 2025 and December 31, 2024; and \$16,000 aggregate liquidation preference as of March 31, 2025 and December 31, 2024	42,963	42,963
Series C preferred stock, par value \$0.001: 142,000,000 shares authorized as of March 31, 2025 and December 31, 2024; 116,200,835 shares issued and outstanding as of March 31, 2025 and December 31, 2024; and \$415,616 and \$408,715 aggregate liquidation preference as of March 31, 2025 and December 31, 2024, respectively	415,616	408,715
Series D preferred stock, par value \$0.001: 102,600,000 shares authorized as of March 31, 2025 and December 31, 2024; 102,516,283 shares issued and outstanding as of March 31, 2025 and December 31, 2024; and \$1,078,273 and \$1,060,712 aggregate liquidation preference as of March 31, 2025 and December 31, 2024, respectively	1,078,273	1,060,712
Total redeemable convertible preferred stock	2,246,113	2,221,651
Shareholders' deficit:		
Common stock \$0.001 par value; 1,173,000,000 and 1,150,000,000 shares authorized as of March 31, 2025 and December 31, 2024, respectively; 36,858,169 and 36,686,819 shares issued as of March 31, 2025 and December 31, 2024, respectively; 35,237,531 and 36,504,319 shares outstanding as of March 31, 2025 and December 31, 2024, respectively; shares issued and outstanding include 43,603 and 662,000 unvested shares subject to repurchase as of March 31, 2025 and December 31, 2024, respectively	38	38
Treasury stock at cost, 1,620,638 and 182,500 shares of common stock as of March 31, 2025 and December 31, 2024, respectively	(16,917)	(330)
Additional paid-in capital	—	—
Related party promissory note receivable (see note 7)	—	(26,456)
Accumulated deficit	(2,583,231)	(2,472,300)
Accumulated other comprehensive income	245	210
Total shareholders' deficit	(2,599,865)	(2,498,838)
Total liabilities, redeemable convertible preferred stock, and shareholders' deficit	\$ 291,583	\$ 343,734

The accompanying notes are an integral part of these condensed consolidated financial statements

**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND
COMPREHENSIVE LOSS (UNAUDITED)**

(amounts in thousands, except share and per share data)	Three Months Ended March 31,	
	2025	2024
Revenue:		
Molecular profiling services	\$ 114,081	\$ 73,233
Pharma research and development services	6,834	7,444
Total revenue	120,915	80,677
Costs and operating expenses:		
Cost of Services – Molecular Profiling Services	60,894	52,894
Cost of Services – Pharma Research and Development Services	2,958	1,669
Selling and marketing expense	39,829	39,609
General and administrative expense (includes related party amounts of \$515 and \$480, for the three months ended March 31, 2025 and 2024, respectively)	52,119	44,354
Research and development expense	23,066	34,376
Total costs and operating expenses	178,867	172,902
Loss from operations	(57,952)	(92,225)
Other income (expense), net:		
Interest income	503	1,768
Interest expense	(12,782)	(9,290)
Changes in fair value of financial instruments	(32,333)	(11,064)
Other expense, net	(17)	(219)
Total other expense, net	(44,629)	(18,804)
Loss before income taxes and provision for income taxes	(102,581)	(111,028)
Provision for income taxes	—	—
Net loss	(102,581)	(111,028)
Other comprehensive (loss) income, net of tax:		
Unrealized gain on available-for-sale securities	—	7
Foreign currency translation adjustments	35	8
Comprehensive loss	(102,546)	(111,013)
Net loss attributable to common shareholders:		
Net loss	(102,581)	(111,028)
Adjustments of redeemable convertible preferred stock to redemption value	(24,462)	(23,113)
Net loss attributable to common shareholders	\$ (127,043)	\$ (134,141)
Net loss per share attributable to common shareholders, basic and diluted	\$ (3.57)	\$ (3.80)
Weighted-average shares used in computing net loss per share attributable to common shareholders, basic and diluted	35,623,042	35,313,037

The accompanying notes are an integral part of these condensed consolidated financial statements

**CONDENSED CONSOLIDATED STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED
STOCK AND SHAREHOLDERS' DEFICIT (UNAUDITED)**

(amounts in thousands, except share data)	Redeemable Convertible Preferred Stock		Common Stock		Treasury Stock		Additional Paid-In Capital	Related Party Promissory Note Receivable	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Shareholders' Deficit
	Shares	Amount	Shares	Amount	Shares	Amount					
Balances at December 31, 2023	<u>734,142,041</u>	<u>\$2,125,284</u>	<u>35,297,278</u>	<u>\$38</u>	<u>182,500</u>	<u>\$ (330)</u>	<u>\$ —</u>	<u>\$(25,701)</u>	<u>\$(2,119,175)</u>	<u>\$218</u>	<u>\$(2,144,950)</u>
Stock-based compensation	—	—	—	—	—	—	4,458	—	—	—	4,458
Issuance of common stock upon exercise of stock options	—	—	39,304	—	—	—	210	—	—	—	210
Interest income from related party promissory notes	—	—	—	—	—	—	—	(186)	—	—	(186)
Adjustment of redeemable convertible preferred Series C and Series D to redemption value	—	23,113	—	—	—	—	(4,668)	—	(18,445)	—	(23,113)
Other comprehensive loss	—	—	—	—	—	—	—	—	—	15	15
Net loss	—	—	—	—	—	—	—	—	(111,028)	—	(111,028)
Balances at March 31, 2024	<u>734,142,041</u>	<u>\$2,148,397</u>	<u>35,336,582</u>	<u>\$38</u>	<u>182,500</u>	<u>\$ (330)</u>	<u>\$ —</u>	<u>\$(25,887)</u>	<u>\$(2,248,648)</u>	<u>\$233</u>	<u>\$(2,274,594)</u>
Balances at December 31, 2024	<u>734,142,041</u>	<u>\$2,221,651</u>	<u>35,842,319</u>	<u>\$38</u>	<u>182,500</u>	<u>\$ (330)</u>	<u>\$ —</u>	<u>\$(26,456)</u>	<u>\$(2,472,299)</u>	<u>\$210</u>	<u>\$(2,498,837)</u>
Stock-based compensation	—	—	—	—	—	—	14,691	—	—	—	14,691
Issuance of common stock upon exercise of stock options	—	—	833,350	—	—	—	1,433	—	—	—	1,433
Interest income from related party promissory notes	—	—	—	—	—	—	—	(128)	—	—	(128)
Payoff of related party promissory notes	—	—	—	—	—	—	—	26,584	—	—	26,584
Repurchases of common stock	—	—	(1,438,138)	—	1,438,138	(16,587)	—	—	—	—	(16,587)
Adjustment of redeemable convertible preferred Series C and Series D to redemption value	—	24,462	—	—	—	—	(16,110)	—	(8,352)	—	(24,462)
Other comprehensive loss	—	—	—	—	—	—	(14)	—	—	35	21
Net loss	—	—	—	—	—	—	—	—	(102,581)	—	(102,581)
Balances at March 31, 2025	<u>734,142,041</u>	<u>\$2,246,113</u>	<u>35,237,531</u>	<u>\$38</u>	<u>1,620,638</u>	<u>\$(16,917)</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$(2,583,231)</u>	<u>\$245</u>	<u>\$(2,599,865)</u>

The accompanying notes are an integral part of these condensed consolidated financial statements

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED)

(amounts in thousands)	Three Months Ended March 31,	
	2025	2024
Cash flows from operating activities		
Net loss	\$(102,581)	\$(111,028)
<i>Adjustments to reconcile net loss to net cash used in operating activities:</i>		
Depreciation and amortization	7,045	17,705
Stock-based compensation expense	14,691	4,458
Non-cash operating lease expense	1,452	1,551
Amortization of debt discounts	1,945	1,590
Changes in fair value of financial instruments	32,333	11,064
Other	456	1,919
<i>Changes in operating assets and liabilities:</i>		
Accounts receivable	7,913	(2,378)
Supplies	2,061	4,024
Prepaid expenses and other current assets	2,470	(81)
Other assets	36	326
Accounts payable	(1,739)	(2,778)
Accrued expenses and other liabilities	2,580	(297)
Net cash used in operating activities	<u>(31,338)</u>	<u>(73,925)</u>
Cash flows from investing activities		
Maturities of marketable securities	—	61,376
Purchases of property and equipment	(2,689)	(1,738)
Net cash provided by (used in) investing activities	<u>(2,689)</u>	<u>59,638</u>
Cash flows from financing activities		
Payments made on finance lease obligations	(22)	(80)
Proceeds from exercise of stock options	1,434	210
Payment of deferred offering costs	(105)	—
Proceeds from the 2023 term loan, net of issuance costs	—	199,978
Purchase of treasury stock	(22)	—
Net cash provided by financing activities	<u>1,285</u>	<u>200,108</u>
Effect of exchange rate changes on cash, cash equivalents, and restricted cash	<u>4</u>	<u>1</u>
Net increase (decrease) in cash, cash equivalents, and restricted cash	(32,738)	185,822
Cash, cash equivalents, and restricted cash at beginning of year	<u>68,028</u>	<u>60,007</u>
Cash, cash equivalents, and restricted cash at end of period	<u>\$ 35,290</u>	<u>\$ 245,829</u>
Supplemental disclosure of cash flow information		
Interest paid	\$ 10,829	\$ 6,080
Supplemental disclosure of non-cash activity		
Cash paid for amounts included in the measurement of lease liabilities		
Operating cash flow used for operating leases	\$ 2,847	\$ 2,853
Operating cash flow used for finance leases	\$ 7	\$ 11
Financing cash flow used for finance leases	\$ 22	\$ 80
Property and equipment included in accounts payable and accrued liabilities	\$ 242	\$ 2,413
Deferred offering costs, accrued but not paid	\$ 4,420	\$ 1,989

The accompanying notes are an integral part of these condensed consolidated financial statements

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Note 1. Nature of the Business

Caris Life Sciences, Inc. (the “Company” or “Caris”) is a patient-centric, next-generation artificial intelligence (“AI”) TechBio company and precision medicine pioneer. The Company commercializes and develops innovative solutions to transform healthcare through the use of comprehensive molecular information, AI, and machine learning (“ML”) algorithms.

The Company’s current molecular profiling services portfolio is focused on oncology and consists of MI Profile, a tissue-based molecular profiling solution, and Caris Assure, a novel, universal blood-based molecular profiling solution, with the aim to address the entire continuum of cancer treatment.

The Company also collaborates with biopharmaceutical companies to provide commercial services and prospective and retrospective testing, along with data and bioinformatics collaborations and novel target identification and discovery solutions.

The Company was incorporated under the laws of the Cayman Islands in November 2011 (Caris Life Sciences, Ltd.) and re-domiciled to be incorporated in Texas in July 2020 (Caris Life Sciences, Inc.) and is headquartered in Irving, Texas. The Company also has locations in Phoenix, Arizona; New York, New York; Cambridge, Massachusetts; Basel, Switzerland; and Tokyo, Japan.

Liquidity and Going Concern

As of March 31, 2025, the Company’s cash and cash equivalents balance was approximately \$31.2 million, and the short-term investments balance was \$2.2 million, and the Company had a 2023 Term Loan (see Note 8) outstanding with a balance of \$400.0 million.

In 2025, the Company issued the 2025 Convertible Notes in the amount of \$30.0 million. In connection with the Company’s Series C redeemable convertible preferred stock, the 2023 Term Loan and the 2025 Convertible Notes, the following payments may become due within 12 months of the date of the issuance of the condensed consolidated financial statements if the Company has not completed an initial public offering raising at least \$100.0 million in gross proceeds prior to such due dates:

1. The Series C redemption rights will become exercisable on March 31, 2026;
2. The Company will be required to make a one-time acceleration payment on December 31, 2025 in an amount equal to 15% of the outstanding principal amount under the 2023 Term Loan (or \$60.0 million based on the principal amount currently outstanding) together with any applicable repayment premium and exit fee as described in the Term Loan agreement on such date; and
3. The 2025 Convertible Notes of \$30.0 million will come due on January 1, 2026.

If these payments become due, the Company’s existing cash resources and projected operating cash flows may not be sufficient to repay these amounts and continue to fund operating activities for at least the next 12 months from the issuance of the condensed consolidated financial statements. These conditions raise substantial doubt as to the Company’s ability to continue as a going concern.

Management intends to raise additional funding through an initial public offering raising at least \$100.0 million in gross proceeds which would eliminate the requirement to make the one-time acceleration payment related to the 2023 Term Loan. Further, the initial public offering would cause the Series C redeemable convertible preferred stock and the 2025 Convertible Note to convert to common stock and thereby not be subject to redemption and repayment upon maturity on March 31, 2026 and January 1, 2026, respectively. Management may seek alternative private financing through additional debt or equity offerings that will fulfill its operating, capital and debt requirements for at least 12 months from the date of the issuance of the condensed consolidated financial statements. However, the Company may not be able to complete such an initial public offering or otherwise secure such financing in a timely manner or on favorable terms, if at all.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 2. Summary of Significant Accounting Policies and Estimates

Basis of Financial Statement Presentation

The condensed consolidated financial statements include the accounts of Caris and its wholly owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

The Company's condensed consolidated financial statements have been prepared in conformity with generally accepted accounting principles in the United States ("GAAP"). Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASUs") of the Financial Accounting Standards Board ("FASB").

