2025 Annual Report

Where Molecular Science
Meets Artificial Intelligence

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2025

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to

Commission file number: 001-42706

CARIS LIFE SCIENCES, INC.
(Exact name of registrant as specified in its charter)

Texas	**85-2077369**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

750 W. John Carpenter Freeway
Suite 800
Irving, TX 75039
(Address of Principal Executive Offices, Zip Code)
(866) 771-8946
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.001 par value	CAI	The Nasdaq Stock Market LLC

Securities registered pursuant to section 12(g) of the Act:

None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.
Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act.
Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).

Yes ☒ No ☐

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	☐	Accelerated filer	☐
Non-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 13(a) of the Exchange Act.

☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report.

☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements.

☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b).

☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act).

Yes ☐ No ☒

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant, as of the last day of the registrant's most recently completed second fiscal quarter, was approximately $3.87 billion based on the closing price of the registrant's common stock on the Nasdaq Global Select Market on June 30, 2025.

As of February 26, 2026, the registrant had 282,579,919 shares of common stock, par value $0.001 per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Certain portions of the registrant's Definitive Proxy Statement relating to the 2026 Annual Meeting of Shareholders, to be filed with the Securities and Exchange Commission within 120 days after the end of the registrant's fiscal year ended December 31, 2025, are incorporated by reference into Part III where indicated.

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Special Note Regarding Forward-Looking Statements

This Annual Report on Form 10-K (this "Annual Report") contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. All statements other than statements of historical facts contained in this Annual Report, including statements regarding our expectations of future results of operations and financial condition, business strategy, future solutions, and launches of new 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 Annual Report include, but are not limited to, statements about:

- developments in the precision oncology industry, including the market size for molecular information services and our biopharma partners' use of molecular information;
- 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 our solutions 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;
- our estimates regarding our expenses, future revenue, and capital requirements; and
- remediating the material weakness in our internal control over financial reporting.

These forward-looking statements are subject to a number of risks, uncertainties, and assumptions, including those described in Part I, Item 1A. "Risk Factors" and elsewhere in this Annual Report and in other filings we make with the Securities and Exchange Commission from time to time. 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 Annual Report may not occur, and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

Although we believe that the expectations reflected in our forward-looking statements are reasonable based on the information available to us when they are made, 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 Annual Report, 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 forward-looking statements. We undertake no obligation to update any forward-looking statements, which speak only as the date they are made, for any reason after the date of this Annual Report.

Part I

Item 1. 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. As of December 31, 2025, we have performed sequencing on over 1,000,000 cases. 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 Molecular Intelligence product portfolio is currently focused on oncology and consists of: (1) our MI Profile Platform, our whole exome sequencing ("WES")/whole transcriptome sequencing ("WTS") tissue-based molecular profiling solutions, (2) our Caris Assure Platform, our WES/WTS blood-based molecular profiling solutions, and (3) our Precision Whole Genome Platform, our whole genome sequencing ("WGS") blood- and tissue-based profiling solutions.

We believe we are well-positioned to realize the full potential of our vision and enable a transition from intuitive to empirical medicine due to the recent convergence of several advancements in biology, medicine, and technology: 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; NGS costs have declined, making NGS more accessible to the healthcare ecosystem; 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 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 WES (all 23,000 encoding DNA genes) and WTS (all 61,000 RNA transcripts that encode proteins) or WGS (sequencing across the entire DNA) on every eligible patient sample (a sample provided by ordering physicians that contains sufficient genetic material for profiling). Our in-depth profiling of patient samples has led to our 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. 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, a WES solution the following year, and our anticipated launch of WGS solutions in 2026, 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 biopharma partners, such as Moderna, AbbVie, Xencor, Merck KGaA and Genentech, 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

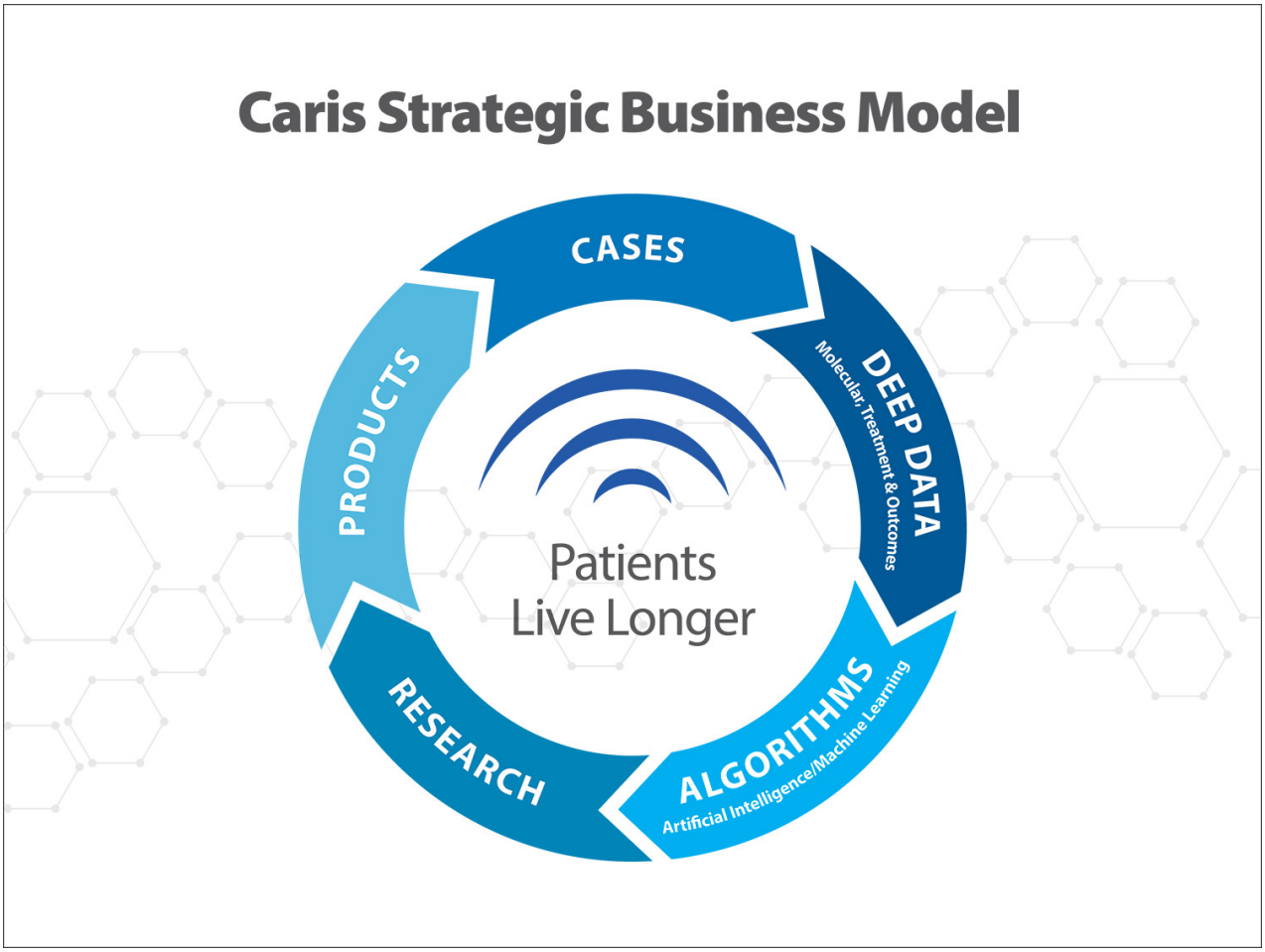
testing through innovative research to improve clinical outcomes for cancer patients. Close connectivity with this valuable network of key opinion leaders ("KOLs") in oncology clinical care, research, and drug development has enabled us to remain at the forefront of precision oncology and closely attuned to the key needs of the most sophisticated researchers.

Our Molecular Intelligence Platform was purpose-built to leverage the convergence of NGS, AI and ML technologies, and high-performance computing.

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 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 that it fuels.

Our multi-omic technology platform is built on the following pillars: (1) our Molecular Intelligence solutions; (2) Caris Discovery; (3) Caris Strategic Data; and (4) Caris Infrastructure. These four 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 four 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 Molecular Intelligence:*** Our MI Profile, Caris Assure and Precision Whole Genome platforms collectively include both marketed and in development comprehensive WES, WTS and WGS solutions. These solutions span the entire continuum of cancer care, including early detection, MRD tracking, therapy selection, and treatment monitoring.
- ***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:*** To assist us with analyzing the data we generate, we utilize AI/ML tools across our clinical testing, R&D, and biopharma business. 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.

The Caris Advantage

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

- **We purpose-built our Molecular Intelligence 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 WES, WTS and WGS, 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 Cancer Seek, part of our MI Profile platform, together with associated professional services, consists of a WES and WTS NGS, immunohistochemical ("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 blood-based profiling solution, Caris Assure, is experiencing rapid adoption in the market.** 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 blood-based solution, which includes clonal hematopoiesis (CH) subtraction through plasma sequencing. 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.
- **Our novel blood-based detection solution, Caris Detect, is expected to launch in 2026.** Our Caris Detect early detection assay is a WGS assay that is intended to overcome some of the current limitations faced by other similar assays. Caris Detect is designed to deliver higher sensitivity while maintaining a low false positive rate due to novel library preparation chemistry, deep sequencing, and a proprietary AI/ML algorithm for cancer detection.
- **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 sequencing over 1,000,000 cases as of December 31, 2025, as well as matched clinical outcomes for many of these patients. 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 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, serving over 6,000 ordering physicians in the United States across all major health systems, academic cancer institutions, and community settings.
- **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 Dean 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 offerings into early detection, MRD, and monitoring.
- Utilize the data generated by our existing solutions to develop new solutions with additional revenue.
- 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 Caris Detect, our WGS, blood-based solution in development, and broader innovation platform in other chronic disease states beyond oncology, including in cardiology, neurology, and metabolic conditions.

Our Caris Molecular Intelligence Solutions

Caris Assure—Our WES/WTS Blood-Based Solution

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). Caris Assure for therapy selection is available in all U.S. states (other than New York, where we intend to apply 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. Customers for Caris Assure include treating physicians as well as researchers and biopharma companies. 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"), tumor mutational burden ("TMB"), and microsatellite instability ("MSI").

In addition to sequencing cell-free DNA and cell-free RNA isolated from the plasma to identify somatic tumor variants, Caris Assure for therapy selection sequences 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.

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.

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.

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 therapy selection solution on the market, featuring over 23,000 gene coverage, 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. 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.

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, we believe the only way to get this understanding is through the WES/WTS sequencing technology underlying Caris Assure. 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 for Minimal Residual Disease Tracking and Treatment Monitoring

We are also developing Caris Assure for minimal residual disease tracking and treatment monitoring. Caris Assure in the minimal residual disease space utilizes 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 bespoke-free approach is designed to enable 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.

We are in the process of conducting studies and analysis to internally validate and refine the Caris Assure for MRD and treatment monitoring in various cancer lineages. We have submitted a technical assessment for Caris Assure MRD for patients with colorectal cancer to MolDX, but cannot provide any assurance on when or if such technical assessment will be accepted. The commercial application of Caris Assure for MRD is subject to further assay development, validation, and reimbursement coverage. Because many of these factors are outside of our control, we cannot be certain when or if Caris Assure for MRD and treatment monitoring markets will become commercially available.

MI Profile—Our WES/WTS Tissue-Based Profiling Solutions

MI Profile is our tissue-based molecular profiling solution for cancer therapy selection, with approximately 170,300 clinical cases in 2025. MI Profile includes MI Cancer Seek, 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.

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.

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 through distributors and direct contracts with hospital systems, where permitted by applicable regulations.

We have obtained a PMA approval from the FDA for certain companion diagnostic and tumor profiling indications for MI Cancer Seek, a WES/WTS NGS assay for which we have obtained a Proprietary Laboratory Analyses ("PLA") code, Current Procedural Terminology ("CPT") code 0211U, which is covered under the NGS NCD. MI Cancer Seek was commercially launched in January 2025, and we currently market it as the WES/WTS NGS component of our MI Profile Platform.

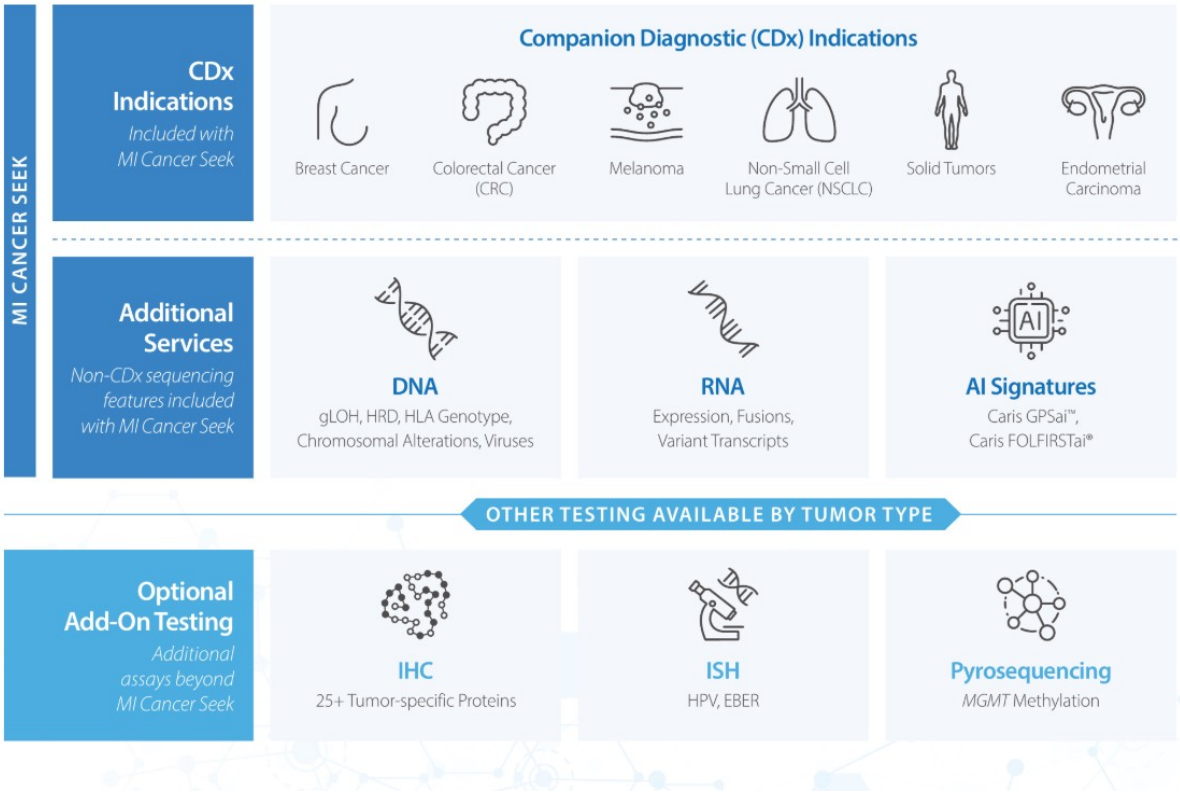
MI Cancer Seek Report

MI Cancer Seek generates a personalized report that provides oncologists with the information to tailor each patient's treatment plan. The MI Cancer Seek 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.

MI Cancer Seek

The current WES/WTS NGS component of our MI Profile Platform is MI Cancer Seek. MI Cancer Seek has obtained FDA approval for use as a companion diagnostic device to identify cancer patients who may benefit from treatment with targeted therapies listed in the accompanying Companion Diagnostic Indications, in accordance with the approved therapeutic product labeling. The companion diagnostic FDA approval currently includes one pan-cancer and five tumor-specific indications that cover 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 WES/WTS 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 CNAs in one gene in patients with breast cancer.



AI Algorithms

Our WES/WTS profiling solutions generate a vast amount of data per clinical case. To interpret this data, we utilize an advanced, AI-powered bioinformatics pipeline. This bioinformatics pipeline includes a sophisticated rules engine, variant calling, fusion calling, copy number prediction, and expression analysis.

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 Cancer 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.

  The latest GPSai model was trained and clinically validated by us through retrospective profiling data from over 200,000 clinical cases using the outside pathologist diagnosis as the baseline. In a prospectively run clinical validation study that we conducted and published in the American Association for Cancer Research's Cancer Research Communications journal, GPSai demonstrated 95.0% accuracy in identifying tumor tissue of origin in

non-'Cancer of Unknown Primary' ("CUP") cases and successfully reported a tissue of origin in 84.0% of CUP and 96.3% of non-CUP cases during retrospective and prospective validations. The clinical validation of GPSai enables 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 Cancer Seek 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.

Molecular Tumor Board Report

We use sequencing data generated by MI Profile to produce the Molecular Tumor Board Report (formerly referred to as QuantumAI report), a research-use-only description of the patient's molecular tumor biology and phenotype characterization using whole exome and whole transcriptome sequencing. The report, which we have analytically validated but not yet clinically validated, contains biological signatures to help oncologists and researchers understand relationships between genetic variations, mutations, and other molecular features and to tailor precision medicine approaches. The report also features AI-powered signatures that leverage whole exome and whole transcriptome data to predict response to specific therapies across multiple cancer types, including glioblastoma, ovarian, breast, pancreatic, and non-small cell lung cancers, as well as the likelihood of brain metastasis. We continue to develop additional predictive signatures and report features.

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. 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.

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 tumor assay is optimally positioned to seamlessly validate these novel biomarkers since they 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 is being 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. 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 MI Clarity—Our Breast Cancer Risk Recurrence Predictor

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, with or without the need for NGS profiling.

We have utilized these tools to develop Caris MI Clarity (formerly called ESPai), an AI-powered multimodal tool for breast cancer recurrence risk stratification. It is developed through research partnerships with ECOG-ACRIN Cancer Research Group (ECOG-ACRIN) and NRG Oncology (NRG), to combine Caris comprehensive WES/WTS, whole slide imaging, and advanced ML platforms. The test was developed using tumor specimens and clinical data from the TAILORx (ECOG) and B-42 (NRG) randomized clinical trials. Our internal validation study results demonstrated an ability to predict risk of both early (0-5 years) and late recurrence (5-15 years) of breast cancer.

Across analytic evaluations, the multimodal AI models (one using comprehensive WES/WTS, whole slide imaging, and clinical data, and another using only whole slide imaging and clinical data) demonstrated enhanced prognostic performance compared to existing recurrence-risk assessment methods, highlighting the potential to support more personalized treatment decision-making in early-stage breast cancer. This new diagnostic test for women with HR-positive, HER2-negative, node-negative breast cancer has the potential to help guide physician decisions about the use of chemotherapy and extended endocrine therapy. We are currently evaluating and pursuing reimbursement and launch pathways for Caris MI Clarity, in versions both with and without WES/WTS.

Precision Whole Genome Platform—Our WGS Tissue- and Blood-Based Profiling Solutions

In 2025, based on our belief in the power of comprehensive profiling, we determined to pursue whole genome sequencing for certain of our assays that are under development. These assays include: Caris Detect, our WGS-based multi-cancer early detection ("MCED") solution; Caris WGS MRD, our WGS and digital droplet PCR (polymerase chain

reaction)-based minimal residual disease solution; and Caris ChromoSeq, our WGS and WTS based assay for therapy selection in hematological (blood) cancers.

We are in the process of conducting studies and analysis to internally validate and refine our WGS assays as LDTs. The commercial application of these assays is subject to further assay development, validation, and reimbursement coverage. Because many of these factors are outside of our control, we cannot be certain when or if each of our WGS assays, including Caris Detect, Caris WGS MRD and Caris ChromoSeq, will become commercially available.

Caris Detect

Caris Detect is our comprehensive blood-based WGS-based MCED assay under development to identify multiple cancer types by analyzing molecular signals circulating in the bloodstream. We have entered into a collaboration agreement with Everlywell to expand access to Caris Detect. We believe that Caris Detect will allow for the detection of cancer at early and more treatable stages, before it can spread, ultimately supporting better outcomes for patients. We expect to launch Caris Detect as an LDT in the first half of 2026. We plan to launch Caris Detect with a self-pay model at a price of $3,500.

We are in the process of validating the performance of Caris Detect for early detection through Achieve 1, an approximately 3,000-subject case-control study of Caris Detect in MCED, that consisted of approximately 66% undiagnosed patients and 33% patients with cancer. We reported an interim readout of results of Achieve 1 in February 2026, and are in the process of completing a blinded validation of nearly 900 samples held out of the initial readout. We are also actively enrolling approximately 25,000 subjects, including non-cancerous subjects, cancerous subjects and subjects with advanced adenomas, in Achieve 2, a subsequent study for Caris Detect in MCED.

We believe that future advances planned for Caris Detect technology have the potential to deliver meaningful innovation in other chronic disease states, including cardiology, neurology, and metabolic conditions.

Caris WGS MRD

We are in the early stages of developing an ultra-low sensitivity, WGS-based, tumor informed assay for MRD in Stage 1, 2, and 3 cancers. This assay utilizes WGS of tumor samples to identify trackers that then can be measured using digital droplet PCR analysis in follow-up testing to track cancer recurrence.

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 cancers using WGS and WTS. We have internally validated this assay, which is based upon the licensed WGS assay and also includes our WTS technology, and are developing it for commercial launch subject to receipt of reimbursement approval from MolDX. We have submitted a technical assessment to MolDX for Caris ChromoSeq for Acute Myeloid Leukemia (AML) and Myelodysplastic Syndrome (MDS). We are also working to expand and validate the assay's capabilities for hematological cancers beyond AML and MDS and currently intend to seek additional coverage from MolDX for additional hematological cancers.

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.

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 Genentech, 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 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 Surfacesome. Cell-surface proteins are key to antibody-based therapeutics, and we have developed our own cell surfacesome 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 data scientists deploys 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 long 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 we have generated, 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. To assist us with analyzing this data, we utilize AI/ML tools across our clinical testing, R&D, and biopharma business.

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 December 31, 2025, the Caris POA was comprised of 99 members, including over 45 National Cancer Institute ("NCI")-designated comprehensive cancer centers.

POA 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 contributing 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 484,000 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.

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.

Data Driving Development of New Clinical Solutions

A significant benefit of generating WES, WTS and WGS results 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 hundreds of 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.

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.

Our basic strategy for molecular signature development is to utilize our proprietary WES/WTS/WGS 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.

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 NovaSeq 6000 and NovaSeq X sequencing systems. 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.

Our solid tissue clinical laboratory in Phoenix, Arizona is an approximately 66,000 square foot, state-of-the-art laboratory. 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 an ISO 13485 certification.

We test patient samples on powerful sequencing systems that are built for high throughput sequencing, scalability, and speed, all economically. Our use of high performance NGS sequencing systems improves our throughput efficiencies and lowers our cost of sequencing. In addition to NGS, we employ other technologies in our operations, including 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 6,000 ordering physicians and partnerships with many top biopharma companies. 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. 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, we have 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 a UK-CA mark for both Caris Assure and MI Cancer Seek. We are considering filing for regulatory approvals in Japan and the European Union.

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, Tempus and Foundation Medicine (Roche). Our competitors in blood-based molecular profiling for MRD tracking and treatment monitoring include Natera, Guardant Health, SAGA Diagnostics, Personalis, BillionToOne, Quest Diagnostics and Adaptive Biotechnologies. Our competitors in core biopharma services include Foundation Medicine (Roche), Guardant Health, Tempus, Natera, and Personalis. 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 of all DNA encoding genes and RNA transcripts utilizing comprehensive WES and WTS, and anticipated sequencing of all DNA using WGS, enables us to provide patients and physicians with industry-leading breadth, depth, and accuracy of multi-omic information; our tissue-based molecular profiling solutions; blood-based profiling solutions; our large and comprehensive multi-modal clinico-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 our business success. To protect our intellectual property, we use a combination of patents, trademarks, copyrights, trade secrets, license agreements, confidentiality agreements and procedures, employee agreements, and other legal and contractual rights.

