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, 2022

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 001-36156

VERACYTE, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**20-5455398**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification Number)
6000 Shoreline Court, Suite 300 South San Francisco, California	**94080**
(Address of Principal Executive Offices)	(Zip Code)

(650) 243-6300
(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, par value, $0.001 per share	VCYT	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 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 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 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 Exchange 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 Exchange Act). Yes ☐ No ☒

As of June 30, 2022, the aggregate market value of common stock held by non-affiliates of the registrant was approximately $1.4 billion, based on the closing price of the common stock as reported on the Nasdaq Global Market for that date.

The number of shares of the registrant's Common Stock outstanding as of February 24, 2023 was 72,149,636.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's proxy statement to be filed with the Securities and Exchange Commission in connection with the solicitation of proxies for the registrant's 2023 Annual Meeting of Stockholders, or the Proxy Statement, are incorporated herein by reference in Part III of this Annual Report on Form 10-K to the extent stated herein. The Proxy Statement will be filed with the Securities and Exchange Commission within 120 days of the registrant's fiscal year ended December 31, 2022.

TABLE OF CONTENTS

Item No.	Page No.
PART I	
Item 1. Business	1
Item 1A. Risk Factors	23
Item 1B. Unresolved Staff Comments	62
Item 2. Properties	62
Item 3. Legal Proceedings	62
Item 4. Mine Safety Disclosure	62
PART II	
Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	62
Item 6. [Reserved]	63
Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations	64
Item 7A. Quantitative and Qualitative Disclosures About Market Risk	80
Item 8. Financial Statements and Supplementary Data	81
Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	114
Item 9A. Controls and Procedures	114
Item 9B. Other Information	116
Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections	116
PART III	
Item 10. Directors, Executive Officers and Corporate Governance	116
Item 11. Executive Compensation	116
Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	116
Item 13. Certain Relationships and Related Transactions, and Director Independence	116
Item 14. Principal Accountant Fees and Services	116
PART IV	
Item 15. Exhibits, Financial Statement Schedules	117
Item 16. Form 10-K Summary	121
SIGNATURES	121

PART I

ITEM 1. BUSINESS

This report contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. When used in this report, the words "expects," "anticipates," "intends," "estimates," "plans," "believes," "continuing," "ongoing," and similar expressions are intended to identify forward-looking statements. These are statements that relate to future events and include, but are not limited to, the factors that may impact our financial results; our expectations regarding revenue; our expectations with respect to our future research and development, general and administrative and selling and marketing expenses and our anticipated uses of our funds; the impact of inflation, rising interest rates and foreign exchange fluctuations, as well as the conflict in Ukraine, energy and supply chain disruptions, and market volatility resulting from the above, on our business; the impact of the COVID-19 pandemic and our expectations regarding the return to pre-COVID-19 volume and revenue levels; changes in our executive officers; our beliefs with respect to the optimization of our processes for the analysis of ribonucleic acid, or RNA, samples; our ability to successfully integrate HalioDx and Decipher Biosciences into our business; our ability to deploy the nCounter Analysis System successfully and run our tests on this platform worldwide; our collaboration with Johnson & Johnson Services, Inc.; our belief in the importance of maintaining libraries of clinical evidence; our expectations regarding the Percepta Nasal Swab classifier for early lung cancer detection, the Envisia classifier on the nCounter system and the LymphMark lymphoma subtyping test; our expectations regarding our diagnostic company partnerships; our ability to have the targeted Atlas platform transferred to our pulmonology indications; our expectations regarding capital expenditures; our anticipated cash needs and our estimates regarding our capital requirements; the timing and success of our transition to a single platform for all of our classifiers and tests; our ability to maintain Medicare coverage for each of our tests; our need for additional financing; potential future sources of cash; our business strategy and our ability to execute our strategy; our ability to achieve and maintain reimbursement from third-party payers at acceptable levels and our expectations regarding the timing of reimbursement; the estimated number of patients who are candidates for our test; the attributes and potential benefits of our tests and any future tests we may develop to patients, physicians and payers; the factors we believe drive demand for and reimbursement of our tests; our ability to sustain or increase demand for our tests; our intent to expand into other clinical areas; our ability to develop new tests, and the timeframes for development or commercialization; our ability to get our data and clinical studies accepted in peer-reviewed publications; our dependence on and the terms of our agreement with Thyroid Cytopathology Partners, or TCP, and on other strategic relationships, and the success of those relationships; our beliefs regarding our laboratory capacity; the potential for future clinical studies to contradict or undermine previously published clinical study results; the applicability of clinical results to actual outcomes; our expectations regarding our international expansion; the occurrence, timing, outcome or success of clinical trials or studies; the ability of our tests to impact treatment decisions; our beliefs regarding our competitive position; our compliance with federal, state and international regulations; the potential impact of regulation of our tests by the Food and Drug Administration, or FDA, or other regulatory bodies; the impact of new or changing policies, regulation or legislation, or of judicial decisions, on our business; the impact of seasonal fluctuations and economic conditions on our business; our belief that we have taken reasonable steps to protect our intellectual property; our belief that our intellectual property will develop and maintain our competitive position; the impact of accounting pronouncements and our critical accounting policies, judgments, estimates, models and assumptions on our financial results; and anticipated trends and challenges in our business and the markets in which we operate. We caution you that the foregoing list does not contain all of the forward-looking statements made in this report.

Forward-looking statements are based on our current plans and expectations and involve risks and uncertainties which could cause actual results to differ materially. These risks and uncertainties include, but are not limited to, those risks discussed in Part I, Item 1A of this report. These forward-looking statements speak only as of the date hereof. We expressly disclaim any obligation or undertaking to update any forward-looking statements contained herein to reflect any change in our expectations with regard thereto or any change in events, conditions or circumstances on which any such statement is based.

When used in this report, all references to "Veracyte," the "company," "we," "our" and "us" refer to Veracyte, Inc., together with its consolidated subsidiaries, unless otherwise noted.

Veracyte, Afirma, Percepta, Envisia, Prosigna, Lymphmark, Decipher, GRID, HalioDx, Brightplex, Immunosign, and the Veracyte logo are registered trademarks of Veracyte, Inc. and its subsidiaries in the U.S. and selected countries. nCounter is the registered trademark of NanoString Technologies, Inc., or NanoString, in the U.S. and selected countries and used by Veracyte under license. Immunoscore is the registered trademark of Institut National de la Santé et de la Recherche Médicale, or Inserm, in the U.S. and selected countries and used by Veracyte under license.

This annual report contains statistical data and estimates that we obtained from industry publications and reports. These publications typically indicate that they have obtained their information from sources they believe to be reliable, but do not guarantee the accuracy and completeness of their information. Some data contained in this annual report is also based on our

internal estimates. Although we have not independently verified the third-party data, we are responsible for its inclusion in the annual report and believe it to be reasonable.

General

At Veracyte, we believe that exceptional cancer care begins with exceptional diagnostics. We are a global diagnostics company that empowers clinicians with the high-value insights they need to guide and assure patients at pivotal moments in the race to diagnose and treat cancer. Our high-performing tests enable clinicians to make more confident diagnostic, prognostic and treatment decisions, helping patients avoid unnecessary procedures and interventions, and speed time to appropriate treatment, thereby improving outcomes for patients all over the world.

Our high performing tests are developed using our proven framework of identifying an unmet clinical need, determining the combination of appropriate biomarkers utilizing cutting-edge genomic and other technologies, and then tuning our assays with deep scientific and machine learning capabilities.

We currently offer tests in thyroid cancer (Afirma); prostate cancer (Decipher Prostate); breast cancer (Prosigna); interstitial lung diseases (Envisia); and bladder cancer (Decipher Bladder). Our Percepta Nasal Swab test is being run in our CLIA lab in support of clinical studies and our tests for kidney cancer and lymphoma are in development, the latter as a companion diagnostic.

We serve global markets with two complementary models. In the United States, we offer laboratory developed tests, or LDTs, through our centralized, Clinical Laboratory Improvement Amendments of 1988, or CLIA, certified laboratories in South San Francisco and San Diego, California, supported by our cytopathology expertise in Austin, Texas. Additionally, primarily outside of the United States, we provide tests to patients through distribution to laboratories and hospitals that can perform the tests locally. Today, this includes our Prosigna test, and in the future, we intend to offer the Envisia, Decipher Prostate and Percepta Nasal Swab tests as in vitro diagnostic, or IVD, tests that run on the nCounter Analysis System. We believe our broad menu of advanced genomic diagnostic tests, combined with our ability to deliver them globally, uniquely positions us in the diagnostics industry.

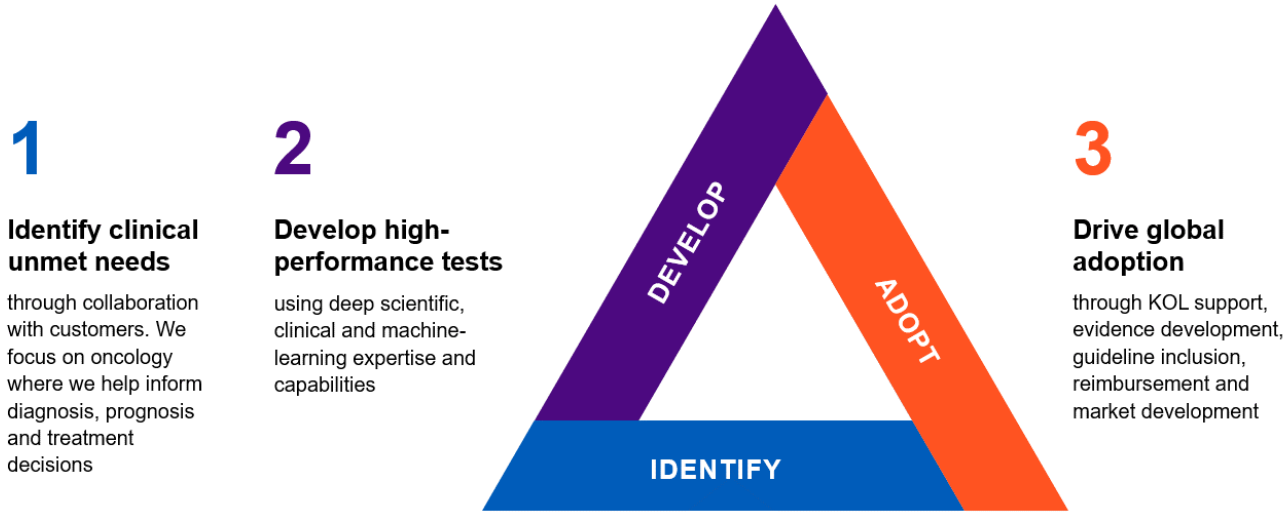
In March 2021, we acquired Decipher Biosciences, expanding our genomic testing menu into urologic cancers. The acquisition also provided us with Decipher GRID (Genomics Resource for Intelligent Discovery), a platform and database that helps drive biopharmaceutical partnerships, key opinion leader, or KOL, engagement and pipeline development in urologic cancers.

In August 2021, we acquired HalioDx SAS and HalioDx Inc., historically a wholly owned subsidiary of HalioDx SAS, (collectively referred to as “HalioDx”), giving us the capabilities and expertise to manufacture our own IVD test kits for use on the nCounter Analysis System. The acquisition also deepened our scientific expertise and capabilities in the rapidly growing area of immuno-oncology further strengthening our offerings to biopharmaceutical and other partners.

We were incorporated in Delaware as Calderome, Inc. in August 2006. Calderome operated as an incubator until early 2008. We changed our name to Veracyte, Inc. in March 2008.

Our Proven Framework for Test Development and Commercialization

We have an established framework to develop and commercialize tests to benefit physicians, patients and payers in the diagnosis, prognosis and treatment of cancer.



Our process begins with our comprehensive strategic planning approach which identifies unmet clinical needs in oncology through a broad examination of the clinical care spectrum, in collaboration with our physician customers and KOL partners. Our experienced medical affairs team supports the process by conducting extensive diligence to understand the patient journey – focusing on diagnosis, prognosis and treatment decision-making – to determine where providing physicians with more accurate and comprehensive information can positively enhance care for patients, enabling them to avoid risky, costly procedures and interventions, and accelerate time to appropriate treatment. This assessment includes determining what specific clinical question our test should answer, where it should be positioned in the patient work-up and what sample type and cutting edge genomic technology should be used. This leads to tests designed to integrate easily into current physician protocols, helping to deliver clinical utility and economic value to physicians, payers, and the healthcare system.

We utilize a comprehensive, platform-agnostic, approach to developing our diagnostic tests that leverages innovations in genomic technology, immuno-oncology, and machine learning, and does so, across numerous biological specimen types. Further, our development activities focus on the same type of sample on which it will be used in clinical practice, which are prospectively collected through Institutional Review Board-approved multicenter clinical trials. This enables us to build extensive, robust biorepositories of patient samples and well-curated clinical, radiological, outcome and other information. This rich content feeds into our machine learning algorithms, which we utilize to create tests that answer specific clinical questions.

We use machine learning algorithms to match biological patterns with “clinical truth,” or the true diagnosis or clinical outcome, which allows us to predict the presence, or absence, of disease or a patient’s prognosis in a clinical setting. For biomarker discovery and product development, we utilize machine learning to select the genomic, clinical or other features from our biorepository that best distinguish the condition we are trying to identify. This provides us with exquisite data to be able to validate our tests with exceptional performance.

We then drive adoption and access to our tests by cultivating further KOL support and developing robust clinical evidence in an effort to gain reimbursement, and ultimately guideline inclusion. In addition to publishing the results of clinical validation studies, we also publish analytical validation studies to establish the reproducibility of our tests across lab instruments, operators and samples. We engage KOLs and community physicians in studies to build the clinical utility evidence needed to support coverage policies and reimbursement from Medicare and private payers. Additionally, our clinical and medical affairs teams continue to liaise with physicians on user-experience, decision impact and other studies. To date, we estimate that approximately 200 studies demonstrating the performance and clinical utility of our CLIA-based tests have been published in peer-reviewed medical journals.