Unaudited Interim Consolidated Financial Information

The unaudited condensed consolidated financial statements have been prepared on the same basis as the annual consolidated financial statements and reflect, in the opinion of management, all adjustments of a normal and recurring nature that are necessary for the fair statement of the Company's financial position as of March 31, 2025 and its results of operations and cash flows for the three months ended March 31, 2025 and 2024. The results of operations for the three months ended March 31, 2025 are not necessarily indicative of the results to be expected for the year ending December 31, 2025, or for any other future annual or interim period. The condensed consolidated balance sheet as of December 31, 2024 included herein was derived from the audited financial statements as of that date. Certain information and footnote disclosures normally included in consolidated financial statements prepared in accordance with GAAP have been condensed or omitted from these unaudited condensed consolidated financial statements.

Reverse Stock Split

Effective June 1, 2025, the Company's Board approved a one-for-four reverse stock split of the Company's common stock. This also resulted in an adjustment to the conversion price for each series of the Company's convertible preferred stock, to the underlying number of shares outstanding with respect to the restricted stock units, and to the exercise prices and number of shares of common stock underlying the outstanding stock options. Accordingly, all share and per share information relating to common stock for all periods presented in the accompanying consolidated financial statements and notes thereto have been retroactively adjusted. The shares of common stock retain a par value of \$0.001 per share. Accordingly, an amount equal to the excess was reclassified from common stock to additional paid-in capital or, in the absence of additional paid-in-capital, accumulated deficit.

Use of Estimates

The preparation of the condensed consolidated financial statements in conformity with GAAP in the United States requires the use of estimates and assumptions about future events that affect the amounts reported in the Company's condensed consolidated financial statements and related notes, including the amounts of assets and liabilities, the disclosure of contingent liabilities at the date of the condensed consolidated financial statements, and the reported amounts of revenues and expenses during the periods reported.

Significant estimates and assumptions are used for, but not limited to:

- revenue recognition
- fair value of stock-based awards and common stock
- fair value of financial assets and liabilities

Future events and their effects cannot be predicted with certainty. Accordingly, the accounting estimates require the exercise of judgment. These estimates and assumptions are based on current facts, historical experience and various other factors believed to be reasonable under the circumstances, the results

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

of which form the basis for making judgments about the carrying values of assets and liabilities and the recording of expenses that are not readily apparent from other sources. The accounting estimates used in the preparation of the Company's condensed consolidated financial statements may change as new events occur, additional information is obtained, and the operating environment changes. The Company will evaluate and update the assumptions and estimates on an ongoing basis and may employ outside experts to assist in its evaluation, as considered necessary. Actual results could materially differ from those estimates.

Cash, Cash Equivalents, and Restricted Cash

The Company considers all highly liquid investments with original maturities of three months or less from date of acquisition to be cash equivalents. Refer to Note 4 for information on the Company's restricted cash.

Revenue Recognition

The Company recognizes revenue under ASC Topic 606, *Revenue from Contracts with Customers* ("ASC 606"). Revenue is recognized when control of goods and services are transferred to customers, in an amount that reflects the consideration the Company expects to be entitled to in exchange for those services.

ASC 606 provides for a five-step model that includes:

- Step 1: Identify the contract(s) with a customer.
- Step 2: Identify performance obligations in the contract.
- Step 3: Determine the transaction price.
- Step 4: Allocate the transaction price to the performance obligations in the contract.
- Step 5: Recognize revenue when (or as) the entity satisfies a performance obligation.

The Company derives revenue from two distinct channels:

- Molecular profiling services involving the provision of precision oncology solutions utilizing MI Profile and Caris Assure.
- Pharma research and development services involving delivery of laboratory, strategic data, and research services to biopharmaceutical customers.

Molecular Profiling Services

For the majority of its molecular profiling services, the Company recognizes revenue from the sale of its precision oncology solutions, provided to customers, including certain hospitals, institutions and patients, at the point in time when the results of the profiling services are delivered to ordering physicians. Most cases requested on behalf of customers are provided without a written agreement; however, the Company determines that an implied contract exists with its customers for whom a physician orders the case. Results from molecular profiling services are delivered via fax, electronically, or in hard copy. Shipping and handling activities are considered fulfillment activities and as such, amounts incurred are recorded within Cost of Services—Molecular Profiling Services on the condensed consolidated statements of operations and comprehensive loss. The Company identifies each sale of the Company's profiling service as a distinct performance obligation. Payment terms are a function of a patient's existing insurance benefits and applicable reimbursement contracts established between the Company and payers. Collection of consideration the Company expects to receive typically occurs within 90 to 120 days of billing. Occasionally, payers may recoup or we may refund consideration, mainly as a result of claim processing.

The total consideration to which the Company expects to be entitled in exchange for the Company's services may be fixed or variable. Consideration includes reimbursement from patients, hospitals, and third-party commercial and governmental payers, such as insurance companies, adjusted for variable consideration related to implicit price concessions that the Company may grant. The Company estimates the variable consideration under a portfolio approach for third-party payers, hospitals and patients with similar reimbursement characteristics. This includes analysis of an average reimbursement per case per

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

portfolio and a percentage of cases reimbursed by considering the historical reimbursement data (including any refunds and recoupments) from such third-party payers, hospitals and patients. Specifically, the Company calculates the historical average reimbursement rates for each portfolio and applies an estimated reimbursement rate, based on historical trends, to the number of cases delivered each period. The period for which historical data is drawn upon is determined on a by-portfolio basis for each payer group, taking into consideration the average collection period. Additionally, the estimate also considers current contractual and statutory requirements, patient insurance eligibility and payer reimbursement contracts, and any known current or anticipated reimbursement trends not reflected in the historical data and only recognizes revenue for variable consideration that the Company determines is probable will not result in a significant reversal in the future. The Company monitors the estimated amount to be collected at each reporting period based on actual cash collections in order to assess whether a revision to the estimate is required. Subsequent changes to the estimate of the transaction price are recorded as adjustments to molecular profiling services revenue in the period where such changes occur. Both the estimate and any subsequent revision are uncertain and require the use of management's judgment in the estimation of the variable consideration and application of the constraint for such variable consideration.

Pharma Research and Development Services

The Company collaborates with biopharmaceutical companies to provide commercial services and prospective and retrospective testing, along with data and bioinformatics collaborations and novel target identification and discovery solutions.

Contracts with biopharmaceutical customers may include multiple distinct performance obligations, such as molecular profiling services, pharma research and development services, and strategic data services. The Company evaluates the terms and conditions included within its contracts with biopharmaceutical customers for proper revenue recognition, including whether services are capable of being distinct and considered distinct within the context of the contract. The performance obligations for biopharmaceutical customers vary by contract. Such contracts may include a performance obligation to provide molecular profiling services, to facilitate the development and regulatory approval of drugs, or to provide target discovery services. Under those contracts, the Company receives payments upon the achievement of milestones, as well as provision of on-going support. The transaction price of the development services contracts may include variable consideration, due to the uncertainty associated with the achievement of the milestones. In making the assessment of whether variable consideration should be included in the transaction price, the Company considers its historical experience with similar milestones, the degree of complexity and uncertainty associated with each milestone, and whether achievement of the milestone is dependent on parties other than the Company. The Company recognizes pharma research and development services revenue over the period in which biopharmaceutical research and development services are provided. Depending on the nature of the service, the Company recognizes revenue using either the output or input method to measure progress, whichever provides a more faithful depiction of the transfer of goods or services. Use of an output method or input method to depict the transfer of services generally does not result in a material difference with respect to the timing of revenue recognition because most services commence and end within the same reporting period. A constraint for variable consideration is applied such that it is probable a significant reversal of revenue will not occur when the uncertainty associated with the contingency is resolved. Application of the constraint for variable consideration is updated at each reporting period as a revision to the estimated transaction price.

Standalone Selling Price

The Company determines standalone selling prices by considering the historical selling prices of its performance obligations in similar transactions, where applicable, as well as other factors, including, but not limited to, the price that customers in the market would be willing to pay, competitive pricing from other vendors, industry publications, current pricing practices and management estimates.

Contract Balances

The timing of revenue recognition may differ from the timing of invoicing to customers. Accounts receivable are recorded at the invoiced amount, net of an allowance for credit losses. A receivable is recognized

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

in the period the Company delivers goods or provides services, or when the right to consideration is unconditional. In situations where revenue recognition occurs before invoicing, an unbilled receivable is created, which represents a contract asset. As of March 31, 2025 and December 31, 2024, the unbilled receivable balance was \$1.6 million and \$4.6 million, respectively, which is included in accounts receivable on the condensed consolidated balance sheets.

The Company recognizes contract liabilities primarily related to payments received in advance of satisfaction of performance obligations from contracts with customers. Contract liabilities are relieved as the Company fulfills its obligations under the contract and revenue is recognized. As of March 31, 2025 and December 31, 2024, the contract liability balance was \$7.7 million and \$7.5 million, respectively, which is included in accrued expenses and other current liabilities on the condensed consolidated balance sheets.

The following table shows the changes in the contract liabilities during the period:

	(amounts in thousands)
Balance at December 31, 2024	\$ 7,470
Increase in contract liabilities	3,774
Revenue recognized during the period that was included in deferred revenues at the beginning of the period	(1,797)
Revenue recognized from performance obligations satisfied within the same period	(1,783)
Balance at March 31, 2025	<u>\$ 7,664</u>

The amount of revenue recognized during the three months ended March 31, 2024 pertaining to amounts deferred as of December 31, 2023 was \$2.0 million.

Transaction Price Allocated to Remaining Performance Obligations

The transaction price allocated to remaining performance obligations represents contracted revenue that has not yet been recognized, which includes contract liabilities and non-cancelable amounts that will be invoiced and recognized as revenue in future periods and excludes performance obligations that are subject to cancellation terms. The Company has elected not to disclose information regarding the transaction price allocated to the remaining performance obligations for which the original expected duration of the contract is one year or less. The amount of transaction price allocated to the remaining performance obligations for contracts with original expected duration over one year as of March 31, 2025 was \$7.1 million. The Company expects to recognize the amounts within twelve months from the respective balance sheet dates.

Additionally, for the three months ended March 31, 2025 and 2024, the Company recorded \$3.9 million and \$(3.9) million of adjustments to revenue related to services delivered in prior periods, respectively, which is based on variability that was subsequently resolved.

Practical Expedients and Contract Costs

Payment terms and conditions vary by contract and customer. In instances where the timing of the Company's revenue recognition differs from the timing of its invoicing, the Company does not assess whether a contract has a significant financing component if the expectation at contract inception is such that the period between payment by the customer and the transfer of the promised services to the customer will be one year or less.

As a practical expedient, the Company recognizes the incremental costs of obtaining contracts, such as sales commissions, as expenses when incurred, if the amortization period of the asset that the Company otherwise would have recognized for the capitalized costs is one year or less. Sales commissions are recorded within selling and marketing expense on the condensed consolidated statements of operations and comprehensive loss. The Company did not capitalize any sales commissions or contract fulfillment costs for the periods ended March 31, 2025 and December 31, 2024.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)*Collaboration agreements*

The Company is party to various collaboration and licensing agreements under which the Company out-licenses certain know-how and molecular data. The collaboration arrangements are intended to solidify the Company's third-party partnerships to align oncology capabilities and create industry-leading molecular oncology research platforms to accelerate drug development and novel research. Under these collaboration arrangements, the Company generally receives a split of fees from its collaborative partners that are earned pursuant to statements of work ("SOWs") executed with end users of the Company's licensed molecular data.

The Company's collaboration and licensing agreements are within the scope of ASC Topic 808, Collaborative Arrangements ("ASC 808") and ASC 606 because the counterparty to these agreements meets the definition of a customer. As such, the Company recognizes revenue earned from the licenses of molecular data granted to the Company's collaborative partners in accordance with ASC 606. Each license of molecular data granted by the Company to a collaborative partner represents a distinct performance obligation in the contract. The transaction price for a given arrangement is entirely variable and depends on the SOWs executed by the counterparty with end users. The amount of revenue allocated to each license is equal to the amount of revenue to which the Company expects to be entitled. The Company recognizes revenue at the point in time that it delivers the molecular data to the third-party collaborative partner. For the three months ended March 31, 2025 and 2024, the Company recognized collaboration revenue of \$1.3 million and \$1.4 million, respectively, which is included in revenue from pharma research and development services on the condensed consolidated statements of operations and comprehensive loss.

Cost of Services—Molecular Profiling Services

Cost of services for molecular profiling services generally consists of cost of materials, direct labor including bonus and stock-based compensation, and equipment maintenance and depreciation expenses associated with processing cases (including accessioning, sequencing, quality control analyses and shipping charges to transport tissue samples), freight and profile results for ordering physicians. Costs associated with completing the molecular profiling services are recorded as the service is performed, regardless of when revenue is recognized with respect to the service.

Cost of Services—Pharma Research and Development Services

Cost of services for pharma research and development services generally consists of cost incurred for the performance of the services requested by the Company's biopharmaceutical customers related to the delivery of laboratory, strategic data and research services, and will vary depending on the nature, timing, and scope of customer projects. Costs associated with delivering pharma research and development services are recorded as incurred.