Patents

We enter into invention/patent assignment agreements with employees and consultants requiring assignment of inventions developed 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 December 30, 2025, we owned 68 patents (including four allowances) and 77 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 18 issued U.S. patents, 21 pending U.S. applications, 50 foreign patents (including four allowances), and 56 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 December 30, 2025, we owned 121 patents (including one allowance), 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 17 issued U.S. patents and one allowance, five pending U.S. applications, 103 foreign patents, and 19 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:

- 47 patents (including one allowance) and 11 pending applications directed to systems and methods for comprehensive molecular profiling for cancer patients independent of cancer type. These include 15 issued U.S. patents and two pending U.S. applications, and 32 foreign patents (including one allowance) and 9 pending foreign applications between Australia, Canada, China, Europe, India, Israel, Japan, Mexico, Singapore, South Africa, and South Korea. These patents and applications are Caris-owned and assigned to our subsidiary Caris MPI, Inc., and are expected to expire between 2027 and 2033;
- Two issued patents in Japan, one issued patent in Australia, an allowance in Israel, and 16 pending applications directed to AI/ML systems and methods for predicting cancer type. These include two pending U.S. applications, one PCT application, and 13 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
- 16 patents (including two allowances) and 14 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 13 foreign patents (including two allowances) and 12 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:

- 19 pending applications directed to AI/ML systems and methods for characterizing cancers, including predicting response to various cancer treatments. These applications are Caris-owned and are expected to expire in 2041;
- Seven 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 2046; 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 five 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;
- 56 patents (including one allowance) and six 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
- 18 patents and 18 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.

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, have analytically validated 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. We do not yet have specific plans regarding the timing of an FDA or other regulatory submission, if any, for Caris Assure for therapy selection. 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[(1)]	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 2026	Potential to submit PMA application, a de novo 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

[(1)] Related professional services are covered by other NY CLEP approvals.

The FDA premarket review process requires significant resources and accurate device descriptions including intended use, indications, target population, performance characteristics, labeling and marketing claims. These factors, combined with device classification and predicate device availability, determine the appropriate submission type and regulatory pathway.

The FDA encourages participation in the FDA's Pre-Submission Program and we may have formal meetings with CDRH to obtain non-binding feedback on study designs and regulatory strategy for solutions we intend to submit for premarket review.

We have obtained PMA approval for MI Cancer Seek as a companion diagnostic and tumor profiling device. We 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."

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.

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.

We are subject to complex and evolving U.S. laws and regulations governing diagnostic products. Clinical LDTs are regulated by CLIA and applicable state laws. The FDC Act defines medical devices to include in vitro diagnostic reagents and other articles intended for use in diagnosis, treatment, or prevention of disease. The FDA regulates the research, testing, manufacturing, safety, labeling, premarket clearance or approval, marketing, and distribution of medical devices to ensure they 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

CLIA establishes quality standards for U.S. laboratories performing testing on human specimens for diagnosis, prevention, or treatment of disease.

CLIA requires laboratories to obtain federal certification and maintain compliance with operational, personnel, quality control, and proficiency testing requirements. CMS administers the CLIA certification program. For every LDT used in clinical testing, CLIA requires analytical validation of performance characteristics including accuracy, precision, specificity, sensitivity, reportable range, and reference interval. Certified laboratories performing certain testing categories must enroll in approved proficiency testing programs. Failure to comply with CLIA requirements can result in loss of certification or revocation of the laboratory's CLIA certificate.

We operate two clinical laboratory facilities in Phoenix, Arizona with CAP and CLIA accreditations. CLIA-accredited laboratories are inspected every two years.

Prior to offering new solutions, we must satisfy notification requirements to regulatory and accrediting bodies. CLIA-accredited laboratories are reviewed biannually by CMS-approved accreditation organizations and may be subject to additional inspections.

Non-compliance with CLIA requirements may result in enforcement actions including suspension or revocation of CLIA certification, corrective action plans, monetary penalties, or other sanctions that could materially adversely impact our business.

State Laboratory Licensure Laws

In addition to federal CLIA certification, certain states including Maryland, Pennsylvania, New York, California, and Rhode Island require state laboratory licenses with standards for laboratory operations. CLIA provides that states may adopt more stringent regulations. New York requires premarket approval of certain tests including LDTs.

Our Arizona laboratories have obtained out-of-state licenses where required.

Non-compliance may result in suspension, revocation, financial penalties, or other sanctions that could materially adversely impact our business.

Some states also impose registration/licensing on medical device manufacturers, with violations resulting in denial, suspension, revocation, fines, and penalties.

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 governing medical device development, testing, manufacture, labeling, storage, premarket clearance or approval, advertising, promotion, and distribution.

Laboratory Developed Tests

IVDs are medical devices used in disease diagnosis. The FDA historically considered LDTs a subset of IVDs designed, manufactured, and used within a single laboratory, historically exercising enforcement discretion.

The FDA issued the LDT Final Rule in May 2024 to phase out enforcement discretion and impose medical device requirements; however, a federal district court vacated this rule in March 2025 and the FDA ultimately rescinded this rule in 2025. It remains uncertain whether or when the FDA may in future exercise, or attempt to exercise, medical device authority over LDTs.

FDA Classification and Premarket Review of Medical Devices

PMA Pathway. The FDA categorizes medical devices into three classes (I, II, or III) based on risk and regulatory controls necessary for safety and effectiveness. Class I devices have lowest risk and require adherence to General

Controls. Class II devices require General Controls and special controls. Class III devices pose greatest risks and require PMA approval.

Class III devices require PMA approval before marketing. Obtaining PMA approval requires submission of valid scientific evidence, complete analytical and clinical performance data, and device information. The FDA reviews the application, may convene an advisory panel, and inspects manufacturing facilities for Quality System Regulation ("QSR") compliance. The statutory review period is 180 days, though in practice reviews often take significantly longer. The FDA collects user fees for PMA submissions.

FDA will approve the device if it determines there is reasonable assurance of safety and effectiveness. FDA may approve a PMA with post-approval conditions including restrictions on labeling, promotion, and distribution, or requirements for additional clinical studies or post-market surveillance. Failure to comply with conditions of approval can result in material adverse enforcement action, including withdrawal of approval.

Certain changes to an approved device require submission of a PMA supplement or new PMA depending on the nature and significance of the changes.

510(k) Notification Pathway. To obtain 510(k) clearance, a manufacturer must demonstrate the proposed device is "substantially equivalent" to a legally marketed predicate device. The process usually takes three to 12 months but often takes longer. The FDA may require additional information including clinical data and collects user fees for submissions. If the FDA agrees the device is substantially equivalent to a lawfully marketed predicate device, it grants 510(k) clearance. If not substantially equivalent, the device is designated Class III, requiring PMA approval or a de novo classification request for low to moderate risk devices. Once a de novo classification is granted, the device receives Class I or II classification and may serve as a 510(k) predicate for future devices.

After receiving 510(k) clearance or de novo classification, modifications significantly affecting safety or effectiveness require new 510(k) clearance, PMA approval, or de novo classification. Manufacturers determine whether changes require new submissions, but the FDA may disagree and require the manufacturer to cease marketing until new authorization is obtained.

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 sometimes required for 510(k) submissions. All clinical investigations must be conducted in accordance with FDA's IDE regulations. For significant risk devices, the sponsor must submit an IDE application to the FDA supported by appropriate data showing it is safe to test in humans. The IDE becomes effective 30 days after FDA receipt unless the FDA objects.

Studies must be approved by and conducted under IRB oversight. If FDA and IRB approve, human clinical trials may begin at approved sites with approved patient numbers. For significant risk devices, progress reports must be submitted to FDA and IRBs. For non-significant risk devices, sponsors may begin trials after IRB approval without separate FDA approval but must follow abbreviated IDE requirements. Acceptance of an IDE application does not guarantee FDA will allow the IDE to become effective or that trial data will support device safety and effectiveness.

During a study, sponsors must comply with applicable FDA requirements including trial monitoring, IRB review, adverse event reporting, and record keeping. Clinical investigators must obtain patient informed consent and comply with all reporting requirements. We, the FDA, or the IRB could suspend or terminate a clinical trial at any time if risks to subjects outweigh anticipated benefits.

Expedited Development and Review Programs. The FDA has established programs including Breakthrough Device designation that offer manufacturers opportunities to interact with the FDA more frequently to expedite commercialization. The program is available to devices that provide more effective treatment or diagnosis of life threatening or irreversibly debilitating diseases and meet certain eligibility criteria.

Postmarket Regulation. After a device is cleared or approved, numerous regulatory requirements continue to apply, including: establishment registration and device listing; QSR compliance; labeling regulations and off-label promotion prohibitions; approval of product modifications; Medical Device Reporting; correction, removal, and recall reporting; post-market surveillance; and Unique Device Identifier requirements.

Manufacturers must comply with QSR requirements and are subject to periodic FDA inspections. Failure to maintain QSR compliance could result in manufacturing restrictions, product recalls, or seizures. Discovery of previously unknown problems with products could result in restrictions on the device, including removal from the market or device recalls.

FDA Enforcement Powers. The FDA has broad regulatory compliance and enforcement powers. If the FDA determines a manufacturer has failed to comply with applicable requirements, it can take various compliance or enforcement actions including: warning letters, fines, injunctions, and civil penalties; recalls or seizures; manufacturing restrictions or shutdowns; refusing or delaying marketing clearances or approvals; withdrawing clearances or approvals already granted; refusing export approvals; or criminal prosecution.

Healthcare Fraud and Abuse Oversight

A variety of federal and state laws prohibit fraud and abuse involving healthcare programs and private insurers. These laws are interpreted broadly and actively enforced by CMS, DOJ, and OIG. Violations may result in significant penalties including administrative and civil fines, criminal penalties, loss of licensure, disgorgement, imprisonment, exclusion from federal healthcare programs, and additional reporting obligations.

Federal and State Physician Self-Referral Prohibitions. The federal Stark Law generally prohibits entities from billing Medicare or Medicaid for designated health services, including laboratory services, when the ordering physician or immediate family member has an ownership interest or compensation arrangement with that entity, unless certain exceptions apply. The Stark Law is a strict liability statute. Sanctions include denial of payment, refunds, monetary penalties, and exclusion from federal healthcare programs. Violations may also serve as the basis for FCA liability. Many states have similar self-referral bans that may extend to all payers.

The Anti-Kickback Statute. The federal AKS prohibits knowingly and willfully offering, paying, soliciting, or receiving remuneration to induce referrals of items or services reimbursable by federal healthcare programs. Remuneration is broadly defined to include anything of value. The AKS contains statutory exceptions and regulatory safe harbors that protect certain arrangements if specific requirements are met. Violations may result in significant penalties including imprisonment, fines, and exclusion from federal healthcare programs, and may also incur FCA liability. Some states have similar AKS laws that may apply to all payers.

Eliminating Kickbacks in Recovery Act. EKRA is an all-payer anti-kickback law that criminalizes paying or offering remuneration to induce referrals to recovery homes, substance use clinical treatment facilities, or laboratories. Although there is overlap between EKRA's exceptions and AKS safe harbors, compliance with an AKS safe harbor does not guarantee protection under EKRA. DOJ has not yet issued clarifying regulations, and relationships between laboratories and physicians, sales representatives, hospitals, and customers may be subject to scrutiny under EKRA.

False Claims Act. The FCA prohibits knowingly submitting false claims, making false records or statements to secure payment, or knowingly retaining overpayments from the federal government. Claims resulting from AKS violations may constitute false claims under the FCA. Penalties include payment of up to three times actual damages, substantial per-claim civil penalties, and possible exclusion from federal healthcare programs. The FCA's qui tam provisions allow private individuals to bring actions on behalf of the government and share in recoveries. Several states have similar laws that may apply 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. The false statements statute prohibits knowingly and willfully falsifying, concealing, or making materially false statements in connection with healthcare delivery or payment. Violations may result in fines, imprisonment, or exclusion from government healthcare programs.

Civil Monetary Penalties Law. The federal CMP law prohibits, among other things, offering remuneration to federal healthcare program beneficiaries to influence their ordering decisions, employing or contracting with excluded individuals or entities, billing for services requested by unlicensed or excluded providers, and billing for medically unnecessary services. Penalties include exclusion from federal healthcare programs and substantial fines.

Physician Payments Sunshine Act. The Sunshine Act requires certain manufacturers to collect and report annually to CMS data on payments and transfers of value to U.S. licensed physicians, teaching hospitals, and certain advanced non-physician healthcare practitioners. The Open Payments program is administered by CMS. Several states have similar reporting requirements.

While we intend to comply with applicable fraud and abuse laws, some of our arrangements may become subject to regulatory scrutiny, and we cannot be certain we will be found in compliance following any such review.

Other Potentially Applicable State Laws

Other Potentially Applicable State Laws. States may have additional fraud and abuse laws including fee-splitting restrictions, insurance fraud laws, anti-markup laws, direct billing requirements, prohibitions on waiving patient cost-sharing, prohibitions on providing solutions at no or discounted cost to induce adoption, and corporate practice of medicine prohibitions. Violations may result in civil or criminal penalties and sanctions.

Additional International Regulation and Product Approval

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

The European Union adopted IVDR 2017/746 in May 2017, replacing the IVD Directive in May 2022. IVDR requires notified body involvement for many more IVDs. Transitional provisions allow IVDs with certificates under the IVD Directive to continue until May 2024 at the latest. After transitional periods, only IVDR CE-marked IVDs may be placed on EU markets.

Other Jurisdictions

Expanding into other countries requires compliance with varying healthcare and other laws and regulations that are complex, change frequently, and differ among jurisdictions.

Coverage and Reimbursement

Reimbursement and billing for clinical laboratory services is highly complex. Laboratories must bill various payers including federal healthcare programs (Medicare, Medicaid, TRICARE), Medicare Advantage plans, private insurers, and managed care organizations, each with different billing requirements and audit requirements.

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.

A payer's decision to cover a solution does not guarantee adequate reimbursement. Third-party payers increasingly examine medical necessity and cost-effectiveness of clinical laboratory tests in addition to safety and efficacy. Coverage and reimbursement differ significantly among payers. The coverage determination process is often time-consuming and costly, requiring us to provide scientific and clinical support to each payer separately, with no assurance of consistent coverage or adequate reimbursement. In certain foreign markets, governments control coverage and pricing of healthcare products. The marketability of our solutions may suffer if payers fail to provide adequate coverage and reimbursement. Coverage policies and reimbursement rates may change at any time.

Coverage and Reimbursement in the United States

In the United States, there is no uniform coverage for clinical laboratory tests, and obtaining coverage for genomic sequencing solutions is particularly challenging. Medicare is the largest healthcare payer in the United States and a significant payer for cancer-related laboratory services. Many U.S. payers look to Medicare policies as a benchmark for their own coverage and reimbursement decisions. Medicare provides traditional fee-for-service coverage and Medicare Advantage coverage administered by private insurers.

Medicare's NGS NCD, established in 2018 and updated in 2020, provides national Medicare coverage for certain molecular diagnostic tests meeting specified criteria. MACs may provide local coverage of other NGS tests through LCDs. Palmetto GBA administers Medicare's MolDX, which issues LCDs for molecular diagnostic tests not approved or cleared by the FDA. Our MAC is Noridian, which relies on MolDX for coverage and pricing determinations. To achieve MolDX coverage, a test must demonstrate analytical and clinical validity, and clinical utility. Our MI Cancer Seek solution has Medicare coverage under the NGS NCD. Our MI Tumor Seek Hybrid solution and Caris Assure solution for therapy selection are covered by Medicare under the MolDX Program. MolDX has issued LCDs providing coverage for MRD for CRC, breast cancer, lung cancer, and other indications when applicable coverage criteria are satisfied, and for NGS assays for myeloid malignancies. In order to obtain MolDX coverage for Caris ChromoSeq, we will need to submit, and MolDX will need to approve, a technical assessment.

Coding plays a significant role in reimbursement. CPT codes and PLA codes (maintained by the AMA) are used for medical and laboratory services billing. Z-Code Identifiers are used by certain payers including MolDX to supplement CPT codes for molecular diagnostics tests. In July 2020, the AMA issued PLA code CPT 0211U for our MI Cancer Seek solution. CMS established national pricing at $8,455 under the CLFS. Our MI Tumor Seek Hybrid solution uses CPT code 81479 and unique Z-Code Identifiers. In July 2024, the AMA issued PLA code CPT 0485U for Caris Assure for therapy selection. In November 2024, CMS determined to price Caris Assure using the "Gapfill" method, which resulted in a price under the CLFS of $3,649, effective January 1, 2026. Changes to coverage policies or codes may result in significant changes in reimbursement.

Our early detection solution could be considered a screening test and is not currently covered by Medicare. Medicare coverage for preventive services must be expressly authorized by statute or by CMS under an NCD and historically required specified criteria including United States Preventive Services Task Force ("USPSTF") recommendation with a grade of A or B. Recent legislation enacted as part of the Consolidated Appropriations Act, 2026, creates an alternative pathway for FDA-approved MCED tests beginning in 2028 without requiring USPSTF endorsement. None of our early detection solutions have received an "A" or "B" grade from USPSTF. Under the traditional NCD pathway, the NCD process may take multiple years, and it is possible that our early detection solution Caris Detect will not become eligible for Medicare coverage through that pathway. The alternative pathway would require us to obtain FDA approval for Caris Detect, and any reimbursement may not adequately cover our costs. We do not currently have plans to seek Medicare coverage for Caris Detect. We currently plan to launch Caris Detect as a cash pay only test, however, the scale of adoption of Caris Detect may be impacted by whether coverage is available for Caris Detect or competitor tests.

The Protecting Access to Medicare Act of 2014

The Protecting Access to Medicare Act of 2014 ("PAMA"). PAMA (as amended) requires certain laboratories to report private payer payment rates, test volumes, and HCPCS codes. CMS uses this data to calculate weighted median payment rates to establish revised Medicare CLFS reimbursement rates for CDLTs. The reimbursement rate we receive for newly developed tests may be affected by payment rates from private payers. PAMA codified Medicare coverage rules for laboratory tests and authorizes CMS to consolidate coverage policies among laboratory-specific MACs. The revised reimbursement methodology generally results in relatively lower reimbursement amounts. Reductions are limited to 0% in 2026 and 15% per test per year in 2027 through 2029. Data reporting occurs in three-year cycles, with the next cycle beginning in 2026. Given uncertainties in PAMA's price-setting process, we cannot predict how payments under the CLFS may change from year to year.

Healthcare Reform

There have been numerous legislative and regulatory changes to the healthcare system in the United States and certain foreign jurisdictions. Changes in healthcare policy could increase our costs, subject us to additional regulatory requirements, decrease our revenue, and adversely impact sales of and reimbursement for our solutions. The ACA, signed into law in March 2010, substantially changed healthcare financing by governmental and private insurers and included provisions governing enrollment in federal healthcare programs, reimbursement adjustments, and fraud and abuse. Since enactment, there have been judicial, Congressional, and executive branch challenges to aspects of the ACA. The Inflation

Reduction Act of 2022 (the "IRA") extended enhanced subsidies for ACA marketplace coverage through 2025 and eliminated the Medicare Part D "donut hole" beginning in 2025. Other legislative changes since the ACA include the Budget Control Act of 2011 (reducing Medicare provider payments through 2032), the American Rescue Plan Act of 2021 (requiring additional Medicare payment reductions delayed until 2025), the American Taxpayer Relief Act of 2012 (reducing CMS payments and extending statute of limitations for Medicare overpayment recovery), and the One Big Beautiful Bill Act enacted in July 2025 (imposing significant Medicaid funding reductions). We believe there will continue to be proposals to reduce costs while expanding healthcare benefits. 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 federal, state, and foreign laws and regulations, govern the collection, dissemination, use, access to, confidentiality, and security of personal information, including health-related information. In the U.S., data breach notification laws, HIPAA, HITECH, and consumer protection laws apply. We are a HIPAA Covered Entity for healthcare services and a Business Associate for certain services, requiring policies for PHI protection, administrative/physical/technical safeguards, and breach notifications. Many states have healthcare privacy and genetic testing laws requiring patient consent and protecting test results. Privacy and security laws constantly evolve and can result in investigations, penalties, and data processing restrictions. We are subject to Section 4004 of the 21st Century Cures Act and HHS regulations for patient access to EHI and interoperability.

Other International Privacy and Security Regulations. We are subject to evolving global data privacy, security, cross-border transfer, and localization laws. Many governments are implementing or expanding data protection regimes, resulting in additional compliance costs and risks. Laws are subject to change and uncertain interpretation and could result in claims, changes to business practices, penalties, increased costs, or harm to our business.

We rely on IT systems including third-party hosted services storing personal data, creating cybersecurity risk. A cybersecurity incident could result in system unavailability, data loss/misuse/unauthorized disclosure, negative publicity, reputational damage, litigation, and regulatory investigations. Data breach notification laws may require notifying regulators, affected individuals, and other third parties.

Our Employees

As of December 31, 2025, we had 1,846 employees. 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 programs are 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.

Corporate History

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.

Available Information

Our website address is https://www.carislifesciences.com. At our Investor Relations website, https://investor.carislifesciences.com, we make available free of charge a variety of information for investors, including our

Annual Report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and any amendments to those reports, as soon as reasonably practicable after we electronically file that material with or furnish it to the Securities and Exchange Commission (the "SEC"). We intend to use our Investor Relations website as a distribution channel of material information about the Company and for complying with our disclosure obligations under Regulation FD. The information we post on our Investor Relations website may be deemed material. Accordingly, investors should subscribe to our investor alerts, in addition to following our press releases, SEC filings, public conference calls and webcasts. The SEC also maintains a website that contains our SEC filings at www.sec.gov. Information contained on, or connected to, these websites does not and will not constitute part of this Annual Report on Form 10-K, or any other filings with, or any information furnished or submitted to, the SEC.

Item 1A. Risk Factors

A description of risks and uncertainties facing our business is set forth below. You should carefully consider the risks described below, as well as the other information in this Annual Report on Form 10-K ("Annual Report"), including our audited consolidated financial statements and the related notes and Part II Item 7 titled "Management's Discussion and Analysis of Financial Condition and Results of Operations." Additional risks and uncertainties that we are not currently aware of, or that we currently believe are not material, may also adversely affect our business. 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 price of our securities could decline, and you may lose all or part of your investment.

Risk Factors Summary

The following is a summary of the most significant risks, challenges and uncertainties facing our business. This summary should be read in conjunction with the risk factors described below in this section and should not be considered an exhaustive list or summary of all of the significant or material risks, challenges and uncertainties that we face.

- The precision medicine industry is highly competitive and subject to rapid change.
- We have incurred significant losses since inception, may 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 certain of our solutions as planned 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, Caris Assure, Caris Detect and other solutions. We may be unsuccessful in continuing the commercialization and growing the adoption of these solutions, which would adversely affect our business, financial condition, results of operations, and growth prospects.
- If we are unable to support demand for our solutions, 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 coverage and/or adequate 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.
- If we or our partners fail to comply with healthcare or 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 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.

- We have current solutions marketed as laboratory-developed tests (LDT) 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.
- If our information technology systems or those of third parties with whom we work are compromised, or if we fail to comply with evolving privacy and data security laws, we could face regulatory investigations, litigation, fines, business disruptions, reputational harm, and loss of revenue, which could adversely affect our business operations and financial results.
- 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 results
- 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.
- Our executive officers, directors, and principal shareholders, including, in particular, David Dean Halbert, our Founder, Chairman, and Chief Executive Officer, 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.