Our ability to develop rigorous clinical evidence for our tests has enabled their inclusion in leading clinical practice guidelines, including those from the National Comprehensive Cancer Network, or NCCN. Our CLIA model enables us to manage the rollout of our tests and bill payers directly, which facilitates test adoption and helps us work directly with payers to secure payment, as well as coverage policies. We employ a team of in-house claims processing and reimbursement specialists who work with payers, physician practices and patients to optimize reimbursement. We have achieved Medicare reimbursement for all our commercially supported tests. We expect to continue to focus on increasing adoption, coverage, and reimbursement of our tests and to build upon our extensive library of clinical evidence.

Our tests address unmet clinical needs in seven of the 10 most prevalent cancers by U.S. incidence and are sold directly to physicians through our specialized sales teams. Our experienced marketing teams help drive penetration through a range of strategies and tactics, including medical conference participation and events, speaker programs, digital marketing programs, advocacy group engagement and other initiatives.

By leveraging our internal technology and bioinformatics capabilities across our growing database of highly-curated data for more than 375,000 patient samples, we will have the ability to further drive new product development in existing and future indications and offer unique insights to biopharmaceutical researchers. Our data assets and biorepositories may include RNA, DNA, variant, fusion and other genomic data, immune-response data, and well-curated clinical, radiological, outcome and other information.

Serving the U.S. Market Through Our CLIA Labs

Our tests are improving patient care in thyroid, prostate, lung, and bladder cancer, as well as in interstitial lung disease.

Currently all of our tests in the U.S. are serviced through our own CLIA certified laboratories in South San Francisco and San Diego, California, and Austin, Texas. We manage our labs with a focus on operational excellence and continuous improvement. We measure performance using such criteria as lab-processing turnaround time, failure rates and deviation vs. control. We have an active monitoring program to ensure lab operations exceed regulatory requirements. We use a systematic, analytical approach aimed at delivering optimal outcomes for patients and referring physicians, while driving cost and lab-efficiency improvement as we scale operations.

Our Clinical Diagnostic Tests Offered Through Our CLIA Labs

Thyroid Cancer - Afirma Genomic Sequencing Classifier

Each year in the United States, an estimated 565,000 people undergo fine needle aspiration, or FNA, biopsy evaluation for potentially cancerous thyroid nodules. We estimate that more than 110,000 of these patients receive indeterminate results (not clearly benign or malignant) based on traditional cytopathology evaluation. Historically, most of these patients were referred to diagnostic surgery, even though 70 to 80 percent of the time, the nodules proved to be benign.

We developed the Afirma Genomic Sequencing Classifier, or GSC, to determine which patients with indeterminate results are actually benign so that these patients may avoid unnecessary, costly surgery that often leads to the need for lifelong daily thyroid hormone replacement drugs. The test was developed with RNA whole-transcriptome sequencing and machine learning technology to provide physicians with clinically actionable results from the same FNA biopsy used for initial cytopathology.

Strong clinical validation data from a multicenter cohort of prospectively collected patient samples were published in *JAMA Surgery*. The findings showed that Afirma GSC has a sensitivity of 91% and specificity of 68%, meaning that in a patient population with 24% cancer prevalence – which is what would be expected in clinical practice – the test can identify more than two-thirds of benign thyroid nodules, with a negative predictive value, or NPV, of 96%. A meta-analysis of 13 independent studies assessing the test's performance in a real-world clinical setting found a sensitivity of 97%, a specificity of 88%, and an NPV of 99%, reinforcing Afirma's performance.

Afirma GSC and its predecessor, the Afirma Gene Expression Classifier, are supported by more than 70 peer-reviewed, published studies. These include the original clinical validation study, which was published in *The New England Journal of Medicine*. Afirma testing is included in leading practice guidelines and is covered for over 275 million Medicare and commercial health plan enrollees in the United States.

Our sales team sells Afirma GSC to endocrinologists and other physicians who perform FNA biopsies on patients with thyroid nodules. We estimate that approximately 70% of our testing volume comes from physicians in hospital or institutional settings and the remaining 30% comes from community-based practices. Physicians can order Afirma GSC testing in one of two ways: by submitting indeterminate FNA samples directly to Veracyte for genomic testing or by submitting FNA samples for initial cytopathology analysis by our partner, Thyroid Cytopathology Partners, with genomic testing performed by Veracyte when the cytopathology is indeterminate.

Prostate Cancer - Decipher Prostate Biopsy and Radical Prostatectomy, or RP, Genomic Classifiers

An estimated 288,000 men are diagnosed with prostate cancer each year in the United States. Prior to the utilization of genomics, clinicians relied solely on clinical parameters, such as prostate-specific antigen, or PSA, level and pathology to determine the appropriate treatment for each patient. But those factors alone do not always reflect the true biology of the tumor, which often leads to over- and under-treatment of patients with localized prostate cancer. The Decipher Prostate Genomic Classifier test results dramatically improve the physician's ability to personalize therapy for each patient and make more appropriate treatment decisions.

The Decipher Prostate cancer tests, developed through whole-transcriptome analysis and machine learning, are used across localized disease to predict a patient's risk of progressing to metastatic disease within five years, which helps physicians determine an appropriate treatment plan. The Decipher Prostate Biopsy test is performed on a prostate biopsy sample following a cancer diagnosis to inform whether the patient is a candidate for active surveillance, needs monotherapy or may benefit from multi-modal or intensified therapy. The Decipher Prostate RP test is performed on surgical tissue to guide decision-making regarding treatment timing following radical prostatectomy and to help determine whether patients undergoing salvage radiotherapy may benefit from the addition of hormone therapy or may safely avoid hormone therapy and its side effects.

The Decipher Prostate Genomic Classifier is currently being investigated in seven National Cancer Institute-sponsored, phase 3, prospective, randomized controlled clinical trials; 24 phase 2/3 prospective trials; and more than 20 retrospective studies of phase 3 randomized controlled trials. Many of these trials require Decipher Prostate testing for study inclusion. The test's performance and utility has been evaluated in approximately 70 peer-reviewed, published studies.

The NCCN Clinical Practice Guidelines in Oncology, or NCCN Guidelines, for Prostate Cancer (v1.2023) includes a new table (Table 1) in Principles of Risk Stratification summarizing the characteristics of different tools used for initial risk stratification of clinically localized prostate cancer. In this table, Decipher Prostate is the only gene expression test with the highest level of evidence (Level 1) for validation. The NCCN Guidelines also uniquely suggest use of the Decipher Prostate RP test to inform treatment recommendations, post surgery, based on the patient's Decipher score. Decipher Prostate is covered by Medicare and commercial payers representing approximately 195 million enrollees.

Lung Cancer - Percepta Nasal Swab Test

Lung cancer has the highest mortality rate of all cancers worldwide, causing approximately 1.8 million deaths each year. Lung nodules are typically the first sign of lung cancer and cannot be ignored – however, most of them are benign. Physicians currently have limited objective tools to help accurately determine which patients with lung nodules found on CT scans have cancer. Approximately 15 million patients are now recommended for annual lung cancer CT screening to detect potentially cancerous lung nodules early. Today, approximately 1 million Americans are screened annually for lung cancer, and about 1.6 million lung nodules are found incidentally. We developed the Percepta Nasal Swab test to help physicians more accurately, quickly and confidently identify lung cancer risk so that patients whose lung nodules are benign may avoid unnecessary invasive procedures and patients whose nodules are likely cancerous may proceed to further diagnostic work-up and, if necessary, treatment.

The Percepta Nasal Swab test is built upon foundational "field of injury" science - through which genomic changes associated with lung cancer in current and former smokers to detect smoking-related damage associated with lung cancer in current or former smokers, but uses a sample collected non-invasively from the nasal passage. Veracyte developed the final classifier using RNA whole-transcriptome sequencing and machine learning on a training set of nasal samples from more than 1,100 patients representing a wide range of lung and tumor biology.

In clinical validation data presented at the 2021 American College of Chest Physicians, or CHEST, Annual Meeting, when the Percepta Nasal Swab test identified patients as low risk, its sensitivity was 97%, providing a negative predictive value, or NPV, of 98% in a population with the 25% cancer prevalence that would be expected in a broad cohort with suspicious lung nodules. This NPV would assist physicians in avoiding unnecessary invasive procedures in these patients with a very small likelihood of missing a cancer. When the test identified patients as high risk, its specificity was 92%, for a positive predictive value, or PPV, of 70% at a malignancy rate of 25%. Given these data, we believe the Percepta Nasal Swab test would assist physicians in directing these patients to further procedures so they could obtain an accurate diagnosis and speed time to treatment, if necessary. Patients in the moderate risk group could be managed according to current clinical guidelines. We are running the Percepta Nasal Swab test in our CLIA lab in support of our clinical utility study, in an effort to demonstrate data to help drive Medicare and private payer coverage, as well as clinical adoption.

ILD/IPF - Envisia Genomic Classifier

Each year in the United States approximately 200,000 patients are suspected of having an interstitial lung disease, or ILD, including idiopathic pulmonary fibrosis, or IPF, which is among the most common and deadly of these lung-scarring diseases. Obtaining an accurate, timely IPF diagnosis is important given the availability of drugs that can slow the progression of this debilitating disease, as well as the need to avoid inappropriate and potentially harmful treatment. Additionally, prognostic information may help physicians determine treatment plans for patients with ILDs, including IPF.

Limitations in current technologies make IPF notoriously difficult to diagnose, often leading to treatment delays, repeated misdiagnoses, patient distress and added healthcare expenses. Physicians routinely use high-resolution computed tomography, or HRCT, imaging to identify usual interstitial pneumonia, or UIP, the pattern whose presence is essential to IPF diagnosis. This approach, however, frequently provides inconclusive results, with current guidelines recommending consideration of

surgery to secure a more definitive diagnosis. Such surgeries are risky and expensive, and many patients are too frail to undergo the procedure.

The Envisia classifier is the first test of its kind for improving the diagnosis of ILDs, including IPF, without the need for surgery. The test identifies usual interstitial pneumonia, or UIP, a pattern that is essential to the diagnosis of IPF, with high accuracy on patient samples that are obtained through transbronchial biopsy, a nonsurgical procedure that is commonly used in lung evaluation.

The Envisia classifier is supported by clinical data published in eight peer-reviewed journals, including *The Lancet Respiratory Medicine* and *American Journal of Respiratory and Critical Care Medicine*. In 2022, an updated global (ATS/ERS/JRS/ALAT) clinical practice guideline highlighted the role of the Envisia Classifier in the diagnosis of IPF with more than 40% of the guideline authors voting to recommend Envisia testing. The guideline points to a newly published meta-analysis in *AnnalsATS* demonstrating consistently high specificity of 92% across 4 separate studies.

We obtained Medicare coverage for the Envisia classifier through the Molecular Diagnostics Services Program, or MolDX, program in 2019. We estimate that half of the patients evaluated for ILDs/IPF in the United States are covered by Medicare.

Bladder Cancer - Decipher Bladder Genomic Classifier

Each year in the U.S., nearly 85,000 people are expected to be diagnosed with bladder cancer. Patients diagnosed with non-metastatic muscle-invasive bladder cancer, or MIBC, often undergo neoadjuvant chemotherapy, or NAC, prior to standard-of-care radical cystectomy, even though the absolute survival benefit associated with the addition of NAC to radical cystectomy is just 5-10%. Until recently, there was no reliable way to determine which MIBC tumors would – or would not – respond to chemotherapy.

Decipher Bladder is a genomic test that measures the molecular profile of bladder cancer using gene expression analysis from transurethral resected bladder tumor specimens. The test was developed for use in bladder cancer patients with high-grade non-muscle-invasive disease who are being considered for treatment and patients with muscle-invasive disease who face the question of immediate cystectomy or systemic treatment in the neoadjuvant setting prior to cystectomy. Decipher Bladder reports the molecular subtype of the tumor specimen as Luminal or Non-Luminal (Luminal Infiltrated, Basal, Basal Claudin-Low or Neuroendocrine-like), with each subtype having distinct biological composition, clinical behavior and predicted benefit from NAC and may have implications for future therapeutic strategies.

The Decipher Bladder test is supported by multiple peer-reviewed clinical studies demonstrating its ability to identify which patients have a higher risk of upstaging to non-organ confined disease at surgery and which patients may benefit the most from neoadjuvant therapy.

We began commercialization of the Decipher Bladder test in the fall of 2021, following final Medicare coverage for the test in July 2021. The Decipher Bladder test is the first genomic test to be covered by Medicare for patients with bladder cancer.

Driving Global Growth with Distributed IVD Tests

Once we have developed robust clinical evidence and physician adoption of our tests in the United States, we typically then drive further patient access by launching them, as appropriate, into global markets as IVD tests that are run on the nCounter Analysis System. This approach enables our tests to be performed locally in laboratories and hospitals worldwide, which we believe facilitates market access and physician adoption in Europe and other strategic global markets.

In December 2019, we acquired the exclusive worldwide license to the nCounter Analysis System for clinical IVD test use, development and commercialization. We expect this instrument platform to enable a broad range of testing through its ability to simultaneously conduct multiplex evaluation of up to 800 RNA and other targets.

We currently offer IVD testing in breast cancer and, looking forward, we believe we are well positioned to develop and deliver a menu of tests for use on the nCounter Analysis System. Our acquisition of HalioDx in August 2021 provides us with a European headquarters to develop, manufacture and supply our own IVD test kits. We plan to transition manufacturing of our tests, currently produced by NanoString in the U.S., to our facility in France, giving us end-to-end control of our IVD test supply chain. We anticipate the vertical integration of research, development and manufacturing will enhance our ability to efficiently serve the global market with a broad menu of diagnostic tests.