Concentration of Credit Risk

Financial instruments that potentially expose the Company to concentration of credit risk consist primarily of cash, cash equivalents, marketable securities, and accounts receivable. The Company maintains its cash primarily with domestic financial institutions of high credit quality, with balances that exceed amounts insured by the Federal Deposit Insurance Corporation as of March 31, 2025 and December 31, 2024, respectively.

The Company invests in treasury bills issued by the U.S. Government. U.S. treasury bills with original maturities of three months or less are classified within cash equivalents. Short-term marketable securities are comprised of U.S. treasury bills with original maturities between three and twelve months. The Company believes it is not exposed to any significant credit risk on cash, cash equivalents, and marketable securities and performs periodic evaluations of the credit standing of such institutions. The goal of the Company's investment policy is to ensure safety and preservation of the principal balance, and diversification of risk over cash balances held on deposit.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The Company is subject to credit risk from its accounts receivable. The majority of the Company's accounts receivable arise from the provision of molecular profiling services and pharma research and development services and other, primarily with biopharmaceutical companies, all of which have high credit ratings. The Company has not experienced any material losses related to receivables from individual customers, or groups of customers. The Company does not require collateral. Accounts receivable are recorded net of allowance for credit losses, if any. Concentrations of credit risk are limited due to the number of payers and their dispersion across multiple geographic regions.

For the three months ended March 31, 2025 and 2024, the Company's revenues were primarily derived from the sale of the Caris molecular profiling services. As discussed above, payment terms of the services are a function of a patient's existing insurance benefits and applicable reimbursement contracts established between the Company and payers. Revenue associated with each payer, including its affiliated entities, as a percentage of the Company's total revenue for the respective period, and accounts receivable balance attributable to each payer, including its affiliated entities, as a percentage of the Company's total accounts receivable balance at the respective condensed consolidated balance sheet date, are as follows:

Major Payer	% Revenue for the three months ended March 31,		% Accounts receivable as of	
	2025	2024	March 31, 2025	December 31, 2024
Payer 1	51.2%	36.8%	64.3%	16.1%
Payer 2	13.5%	13.6%	10.0%	19.3%
Payer 3	*	*	11.5%	*

* Represents major payers below 10.0%.

Accounts Receivable

Accounts receivable includes billed and unbilled receivables, net of an allowance for expected credit losses. Accounts receivable primarily represent receivables from biopharmaceutical customers and third-party payers. Accounts receivable for pharmaceutical services are established based on the amounts outstanding per the contractual arrangements with biopharmaceutical customers. The Company applies the current expected credit loss standard in ASC Subtopic 326-20, *Financial Instruments—Credit Losses* ("ASC 326-20") and reserves a portion of the accounts receivable based on assessment of the collectability of customer accounts at the time of revenue recognition. The Company regularly reviews the reserve by considering factors such as historical experience, credit quality, the age of the accounts receivable balances, and current economic conditions that may affect a customer's ability to pay.

Receivables deemed to be uncollectible are written-off against the allowance for credit losses at the time such receivables are deemed to be uncollectible under a specific identification or estimated method. Recoveries of accounts receivable previously written off are recorded when received. As of March 31, 2025 and December 31, 2024, the Company had an immaterial allowance for credit losses related to its accounts receivable.

Supplies

Supplies consist primarily of laboratory items and reagents used by the Company in providing services. All supplies are raw materials and are stated at the lower of cost or net realizable value on a first-in, first-out basis. The Company periodically reviews its supplies for excess or obsolescence and writes down obsolete or otherwise unmarketable supplies to their estimated net realizable value. As of March 31, 2025 and December 31, 2024, the amount of write downs associated with the Company's supplies was immaterial.

Deferred Offering Costs

Deferred offering costs consist primarily of accounting, legal, and other fees related to the Company's proposed initial public offering ("IPO"). These costs are recorded as prepaid expenses and other

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

current assets on the condensed consolidated balance sheets. The deferred offering costs will be recorded against IPO proceeds upon the consummation of the IPO. In the event the planned IPO is terminated, the deferred offering costs will be expensed. The Company had \$5.8 million and \$4.5 million of deferred offering costs as of March 31, 2025 and December 31, 2024, respectively.

Property and Equipment, Net

The Company reports property and equipment at cost, net of accumulated depreciation, amortization, and any asset impairments. The cost of properties held under finance leases is equal to the present value of lease payments not yet paid, adjusted for initial direct costs, prepaid lease payments and lease incentives received. Major improvements which add to productive capacity or extend the life of an asset are capitalized. Normal repairs and maintenance are expensed as incurred. When assets are retired or otherwise disposed of, the cost and related accumulated depreciation and amortization are removed from the accounts, and any resulting gain or loss is reflected in the accompanying condensed consolidated statements of operations and comprehensive loss for the period.

Depreciation and amortization expenses are calculated on a straight-line basis and applied to asset classes based upon the Company's estimate of the asset class's useful life, as summarized below:

	Estimated Useful Life
Laboratory equipment	3 years
Computer equipment and software	3 years
Furniture and fixtures	5 years
Aircraft	15 years
Leasehold improvements/leased buildings	Lesser of remaining lease term or useful life
Leased equipment	Lesser of initial lease term or 5 years

Computer equipment and software includes the purchases of hardware, software and capitalized labor costs associated with internally developed software.

The Company capitalizes purchased software which is ready-for-service and capitalizes qualifying internal software development costs incurred on significant projects. Capitalization of costs begins when two criteria are met: (1) the preliminary project stage is completed, management with relevant authority authorizes and commits to funding the software project, and (2) it is probable that the software will be completed and used for its intended function. Capitalization ceases when the software is substantially complete and ready for its intended use, including the completion of all significant testing. Costs related to preliminary project activities and post-implementation operating activities are expensed as incurred.

Research and development costs and other computer software maintenance costs related to software development are expensed as incurred.

Capitalized software costs are included in property and equipment, net. These costs are amortized using the straight-line method over the estimated useful life of the underlying software, which is three years.

Fair Value Measurements

Fair value is defined as the exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions market participants would use in pricing an asset or liability.

The basis for these assumptions establishes a three-level fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

- *Level 1*—Observable inputs such as quoted prices in active markets for identical assets and liabilities;

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

- *Level 2*—Inputs, other than quoted prices in active markets, that are observable either directly or indirectly; and
- *Level 3*—Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions.

Assets and liabilities measured at fair value are based on one or more of three valuation techniques. The three valuation techniques are as follows:

- *Market approach*—Prices and other relevant information generated by market transactions involving identical or comparable assets or liabilities;
- *Cost approach*—Amount that would be required to replace the service capacity of an asset (i.e., replacement cost); and
- *Income approach*—Techniques to convert future amounts to a single present amount based on market expectations (including present value techniques, option-pricing models, and lattice models).

Financial instruments consist of cash, cash equivalents, restricted cash, short-term marketable securities, accounts receivable, prepaid expenses and other current assets, accounts payable, accrued expenses and other current liabilities, debt, warrants, and derivative instruments.

As of March 31, 2025 and December 31, 2024, the carrying amounts of the Company's cash equivalents, restricted cash, accounts receivable, prepaid expenses and other current assets, accounts payable, accrued expenses and other current liabilities approximate their fair value based on the short-term nature of these items. There were no transfers between Levels 1, 2 or 3 for the periods ended March 31, 2025 and December 31, 2024.

The Company's financial assets and liabilities subject to fair value measurements on a recurring basis and the level of inputs used in such measurements were as follows:

		As of March 31, 2025				
		Fair Value	Level 1	Level 2	Level 3	
		(amounts in thousands)				
Financial assets						
Short-term marketable securities	\$	2,225	\$2,225	\$—	\$—	
Financial liabilities						
Warrant liability	\$128,691	\$	—	\$—	\$128,691	
Derivative liability	\$	1,342	\$	—	\$	1,342
		As of December 31, 2024				
		Fair Value	Level 1	Level 2	Level 3	
		(amounts in thousands)				
Financial assets						
Short-term marketable securities	\$	2,201	\$2,201	\$—	\$—	
Financial liabilities						
Warrant liability	\$91,642	\$	—	\$—	\$91,642	
Derivative liability	\$	6,058	\$	—	\$	6,058

Warrant liability

The Company utilized a probability-weighted scenario approach factoring in various exit strategies and the related timing of such to estimate the fair value of its warrant liability. For each scenario, the Company utilized a Black-Scholes option pricing model with the following assumptions:

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

- *Fair value per share of the underlying stock*—The fair value of the underlying stock represents the fair value of the Company’s Series C preferred stock that the warrants are convertible into.
- *Volatility*—The volatility is derived from historical volatilities of several unrelated publicly-listed peer companies, since the Company has no trading history. When making the selections of industry peer companies to be used in the volatility calculation, the Company considers the size, operational and economic similarities to the Company’s principal business operations.
- *Risk-free interest rate*—The risk-free interest rate is based on U.S. treasury yield as of the measurement dates interpolated to match the maturity equal to the respective term to exit.
- *Dividend yield*—The expected dividend assumption is based on the Company’s current expectations about the Company’s anticipated dividend policy.
- *Expected term (years)*—Based on expected term under various exit strategies.

The below table summarizes the significant unobservable inputs used in the fair value measurement of the warrant liability as of March 31, 2025 and December 31, 2024:

	As of March 31, 2025		As of December 31, 2024	
	2018 Warrants	2020 Warrants	2018 Warrants	2020 Warrants
Fair value per share of the underlying stock	\$4.76–\$7.43	\$4.76–\$7.43	\$3.66–\$5.65	\$3.66–\$5.65
Expected volatility	46.0%–62.0%	59.4%–62.0%	47.6%–63.0%	61.2%–63.0%
Risk-free interest rate	4.2%–4.3%	3.9%–4.3%	4.2%–4.3%	4.3%
Expected dividend yield	—%	—%	—%	—%
Expected term (years)	0.19–0.50	0.19–2.75	0.29–0.75	0.29–2.25

Derivative liability

On January 18, 2023, the Company entered into a credit agreement (the “New Term Loan Agreement”) under which the Company issued senior, secured promissory notes (the “2023 Term Loan”) by which the New Term Loan lenders agreed to lend the Company up to an aggregate principal amount of \$400.0 million, \$200.0 million of which was received by the Company upon issuance, and \$200.0 was drawn down in March 2024. The Company identified certain embedded features in the 2023 Term Loan, including various contingent prepayment, compensatory payment, and default interest rate features, that are required to be bifurcated from the 2023 Term Loan and separately accounted for in the condensed consolidated financial statements as a compound derivative liability.

Fair value of the derivative liability was estimated using the discounted cash flow method under the income approach. This approach involves significant Level 3 inputs and assumptions including an estimated probability and timing of certain contingent events, such as events of default, change of control, sale of assets, etc. The analysis also required the selection of a discount rate representative of the Company’s credit risk. The discount rate used for the initial fair value was calibrated to the transaction.

Refer to Note 8 for additional information about the compound embedded derivative liability.

Debt

As of March 31, 2025, the estimated fair value of the 2023 Term Loan, excluding the bifurcated embedded derivative, was \$377.8 million, compared to a carrying value of \$375.1 million. As of December 31, 2024, the estimated fair value of the 2023 Term Loan, excluding the bifurcated embedded derivative, was \$380.9 million, compared to a carrying value of \$373.1 million. The Company estimated the fair value of the 2023 Term Loan as of based on a discounted cash flow analysis, and an income approach, which represented the use of Level 3 inputs in the fair value hierarchy.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Goodwill

Goodwill represents the excess of the purchase price over the fair value of net identifiable assets and liabilities acquired through a business combination. The Company evaluates goodwill for impairment in accordance with ASC Topic 350, *Intangibles—Goodwill and Other* on an annual basis on October 1, or more frequently if events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. The Company first assesses qualitative factors to determine whether it is more likely than not that the fair value of a reporting unit is less than its carrying amount, or the Company may determine to proceed directly to the quantitative impairment test.

If the Company assesses qualitative factors and concludes that it is more likely than not that the fair value of a reporting unit is less than its carrying amount or if the Company determines not to use the qualitative assessment, then a quantitative impairment test is performed. The factors utilized in the qualitative assessment include macroeconomic conditions, industry and market considerations, cost factors, overall financial performance, and Company-specific events. The quantitative impairment test requires comparing the fair value of the reporting unit to its carrying value, including goodwill. The fair value of the reporting unit is determined based on the present value of estimated cash flows using available information regarding expected cash flows of each reporting unit, discount rates, and the expected long-term cash flow growth rates.

The Company has identified that its business operates as a single operating segment which is also a single reporting unit for purposes of testing goodwill for impairment. An impairment exists if the fair value of the reporting unit is lower than its carrying value. If the fair value of the reporting unit is lower than its carrying value, the Company would record an impairment loss equal to the excess of the reporting unit's carrying value over its fair value.

There were no impairment losses for the periods ended March 31, 2025 and 2024.

Research and Development Costs

Research and development costs are expensed as incurred. Research and development expenses consist of costs incurred in performing research and development activities. The costs include direct costs for salaries and benefits, materials, contract services and other outside costs, and costs to acquire in-process research and development projects and technologies that have no alternative future use.