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 and regulatory environments. 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 continue 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, may 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, 2025 and 2024, we incurred net losses of $68.1 million and $281.9 million, respectively. As of December 31, 2025, we had an accumulated deficit of $2.5 billion. To date, we have financed our operations principally from the sale of convertible preferred stock, the incurrence of indebtedness, the proceeds of our June 2025 initial public offering (“IPO”), 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 develop and validate solutions, obtain marketing authorization, efforts to obtain and manage reimbursement, 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 future profitability. We expect to continue to incur significant expenses for the foreseeable future, and may incur operating losses in the short term 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;
- 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 or other regulatory approvals 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, or pursue, claims or lawsuits related to our business, 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 cannot be sure that we will achieve annual GAAP profitability or remain profitable for any substantial period of time. While we have commercially launched MI Cancer Seek in the United States and plan to capitalize on the potential of new profiling solutions for early detection, MCED, 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 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 our MI Profile and Caris Assure for therapy selection and other 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 validation studies, clinical trials and published in peer-reviewed journals;
- the rate of adoption and/or endorsement of our solutions by clinicians, key opinion leaders ("KOLs"), advocacy groups, and biopharma companies;
- the ability of our newer or in-development solutions, such as Caris Assure, Caris Detect, MI Clarity and Caris ChromoSeq, and other 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 provide coverage and reimbursement for our solutions;
- the development or introduction of competing products, including the expansion of the capabilities of existing products;
- the market acceptance of existing or future 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 "—Our future success and growth will depend in part on market acceptance and commercial success of our MI Cancer Seek, Caris Assure and Caris Detect solutions. We may be unsuccessful in continuing the commercialization and growing the adoption of these solutions, 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 certain of our solutions as planned 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, which in turn depends on 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 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. The application of our solutions in early detection, MCED, MRD tracking, and treatment monitoring, for which in some cases we are still collecting data and designing or refining assays to support, may not be as effective as we anticipate. We cannot assure you that our validation studies or clinical trials will support intended use and commercialization of our solutions or that we will be able to launch such solutions commercially on the timing that we anticipate or at all. If our solutions are ineffective or do not consistently perform as expected, 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, other regulatory authorities or payers 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, which submissions were completed in early November 2025. Our failure to satisfactorily 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 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 operations.

Finally, generating the clinical data necessary to validate and support the launch of our solutions and new versions of our 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 our solutions for early detection, MCED, MRD tracking, and treatment monitoring or disease recurrence, 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, reimbursement 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 84.4% of our revenue for the year ended December 31, 2025. 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 (including the Medicare reimbursement rate for MI Cancer Seek), the availability of clinical data that supports the value of MI Profile and its inclusion 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, that case volume will continue to grow at its current rate or that MI Cancer Seek will maintain its current reimbursement rate. Case volume growth could slow, which 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, Caris Assure, Caris Detect and other solutions. We may be unsuccessful in continuing the commercialization and growing the adoption of these solutions, which would adversely affect our business, financial condition, results of operations, and growth prospects.

Facilitating increased adoption among physicians of MI Cancer Seek is a key expected driver of our growth, particularly in the near and medium term. The success of MI Cancer Seek will depend upon, among other things, the extent to which our FDA approval continues to facilitate increased adoption and use of the solution by physicians as a companion diagnostic tool.

We seek ultimately to offer blood-based profiling solutions to address the entire continuum of cancer treatment. Realizing the potential of our blood-based solutions across disease states is a key component of our long-term business strategy. The commercial success of Caris Assure for therapy selection, of which we initiated the broad commercial launch in the first quarter of 2024, and our future solutions across the cancer treatment continuum, including Caris Detect, will depend upon, among other things, analytical validation studies and clinical trials that demonstrate their effectiveness, the continued adoption of Caris Assure for therapy selection and the commercial launch and adoption of our other solutions, including Caris Detect, by physicians, the medical community, patients, and third-party payers, and our ability to successfully run and market Caris Assure, our other solutions, including Caris Detect, in substantial quantities or to manage and expand the required infrastructure to do so, including large-scale laboratory and information technology systems.

The launch of Caris Detect is subject to uncertainties and dependencies that could delay or prevent commercialization. Our launch timing depends on our ability to successfully complete technical implementation and quality-control processes, both internally and with our collaboration partner, and to complete interoperability tasks with our collaboration partner. Any delays or failures in completing these technical, operational, or quality-control requirements could delay or prevent the launch of Caris Detect. Further, our ability to launch and continue marketing Caris Detect depends on the completion of, and obtaining favorable data from, additional studies, including our Achieve 2 study, that is consistent with or improves upon existing data. If future data is less favorable, we may decide not to market Caris Detect.

Maintaining and expanding market acceptance of our solutions, marketing, and laboratory capabilities are expensive and time-consuming. If these solutions are not successfully commercialized and expanded, 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 our solutions, 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 reimbursement 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 larger scale while retaining expected turnaround times. We will also need additional equipment and certified and licensed laboratory personnel to process higher volumes of testing and analytical 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 have started the process of identifying and evaluating additional facilities to increase product development and operational capacity. Expanding laboratory capacity will require significant resources, and we may encounter difficulties and delays in construction, procuring laboratory equipment, permits, licenses, achieving necessary validation(s), and certifications (including CLIA certification and College of American Pathologists ("CAP") accreditation, or completing the technology implementation) for any new or expanded facility. If we are unable to identify or complete construction, permitting and accreditation in a timely and satisfactory manner, or meet demand for our solutions at new or existing facilities on a timely basis or at all, our reputation and commercial activities would be negatively impacted. Further, certain of our solutions require specific and complex and made-to-order sequencing equipment and supplies, and we may be unable to procure such equipment or supplies on the timelines we desire.

The value of our 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.

As we grow, we expect to add new associates in our facilities including any new labs we acquire, construct, expand or improve. 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 continue to operate as a public company, we may need to add 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, reimbursement, 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;
- seasonal variations in patients' ordering of diagnostic tests or scheduling of medical procedures;
- the timing of entry into, and revenue recognition associated with activities under, agreements related to our pharma research and development services;
- 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, customers 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 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 constraints for such variable consideration. Due to this variability and unpredictability, previously recorded revenue adjustments are not necessarily 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 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 coverage and/or adequate 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 provide investors with a complete picture of the health or trajectory of our business. Investors should not rely solely 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 or timeline for our product development falls 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 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.

If Caris POA members or other KOLs within the broader precision oncology industry determine that our platforms, 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 or sustain profitability.

The publication of clinical data using our solutions in peer-reviewed journals is also crucial to our success. We cannot control when, if ever, results are published, which may delay or limit broad adoption and use of our solutions. Our ability to publish may be limited by factors including increased difficulty in obtaining journal acceptance, conflicts of interest, lack of qualified peer reviewers, delays in completing validation studies or clinical trials, poor study design or lack of compelling performance data, as well as delays in the review, and publication process. If our solutions do not receive sufficient favorable exposure in peer-reviewed publications or are not well received by clinicians, the adoption rates and positive reimbursement coverage determinations could be adversely affected.

If our solutions, or solutions we develop in the future, do not receive coverage and/or adequate 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 from third-party payers, including government and commercial payers, for assays that comprise our MI Profile and Caris Assure platforms, and any solutions we may offer in the future. Obtaining approvals from third-party payers to cover our solutions and establishing and maintaining 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, and many payers work with laboratory benefit managers to make coverage and reimbursement determinations. If we are unable to provide payers with sufficient evidence of the clinical utility and validity of our solutions, they may not provide coverage or reimbursement, may provide coverage but limited reimbursement, or may terminate or decrease coverage or reimbursement 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 coverage or reimbursement in the past does not guarantee that such solution will remain approved for coverage or 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.

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 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 a 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 and maintaining 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 laboratory tests during the billing process is complex, and may not enable coverage and adequate reimbursement rates. Moreover, 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 coverage of certain diagnostic tests, creating conditions for coverage and otherwise limiting the amounts that they will pay for such tests. Cost control initiatives could decrease the price that we would receive for any solutions in the future, which would limit our revenue and profitability.

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 the Centers for Medicare & Medicaid Services ("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 next generation sequencing ("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 MolDX, 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 MolDX to make local coverage and pricing determinations relating to molecular testing. To achieve coverage under MolDX, 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. If CMS modifies or withdraws the NGS NCD, that could adversely affect our revenues, financial condition and results of operations.

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.

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 MolDX. MI Tumor Seek Hybrid is covered by Medicare as of August 3, 2022.

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 MolDX. 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).

In order to obtain MolDX coverage for Caris ChromoSeq, we have submitted, and MolDX will need to approve, a technical assessment for Caris ChromoSeq. There can be no assurances that we will be successful in obtaining Medicare coverage for Caris ChromoSeq.

Immunohistochemical Tests

As part of our MI Profile platform, 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, 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). 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, are subject to these reporting requirements in 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.

Congress has passed legislation that delayed data reporting requirements for CDLTs and further delayed the phase-in of payment reductions under the CLFS from private payer rate implementation. Most recently, under the Consolidated Appropriations Act, 2026, Congress amended PAMA to provide that the next data collection period will be from January 1, 2025 through June 30, 2025, with a data reporting period of May 1, 2026 through July 31, 2026. Changes to CDLT rates on the CLFS resulting from this PAMA reporting cycle will go into effect on January 1, 2027. Any reductions (but not increases) to reimbursement rates based on reported private payer rates are limited to 0% through December 31, 2026, and 15% per test per year from 2027 through 2029. The subsequent data reporting periods for CDLTs will occur in three-year cycles and CLFS rates for CDLTs will be updated every three years. We will be required to report private payer data for MI Cancer Seek and Caris Assure in the 2026 PAMA reporting cycle, which could impact Medicare reimbursement rates for these solutions as of January 1, 2027. 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, MRD/Monitoring and Screening and Early Detection Intended Uses for Our Solutions

Our proprietary molecular signature tests, GPSai and FOLFIRSTai, as well as MI Clarity, our MRD and monitoring solutions and Caris Detect are not currently covered by Medicare. Obtaining Medicare coverage for these tests would require significant investments and could ultimately be unsuccessful or could take several years to achieve. Traditional fee-for-service Medicare generally does not cover screening tests, such as Caris Detect, which are considered preventive services, that are performed in the absence of signs or symptoms of illness or injury, unless explicitly authorized by statute. The Medicare Improvements for Patients and Providers Act of 2008 authorizes the CMS to cover additional preventive services if the service is (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, and (c) appropriate for Medicare beneficiaries. Coverage through an NCD process generally requires or is significantly more likely following FDA approval. Therefore, Caris Detect may not be eligible for traditional Medicare coverage unless we pursue substantial additional measures and/or legislation is enacted to expressly authorize CMS to cover FDA-approved early cancer screening tests. Congress has enacted, as part of the Consolidated Appropriations Act, 2026, legislation that would provide a more streamlined pathway to Medicare coverage for FDA-approved MCED tests without requiring USPSTF endorsement. This legislation would establish Medicare reimbursement for MCED tests beginning in 2028, however, reimbursement would initially be set at the rate for multi-target stool DNA screening tests for colorectal cancer (the 2026 CLFS rate is approximately $509). It is possible that the reimbursement rate may not adequately cover our costs and would still require us to obtain FDA approval for Caris Detect before becoming eligible for coverage under the new pathway. We currently plan to launch

Caris Detect as a cash pay only test, however, the scale of adoption of Caris Detect may be impacted by whether coverage is available for Caris Detect or competitor tests. We do not currently have plans to seek Medicare coverage for Caris Detect, and if we do not do so, its commercial adoption and its ability to compete with other providers' early detection tests which may be covered, may be negatively impacted.

In addition, we are developing capabilities 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, and we successfully obtain MoIDX approval, 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, 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 from commercial payers. When we contract with a payer as a participating provider, reimbursements are generally made pursuant to a negotiated fee schedule and are limited to only covered indications, often requiring prior authorization. Although we are a participating provider with many commercial payers, certain payers may not cover our solutions based on existing medical policy and may treat our solutions as experimental and investigational or import restrictive coverage criteria. Additionally, some payers have implemented, or are implementing, laboratory benefit management programs using third-party benefit managers, which may result in payers resisting coverage for our solutions in favor of less expensive tests, requiring pre-authorization, or imposing additional pricing pressure and substantial administrative burdens. We expect to continue to focus substantial resources on increasing adoption of, and coverage and reimbursement for, our solutions. We believe it may take several years to achieve broad coverage and adequate contracted reimbursement with a majority of payers for our new solutions. However, we cannot predict whether, under what circumstances, or at what price levels payers will cover and reimburse our existing and future 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.

Further, 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.

Even where we establish relationships with commercial payers to provide our future solutions at negotiated rates, such agreements do 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. In addition to the available Medicare coverage for therapy selection, we plan to market Caris Detect and our solutions for 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. Such marketing efforts may not be successful. 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.

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, including 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 healthcare 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 results" and Part I, Item 3. "Legal Proceedings." The failure to report and return an overpayment to Medicare or Medicaid 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 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 healthcare 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 results" and Part I, Item 3. "Legal Proceedings."

We currently handle our own billing and coding for our solutions but use a vendor for revenue cycle management services, such as billing and coding software and other related operations. Our business, financial condition, and results of operations may be affected by the ability of us and 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, 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, 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. This may significantly delay our ability to continue to develop and commercialize any 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.

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. In addition, we do not have written supply agreements with certain of our suppliers, 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 seek and 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 is 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 or 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 businesses or assets; and
- finance capital expenditures and general and administrative expenses.

As of December 31, 2025, we had $796.3 million of cash and cash equivalents and $2.3 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.

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 expanding, locating and/or constructing facilities for additional laboratory capacity;
- 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 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. 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 credit agreement, dated January 18, 2023 (the "2023 Term Loan Agreement"), under which we issued senior, secured promissory notes (the "2023 Term Loan") by which the 2023 Term Loan lenders agreed to lend us up to an aggregate principal amount of $400.0 million, $200.0 million of which was received upon issuance, and $200.0 million of which was drawn down in March 2024. 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 damaged 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 in the process of locating facilities for additional laboratory capacity. 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. Samples may degrade over time, which could negatively impact our ability to use such samples for research and development or 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, tornadoes, hurricanes, 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 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, tornadoes, hurricanes, 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 current and future solutions, 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 solutions are intended to be used to detect cancers or potential cancers in patients. A detection of cancer (or of recurrence of cancer) would need to be followed up with a cancer diagnosis or review by a physician. Because our solutions may not detect all forms or instances of cancer, a negative test would not conclusively rule out the presence or recurrence 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.

Although we maintain product and professional liability insurance, we may not be fully protected 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 is intensely competitive. Our competitors include numerous companies offering or seeking to offer tissue-based molecular profiling, blood-based early detection, blood-based therapy selection, MRD tracking, treatment monitoring, biopharma services, and genomic data and AI services. Competitors have or may have substantially greater financial, technical, and other resources, such as larger R&D staff and more established marketing and sales forces. Competitors may develop, acquire, or license tests or services that are more effective or less costly than our solutions. Established medical technology, biotechnology, or biopharma companies, including some of our customers, may invest heavily to develop tests that could make our solutions less competitive than we anticipate.

We may not be able to compete effectively or keep pace with the rapid rate of change in our industry. This could render our solutions obsolete or less attractive, result in significant price reductions, result in us not introducing new products, or substantially limit the number 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, additional costs, 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 or other regulatory agencies 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, such as the October 2025 AWS outage, 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.

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 bioinformatics and 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 AI/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.

Additionally, the risks and challenges presented by AI and ML could undermine public confidence in AI and ML, which could slow their 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.

Our business also increasingly relies on AI to improve our services. 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 laws intended to regulate and/or require disclosures in connection with the usage of AI, including in interactions with customers, patients or other market participants. For example, Colorado and Utah have passed laws

requiring disclosures and compliance efforts associated with different uses of AI. Other states are considering or have passed laws regulating the use of AI in patient-facing communications, generation of medical reports, claims processing, and other areas that may apply to or impact our business. In December 2025, the President signed an executive order seeking to establish federal preemption of state AI laws and establishing an AI Litigation Task Force to challenge state AI laws in court, creating legal uncertainty as to whether and which state AI regulations will be challenged or remain enforceable. The executive order itself may face legal challenges. The EU's AI Act also may limit our ability to utilize AI or make utilization of such technology more expensive. States, the federal government or other non-U.S. governments could pass additional legislation or implement regulations further impacting businesses' use of AI/ML, which could impact our operations and impose additional costs or liability on us. In general, the effects of AI regulations are difficult to predict, and we expect other jurisdictions will adopt similar laws. 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 or otherwise inaccurate. Any bias or inaccuracy in a model could result in limits on the applicability or accuracy of the model or could lead us to make decisions that could disadvantage or adversely impact certain individuals (or classes of individuals).

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 Dean 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, pharmaceutical and biotechnology businesses. We also face competition from other industry participants, 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 equity incentive 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, technical support issues, 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. 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.

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. 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.

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 on a timely basis. In addition, our ability to monitor third parties’ and vendors’ information security practices is limited, and these third parties may not have adequate information security measures in place. Despite the precautionary measures we and the third parties with whom we work have taken, there is a risk that our security measures will not be fully effective in the future. If the third parties with whom we work experience a security incident or other interruption, we could experience adverse consequences

Such security incidents or service interruptions could result in operational or business delays, costly disclosure and compliance efforts, 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. Further, if we were required or decide 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.

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.

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 Caris Detect for early detection, solutions for minimal residual disease and treatment monitoring and Caris ChromoSeq for hematological (blood) cancers, solutions for recurrence prediction, such as MI Clarity, 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 or growing 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 cultivate these efforts into a sustainable or growing 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 generally 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, identify potential drug targets and help biopharma partners develop drug therapeutics through our drug target and therapeutic discovery business, Caris Discovery.

Our success in the future depends in part on our ability to maintain and expand these relationships with our biopharma partners and to build new such relationships. 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 enter into; 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 is satisfied with the quality or data or targets that we license to them, obtains positive data in its clinical trials, is able to successfully obtain regulatory

approval and subsequently commercialize 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.

We engage in discussions with biopharma companies regarding commercial opportunities. There is no assurance that any such 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 properly obtain, collect, package and ship viable samples to us, our patients and their physicians may experience problems and delays in receiving test results, which could harm our reputation and our business, financial condition, and results of operations. If our current providers become unable to continue services for us or if our clients cannot readily access collection providers, we may be unable to compete effectively with laboratories that have greater access to collection providers.

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, storage, or transportation of samples due to labor disruptions, weather, natural disaster, terrorist acts, threats, or other reasons could adversely affect the samples and our ability to timely process the samples, which could harm our ongoing research studies and our business.

The validation and clinical trial process is lengthy and expensive with uncertain outcomes. We have encountered delays, and may encounter future substantial delays, in our validation studies or clinical trials, and may therefore be unable to complete our validation studies or 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 applicable laws and regulations, and are subject to oversight by regulatory agencies and institutional review boards (“IRBs”).

The results of validation studies, 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 does not ensure that we will achieve similar results in future validation studies or clinical trials. In addition, data from validation studies, as well as preclinical and clinical data, are often susceptible to various interpretations and analyses, and many companies that have believed their products performed satisfactorily in such evaluations 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:

- our ability to locate sufficient samples or enroll patients for a validation study or clinical trial;
- the inability to generate sufficient in vitro or in vivo data to support the initiation or continuation of validation studies or 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 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 MolDX 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 or Stark Law constitutes a false or fraudulent claim 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;
- 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, fraud and abuse, consumer protection, and unfair competition laws that may apply to our business practices, and which may include "whistleblower" provisions, 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; and 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.

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. For example, the DOJ and HHS have created a DOJ-HHS False Claims Act working group to identify FCA violations involving priority enforcement areas. 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 in the future may be, subject to actions or investigations relating to our arrangements and interactions with healthcare professionals, healthcare institutions, payers 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 results."

Efforts to ensure that our business arrangements will comply with applicable laws, including healthcare laws and regulations, may involve substantial costs. In addition, 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 participants in connection with validation studies and 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 (e.g., HIPAA), consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), and other similar laws (e.g., wiretapping laws).

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 and laws governing the privacy of consumer health data, including genetic information.

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. Moreover, we are subject to laws, regulations, and standards

governing certain marketing, advertising, and other communications conducted by telephone, fax, or text. In addition, because we accept debit and credit card payments, we are subject to the Payment Card Industry Security Standard ("PCI-DSS"), issued by the Payment Card Industry Security Standards Council. We rely on third-party payment processors to process such payments who are also separately subject to PCI-DSS.

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.

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.

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 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 requirements for processing personal data in those jurisdictions. 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. 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. 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 due to data localization requirements or limitations on cross-border data flows. For example, Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross-border data transfer laws. 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.

Regulators in the United States are also increasingly scrutinizing certain personal data transfers and have imposed certain data localization requirements. For example, the U.S. Department of Justice's final rule implementing Executive Order 14117 prohibits or restricts certain data transactions involving bulk sensitive personal data, including human genomic data, with "countries of concern," including China, Russia, Iran, North Korea, Cuba, and Venezuela. Compliance may require us to implement additional security measures, conduct enhanced due diligence on vendors and collaborators, and modify or terminate certain international collaborations or data sharing arrangements. Violations could subject us to civil and criminal penalties, and exclusion from participation in federal and state programs.

The development and use of AI also presents various privacy and data security risks that may impact our business and is subject to various laws as described above in "— 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." 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.

We furnish biopharma partners and academic researchers information that has been de-identified in accordance with applicable laws, regulations, and the requirements governing the clinical trial. We rely on various methods to de-identify data, however, we may fail to properly de-identify data due to technical errors, process failures, or evolving regulatory standards regarding what constitutes adequate de-identification, which could result in the inadvertent disclosure of PHI or other sensitive personal information in violation of HIPAA or other applicable laws. 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. 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), including those described above, are quickly changing and 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.

Compliance with such 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, 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 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. We also intend to launch our future solutions, such as Caris Detect and Caris ChromoSeq, as LDTs. The FDA has historically considered 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 prior 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.

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.

However, a federal court vacated the LDT Final Rule in March 2025, and the FDA ultimately rescinded the LDT Final Rule in September 2025. It is uncertain whether or when the FDA may be able to 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 FDA approval or clearance. Such uncertainty and the FDA's actions in response could have a material adverse effect on our business and operations.

In light of this uncertainty, 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. 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 otherwise 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 research use only ("RUO") or investigational use only ("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 and monitoring 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, MRD or monitoring tracking, or if we will be able to obtain such approval on a timely basis or at all.

To our knowledge, the FDA has never granted marketing authorization for an early detection test and has only granted marketing authorization in limited instances for MRD or monitoring tests. Therefore, obtaining FDA approval for our solutions for early detection, MRD or monitoring tracking would present 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 and monitoring tests. As such, we believe the FDA requirements that will govern any early detection, MRD tracking or monitoring 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 and monitoring 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 applicable rules and regulations; 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 and abuse 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. 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. For additional information, see the risk factor "— 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 results."

Employee use of generative AI tools in business operations may expose us to intellectual property, cybersecurity, and privacy risks.

We permit employees to use certain authorized generative AI tools to enhance productivity and support business operations. Employee use of generative AI presents risks, including that employees may use unauthorized tools and may inadvertently input confidential information, trade secrets, proprietary data, or PHI into third-party AI systems, potentially compromising our intellectual property or violating privacy and data security obligations, including HIPAA. AI tools may also generate outputs that infringe third-party intellectual property rights, exposing us to infringement claims. Additionally, AI systems may be vulnerable to cybersecurity threats, including data breaches, unauthorized access, or manipulation of outputs. Moreover, third parties that license artificial intelligence technologies to us may impose unfavorable licensing terms or terminate the licenses altogether, which would require us to seek licenses from alternative sources to avoid disruptions in feature delivery. Failure to adequately govern employee use of AI tools could result in

legal liability, regulatory penalties, loss of intellectual property, reputational harm, and other adverse consequences that could adversely affect our business, financial condition, and results of operations.

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 results.

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 healthcare 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 Part I, Item 3. "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, 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. CMS's 2026 CRUSH (Comprehensive Regulations to Uncover Suspicious Healthcare) initiative, a cost control and fraud prevention initiative targeting among other things laboratory and molecular diagnostic testing, may result in heightened audit activity and expanded enforcement activities. 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, the Inflation Reduction Act of 2022 (the "IRA") was signed into law, which among other things, extended enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminated 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. The One Big Beautiful Bill Act (the "OBBBA"), which was enacted in July 2025, imposed significant reductions in the funding of the Medicaid program. Such reductions are expected to decrease the number of persons enrolled in Medicaid and reduce the services covered by Medicaid, which could adversely affect our sales of our solutions and limit the number of patients receiving procedures associated with the use of our solutions. The OBBBA also declined to extend ACA enhanced advanced premium tax credits which expired at the end of 2025, which, among other provisions in the law, is anticipated to reduce the number of Americans with health insurance more broadly. Although the effect on our business cannot yet be predicted, a decrease in the number of insured patients or reimbursement levels for any future solutions could affect our revenue. It is also possible that efforts to reform, modify, or repeal parts of the ACA may continue.