Breast Cancer - Prosigna Breast Cancer Assay

Breast cancer is the most common cancer and the leading cause of cancer-related death in women worldwide. In 2020, there were an estimated 2.3 million new cases of the disease. Hormone receptor positive breast cancer is the most prevalent type of breast cancer, comprising approximately 70% of cases. Of these, we estimate that the global early-stage breast cancer recurrence market is significant, with approximately 750,000 patients potentially eligible for the Prosigna Breast Cancer Assay

annually. This is comprised of approximately 280,000 patients in the United States and 270,000 across the major markets in Europe.

Information about individual patients' prognosis is the foundation of treatment decision-making and recommendations in breast cancer. However, traditional non-molecular tests are often insufficient to reliably determine patients' individual risk of recurrence and, therefore, adequately inform therapy decisions.

The Prosigna Breast Cancer Assay is a clinically validated prognostic assay that uses advanced genomic technology and combines clinical and pathological information to help inform next steps for post-menopausal women with early-stage, hormone receptor positive breast cancer, helping them avoid unnecessary toxic chemotherapy or under-treatment. The assay is performed in laboratories in EMEA, as well as the U.S. and other selected countries. The Prosigna Breast Cancer Assay analyzes the activity of 46 genes in the PAM50 gene signature, and based on molecular subtypes, proliferation score, and clinical-pathological features, can provide a hormone-receptor positive, early-stage breast cancer patient and their physician with a prognostic risk-of-recurrence score that indicates the probability of cancer recurrence over the next ten years.

The Prosigna assay is clinically validated in studies published in *Annals of Oncology* and the *Journal of Clinical Oncology.* Medicare coverage for Prosigna has been in effect since 2015. The test is recommended in guidelines from the National Comprehensive Cancer Network and the American Society of Clinical Oncology in the United States. Outside of the United States, the test is included in leading medical guidelines, including from the National Institute for Health and Care Excellence in the United Kingdom and the European Society for Medical Oncology, or ESMO.

The Prosigna assay utilizes formalin-fixed and paraffin-embedded breast cancer tissue and is offered as an IVD test that runs on the nCounter Analysis System. The test has been CE-IVD marked, showing that it conforms with European Union regulations, and is available for use by healthcare professionals in the European Union and other countries that recognize the CE mark, as well as in Canada, Israel, Australia, New Zealand and Hong Kong. The Prosigna test is FDA 510(k) cleared in the United States for use on the nCounter Analysis System.

The Prosigna Breast Cancer Assay is sold to laboratories by our direct sales team, who also lead efforts to gain support among KOLs in breast cancer oncology.

Biopharmaceutical and Other Revenue

We have formed numerous biopharmaceutical partnerships that derive value out of our current assets or future ones. Through development and commercialization of our tests, we have built or gained access to unique biorepositories that include extensive clinical cohorts and whole-genome RNA sequencing and other data, such as immuno-oncology.

Biopharmaceutical customers may be interested in leveraging our data to: first, understand or confirm a drug's method of action by looking at patients' gene expression profiles or tumor microenvironment pre- and post-treatment; second, identify predictive or prognostic biomarkers for drug response, toxicity or disease progression, which define the ideal patient subpopulation for a given therapy; and/or lastly, identify patient populations with rare genetic variations for clinical trials or existing therapies. We also offer customized biomarker testing and analytical services to our biopharmaceutical partners, helping them advance their goals.

Through the acquisition of HalioDx in 2021, we bolstered our offering to these customers by gaining expertise in immuno-oncology. Our immuno-oncology offerings to biopharmaceutical partners focus on the implications of the tumor microenvironment using tools such as Immunoscore IC, Immunosign, our Brightplex innovative technology, and our Veracyte Biopharma Atlas dedicated database. Immunogram, our multi-modal platform, provides a comprehensive understanding of the tumor immune microenvironment by seamlessly integrating data from a variety of genomic, transcriptomic, and proteomic platforms. We believe our immuno-oncology capabilities and offerings are complementary to – and in the future may be more integrated into – our core genomic diagnostics business.

Additionally, we deploy our know-how in IVD test development to develop and manufacture such tests for other diagnostic companies in indications that are noncompetitive to Veracyte.

COVID-19 and Macroeconomic Factors

We believe the COVID-19 outbreak, including its numerous variants, impacted our total test volumes primarily during 2020 and 2021. Our customers, third-party contract manufacturers, carriers, suppliers and collaboration partners have been affected by the closure of hospitals, doctors' offices, manufacturing sites, or country borders, among other measures put in place around the world. Layoffs, furloughs and unplanned loss of staff in the medical industry and otherwise during the pandemic have had, and will continue to have, negative impacts on the demand for and supply of medical care and diagnostic tests, which affects the frequency with which tests are ordered, and the ability of doctors and hospitals to administer such tests. Further the inability to travel and conduct face-to-face meetings can also make it more difficult to expand utilization of our products into new geographies and to drive awareness of our products.

Our Decipher Prostate test has been least impacted by the pandemic because our customers are mostly community-based urology practices, which generally remained more accessible to patients and our sales reps. Our Afirma thyroid cancer test was impacted by COVID-19 in 2020 and portions of 2021 as a majority of our samples come from large institutions which are less accessible to patients and our reps. We believe our pulmonology business was the most impacted since the bronchoscopy procedures used to collect samples for our Envisia test are considered elective procedures and are performed in hospital settings, which have been more restrictive. Further, these tests are ordered by pulmonologists who could be largely preoccupied with caring for COVID-19 patients.

In addition, ongoing interest rate increases and inflation in the U.S. and other markets globally may heighten the risk of an economic downturn or recession and volatility and dislocation in the capital or credit markets in the U.S. or globally. Moreover, the continued strengthening of the U.S. dollar compared to other currencies (including the Euro, in which a material portion of our European sales and costs are denominated), has impacted and may continue to impact our results of operations. We intend to continue to monitor macroeconomic conditions closely and may determine to take certain financial or operational actions in response to such conditions as appropriate. Finally, the measures taken by Russia in response to European support for Ukraine have increased the risk of disruptions to energy supplies in Europe, which may impact our ability to manufacture tests from our facility in Marseille, France.

The extent of the impact of COVID-19 and other macroeconomic factors on our future liquidity and operational performance will depend on certain developments, including the deployment and long-term efficacy of vaccines; the duration and spread of the outbreak particularly in the form of more transmissible variants; the impact on our customers' operations; the impact to our sales and renewal cycles; changes in central bank policies and interest rates; rates of inflation; and changes in foreign currency exchange rates. See Risk Factors for further discussion.

Reimbursement

United States

Revenue from our tests comes from several sources, including commercial third-party payers, such as insurance companies and health maintenance organizations, government payers, such as Medicare and Medicaid, and patients.

Medicare generally covers molecular diagnostic tests through the individual Medicare Administrative Contracts, or MACs. Medicare coverage for most of Veracyte’s tests is determined through the MolDX program, administered by the MAC Palmetto GBA. Through Local Coverage Determinations, or LCDs, and associated coverage articles, MolDX covers Afirma GSC, Envisia, Decipher Prostate, Decipher Bladder, and Prosigna. For testing services that do not fall within the scope of the MolDX program, coverage may be adjudicated by the MAC with jurisdiction over the laboratory that performs the test, either via an LCD or on a claim-by-claim basis.

Since 1984, Medicare has paid for clinical diagnostic laboratory tests, or CDLTs, on the Clinical Laboratory Fee Schedule, or CLFS, under section 1833(h) of the Social Security Act, or the SSA. Section 216(a) of the Protecting Access to Medicare Act of 2014, or PAMA, made extensive revisions to the Medicare CLFS coding, rate setting processes, and laboratory payment reporting for CDLTs, and created a new subcategory of CDLTs called Advanced Diagnostic Laboratory Tests, or ADLTs, with separate reporting and payment requirements.

In 2016, the Centers for Medicare and Medicaid Services, or CMS, issued the final rule to implement the requirements of PAMA, which significantly revised the Medicare payment system for CDLTs. The final rule was implemented on January 1, 2018, for the private payer rate-based fee schedule required by PAMA. Under the final rule, for CDLTs furnished on or after January 1, 2018, the amount Medicare pays is equal to the weighted median of private payer rates for the CDLTs, reported triennially for CDLTs, and annually for ADLTs. Congress has extended the first payment cycle under PAMA by an additional three years for CDLTs, moving the next data reporting period under PAMA from 2020 to 2023 for final private payer payments made between January 1 and June 30, 2019, extending the applicability of the payment rates that took effect in 2018 through December 31, 2023.

We submit claims to payers directly using unique American Medical Association Current Procedural Terminology, or CPT, codes when they exist for our products and services and use either miscellaneous or common CPT codes for non-proprietary testing services or when unique codes do not exist. Third-party payers, including Medicare, have specific and often complex billing rules, failure to abide by which may result in denials, audits, and/or refund requests. We work with commercial payers to establish medical coverage policies for our tests and services, negotiate network status and contracted rates. Payment from third-party payers differs depending on whether we have entered into a contract with the payers as a “contracted provider” or do not have a contract and are considered a “non-contracted provider.” Payers will often reimburse non-contracted providers, if at all, at a lower rate than contracted providers.

When we contract to serve as a contracted provider, reimbursements are made pursuant to a negotiated fee schedule and are limited to only covered indications. Becoming a contracted provider generally results in higher reimbursement for covered indications and lack of reimbursement for non-covered indications. As a result, the impact of becoming a contracted provider with a specific payer will vary.

In some cases, third party payers may request audits of the amounts paid to us. This may require us to repay certain amounts to payers as a result of such audits.

Factors that impact reimbursement:

- Variability in medical policies indicating coverage for our products and services
- Network status and claims adjudication as in-network or out of network and corresponding patient co-pay/coinsurance responsibilities
- Patient financial assistance programs
- Changes to AMA-CPT coding rules and edits
- Medicare clinical laboratory and physician fee schedules
- Government sequestration
- Medicaid fee schedules
- Contracted rates for our diagnostics
- Utilization management or prior authorization processes and steps put in place by commercial payers ensuring medical necessity of services ordered for patients
- Billing errors
- Claims disputes

For the years ended December 31, 2022, 2021 and 2020, respectively, revenue was represented by the indicated percent for each payer:

Medicare accounted for 31%, 30% and 24% of our revenue. Medicaid accounted for 2%, 2%, and 2% of our revenue. Private commercial payers accounted for 52%, 54%, and 61% of our revenue.

Outside the United States

Outside of the United States, we bill hospital and laboratory customers directly for test kits they order. Our customers subsequently bill third-party payers for reimbursement. Prosigna test marketing has initially targeted private and cash-pay markets in Europe. We will continue to drive Prosigna reimbursement efforts in Europe and other global markets through the development of clinical and other evidence to support the test's inclusion in guidelines and coverage programs. The test is currently reimbursed in Germany, France, Spain, Portugal, Italy, Netherlands, Norway, Sweden, Denmark, Austria, Lithuania, Switzerland, Canada, England, Scotland, and Israel.

Competition

Our main competition from diagnostic companies or academic institutions are those that use next generation sequencing technology or other methods to measure genomic biomarkers in disease areas addressed by our tests.

Primary competition in the broader test space comes from traditional methods used by physicians to diagnose and manage patient care decisions. Many of the traditional practices have been the standard of care in the United States for many years, and we need to continue to educate physicians about the benefits of Veracyte's tests, which have the potential to change clinical practice and improve patient outcomes.

Our Afirma test faces competition from companies and academic institutions that use next generation sequencing technology or other methods to measure mutational markers such as BRAF and KRAS, along with numerous other mutations. These organizations include, for example, Interpace Diagnostics Group, Inc., CBLPath, Inc./University of Pittsburgh Medical Center and others who are developing new products or technologies that may compete with our tests.

Our Decipher Prostate test faces competition from Myriad Genetics and MDxHealth, which offer genomic testing for prognostic purposes within localized prostate cancer. Additionally, traditional methods used by pathologists and clinicians to estimate risk of disease progression pose competitive threats to our business. Companies combining these traditional methods with artificial intelligence could potentially emerge as competitors, but most of these technologies are currently in the research stage. In bladder cancer, we are not currently aware of a direct competitor offering genomic testing for prognostic purposes that match the intended use population for our test. However, DNA mutational analysis, traditional clinical methods and nomograms are currently in use by physicians for similar purposes.

We believe our primary competition in pulmonology with our Envisia classifier will similarly come from traditional methods used by physicians to diagnose the related diseases. For the Percepta Nasal Swab test, we expect competition from companies focused on lung cancer such as Biodesix, Inc. We believe our principal competitor in the breast cancer diagnostics market is Exact Sciences, Inc., which currently commands a substantial majority of the market. Other competitors in the breast cancer diagnostics market include Myriad Genetics, Inc. and Agendia, Inc.

Increasing acceptance and knowledge of the importance of earlier screening and diagnostic testing linked with improved patient outcomes and therapy selection is leading to more companies developing genomic testing services and technologies. We may also face competition from companies informing treatment decisions such as Guardant Health or Foundation Medicine, Inc. Competition could also emerge from competitors, using alternative samples, such as blood, urine or sputum.

We also face competition from commercial laboratories, such as Laboratory Corporation of America Holdings and Sonic Healthcare USA, with strong infrastructure to support the commercialization of diagnostic services. In addition, competitors may develop their own versions of our solutions in countries we may seek to enter where we do not have patents or where our intellectual property rights are not recognized and compete with us in those countries, including encouraging the use of their solutions by physicians in other countries.