Advertising

The Company expenses advertising costs as incurred. The Company incurred advertising costs of \$0.1 million and \$0.2 million for the three months ended March 31, 2025 and 2024, respectively.

Self-Insurance

The Company offers medical insurance coverage to eligible employees under a self-insured program managed by a third-party administrator, leveraging stop-loss insurance policies to mitigate risk. The Company records an estimate of its liability for medical claims, which includes the incurred claims amount plus an estimate of incurred, but not reported claims. Self-insurance liability of \$2.0 million and \$1.9 million for the periods ended March 31, 2025 and December 31, 2024, respectively, is included within accrued expenses and other current liabilities on the condensed consolidated balance sheets.

Net Loss per Share Attributable to Common Shareholders

The Company calculates its basic and diluted net loss per share attributable to common shareholders in conformity with the two-class method required for companies with participating securities. Each series of the Company's redeemable convertible preferred stock is considered to be a participating security because the preferred shareholders have a right to receive dividends on a pari passu basis with the Company's common shareholders. The two-class method determines net income (loss) per share for each class of common stock and participating security according to dividends declared or accumulated and participating rights in

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

undistributed earnings. The two-class method requires income (loss) available to common shareholders for the period to be allocated between common and participating securities based upon the respective rights of each to share in earnings as if all income (loss) for the period had been distributed. The participating securities are not required to participate in the losses of the Company, and therefore during periods of loss there is no allocation required under the two-class method between common and participating securities.

Because the Company has reported a net loss for the three months ended March 31, 2025 and 2024, basic net loss per share attributable to common shareholders is calculated by dividing net loss attributable to common shareholders by the weighted-average common stock outstanding during the period, without consideration for potential common stock equivalents. Net loss attributable to common shareholders is equal to net loss, less accretion on preferred securities to their redemption value to the extent such securities are outstanding. Diluted net loss per share attributable to common shareholders is calculated by adjusting the weighted-average stock outstanding for the dilutive effect of potential common stock equivalents outstanding. For purposes of calculating the diluted net loss per share attributable to common shareholders, convertible preferred stock, convertible promissory notes, warrants, and stock options are considered to be potential common stock equivalents but are excluded from the calculation of diluted net loss per share attributable to common shareholders because their effect would be anti-dilutive. Therefore, basic and diluted net loss per share attributable to common shareholders was the same for all periods presented.

Income Taxes

The Company accounts for income taxes under the asset and liability method as set forth in ASC 740 “*Income Taxes*” (“ASC 740”). Under this method, deferred tax assets and liabilities are determined based on the differences between the financial statement and tax bases of assets and liabilities by using enacted tax rates in effect for the year in which the differences are expected to reverse. Valuation allowances are established when necessary to reduce deferred tax assets to the amounts expected to be realized.

The calculation of the Company’s tax liabilities involves dealing with uncertainties in the application of complex tax laws and regulations in a multitude of jurisdictions across its global operations. The Company records uncertain tax positions in accordance with ASC 740 on the basis of a two-step process in which (1) we determine whether it is more likely than not that the tax positions will be sustained on the basis of the technical merits of the position and (2) for those tax positions that meet the more-likely-than-not recognition threshold, we recognize the largest amount of tax benefit that is more than 50% likely to be realized upon ultimate settlement with the related taxing authority. For tax positions not meeting the more likely than not test, no tax benefit is recorded.

At March 31, 2025 and December 31, 2024, the Company has accumulated net operating loss carryforwards in both the U.S. and foreign jurisdictions, and no provision for income taxes is required. The Company’s deferred tax assets are subject to a full valuation allowance.

Recently Issued Accounting Pronouncements Not Yet Adopted

In December 2023, the FASB issued ASU No. 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures* which requires presentation of specific categories of reconciling items, as well as reconciling items that meet a quantitative threshold, in the reconciliation between the income tax provision and the income tax provision using statutory tax rates. The standard also requires disclosure of income taxes paid disaggregated by jurisdiction with separate disclosure of income taxes paid to individual jurisdictions that meet a quantitative threshold. For public business entities, the ASU is effective for annual periods beginning after December 15, 2024, with early adoption permitted. For entities other than public business entities, the ASU is effective for annual periods beginning after December 15, 2025. The amendments of the ASU should be applied on a prospective basis; however, entities have the option to apply retrospectively for each period presented. The Company does not expect the adoption of this new standard in 2026 to have an impact on its condensed consolidated financial position, results of operations, or cash flow.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

In November 2024, the FASB issued ASU No. 2024-03, *Income Statement- Reporting Comprehensive Income-Expense disaggregation disclosures (Subtopic 220-40) Disaggregation of Income Statement Expenses*. This ASU requires disclosure of specified information about certain costs and expenses in the notes to financial statements. This ASU is effective for annual periods beginning after December 15, 2026, and interim periods within fiscal years beginning after December 15, 2027. Adoption of this ASU should be applied on a prospective basis. Early adoption is permitted. We are currently evaluating the impact that this guidance will have on the disclosures within our financial statements, and expect to adopt this ASU for the year ending December 31, 2027.

Note 3. Condensed Consolidated Balance Sheet and Statement of Operations and Comprehensive Loss Components

Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following:

	As of March 31, 2025	As of December 31, 2024
	(amounts in thousands)	
Prepaid expenses	\$ 11,924	\$ 13,562
Other current assets	7,654	6,708
Total prepaid expenses and other current assets	<u>\$ 19,578</u>	<u>\$ 20,270</u>

Property and Equipment, Net

Property and equipment, net consist of the following:

	As of March 31, 2025	As of December 31, 2024
	(amounts in thousands)	
Computer equipment and software	\$ 77,118	\$ 73,312
Capitalized software	22,622	25,921
Laboratory equipment	103,900	103,795
Furniture and fixtures	9,110	9,110
Leasehold improvements/Leased buildings	63,290	63,039
Aircraft and leased equipment	21,249	21,249
Total property and equipment	297,289	296,426
Less: accumulated depreciation and amortization	(235,638)	(228,609)
Property and equipment, net	<u>\$ 61,651</u>	<u>\$ 67,817</u>

Total depreciation and amortization expense was \$7.0 million and \$17.7 million for the three months ended March 31, 2025 and 2024, respectively.

Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consist of the following:

	As of March 31, 2025	As of December 31, 2024
	(amounts in thousands)	
Trade accruals	\$ 5,470	\$ 7,131
Accrued payroll and employee medical	14,264	17,882

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

	As of March 31, 2025	As of December 31, 2024
	(amounts in thousands)	
Accrued bonus	33,150	25,736
Current portion of early exercise stock option liability	327	4,957
Contract liability	7,664	7,470
Current portion of operating lease liabilities	6,023	6,080
Other accrued expenses	11,337	8,286
Total accrued expenses and other current liabilities	<u>\$78,235</u>	<u>\$77,542</u>

Other Long-Term Liabilities

Other long-term liabilities consist of the following:

	As of March 31, 2025	As of December 31, 2024
	(amounts in thousands)	
Long-term operating lease liabilities, net of current portion	\$37,067	\$38,651
Long-term portion of early exercise stock option liability	380	5,767
Total other long-term liabilities	<u>\$37,447</u>	<u>\$44,418</u>

Note 4. Guaranty Agreement and Restricted Cash

The Company entered into a lease agreement with KCP NNN II Leasehold 4, LLC on July 25, 2019 to lease 114,500 square feet of space in Irving, Texas. As part of the lease agreement, the Company delivered an unconditional, irrevocable letter of credit for \$3.4 million from a nationally recognized bank. The Company obtained this letter of credit and placed \$3.4 million in a security deposit account. As of March 31, 2025 and December 31, 2024, amounts outstanding are \$2.7 million and are included within cash, cash equivalents, and restricted cash and other assets on the condensed consolidated balance sheets.

The remaining restricted cash amounts are not material individually.

The following table provides a reconciliation of cash, cash equivalents, and restricted cash reported within the condensed consolidated balance sheet that sum to the total of the amounts shown in the condensed consolidated statements of cash flows. Restricted cash is presented within cash, cash equivalents, and restricted cash and other assets on the condensed consolidated balance sheets.

	Condensed consolidated balance sheet line item	As of March 31, 2025	As of December 31, 2024
		(amounts in thousands)	
Cash and cash equivalents	Cash, cash equivalents, and restricted cash	\$31,201	\$63,950
Restricted cash—short-term	Cash, cash equivalents, and restricted cash	1,503	1,492
Restricted cash—long-term	Other assets	2,586	2,586
Total		<u>\$35,290</u>	<u>\$68,028</u>

Note 5. Income Taxes

The Company is subject to tax liabilities imposed by multiple jurisdictions. The Company determines our best estimate of the annual effective tax rate at each interim period using expected annual pre-tax earnings, statutory tax rates, and available tax planning opportunities. Certain significant or unusual items are separately recognized in the quarter in which they occur, which can cause variability in the effective tax rate from quarter to quarter. The Company recognizes interest and penalties related to uncertain tax positions, if any, as an income tax expense.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The effective tax rate on income for the three months ended March 31, 2025 and 2024 is 0%. For the three months ended March 31, 2025 and 2024, the tax rates differed from the U.S. federal statutory rate of 21.0% primarily due to the impact of net operating losses and valuation allowances.

The Company is subject to taxation in the United States and various states and foreign jurisdictions. As of March 31, 2025, all loss years remain open to examination by the taxing authorities.

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for temporary differences between the financial reporting bases and tax bases of assets and liabilities based on enacted tax rates expected to be in effect when such amounts are realized or settled. However, deferred tax assets are recognized only to the extent that it is more likely than not that they will be realized based upon consideration of available evidence, including future reversals of existing taxable temporary differences, future projected taxable income, the length of the tax asset carryforward periods and tax planning strategies. The effects of remeasurement of deferred tax assets and liabilities resulting from changes in tax rates are recognized in income in the period of enactment.

Note 6. Redeemable Convertible Preferred Stock

Redeemable convertible preferred stock as of March 31, 2025 and December 31, 2024, consisted of the following:

(amounts in thousands, except share and per share amounts)	As of March 31, 2025				
	Shares Authorized	Shares Issued and Outstanding	Original Issue Price Per Share	Aggregate Liquidation Preference	Net Carrying Value
Series A Preferred Stock	490,000,000	485,795,293	\$0.61	\$ 296,335	\$ 709,261
Series B Preferred Stock	30,000,000	29,629,630	\$0.54	16,000	42,963
Series C Preferred Stock	142,000,000	116,200,835	\$2.76	415,616	415,616
Series D Preferred Stock	102,600,000	102,516,283	\$8.10	1,078,273	1,078,273
Total redeemable convertible preferred stock	764,600,000	734,142,041		\$1,806,224	\$2,246,113

(amounts in thousands, except share and per share amounts)	As of December 31, 2024				
	Shares Authorized	Shares Issued and Outstanding	Original Issue Price Per Share	Aggregate Liquidation Preference	Net Carrying Value
Series A Preferred Stock	490,000,000	485,795,293	\$0.61	\$ 296,335	\$ 709,261
Series B Preferred Stock	30,000,000	29,629,630	\$0.54	16,000	42,963
Series C Preferred Stock	142,000,000	116,200,835	\$2.76	408,715	408,715
Series D Preferred Stock	102,600,000	102,516,283	\$8.10	1,060,712	1,060,712
Total redeemable convertible preferred stock	764,600,000	734,142,041		\$1,781,762	\$2,221,651

The rights, preferences, and privileges of the redeemable convertible preferred stock are as follows:

Voting Rights

On any matter presented to the shareholders of the Company for their action or consideration at any meeting of shareholders of the Company (or by written consent of shareholders in lieu of meeting), each holder of outstanding shares of preferred stock will be entitled to cast the number of votes equal to the number of whole shares of common stock into which the shares of preferred stock held by such holder are convertible as of the record date for determining shareholders entitled to vote on such matter.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)*Dividends*

All classes of preferred stock are entitled to receive dividends out of any assets legally available only when, as, and if declared by the Company's board of directors, prior to and in preference to any declaration or payment of any dividend on the common stock.

Liquidation Preference

In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Company, the holders of shares of Series C and Series D preferred stock then outstanding will be entitled to be paid out of the assets of the Company available for distribution to its shareholders at an amount per share equal to the greater of (i) the Series C and Series D original issue price, plus (A) any dividends declared but unpaid thereon and (B) a 7.0% cumulative accruing dividend, compounding annually from the date of issuance of such share of Series C and Series D preferred stock, (ii) the amount that the holder of a share of Series C and Series D preferred stock would have received upon conversion to common stock, or (iii) solely with respect to the Series D preferred stock, 1.2 times the Series D original issue price. The Series A and Series B preferred stock are then paid on a pro rata, pari passu basis an amount equal to the greater of (i) the respective original issue price plus any dividends declared but unpaid thereon, and (ii) the amount that the holder of a share of Series A or Series B preferred stock, respectively, would receive upon conversion to common stock. The remaining proceeds will be distributed to the holders of common stock.