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 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 based on statutory triggers if legislation increased the federal deficit. As a result of the OBBBA, an additional Medicare payment reduction of up to 4% would have taken effect in January 2026 based on Statutory Pay-As-You-Go Act triggers. Subsequent legislation passed by Congress waived PAYGO sequestration, but there is no guarantee of future waivers. In addition, various bills have been introduced to amend PAMA. 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, which reductions could potentially lower the price that we receive for future solutions.

In addition to changing federal policy and regulatory oversight, states and third-party payers may also introduce proposals and polices 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, or other future federal or state measures, 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 presidential administration is pursuing policies to reduce regulations and expenditures across government such as HHS, the FDA, CMS, and related agencies, resulting in among other things the recent layoffs across HHS, including the FDA and CMS. 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, including disruptions and delays in guidance, review, reimbursement and approval of our solutions. See "—Changes in funding or disruptions at the FDA and other government agencies caused by funding shortages, staffing limitations, or policy changes 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." 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, 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 seeking FDA approval or clearance 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 marketing a new medical device in the United States, a company must obtain FDA clearance or approval through one of three pathways, unless an exemption applies. In the 510(k) clearance process, the FDA must determine that a proposed device is "substantially equivalent" to a legally-marketed "predicate" device. To be "substantially equivalent," the proposed device must have the same intended use and either the same technological characteristics or different technological characteristics that do not raise different questions of safety or effectiveness as compared to the predicate device. In the PMA approval process, the FDA must determine that a proposed device is safe and effective for its intended use based on extensive data, generally including technical, pre-clinical, clinical trial, manufacturing and labeling data. The PMA process is typically required for higher-risk devices such as life-sustaining, life-supporting or implantable devices. Historically, the FDA has regulated many companion diagnostic devices as higher-risk devices that require approval of a PMA application. However, in November 2025, the FDA issued a proposed rule, which if allowed to go into effect in its current form, would reclassify certain nucleic acid-based test systems indicated for use with approved oncology therapeutics, which we believe would include our MI Cancer Seek, from Class III to Class II, which would allow manufacturers to seek 510(k) clearance rather than PMA approval for such devices. In the de novo classification process, a manufacturer of a novel device, which under the FDCA would otherwise be automatically classified as Class III and require the submission and approval of a PMA, can request reclassification from Class III to Class I or Class II based on the device's risk profile and, if such de novo request is granted, may use the device 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. 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.

Any modification to a product for which we receive marketing authorization may require us to submit a new 510(k) notification, a supplemental PMA, or a de novo request, and receive clearance or approval, prior to implementing the change. For example, modifications 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 require a new marketing authorization. Manufacturers must make such determinations in the first instance, but the FDA may review and disagree with those decisions. If the FDA disagrees with our determination that new marketing authorization is unnecessary for a modification, we may be required to cease marketing or recall the modified product until we obtain such authorization, and we may be subject to significant regulatory fines or penalties. If the FDA requires a lengthier, more rigorous

examination for future solutions or modifications 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 or genomic predisposition to certain conditions. Similarly, these concerns may lead patients to decline 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 solutions were 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. 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. For any new laboratory facility, we 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 contemplating building additional laboratory space) 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 blood-based Arizona facility or any new facilities that we may develop, 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 form 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 validation studies or 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 our solutions under development, which disclosures are 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. 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 and top-line, preliminary, or final 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 "—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, on February 2, 2026, the FDA's final rule implementing the FDA's Quality Management System Regulation ("QMSR") became effective. The QMSR, which replaced the FDA's former Quality System Regulation ("QSR"), sets forth the FDA's cGMP requirements for medical devices, and among other things, incorporates by reference certain elements of 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, and although our quality management system is designed to comply with ISO:13485, the FDA has indicated that ISO:13485 certification alone will not ensure compliance under the QMSR, nor will ISO certification exempt manufacturers from FDA inspection. The QMSR also includes certain compliance obligations, such as those relating to unique device identification, product traceability, and maintenance of complaint and service records, that align more closely with the FDA's existing medical device requirements than with ISO standards. Accordingly, it remains unclear the extent to which the QMSR may impose additional or different regulatory requirements on us that could increase the costs of compliance or otherwise negatively affect our business. If we are unable to comply with the QMSR, 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. 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." 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 QMSR 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 QMSR 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. 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. In addition to FTC enforcement, the FDA regulates the advertising and promotion of our solutions, including any claims regarding efficacy, performance, or clinical utility. The FDA requires that promotional claims be truthful, not misleading, and consistent with product labeling. We must have competent and reliable evidence to support claims we make about the performance or benefits of our solutions. If the FTC, or comparable governmental authorities determine that we lack adequate substantiation for our claims, or that our promotional materials are false or misleading, we could be subject to enforcement actions, including the issuance of warning letters or untitled letters, injunctions, seizures, civil fines, and, in extreme cases, criminal prosecution. The FDA or FTC may also find promotional communications misleading based on the omission of material facts, even if the statements made are technically accurate. For example, failure to adequately disclose limitations of our solutions, the context in which clinical data was generated, or other material information could be deemed misleading by the FDA or the FTC. Furthermore, FDA or FTC findings of misleading promotional statements or practices could trigger litigation against us under federal and state consumer protection and unfair trade practices laws, which could result in significant damages, injunctive relief, and reputational harm independent of any enforcement action.

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 RUO, or for 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 institutions. In addition, certain components incorporated

into our products are sourced from third-party suppliers as RUO or IUO products. 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. Such changes could also affect the availability of RUO or IUO components from our suppliers, and if we are unable to source these components, we may not be able to offer certain of our products or solutions, or may face increased costs or delays in identifying and qualifying alternative components. 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 CMS, the FDA and other government agencies caused by funding shortages, staffing limitations, or policy changes 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 CMS, 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 or delays in reimbursement approvals, which could adversely affect our business. For example, in recent years, the U.S. government has shut down several times (including for forty-three days commencing October 1, 2025) and certain regulatory agencies, such as CMS and the FDA, have had to furlough critical employees and stop critical activities. In addition, the current presidential administration has issued certain policies and Executive Orders directed towards reducing the employee headcount and costs associated with U.S. administrative agencies, including CMS and the FDA, and it remains unclear the degree to which these efforts may limit or otherwise adversely affect CMS's and the FDA's ability to conduct routine activities.

If a future prolonged shutdown occurs, or if funding shortages, staffing limitations or policy changes 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 laws or regulations allowing broad consent, the regulatory definition of "research" or other laws and regulations that govern our research change 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. Life sciences companies have at times been a priority target for FCPA enforcement by the Securities and Exchange Commission and Department of Justice, and can face heightened scrutiny due to frequent interactions with government-employed healthcare providers in foreign jurisdictions. 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. 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, 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 international distributors 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 proceeding. 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 in 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. We have been, and are currently, involved in litigation that we initiated against former employees and competitors to protect our trade secrets and other confidential information and other restrictive covenants, and we may face or initiate similar litigation in the future. Such litigation can be expensive, time-consuming, and uncertain in outcome. 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 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 December 31, 2025, we and our subsidiaries had approximately $400.0 million aggregate principal amount of debt outstanding under the 2023 Term Loan. 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 Part II, Item 7. "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 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 substantially all of our assets, including 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 ongoing 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. 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 Ownership of Our Common Stock

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

We cannot predict the prices at which our common stock will continue to trade, and the limited public float of our common stock may lead to increased price volatility. 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;
- the degree to which the launch, performance 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, clinical trials, and product launches for our solutions and solutions from our competitors;
- 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, or cease to 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 relies in part on the research and reports that industry or securities analysts publish about us or our business. 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 in the public market, or the perception that such sales could occur, 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, 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 pre-IPO equity holders have substantial unrecognized gains on the value of the equity they hold, 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.

Up to 22,106,373 shares of our common stock and 4,273,052 shares of our common stock may be issued upon exercise of outstanding stock options or vesting and settlement of outstanding RSUs under our 2020 Plan and 2025 Plan, respectively, in each case as of December 31, 2025, and up to approximately 14,325,159 shares of our common stock remained available for future issuance under our 2025 Incentive Plan ("2025 Plan") and our Employee Stock Purchase Plan ("ESPP") as of December 31, 2025, and will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, exercise limitations, and Rule 144 and Rule 701 under the Securities Act. We have filed a registration statement to register all of the shares of common stock issuable upon exercise of options or other equity incentive awards granted under our 2025 Plan or issued pursuant to our ESPP and with respect to our 2020 Plan, all shares of common stock issuable upon the exercise of stock options or RSUs granted under our 2020 Plan that were outstanding as of the IPO. 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, certain of our large pre-IPO shareholders have rights, subject to some conditions, 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.

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, convertible debt financings, 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 additional 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.

Our executive officers, directors, and principal shareholders, including, in particular, David Dean Halbert, our Founder, Chairman, and Chief Executive Officer, 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.

As of December 31, 2025, David Dean Halbert, our Founder, Chairman, and Chief Executive Officer, beneficially owns approximately 43.9% of our outstanding common stock. As a result, Mr. Halbert is 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, adoption or amendment of equity incentive plans and the approval of significant corporate transactions, regardless of whether others believe that any such action or transaction is in our best interests.

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 as of and for the year ended December 31, 2024, we identified a material weakness in our internal control over financial reporting which remains unremediated as of December 31, 2025. 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 necessary to account for and disclose accounting transactions that 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 annual report for the year ending December 31, 2026. 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 these requirements, 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, 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 annual report for the year ending December 31, 2026.

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 will cease to be an emerging growth company upon the earliest of: (i) the end of the fiscal year following the fifth anniversary of our IPO (*i.e.* the fiscal year ending December 31, 2030), (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 since 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. We have elected to avail ourselves of this transition period, and therefore our condensed consolidated financial statements may not be comparable to the financial statements of issuers who are required to comply with the effective dates for new or revised accounting standards that are applicable to public companies. This may make our common stock less attractive to investors. In addition, if we cease to be an emerging growth company, we will no longer be able to use the extended transition period for complying with new or revised accounting standards.

We have incurred and expect to continue to incur increased costs as a result of operating as a public company, and our management is and 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 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 have increased and will further increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, the rules and regulations applicable to us as a public company have made it, and may in the future, 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.

We are required to maintain disclosure controls and procedures to support compliance with 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 described above, 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 ASC 606 revenue accounting standard, management made judgments and assumptions based on our interpretation of the new standard. The new revenue standard is principles-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 do not intend to pay dividends for the foreseeable future, and our investors 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 preferred securities or indebtedness. 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 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 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:

- 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. 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.

Provisions in our amended and restated certificate of formation and our amended and restated bylaws may limit our shareholders' ability to bring claims against, or obtain a favorable judicial forum for disputes with, us or our directors, officers, or employees and may discourage or increase the cost of bringing such claims.

Our amended and restated certificate of formation provides 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 (subject to the ownership requirements in our Amended and Restated Bylaws);
- 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 also provides 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.

In addition, our amended and restated bylaws require that any shareholder or group of shareholders seeking to institute a derivative proceeding on behalf of the Company must beneficially own at least three percent (3%) of our outstanding common stock at the time the proceeding is instituted. This ownership threshold may discourage or prevent shareholders with smaller holdings from pursuing derivative claims, even if such claims have merit, and could limit accountability for alleged misconduct by our directors or officers.

The choice of forum and derivative proceedings threshold provisions may limit a shareholder's ability to bring a claim, or 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 claims 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 any of these provisions to be 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 such matters, 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. 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 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";
- 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 had an adverse impact on global economic conditions for a period of time in the recent past. 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.

Additionally, 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 crises, 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 December 31, 2025, we had NOL carryforwards of $1.3 billion for federal income tax purposes and $1.0 billion 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. As of December 31, 2025, 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 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. In addition, the OBBBA, which was enacted in July 2025, introduced additional reforms, including by permanently extending certain provisions of the Tax Cuts and Jobs Act. 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.

Evolving expectations regarding environmental, social, and governance ("ESG") matters could increase our costs, harm our reputation, and adversely impact our financial results.

There has been evolving public focus by investors, patients, activists, the media, and governmental and nongovernmental organizations on a variety of environmental, social, governance and other sustainability matters. We may experience regulatory or commercial pressure regarding commitments or disclosures relating to sustainability matters, including the design and implementation of specific risk mitigation strategic initiatives relating to sustainability and AI, which may require us to implement or change policies, provide additional disclosures, or dedicate significant time and resources. If we are not effective in addressing environmental, social, governance or other sustainability matters affecting our business, setting and meeting relevant goals, or meeting stakeholders' varied expectations in these areas, our reputation and financial results may suffer. We may also be subject to new or existing laws, regulations or reporting requirements relating to ESG matters. If we fail to comply with such laws, or fail to provide complete and accurate information to our suppliers, customers or other business partners, we could be subject to penalties and our reputation and business could be adversely impacted.

Item 1B. Unresolved Staff Comments

None.

Item 1C. Cybersecurity

Our business model requires that we collect, analyze and store sensitive data including patient health information (including genomic information), insurance information, and other personally identifiable and personal health information. Our business also relies on sensitive intellectual property and other proprietary business information. Cybersecurity and data privacy are important to protecting our proprietary information and maintaining the trust of patients, medical practitioners, business partners, suppliers and employees.

Risk Management and Strategy

We have established a cybersecurity risk management program designed to identify, assess, and manage risks from cybersecurity threats to the Company's information systems, data, technology assets, and operations. This program is integrated into our overall company-wide risk management and is informed by the National Institute of Standards and Technology Cybersecurity Framework (NIST CSF) 2.0, and is designed to incorporate an emphasis on HIPAA.

Risk Assessment Process. We assess Cybersecurity risks based on likelihood and significance of impact, across technical, financial, physical, and regulatory/compliance risks. Our risk criteria focus on the confidentiality, availability, integrity, and privacy of patient data, customer data and business-critical systems. Our policy is to conduct a formal

information technology risk assessment and external network and production application penetration tests at least annually. Our in-house team also conducts periodic penetration tests.

Risk Response. The Company employs four primary risk response options: mitigate, accept, transfer, or eliminate, and the Company develops risk treatment plans for risks as appropriate. We endeavor to maintain other safeguards that are designed to prevent unauthorized access to our systems, such as two-factor authentication and password complexity requirements, and we also provide mandatory periodic information security training to employees to enhance awareness of information security issues. We maintain defense-in-depth controls for systems and seek to prioritize vulnerability management toward highest impact risk reduction.

Third-Party Engagement. We engage third-party security advisors and consultants to conduct independent cybersecurity risk assessments and advise on risk management methods. We also engage third parties for network monitoring and alerting and penetration testing.

Third-Party Vendor Risk Management. We have developed and are in the process of implementing a risk management program for vendors who access, process, store, or transmit Company data or systems. Our programs provide for vendors to be classified by risk level and assessed through questionnaires and review of vendor security protocols, and for us to address identified risks as needed through remediation plans and contractual terms. Per our policies, higher-risk vendor relationships are subject to ongoing monitoring and periodic reassessments, including review of SOC 2 (System and Organization Controls 2) or equivalent security reports where applicable.

Incident Response. The Company maintains a Cyber Security Incident Response Plan that employs an incident severity classification system that guides response actions and escalation procedures. This plan establishes a Cybersecurity Incident Response Team with defined roles including the direct involvement of our Chief Information Security Officer. The incident response plan is informed by the NIST CSF.

Risks and Incidents. As of the date of this filing, we have not identified any cybersecurity risks, nor are we aware that we have experienced cybersecurity incidents, in each case that have materially affected, or are reasonably likely to materially affect, the Company's business strategy, results of operations, or financial condition. However, cybersecurity risks represent an ongoing concern and the threat landscape continues to evolve. While we have implemented controls and procedures to manage these risks, including those described herein, there can be no guarantee that these measures will prevent all cybersecurity incidents. For additional information regarding cybersecurity risks, see “Risk Factors” in Part I, Item 1A of this Form 10-K, in particular the risk factor titled “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.”

Governance

Board Oversight. The Audit Committee of the Board of Directors has primary board-level responsibility for oversight of the Company's cybersecurity risk management as set forth in its charter. The Audit Committee discusses risk management policies with management and oversees steps taken by management to monitor and control these risks, and generally receives reports on cybersecurity issues from the Chief Information Security Officer twice per year. Our incident response procedures provide for notification of the Board of Directors or of the Audit Committee Chair as appropriate based on determined severity of an incident.

Management Role. The Company's Chief Information Security Officer has extensive experience in cybersecurity, incident response and federal law enforcement, and serves as incident commander with leadership responsibility for cybersecurity incident response and oversight of the overall security program. The information security team includes additional members with responsibility for directly leading incident response specifics and for conducting investigations.

Reporting and Coordination. The Company provides periodic reports to senior leadership on risk mitigation progress aligned with business priorities. We maintain additional controls to enhance cross-functional coordination, including reports from the Chief Compliance Officer and Chief Information Security Officer to the Audit Committee, notification of the internal audit and legal teams of incidents, engagement of the legal department for incident response and inclusion of representatives from human resources, lab operations, and physical security in the incident response teams to ensure cross-functional coordination during cybersecurity incidents.

Item 2. Properties

Our corporate headquarters in Irving, Texas, consist of approximately 30,500 square feet leased through 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 2031, respectively. We also lease an approximately 59,000 square foot R&D laboratory facility in Tempe, Arizona and an approximately 114,500 square foot office facility in Irving, Texas, with leases expiring in 2031 and 2035, respectively. The facility in Irving, Texas is continuing to be built-out and we are currently assessing the potential utilization of this property.

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.

While we believe that our facilities are adequate to meet our current needs, we expect to expand our facilities as our operations grow over time. We believe suitable additional space will be available to accommodate any such expansion of our operations.

Item 3. 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 healthcare 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 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 results."

Item 4. Mine Safety Disclosure

Not applicable.

Part II

Item 5. Market for Registrant's Common Equity, Related Shareholder Matters and Issuer Purchases of Equity Securities

Market Information

Our common stock is traded on the Nasdaq Global Select Market under the symbol "CAI."

Holders of Record

As of February 26, 2026, there were 205 holders of record of our common stock. Because many of our shares of common stock are held by brokers and other institutions on behalf of shareholders, we are unable to estimate the total number of shareholders represented by these record holders.

Dividend Policy

We have never declared or paid any dividends on our common stock, and we do not currently intend to do so 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, capital requirements as well as contractual, legal, tax, and regulatory restrictions, and such other factors as our board of directors may deem relevant.

Recent Sales of Unregistered Equity Securities

The Company made no sales of unregistered equity securities during the year ended December 31, 2025, other than those disclosed in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2025 and in our Registration Statement on Form S-1/A, filed with the SEC on June 16, 2025.

Use of Proceeds

On June 20, 2025, we completed our initial public offering pursuant to a registration statement on Form S-1 (File No. 333-287551), declared effective by the SEC on June 17, 2025. We received net proceeds of $519.5 million after deducting underwriting discounts and commissions of $39.8 million and offering expenses of $9.0 million. There has been no material change in the expected use of the net proceeds from our IPO as described in the final prospectus filed with the SEC on June 20, 2025.

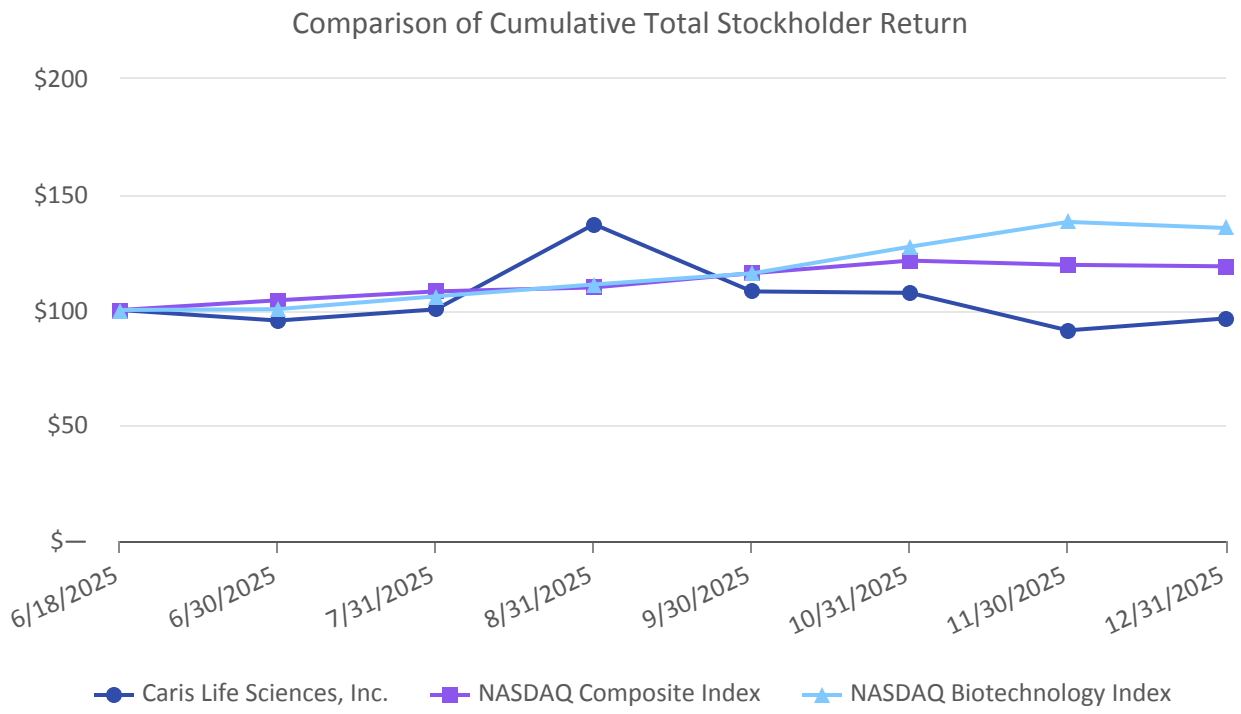
Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

Stock Performance Graph

The performance graph set forth below is not deemed to be "soliciting material" or to be "filed" with the Securities and Exchange Commission for purposes of Section 18 of the Exchange Act, and will not be deemed to be incorporated by reference into any filing under the Securities Act or the Exchange Act.

The graph below shows the cumulative return to our shareholders from June 18, 2025 (the date that our common stock commenced trading on the Nasdaq Global Select Market) through December 31, 2025 relative to the Nasdaq Composite Index and the Nasdaq Biotechnology Index. The graph assumes that $100 was invested in our common stock, the Nasdaq Composite Index and the Nasdaq Biotechnology Index at their respective closing prices on June 18, 2025 and that gross dividends were reinvested. The stock price performance shown in the graph represents past performance and should not be considered an indication of future stock price performance.



Item 6. [Reserved]

Item 7. 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 Annual Report on Form 10-K ("Annual Report"). 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 Part I. Item 1A. Risk Factors and elsewhere in this Annual Report. See the section titled "Special Note Regarding Forward-Looking Statements" elsewhere in this Annual Report. Our historical results are not necessarily indicative of the results that may be expected for any period in the future. Unless context requires otherwise, references to "we," "us," "our," "Caris," or "the Company" here refer to Caris Life Sciences, Inc. together with its wholly owned subsidiaries. The following discussion provides a narrative of our financial condition and results of operations for the year ended December 31, 2025 compared to the fiscal year ended December 31, 2024. A discussion regarding our financial condition and results of operations for the fiscal year ended December 31, 2024, including a comparison to our results of operations for the fiscal year ended December 31, 2023, can be found in "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our final prospectus for our initial public offering, dated June 17, 2025 and filed with the Securities and Exchange Commission on June 20, 2025.

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 tests we have run on over 1,000,000 cases as of December 31, 2025. Our Caris Molecular Intelligence 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 Molecular Intelligence product portfolio consists of our MI Profile Platform, our whole exome sequencing (WES)/whole transcriptome sequencing (WTS) tissue-based molecular profiling solutions that have generated the majority of our revenue to date, our Caris Assure Platform, our WES/WTS blood-based molecular profiling solutions, and our Precision Whole Genome Platform, our whole genome sequencing (WGS) blood- and tissue-based profiling solutions. 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 biopharma partners, such as Moderna, AbbVie, Xencor, Merck KGaA and Genentech, 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.

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.