We believe key factors contributing to our success in the market include our scientific and technological excellence, evidence of clinical differentiation, strong KOL support and payer coverage policies for our tests. We believe our strength across these areas form a barrier to entry and a competitive advantage. However, our competitive landscape may change over time as new competitors enter the market. As we add new tests and services, we will face many of these same competitive risks for these new tests as well.

Patents and Proprietary Technology

In order to remain competitive, we must develop and maintain protection of the proprietary aspects of our technologies. To that end, we rely on a combination of patents, copyrights and trademarks, as well as contracts, such as confidentiality, invention assignment and licensing agreements. We also rely upon trade secret laws to protect unpatented know-how and continuing technological innovation. In addition, we have what we consider to be reasonable security measures in place to maintain confidentiality. Our intellectual property strategy is intended to develop and maintain our competitive position.

We apply for and in-license patents covering our products and technologies and uses thereof, as we deem appropriate; however, we may fail to apply for patents on important products and technologies in a timely fashion or at all, or we may fail to apply for patents in potentially relevant jurisdictions. Certain of our issued patents expire between 2024 and 2038 and are related to methods used in thyroid cancer diagnostics, urologic cancers diagnostics, lung cancer and disease diagnostics, breast cancer diagnostics, and immuno-oncology diagnostics.

We intend to file additional patent applications in the United States and abroad to strengthen our intellectual property rights; however, our patent applications may not result in issued patents in a timely fashion or at all, and we cannot assure investors that any patents that have issued or might issue will protect our technology. We may receive notices of claims of potential infringement from third parties in the future.

We hold or in-license registered trademarks in the United States for “Veracyte,” “Afirma,” “Percepta,” “Envisia,” “Prosigna,” “Lymphmark,” “Decipher,” “GRID,” “HalioDx,” “Immunoscore,” “Brightplex,” “Immunosign,” and the Veracyte logo. We also hold registered trademarks in various jurisdictions outside of the United States.

We require all employees and consultants working for us to execute confidentiality agreements, which provide that all confidential information received by them during the course of the employment or consulting relationship be kept confidential, except in specified circumstances. Our agreements with our employees provide that all inventions, discoveries and other types of intellectual property, whether or not patentable or copyrightable, conceived by the individual while he or she is employed by us, are assigned to us. We cannot provide any assurance, however, that employees and consultants will abide by the confidentiality or assignment terms of these agreements. Despite measures taken to protect our intellectual property, unauthorized parties might copy aspects of our technology or obtain and use information that we regard as proprietary.

Environmental Matters

Our operations require the use of hazardous materials (including biological materials) which subject us to a variety of federal, state and local environmental and safety laws and regulations. Some of these regulations provide for strict liability, holding a party potentially liable without regard to fault or negligence. We could be held liable for damages and fines as a result of our, or others’, business operations should contamination of the environment or individual exposure to hazardous substances occur. We cannot predict how changes in laws or new regulations will affect our business operations, or the cost of compliance. Historically, the cost of compliance for these safety laws and regulations related to the protection of the environment has not materially impacted our operations. There were no material capital expenditures related to environmental compliance in the

year ended December 31, 2022. Similarly, we do not anticipate any significant expenditures for the year ended December 31, 2023.

Raw Materials and Suppliers

We procure reagents, equipment, and other materials that we use to perform our tests from sole suppliers. We also purchase components used in our collection kits from sole-source suppliers. Some of these items are unique to these suppliers and vendors. In addition, we utilize external providers to assemble and distribute our sample collection kits. While we have developed alternate sourcing strategies for these materials and vendors, we cannot be certain whether these strategies will be effective, or the alternative sources will be available when we need them. If these suppliers can no longer provide us with the materials we need to perform the tests and for our collection kits, if the materials do not meet our quality specifications or are otherwise unusable, if we cannot obtain acceptable substitute materials, if materials become unavailable due to COVID-19 related increases in demand for the materials, or if we elect to change suppliers, an interruption in test processing could occur, we may not be able to deliver patient reports and we may incur higher one-time switching costs. Any such interruption may significantly affect our future revenue, cause us to incur higher costs, and harm our customer relationships and reputation. In addition, in order to mitigate these risks, we maintain inventories of these supplies at higher levels than would be the case if multiple sources of supply were available. If our test volume decreases or we switch suppliers, we may hold excess inventory with expiration dates that occur before use which would adversely affect our losses and cash flow position. As we introduce any new test, we may experience supply issues as we ramp test volume.

Legal Proceedings

From time to time, we may be party to lawsuits in the ordinary course of business. We are currently not a party to any material legal proceedings.

Regulation

Clinical Laboratory Improvement Amendments of 1988, or CLIA

As a clinical reference laboratory, we are required to hold certain federal, state and local licenses, certifications and permits to conduct our business. We are subject to CLIA, a federal law that regulates clinical laboratories that test specimens derived from humans for the purpose of providing information for the diagnosis, prevention or treatment of disease. Under CLIA, which is administered by CMS, we are required to hold a certificate applicable to the type of laboratory examinations and tests we perform and to comply with standards covering personnel qualifications, facilities administration, quality systems, inspections, and proficiency testing. We must maintain CLIA compliance and certification to sell our tests and be eligible to bill state and federal healthcare programs, as well as many private third-party payers.

Moreover, if one of our clinical reference laboratories is out of compliance with CLIA requirements, we may be subject to sanctions such as suspension, limitation or revocation of our CLIA certificate, as well as directed plan of correction, state on-site monitoring, civil money penalties, civil injunctive suit or criminal penalties, or cancellation of our approval to receive payments under Medicare for our services. If we were to be found out of compliance with CLIA requirements and subjected to sanctions, our business could be harmed.

We hold CLIA certifications to perform testing at our South San Francisco and San Diego, California; Richmond, Virginia; and Austin, Texas laboratory locations. To renew our CLIA certificates, we are subject to survey and inspection every two years to assess compliance with program standards. Moreover, CLIA inspectors may conduct random inspections of our clinical reference laboratories. If we in the future fail to maintain CLIA certificates in our laboratory locations, we would be unable to bill for services provided by state and federal healthcare programs, as well as many private third-party payers, which may have an adverse effect on our business, financial condition and results of operations.

State Laboratory Licensing

California Laboratory Licensing

In addition to federal certification requirements of laboratories under CLIA, licensure is required and maintained for our South San Francisco and San Diego, California and Richmond, Virginia clinical reference laboratories under California law. Such laws establish standards for the day-to-day operation of a clinical reference laboratory, including the training and skills required of personnel and quality control. In addition, California laws mandate proficiency testing, which involves testing of specimens that have been specifically prepared for the laboratory.

If our clinical reference laboratories are out of compliance with California standards, the California Department of Public Health, or CDPH, may suspend, restrict or revoke our license to operate our clinical reference laboratories, assess substantial civil money penalties, or impose specific corrective action plans. Any such actions could materially affect our business. We maintain current licenses in good standing with CDPH. However, we cannot provide assurance that CDPH will at all times in the future find us to be in compliance with all such laws.

New York Laboratory Licensing

Our clinical reference laboratories are required to be licensed by New York, under New York laws and regulations before we receive specimens from New York. The New York laws and regulations establish standards for:

- quality management systems;
- qualifications, responsibilities, and training;
- facility design and resource management;
- pre-analytic, analytic (including validation and quality control), and post-analytic systems; and
- quality assessments and improvements.

New York law also mandates proficiency testing for laboratories licensed under New York law, regardless of whether such laboratories are located in New York. If a laboratory is out of compliance with New York statutory or regulatory standards, the New York State Department of Health, or NYSDOH, may suspend, limit, revoke or annul the laboratory's New York license, censure the holder of the license or assess civil money penalties. Statutory or regulatory noncompliance may result in a laboratory's operator being found guilty of a misdemeanor under New York law. NYSDOH also must approve laboratory developed tests before the test is offered in New York; approval has been received for the Afirma GSC, Envisia, Decipher Prostate and Decipher Bladder tests. NYSDOH approval has also been received for Percepta Nasal Swab in support of our clinical trial. Should we be found out of compliance with New York laboratory standards of practice, we could be subject to such sanctions, which could harm our business. We maintain a current license in good standing with NYSDOH for our South San Francisco and San Diego, California and Austin, Texas laboratories. We cannot provide assurance that the NYSDOH will at all times find us to be in compliance with applicable laws.

Other States' Laboratory Licensing

In addition to New York and California, other states require licensing of in-state and out-of-state laboratories under certain circumstances. For example, Pennsylvania, Maryland and Rhode Island require licenses to test specimens from patients in those states. We have obtained licenses from states where we believe we are required to be licensed and believe we are in compliance with applicable licensing laws.

From time to time, we may become aware of other states that require in-state or out-of-state laboratories to obtain licensure in order to accept specimens from, or conduct laboratory operations in, the state, and it is possible that other states will have such requirements in the future. If we identify any other state with such requirements or if we are contacted by any other state advising us of such requirements, we intend to comply with such requirements.

United States Regulation of Laboratory Testing

Food and Drug Administration: In Vitro Diagnostics and Diagnostic Kits

IVDs and diagnostic kits, including collection systems that are sold and distributed in the United States, are regulated as medical devices by the FDA. Devices subject to FDA regulation must undergo premarket review prior to commercialization unless exempt from such review. In addition, manufacturers of medical devices must comply with various regulatory requirements under the Federal Food, Drug, and Cosmetic Act, or FDC Act, and implementing regulations promulgated thereunder. Entities that fail to comply with FDA requirements may be subject to, among other things, issuance of inspectional observations on Form FDA-483, untitled or warning letters, recalls, import detentions, seizures, or injunctions, including orders to cease manufacturing, and can be liable for civil money penalties or criminal prosecution.

The FDC Act sets forth the classifications of medical devices into one of three categories based on the risks associated with the device and prescribes the levels of controls appropriate for each of the three classes to help ensure reasonable assurance of safety and effectiveness. Class I devices are considered to be low risk and are generally exempt from FDA premarket notification requirements. Class I devices are subject to general regulatory controls. When general controls are

considered insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide such assurance, FDA will classify the device as a Class II device. Unless exempt, for Class II devices, the FDC Act requires the submission to FDA of a premarket notification, referred to as a "510(k)," which must provide data and information showing that the device is substantially equivalent to an already legally marketed device, referred to as a predicate device, with respect to the indications for use and the product's technological characteristics. If the data and information are sufficient to show that the device is substantially equivalent to the predicate device, FDA issues a Substantially Equivalent letter clearing the device for marketing.

If there is insufficient information to support classifying a device into Class I or Class II and the device is life-sustaining or life-supporting or is substantially important in preventing impairment of human health or presents a potential unreasonable risk of illness or injury, FDA places the device into Class III. Class III devices are considered the highest risk devices and generally require significant data and information, including testing data and data from nonclinical and clinical studies, to provide reasonable assurance of the device's safety and effectiveness. For Class III devices, FDA requires the submission and FDA approval of a premarket application, or PMA, before they can be marketed.

Certain devices are classified as Class III devices automatically, by operation of law, when the device does not have a predicate device or is found to not be substantially equivalent to a predicate device. If there is sufficient evidence to show that the device is a lower risk device, a manufacturer may ask FDA to reclassify the device into Class II or Class I by submitting a *De Novo* classification request. When FDA reclassifies a device through the *De Novo* process, other manufacturers of the same device type do not necessarily have to submit a *De Novo* request or a PMA in order to legally market the device. Instead, manufacturers can submit a 510(k), unless the device has been classified as 510(k)-exempt, to legally market their device, because the device that was the subject of the original *De Novo* request can serve as a predicate device for a substantial equivalence determination. If FDA does not issue an order granting the *De Novo* request for reclassification, the device will remain a Class III device and be subject to PMA requirements to obtain marketing authorization.

Establishments that manufacture or, in certain situations, distribute FDA-related medical devices, including manufacturers, repackagers and relabelers, specification developers, and initial importers, are required to register and list their devices with the FDA, including payment of annual user fees.

Devices that may be legally marketed are subject to numerous regulatory requirements. These include: good manufacturing practice for medical devices as set out in the Quality System Regulation, or QSR, labeling regulations, restrictions on promotion and advertising, the Medical Device Reporting regulation, or MDR (which requires manufacturers to report certain adverse events and product malfunctions to the FDA), and the Reports of Corrections and Removals regulation (which requires manufacturers to report certain field actions to the FDA). Certain corrections and market removals may also be subject to FDA's recall regulation and procedures.

The FDA has issued a regulation outlining specific requirements for "specimen transport and storage containers." "Specimen transport and storage containers" are medical devices "intended to contain biological specimens, body waste, or body exudate during storage and transport" so that the specimen can be destroyed or used effectively for diagnostic examination. A specimen transport and storage container is classified as a Class I exempt device, which means that the device is exempt from the 510(k) premarket notification requirement and, if not labeled or otherwise represented as sterile, the QSR, except for recordkeeping and complaint handling requirements. These 510(k) exempt devices are still subject to general controls, including MDR requirements, the reporting of corrections and removals, and establishment registration and product listing.

In our FDA registration, we have listed the containers we provide for collection and transport of Afirma GSC and Envisia samples from a physician to our clinical reference laboratory as Class I devices in accordance with the classification of regulation for the specimen transport and storage container. If the FDA were to determine that our sample collection containers are not Class I devices, we may be required to file 510(k) premarket notifications and obtain FDA clearance to manufacture and market the containers, which could be time consuming and expensive.

The FDA enforces the requirements described above by various means, including inspection and market surveillance. If the FDA finds a violation, it can institute a wide variety of enforcement actions, ranging from an Untitled Letter or Warning Letter to more severe sanctions such as:

- fines, injunctions, and civil money penalties;
- recall or seizure of products;
- operating restrictions, partial suspension or total shutdown of production; and

- criminal prosecution.