Conversion Rights

The holders of the Company's Series A, Series B, Series C and Series D preferred stock have the right to convert their shares into a number of fully paid and nonassessable shares of common stock as determined by dividing the respective Series A, Series B, Series C and Series D preferred stock original issue price by the conversion price in effect at the time. The initial conversion price of the Series A, Series B, Series C and Series D preferred stock was \$0.61, \$0.54, \$2.76 and \$8.10, respectively, and is subject to adjustment in accordance with anti-dilution provisions provided for in the Company's Certificate of Formation. The Company's Certificate of Formation also specifies that, solely with respect to the calculation of the conversion of the Series C preferred stock in connection with an initial public offering, the original issue price and the initial conversion price of the Series C preferred stock are both equal to \$4.58. As of March 31, 2025, each share of Series A, Series B, Series C and Series D preferred stock was convertible into 0.25 share of common stock.

Redemption Rights

At any time on or after the fifth anniversary of the Series C and Series D original issue date, which will begin for Series C in March 2026 and for Series D in May 2026, upon written notice from the applicable shareholders, the Series C and Series D shares shall be redeemed by the Company at a price per share equal to the greater of (i) the original issue price plus (a) all declared by unpaid dividends thereon and (b) a 7.0% cumulative accruing dividend, compounding annually, or (ii) the fair market value as determined by an independent appraiser.

Anti-dilution

Subject to certain exceptions, the conversion price of the Series A and Series B preferred stock is subject to broad-based weighted average adjustment to prevent dilution in the event that the Company issues additional shares at a purchase price less than the then-applicable conversion price of the Series A and Series B preferred stock, respectively. Subject to certain exceptions, in the event the Company sells additional shares of stock at a price per share less than the Series C and Series D original issue price, the conversion price of the Series C preferred stock is adjusted to the lower price that the Company sells shares in such offering, and the conversion price of the Series D preferred stock is adjusted based on a broad-based weighted average anti-dilution formula. In the event the Company sells shares in an initial public offering for less than 1.11111 times the applicable Series C conversion price, then the Series C conversion price will be reduced (but never increased), concurrently with such issuance to 90.0% of the purchase price in such initial

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

public offering. In the event the Company sells shares in an initial public offering for less than 110.0% of the applicable Series D conversion price, then the series D conversion price will be reduced (but never increased), concurrently with such issuance to 90.0% of the purchase price in such initial public offering.

Note 7. Shareholders' Equity

Common Stock

As of March 31, 2025 and December 31, 2024, 1,173,000,000 and 1,150,000,000 shares of common stock with a \$0.001 par value were authorized, respectively. There were 35,237,531 and 35,842,319 shares outstanding at March 31, 2025 and December 31, 2024, respectively.

Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company's shareholders. Common shareholders are entitled to receive dividends if and when declared by the Company's board of directors, subject to the preferential dividend rights of any preferred stock then outstanding. No dividends have been declared or paid by the Company since its inception.

Treasury Stock

During the three months ended March 31, 2025, the Company repurchased 1,438,138 shares of common stock for an amount of \$16.6 million, mainly associated with previously early-exercised options. Refer to below for further details. No common shares were repurchased during the year ended December 31, 2024. Repurchased common stock is shown on the condensed consolidated balance sheets and condensed consolidated statements of redeemable convertible preferred stock and shareholders' deficit as treasury stock. The Company had 1,620,638 and 182,500 shares of treasury stock as of March 31, 2025 and December 31, 2024, respectively. These shares have not been retired. The Company has not reissued any shares of treasury stock as of March 31, 2025 and December 31, 2024.

2020 Incentive Plan

Pursuant to the 2020 Incentive Plan (the "Plan"), the Company may grant awards of options, restricted awards, performance awards or share appreciation rights to employees, consultants, and directors of the Company. A total of 26,091,009 shares of common stock are reserved for issuance upon the exercise of all awards granted or available to be granted under the Plan as of March 31, 2025.

To the extent permitted by applicable laws or any exchange rule, any shares of common stock issued under this Plan that are issued (a) in connection with the Company's acquisition of an unaffiliated business entity, (b) to the employees of such entity, and (c) in substitution of equity incentive awards previously issued to such employees by such entity shall not reduce the number of shares of common stock available for issuance under the Plan.

The Plan provides for a repurchase feature for vested stock-based awards at the option of the Company if the employee's continuous service terminates for any reason, with or without cause, including death or disability. The repurchase shall be exercisable at a price equal to the fair market value of vested shares or, in the case of exercisable options, the fair market value of the common stock underlying such unexercised options less the aggregate exercise price of such options. The Company's repurchase lapses when the Company's common stock becomes publicly traded.

Option Activity

Under the Plan, the Company has granted incentive stock options and non-qualified stock options to its employees and other service providers (non-employees). Most of the Company's stock options vest incrementally over five years, subject to the grantee's continuous employment with the Company ("time-vesting options"). The Company recognizes compensation cost on a straight-line basis over the requisite service period for its time-vesting options. In addition to its time-vesting options, the Company has also granted stock options to certain non-employees for which vesting is tied to the grantee's performance

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

(“performance-vesting options”). The Company evaluates whether it is probable that the performance metric will be achieved for its performance-vesting options and recognizes compensation cost on a straight-line basis over the implied service period if achievement of the performance metric is deemed probable. No option shall be exercisable after the expiration of 10 years from the date it was granted. The exercise price of each option shall be not less than 100.0% of the fair market value of the common stock subject to the option on the date the option is granted.

The following tables summarize the Company’s stock option activity during the three months ended March 31, 2025:

	Options Outstanding			
	Number of Options	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contract Term (in years)	Aggregate Intrinsic Value (in thousands)
Total outstanding as of December 31, 2024:	21,770,225	\$ 9.06	5.40	\$226,117
Granted	2,835,296	18.60		—
Exercised	(171,484)	8.34		1,766
Cancelled/forfeited	(320,555)	9.78		2,839
Total outstanding as of March 31, 2025	<u>24,113,482</u>	<u>\$10.18</u>	<u>5.71</u>	<u>\$361,193</u>
Total exercisable as of March 31, 2025	16,850,241	\$ 7.20	4.44	\$302,635
Total vested or expected to vest as of March 31, 2025	22,975,156	\$ 9.82	5.56	\$352,524

	Unvested/Vested Activity			
	Options	Weighted Average Exercise Price	Weighted Average Grant Date Fair Value	Average Remaining Life (in years)
Unvested outstanding, as of December 31, 2024	6,658,321	\$15.79	\$ 9.39	3.30
Granted	2,835,296	18.60	15.56	
Cancelled/forfeited	(35,716)	16.75	10.50	
Vested, outstanding shares	(1,497,160)	14.54	9.60	
Unvested outstanding, as of March 31, 2025	<u>7,960,741</u>	17.02	11.54	3.41
Early exercised unvested, end of period	43,605	\$16.20	\$10.37	

Aggregate intrinsic value represents the difference between the estimated fair value of the underlying common stock and the exercise price of outstanding, in-the-money options.

The weighted average grant date fair value of options granted during the three months ended March 31, 2025 was \$15.56 per option. The total grant date fair value of options vested during the three months ended March 31, 2025 and 2024 was \$14.4 million and \$5.9 million, respectively. The total intrinsic value of options exercised during the three months ended March 31, 2025 and 2024 was \$1.8 million and \$0.4 million, respectively.

Modification to stock options

On November 9, 2021 and February 23, 2022, the Company granted stock options to certain executives that are exercisable upon vesting for 331,250 shares and 2,000,000 shares of the Company’s common stock, respectively (the “Prior Stock Options”). The Prior Stock Options vested over five years. On August 11, 2022, the Company’s Compensation Committee approved a modification to the Prior Stock Options, which was communicated to holders of the Prior Stock Options on September 1, 2022. The

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

modification reduced the exercise price to \$16.20 and modified the vesting conditions such that 20.0% vest upon grant, while the remainder vest over the following four years. The total number of grantees affected by this modification was twelve. The modification was not mandatory, but rather could be elected by holders of the Prior Stock Options on an individual holder basis. If the holder elected to participate, the holder's Prior Stock Options were immediately canceled, and the Company issued the holder an equivalent number of new stock options in exchange (the "New Stock Options") which could be early exercised prior to vesting. All of the holders elected to participate in the modification and exchanged their Prior Stock Options for New Stock Options. In addition, as an alternative to paying cash, holders of the New Stock Options that elected to exercise their options were able to pay for the exercise price by executing a full recourse promissory note with the Company that is secured by the holder's restricted shares that are issued upon early exercise. Five grantees elected to early exercise 1,530,000 options utilizing the promissory note.

The principal of each note is equal to the exercise price of the New Stock Options. Interest on the unpaid balance will compound annually and accrue at a fixed rate per annum equal to the mid-term applicable federal rate in effect on the issuance of the note. The maturity date of the notes is the earlier of (1) December 31, 2030 or (2) the occurrence of a change in control event, unless an acceleration event occurs sooner. An acceleration event would generally occur if required to ensure compliance with Section 402 of the Sarbanes-Oxley Act of 2002, the termination of the holder's employment, the insolvency of the holder or the breach of any warranty of the holder. The holder may elect to prepay the outstanding principal and accrued interest balance of the promissory note at any time without penalty.

In addition to the outstanding balance of the note becoming due and payable immediately, upon the occurrence of an acceleration event, if the holder defaults on payment of the note, then interest will accrue at the maximum rate permitted by applicable law. The Company will have full recourse against the holder for failure to pay the note as and when due. Such promissory notes will be secured by the restricted shares issued to the holder that are underlying the note. If the note is not repaid upon an event of default or acceleration event, the Company has the right to repurchase the restricted shares issued upon the exercise of the note for fair market value, which proceeds will apply to repayment of the note (with any remaining balance remaining due).

The Company accounted for the modification as a Type I (Probable to Probable) modification under ASC 718 that does not change the classification of the award (i.e., the New Stock Options continue to be classified within equity). The Company calculated the fair value of the Prior Stock Options and New Stock Options immediately prior to and after the modification using the Black-Scholes option pricing model. The incremental fair value was added to the original unrecognized compensation cost to arrive at the new unrecognized compensation cost, to be recognized over the remaining requisite service period.

Unvested stock received from early exercises of the New Stock Options are subject to a right of repurchase at the lesser of (i) original issuance price or (ii) then-current fair market value in the event of the employee's termination, either voluntary, or involuntary. The Company's repurchase right with respect to these shares typically lapse over four years as the shares become vested. Early exercises of stock options are not deemed to be substantive exercises for accounting purposes and accordingly, consideration received for exercises of unvested stock options is initially recorded as a liability and subsequently reclassified into shareholders' deficit as the related shares vest. As of March 31, 2025 and December 31, 2024, 43,605 and 662,000 shares from options exercised to date were subject to repurchase at a price of \$16.20 per share. Of the amount subject to repurchase as of March 31, 2025 and December 31, 2024, \$0.3 million and \$5.0 million was recorded within other accrued expenses and current liabilities, respectively, and \$0.4 million and \$5.8 million was recorded within other long-term liabilities on the condensed consolidated balance sheets, respectively. In addition, as the early exercise was performed via issuance of a promissory note, a corresponding debt amount, plus related interest income was recorded as contra-equity. The total amount presented as contra-equity as of December 31, 2024 \$26.5 million, which includes interest income and the impact from exercises of both the vested portion of the New Stock Options and early exercises.

On March 3, 2025, the Company repurchased 1,429,213 common stock shares issued upon early exercise of stock options at \$18.60 per share and proceeds were used to pay off the promissory notes and accrued interests. Repurchased common stock shares included 810,816 and 618,397 common stock shares,

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

respectively, that were for options vested and unvested at the time of the repurchase, respectively. On the same day, the Company granted 1,530,000 new stock options to the same employees. New options were issued at an exercise price of \$18.60 per share, have the same vesting status as cancelled options and are not early exercisable. The other terms of the new options are substantially the same as the original options.

The Company accounted for the repurchase of the shares and grant of the new options as a Type I (Probable to Probable) modification under ASC 718. The Company calculated the fair value of the original options and new options immediately prior to and after the modification using the Black-Scholes option pricing model based on the following assumptions: risk-free interest rate of 3.93% – 3.99%; dividend yield of 0.00%; stock price volatility of 68.96% – 69.48%; and an expected life of 5.0 – 5.3 years. The total incremental fair value was \$15.1 million, of which \$8.6 million corresponding to the vested options was immediately recognized as compensation expense, with the remaining \$6.5 million and the original unrecognized compensation cost of \$5.7 million being recognized over the remaining requisite service period.

Restricted Awards Activity

The Company grants restricted stock units that will be settled in shares of the Company's common stock upon vesting to its employees and non-employee directors.

Vesting of the restricted stock units is contingent upon the Company completing either an initial public offering of its common stock or a change of control. The Company has determined that these performance conditions are not probable of being achieved, and thus has not recognized any compensation expense associated with its restricted stock units.