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 the MI Profile Platform, we believe that increased profiling volumes will meaningfully contribute to our growth in 2026 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 the Caris Assure Platform, which utilized genomic data generated by the MI Profile Platform 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.

For the years ended December 31, 2025 and 2024, we generated total revenue of $812.0 million and $412.3 million, respectively, and incurred net losses of $68.1 million and $281.9 million, respectively. Our Adjusted EBITDA was $137.7 million and $(189.6) million for the years ended December 31, 2025 and 2024, respectively. We may incur net losses in the near future, and our expenses are expected to 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 positive (negative) cash flows from operations of $83.2 million and $(245.2) million for the years ended December 31, 2025 and 2024, respectively. Our free cash flow was $66.9 million and $(253.6) million for the years ended December 31, 2025 and 2024, respectively. For additional information regarding non-GAAP measures Adjusted EBITDA and free cash flow, see "—Non-GAAP Financial Measures." Additionally, as of December 31, 2025, we had cash, cash equivalents, restricted cash, and marketable securities of $802.3 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."

On June 20, 2025, we completed our initial public offering ("IPO") of our common stock, in which the Company issued and sold 23,529,412 shares of its common stock at a price of $21.00 per share, which resulted in net proceeds of $459.5 million after deducting underwriting discounts and commissions and before deducting offering costs of $9.0 million. Additionally, on June 25, 2025, the underwriters exercised their full over-allotment option and purchased from the Company an additional 3,529,411 shares of common stock at the IPO price, which resulted in net proceeds to the Company of $68.9 million after deducting discounts and commissions.

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 Part I. Item 1A. "Risk Factors" of this Annual Report.

- ***Market acceptance and commercial success of our solutions.*** Our success and future growth will depend on maintaining and expanding market acceptance of our current and future 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. Changes in our case volumes and the pricing of our solutions, however, are generally not impacted by cancer type. For the years ended December 31, 2025 and 2024, the number of clinical cases was 199,300 and 162,850, respectively. We commercially launched our MI Cancer Seek solution in January 2025 as the WES/WTS NGS component of our MI Profile platform. We initiated the broad commercial launch of Caris Assure for therapy selection in the first quarter of 2024. Realizing the potential of Caris Assure and our future solutions, including Caris Detect, across the cancer treatment continuum is a key component of our business strategy. The commercial success of our solutions will depend upon, among other things, additional validation studies and clinical trials that demonstrate the effectiveness of our solutions, particularly for early detection, MCED, MRD tracking, and treatment monitoring, and the continued adoption of Caris Assure and the adoption of our other solutions, including Caris Detect, 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 be 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.
- ***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 that could 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. While the average selling prices ("ASPs") for Caris Assure, MI Tumor Seek Hybrid, 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 overall 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 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 business 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, research 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 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, primarily due to the additional costs of operating as a public company, which include additional legal, accounting, corporate governance, and investor relations expenses, as well as higher directors' and officers' insurance premiums. In addition, we incur stock-based compensation expense related to our equity incentive plans.

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 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 loan and convertible notes, 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 derivative liabilities. Our warrants were 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. All warrants were exercised upon the closing of the IPO.

Other Expense, Net

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

Results of Operations

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

(amounts in thousands)	Years Ended December 31,		
	2025	2024	2023
Revenue:			
Molecular profiling services	$ 766,719	$ 349,115	$ 278,748
Pharma research and development services	45,314	63,145	27,380
Total revenue	**812,033**	**412,260**	**306,128**
Costs and operating expenses [1]:			
Cost of Services - Molecular profiling services	262,353	223,075	207,509
Cost of Services - Pharma research and development services	10,512	10,403	9,309
Selling and marketing expense	167,506	152,602	142,925
General and administrative expense	224,965	169,386	149,053
Research and development expense	101,584	113,916	116,883
Total costs and operating expenses	**766,920**	**669,382**	**625,679**
Income (Loss) from operations	45,113	(257,122)	(319,551)
Other expense, net:			
Interest income	16,497	7,122	11,258
Interest expense	(56,853)	(50,025)	(31,610)
Changes in fair value of financial instruments	(52,285)	18,484	11,094
Other expense, net	(20,560)	(349)	(12,606)
Total other expense, net	**(113,201)**	**(24,768)**	**(21,864)**
Loss before income taxes and provision for income taxes	**(68,088)**	**(281,890)**	**(341,415)**
Provision for income taxes	—	—	—
Net loss	**$ (68,088)**	**$ (281,890)**	**$ (341,415)**

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

	Years Ended December 31,		
	2025	2024	2023
	(amounts in thousands)		
Cost of services - Molecular profiling services	$ 3,591	$ 1,669	$ 1,504
Cost of services - Pharma research and development services	25	11	10
Selling and marketing expense	9,582	4,301	3,400
General and administrative expense	45,684	8,448	6,983
Research and development expense	11,124	4,214	3,344
Total	$ 70,006	$ 18,643	$ 15,240

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

	Years Ended December 31,		
	2025	2024	2023
Revenue:			
Molecular profiling services	94%	85%	91%
Pharma research and development services	6%	15%	9%
Total revenue	**100%**	**100%**	**100%**
Costs and operating expenses [1]:			
Cost of Services - Molecular profiling services	32%	54%	68%
Cost of Services - Pharma research and development services	1%	3%	3%
Selling and marketing expense	21%	37%	47%
General and administrative expense	28%	41%	49%
Research and development expense	13%	28%	38%
Total costs and operating expenses	**94%**	**162%**	**204%**
Income (Loss) from operations	6 %	(62)%	(104)%
Other expense, net:			
Interest income	2%	2%	4%
Interest expense	(7)%	(12)%	(10)%
Changes in fair value of financial instruments	(6)%	4%	4%
Other expense, net	(3)%	— %	(4)%
Total other expense, net	**(14)%**	**(6)%**	**(7)%**
Loss before income taxes and provision for income taxes	**(8)%**	**(68)%**	**(112)%**
Provision for income taxes	—%	—%	—%
Net loss	**(8)%**	**(68)%**	**(112)%**

Comparison of the Years Ended December 31, 2025 and 2024

Revenue

	Years Ended December 31,		Change	
	2025	2024	$	%
	(amounts in thousands)			
Molecular profiling services	$ 766,719	$ 349,115	$ 417,604	119.6%
Pharma research and development services	45,314	63,145	(17,831)	(28.2)%
Total revenue	$ 812,033	$ 412,260	$ 399,773	97.0%

Total revenue was $812.0 million for the year ended December 31, 2025, compared to $412.3 million for the year ended December 31, 2024, an increase of $399.8 million, or 97.0%.

Molecular Profiling Services Revenue

Molecular profiling services revenue increased to $766.7 million for the year ended December 31, 2025, from $349.1 million for the year ended December 31, 2024, an increase of $417.6 million, or 119.6%.

MI Profile and Caris Assure clinical testing revenue increased year over year, driven primarily by higher reimbursement and higher clinical case volume. The average selling price for our MI Profile platform increased due to the launch of MI Cancer Seek and the associated higher reimbursement. In addition, therapy selection clinical cases increased from 146,600 MI Profile cases and 16,250 Caris Assure cases for the year ended December 31, 2024, to 170,300 MI Profile cases and 29,000 Caris Assure cases for the year ended December 31, 2025.

Revenue from clinical cases for patients covered by Medicare represented approximately 39.6% and 39.0% of our molecular profiling services revenue for the years ended December 31, 2025 and 2024, respectively.

The following table sets forth the relative impacts of clinical volume and ASP on our increase in molecular profiling services revenue from 2024 to 2025.

	(amounts in thousands)
Molecular profiling services revenue for the twelve months ended December 31, 2024	$ 349,115
MI Profile volume increase	51,979
MI Profile ASP increase due to solution and payer mix	311,383
Caris Assure for therapy selection volume and ASP increase	54,242
Molecular profiling services revenue for the twelve months ended December 31, 2025	$ 766,719

Pharma Research and Development Services Revenue

Pharma research and development services revenue decreased to $45.3 million for the year ended December 31, 2025, from $63.1 million for the year ended December 31, 2024, a decrease of $17.8 million, or 28.2%. This decrease was primarily attributed to the timing of contract execution of $18.9 million, along with a reduction in research revenue of $1.0 million. The decreases were partially offset by an increase within pharma profiling services of $2.1 million.

Cost of Services

	Years Ended December 31,		Change	
	2025	2024	$	%
	(amounts in thousands)			
Cost of services - Molecular profiling services	$ 262,353	$ 223,075	$ 39,278	17.6 %
Cost of services - Pharma research and development services	$ 10,512	$ 10,403	$ 109	1.0 %

Cost of Services - Molecular Profiling Services

Cost of services - Molecular profiling services was $262.4 million for the year ended December 31, 2025, compared to $223.1 million for the year ended December 31, 2024, an increase of $39.3 million, or 17.6%.

The blood laboratory contributed a $28.3 million increase, in addition to an increase within the tissue laboratory of $11.0 million. The blood laboratory increase was primarily driven by an increase in materials and related testing costs of $22.4 million, an increase in labor costs of $3.2 million, and a $4.3 million increase in utilities, rent, and allocated overhead, due to the increased volume from broad launch in the first quarter of 2024, offset by a decrease in inventory adjustments of $0.5 million. The tissue lab increase was driven primarily by an increase in materials and related testing costs of $5.6 million, an increase in labor costs of $5.1 million, and a $0.9 million increase in utilities, rent, and allocated overhead, driven by increased case volume.

Cost of Services - Pharma Research and Development Services

Cost of services - Pharma research and development services was $10.5 million for the years ended December 31, 2025 and 2024.

Gross Profit

Gross profit, calculated as total revenue less cost of services, was $539.2 million for the year ended December 31, 2025, compared to $178.8 million for the year ended December 31, 2024, an increase of $360.4 million, or 201.6%, primarily due to the increase in molecular profiling services revenue.

Selling and Marketing Expense

	Years Ended December 31,		Change	
	2025	2024	$	%
	(amounts in thousands)			
Selling and marketing expense	$ 167,506	$ 152,602	$ 14,904	9.8 %

Selling and marketing expenses were $167.5 million for the year ended December 31, 2025, compared to $152.6 million for the year ended December 31, 2024, an increase of $14.9 million, or 9.8%. This increase was primarily due to a $10.4 million increase in personnel costs to support existing solutions, a $1.0 million increase in professional services, and a $2.7 million increase in travel and marketing expenses.

General and Administrative Expense

	Years Ended December 31,		Change	
	2025	2024	$	%
	(amounts in thousands)			
General and administrative expense	$ 224,965	$ 169,386	$ 55,579	32.8 %

General and administrative expenses were $225.0 million for the year ended December 31, 2025, compared to $169.4 million for the year ended December 31, 2024, an increase of $55.6 million, or 32.8%. This increase was primarily due to an increase of $37.2 million in stock-based compensation, primarily driven by expense from awards with an IPO-related vesting condition, a $13.9 million increase in labor costs and benefits associated with an expansion of personnel, a $9.2 million increase in consulting, audit and legal professional fees, a $2.7 million increase related to utilities and cloud computing usage, a $1.5 million increase in insurance expenses, a $2.0 million increase related to an increase in software licenses held, and a $3.5 million increase in travel expenses, offset by a $14.0 million decrease in depreciation expense.

Research and Development Expense

	Years Ended December 31,		Change	
	2025	2024	$	%
	(amounts in thousands)			
Research and development expense	$ 101,584	$ 113,916	$ (12,332)	(10.8)%

Research and development expenses were $101.6 million for the year ended December 31, 2025, compared to $113.9 million for the year ended December 31, 2024, a decrease of $12.3 million, or 10.8%. The decrease was primarily driven by a reduction of $15.8 million in material and reference testing costs associated with the development of Caris Assure and FDA submission of MI Cancer Seek in 2024 and a $2.1 million reduction in allocated overhead, partially offset by a $4.4 million increase in labor costs, benefits, and stock-based compensation primarily from awards with an IPO-related vesting condition and a $2.0 million increase in utilities and cloud computing usages.

Other Expense, Net

	Years Ended December 31,		Change	
	2025	2024	$	%
	(amounts in thousands)			
Interest income	$ 16,497	$ 7,122	$ 9,375	131.6 %
Interest expense	(56,853)	(50,025)	(6,828)	13.6%
Changes in fair value of financial instruments	(52,285)	18,484	(70,769)	(382.9%)
Other expense, net	(20,560)	(349)	(20,211)	5,791.1 %
Total other expense, net	$ (113,201)	$ (24,768)	$ (88,433)	357.0%

Interest Income

Interest income was $16.5 million for the year ended December 31, 2025, compared to $7.1 million for the year ended December 31, 2024, an increase of $9.4 million, or 131.6%. This increase was primarily due to higher cash balances within our interest-earning bank accounts.

Interest Expense

Interest expense was $56.9 million for the year ended December 31, 2025, compared to $50.0 million for the year ended December 31, 2024, an increase of $6.8 million, or 13.6%. This increase was primarily due to increased interest expense associated with $200.0 million of additional borrowing under the 2023 Term Loan, which was drawn on March 5, 2024, and increased amortization of debt discount associated with the 2025 Convertible Notes (as defined below).

Changes in Fair Value of Financial Instruments

Changes in fair value of financial instruments was $(52.3) million for the year ended December 31, 2025, compared to $18.5 million for the year ended December 31, 2024, a decrease of $70.8 million, or 382.9%. This decrease is mainly driven by the change in warrant and derivative fair values, along with their extinguishment at IPO, during the year ended December 31, 2025.

Other Expense, Net

Other expense, net was $20.6 million for the year ended December 31, 2025, compared to $0.3 million for the year ended December 31, 2024, an increase of $20.2 million. This increase was primarily due to the debt extinguishment expense of the 2025 Convertible Notes recorded of $19.9 million upon the IPO during the year ended December 31, 2025.

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:

	Years Ended December 31,	
	2025	2024
	(amounts in thousands)	
Net loss	$ (68,088)	$ (281,890)
Interest income	(16,497)	(7,122)
Interest expense	56,853	50,025
Changes in fair value of financial instruments	52,285	(18,484)
Other expense, net	20,560	349
Depreciation and amortization expense	22,615	48,913
Stock-based compensation expense	70,006	18,643
Adjusted EBITDA	$ 137,734	$ (189,566)

Free Cash Flow

We define free cash flow as net cash provided by (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 provided by (used in) operating activities, capital expenditures, and our other GAAP results.

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

	Years Ended December 31,	
	2025	2024
	(amounts in thousands)	
Net cash provided by (used in) operating activities	$ 83,155	$ (245,199)
Less: purchases of property and equipment	(16,260)	(8,444)
Free cash flow	$ 66,895	$ (253,643)

Liquidity and Capital Resources

Sources of Liquidity

We may incur 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. As of December 31, 2025, we had an accumulated deficit of $2.5 billion.

To date, we have funded our operations principally from the issuance of stock in private financings, issuance of common stock through our IPO, term loan borrowings and convertible debt, and through revenue from molecular profiling and pharma research and development services. As of December 31, 2025, we had cash and cash equivalents of

$796.3 million and short-term marketable securities of $2.3 million. We believe our existing cash and cash equivalents (which includes the net proceeds from our Pre-IPO Financing (defined in Note 2 to our consolidated financial statements, included in Part II. Item 8 "Financial Statements and Supplementary Data" of this Annual Report) and the IPO), short-term marketable securities, and anticipated cash flows from operations will provide sufficient capital and liquidity to fund our operating expenses and capital expenditure requirements for at least the next 12 months. We may, 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.

Cash Flows

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

	Years Ended December 31,		
	2025	2024	2023
	(amounts in thousands)		
Net cash provided by (used in) operating activities	$ 83,155	$ (245,199)	$ (276,100)
Net cash provided by (used in) investing activities	$ (16,260)	$ 52,932	$ 214,774
Net cash provided by financing activities	$ 664,989	$ 200,292	$ 10,132

Operating Activities

Net cash provided by operating activities during the year ended December 31, 2025 was $83.2 million, which was due to net non-cash charges of $184.4 million, offset by a net loss of $68.1 million and a net change in our operating assets and liabilities of $33.1 million. The net change in our operating assets and liabilities was primarily the result of a $29.8 million increase in accounts receivable, a $20.8 million increase in supplies, and a $5.2 million increase in prepaid expenses and other current assets, offset by an $11.0 million increase in accounts payable, and an $11.5 million increase in accrued expenses and other liabilities. Net non-cash charges primarily consisted of $22.6 million of depreciation and amortization expense, $70.0 million of stock-based compensation expense (including $19.5 million of stock-based compensation expense associated with RSUs vested upon the IPO), $5.6 million of non-cash operating lease expense, $12.8 million in amortization of debt discount costs, a $52.3 million loss within changes in the fair value of financial instruments, and a $19.9 million loss on debt extinguishment associated with our IPO.

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, offset by net 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, and a $1.4 million increase in prepaid expenses and other current assets, offset by a $5.5 million decrease in supplies, and a $0.8 million increase in accrued expenses and other liabilities. Net non-cash charges primarily consisted of $48.9 million of depreciation and amortization expense, $18.6 million of stock-based compensation expense, $5.6 million of non-cash operating lease 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.

Investing Activities

Net cash used in investing activities during the year ended December 31, 2025 was $16.3 million, which was primarily due to purchases of property and equipment of $16.3 million.

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 property and equipment of $8.4 million.

Financing Activities

Net cash provided by financing activities during the year ended December 31, 2025 was $665.0 million, which was primarily due to proceeds from exercises of stock options of $7.6 million, issuance of Series E Preferred Stock, net of issuance costs, of $87.6 million, issuance of Series F Preferred Stock, net of issuance costs, of $33.6 million, issuance of the 2025 Convertible Notes, net of issuance costs, of $27.9 million, issuance of warrants of $10.3 million, and proceeds from the IPO, net of underwriting discounts and commissions, of $528.5 million, offset by the payment of taxes withheld

from net settlement of equity awards of $18.6 million, payment of deferred offering costs of $7.7 million, and payments from debt modification of $4.0 million.

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 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 December 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 1.0% 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.

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, 2025, the interest rate was 10.5%. 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 12.3%.

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 our business, mergers or acquisitions, indebtedness, encumbrances, distributions, investments, transactions with affiliates, and subordinated debt. As of December 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 were issued in an aggregate principal amount of $30.0 million. The 2025 Convertible Notes accrued interest at a rate of 8% per annum, payable quarterly in cash, and were to mature on January 1, 2026 unless earlier converted. 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 were not initially exercisable for any shares of common stock, but such warrants became exercisable for a specified dollar value of shares on a monthly basis commencing on June 1, 2025 if we had not completed an initial public offering by such date. Any exercisable portion of the warrants were automatically exercised prior to the closing of the IPO, such warrants terminated upon the closing of the IPO and all 2025 Convertible Notes (plus accrued interest) converted into shares of common stock upon the closing of the IPO.

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, selling and marketing expenditures, clinical and regulatory expenditures, purchases of testing equipment, and build out of our laboratories. Cash used to fund such activities is impacted by the timing of when we pay or prepay these expenses.

We expect that 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. In 2026, we expect to incur

increased expenses related to commercial expansion and increase in pipeline trial activities. 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 costs of expanding, maintaining, and upgrading our laboratory infrastructure, including investments in sequencing capacity, equipment, and related technology;
- 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 and marketing our solutions, including any regulatory authorization or marketing approval that may be required and the expansion of our commercial teams;
- 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.

Critical Accounting Policies and Estimates

Our consolidated financial statements have been prepared in conformity with GAAP. Any reference in this section 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 in Part II. Item 8 "Financial Statements and Supplementary Data" of this Annual Report, 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, other service providers 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.* Prior to our common stock being publicly traded, the fair value of the common stock underlying our stock options was determined by our compensation committee, with input from valuation reports prepared by third-party valuation specialists. Subsequent to our IPO, the fair value of our common stock is determined based on the closing market price of our common stock.
- *Expected price volatility.* Prior to our common stock being publicly traded, the expected price volatility for our stock options was 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. Subsequent to our IPO, expected volatility is based on the historical volatility of our common stock.
- *Risk-free interest rate.* The risk-free interest rate was 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 represented the period of time over which the options granted were expected to remain outstanding and was 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 utilized 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.

Following the IPO, the fair value of RSUs is based on the closing price of our common shares on the Nasdaq Global Select Market on the trading day prior to the grant date.

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.

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 date on which we are deemed to be a "large accelerated filer" as defined in Rule 12b-2 under the Exchange Act, which would occur on the last day of the fiscal year in which 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 the IPO (*i.e.* the fiscal year ending December 31, 2030).

Recent Accounting Pronouncements

See Note 2 of our consolidated financial statements, included in Part II. Item 8 "Financial Statements and Supplementary Data" of this Annual Report, for more information regarding recently issued accounting pronouncements.

Item 7A. 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 December 31, 2025, we had cash, cash equivalents, and restricted cash of $800.0 million, and short-term marketable securities of $2.3 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 December 31, 2025. A hypothetical 100 basis point adverse movement in the interest rate would increase our annual interest expense by $4.0 million. As of December 31, 2025, 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%, with a February 2026 maturity. We did not receive any settlement payments from the counterparty to the interest rate cap for the year ended December 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.

Inflation Risk

We do not believe that inflation has had a material effect on our business, financial condition or results of operations, other than its impact on the general economy, which includes labor costs. Nonetheless, if our costs, in particular personnel-related costs, continue to become subject to significant inflationary pressures, we may not be able to fully offset such higher costs through price increases. Our inability or failure to do so could harm our business, financial condition and results of operations.

Item 8. Financial Statements and Supplementary Data

Caris Life Sciences, Inc.
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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 sheets of Caris Life Sciences, Inc. and subsidiaries (the "Company") as of December 31, 2025 and 2024, the related consolidated statements of operations and comprehensive loss, redeemable convertible preferred stock and shareholders' equity (deficit), and cash flows, for each of the two years in the period ended December 31, 2025, 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, 2025 and 2024, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2025, in conformity with accounting principles generally accepted in the United States of America.

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 audits. 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 audits 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 audits, 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 audits 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 audits 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 audits provide a reasonable basis for our opinion.