Federal Oversight of Laboratory Developed Tests and Research Use Only Products

Clinical laboratory tests like our proprietary genomic tests are regulated under CLIA, as administered by CMS, as well as by applicable state laws. Clinical laboratory tests that are developed and run within a single CLIA-certified laboratory are referred to as laboratory developed tests, or LDTs, by the FDA. Currently, the FDA believes these tests meet the definition of a device under the FDC Act and that it has the authority to regulate them. However, the FDA is exercising enforcement discretion for LDTs, meaning the FDA is not currently enforcing the device regulations that the FDA would apply to such tests, although the FDA may continue to enforce device regulations with respect to certain reagents, instruments, software or components provided by third parties and used to perform LDTs. We believe that the Afirma and Envisia classifiers, as well as our Decipher Prostate and Bladder tests, have been developed and are performed in a manner consistent with the FDA's enforcement discretion policy.

In October 2014, the FDA published a draft guidance document proposing a framework for the regulation of LDTs. In November 2016, the FDA announced that it would not finalize guidance and would instead work with the new Administration, Congress and stakeholders on an updated framework. In January 2017, the FDA issued a discussion paper on LDTs in which it synthesized stakeholder feedback and outlined a substantially revised "possible approach" to the oversight of LDTs, which did not represent a formal position of the FDA and is not enforceable. In a December 2018 statement, the FDA said that there is a need for "a unified approach to the regulation of in vitro clinical tests to protect patient safety, support innovation, and keep pace with the rapidly evolving technology that's helping us find new treatments for disease," and listed key principles of an approach it would support. The FDA has not exercised enforcement discretion over all LDTs. For example, in response to the COVID-19 pandemic, the FDA required LDTs for SARS-CoV-2 to undergo premarket review and obtain Emergency Use Authorization (EUA) in order to remain on the market. The extent to which the FDA will continue to exercise enforcement discretion over other LDTs is unclear. Various legislative proposals have been introduced in recent years to clarify the FDA's regulatory authority over clinical diagnostic tests. Even in the absence of a legislative change, it is possible that the FDA will promulgate regulations, issue guidance, or take other action to exert additional oversight over LDTs.

Some of the materials we use for our tests and that we may use for future tests are IVD products intended and labeled for research use only, or RUO, or investigational use only, or IUO. An RUO product cannot be used for any human clinical purpose and must be labeled "For Research Use Only. Not for use in diagnostic procedures." RUOs are a separate regulatory category and include IVD devices that are in the laboratory research phase of development. They are therefore not subject to most FDA regulatory requirements, so long as they are properly labeled and used in accordance with such labeling. RUOs cannot be marketed with any claims, or in a manner indicating, that the device is safe, effective, or has diagnostic utility, or is intended for human clinical diagnostic or prognostic use. In November 2013, the FDA issued final guidance titled "Distribution of In Vitro Diagnostic Products Labeled for Research Use Only or Investigational Use Only" regarding the distribution, use, and labeling of IVD products labeled RUO or IUO. The FDA has advised that if evidence demonstrates that a product is inappropriately labeled for research or investigational use only, the device would be considered misbranded and adulterated within the meaning of the FDC Act. In the guidance, the FDA stated that the manufacturer's objective intent for an RUO or IUO product's intended use will be determined by examining the totality of circumstances, including advertising, instructions for clinical interpretation, presentations that describe clinical use, and specialized technical support, surrounding the distribution of the product in question.

We cannot predict the ultimate form or impact of any such RUO/IUO, LDT or other guidance and the potential effect on our solutions or materials used to perform or develop our diagnostic services. While we qualify all materials used in our diagnostic services according to CLIA regulations, we cannot be certain that the FDA might not promulgate rules or issue guidance documents that could affect our ability to purchase materials necessary for the performance of our diagnostic services. Should any of the reagents obtained by us from vendors and used in conducting our diagnostic services be affected by future regulatory actions, our business could be adversely affected by those actions, including increasing the cost of service or delaying, limiting or prohibiting the purchase of reagents necessary to perform the service.

We cannot provide any assurance that FDA premarket review or other requirements will not be imposed in the future for our diagnostic services, whether through additional guidance or regulations issued by the FDA, new enforcement policies adopted by the FDA or new legislation enacted by Congress. Legislative proposals addressing oversight of LDTs were introduced in recent years, including the Verifying Accurate Leading-edge IVCT Development (VALID) Act of 2018 in December 2018, the most recent version of which was released in July 2022, and we expect that new legislative proposals will be introduced from time to time. It is possible that legislation could be enacted into law or regulations, or guidance could be

issued by the FDA which may result in new or increased regulatory requirements for us to continue to offer our tests or to develop and introduce new tests.

If premarket review, clearance, or approval is required for the tests that we market as LDTs, our business could be negatively affected until such review is completed and clearance or approval to market is obtained, and the FDA could require that we stop selling our tests pending premarket clearance or approval. If our tests are allowed to remain on the market but there is uncertainty about the legal status of our services, if we are required by the FDA to label them investigational, or if the FDA limits the use and corresponding labeling claims, order levels may decline, and reimbursement may be adversely affected. The regulatory process may involve, among other things, successfully completing additional clinical studies and submitting to the FDA a premarket notification to obtain clearance or submitting a *De Novo* classification request or PMA to obtain approval to market the device. If clearance or approval is required by the FDA, there can be no assurance that our tests will be cleared or approved on a timely basis, if at all, nor can there be any assurance that approved labeling claims or labeling claims subject to cleared indications for use will be consistent with our current claims or adequate to support continued adoption of and reimbursement for our solutions. Ongoing compliance with FDA regulations would increase the cost of conducting our business, and subject us to heightened requirements of the FDA and penalties for failure to comply with these requirements. We may also decide voluntarily to pursue FDA premarket review of our tests to obtain marketing clearance or approval if we determine that doing so would be appropriate.

European Union Regulation of Laboratory Testing

Directive 98/79/EC

In the European Union, or EU, IVDs were previously regulated under EU-Directive 98/79/EC, or the IVDD, and corresponding national provisions.

The IVDD requires that IVDs meet certain essential requirements, which are set out in an annex of the IVDD. To demonstrate compliance with the essential requirements, IVDs must undergo a conformity assessment procedure. As a general rule, demonstration of conformity of IVDs and their manufacturers with the essential requirements must be based, among other things, on the evaluation of clinical data supporting the safety and performance of the products during normal conditions of use.

IVDs must bear the CE marking of conformity when they are placed on the market, unless a specific exemption applies. Compliance with the IVDD essential requirements is a prerequisite for a manufacturer to be able to affix a CE mark, which is a declaration by the manufacturer that the IVD meets all the appropriate requirements under the IVDD and corresponding national provisions, as applicable.

Under the IVDD, for most IVDs manufacturers used to “self-declare” the conformity of their IVDs with the essential requirements of the IVDD. For some types of IVDs listed in Annex II of the IVDD, a conformity assessment procedure required the intervention of a notified body. Notified regulatory bodies are independent organizations designated by Member States to assess the conformity with the essential requirements of medical devices, including IVDs when required, before a CE mark is affixed to the device and the device is placed on the market. The notified body would typically audit and examine the device’s technical file and the manufacturer’s quality system, though conformity with the relevant harmonized standards – which is ISO 13485:2016 for Quality Management Systems – can be used to demonstrate compliance with these requirements. If satisfied that the IVD conforms to the relevant essential requirements, the notified body issues a certificate of conformity, which the manufacturer uses as a basis for its own declaration of conformity.

In Vitro Diagnostic Medical Device Regulations (2017/746)

The EU regulatory landscape concerning medical devices and IVDs is significantly changing. The IVDD was replaced with the full implementation of the In Vitro Diagnostic Medical Device Regulations (2017/746), or IVDR, in the EU on 26 May 2022. This is, however, subject to relevant transitional periods, as amended.

The main aims of the IVDR are to standardize diagnostic procedures throughout the EU, increase reliability of diagnostic analysis and enhance patient safety. As such, IVDs will be subject to additional regulatory scrutiny once the IVDR has come into force fully.

The IVDR introduces a rule-based classification system, whereby IVDs must be classified into one of four classes: A, B, C or D. Class A is the lowest risk, and Class D is the highest. These take into account the intended purpose of the IVD and its inherent risks. The IVDR also introduces new requirements for conformity assessments. In particular, substantially more IVDs

will require the involvement of a notified body to be able to affix a CE mark to the IVD. In addition, under the IVDR there is a greater emphasis on post-market surveillance and submission of post-market performance follow-up reports.

Many LDTs, or in-house tests, were not regulated by the IVDD. However, the IVDR sets out a number of provisions that apply to such tests, and requirements that must be met in order to be able to place the test on the market in the EU. The IVDR also introduces a new classification system for companion diagnostics which are now specifically defined. Companion diagnostics have to undergo a conformity assessment by a notified body. Before it can issue a certificate of conformity, the notified body has to seek a scientific opinion from the European Medicines Agency or the relevant national competent authority on the suitability of the companion diagnostic to the medicinal product concerned.

IVDs with existing valid notified body-issued CE certificates may currently continue to place those devices on the market (if unchanged) until 27 May 2024 or until their certificate expires, whichever occurs first. However, it is estimated that 80-90% of IVDs will not qualify for this grace period because they are self-certified under the IVDD but will require the involvement of a notified body to obtain a CE mark and demonstrate compliance with the IVDR. Due to the lack of capacity on the part of EU notified regulatory bodies to deal with the volume of IVDs requiring their input, the EU Commission adopted a proposal to amend the transitional provisions of the IVDR. This proposal would extend certain transitional provisions where IVDs can continue to be placed on the market under the IVDD for a certain period of time. The applicable amended transitional periods are based on the risk class of the IVD, with higher risk IVDs needing to be fully compliant with the IVDR in a shorter time period than lower risk IVDs.

United Kingdom, or UK, Regulation of Laboratory Testing

Following the UK's departure from the EU, the IVDR will not be implemented in Great Britain (England, Scotland and Wales). The previous UK legislation that implemented the IVDD, the Medical Devices Regulations 2002 (SI 2002 No 618, as amended), or the 2002 Regulations, remains applicable. As such, the regulatory regime for IVDs in Great Britain will continue to be based on the requirements derived from the IVDD, though the UK is currently conducting a consultation on the medical device and IVD regime, including whether to align with the IVDR going forward.

Since January 1, 2021, new regulations require medical devices and IVDs to be registered with the Medicines and Healthcare products Regulatory Agency, or MHRA, before being placed on Great Britain market (but manufacturers were given a grace period of four to 12 months to comply with the new registration process). The MHRA will only register devices where the manufacturer or their UK Responsible Person has a registered place of business in the UK. As such, manufacturers based outside the UK need to appoint a UK Responsible Person that has a registered place of business in the UK to register devices with the MHRA in line with the grace periods.

In addition, a new route to market and accompanying mark, the UKCA, has been introduced to enable manufacturers to place medical devices and IVDs on the market in Great Britain. The requirements for this route to market are based on the requirements derived from EU law as currently implemented in the UK. CE marks and certificates issued by EU-designated notified regulatory bodies will continue to be valid for the Great Britain market until June 30, 2023. For medical devices, including IVDs, placed on the market in Great Britain after this period, the UKCA marking will be mandatory. In contrast, UKCA marking and certificates issued by UK notified regulatory bodies are not recognized on the EU market.

The position in Northern Ireland is different to Great Britain. The rules for placing medical devices and IVDs on the Northern Ireland market align with the rules in the EU and, as such, the IVDR will apply in Northern Ireland and will take effect in accordance with EU timeframes and transitional periods. Therefore, devices marketed in Northern Ireland will require assessment according to the EU regulatory regime. Such assessment may be conducted by an EU notified body, in which case a CE mark will be required before placing the device on the market in the EU or Northern Ireland. Alternatively, if a UK notified body conducts such assessment, a "UKNI" mark will be applied, and the device may only be placed on the market in Northern Ireland and not the EU.

Privacy and Fraud and Abuse Compliance

Health Insurance Portability and Accountability Act and State Data Privacy Laws

Under the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, the U.S. Department of Health and Human Services, or HHS, has issued regulations to protect the privacy and security of protected health information used or disclosed by covered entities, which include health care providers, such as us. HIPAA also regulates standardization of data content, codes and formats used in health care transactions and standardization of identifiers for health plans and providers. In

2009, Congress amended HIPAA through the Health Information Technology for Economic and Clinical Health Act, or HITECH. The implementing regulations of HIPAA, as amended by HITECH, were last modified in 2013 and resulted in significant changes to the privacy, security, breach notification, and enforcement requirements with which we must comply. Among these changes, covered entities are now vicariously liable for violations of HIPAA resulting from acts or omissions of their business associates where the business associate is an agent of the covered entity and was acting within the scope of its agency, regardless of whether the covered entity and business associate entered into a business associate agreement in compliance with HIPAA. Penalties for violations of HIPAA regulations include civil and criminal penalties. Additionally, HHS on January 21, 2021 and November 28, 2022 issued notices of proposed rulemaking that contain proposed modifications to the HIPAA regulations in relation to substance use disorder records as well as efforts to encourage coordination of care for patients. In the event that HHS issues final changes to the HIPAA regulations based on its proposals in the notices of proposed rulemaking, we would be required in the future to comply with the HIPAA regulations as amended.

We have developed and implemented policies and procedures designed to comply with HIPAA's privacy, security, and breach notification requirements. We may not use or disclose protected health information in any form, including electronic, written, or oral, in a manner that is not permitted under HIPAA, and we are required to implement security measures to ensure the confidentiality, integrity, and availability of the electronic protected health information that we create, receive, maintain, or transmit. While we have some flexibility in determining which security safeguards are reasonable and appropriate to implement for our operations, it nonetheless requires significant effort and expense to ensure continuing compliance with the HIPAA security rule. We are also required to comply with the administrative simplification standards under HIPAA when we conduct the electronic transactions regulated by HIPAA, including by using standard code sets and formats and standardized identifiers for health plans and providers. The requirements under HIPAA and its implementing regulations may change periodically and could have an effect on our business operations if compliance becomes substantially costlier than under current requirements.