The following table summarizes the Company's restricted stock unit activity for the three months ended March 31, 2025:

	Number of Restricted Stock Units	Weighted Average Grant Date Fair Value
Unvested as of December 31, 2024	762,500	\$18.19
Granted	522,040	\$18.60
Unvested as of March 31, 2025	<u>1,284,540</u>	<u>\$18.36</u>

Stock-Based Compensation Expense

The Company recorded stock-based compensation expense in the condensed consolidated statements of operations and comprehensive loss as follows:

	Three Months Ended March 31,	
	2025	2024
	(amounts in thousands)	
Cost of services—Molecular profiling services	\$ 466	\$ 427
Cost of services—Pharma research and development services	1	2
Selling and marketing expense	1,243	1,118
General and administrative expense	10,636	1,945
Research and development expense	2,346	966
Total	<u>\$14,691</u>	<u>\$4,458</u>

There was no tax benefit associated with the above stock-based compensation expense.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Valuation of Stock-Based Awards to Employees

The Company records stock-based compensation expense for stock-based awards based on the estimated fair value of the awards on the date of the grant. The fair value of the Company's restricted stock units is based on the fair value of the Company's common stock at the date of grant.

The Company estimates the fair value of stock options using a Black-Scholes option pricing model. The absence of a public market for the Company's common stock requires the Company's board of directors to estimate the fair value of its common stock for purposes of granting options and for determining stock-based compensation expense by considering several objective and subjective factors, including contemporaneous third-party valuations, actual and forecasted operating and financial results, market conditions and performance of comparable publicly traded companies, developments and milestones in the Company, the rights and preferences of common and convertible preferred stock, transactions involving the Company's common stock, and assumptions for a discount for lack of marketability. The fair value of the Company's common stock was determined in accordance with the applicable elements of the American Institute of Certified Public Accountants Accounting and Valuations Guide, *Valuation of Privately Held Company Equity Securities Issued as Compensation*.

The key assumptions used in determining the fair value of options granted and a summary of the methodology applied to develop each assumption are as follows:

	Three Months Ended March 31, 2025
Expected volatility	69.0%–69.5%
Risk-free interest rate	3.9%–4.1%
Expected term (years)	5.00–6.55
Expected dividend rate	—%
Expected forfeiture rate	0.0%–8.3%

No awards were granted during the three months ended March 31, 2024.

Expected volatility. This is a measure of the amount by which the share price has fluctuated or is expected to fluctuate. An increase in the expected price volatility will increase the fair value of the option granted and the related compensation expense. As the Company is not publicly traded, the expected price volatility for the Company's options was determined by using an average of historical volatilities of selected industry peers deemed to be comparable to the business corresponding to the expected term of the awards.

Risk-free interest rate. The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the time of grant for U.S. Treasury notes with maturities corresponding to the expected term of the awards.

Expected term. This is the period of time over which the options granted are expected to remain outstanding and is based on the Company's estimate, taking into consideration vesting term, contractual term and historical actual lives. Options granted have a maximum term of ten years. An increase in the expected life will increase the fair value of the option granted and the related compensation expense. Due to the lack of historical share option exercise data, the Company utilizes the simplified method for determining the expected term.

Dividend rate. The Company has not made any dividend payments, nor does it have plans to pay dividends in the foreseeable future. Therefore, an expected dividend yield of zero is utilized.

Forfeitures. Forfeitures are estimated at the time of grant and reduce compensation expense ratably over the vesting period. This estimate is adjusted periodically based on the extent to which actual forfeitures differ, or are expected to differ, from the previous estimate.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Note 8. Long-Term Debt

The carrying value of debt presented within current portion of notes payable and long-term indebtedness, net of debt discounts on the condensed consolidated balance sheets as of March 31, 2025 and December 31, 2024 includes the following components:

	As of March 31, 2025	As of December 31, 2024
	(amounts in thousands)	
Term loan Initial Draw—January 18, 2023	\$200,000	\$200,000
Exit fee on term loan—January 18, 2023	2,000	2,000
Term loan Subsequent Draw—March 5, 2024	200,000	200,000
Exit fee on term loan—March 5, 2024	2,000	2,000
Less: Amortized debt discounts and financing costs ⁽¹⁾	(28,918)	(30,863)
Net debt	<u>\$375,082</u>	<u>\$373,137</u>
Compound bifurcated derivative liability	\$ 1,342	\$ 6,058

- (1) Includes debt discounts of \$28.3 million associated with the initial carrying value of compound bifurcated derivative liability.

Maturities of the Company's debt are expected to be as follows as of March 31, 2025:

	Amount
Years Ending December 31,	
Remainder of 2025 ⁽¹⁾	\$ 60,000
2026	—
2027	—
2028	340,000
2029	—

- (1) Represents 15% of the outstanding principal amount under the 2023 Term Loan Agreement, which is due on the earlier of (x) for dates prior to January 1, 2026, any date that the redemption rights in respect of our Series C preferred stock or Series D preferred stock are or may become exercisable within 90 days following such date, or (y) January 1, 2026 or the first date thereafter if, as of such date, the redemption rights in respect of our Series C preferred stock or Series D preferred stock are or may become exercisable on or prior to the date that is six months after the maturity date. The Series C preferred stock redemption rights may be exercised on or after March 31, 2026. All outstanding shares of our Series C preferred stock and Series D preferred stock will convert into shares of common stock as part of the Preferred Stock Conversion and any redemption rights thereunder will terminate in connection with the completion of this offering and consequently, the payments disclosed herein would not be applicable.

Term Loan Refinancing

On September 21, 2018, the Company entered into a secured term loan agreement (the "Original Term Loan Agreement") with Sixth Street Specialty Lending, Inc. and Barnett Debt Holdings, LLC (collectively, the "Original Term Loan Lenders"), which provided the Company with an initial term loan of \$50.0 million (the "2018 Term Loan") and a delayed term loan draw option of \$50.0 million, which the Company drew down in full on October 4, 2019 (the "2019 Term Loan"). On April 2, 2020, the Company amended the Original Term Loan Agreement (the "Amended Term Loan Agreement") to obtain additional term loan proceeds of \$75.0 million (the "2020 Term Loan" and collectively with the 2018 Term Loan and the 2019 Term Loan, the "Original Term Loans").

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

On January 18, 2023, the Company entered into the New Term Loan Agreement with OrbiMed Royalty & Credit Opportunities III, LP, OrbiMed Royalty & Credit Opportunities IV, LP (collectively, “OrbiMed”), and Braidwell Transaction Holdings LLC (“Braidwell”, and collectively with OrbiMed, the “New Term Loan Lenders”). Pursuant to the New Term Loan Agreement, the Company issued senior, secured promissory notes by which the New Term Loan Lenders agree to lend the Company up to an aggregate principal amount of \$400.0 million, \$200.0 million of which was received by the Company upon issuance (the “Initial Draw”), and the remaining \$200.0 million was received by the Company in March 2024 (the “Delayed Draw”).

Until the earlier of December 31, 2024 or the date on which the 2024 Term Loan amount was fully drawn, which occurred on March 5, 2024, the undrawn balance of the New Term Loan Commitment was subject to a fee of 0.5% per annum. The outstanding principal amount of the 2023 Term Loan is due and payable on January 18, 2028. If an event of default occurs and is continuing, the New Term Loan Lenders may declare all amounts outstanding under the New Term Loan Agreement to be immediately due and payable. A final payment exit fee equal to 1.0% of the amount funded under the New Term Loan Agreement is due upon prepayment or maturity. Amounts borrowed pursuant to the New Term Loan Agreement may be prepaid at any time. Upon prepayment, the Company is subject to a prepayment penalty based on the timing of repayment.

The 2023 Term Loan bears interest at a rate per annum equal to a fixed margin of 6.5% plus the greater of (a) forward-looking three-month secured overnight financing rate (“SOFR”) and (b) 2.5%. In the event of default, the fixed margin shall increase by 3.0% per annum. As of March 31, 2025, the interest rate was 10.8%. Regular quarterly payments are interest-only for the 60-month term of the New Term Loan Agreement, with the principal due at maturity. The effective interest rate for the Initial Draw of the 2023 Term Loan is 17.0%, and the effective interest rate for the Delayed Draw of the 2023 Term Loan is 12.0%.

The Company’s obligations under the New Term Loan Agreement are secured by a first lien security interest in substantially all of the assets of the Company and its subsidiaries. The New Term Loan Agreement contains certain customary representations and warranties, affirmative and negative covenants, financial covenants, and events of default applicable to the Company and its subsidiaries. Additional covenants include those restricting dispositions, fundamental changes to its business, mergers or acquisitions, indebtedness, encumbrances, distributions, investments, transactions with affiliates and subordinated debt. At March 31, 2025, the Company is in compliance with all covenants.

The Company identified multiple embedded derivatives that require bifurcation from the 2023 Term Loan. They are separately accounted for in the condensed consolidated financial statements as one compound derivative liability. Those embedded features include various contingent prepayment and compensatory payment features as well as interest rate increases upon an event of default.

Interest Expense

The components of interest expense associated with the Company’s long-term indebtedness, excluding finance leases, are as follows:

	Three Months Ended March 31,	
	2025	2024
	(amounts in thousands)	
Debt discount amortization	\$ 1,945	\$1,589
Interest expense	10,829	7,690
Interest expense on long-term indebtedness, excluding finance leases	<u>\$12,774</u>	<u>\$9,279</u>

Warrant Liability

As part of the Original Term Loan Agreement, the Company issued 13,694,623 warrants (the “2018 Warrants”). In connection with the amendment to the Original Term Loan Agreement in 2020, the

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Company issued an additional 11,399,814 warrants (the “2020 Warrants”) and amended the 2018 Warrants. Furthermore, these amendments also permit the exercise of both the 2018 Warrants and 2020 Warrants into Series C preferred stock or common stock at the option of the holder. The 2018 Warrants are exercisable into Series C preferred stock at a price of \$1.61 and into common stock at a price of \$6.44. The 2020 Warrants are exercisable into Series C preferred stock at a price of \$1.93 and into common stock at a price of \$7.73. As a result of the amendment to permit exercise of the warrants into redeemable preferred stock, the warrants are classified as a liability pursuant to the guidance in ASC 480. Therefore, the warrants are reported at fair value within warrant liabilities on the condensed consolidated balance sheets, with changes in fair value reported within changes in fair value of financial instruments on the condensed consolidated statements of operations and comprehensive loss.

The following table reflects the changes in fair values associated with these warrants.

	2018 Warrants	2020 Warrants
Warrants granted	13,694,623	11,399,814
Exercise price	\$1.61	\$1.93
Exercise period	Earlier of 7 years from the date of issuance, or immediately after closing IPO	
Fair value at date of issuance	\$0.8 million	\$7.9 million
	(amounts in thousands)	
Fair value at December 31, 2023		\$54,540 \$44,193
Decrease in fair value		(2,911) (4,180)
Fair value at December 31, 2024		\$51,629 \$40,013
Increase in fair value		20,405 16,644
Fair value at March 31, 2025		<u>\$72,034</u> <u>\$56,657</u>

Note 9. Commitments and Contingencies**Purchase Obligations**

The Company enters into various supply agreements that contains purchase commitments. Most of the commitments are based on a binding forecast for an agreed-upon period, which is 12-month or less.

Corporate Liability and Insurance

The Company maintains professional liability, general liability, and other customary insurance on a claims-made basis in amounts deemed appropriate by the Company’s management based upon historical claims and the nature and risks of the Company. The Company’s business may subject the Company to litigation and liability for damages. The Company believes that current insurance protection is adequate for present business operations, but there can be no assurance that the Company will be able to maintain professional and general liability insurance coverage in the future or that such insurance coverage will be available on acceptable terms or adequate to cover any or all potential product or professional liability claims. A successful liability claim in excess of insurance coverage could have a material adverse effect on the Company.

Litigation

During the ordinary course of business, the Company has become and may in the future become subject to pending and threatened legal and regulatory actions and proceedings. While it is not feasible to predict or determine the ultimate outcome of these matters, the Company believes that none of its current legal proceedings will have a material adverse effect on its financial position, results of operations, or cash flows for the periods ended March 31, 2025 and December 31, 2024.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**Note 10. Related Parties**

The Company's officers and directors have ownership interests in certain vendors providing services to the Company. During the three months ended March 31, 2025 and 2024, the Company made payments to these entities for services and expenses for \$0.7 million and \$0.5 million, respectively.

Note 11. Net Loss Per Share Attributable to Common shareholders

The following table sets forth the computation of the basic and diluted net loss per share attributable to common shareholders:

(amounts in thousands, except share and per share data)	Three Months Ended March 31,	
	2025	2024
Net loss	\$ (102,581)	\$ (111,028)
Adjustments of redeemable convertible preferred stock to redemption value	(24,462)	(23,113)
Net loss attributable to common shareholders	<u>\$ (127,043)</u>	<u>\$ (134,141)</u>
Net loss per share attributable to common shareholders, basic and diluted	\$ (3.57)	\$ (3.80)
Weighted-average shares used in computing net loss per share attributable to common shareholders, basic and diluted	35,623,042	35,313,037

The following common stock equivalents were excluded from the calculation of diluted net loss per share attributable to common shareholders for the periods presented as they had an anti-dilutive effect:

	Three Months Ended March 31,	
	2025	2024
Series A preferred stock	121,448,823	121,448,823
Series B preferred stock	7,407,408	7,407,408
Series C preferred stock	29,050,209	29,050,209
Series D preferred stock	25,629,071	25,629,071
Outstanding warrants	6,273,609	6,273,609
Outstanding stock options	24,113,482	21,501,676
Unvested shares subject to repurchase	43,603	968,000
Total	<u>213,966,205</u>	<u>212,278,796</u>

Note 12. Segment and Geographic Information

The Company operates as a single operating segment. An operating segment is defined as a component of an entity for which discrete financial information is available and regularly reviewed by the entity's chief operating decision maker ("CODM") in deciding how to allocate resources and in assessing performance. The Company's CODM, its Chairman and Chief Executive Officer, manages the Company's operations on a consolidated basis for the purposes of allocating resources, making operating decisions and evaluating financial performance.