/s/ Deloitte & Touche LLP

San Jose, California
March 3, 2026

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 statements of operations and comprehensive loss, changes in redeemable convertible preferred stock and shareholders' equity (deficit) and cash flows of Caris Life Sciences, Inc. (the Company) for the year ended December 31, 2023, 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 results of its operations and its cash flows for the year ended December 31, 2023 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 fifth 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, 2025	As of December 31, 2024
Assets		
Current assets:		
Cash, cash equivalents, and restricted cash	$ 797,799	$ 65,442
Short-term marketable securities	2,295	2,201
Accounts receivable	112,140	88,244
Supplies	63,625	39,572
Prepaid expenses and other current assets	21,941	20,270
Total current assets	997,800	215,729
Property and equipment, net	63,170	67,817
Goodwill	19,344	19,344
Other assets	45,349	40,844
Total assets	**$ 1,125,663**	**$ 343,734**
Liabilities, Redeemable Convertible Preferred Stock, and Shareholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 39,206	$ 27,791
Accrued expenses and other current liabilities	87,770	77,542
Current portion of indebtedness	169	60,090
Total current liabilities	127,145	165,423
Long-term indebtedness, net of debt discounts	378,823	319,438
Warrant liabilities	—	91,642
Other long-term liabilities	42,388	44,418
Total liabilities	548,356	620,921
Commitments and contingencies (see note 10)		
Redeemable convertible preferred stock:		
Series A preferred stock, par value $0.001: no and 490,000,000 shares authorized as of December 31, 2025 and December 31, 2024, respectively; no and 485,795,293 shares issued and outstanding as of December 31, 2025 and December 31, 2024, respectively; and $296,335 aggregate liquidation preference as of December 31, 2024	—	709,261
Series B preferred stock, par value $0.001: no and 30,000,000 shares authorized as of December 31, 2025 and December 31, 2024, respectively; no and 29,629,630 shares issued and outstanding as of December 31, 2025 and December 31, 2024, respectively; and $16,000 aggregate liquidation preference as of December 31, 2024	—	42,963
Series C preferred stock, par value $0.001: no and 142,000,000 shares authorized as of December 31, 2025 and December 31, 2024, respectively; no and 116,200,835 shares issued and outstanding as of December 31, 2025 and December 31, 2024, respectively; and $408,715 aggregate liquidation preference as of December 31, 2024	—	408,715

Series D preferred stock, par value $0.001: no and 102,600,000 shares authorized as of December 31, 2025 and December 31, 2024, respectively; no and 102,516,283 shares issued and outstanding as of December 31, 2025 and December 31, 2024, respectively; and $1,060,712 aggregate liquidation preference as of December 31, 2024	—	1,060,712
Redeemable convertible preferred stock	—	2,221,651
Shareholders' equity (deficit):		
Preferred stock, $0.001 par value per share; 100,000,000 and no shares authorized as of December 31, 2025 and December 31, 2024, respectively; no shares issued and outstanding as of December 31, 2025 and December 31, 2024	—	—
Common stock $0.001 par value; 2,800,000,000 and 1,150,000,000 shares authorized as of December 31, 2025 and December 31, 2024, respectively; 284,137,810 and 36,686,819 shares issued as of December 31, 2025 and December 31, 2024, respectively; 282,526,097 and 36,504,319 shares outstanding as of December 31, 2025 and December 31, 2024, respectively; shares issued and outstanding include 23,446 and 662,000 unvested shares subject to repurchase as of December 31, 2025 and December 31, 2024, respectively	283	38
Treasury stock at cost, 1,611,713 and 182,500 shares of common stock as of December 31, 2025 and December 31, 2024, respectively	(16,896)	(330)
Additional paid-in capital	3,141,720	—
Related party promissory note receivable (see note 7)	—	(26,456)
Accumulated deficit	(2,548,736)	(2,472,300)
Accumulated other comprehensive income	936	210
Total shareholders' equity (deficit)	577,307	(2,498,838)
Total liabilities, redeemable convertible preferred stock, and shareholders' equity (deficit)	**$ 1,125,663**	**$ 343,734**

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,		
	2025	2024	2023
Revenue:			
Molecular profiling services	$ 766,719	$ 349,115	$ 278,748
Pharma research and development services	45,314	63,145	27,380
Total revenue	**812,033**	**412,260**	**306,128**
Costs and operating expenses:			
Cost of Services - Molecular profiling services	262,353	223,075	207,509
Cost of Services - Pharma research and development services	10,512	10,403	9,309
Selling and marketing expense	167,506	152,602	142,925
General and administrative expense (see note 11)	224,965	169,386	149,053
Research and development expense	101,584	113,916	116,883
Total costs and operating expenses	**766,920**	**669,382**	**625,679**
Income (Loss) from operations	**45,113**	**(257,122)**	**(319,551)**
Other expense, net:			
Interest income	16,497	7,122	11,258
Interest expense	(56,853)	(50,025)	(31,610)
Changes in fair value of financial instruments	(52,285)	18,484	11,094
Other expense, net	(20,560)	(349)	(12,606)
Total other expense, net	**(113,201)**	**(24,768)**	**(21,864)**
Loss before income taxes and provision for income taxes	**(68,088)**	**(281,890)**	**(341,415)**
Provision for income taxes	—	—	—
Net loss	**(68,088)**	**(281,890)**	**(341,415)**
Other comprehensive income (loss), net of tax:			
Unrealized gain on available-for-sale securities	—	7	(1,660)
Foreign currency translation adjustments	726	(15)	180
Comprehensive loss	**(67,362)**	**(281,898)**	**(342,895)**
Net loss attributable to common shareholders:			
Net loss	(68,088)	(281,890)	(341,415)
Deemed dividend from Series D redeemable convertible preferred stock (see note 6)	(384,436)	—	—
Adjustments of redeemable convertible preferred stock to redemption value	(85,433)	(96,367)	(121,112)
Net loss attributable to common shareholders	**$ (537,957)**	**$ (378,257)**	**$ (462,527)**

Net loss per share attributable to common shareholders, basic and diluted	$ (3.22)	$ (10.66)	$ (13.24)
Weighted-average shares used in computing net loss per share attributable to common shareholders, basic and diluted	167,205,616	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' EQUITY (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' Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount					
Balances at December 31, 2022	**703,086,140**	**$ 1,954,172**	**34,376,983**	**$ 37**	**182,500**	**$ (330)**	**$ —**	**$ (24,969)**	**$ (1,678,549)**	**$ 1,698**	**$ (1,702,113)**
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	**734,142,041**	**$ 2,125,284**	**35,297,278**	**$ 38**	**182,500**	**$ (330)**	**$ —**	**$ (25,701)**	**$ (2,119,175)**	**$ 218**	**$ (2,144,950)**
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 preferred stock to redemption value	—	96,367	—	—	—	—	(25,133)	—	(71,234)	—	(96,367)
Other comprehensive income	—	—	—	—	—	—	—	—	—	(8)	(8)
Net loss	—	—	—	—	—	—	—	—	(281,890)	—	(281,890)
Balances at December 31, 2024	**734,142,041**	**$ 2,221,651**	**35,842,319**	**$ 38**	**182,500**	**$ (330)**	**$ —**	**$ (26,456)**	**$ (2,472,299)**	**$ 210**	**$ (2,498,837)**
Issuance of Series E Preferred Stock, net of issuance costs	12,345,674	57,217	—	—	—	—	—	—	—	—	—
Issuance of Series F Preferred Stock, net of issuance costs	4,657,401	21,617	—	—	—	—	—	—	—	—	—
Stock-based compensation	—	—	—	—	—	—	70,006	—	—	—	70,006
Issuance of common stock upon exercise of stock options	—	—	2,427,277	2	—	—	7,637	—	—	—	7,639
Shares withheld for taxes related to net exercise of options	—	—	(414,308)	(1)	—	—	(18,551)	—	—	—	(18,552)
Repurchase and cancellation of common stock	—	—	(15,006)	—	—	—	(113)	—	—	—	(113)
Vesting of shares from early exercised stock options	—	—	—	—	—	—	327	—	—	—	327
Issuance of common stock for RSUs vested or settled	—	—	1,063,250	—	—	—	—	—	—	—	—
Shares withheld for taxes related to settled RSUs	—	—	(421,417)	—	—	—	—	—	—	—	—
Interest income from related party promissory notes	—	—	—	—	—	—	—	(128)	—	—	(128)
Payment of related party promissory notes	—	—	—	—	—	—	—	26,584	—	—	26,584
Repurchase of common stock from early exercises	—	—	(1,429,213)	—	1,429,213	(16,566)	—	—	—	—	(16,566)
Adjustment of preferred stock to redemption value	—	85,433	—	—	—	—	(77,084)	—	(8,349)	—	(85,433)
Conversion of preferred stock to common stock, including the derecognition of associated embedded derivatives of $60,086	(751,145,116)	(2,385,918)	211,378,638	211	—	—	2,445,793	—	—	—	2,446,004
Issuance of common stock in connection with initial public offering, net of offering costs, underwriting discounts and commissions	—	—	27,058,823	27	—	—	519,425	—	—	—	519,452
Net exercise of the 2018 and 2020 Warrants in connection with initial public offering	—	—	4,174,907	4	—	—	131,742	—	—	—	131,746
Net exercise of the 2025 Warrants in connection with initial public offering	—	—	784,231	—	—	—	15,926	—	—	—	15,926
Conversion of the 2025 Convertible Note, including the derecognition of associated embedded derivatives of $13,082	—	—	2,076,596	2	—	—	46,640	—	—	—	46,642
Other comprehensive income	—	—	—	—	—	—	(28)	—	—	726	698
Net loss	—	—	—	—	—	—	—	—	(68,088)	—	(68,088)
Balances at December 31, 2025	**—**	**$ —**	**282,526,097**	**$ 283**	**1,611,713**	**$ (16,896)**	**$ 3,141,720**	**$ —**	**$ (2,548,736)**	**$ 936**	**$ 577,307**

The accompanying notes are an integral part of these consolidated financial statements

CONSOLIDATED STATEMENTS OF CASH FLOWS

(amounts in thousands)	Years Ended December 31,		
	2025	2024	2023
Cash flows from operating activities			
Net loss	$ (68,088)	$ (281,890)	$ (341,415)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	22,615	48,913	49,001
Stock-based compensation expense	70,006	18,643	15,241
Non-cash operating lease expense	5,585	5,601	4,332
Amortization of debt discounts	12,768	7,054	5,378
Changes in fair value of financial instruments	52,285	(18,484)	(11,094)
Loss on debt extinguishment	19,895	—	10,915
Other	1,216	4,031	(1,329)
Changes in operating assets and liabilities:			
Accounts receivable	(29,789)	(33,816)	(15,081)
Supplies	(20,750)	5,459	(4,435)
Prepaid expenses and other current assets	(5,150)	(1,408)	4,544
Other assets	48	121	(588)
Accounts payable	11,035	(226)	7,171
Accrued expenses and other liabilities	11,479	803	1,260
Net cash provided by (used in) operating activities	83,155	(245,199)	(276,100)
Cash flows from investing activities			
Maturities of marketable securities	—	61,376	300,488
Purchases of marketable securities	—	—	(63,395)
Purchases of property and equipment	(16,260)	(8,444)	(22,319)
Net cash provided by (used in) investing activities	(16,260)	52,932	214,774
Cash flows from financing activities			
Payments made on finance lease obligations	(106)	(157)	(743)
Proceeds from exercise of stock options	7,637	1,530	1,865
Payment of taxes withheld from net settlement of exercised options and vested RSUs	(18,551)	—	—
Payment of deferred offering costs	(7,710)	(1,059)	—
Payment of third-party debt issuance costs	—	—	(2,300)
Proceeds from the 2023 term loan, net of issuance costs	—	199,978	191,310

Repurchase of common stock	(113)	—	—
Repayment of the Original Term Loans	—	—	(180,000)
Issuance of Series E Preferred Stock, net of issuance costs	87,637	—	—
Issuance of Series F Preferred Stock, net of issuance costs	33,601	—	—
Issuance of the 2025 Convertible Notes, net of issuance costs	27,865	—	—
Issuance of the 2025 Warrants	10,270	—	—
Payments of 2023 term loan amendment fee	(4,000)	—	—
Proceeds from initial public offering, net of underwriting discounts and commissions	528,459	—	—
Net cash provided by financing activities	664,989	200,292	10,132
Effect of exchange rate changes on cash, cash equivalents, and restricted cash	130	(4)	62
Net increase (decrease) in cash, cash equivalents, and restricted cash	732,014	8,021	(51,132)
Cash, cash equivalents, and restricted cash at beginning of period	68,028	60,007	111,139
Cash, cash equivalents, and restricted cash at end of period	$ 800,042	$ 68,028	$ 60,007
Supplemental disclosure of cash flow information			
Interest paid	$ 43,520	$ 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	$ 11,599	$ 11,297	$ 12,062
Operating cash flow used for finance leases	$ 35	$ 36	$ 78
Financing cash flow used for finance leases	$ 106	$ 157	$ 743
Lease liabilities arising from obtained right-of-use-assets:			
Operating leases	$ 3,851	$ 725	$ 4,782
Finance leases	$ 312	$ 42	$ —
Property and equipment included in accounts payable and accrued liabilities	$ 2,448	$ 2,052	$ 894
Conversion of convertible debt to Series C Preferred Stock	$ —	$ —	$ 50,000
Non-cash considerations	$ 5,918	$ —	$ —
Deferred offering costs, accrued but not paid	$ —	$ 3,266	$ 254
Conversion of 2025 Convertible Notes and accrued interest to common stock upon initial public offering	$ 33,558	$ —	$ —
Conversion of redeemable convertible preferred stock to common stock upon initial public offering	$ 2,385,918	$ —	$ —

Exercise of warrants upon initial public offering	$	147,671	$	—	$	—
Reclassification of deferred offering costs to additional paid-in capital upon initial public offering	$	9,007	$	—	$	—
Deemed dividend from Series D redeemable convertible preferred stock	$	384,436	$	—	$	—

The accompanying notes are an integral part of these 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 the MI Profile platform, a tissue-based molecular profiling solution, and Caris Assure, a novel blood-based molecular profiling solution.

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 is a Texas corporation (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.

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").

Pre-IPO Financing

On April 1, 2025, the Company closed a private financing in which the Company issued a combination of senior convertible notes (the "2025 Convertible Notes") with warrants (the "2025 Warrants") to acquire shares of common stock, Series E redeemable convertible preferred stock ("Series E Preferred Stock") and Series F redeemable convertible preferred stock ("Series F Preferred Stock"), for an aggregate of $167.7 million. Investors in the private financing generally participated in each of the instruments. The 2025 Convertible Notes had an aggregate principal amount of $30.0 million. The 2025 Convertible Notes accrued interest at a rate of 8% per annum, payable quarterly in cash, and were scheduled to mature on January 1, 2026. The 2025 Warrants were not initially exercisable for any shares of common stock, but such warrants became exercisable for a specified dollar value of shares on a monthly basis commencing on June 1, 2025 if the Company had not completed an initial public offering ("IPO") by such date. The Series E Preferred Stock and Series F Preferred Stock both were issued at an original issue price of $8.10 per share for gross proceeds of approximately $137.7 million. Additionally, the gross proceeds of $167.7 million, less issuance costs of $8.3 million, were allocated as follows: $27.9 million to the 2025 Convertible Notes, $10.3 million to the 2025 Warrants, $87.6 million to the Series E Preferred Stock, and $33.6 million to the Series F Preferred Stock.

Upon the closing of the Company's IPO, the 2025 Convertible Notes (plus accrued interest), Series E Preferred Stock and Series F Preferred Stock (plus an 8% accrued dividend in connection with the preferred stock) converted into common stock at a price equal to 70% of the initial public offering price per share. Although structured and referred to as a legal-form conversion, this feature effectively functions as a share-settled redemption provision for accounting purposes. In addition, upon the closing of the IPO, the 2025 Warrants were net exercised into 784,231 shares of the Company's common stock.

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 and warrants.

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.

Initial Public Offering

On June 20, 2025, the Company completed its IPO of common stock, in which the Company issued and sold 23,529,412 shares of its common stock at an IPO price of $21.00 per share, which resulted in net proceeds of $459.5 million after deducting underwriting discounts and commissions of $39.8 million and before deducting offering costs of $9.0 million. Additionally, on June 25, 2025, the underwriters exercised in full their over-allotment option and purchased from the Company an additional 3,529,411 shares of common stock at the IPO price, which resulted in net proceeds to the Company of $68.9 million after deducting discounts and commissions.

An amended and restated certificate of formation, which authorized 2,800,000,000 shares of common stock and 100,000,000 shares of preferred stock, became effective on June 20, 2025 in connection with the closing of the IPO. As of December 31, 2025, no shares of preferred stock were outstanding.

In connection with the IPO, all outstanding shares of the Company’s then-outstanding redeemable convertible preferred stock, inclusive of accrued dividends, automatically converted into 211,378,638 shares of common stock. Refer to Note 6 for additional information. Additionally, all of the Company’s then-outstanding 2025 Convertible Notes converted into an aggregate of 2,076,596 shares of common stock upon the IPO. As the IPO was not completed by June 1, 2025, 784,231 shares of common stock were issued on June 20, 2025 at an exercise price of $0.04 per share in connection with the automatic net exercise of the warrants issued in connection with the 2025 Convertible Notes. Lastly, the 2018 and 2020 warrants (as described in Note 8) were net exercised into 4,174,907 shares of common stock as outlined in the terms of the applicable warrant agreements.

In connection with the IPO, the Company recognized $19.5 million of stock-based compensation expense due to vesting of previously-granted restricted stock units. The vesting of such restricted stock units was contingent upon the Company completing either an IPO of its common stock or a change of control. The vested restricted stock units were settled in August 2025. Refer to Note 7 for additional information.

Prior to the IPO, deferred offering costs, which consisted of accounting, legal and other fees directly related to the IPO, were capitalized as prepaid expenses and other current assets on the consolidated balance sheets. In connection with the IPO, $9.0 million of deferred offering costs were reclassified to additional paid-in capital as a reduction of the net proceeds received from the IPO.

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.

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.

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. 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.

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, 2025 and 2024, the unbilled receivable balance was $7.2 million and $4.6 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, 2025 and 2024, the contract liability balance was $24.5 million and $7.5 million, respectively, which is included in accrued expenses and other current liabilities on the 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	32,576
Revenue recognized during the period that was included in deferred revenues at the beginning of the period	(7,400)
Revenue recognized from performance obligations satisfied within the same period	(8,154)
Balance at December 31, 2025	$ 24,492

The amount of revenue recognized during the years ended December 31, 2024 and 2023 pertaining to amounts deferred as of December 31, 2023 and 2022 was $5.4 million and $0.7 million, respectively.

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, 2025 was $6.5 million. The Company expects to recognize the amount within twelve months from the balance sheet date.

Additionally, for the years ended December 31, 2025, 2024, and 2023, the Company recorded $33.6 million, $3.9 million, and $(1.9) million, respectively, 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, 2025, 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.

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, 2025, 2024, and 2023, the Company recognized collaboration revenue of $11.4 million, $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 and liquid 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 December 31, 2025 and 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.

The Company is subject to credit risk from its accounts receivable. The Company's accounts receivable arise from the provision of molecular profiling services and pharma research and development services, 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, 2025, 2024, and 2023, the Company's revenues were primarily derived from the sale of 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 consolidated balance sheet date, are as follows:

	% Revenue for the years ended December 31,			% Accounts receivable as of December 31,	
Major Payer	**2025**	**2024**	**2023**	**2025**	**2024**
Payer 1	37.4%	33.1%	35.8%	18.4%	16.1%
Payer 2	21.1%	14.0%	14.0%	22.6%	19.3%
Payer 3	11.6%	*	11.0%	*	*

* Represents major payers below 10.0%.

In addition, as of December 31, 2025 and 2024, one biopharmaceutical customer group represented 17.9% and 22.3% of total accounts receivable, respectively.

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, 2025 and 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. For the years ended December 31, 2025 and 2024, the amount of write downs associated with the Company's supplies were $2.6 million and $4.0 million, respectively. For the year ended December 31, 2023, the Company had an immaterial amount of write downs associated with the Company's supplies.

Deferred Offering Costs

Deferred offering costs consist primarily of accounting, legal, and other fees related to the Company's then-proposed IPO. The Company had $4.5 million of deferred offering costs as of December 31, 2024. Prior to the IPO, deferred offering costs were capitalized on the consolidated balance sheet. Upon the consummation of the IPO, $9.0 million of deferred offering costs were reclassified into additional paid-in capital as an offset against IPO proceeds.

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 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. 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 $2.3 million and $1.1 million in development costs for internal use software for the years ended December 31, 2025 and 2024, 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 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. These warrants converted into shares of common stock immediately prior to the IPO on June 20, 2025. 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
- *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 December 31, 2025 and 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 years ended December 31, 2025, 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, 2025			
	Fair Value	Level 1	Level 2	Level 3
Financial assets	(amounts in thousands)			
Short-term marketable securities	$ 2,295	$ 2,295	$ —	$ —

	As of December 31, 2024			
	Fair Value	Level 1	Level 2	Level 3
Financial assets	(amounts in thousands)			
Short-term marketable securities	$ 2,201	$ 2,201	$ —	$ —
Financial liabilities				
Warrant liability	$ 91,642	$ —	$ —	$ 91,642
Derivative liability	$ 6,058	$ —	$ —	$ 6,058

2018 and 2020 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 relating to the 2018 Warrants and the 2020 Warrants. 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 2018 and 2020 warrant liabilities as of December 31, 2024. The warrants were reclassified from liability to equity upon the IPO as they were exercised into Series C preferred stock, which was converted to common stock. The difference between the fair value of the warrants immediately prior to the reclassification and its prior fair value was recorded in the consolidated statement of operations and comprehensive loss as changes in fair value of financial instruments. The fair

value immediately prior to the reclassification is based on the total number of common stock issued upon exercise and conversion, multiplied by the public offering price of $21.00 per share.

	As of December 31, 2024	
	2018 Warrants	2020 Warrants
Fair value per share of the underlying stock	$3.66 - $5.65	$3.66 - $5.65
Expected volatility	47.6% - 63.0%	61.2% - 63.0%
Risk-free interest rate	4.2% - 4.3%	4.3%
Expected dividend yield	—%	—%
Expected term (years)	0.29 - 0.75	0.29 - 2.25

2025 Warrant Liability - Pre-IPO Financing

The Company utilized a probability-weighted scenario approach factoring in various exit scenarios and the related timing of such to estimate the fair value of its warrants that were issued in conjunction with the 2025 Convertible Notes. Upon issuance as of April 1, 2025, the fair value of these warrants was $10.3 million. Immediately prior to the IPO, the fair value of these warrants was $16.5 million.

Derivative Liability - 2023 Term Loan

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 million of which 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 consolidated financial statements as a compound derivative liability.

Fair value of the derivative liability as of December 31, 2024 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. The value of the derivative liability in connection with the 2023 Term Loan reduced to zero upon the IPO, as the contingent prepayment is no longer required.

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.

Derivative Liability - Pre-IPO Financing

In estimating the fair value of the bifurcated derivatives related to the Series E Preferred Stock, Series F Preferred Stock and the 2025 Convertible Notes, the Company applied the with-and-without methodology as of April 1, 2025. This approach calculates the value of the bifurcated embedded derivative as the difference between the value of each instrument including the derivative and the value of each instrument excluding the derivative. Upon issuance on April 1, 2025, the fair values of the bifurcated embedded derivatives relating to the Series E Preferred Stock, Series F Preferred Stock, and 2025 Convertible Notes were $30.1 million, $11.9 million, and $21.2 million, respectively. Immediately prior to the IPO, the fair values of these bifurcated derivatives were $43.6 million, $16.5 million, and $13.1 million, respectively, determined as the excess of each instrument’s fair value immediately prior to the IPO over the sum of its original proceeds and any accrued interest or dividends. Upon the IPO, the derivative liabilities were derecognized in conjunction with the conversion of the 2025 Convertible Notes, Series E Preferred Stock, and Series F Preferred Stock, and the issuance of the associated shares was recorded in common stock and additional paid-in capital.

Debt - 2023 Term Loan

As of December 31, 2025, the estimated fair value of the 2023 Term Loan, was $373.5 million, compared to a carrying value of $378.5 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 December 31, 2025 based on a discounted cash flow analysis which represented the use of Level 3 inputs in the fair value hierarchy.

2025 Convertible Notes, Series E Preferred Stock, and Series F Preferred Stock - Pre-IPO Financing

The Company calculated the fair value of the 2025 Convertible Notes, as well as the Series E Preferred Stock, Series F Preferred Stock, and warrants as of April 1, 2025 using a calibrated approach that aligned the total fair value of the instruments with the cash proceeds received. Upon issuance as of April 1, 2025, the fair value of the 2025 Convertible Notes, the Series E Preferred Stock and the Series F Preferred Stock were $29.4 million, $92.5 million, and $35.5 million respectively. Immediately prior to the IPO, the fair value of the 2025 Convertible Notes was $43.6 million, based on the total number of common stock issued upon conversion, multiplied by the initial public offering price of $21.00 per share.

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, 2025, 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 $3.6 million, $1.2 million, and $0.6 million for the years ended December 31, 2025, 2024, and 2023, 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 $2.2 million and $1.9 million as of December 31, 2025 and 2024, 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 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, 2025, 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 the deemed dividend from Series D redeemable convertible preferred stock and accretion on preferred securities to their redemption value to the extent such securities are outstanding during the period, where applicable. 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, redeemable convertible preferred stock, promissory notes, warrants, restricted stock units, 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, 2025 and 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 Adopted Accounting Pronouncements

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. The ASU applies to all entities subject to income taxes and is intended to help investors better understand an entity's exposure to potential changes in jurisdictional tax legislation and assess income tax information that affects cash flow forecasts and capital allocation decisions. The ASU is effective for annual periods beginning after December 15, 2024, with early adoption permitted. The Company adopted this ASU on January 1, 2025. The adoption had no material impact on the Company's financial statements.

Recently Issued Accounting Pronouncements Not Yet Adopted

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 fiscal year beginning January 1, 2027.