In addition to federal privacy regulations, there are a number of state laws governing confidentiality of health information that are applicable to our business. In particular, we are subject to the California Confidentiality of Medical Information Act, which is similar to but in some ways more restrictive than the HIPAA regulations, and the California Consumer Privacy Act, or CCPA, which was enacted in California in 2018 and substantially amended and expanded thereafter, most significantly by a ballot initiative adopted in November 2020 that enacted the California Privacy Rights Act. The California Privacy Rights Act amends and substantially expands the CCPA. The CCPA, among other things, requires covered companies to provide disclosures to California consumers concerning the collection and sale of personal information, and gives such consumers the right to opt-out of certain sales of personal information. The amendments to the CCPA that were adopted by ballot initiative include provisions creating a new category of "sensitive personal information" that is subject to more stringent protections than other personal information, and new requirements regarding sharing personal information for advertising purposes. In addition, the amendments established a new California Privacy Protection Agency, which has authority both to implement and enforce the CCPA. The new agency is currently drafting implementing regulations that are expected to become effective July 1, 2023, and is anticipated to be vigorous in its enforcement actions. At the same time, other states, including Colorado and Virginia, have enacted CCPA-like laws, and other states are expected to follow suit. Monitoring the development, enactment and implementation of these laws and regulations issued pursuant to them adds to our compliance costs and we face penalties if we fail to adopt comprehensive compliance measures, including documenting the steps we have taken to comply.

EU and UK Data Protection Regime

The processing of personal data, including patients' personal health data, in the European Economic Area, or EEA, and the UK is governed by the General Data Protection Regulation, or the GDPR. The GDPR applies to any company established in the EEA and to companies established outside the EEA that process personal data in connection with the offering of goods or services to data subjects in the EEA or the monitoring of the behavior of data subjects in the EEA. The GDPR enhances data protection obligations for data controllers of personal data, including inter alia stringent requirements relating to lawful and legitimate basis and purposes for the processing of personal data, the consent of data subjects, expanded disclosures about how personal data is used, requirements to conduct privacy impact assessments for "high risk" processing, limitations on retention of personal data, appointment of data protection officers, conclusion of data processing agreements, mandatory data breach notification and "privacy by design" requirements, and creates direct obligations on service providers acting as data processors.

The GDPR also imposes strict rules on the transfer of personal data outside of the EEA to countries that do not ensure an adequate level of protection. Until recently, one such data transfer mechanism was the EU-US Privacy Shield, but the Privacy Shield was invalidated for international transfers of personal data in July 2020 by the Court of Justice of the European Union, or CJEU. Following the CJEU's decision and an executive order issued by President Biden on October 7, 2022, the European Commission on December 13, 2022 announced that it had begun the process of adopting a new adequacy decision that would permit data transfers to the United States under an updated EU-US Data Privacy Framework and attempt to address the

shortcomings of the Privacy Shield identified in the CJEU's decision. If the new adequacy decision is ultimately adopted by the European Commission, some uncertainty would remain as it is widely expected that the new adequacy decision will also be challenged before the CJEU. Separately, the CJEU upheld the validity of standard contractual clauses, or SCCs, as a legal mechanism to transfer personal data but companies relying on SCCs will, subject to additional guidance from regulators in the EEA, need to evaluate and implement supplementary measures that provide privacy protections additional to those provided under SCCs. It remains to be seen whether SCCs will remain available.

Failure to comply with the requirements of the GDPR and the related national data protection laws of the EEA Member States may result in fines up to €20 million or 4% of a company's global annual revenues for the preceding financial year, whichever is higher. Moreover, the GDPR grants data subjects the right to claim material and non-material damages resulting from infringement of the GDPR. In June 2021, the CJEU issued a ruling that expanded the scope of the "one stop shop" under the GDPR. According to the ruling, the competent authorities of EU Member States may, under certain strict conditions, bring claims to their national courts against a company for breaches of the GDPR, including unlawful cross-border processing activities, even if such company does not have an establishment in the EU member state in question and the competent authority bringing the claim is not the lead supervisory authority.

In addition, further to the UK's exit from the EU on January 31, 2020, the GDPR ceased to apply in the UK at the end of the transition period on December 31, 2020. However, as of January 1, 2021, the UK's European Union (Withdrawal) Act 2018 incorporated the GDPR (as it existed on December 31, 2020, but subject to certain UK-specific amendments) into UK law, referred to as the UK GDPR. The UK GDPR and the UK Data Protection Act 2018 set out the UK's data protection regime, which is independent from but aligned to the EU's data protection regime. Non-compliance with the UK GDPR may result in monetary penalties of up to £17.5 million or 4% of worldwide revenue, whichever is higher. With respect to transfers of personal data from the EEA to the UK, on June 28, 2021, the European Commission issued an adequacy decision in respect of the UK's data protection framework, enabling data transfers from EU member states to the UK to continue without requiring organizations to put in place contractual or other measures in order to lawfully transfer personal data between the territories. While it is intended to last for at least four years, the European Commission may unilaterally revoke the adequacy decision at any point, and, if this occurs, it could lead to additional costs and increase our overall risk exposure.

Other Privacy Laws

New laws governing privacy may be adopted in the future from time to time. We have taken steps to comply with health information privacy requirements to which we are aware that we are subject. For example, the Personal Information Protection Law, or PIPL, was recently implemented in China, and broadly regulates the processing of personal information and imposes compliance obligations and penalties comparable to those of the GDPR. However, we can provide no assurance that we are or will remain in compliance with diverse privacy requirements in all of the jurisdictions in which we do business. Failure to comply with privacy requirements could result in civil or criminal penalties, which could have a materially adverse effect on our business.

Corporate Practice of Medicine

Numerous states, including California and Texas, have enacted laws prohibiting corporations such as us from practicing medicine and employing or engaging physicians to practice medicine. These laws are designed to prevent interference in the medical decision-making process by anyone who is not a licensed physician. This prohibition is generally referred to as the prohibition against the corporate practice of medicine. Violation of this prohibition may result in civil or criminal fines, as well as sanctions imposed against us or the professional through licensing proceedings. The pathologists who review and classify thyroid FNA cytopathology results for Afirma are employed by TCP, a Texas professional association, pursuant to services agreement between us and TCP. Pursuant to the agreement, we pay TCP a monthly fee on a per FNA basis, and TCP manages and supervises the pathologists who perform the cytopathology services as a component of the Afirma solution.

Federal and State Physician Self-Referral Prohibitions

We are subject to the federal physician self-referral prohibitions, commonly known as the Stark Law, and to similar restrictions under the self-referral prohibitions of certain states in which we operate, including California's Physician Ownership and Referral Act, or PORA. Together these restrictions generally prohibit us from billing a patient or any governmental or private payer for any diagnostic services when the physician ordering the service, or any member of such physician's immediate family, has an investment interest in or compensation arrangement with us, unless the arrangement meets an exception to the prohibition.

Both the Stark Law and PORA contain an exception for compensation paid to a physician for personal services rendered by the physician meeting certain contractual requirements. We have compensation arrangements with a number of physicians for personal services, such as speaking engagements and consulting activities. We have structured these arrangements with terms intended to comply with the requirements of the personal services exception to Stark and PORA.

However, we cannot be certain that regulators would find these arrangements to be in compliance with Stark, PORA or similar state laws. We would be required to refund any payments we receive pursuant to a referral prohibited by these laws to the patient, the payer or the Medicare program, as applicable.

Sanctions for a violation of the Stark Law include the following:

- denial of payment for the services provided in violation of the prohibition;
- refunds of amounts collected by an entity in violation of the Stark Law;
- a civil penalty of up to $15,000 for each service arising out of the prohibited referral;
- possible exclusion from federal healthcare programs, including Medicare and Medicaid; and
- a civil penalty of up to $100,000 against parties that enter into a scheme to circumvent the Stark Law's prohibition.

These prohibitions apply regardless of the reasons for the financial relationship and the referral. No finding of intent to violate the Stark Law is required for a violation. In addition, knowing violations of the Stark Law may also serve as the basis for liability under the Federal False Claims Act which prohibits knowingly presenting, or causing to be presented, a false, fictitious, or fraudulent claim for payment to the U.S. Government.

Further, a violation of PORA is a misdemeanor and could result in civil penalties and criminal fines. Finally, other states have self-referral restrictions with which we have to comply that differ from those imposed by federal and California law. While we have attempted to comply with the Stark Law, PORA and similar laws of other states, it is possible that some of our financial arrangements with physicians could be subject to regulatory scrutiny at some point in the future, and we cannot provide assurance that we will be found to be in compliance with these laws following any such regulatory review.

Federal and State Anti-Kickback Laws

The federal Anti-kickback Statute makes it a felony for any person or entity, including a laboratory, to knowingly and willfully offer, pay, solicit or receive remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing, arranging for, or recommending of an item or service that is reimbursable, in whole or in part, by a federal health care program. A violation of the Anti-kickback Statute may result in imprisonment for up to ten years and criminal fines of up to $100,000. Convictions under the Anti-kickback Statute result in mandatory exclusion from federal health care programs for a minimum of five years. In addition, HHS has the authority to impose civil assessments and fines and to exclude health care providers and others engaged in prohibited activities from Medicare, Medicaid and other federal health care programs. Actions which violate the Anti-kickback Statute can also lead to liability under the Federal False Claims Act, which prohibits, among other things, knowingly presenting, or causing to be presented, a false or fraudulent claim for payment to the U.S. Government.

Although the federal Anti-kickback Statute applies only to federal health care programs, a number of states, including California, have passed statutes substantially similar to the Anti-kickback Statute pursuant to which similar types of prohibitions are made applicable to all other health plans and third-party payers. California's fee-splitting and Anti-kickback Statute, Business and Professions Code Section 650, and its Medi-Cal Anti-kickback statute, Welfare and Institutions Code Section 14107.2, have been interpreted by the California Attorney General and California courts in substantially the same way as HHS and the courts have interpreted the federal Anti-kickback Statute. A violation of Section 650 is punishable by imprisonment and fines of up to $50,000. A violation of Section 14107.2 is punishable by imprisonment and fines of up to $10,000.

Federal and state law enforcement authorities scrutinize arrangements between health care providers and potential referral sources to ensure that the arrangements are not designed as a mechanism to induce patient care referrals or induce the purchase or prescribing of particular products or services. The law enforcement authorities, the courts and Congress have also demonstrated a willingness to look behind the formalities of a transaction to determine the underlying purpose of payments between health care providers and actual or potential referral sources. Generally, courts have taken a broad interpretation of the scope of the Anti-kickback Statute, holding that the statute may be violated if merely one purpose of a payment arrangement is to induce or reward referrals or purchases.

The federal Anti-kickback Statute includes statutory exceptions and provides for a number of regulatory safe harbors. If an arrangement meets the provisions of a safe harbor, it is deemed not to violate the Anti-kickback Statute. An arrangement must fully comply with each element of an applicable safe harbor in order to qualify for protection. Many state anti-kickback statutes have analogous exceptions or safe harbors to those of the federal Anti-kickback Statute. These state anti-kickback statutes have generally been interpreted consistently with the Anti-kickback Statute.

Among the safe harbors that may be relevant to us is the discount safe harbor. The discount safe harbor potentially applies to discounts provided by providers and suppliers, including laboratories, to physicians or institutions. If the terms of the discount safe harbor are met, the discounts will not be considered prohibited remuneration under the Anti-kickback Statute. California does not have a discount safe harbor. However, as noted above, Section 650 has generally been interpreted consistent with the Anti-kickback Statute.

The personal services safe harbor to the Anti-kickback Statute provides that remuneration paid for personal services will not violate the Anti-kickback Statute provided all of the elements of that safe harbor are met. Our personal services arrangements with some physicians and other parties may not meet each requirement of this safe harbor. Failure to meet the terms of this, or any other, safe harbor does not necessarily render an arrangement illegal. Rather, the government may evaluate such arrangements on a case-by-case basis under the language of the statute, taking into account all facts and circumstances.

While we believe that we are in compliance with the Anti-kickback Statute, Section 650, and Section 14107.2, there can be no assurance that our relationships with physicians, academic institutions and other customers or parties will not be subject to investigation or challenge under such laws. If imposed for any reason, sanctions under the Anti-kickback Statute, Section 650, or Section 14107.2 could have a negative effect on our business.

Other Federal and State Fraud and Abuse Laws

In addition to the requirements discussed above, several other health care fraud and abuse laws could have an effect on our business. For example, provisions of the Social Security Act permit Medicare and Medicaid to exclude an entity that charges the federal health care programs substantially in excess of its usual charges for its services. The terms "usual charge" and "substantially in excess" are ambiguous and subject to varying interpretations, though the HHS' Office of the Inspector General, or HHS-OIG, has provided some guidance on the topic.

Further, the federal False Claims Act prohibits a person from knowingly presenting or causing to be presented a false or fraudulent claim to, making a false record or statement in order to secure payment from or retaining an overpayment by the federal government. In addition to actions initiated by the government itself, the statute authorizes actions to be brought on behalf of the federal government by a private party, known as a relator or commonly referred to as a whistleblower, having knowledge of the alleged fraud. Because the complaint is initially filed under seal, the action may be pending for some time before the defendant is even made aware of the action. If the government is ultimately successful in obtaining redress in the matter or if the relator succeeds in obtaining redress without the government's involvement, then the relator will receive a percentage of the recovery. Finally, the Social Security Act includes its own provisions that prohibit the filing of false claims or submitting false statements in order to obtain payment. Violation of these provisions may result in up to treble damages, substantial civil penalties, fines, imprisonment or combination of the above, and possible exclusion from Medicare or Medicaid programs. California has an analogous state false claims act applicable to all payers, as do many other states; however, we may not be aware of all such rules and statutes and cannot provide assurance that we will be in compliance with all such laws and regulations.