Net loss as reported on the condensed consolidated statements of operations and comprehensive loss is used by the CODM to assess segment performance against management budgets and prior period operating results for the purpose of making results-driven decisions about organizational resource allocation.

Segment revenues are derived from molecular profiling, strategic data, and research services that are delivered to the Company's biopharmaceutical and clinical customers, who are predominantly located in the United States. The Company provides these services primarily by leveraging the Company's proprietary technologies and clinico-genomic database, which are core to the Company's operations and are deployed similarly across the service offerings.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The table below is a summary of the segment profit or loss, including significant segment expenses:

	Three Months Ended March 31,	
	2025	2024
	(amounts in thousands)	
Revenue	\$ 120,915	\$ 80,677
Less:		
Cost of services—Molecular profiling services	60,894	52,894
Cost of services—Pharma research and development services	2,958	1,669
Selling and marketing expense	39,829	39,609
General and administrative expense	52,119	44,354
Research and development expense	23,066	34,376
Interest income	503	1,768
Interest expense	(12,782)	(9,290)
Changes in fair value of financial instruments	(32,333)	(11,064)
Other expense, net	(17)	(219)
Segment and consolidated net loss	<u><u>\$(102,581)</u></u>	<u><u>\$(111,028)</u></u>

The following table sets forth the Company's revenue by geographic areas based on the customer's location:

	Three Months Ended March 31,	
	2025	2024
	(amounts in thousands)	
United States	\$ 118,432	\$ 78,430
International	2,483	2,247
Total revenue	<u><u>\$ 120,915</u></u>	<u><u>\$ 80,677</u></u>

No single country outside of the United States accounted for more than 10.0% of total revenue during each of the three months ended March 31, 2025 and 2024. As of March 31, 2025 and December 31, 2024, approximately 99.0% of the Company's total assets are located in the United States.

Note 13. Employee Benefit Plan

The Company sponsors a 401(k) plan, and pursuant to its terms, eligible employees can elect to contribute to the 401(k) plan, subject to certain limitations, up to the lesser of the statutory maximum or 100.0% of eligible compensation on a pre-tax basis. For the three months ended March 31, 2025 and 2024, the Company contributed \$1.9 million and \$2.2 million, respectively, to match employee contributions as permitted by the plan. The Company pays the administrative costs for the plan.

Note 14. Subsequent Events

On April 1, 2025, the Company closed a private financing in which it issued a combination of senior convertible notes (the "2025 Convertible Notes"), Series E convertible preferred stock and Series F convertible preferred stock, for an aggregate of \$167.7 million. The 2025 Convertible Notes have an aggregate principal amount of \$30.0 million. The 2025 Convertible Notes accrue interest at a rate of 8% per annum, payable quarterly in cash, and mature on January 1, 2026. The Company issued 12,345,674 shares of Series E convertible preferred stock with a purchase price of \$8.10 per share, for aggregate proceeds of \$100.0 million. The Company also issued 4,657,401 shares of Series F convertible preferred stock with a purchase price of \$8.10 per share, for aggregate proceeds of \$37.7 million. In connection with this financing, the Company also issued warrants to acquire shares of common stock to the holders of the 2025 Convertible Notes.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

These warrants are not initially exercisable for any shares of common stock, but such warrants become exercisable for a specified dollar value of shares on a monthly basis commencing on June 1, 2025 if we have not completed an initial public offering by such date. Any exercisable portion of the warrants will be automatically exercised prior to the closing of the initial public offering and such warrants will terminate upon the closing of the offering.

Immediately prior to and in connection with the completion of the initial public offering, the 2025 Convertible Notes, Series E convertible preferred stock and Series F convertible preferred stock (plus an 8% accretion in connection with the preferred stocks) will convert into common stock at a price equal to 70% of the initial public offering price per share.

As further disclosed in Note 2, the Company effected a one-for-four reverse stock split of its common stock. The reverse stock split was effective June 1, 2025.

There were no other significant subsequent events identified through the date that the condensed consolidated financial statements were issued, that could impact the financial statements.

Through and including _____, 2025 (the 25th day after the date of this prospectus), all dealers effecting transactions in the common stock, whether or not participating in this offering, may be required to deliver a prospectus. This delivery requirement is in addition to the dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to an unsold allotment or subscription.

23,529,412 Shares



Common Stock

PROSPECTUS

BofA Securities
J.P. Morgan
Goldman Sachs & Co. LLC
Citigroup
TD Cowen
Evercore ISI
Guggenheim Securities
BTIG
Wolfe | Nomura Alliance

, 2025

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 13. Other Expenses of Issuance and Distribution

The following table presents the costs and expenses, other than underwriting discounts and commissions, payable in connection with this offering. All amounts are estimates except the SEC registration fee, the FINRA filing fee, and Nasdaq listing fee. Except as otherwise noted, all the expenses below will be paid by us.

SEC registration fee	\$ 82,854
FINRA filing fee	81,676
Nasdaq listing fee	295,000
Printing and engraving expenses	200,000
Legal fees and expenses	4,500,000
Accounting fees and expenses	1,921,680
Transfer agent and registrar fees	4,500
Miscellaneous fees and expenses	314,289
Total	<u>\$7,400,000</u>

Item 14. Indemnification of Directors and Officers

Caris Life Sciences, Inc. was incorporated under the laws of Texas.

The Texas Business Organizations Code (the “TBOC”) permits a corporation to indemnify a director who was, is or is threatened to be a named defendant or respondent in a proceeding as a result of the performance of his or her duties if such person acted in good faith and, in the case of conduct in the person’s official capacity as a director, in a manner he or she reasonably believed to be in the best interests of the corporation and, in all other cases, that the person reasonably believed his or her conduct was not opposed to the best interests of the corporation and with respect to any criminal action or proceeding, that such person had no reasonable cause to believe his or her conduct was unlawful. Subject to certain exceptions, the TBOC further permits a corporation to eliminate in its charter all monetary liability of the corporation’s directors to the corporation or its shareholders for conduct in performance of such director’s duties, but not for a breach of the director’s duty of loyalty or receipt of an improper benefit. Our amended and restated certificate of formation will provide that a director or officer of the corporation will not be liable to the corporation or its shareholders for monetary damages for any act or omission by such person in the performance of his or her duties, except that there will be no limitation of liability to the extent the director or officer has been found liable under applicable law for: (i) breach of such person’s duty of loyalty owed to the corporation or its shareholders; (ii) an act or omission not in good faith that constitutes a breach of duty of such person to the corporation or that involves intentional misconduct or a knowing violation of the law; (iii) a transaction from which such person received an improper benefit, regardless of whether the benefit resulted from an action taken within the scope of such person’s duties; or (iv) an act or omission for which the liability of such person is expressly provided for by an applicable statute.

Sections 8.101 and 8.103 of the TBOC provide that a corporation may indemnify a person who was, is or is threatened to be a named defendant or respondent in a proceeding because the person is or was a director only if a determination is made that such indemnification is permissible under the TBOC: (i) by a majority vote of the directors who at the time of the vote are disinterested and independent, regardless of whether such directors constitute a quorum; (ii) by a majority vote of a board committee designated by a majority of disinterested and independent directors and consisting solely of disinterested and independent directors; (iii) by special legal counsel selected by the board of directors or a committee of the board of directors as set forth in (i) or (ii); (iv) by the shareholders in a vote that excludes the shares held by directors who are not disinterested and independent; or (v) by a unanimous vote of the shareholders.

Section 8.104 of the TBOC provides that the corporation may pay or reimburse, in advance of the final disposition of the proceeding, reasonable expenses incurred by a present director who was, is or is

threatened to be made a named defendant or respondent in a proceeding after the corporation receives a written affirmation by the director of his or her good faith belief that he or she has met the standard of conduct necessary for indemnification under Section 8.101 and a written undertaking by or on behalf of the director to repay the amount paid or reimbursed if it is ultimately determined that he or she has not met that standard or if it is ultimately determined that indemnification of the director is not otherwise permitted under the TBOC. Section 8.105 also provides that reasonable expenses incurred by a former director, or a present or former employee, agent, or officer of the corporation, who was, is or is threatened to be made a named defendant or respondent in a proceeding may be paid or reimbursed by the corporation, in advance of the final disposition of the action, as the corporation considers appropriate.

Section 8.105 of the TBOC provides that, subject to restrictions in its certificate of formation and to the extent consistent with other law, a corporation may indemnify and advance expenses to a person who is not a director, including an officer, employee, or agent of the corporation as provided by: (i) the corporation's governing documents; (ii) an action by the corporation's governing authority; (iii) resolution by the shareholders; (iv) contract; or (v) common law. As consistent with Section 8.105, persons who are not directors may seek indemnification and advancement of expenses from a corporation to the same extent that directors may seek indemnification and advancement of expenses from a corporation.

Further, our amended and restated certificate of formation and amended and restated bylaws will provide that we must indemnify our directors and officers to the fullest extent authorized by law. We are also expressly required to advance certain expenses to our directors and officers, except for claims brought by us, and carry directors' and officers' insurance providing indemnification for our directors and officers for some liabilities. We believe that these indemnification provisions and the directors' and officers' insurance are useful to attract and retain qualified directors and executive officers.

We have also entered into, or will enter into prior to the completion of this offering, indemnification agreements with each of our directors and executive officers. The indemnification agreements provide, or will provide, among other things, for indemnification to the fullest extent permitted by the TBOC and our amended and restated certificate of formation and amended and restated bylaws against (i) any and all direct and indirect liabilities and reasonable expenses, including judgments, fines, penalties, interest and amounts paid in settlement of any claim with our approval and reasonable counsel fees and disbursements and (ii) any liabilities incurred as a result of serving as a director, officer, employee, or agent (including as a trustee, fiduciary, partner, or manager or in a similar capacity) of another enterprise or an employee benefit plan at our request. The indemnification agreements also provide for, or will provide for, the advancement or payment of expenses to the indemnitee and for reimbursement to us if it is found that such indemnitee is not entitled to such indemnification under applicable law and our amended and restated certificate of formation and amended and restated bylaws or the terms of the indemnification agreements.

We expect to maintain standard policies of insurance that provide coverage (i) to our directors and officers against loss rising from claims made by reason of breach of duty or other wrongful act and (ii) to us with respect to indemnification payments that we may make to such directors and officers. The underwriting agreement provides for indemnification by the underwriters of us and our officers and directors, and by us of the underwriters, for certain liabilities arising under the Securities Act or otherwise in connection with this offering.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers, or persons controlling us under any of the foregoing provisions, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

Item 15. Recent Sales of Unregistered Securities

The following sets forth information regarding all unregistered securities sold by us since January 1, 2022:

Convertible Notes Issuances

In April 2025, we issued convertible notes in the aggregate principal amount of \$30.0 million to 12 accredited investors.

Preferred Stock Issuances

In September 2023, we issued an aggregate of 31,055,901 shares of our Series C preferred stock, par value \$0.001 per share, to three lenders at a conversion price of \$1.61 per share, in connection with the conversion of the original aggregate principal amount of \$50,000,000 outstanding under a convertible loan agreement with such lenders. Upon such conversion and following our cash payment of \$3,002,567.25 in respect of accrued and unpaid pay-in-kind interest under the convertible loan agreement, all of our obligations under the convertible loan agreement were deemed satisfied in full, and the agreement irrevocably terminated.

In April 2025, we issued an aggregate of 12,345,674 shares of our Series E preferred stock, par value \$0.001 per share, to 12 accredited investors at a purchase price of \$8.10 per share, for an aggregate purchase price of \$99,999,959.40.

In April 2025, we issued an aggregate of 4,657,401 shares of our Series F preferred stock, par value \$0.001 per share, to 11 accredited investors at a purchase price of \$8.10 per share, for an aggregate purchase price of \$37,724,948.10.

Warrant Issuances

In April 2025, we issued warrants to purchase shares of our common stock, at an exercise price of \$0.04 per share, if exercised on or before June 30, 2025. In connection with this offering, these warrants will be exercised in full, on a cashless basis, for 844,429 shares of our common stock, based on an assumed initial public offering price of \$19.50 per share, which is the midpoint of the price range set forth on the cover page of this prospectus.

Equity Plan-Related Issuances

From January 1, 2022 through the date of this registration statement, we granted to our employees, officers, and directors options to purchase an aggregate of 15,089,718 shares of our common stock at per share exercise prices ranging from \$16.20 to \$19.50, and restricted stock units representing an aggregate of 1,292,665 shares of our common stock, under our 2020 Incentive Plan. From January 1, 2022 through the date of this registration statement, we issued an aggregate of 4,139,326 shares of common stock at per share purchase prices ranging from \$2.44 to \$22.40 pursuant to the exercise of options by our employees, officers, and directors.