In September 2025, the FASB issued ASU No. 2025-06, *Intangibles - Goodwill and Other - Internal-Use Software*. This ASU removes all references to prescriptive and sequential software development stages throughout Subtopic 350-40. This will require an entity to change how it starts capitalizing software costs, along with updating how entities evaluate the probable-to-complete recognition threshold. For all entities, the ASU is effective for annual reporting periods beginning after December 15, 2027, with early adoption permitted. The amendments of this ASU can be applied using any of the following three approaches: prospective transition approach; modified transition approach that is based on the status of the project and whether software costs were capitalized before the date of adoption; and retrospective transition approach. We are currently evaluating the impact that this guidance will have, and expect to adopt this ASU for the year ending December 31, 2028.

In December 2025, the FASB issued ASU No. 2025-11, *Interim Reporting (Topic 270) Narrow-Scope Improvements*. This ASU clarifies interim disclosure requirements and the applicability of Topic 270. The amendment's objective is to provide clarity on the current interim reporting requirements. The ASU also includes a disclosure principle that requires entities to disclose events since the end of the last annual reporting period that have a material impact on the entity. The amendments of this ASU are required to be adopted for interim periods within annual reporting periods beginning after December 15, 2027. Early adoption is permitted. The amendments of this ASU can be applied either prospectively or retrospectively to any or all prior periods presented in the financial statements. We are currently evaluating the impact that this guidance will have.

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,	
	2025	2024
	(amounts in thousands)	
Prepaid expenses	$ 19,586	$ 13,562
Other current assets	2,355	6,708
Total prepaid expenses and other current assets	$ 21,941	$ 20,270

Property and Equipment, Net

Property and equipment, net consist of the following:

	As of December 31,	
	2025	2024
	(amounts in thousands)	
Computer equipment and software	$ 76,430	$ 73,312
Capitalized software	27,898	25,921
Laboratory equipment	106,227	103,795
Furniture and fixtures	8,368	9,110
Leasehold improvements/Leased buildings	63,812	63,039
Aircraft and leased equipment	21,415	21,249
Total property and equipment	304,150	296,426
Less: accumulated depreciation and amortization	(240,980)	(228,609)
Property and equipment, net	$ 63,170	$ 67,817

Total depreciation and amortization expense was $22.6 million, $48.9 million, and $49.0 million for the years ended December 31, 2025, 2024, and 2023, respectively.

Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consist of the following:

	As of December 31,	
	2025	2024
	(amounts in thousands)	
Trade accruals	$ 6,887	$ 7,131
Accrued payroll and employee medical	11,104	17,882
Accrued bonus	31,487	25,736
Current portion of early exercise stock option liability	327	4,957
Contract liability	24,492	7,470
Current portion of operating lease liabilities	6,359	6,080
Other accrued expenses	7,114	8,286
Total accrued expenses and other current liabilities	$ 87,770	$ 77,542

Other Long-Term Liabilities

Other long-term liabilities consist of the following:

	As of December 31,	
	2025	2024
	(amounts in thousands)	
Long-term operating lease liabilities, net of current portion	$ 42,335	$ 38,651
Long-term portion of early exercise stock option liability	53	5,767
Total other long-term liabilities	$ 42,388	$ 44,418

Other Expense, Net

Other expense, net consists of the following:

	Years Ended December 31,		
	2025	2024	2023
	(amounts in thousands)		
Loss on debt extinguishment	$ (19,895)	$ —	$ (10,915)
Other	(665)	(349)	(1,691)
Total other income (expense), net	$ (20,560)	$ (349)	$ (12,606)

Note 4. 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 December 31, 2025 and 2024, amounts outstanding are $2.1 million and $2.7 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, 2025	As of December 31, 2024
		(amounts in thousands)	
Cash and cash equivalents	Cash, cash equivalents, and restricted cash	$ 796,274	$ 63,950
Restricted cash - short-term	Cash, cash equivalents, and restricted cash	1,525	1,492
Restricted cash - long-term	Other assets	2,243	2,586
Total		$ 800,042	$ 68,028

Note 5. Income Taxes

For financial reporting purposes, income before income taxes includes the following components:

	Years Ended December 31, 2025	Years Ended December 31, 2024	Years Ended December 31, 2023
	(amounts in thousands)		
United States	$ (70,469)	$ (283,720)	$ (339,724)
Foreign	2,381	1,830	(1,691)
Total	$ (68,088)	$ (281,890)	$ (341,415)

The Company had no income tax expense or benefit for the years ended December 31, 2025, 2024, and 2023. A reconciliation of the provision for income taxes to the amount computed by applying the 21% statutory U.S. federal income tax rate to income before income taxes after the adoption of ASU 2023-09 is as follows:

	Year ended December 31, 2025 Amount	Year ended December 31, 2025 Percent
	(amounts in thousands)	
U.S. Federal statutory tax rate	$ (14,299)	21.0 %
Effect of cross-border tax laws	14	— %
Nontaxable or nondeductible items:		
Permanent differences - warrant fair value	16,784	(24.7)%
Permanent differences - other	1,495	(2.2)%
Adjustments to NOLs	(1,144)	1.7 %
Valuation allowance	(5,888)	8.7 %
Other	3,538	(5.2)%
State and local income taxes, net of federal income tax effect	—	— %
Foreign tax effects	(500)	0.7 %
Effective tax rate	$ —	— %

A reconciliation of the provision for income taxes to the amount computed by applying the 21% statutory U.S. federal income tax rate to income before income taxes for years prior to the adoption of ASU 2023-09 is 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	$ —	$ —

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,	
	2025	2024
	(amounts in thousands)	
Deferred tax assets		
Net operating loss carryforward	$ 309,547	$ 290,514
Accrued liabilities	9,997	8,449
Stock-based compensation	14,039	5,993
Interest limitation	44,214	35,614
Research and development credits	2,842	2,842
Intangibles	3,164	3,557
Lease obligation	12,278	11,601
Contractual allowances	18,268	16,867
Research and development costs	—	52,140
Property and equipment basis difference	3,745	4,796
Others	6,227	1,956
Total deferred tax assets	424,321	434,329
Deferred tax liabilities		
Right of use assets	(10,033)	(9,033)
Excess tax goodwill amortization	(281)	(262)
Derivative liability fair value adjustment	(3,598)	(3,456)
Others	—	—
Total deferred tax liabilities	(13,912)	(12,751)
Valuation allowance	(410,409)	(421,578)
Net deferred tax asset (liability)	$ —	$ —

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, 2025. 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, 2025, a valuation allowance of $410.4 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 $11.2 million and $67.3 million during the fiscal years ended December 31, 2025 and 2024, 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 $2,250.3 million which expire as follows:

Expiration Year	Federal	State	Foreign	Total
		(amounts in thousands)		
2025 - 2030	$ 6,338	$ 11,695	$ 7,125	$ 25,158
2031 - 2040	209,538	284,733	2,489	496,760
2041 - 2045	—	534,354	—	534,354
Indefinite	1,041,526	152,472	—	1,193,998
Total	$ 1,257,402	$ 983,254	$ 9,614	$ 2,250,270

The 2018 through 2025 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, 2024 and continue to monitor for changes that could trigger a limitation. Based on this analysis, the Company does 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, 2025 and 2024, 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, 2025.

The Company is subject to taxation in the United States and various states and foreign jurisdictions. As of December 31, 2025, 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.

The Company accounts for uncertainty in income taxes in accordance with ASC Topic 740, *Income Taxes* ("ASC 740"). Through December 31, 2025, 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, 2025.

Note 6. Redeemable Convertible Preferred Stock

As of December 31, 2025, there were no shares of redeemable convertible preferred stock outstanding.

On April 1, 2025, the Company entered into a preferred stock purchase agreement with certain investors pursuant to which it issued a total of 12,345,674 and 4,657,401 shares of Series E Preferred Stock and Series F Preferred Stock, respectively, at $8.10 per share for gross proceeds of approximately $137.7 million. Allocated issuance costs paid in connection with the Series E Preferred Stock and Series F Preferred Stock were approximately $6.8 million.

The Company has previously issued shares of Series A, Series B, Series C, and Series D convertible preferred stocks. Upon the closing of the IPO on June 20, 2025, all outstanding shares of the Company's redeemable convertible preferred stock, including Series E and F, converted into an aggregate of 211,378,638 shares of common stock.

The following table summarizes the redeemable convertible preferred stock outstanding immediately prior to their conversion into common stock (excluding the 2018 and 2020 warrants that, prior to our IPO, were exercisable for Series C convertible preferred stock), and the rights and preferences of the Company's respective series preceding the Company's IPO in June 2025:

	As of June 20, 2025				
	Shares Authorized	Shares Issued and Outstanding	Original Issue Price Per Share	Aggregate Liquidation Preference	Net Carrying Value
	(amounts in thousands, except share and per share amounts)				
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
Series E Preferred Stock	12,345,678	12,345,674	$ 8.10	101,786	145,412
Series F Preferred Stock	10,493,827	4,657,401	$ 8.10	38,399	54,857
Total redeemable convertible preferred stock	787,439,505	751,145,116		$ 1,946,409	$ 2,446,382

As of December 31, 2024, redeemable convertible preferred stock consisted of the following:

	As of December 31, 2024				
	Shares Authorized	Shares Issued and Outstanding	Original Issue Price Per Share	Aggregate Liquidation Preference	Net Carrying Value
	(amounts in thousands, except share and per share amounts)				
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 redeemable convertible preferred stock was classified as mezzanine equity pursuant to the guidance in ASC 480. The rights, preferences, and privileges of the redeemable convertible preferred stock were 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.

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, Series D and Series E 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, Series D and Series E 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, Series D and Series E preferred stock, (ii) the amount that the holder of a share of Series C, Series D and Series E 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 F Preferred Stock then outstanding will then 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 F Preferred Stock original issue price, plus (A) any dividends declared but unpaid thereon and (B) a 8.0% cumulative accruing dividend, compounding annually from the date of issuance of such share of Series F Preferred Stock, (ii) 1.5 times the Series F Preferred Stock original issue price, or (iii) the amount that the holder of a share of Series F Preferred Stock would have received upon conversion to common stock.

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, Series D, Series E and Series F 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, Series D, Series E and Series F 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, Series D, Series E and Series F preferred stock was $0.61, $0.54, $2.76, $8.10, $8.10, and $8.10, respectively, and is subject to adjustment in accordance with anti-dilution provisions provided for in the Company's Certificate of Formation. In connection with and shortly before the closing of the Pre-IPO Financing, the Company amended and restated its Certificate of Formation. Under this amended and restated Certificate of Formation, and solely for purposes of calculating the conversion of the Series C preferred stock in connection with an initial public offering, both the original issue price and the initial conversion price of the Series C preferred stock were revised from $2.76 to $4.58.

Upon the closing of the IPO, the Series E and Series F Preferred Stock will convert into common stock at a price equal to 70% of the initial public offering price per share. This legal-form conversion upon an initial public offering effectively functions as a share-settled redemption provision for accounting purposes and is accounted for as a bifurcated derivative liability in accordance with ASC 815.

As a result of the IPO, the aforementioned conversion price adjustment for Series D preferred stock was triggered due to the IPO price being less than 1.11111 times the then-current conversion price. Consequently, the Company recorded a deemed dividend, which increased net loss attributable to common shareholders by $384.4 million. The deemed dividend equals the fair value of incremental shares of common stock resulting from the triggering of this feature.

Redemption Rights

At any time on or after March 2026 with respect to our Series C preferred stock, and May 2026 in respect of our Series D and Series E preferred stock, upon written notice from the applicable shareholders, the Series C, Series D and Series E 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, Series B, Series D, Series E and Series F 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. Subject to certain

exceptions, in the event the Company sells additional shares of stock at a price per share less than the Series C 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. 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 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 and Equity Compensation

Preferred Stock

In connection with the IPO, the Company's amended and restated certificate of formation became effective, which authorized the issuance of 100,000,000 shares of preferred stock with a par value of $0.001 per share. As of December 31, 2025, there were no shares of preferred stock issued and outstanding.

Common Stock

As of December 31, 2025 and 2024, 2,800,000,000 and 1,150,000,000 shares of common stock with a $0.001 par value were authorized, respectively. There were 282,526,097 and 35,842,319 shares outstanding as of December 31, 2025 and 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 and compliance with our contractual obligations. No dividends have been declared or paid by the Company since its inception.

Treasury Stock

During the year ended December 31, 2025, the Company repurchased 1,429,213 shares of common stock for an amount of $16.6 million associated with previously early-exercised options. Refer to below under "Option Activity — Modifications to Stock Options" for further details. No common shares were repurchased during the year ended December 31, 2024. Such repurchased common stock is shown as treasury stock on the consolidated balance sheets and consolidated statements of redeemable convertible preferred stock and shareholders' equity (deficit). The Company had 1,611,713 and 182,500 shares of treasury stock as of December 31, 2025 and 2024, respectively. These shares have not been retired. The Company has not reissued any shares of treasury stock as of December 31, 2025 and 2024.

2020 Incentive Plan

Prior to the IPO, the 2020 Incentive Plan (the "2020 Plan") provided for the Company's grant of awards of options, restricted awards, performance awards or share appreciation rights to employees, consultants, and directors of the Company. A total of 22,106,373 shares of common stock are reserved for issuance upon the exercise of all awards granted or available to be granted under the 2020 Plan as of December 31, 2025. In June 2025, in connection with the IPO and the adoption of the 2025 Plan (as defined below), the Company will not make any additional grants under the 2020 Plan. Any outstanding awards granted under the 2020 Plan remain subject to the terms of the 2020 Plan, and any shares underlying outstanding awards under the 2020 Plan that expire or are repurchased, forfeited, canceled, or withheld will become available for issuance under the 2025 Incentive Plan.

2025 Incentive Plan

The Company's Board of Directors has adopted, and the shareholders approved, the 2025 Incentive Plan (the "2025 Plan"), which became effective in connection with the IPO. The 2025 Plan provides for the grant of incentive stock options ("ISOs"), nonstatutory stock options ("NSOs"), share appreciation rights, restricted awards, performance awards, and other awards. As of December 31, 2025, a total of 4,273,052 shares of common stock were reserved for issuance in settlement of awards granted under the 2025 Plan. The material terms of the 2025 Plan are substantially similar to the 2020 Plan, except with respect to the number of authorized shares, which initially equaled 15,125,002 shares, plus the number of shares that would return to the share reserve of the 2020 Plan following the pricing of the Company's initial public offering.

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.

To the extent permitted by applicable laws or any exchange rule, any shares of common stock issued under the 2025 Incentive 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 2025 Incentive Plan.

Employee Stock Purchase Plan

The Company's Board of Directors has adopted, and the shareholders approved, the 2025 Employee Stock Purchase Plan (the "ESPP"), which became effective in connection with the IPO. The ESPP enables eligible employees to purchase shares of the Company's common stock with payroll deductions. A total of 2,571,250 shares of the Company's common stock were initially reserved for issuance under the ESPP. As of December 31, 2025, 2,571,250 shares under the ESPP were available for purchase.

The number of shares reserved for issuance and sale under the ESPP will increase automatically 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 the Common Stock outstanding on the last day of the immediately preceding fiscal year, unless the ESPP administrator should decide to increase the number of shares available under the ESPP by a lesser amount.

The 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.

Unless otherwise determined by the compensation committee, the ESPP will provide for separate six-month offering periods beginning on December 1 and June 1 of each year.

The Company began recognizing stock-based compensation expense related to the ESPP upon commencement of the initial offering period on December 1, 2025. Compensation expense is recognized on a straight-line basis over the six-month offering period, based on the fair value of the purchase rights granted to participants as determined under ASC 718. The impact of the ESPP on the Company's consolidated financial statements for the year ended December 31, 2025 was not material. For the year ended December 31, 2025, no shares were issued under the ESPP.

Option Activity

Under the 2020 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. The Company has not granted stock options under the 2025 Plan as of December 31, 2025.

The following tables summarize the Company's stock option activity during the year ended December 31, 2025:

	Options Outstanding			
	Number of Options	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contract Term	Aggregate Intrinsic Value
			(in years)	(in thousands)
Total outstanding as of December 31, 2024:	21,770,225	$ 9.06	5.40	$ 226,117
Granted	3,085,295	18.79		
Exercised	(1,765,396)	7.44		
Forfeited or expired	(1,204,616)	15.21		
Total outstanding as of December 31, 2025	21,885,508	$ 10.23	4.99	$ 366,605
Total exercisable as of December 31, 2025	16,574,065	$ 7.86	4.01	$ 316,940
Total vested or expected to vest as of December 31, 2025	21,212,471	$ 9.99	4.89	$ 360,500

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, 2025, 2024, and 2023 was $15.43, $12.37 and $9.52 per option, respectively. The total intrinsic value of options exercised during the years ended December 31, 2025, 2024, and 2023 was $21.2 million, $2.8 million, and $6.8 million, respectively. The total grant date fair value of options vested during the years ended December 31, 2025, 2024, and 2023 was $17.3 million, $13.5 million, and $10.4 million, respectively.

Cash received for exercises of stock options during the years ended December 31, 2025, 2024, and 2023 was $7.6 million, $1.5 million, and $1.9 million, respectively.

As of December 31, 2025, there was approximately $51.5 million of total unrecognized stock-based compensation cost related to the unvested options, which 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 2.80 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 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 was equal to the exercise price of the New Stock Options. Interest on the unpaid balance compounded annually and accrued 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 was 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 would accrue at the maximum rate permitted by applicable law. The Company would have full recourse against the holder for failure to pay the note as and when due. Such promissory notes were secured by the restricted shares issued to the holder that were 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 lapses 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’ equity (deficit) as the related shares vest. As of December 31, 2025 and 2024, 23,446 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 December 31, 2025 and 2024, $0.3 million and $5.0 million was recorded within other accrued expenses and current liabilities, respectively, and $0.1 million and $5.8 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 was $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 interest. Repurchased common stock shares included 810,816 and 618,397 common shares, 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 terms as the repurchased options and are not early exercisable.

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

During the year ended December 31, 2025, the Company granted restricted stock units that will be settled in shares of the Company's common stock upon vesting to its employees, consultants, and non-employee directors.

Vesting of the restricted stock units granted prior to the IPO was generally contingent upon the Company completing either an initial public offering of its common stock or a change in control. In connection with the IPO, the Company settled an aggregate of 1,048,250 fully vested RSUs (“IPO Settled RSUs”) in August 2025. The Company withheld 415,389 shares of common stock issuable upon settlement of the IPO Settled RSUs and recorded a tax withholding liability of $12.4 million, all of which were subsequently remitted to the taxing authorities. Vesting of restricted stock

units granted after the IPO generally occurs incrementally over four years, subject to the grantee's continuous service with the Company. Following the IPO, the fair value of RSUs is based on the closing price of our common shares on the Nasdaq Global Select Market on the trading day prior to the grant date.

The following table summarizes the Company's restricted stock unit activity for the year ended December 31, 2025:

	Number of Restricted Stock Units	Weighted Average Grant Date Fair Value
Unvested as of December 31, 2024	762,500	$ 18.19
Granted	4,986,007	$ 21.09
Vested	(1,063,250)	$ 18.24
Cancelled/forfeited	(190,915)	$ 23.03
Unvested as of December 31, 2025	4,494,342	$ 21.18

The total unrecognized compensation expense related to unvested restricted stock units as of December 31, 2025 was $81.6 million, which 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 3.30 years. The fair value of RSUs vested was $9.8 million for the year ended December 31, 2025. No RSUs vested during the years ended December 31, 2024 and 2023.

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,		
	2025	2024	2023
	(amounts in thousands)		
Cost of services - Molecular profiling services	$ 3,591	$ 1,669	$ 1,504
Cost of services - Pharma research and development services	25	11	10
Selling and marketing expense	9,582	4,301	3,400
General and administrative expense	45,684	8,448	6,983
Research and development expense	11,124	4,214	3,344
Total	$ 70,006	$ 18,643	$ 15,240

There was no tax benefit associated with the above stock-based compensation expense.

Valuation of Stock-Based Awards

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. Prior to the IPO, the absence of a public market for the Company’s common stock required 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*. Subsequent to the Company's IPO, the fair value of the Company's common stock is determined based on its closing market price.

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,		
	2025	**2024**	**2023**
Expected volatility	68.3% - 69.5%	62.5% - 68.4%	64.3% - 77.2%
Risk-free interest rate	3.9% - 4.2%	3.7% - 4.6%	3.5% - 4.4%
Expected term (years)	5.00 - 6.55	5.97 - 6.60	5.90 - 7.50
Expected dividend rate	—%	—%	—%
Expected forfeiture rate	0.0% - 8.5%	8.3% - 8.5%	8.4% - 8.6%

The Company estimates the fair value of stock purchase rights granted under the ESPP at the start of the offering period using the Black-Scholes options-pricing model. Key weighted-average assumptions used in the model include expected stock price volatility, risk-free interest rate, expected term (equal to the six-month offering period), expected dividend yield, and expected forfeiture rate. The Company uses historical data to estimate expected volatility and other assumptions consistent with those used for stock option valuations.

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 was not publicly traded prior to June 2025, 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. Subsequent to the Company's IPO, expected volatility is based on the historical volatility of its common stock.

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 indebtedness and long-term indebtedness, net of debt discounts on the consolidated balance sheets as of December 31, 2025 and 2024 includes the following components:

	As of December 31,	
	2025	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]	(25,550)	(30,863)
Net debt	$ 378,450	$ 373,137
Compound bifurcated derivative liability	$ —	$ 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 December 31, 2025:

	Amount
	(amounts in thousands)
Years Ending December 31,	
2026	$ —
2027	—
2028	400,000

Term Loan

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 (the "2023 Term Loan"), $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.

Until the earlier of December 31, 2024 or the date on which the 2023 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, 2025, the interest rate was 10.5%. 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. As of December 31, 2025, the Company is in compliance with all covenants.

On April 1, 2025, the Company entered into an amendment of the 2023 Term Loan agreement. The amendment allowed for various consents from the lenders of the 2023 Term Loan as it relates to the 2025 Convertible Note, issued as part of the Pre-IPO financing. As part of the amendment, the Company paid an amendment fee of 1%, or $4.0 million. The Company evaluated the transaction and accounted for the amendment as a debt modification.

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 as of December 31, 2024 and 2023. The value of the derivative liability in connection with the 2023 Term Loan reduced to zero upon the IPO, as the contingent prepayment is no longer required. 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.

Interest Expense

The components of interest expense associated with the Company's long-term indebtedness and the 2025 Convertible Note, excluding finance leases, are as follows:

	Years Ended December 31,		
	2025	2024	2023
	(amounts in thousands)		
Debt discount amortization	$ 12,768	$ 7,052	$ 5,378
Interest expense	44,046	42,938	26,157
Interest expense on long-term indebtedness, excluding finance leases	$ 56,814	$ 49,990	$ 31,535

2018 and 2020 Warrant Liability

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. As part of the Original Term Loan Agreement, the Company issued a warrant to purchase 13,694,623 shares of Series C preferred stock (the "2018 Warrants"). In connection with the amendment to the Original Term Loan Agreement in 2020, the Company issued an additional warrant to purchase 11,399,814 shares of Series C preferred stock (the "2020 Warrants") and amended the 2018 Warrants. Furthermore, these amendments also permitted 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 were reported at fair value within warrant 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.

As discussed in Note 2, the warrants were reclassified from liability to equity upon the IPO. The difference between the fair value of the warrants immediately prior to the reclassification and its prior fair value was recorded in the consolidated statement of operations and comprehensive loss as changes in fair value of financial instruments. The fair value immediately prior to the reclassification was $131.7 million, and is based on the total number of common stock issued upon exercise and conversion, multiplied by the public offering price of $21.00 per share.

For the years ended December 31, 2025, 2024, and 2023, the Company recorded $(40.1) million, $(7.1) million, and $0.3 million in changes in fair value of financial instruments, respectively, associated with the fair value changes of the 2018 and 2020 warrants.

2025 Convertible Notes

On April 1, 2025, the Company issued 2025 Convertible Notes to certain investors in aggregate principal amount of $30.0 million. The 2025 Convertible Notes were scheduled to mature on January 1, 2026, accrued interest at a rate of 8% per annum, and, upon the closing of the IPO, converted at a conversion price equal to 70% of the initial public offering price per share, or into 2,076,596 shares of the Company's common stock (inclusive of accrued interest), based on the initial public offering price of $21.00 per share. This legal-form conversion upon an initial public offering effectively functions as a share-settled redemption provision for accounting purposes and is accounted for as a bifurcated derivative liability in accordance with ASC 815. The 2025 Convertibles Notes were classified as a liability pursuant to the guidance in ASC 470 as they represented legal-form debt with a stated maturity and an obligation for the issuer to repay both principal and interest.