In general, in recent years U.S. Attorneys' Offices have increased scrutiny of the healthcare industry, as have Congress, the Department of Justice, the HHS-OIG and the Department of Defense. These bodies have all issued subpoenas and other requests for information to conduct investigations of, and commenced civil and criminal litigation against, healthcare companies based on financial arrangements with health care providers, regulatory compliance, product promotional practices and documentation, and coding and billing practices. Whistleblowers have filed numerous qui tam lawsuits against healthcare companies under the federal and state False Claims Acts in recent years, in part because the whistleblower can receive a portion of the government's recovery under such suits.

In addition, in October 2018, the Eliminating Kickbacks in Recovery Act of 2018, or EKRA, was enacted as part of the SUPPORT for Patients and Communities Act (P.L 115-271). This law prohibits the solicitation, receipt, payment or offering of any remuneration in return for referring a patient or patronage to a recovery home, clinical treatment facility, or laboratory for services covered by both government and private payers. EKRA also applies to the payment or offering of remuneration in

exchange for an individual using the services of a recovery home, clinical treatment facility, or laboratory. To date, neither the Department of Justice nor HHS has issued guidance further interpreting or implementing EKRA.

Finally, under the Protecting Access to Medicare Act of 2014, or PAMA, laboratories are required to report to CMS the private payer payment rates and test volumes paid by private payers based on final payments made during a specific "data collection period." This data reporting requirement is triennial for most clinical diagnostic laboratory tests (annual for ADLTs), with the first data reporting period occurring in 2017 for final payments made in January through June 2016. The next data reporting period will be in 2024 for final payments made in January through June 2019. When reporting data under PAMA, the President, CEO, or CFO of a reporting entity, or an individual who has been delegated authority to sign for, and who reports directly to, such an officer, must sign the certification statement and be responsible for assuring that the data provided are accurate, complete, and truthful, and meets all the required reporting parameters. Failure to report or misrepresentation or omission in reporting can result in civil penalties of up to $10,000 per day for each violation and other penalties. We believe we are in compliance with the PAMA reporting requirements, but there can be no assurance that our reporting practices will not be scrutinized under the PAMA regulations.

International

Many countries in which we may offer any of our tests in the future have anti-kickback regulations prohibiting providers from offering, paying, soliciting or receiving remuneration, directly or indirectly, in order to induce business that is reimbursable under any national health care program. The IVDD and IVDR prohibit the offer of inducements, particularly financial, that might influence the judgement of notified regulatory bodies and their personnel to carry out their conformity assessment activities. The IVDD and IVDR do not address the question of inducements offered to healthcare professionals or other third parties, though Member States may implement their own national laws in this regard. For example, Sapin II is the French anti-corruption law, which imposes regulations to prevent and detect bribery and corruption through increased corporate transparency, reinforced internal monitoring, and enhanced whistleblower protection. In the UK, the 2002 Regulations do not address the question of inducements offered to healthcare professionals to prescribe, sell, supply or recommend use of a particular medical device or IVD or to offer the relevant device company any other benefit. These activities are, however, prohibited by the Bribery Act 2010, which provides general offenses relating to bribery and receiving a bribe.

In addition, the largest medical device manufacturer's industry association, MedTech Europe, issues a Code of Business Practice, or the MedTech Code, which is obligatory for its member associations and member companies, and regulates their interactions with the medical community and other stakeholders. The MedTech Code prevents member companies from offering and providing educational grants to individual health care providers with certain exceptions and has phased out the provision of financial or in-kind support directly to individual health care providers to cover costs for their attendance at third-party organized educational events (with the exception of procedure training). It also sets out transparency obligations with regard to all interactions with health care providers, in terms of notification to the health care provider's superiors or relevant health institutions before the interaction may take place, disclosure of payments (made as educational grants) and a centralized platform for the approval of conferences and other events.

In situations involving physicians employed by state-funded institutions or national health care agencies, violation of the local anti-kickback law may also constitute a violation of the United States Foreign Corrupt Practices Act, or FCPA. The FCPA prohibits any U.S. individual, business entity or employee of a U.S. business entity to offer or provide, directly or through a third party, including any potential distributors we may rely on in certain markets, anything of value to a foreign government official with corrupt intent to influence an award or continuation of business or to gain an unfair advantage, whether or not such conduct violates local laws. In addition, it is illegal for a company that reports to the SEC to have false or inaccurate books or records or to fail to maintain a system of internal accounting controls. We will also be required to maintain accurate information and control over sales and distributors' activities that may fall within the purview of the FCPA, its books and records provisions and its anti-bribery provisions.

The standard of intent and knowledge in FCPA anti-bribery cases is minimal -- intent and knowledge are usually inferred from that fact that bribery took place. The accounting provisions do not require intent. Violations of the FCPA's anti-bribery provisions for corporations and other business entities are subject to a fine of up to $2 million and officers, directors, stockholders, employees, and agents are subject to a fine of up to $250,000 and imprisonment for up to five years. Other countries, including other Organisation for Economic Co-operation and Development Anti-Bribery Convention members, have similar anti-corruption regulations.

When marketing our tests outside of the United States, we may be subject to foreign regulatory requirements governing human clinical testing, prohibitions on the import of tissue necessary for us to perform our tests or restrictions on the export of

tissue imposed by countries outside of the United States or the import of tissue into the United States, and marketing approval. These requirements vary by jurisdiction, differ from those in the United States and may in some cases require us to perform additional pre-clinical or clinical testing. In many countries outside of the United States, coverage, pricing and reimbursement approvals are also required.

Teams and Culture

Our People. At December 31, 2022, we had 787 employees. None of our U.S. employees are the subject of collective bargaining arrangements, and our management considers its relationships with employees to be good.

Diversity, Inclusion, and Belonging. The Company believes in an inclusive workforce, where diverse backgrounds are represented, engaged and empowered to inspire innovative ideas and decisions. Women comprise 59% of our employees, including over half of our executive leadership team and 41% at the Vice President level and above in the United States, as of December 31, 2022. In addition, three of nine members of our Board of Directors, including our Chairwoman, are female as of December 31, 2022. Additionally, as of December 31, 2022, 50% of our U.S. employees are non-White. We strive to further advance diversity among our employees and believe that the resulting range of employee ideas, experiences and perspectives strengthens our company.

We pride ourselves on our strong culture, which encourages innovation, collaboration, and mutual respect. We were named a Bay Area “Top Workplace” by the Bay Area News Group in 2022, marking the ninth consecutive year we received this distinction. This award is based solely on employee feedback gathered through an anonymous, third-party survey. In 2022, we defined a new set of core values across the company: Patients; Innovation; Results; Collaboration; and Compassion. Individual members of our leadership team have volunteered to sponsor each aspirational value to ensure the values are embedded into our culture.

Corporate and Other information

We were incorporated in Delaware as Calderome, Inc. in August 2006. Calderome operated as an incubator until early 2008. We changed our name to Veracyte, Inc. in March 2008. Our principal executive offices are located at 6000 Shoreline Court, Suite 300, South San Francisco, California 94080, and our phone telephone number is (650) 243-6300. We completed our initial public offering in October 2013, and our common stock is listed on The Nasdaq Global Market under the symbol “VCYT.”

Our website address is www.veracyte.com. Through a link on the Investor Relations section of our website, we make available the following filings as soon as reasonably practicable after they are electronically filed with or furnished to the Securities and Exchange Commission (SEC): 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 filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act. All such filings are available free of charge. The information posted on our website is not incorporated into this report. The SEC maintains a website that contains reports, proxy and information statements and other information regarding our filings at www.sec.gov.

ITEM 1A. RISK FACTORS

Summary of Risk Factors

Investing in our common stock involves a high degree of risk. You should carefully review the "Risk Factors" section before you invest in shares of our common stock. Listed below are some of the more significant risks relating to an investment in our common stock.

Risks Related to Our Business

- We have a history of losses, and we expect to incur net losses for the foreseeable future and may never achieve or sustain profitability.
- Our financial results currently depend mainly on sales of our Afirma and Decipher Prostate tests, and we will need to generate sufficient revenue from these and our other diagnostic tests to grow our business.
- If we are unable to grow sales of our portfolio of tests including Prosigna, Envisia, and Decipher Bladder, or we are unable to launch or commercialize our new tests, our business may suffer.
- We depend on a few payers for a significant portion of our revenue and if one or more significant payers stops providing reimbursement or decreases the amount of reimbursement for our tests, our revenue could decline.
- If payers do not provide reimbursement, rescind or modify their reimbursement policies, delay payments for our tests, recoup past payments, or if we are unable to successfully negotiate additional reimbursement contracts, our commercial success could be compromised.
- We may experience limits on our revenue if physicians decide not to order our tests or if patients decide not to use our tests as a result of increased costs, fees or changing insurer policies.
- If we fail to comply with federal, state and foreign licensing requirements, we could lose the ability to perform our tests or experience disruptions to our business.
- Our quarterly operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts for various reasons, including in response to the way we recognize revenue and/or the amount of cash we generate, which may cause our stock price to fluctuate or decline.
- If our general strategy of seeking growth through acquisitions and collaborations is not successful, or if we do not successfully integrate companies or assets that we acquire into our business, our prospects and financial condition will suffer.
- Our future success and international growth depends, in part, on our ability to adapt and manufacture select tests to be performed on the nCounter Analysis System.
- The growth that we are expecting in our biopharma services business may not transpire.
- The COVID-19 pandemic has had, and may continue to have, an adverse effect on certain of our business, results of operations and financial condition.
- We rely on sole suppliers for some of the reagents, equipment, and other materials used to perform our tests, and we may not be able to find replacements or transition to alternative suppliers.
- We depend on a specialized cytopathology practice to perform the cytopathology component of our Afirma test, and our ability to perform our diagnostic solution would be harmed if we were unexpectedly unable to secure a replacement.
- We may be unable to manage our future growth effectively, which could make it difficult to execute our business strategy.
- If we are unable to support demand for our commercial tests, services or products, our business could suffer.
- Changes in healthcare policy, including legislation reforming the U.S. healthcare system, may have a material adverse effect on our financial condition and operations.
- Because of Medicare billing rules, we may not receive reimbursement for all tests provided to Medicare patients.
- If the FDA or foreign authorities were to begin regulating those of our tests that they do not currently regulate, we could incur substantial costs and delays associated with trying to obtain premarket clearance, approval or certification.

- Obtaining marketing authorization or certification by the FDA and foreign regulatory authorities or notified regulatory bodies for our diagnostic tests will take significant time and require significant research, development and clinical study expenditures and ultimately may not succeed.
- If we are unable to compete successfully, we may be unable to increase or sustain our revenue or achieve profitability.
- We depend on our senior management team, and the loss of one or more of our executive officers, or the inability to attract and retain highly-skilled employees or other key personnel could adversely affect our business.
- Billing for our diagnostic tests is complex, and we must dedicate substantial time and resources to the billing process to be paid.
- If our internal sales force is less successful than anticipated, our business expansion plans could suffer and our ability to generate revenue could be diminished.
- Developing new products involves a lengthy and complex process, and if we do not achieve our projected development and commercialization goals in the time frames we announce and expect, our business will suffer and our stock price may decline.
- We must successfully integrate the HalioDx and Decipher Biosciences businesses to realize the financial goals that we currently anticipate.
- Aspects of our international business expose us to business, personnel, regulatory, political, operational, financial, and economic risks associated with doing business outside of the United States.
- Our operating results may be adversely affected by unfavorable macroeconomic and market conditions.
- Security breaches, loss of data and other disruptions to our or our third-party service providers' data systems could compromise sensitive information related to our business or prevent us from accessing critical information and expose us to liability, which could adversely affect our business and our reputation.
- If we are unable to protect our intellectual property effectively, our business would be harmed.
- We may be involved in litigation related to intellectual property, which could be time-intensive and costly and may adversely affect our business, operating results or financial condition.

Risks Related to Being a Public Company

- If we are unable to implement and maintain effective internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our reported financial information and the market price of our common stock may be negatively affected.

Risks Related to Our Common Stock

- Our stock price may be volatile, and you may not be able to sell shares of our common stock at or above the price you paid.

Risks Related to Our Business

We have a history of losses, and we expect to incur net losses for the foreseeable future and may never achieve or sustain profitability.

We have incurred net losses since our inception. For the year ended December 31, 2022, we had a net loss of $36.6 million and as of December 31, 2022, we had an accumulated deficit of $393.7 million. We expect to incur additional losses in the future, and we may never achieve revenue sufficient to offset our expenses. We have experienced and may continue to experience decreases in total test volume due to the impact of COVID-19, including as a result of additional COVID-19 variants. Additionally, in 2022, widespread inflationary pressures in the U.S. and across global economies resulted in higher costs for our raw materials, non-material costs, labor and other business costs, and significant increases in the future could adversely affect our results of operations. We expect to continue to devote substantially all of our resources to increase adoption of and reimbursement for our molecular diagnostic portfolio of tests, and the development of additional tests. We may never achieve or sustain profitability, and our failure to achieve and sustain profitability in the future could cause the market price of our common stock to decline.

Our financial results currently depend mainly on sales of our Afirma and Decipher Prostate tests, and we will need to generate sufficient revenue from these and our other diagnostic tests to grow our business.