The issuances of the securities in the transactions described above were deemed to be exempt from registration under the Securities Act in reliance upon Section 4(a)(2) of the Securities Act and/or Rule 506, Rule 701, or Regulation S promulgated thereunder. The securities were issued directly by us and did not involve a public offering or general solicitation. The recipients of such securities represented their intentions to acquire the securities for investment purposes only and not with a view to, or for sale in connection with, any distribution thereof.

None of the transactions set forth in Item 15 involved any underwriters, underwriting discounts or commissions, or any public offering. All recipients had adequate access, through their relationships with us, to information about us.

Item 16. Exhibits and Financial Statement Schedules

(a) Exhibits. The following exhibits are included herein or incorporated herein by reference:

Exhibit Number	Description
1.1*	<u>Form of Underwriting Agreement.</u>
3.1*	<u>Amended and Restated Certificate of Formation of Registrant, as amended to date and as currently in effect.</u>
3.2*	<u>Form of Amended and Restated Certificate of Formation of Registrant, to be effective upon the completion of this offering.</u>
3.3*	<u>Amended and Restated Bylaws of Registrant, as currently in effect.</u>
3.4*	<u>Form of Amended and Restated Bylaws of Registrant, to be effective upon the completion of this offering.</u>
4.1*	<u>Form of Registrant's common stock certificate.</u>
4.2+*	<u>Amended and Restated Investors' Rights Agreement, dated as of April 1, 2025, among the Registrant and certain of its shareholders.</u>
5.1	<u>Opinion of Latham & Watkins LLP.</u>
10.1(a)+*	<u>Credit Agreement, dated as of January 18, 2023, among the Registrant, the lenders party thereto, and Wilmington Trust, National Association, as administrative agent and collateral agent.</u>
10.1(b)+*	<u>First Amendment to Credit Agreement, dated as of April 1, 2025, among the Registrant, the lenders party thereto, and Wilmington Trust, National Association, as administrative agent and collateral agent.</u>
10.2(a)+§*	<u>Supply Agreement, dated as of September 21, 2022, by and between Caris MPI, Inc. and Illumina, Inc.</u>
10.2(b)+§*	<u>Master Supply Agreement, effective as of July 8, 2024, by and between Roche Diagnostics Corporation and Caris MPI, Inc.</u>
10.3(a)+§*	<u>Lease Agreement, dated as of March 1, 2019, by and between WPT LAND 2 LP and 23andMe, Inc., as amended.</u>
10.3(b)+§*	<u>Industrial Real Estate Lease (Single-Tenant Facility), dated as of August 19, 2009, by and between Liberty Cotton Center, LLC and CDx Holdings, Inc., as amended.</u>
10.3(c)+§*	<u>Lease, dated as of July 25, 2019, by and between KCP NNN II Leasehold 4, LLC and Caris MPI, Inc.</u>
10.4(a)†*	<u>Caris Life Sciences, Inc. Amended and Restated 2020 Incentive Plan.</u>
10.4(b)†*	<u>Form of Incentive Stock Option Award Agreement under the Amended and Restated 2020 Incentive Plan.</u>
10.4(c)†*	<u>Form of Nonqualified Stock Option Award Agreement under the Amended and Restated 2020 Incentive Plan.</u>
10.4(d)†*	<u>Form of Nonqualified Stock Option Award Agreement under the Amended and Restated 2020 Incentive Plan (Nonemployee Director).</u>
10.4(e)†*	<u>Form of Restricted Stock Unit Award Agreement under the Amended and Restated 2020 Incentive Plan.</u>
10.4(f)†*	<u>Form of Restricted Stock Unit Award Agreement under the Amended and Restated 2020 Incentive Plan (Chief Executive Officer).</u>
10.4(g)†*	<u>Form of Restricted Stock Unit Award Agreement under the Amended and Restated 2020 Incentive Plan (Non-Employee Director).</u>
10.5(a)†*	<u>Caris Life Sciences, Inc. 2025 Incentive Plan, as amended and restated.</u>
10.5(b)†*	<u>Form of Restricted Stock Unit Award Agreement under the 2025 Incentive Plan, as amended and restated.</u>
10.6†*	<u>Caris Life Sciences, Inc. Employee Stock Purchase Plan, as amended and restated.</u>

Exhibit Number	Description
10.7†§*	<u>Executive Employment Agreement, dated as of February 1, 2010, by and between the Registrant and David Spetzler.</u>
10.8†*	<u>First Amendment to Employment Agreement, dated as of July 27, 2015, by and between the Registrant and David Spetzler.</u>
10.9†§*	<u>Employment Agreement, dated as of May 31, 2018, by and between Caris Science, Inc. and Brian Brille.</u>
10.10†*	<u>Caris Life Sciences, Inc. Executive and Director Change in Control Plan.</u>
10.11†*	<u>Non-Employee Director Compensation Program.</u>
10.12*	<u>Form of Indemnification Agreement.</u>
16.1*	<u>Letter from Ernst & Young LLP to the Securities and Exchange Commission.</u>
21.1*	<u>Subsidiaries of the Registrant.</u>
23.1	<u>Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm.</u>
23.2	<u>Consent of Deloitte & Touche LLP, Independent Registered Public Accounting Firm.</u>
23.3	<u>Consent of Latham & Watkins LLP (contained in Exhibit 5.1).</u>
23.4*	<u>Consent of Nephron Research LLC.</u>
24.1*	<u>Power of Attorney (included on signature page).</u>
107	<u>Filing Fee Table.</u>

* Previously filed.

† Indicates a management contract or compensatory plan or arrangement.

+ Certain of the schedules and attachments to this exhibit have been omitted pursuant to Regulation S-K, Item 601(a)(5). The registrant hereby undertakes to provide further information regarding such omitted materials to the SEC upon request.

§ Certain portions of this exhibit (indicated by “[***]”) have been redacted pursuant to Regulation S-K, Item 601(a)(6).

(b) Financial Statement Schedules. All schedules have been omitted because the information required to be presented in them is not applicable or is shown in the consolidated financial statements or related notes.

Item 17. Undertakings

The undersigned registrant hereby undertakes to provide to the underwriter at the closing specified in the underwriting agreements certificates in such denominations and registered in such names as required by the underwriter to permit prompt delivery to each purchaser.

Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

The undersigned registrant hereby undertakes that:

(1) For purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A

and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

(2) For the purpose of determining any liability under the Securities Act of 1933, as amended, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused this Amendment No. 2 to Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in Irving, Texas, on this 16th day of June, 2025.

CARIS LIFE SCIENCES, INC.

/s/ David D. Halbert

David D. Halbert
Founder, Chairman, and Chief Executive Officer

Pursuant to the requirements of the Securities Act of 1933, as amended, this Amendment No. 2 to Registration Statement has been signed by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
/s/ David D. Halbert _____ David D. Halbert	Founder, Chairman, and Chief Executive Officer <i>(Principal Executive Officer)</i>	June 16, 2025
/s/ Luke Power _____ Luke Power	Senior Vice President, Chief Financial Officer, and Chief Accounting Officer <i>(Principal Financial and Accounting Officer)</i>	June 16, 2025
* _____ George H. Poste	Vice Chairman	June 16, 2025
* _____ Jonathan Knowles	Vice Chairman	June 16, 2025
* _____ Brian J. Brille	Vice Chairman and Executive Vice President	June 16, 2025
* _____ Peter M. Castleman	Director	June 16, 2025
* _____ David Fredrickson	Director	June 16, 2025
* _____ Joseph E. Gilliam	Director	June 16, 2025
* _____ Jon S. Halbert	Director	June 16, 2025
* _____ Laura I. Johansen	Director	June 16, 2025
* _____ Lloyd B. Minor	Director	June 16, 2025

Signature	Title	Date
* _____ Danny Phillips	Director	June 16, 2025
* _____ Jeffrey Vacirca	Director	June 16, 2025
*By: /s/ Luke Power _____ Luke Power <i>Attorney-in-fact</i>		

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LATHAM & WATKINS LLP

June 16, 2025

Caris Life Sciences, Inc.
 750 W. John Carpenter Freeway
 Suite 800
 Irving, TX 75039

FIRM / AFFILIATE OFFICES

Austin	Milan
Beijing	Munich
Boston	New York
Brussels	Orange County
Century City	Paris
Chicago	Riyadh
Dubai	San Diego
Düsseldorf	San Francisco
Frankfurt	Seoul
Hamburg	Silicon Valley
Hong Kong	Singapore
Houston	Tel Aviv
London	Tokyo
Los Angeles	Washington, D.C.
Madrid	

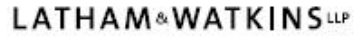
Re: Registration Statement on Form S-1 (File No. 333-287551)
Up to 27,058,823 shares of common stock, \$0.001 par value per share

To the addressee set forth above:

We have acted as special counsel to Caris Life Sciences, Inc., a Texas corporation (the “**Company**”), in connection with the proposed issuance of up to 27,058,823 shares of common stock, \$0.001 par value per share (the “**Shares**”). The Shares are included in a registration statement on Form S-1 under the Securities Act of 1933, as amended (the “**Act**”), initially filed with the Securities and Exchange Commission (the “**Commission**”) on May 23, 2025 (Registration No. 333–287551) (as amended, the “**Registration Statement**”). The term “Shares” shall include any additional shares of common stock registered by the Company pursuant to Rule 462(b) under the Act in connection with the offering contemplated by the Registration Statement. This opinion is being furnished in connection with the requirements of Item 601(b)(5) of Regulation S-K under the Act, and no opinion is expressed herein as to any matter pertaining to the contents of the Registration Statement or related Prospectus, other than as expressly stated herein with respect to the issue of the Shares.

As such counsel, we have examined such matters of fact and questions of law as we have considered appropriate for purposes of this letter. With your consent, we have relied upon certificates and other assurances of officers of the Company and others as to factual matters without having independently verified such factual matters. We are opining herein as to the Business Organizations Code of the State of Texas, and we express no opinion with respect to any other laws.

Subject to the foregoing and the other matters set forth herein, it is our opinion that, as of the date hereof, upon effectiveness of the amended and restated certificate of formation of the Company, in the form most recently filed as an exhibit to the Registration Statement, with the Secretary of the State of Texas, and when the Shares shall have been duly registered on the books of the transfer agent and registrar therefor in the name or on behalf of the purchasers and have been issued by the Company against payment therefor (not less than par value) in the circumstances contemplated by the form of underwriting agreement most recently filed as an exhibit to the Registration Statement, the issue and sale of the Shares will have been duly authorized by all necessary corporate action of the Company, and the Shares will be validly issued, fully paid and nonassessable. In rendering the foregoing opinion, we have assumed that the Company will comply with all applicable notice requirements regarding uncertificated shares provided in the Business Organizations Code of the State of Texas.



This opinion is for your benefit in connection with the Registration Statement and may be relied upon by you and by persons entitled to rely upon it pursuant to the applicable provisions of the Act. We consent to your filing this opinion as an exhibit to the Registration Statement and to the reference to our firm in the Prospectus under the heading “Legal Matters.” We further consent to the incorporation by reference of this letter and consent into any registration statement filed pursuant to Rule 462(b) with respect to the Shares. In giving such consent, we do not thereby admit that we are in the category of persons whose consent is required under Section 7 of the Act or the rules and regulations of the Commission thereunder.

Sincerely,

/s/ Latham & Watkins LLP

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the reference to our firm under the caption "Experts" and to the use of our report dated March 18, 2024 (except for the third paragraph of Note 2, as to which the date is June 9, 2025), in the Registration Statement (Form S-1 No. 333-287551) and related Prospectus of Caris Life Sciences, Inc. for the registration of shares of its common stock.

/s/ Ernst & Young LLP

Dallas, Texas

June 16, 2025

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the use in this Registration Statement No. 333-287551 on Form S-1 of our report dated April 4, 2025 (June 9, 2025 as to the effects of the reverse stock split described in Note 2) relating to the financial statements of Caris Life Sciences, Inc. We also consent to the reference to us under the heading "Experts" in such Registration Statement.

/s/ Deloitte & Touche LLP

San Jose, California
June 16, 2025

Calculation of Filing Fee Table

Form S-1
(Form Type)

Caris Life Sciences, Inc.
(Exact Name of Registrant as Specified in its Charter)

Table 1: Newly Registered Securities

	Security Type	Security Class Title	Fee Calculation Rule	Amount Registered	Proposed Maximum Offering Price Per Unit	Maximum Aggregate Offering Price ⁽¹⁾	Fee Rate	Amount of Registration Fee
Fees to be Paid	Equity	Common stock, \$0.001 par value per share	Rule 457(a)	27,058,823	\$20.00	\$541,176,460 ⁽²⁾	0.00015310	\$82,854.12
Fees Previously Paid	Equity	Common stock, \$0.001 par value per share	Rule 457(a)	27,058,823	\$18.00	\$487,058,814 ⁽²⁾	0.00015310	\$74,568.71
		Total Offering Amounts				\$541,176,46		\$82,854.12
		Total Fees Previously Paid						\$74,568.71
		Total Fee Offsets						—
		Net Fee Due						\$8,285.41

(1) Includes the aggregate offering price of additional shares that the underwriters have the option to purchase to cover over-allotments, if any.

(2) Estimated solely for the purpose of computing the amount of the registration fee pursuant to Rule 457(a) under the Securities Act of 1933, as amended.