Upon the closing of the initial public offering, the 2025 Convertible Notes converted into common stock at a price equal to 70% of the initial public offering price per share. A loss on extinguishment of approximately $19.9 million was recognized, representing the excess of the fair value of the common stock issued over the combined carrying amount of the 2025 Convertible Notes and the related bifurcated derivative liability.

2025 Warrant Liability

On April 1, 2025, the Company also issued warrants to acquire shares of common stock to the holders of the 2025 Convertible Notes. These warrants were not initially exercisable for any shares of common stock, but such warrants became exercisable for a specified dollar value of shares on a monthly basis commencing on June 1, 2025 if the Company did not complete an initial public offering by such date. Additional warrants would have been issued each subsequent month that an initial public offering fails to occur based on a certain percentage. These warrants were classified as a liability pursuant to the guidance in ASC 480 as they represented a conditional obligation to issue a variable number of shares based on a fixed monetary amount known at inception. Therefore, these warrants were reported at fair value within warrant 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. As discussed in Note 2, the 2025 warrants were net exercised into 784,231 shares of the Company's common stock in connection with the IPO. The difference between the fair value of the warrants immediately prior to the IPO and its initial fair value was recorded in the consolidated statement of operations and comprehensive loss as changes in fair value of financial instruments. The fair value immediately prior to the IPO was $16.5 million, and was based on the total number of common stock issued upon exercise and conversion, multiplied by the public offering price of $21.00 per share. The initial allocated proceeds of the warrants were $10.3 million, which represents the fair value of the warrants on April 1, 2025.

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.

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, 2025	As of December 31, 2024
		(amounts in thousands)	
Assets			
Operating leases	Other assets	$ 39,848	$ 34,950
Finance leases	Property and equipment, net	322	40
Total lease assets		$ 40,170	$ 34,990
Liabilities			
Current			
Operating leases	Accrued expenses and other current liabilities	$ 6,359	$ 6,080
Finance leases	Current portion of indebtedness	169	90
Total current lease liabilities		$ 6,528	$ 6,170
Non-current			
Operating leases	Other long-term liabilities	$ 42,335	$ 38,651
Finance leases	Long-term indebtedness, net of debt discounts	373	243
Total non-current lease liabilities		42,708	38,894
Total lease liabilities		$ 49,236	$ 45,064

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	Years Ended December 31, 2025	Years Ended December 31, 2024	Years Ended December 31, 2023
		(amounts in thousands)		
Operating lease cost	Cost of Services - Molecular profiling services	$ 1,849	$ 1,607	$ 1,935
Operating lease cost	Cost of Services - Pharma research and development services	21	40	13
Operating lease cost	General and administrative expense	6,852	6,738	8,037
Operating lease cost	Research and development expense	2,026	2,416	2,116
Finance lease cost:				
Amortization of ROU assets	General and administrative expense	81	128	500
Interest on lease liabilities	Interest expense	37	37	78
Total finance lease cost		$ 118	$ 165	$ 578

The table below presents additional information related to the Company's leases:

	As of December 31,	
	2025	2024
Weighted average remaining lease terms		
Operating leases	7.31 years	8.04 years
Finance leases	3.12 years	3.28 years
Weighted average discount rate		
Operating leases	11.3%	11.3%
Finance leases	10.5%	10.0%

Short-term lease costs and variable lease costs were immaterial for the years ended December 31, 2025, 2024 and 2023. As of December 31, 2025, the Company did not have any additional operating and finance leases that had not yet commenced, except for the below.

The following table sets forth by year, maturities of operating and finance lease liabilities as of December 31, 2025:

(amounts in thousands)	Operating Leases	Finance Leases	Total
Years Ended December 31,			
2026	$ 11,333	$ 215	$ 11,548
2027	10,267	213	10,480
2028	9,203	132	9,335
2029	8,588	72	8,660
2030	8,791	—	8,791
Thereafter	24,213	—	24,213
Total lease payments	72,395	632	73,027
Less imputed interest	(23,701)	(90)	(23,791)
Present value of lease liabilities	$ 48,694	$ 542	$ 49,236

Total lease payments exclude $17.6 million of legally binding minimum lease payments for leases signed but not yet commenced.

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 months or less. Future minimum purchase commitments under such agreements amount to $7.6 million, of which all are due in 2026. The total amount of supplies purchased for the years ended December 31, 2025 and 2024 under such agreements was $30.0 million and $32.3 million, respectively.

Additionally, the Company has non-cancellable purchase commitments with its cloud computing services provider and for software subscriptions to support operations in the ordinary course of business. For the years ended December 31, 2025 and 2024, the Company purchased cloud computing services and software subscriptions of $21.3

million and $9.9 million, respectively, related to non-cancelable agreements. As of December 31, 2025, future non-cancellable commitments with remaining terms in excess of one year under these agreements were as follows:

	Amount
	(amounts in thousands)
Years Ended December 31,	
2026	$ 16,121
2027	17,047
2028	517
Total purchase commitments	$ 33,685

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 are likely to have a material adverse effect on its financial position as of December 31, 2025 and 2024, nor its results of operations or cash flows for the years ended December 31, 2025, 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, 2025, 2024, and 2023, the Company made payments to these entities for services and expenses for $2.6 million, $1.8 million, and $2.1 million, respectively.

Additionally, during the years ended December 31, 2025, 2024, and 2023, the Company recorded general and administrative expenses from related parties of $2.5 million, $1.9 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:

	Years Ended December 31,		
(amounts in thousands, except share and per share data)	**2025**	**2024**	**2023**
Net loss	$ (68,088)	$ (281,890)	$ (341,415)
Deemed dividend from Series D redeemable convertible preferred stock	(384,436)	—	—
Adjustments of redeemable convertible preferred stock to redemption value	(85,433)	(96,367)	(121,112)
Net loss attributable to common shareholders	$ (537,957)	$ (378,257)	$ (462,527)
Net loss per share attributable to common shareholders, basic and diluted	$ (3.22)	$ (10.66)	$ (13.24)
Weighted-average shares used in computing net loss per share attributable to common shareholders, basic and diluted	167,205,616	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,		
	2025	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
Unvested RSUs	4,494,342	762,500	—
Outstanding stock options	21,885,508	21,770,201	21,762,226
Shares committed under ESPP	146,450	—	—
Unvested shares subject to repurchase	23,446	662,000	968,000
Total	26,549,746	213,003,821	212,539,346

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,		
	2025	2024	2023
	(amounts in thousands)		
Revenue:			
Molecular profiling services	$ 766,719	$ 349,115	$ 278,748
Pharma research and development services	45,314	63,145	27,380
Revenue	812,033	412,260	306,128
Less:			
Cost of services - Molecular profiling services	262,353	223,075	207,509
Cost of services - Pharma research and development services	10,512	10,403	9,309
Selling and marketing expense	167,506	152,602	142,925
General and administrative expense	224,965	169,386	149,053
Research and development expense	101,584	113,916	116,883
Total costs and operating expenses	766,920	669,382	625,679
Income (Loss) from operations	45,113	(257,122)	(319,551)
Interest income	16,497	7,122	11,258
Interest expense	(56,853)	(50,025)	(31,610)
Changes in fair value of financial instruments	(52,285)	18,484	11,094
Other expense, net	(20,560)	(349)	(12,606)
Segment and consolidated net loss	$ (68,088)	$ (281,890)	$ (341,415)

The following table sets forth the Company's revenue by geographic areas based on the customer's location:

	Years Ended December 31,		
	2025	2024	2023
	(amounts in thousands)		
United States	$ 801,393	$ 401,836	$ 293,408
International	10,640	10,424	12,720
Total revenue	$ 812,033	$ 412,260	$ 306,128

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, 2025, 2024, and 2023. As of December 31, 2025 and 2024, approximately 99.0% of the Company's total assets are located in the United States.

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, 2025, 2024, and 2023, the Company contributed $8.4 million, $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

There were no significant subsequent events identified through the date that the consolidated financial statements were issued, that could impact the financial statements.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Limitations on Effectiveness of Controls and Procedures

In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints, and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and principal financial officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended), as of the end of the period covered by this Annual Report on Form 10-K. Based on such evaluation, our principal executive officer and principal financial officer have concluded that these disclosure controls and procedures were not effective at the reasonable assurance level as of December 31, 2025 due to the previously reported material weakness in our internal control over financial reporting pertaining to a lack of sufficient qualified accounting resources, including those necessary to account for and disclose accounting transactions that require complex calculations or thorough evaluation of the accounting literature.

Notwithstanding the material weakness in our internal control over financial reporting as of December 31, 2025, management believes that the consolidated financial statements included in this Form 10-K present fairly, in all material respects, our financial position, results of operations and cash flows for the periods presented in conformity with accounting principles generally accepted in the United States.

Changes in Internal Control over Financial Reporting

During the year ended December 31, 2025, we continued our remediation efforts in connection with the previously identified material weakness. These remediation steps are ongoing and include the following:

- 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

Our management has worked, and continues to work, to strengthen our internal control over financial reporting. We are committed to ensuring that controls are designed and implemented. The previously identified material weakness will not be considered remediated until the applicable remedial controls operate for a sufficient period of time and management has concluded, through testing, that these controls are operating effectively. We will not be able to conclude whether the steps we are taking will fully remediate the material weakness in our internal control over financial reporting until we have completed our remediation efforts and subsequent evaluation of their effectiveness. We may also conclude that additional measures may be required to remediate the material weakness in our internal control over financial reporting, which may necessitate additional implementation and evaluation time.

Other than the foregoing actions to remediate our material weakness, there was no change in our internal control over financial reporting identified during the period covered by this Annual Report on Form 10-K that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Management's Report on Internal Control over Financial Reporting

This Annual Report on Form 10-K does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of our independent registered public accounting firm due to a

transition period established by rules of the SEC for newly public companies. Additionally, our independent registered public accounting firm will not be required to opine on the effectiveness of our internal control over financial reporting pursuant to Section 404 until we are no longer an "emerging growth company" as defined in the JOBS Act.

Item 9B. Other Information

(a) Other Events

On February 25, 2026, the Compensation Committee of our board of directors, or the Committee, approved a form of performance restricted stock unit award agreement, or PSU Agreement, under the Caris Life Sciences, Inc. 2025 Incentive Plan, or the Plan. Performance restricted stock units (PSUs) are anticipated to be granted to certain eligible employees, including named executive officers, in 2026 and would be subject to the satisfaction of (i) performance-based vesting conditions related to financial targets for the 2026 fiscal year performance period, and (ii) service-based vesting conditions following the performance period. PSUs would be subject to the terms and conditions set forth in the Plan and the PSU Agreement. The foregoing description does not purport to be complete and is qualified in its entirety by reference to the PSU Agreement, which is filed as an exhibit to this Annual Report on Form 10-K and is incorporated herein by reference. The Plan is also filed as an exhibit to this Annual Report on Form 10-K.

(b) Disclosure of Trading Arrangements

During the three months ended December 31, 2025, none of our directors or officers (as defined in Rule 16a-1(f) under the Exchange Act) adopted or terminated a "Rule 10b5-1 trading arrangement" or a "non-Rule 10b5-1 trading arrangement," as each term is defined in Item 408 of Regulation S-K.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

Part III

Item 10. Directors, Executive Officers and Corporate Governance

Information about our Executive Officers

The names, ages and professional biographies of our executive officers as of March 3, 2026 are as follows:

Name	*Age*	*Position(s)*
David Dean Halbert, D.Sc. (h.c.)	70	Founder, Chairman, and Chief Executive Officer
Brian J. Brille	65	Vice Chairman and Executive Vice President
David Spetzler, M.S., Ph.D., M.B.A.	50	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

David Dean 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 a member of the board of directors at the International Biomedical Research Alliance, a nonprofit 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 and 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., MBA has served as our President since November 2016. Dr. Spetzler has also served as an adjunct faculty member of the molecular and 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.

Codes of Business Conduct and Ethics

The Company has adopted a Code of Business Conduct and Ethics for directors, officers and employees. This code is available on the Corporate Governance section of the Company's investor relations website at investor.carislifesciences.com. The Company intends to satisfy any disclosure requirements required by law or the Nasdaq Stock Market listing standards regarding amendments to, and waivers of, this code by posting such information on the same website. The inclusion of our investor relations website address in this Annual Report on Form 10-K does not include or incorporate herein by reference the information on or accessible through our website.

Insider Trading Compliance Policy

We have adopted an Insider Trading Compliance Policy governing the purchase, sale, and other dispositions of our securities by directors, officers, employees and designated contractors and advisors that is reasonably designed to promote compliance with insider trading laws, rules, and regulations, and applicable Nasdaq listing standards. A copy of the Company's insider trading policy is filed as Exhibit 19 to this Annual Report on Form 10-K.

The remaining information required by this Item 10 of Form 10-K will be included in our Definitive Proxy Statement to be filed with the SEC in connection with the solicitation of proxies for our 2026 Annual Meeting of Shareholders (the “2026 Proxy Statement”) and is incorporated herein by reference.

Item 11. Executive Compensation

The information required by this Item 11 of Form 10-K will be included in our 2026 Proxy Statement and is incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Shareholder Matters

The information required by this Item 12 of Form 10-K will be included in our 2026 Proxy Statement and is incorporated herein by reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence

The information required by this Item 13 of Form 10-K will be included in our 2026 Proxy Statement and is incorporated herein by reference.

Item 14. Principal Accountant Fees and Services

The information required by this Item 14 of Form 10-K will be included in our 2026 Proxy Statement and is incorporated herein by reference.

Part IV

Item 15. Exhibits, Financial Statement Schedules

(a) Documents filed as part of this report

1. All financial statements

Reference is made to the Financial Statements and Supplementary Data included in Item 8 of Part II hereof.

2. Financial statement schedules

All financial statement schedules have been omitted since the required information was not applicable or was not present in amounts sufficient to require submission of the schedules, or because the information required is included in the consolidated financial statements or the accompanying notes included in this Form 10-K.

3. Exhibits required by Item 601 of Regulation S-K

The exhibits listed in the following Index to Exhibits are filed, furnished or incorporated by reference as part of this Annual Report on Form 10-K.

(b) Exhibits.

		Incorporated by Reference				
Exhibit Number	**Description of Exhibit**	**Form**	**File No.**	**Exhibit**	**Filing Date**	**Filed or Furnished Herewith**
3.1	Amended and Restated Certificate of Formation of Caris Life Sciences, Inc.	8-K	001-42706	3.1	June 20, 2025	
3.2	Amended and Restated Bylaws of Caris Life Sciences, Inc.	8-K	001-42706	3.1	October 30, 2025	
4.1	Form of Caris Life Sciences, Inc. common stock certificate.	S-1/A	333-287551	4.1	June 9, 2025	
4.2	Description of Registrant's Securities					X
4.3#	Amended and Restated Investors' Rights Agreement, dated as of April 1, 2025, among Caris Life Sciences, Inc. and certain of its shareholders.	S-1	333-287551	4.2	May 23, 2025	
10.1(a)#	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.	S-1	333-287551	10.1(a)	May 23, 2025	
10.1(b)#	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.	S-1	333-287551	10.1(b)	May 23, 2025	
10.2(a)#§	Supply Agreement, dated as of September 21, 2022, by and between Caris MPI, Inc. and Illumina, Inc.	S-1	333-287551	10.2(a)	May 23, 2025	
10.2(b)#§	Master Supply Agreement, effective as of July 8, 2024, by and between Roche Diagnostics Corporation and Caris MPI, Inc.	S-1	333-287551	10.2(b)	May 23, 2025	
10.3(a)(1)#§	Lease Agreement, dated as of March 1, 2019, by and between WPT LAND 2 LP and 23andMe, Inc., as amended.	S-1	333-287551	10.3(a)	May 23, 2025	
10.3(a)(2)#	Second Amendment, dated October 5, 2021, to Lease Agreement by and between WPT LAND 2 LP and Caris MPI, Inc.	10-Q	001-42706	10.3(a)(2)	August 12, 2025	
10.3(a)(3)	Third Amendment, dated August 8, 2025, to Lease Agreement by and between WPT LAND 2 LP and Caris MPI, Inc.	10-Q	001-42706	10.1	November 5, 2025	
10.3(b)#§	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.	S-1	333-287551	10.3(b)	May 23, 2025	
10.3(c)#§	Lease, dated as of July 25, 2019, by and between KCP NNN II Leasehold 4, LLC and Caris MPI, Inc.	S-1	333-287551	10.3(c)	June 9. 2025	
10.4(a)†	Caris Life Sciences, Inc. Amended and Restated 2020 Incentive Plan.	S-1/A	333-287551	10.4(a)	May 23, 2025	
10.4(b)†	Form of Incentive Stock Option Award Agreement under the Amended and Restated 2020 Incentive Plan.	S-1	333-287551	10.4(b)	May 23, 2025	
10.4(c)†	Form of Nonqualified Stock Option Award Agreement under the Amended and Restated 2020 Incentive Plan.	S-1	333-287551	10.4(c)	May 23, 2025	
10.4(d)†	Form of Nonqualified Stock Option Award Agreement under the Amended and Restated 2020 Incentive Plan (Nonemployee Director)	S-1	333-287551	10.4(d)	May 23, 2025	
10.4(e)†	Form of Restricted Stock Unit Award Agreement under the Amended and Restated 2020 Incentive Plan.	S-1	333-287551	10.4(e)	May 23, 2025	
10.4(f)†	Form of Restricted Stock Unit Award Agreement under the Amended and Restated 2020 Incentive Plan (Chief Executive Officer).	S-1	333-287551	10.4(f)	May 23, 2025	

		Incorporated by Reference				
10.4(g)†	Form of Restricted Stock Unit Award Agreement under the Amended and Restated 2020 Incentive Plan (Non-Employee Director).	S-1	333-287551	10.4(g)	May 23, 2025	
10.5(a)†	Caris Life Sciences, Inc. 2025 Incentive Plan, as amended and restated.	S-8	333-287551	99.2	June 18, 2025	
10.5(b)†	Form of Restricted Stock Unit Award Agreement under the 2025 Incentive Plan, as amended and restated.	S-1/A	333-287551	10.5(b)	June 9, 2025	
10.5(c)†#	Form of Performance Restricted Stock Unit Award Agreement under the 2025 Incentive Plan, as amended and restated.					X
10.6†	Caris Life Sciences, Inc. Employee Stock Purchase Plan, as amended and restated.	S-8	333-287551	99.3	June 18, 2025	
10.7(a)†§	Executive Employment Agreement, dated as of February 1, 2010, by and between the Registrant and David Spetzler.	S-1	333-287551	10.7	May 23, 2025	
10.7(b)†	First Amendment to Employment Agreement, dated as of July 27, 2015, by and between the Registrant and David Spetzler.	S-1	333-287551	10.8	May 23, 2025	
10.8†§	Executive Employment Agreement, dated as of May 31, 2018, by and between Caris Science, Inc. and Brian Brille.	S-1	333-287551	10.9	May 23, 2025	
10.9†	Caris Life Sciences, Inc. Executive and Director Change in Control Plan.	S-1	333-287551	10.10	May 23, 2025	
10.10†	Non-Employee Director Compensation Program.	S-1	333-287551	10.11	May 23, 2025	
10.11†	Form of Indemnification Agreement.	S-1	333-287551	10.12	May 23, 2025	
19.1	Caris Life Sciences, Inc. Insider Trading Compliance Policy.					X
21.1	Subsidiaries of Caris Life Sciences, Inc.	S-1/A	333-287551	21.1	June 9, 2025	
23.1	Consent of Deloitte & Touche LLP, Independent Registered Public Accounting Firm.					X
23.2	Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm.					X
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
32.1	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					XX
32.2	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					XX
97.1	Caris Life Sciences, Inc. Policy for Recovery of Erroneously Awarded Compensation					X
101.INS	Inline XBRL Instance Document (the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document).					
101.SCH	Inline XBRL Taxonomy Extension Schema Document.					
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.					
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.					
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.					
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.					
104	Cover Page formatted as Inline XBRL and contained in Exhibit 101.					

The registrant has omitted schedules and exhibits pursuant to Item 601(a)(5) of Regulation S-K. The registrant agrees 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).

† Indicates a management contract or compensatory plan or arrangement.

X Filed herewith.

XX The certifications furnished in Exhibits 32.1 and 32.2 are not deemed "filed" for purposes of Section 18 of the Exchange Act, or otherwise subject to the liability of that section, nor shall they be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended.

(c) 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 16. Form 10-K Summary

Not applicable.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

CARIS LIFE SCIENCES, INC.

Date: March 3, 2026

By: /s/ David Dean Halbert

David Dean Halbert

Founder, Chairman, and Chief Executive Officer

Pursuant to the requirements of the Securities Act of 1934, this report has been signed below by the following persons on behalf of the registrant in the capacities and on the dates indicated.

Signature	Title	Date
/s/ David Dean Halbert David Dean Halbert	Founder, Chairman, and Chief Executive Officer *(Principal Executive Officer)*	March 3, 2026
/s/ Luke Power Luke Power	Senior Vice President, Chief Financial Officer, and Chief Accounting Officer *(Principal Financial and Accounting Officer)*	March 3, 2026
/s/ George H. Poste George H. Poste	Vice Chairman	March 3, 2026
/s/ Jonathan Knowles Jonathan Knowles	Vice Chairman	March 3, 2026
/s/ Brian J. Brille Brian J. Brille	Vice Chairman and Executive Vice President	March 3, 2026
/s/ Peter M. Castleman Peter M. Castleman	Director	March 3, 2026
/s/ David Fredrickson David Fredrickson	Director	March 3, 2026
/s/ Joseph E. Gilliam Joseph E. Gilliam	Director	March 3, 2026
/s/ Jon S. Halbert Jon S. Halbert	Director	March 3, 2026
/s/ Laura I. Johansen Laura I. Johansen	Director	March 3, 2026
/s/ Lloyd B. Minor Lloyd B. Minor	Director	March 3, 2026
/s/ Danny Phillips Danny Phillips	Director	March 3, 2026
/s/ Jeffrey Vacirca Jeffrey Vacirca	Director	March 3, 2026

Board of Directors

David Dean Halbert
Founder, Chairman and CEO of Caris Life Sciences

Peter M. Castleman
Former Chairman and Managing Partner, J.H. Whitney & Co.

Brian J. Brille
Vice Chairman and Executive Vice President of Caris Life Sciences

David Fredrickson
EVP, Oncology Business Unit of AstraZeneca PLC

Joseph E. Gilliam
President and Chief Operating Officer of Glaukos Corporation

Jon S. Halbert
Co-Founder and Former Vice Chairman, AdvancePCS

Laura I. Johansen
Former President of Caris Life Sciences; Former SVP and General Counsel of AdvancePCS

Jonathan Knowles, PhD
Former President of Group Research at Roche Holding AG

Lloyd B. Minor, MD
Carl and Elizabeth Naumann Dean of the Stanford University School of Medicine

Danny Phillips
Former Chief Financial Officer and Senior EVP of AdvancePCS

George H. Poste, DVM, PhD, DSc, FRS
Chief Scientist of the Complex Adaptive Systems Initiative at Arizona State University

Jeffrey Vacirca, MD, FACP
Chief Executive Officer and Chairman of the Board of New York Cancer & Blood Specialists; Co-Founder of OneOncology

Executive Officers

David Dean Halbert
Founder, Chairman and CEO

Brian J. Brille
Vice Chairman and Executive Vice President

David Spetzler, MS, PhD, MBA
President

Luke Power
Senior Vice President, Chief Financial Officer and Chief Accounting Officer

J. Russel Denton
Senior Vice President, General Counsel and Secretary

Corporate Address

750 W John Carpenter Fwy
Suite 800
Irving, TX 75039

Annual Meeting of Shareholders

June 4, 2026, 10:00 AM Central Time
www.virtualshareholdermeeting.com/CAI2026

CARIS®
LIFE SCIENCES