Most of our revenue to date has been derived from the sale of our Afirma tests, which are used in the diagnosis of thyroid cancer. We also derive significant revenue from our Decipher urological tests. Over the next few years, we expect to continue to derive a substantial portion of our revenue from sales of our Afirma and Decipher tests. Once tests are clinically validated and commercially available for patient testing, we must continue to develop and publish evidence that our tests are informing clinical decisions in order for them to receive positive coverage decisions by payers. Without coverage policies, our tests may not be reimbursed and we will not be able to recognize revenue. We cannot guarantee that tests we commercialize will gain and maintain positive coverage decisions and therefore, we may never realize revenue from tests we commercialize. In addition, we are in various stages of research and development for other diagnostic tests that we may offer, but there can be no assurance that we will be able to identify other diseases that can be effectively addressed or, if we are able to identify such diseases, whether or when we will be able to successfully commercialize solutions for these diseases and obtain the evidence and coverage decisions from payers. If we are unable to increase sales and expand reimbursement for our Afirma and Decipher Prostate tests, or develop and commercialize other tests, our revenue and our ability to achieve and sustain profitability would be impaired, and the market price of our common stock could decline.

If we are unable to grow sales of our portfolio of tests including Prosigna, Envisia, and Decipher Bladder, or we are unable to launch or commercialize our new tests, our business may suffer.

Although Prosigna, Envisia, and Decipher Bladder have not contributed significant revenue to date, we expect them to grow and become an increasingly important component of our strategic focus, as well as our results of operations. We plan to introduce new tests going forward as well. There can be no assurance that we will be successful in our launch or commercialization of new tests, nor that physicians will request our new tests be performed in sufficient volumes for our revenue to meet our projections. Additionally, we anticipate expanding the reach of our tests to international markets through the distribution of the nCounter Analysis System; if our distribution of this platform is unsuccessful, or if our products are not widely adopted internationally, our business and results of operations may be adversely affected.

We depend on a few payers for a significant portion of our revenue and if one or more significant payers stops providing reimbursement or decreases the amount of reimbursement for our tests, our revenue could decline.

Federal Medicare funding and state budgets are limited and have been placed under tremendous strain in recent years, which is likely to be further exacerbated as a result of reduced tax receipts and greater deficit spending as a result of the COVID-19 pandemic. Such budgetary pressures may force Medicare or state agencies to reduce payment rates or change coverage policies. If there is a decrease in Medicare or other payers' payment rates for our tests, our revenue from Medicare and such payers will decrease and the payment rates for some of our commercial payers may also decrease if they tie their allowable rates to the Medicare rates. These changes could have an adverse effect on our business, financial condition and results of operations.

Revenue for tests performed on patients covered by Medicare and UnitedHealthcare Group was 31% and 10%, respectively, of our revenue for the year ended December 31, 2022, compared with 30% and 10%, respectively, for the year ended December 31, 2021. The percentage of our revenue derived from significant payers is expected to fluctuate from period to period as our revenue fluctuates, as additional payers provide reimbursement for our tests or if one or more payers were to stop reimbursing for our tests or change their reimbursed amounts. Effective January 2012, Palmetto GBA, the regional Medicare Administrative Contractor, or MAC, that handled claims processing for Medicare services over our jurisdiction at that time, issued coverage and payment determinations for our Afirma Classifiers now covered by Noridian Healthcare Solutions, the current MAC for our jurisdiction, through the MolDX program, administered by Palmetto GBA, under an LCD.

On March 1, 2015, CPT code 81545 for the Afirma GEC was issued. On January 1, 2018, the Medicare Clinical Laboratory Fee Schedule payment rate for the Afirma classifier increased from $3,220 to $3,600. This rate is based on the volume-weighted median of private payer payment rates made between January 1 and June 30, 2016, which we reported to the Centers for Medicare & Medicaid Services in 2017 as required under the Protecting Access to Medicare Act of 2014, or PAMA. In December 2019, through the Further Consolidated Appropriations Act of 2020, Congress delayed the next data reporting period from 2020 to 2021 for final payments made between January 1 and June 30, 2019, extending the applicability of the payment rates based on 2017 reporting by one year through December 31, 2021. In March 2020, through the CARES Act, Congress further delayed the next reporting period to 2022 for final payments made between January 1 and June 30, 2019,

extending the applicability for the payment rates based on 2017 reporting through December 31, 2022. In December 2021, through the Protecting Medicare and American Farmers from Sequester Cuts Act, Congress further delayed the next reporting period to 2023. In December 2022, through the Consolidated Appropriations Act of 2023, Congress further delayed the next reporting period to 2024. As a result of the transition from Afirma GEC to Afirma GSC, a new CPT Category I code (81546) was established for the Afirma classifier, effective January 1, 2021. This code went through the national payment determination process for Medicare in 2020, through which CMS priced 81546 at the same rate of $3,600 as 81545. Since the Afirma GSC code 81546 was newly issued in 2021, the first PAMA data collection period for 81546 under the current triennial data collection and reporting process would be January 2026 through June 2026. There is no guarantee that the Afirma GSC Medicare rate will not be negatively impacted starting in 2028 based on the reported weighted median of private commercial payers.

Decipher Prostate Biopsy and Decipher Prostate RP are currently reimbursed by Medicare pursuant to LCDs issued by Palmetto GBA and adopted by Noridian Healthcare Solutions, each acting as a MAC, as well as by a number of commercial payers. However, there are many commercial payers who currently do not provide reimbursement for our prostate genomic tests, or provide only limited reimbursement, and we have contracts for reimbursement with only a limited number of commercial payers for our prostate tests. Our Decipher Prostate tests were assigned a new American Medical Association Current Procedural Terminology code, or CPT code, 81542, for 2020. CPT code changes can result in a risk of an error being made in the claim adjudication process. Such errors can occur with claims submission, third-party transmission or in the processing of the claim by the payer. Claim adjudication errors may result in a delay in payment processing or a reduction in the amount of the payment we receive.

We submit claims to Medicare for Decipher Prostate Biopsy and Decipher Prostate RP using CPT code 81542. CMS assigned 81542 to the gapfilling process in 2020, under which the individual MACs set the payment rate for the test based on the following four factors: 1) charges for the test and routine discounts to charges; 2) resources required to perform the test; 3) payment amounts determined by other payers; and 4) charges, payment amounts, and resources required for other tests that may be comparable or otherwise relevant. 81542 has been priced at $3,873 since January 1, 2021, based on CMS' revision of the median of payment rates set by the MACs through the gapfilling process. There can be no assurance that the Medicare payment rates for Decipher Prostate Biopsy and Decipher Prostate RP will not decrease during a future reporting cycle under PAMA.

An LCD was issued for Prosigna by Palmetto GBA in August 2015, which has been in effect since October 1, 2015. There can be no assurance that the Prosigna payment rate will not decrease during subsequent reporting cycles under PAMA.

Noridian Healthcare Solutions provided Medicare coverage for the Envisia Genomic Classifier on April 11, 2019.

We submit claims to Medicare for Envisia using CPT code 81554, which became effective January 1, 2021. We applied for New ADLT designation for Envisia, and the test was approved as a New ADLT on September 17, 2020. Effective October 1, 2020 through June 30, 2021, the Medicare payment rate for Envisia was set at $5,500, the actual list charge as defined under the ADLT regulations for the test. Veracyte reported private payer rates for Envisia in March 2021, reflecting final payments between October 1, 2020 and February 28, 2021. The volume-weighted median of these reported rates, which was $5,500, set the payment rate for Envisia from July 1, 2021 through December 31, 2022, after which Envisia will be priced based on private payer rates collected and reported annually. Effective January 1, 2023, the Medicare payment rate for 81554 is $5,520. There can be no assurance that the Medicare payment rate for Envisia will not be reduced when it is set based on the volume-weighted median of private payer rates when we are required to report private payer rates for Envisia under PAMA in subsequent reporting cycles.

Effective July 18, 2021, Decipher Bladder is reimbursed by Medicare pursuant to LCDs issued by three MACs and Decipher Bladder is covered by a fourth MAC, Noridian Healthcare Solutions, effective as of July 25, 2021. We have not yet contracted with any commercial payers for reimbursement of Decipher Bladder. Our Decipher Bladder test was assigned a new CPT code, 0016M, for 2020.

We will submit claims to Medicare for Decipher Bladder using CPT code 0016M. CMS assigned 0016M to the gapfilling process in 2021. Since January 1, 2022, the payment rate for 0016M has been $3,489.63, based on the median of payment rates set by the AMCs through the gapfilling process. There is no assurance that the Medicare payment rate for Decipher Bladder will not decrease during a future reporting cycle under PAMA.

Although we have entered into contracts with certain third-party payers that establish in-network allowable rates of reimbursement for many of our tests, payers may suspend or discontinue reimbursement at any time, with or without notice, for technical or other reasons, may require or increase co-payments from patients, or may reduce the reimbursement rates paid to us. Reductions in private payer amounts could decrease the Medicare payment rates for our tests under PAMA. In addition, private payers have begun requiring prior authorization for molecular diagnostic tests. Potential reductions in reimbursement rates or increases in the difficulty of achieving payment could have a negative effect on our revenue.

If payers do not provide reimbursement, rescind or modify their reimbursement policies, delay payments for our tests, recoup past payments, or if we are unable to successfully negotiate additional reimbursement contracts, our commercial success could be compromised.

Physicians might not order our tests unless payers reimburse a substantial portion of the test price. There is significant uncertainty concerning third-party reimbursement of any test incorporating new technology, including our tests. Reimbursement by a payer may depend on a number of factors, including a payer's determination that these tests are:

- not experimental or investigational;
- pre-authorized and appropriate for the specific patient;
- cost-effective;
- supported by peer-reviewed publications; and
- included in clinical practice guidelines.

Since each payer makes its own decision as to whether to establish a coverage policy or enter into a contract to reimburse our tests, seeking these approvals is a time-consuming and costly process.

We are an out-of-network provider with some commercial payers in the U.S. and thus, we do not have control over rates or terms of reimbursement. Without contracted rates for reimbursement, our claims are often denied upon submission, and we must appeal the claims. The appeals process is time consuming and expensive and may not result in payment. In cases where we are out-of-network, there is typically a greater patient cost-share responsibility which may result in further delays and/or decreased likelihood of collection. Payers may attempt to recoup prior payments after review, sometimes after significant time has passed, which would impact future revenue.

We expect to continue to focus substantial resources on increasing adoption, coverage and reimbursement for the Afirma, Decipher Prostate, Prosigna, Envisia and Decipher Bladder and any other future tests we may develop. We believe it will take several years to achieve coverage and contracted reimbursement with a majority of third-party payers. We cannot predict whether, under what circumstances, or at what payment levels payers will reimburse for our tests. Also, payer consolidation is underway and creates uncertainty as to whether coverage and contracts with existing payers will remain in effect. Finally, if there is a decrease in the Medicare payment rates for our tests, the payment rates for some of our commercial payers may also decrease if they tie their allowable rates to the Medicare rates. Reductions in private payer amounts could decrease the Medicare payment rates for our tests under PAMA. Our failure to establish broad adoption of and reimbursement for our tests, or our inability to maintain existing reimbursement from payers, will negatively impact our ability to generate revenue and achieve profitability, as well as our future prospects and our business.

We may experience limits on our revenue if physicians decide not to order our tests.

If we are unable to create or maintain demand for our tests in sufficient volume, we may not become profitable. To generate demand, we will need to continue to educate physicians about the clinical utility and cost-effectiveness of our tests through published papers, presentations at scientific conferences, marketing campaigns and one-on-one education by our sales force. In addition, our ability to obtain and maintain adequate reimbursement from third-party payers will be critical to generating revenue. Moreover, certain patients have been deferring elective procedures and medical visits as a result of the COVID-19 pandemic, and we have experienced, and expect to continue to experience, a reduction in patient demand or physician recommendations, which has and may continue to adversely affect our business.

The Afirma genomic classifier is included in most physician practice guidelines in the United States for the assessment of patients with thyroid nodules. However, historical practice recommended a full or partial thyroidectomy in cases where cytopathology results were indeterminate to confirm a diagnosis.

The strength of the clinical data supporting the use of the Decipher Prostate Biopsy and Decipher Prostate RP tests have led to the tests' inclusion in national guidelines. For example, in the 2020 NCCN Practice Guidelines for Prostate Cancer, the Decipher Prostate RP test is "recommended" for use to improve therapy decision making. It is the only test to achieve this designation for post-surgery patients with localized prostate cancer. Further, in September 2021, the 2022 NCCN guidelines were released and recommend specific treatment decisions for patients based on their Decipher Prostate RP score. Subsequently, Decipher also received a "Level 1" evidence designation in the NCCN's update to the 2023 prostate cancer guidelines.

Although Decipher Prostate Biopsy and Decipher Prostate RP have been integrated into the NCCN guidelines, if we are unsuccessful in maintaining and increasing the level of recommendation of our genomic tests within these guidelines, are unable to cause any new genomic tests we develop to be included in these guidelines, are unable to cause our genomic tests to be included in other influential guidelines, or if our competitors are successful at achieving similar or more extensive guidelines for their tests, we may be at a disadvantage in gaining market acceptance and market share relative to our competitors.

Our lung products are not yet integrated into practice guidelines and physicians may be reluctant to order tests that are not recommended in these guidelines. The Prosigna test is included in practice guidelines in the United States and internationally but faces competition from other products globally.

Because our Afirma, Decipher Prostate Biopsy, Decipher Prostate RP, Envisia, and Decipher Bladder testing services are performed by our certified laboratories under the Clinical Laboratory Improvement Amendments of 1988, or CLIA, rather than by the local laboratory or pathology practice, pathologists may be reluctant to support our testing services as well. Guidelines that include our tests currently may subsequently be revised to recommend another testing protocol, and these changes may result in physicians deciding not to use our tests. Lack of guideline inclusion could limit the adoption of our tests and our ability to generate revenue and achieve profitability. To the extent international markets have existing practices and standards of care that are different than those in the United States, we may face challenges with the adoption of our tests in international markets.

We may experience limits on our revenue if patients decide not to use our tests as a result of increased costs, fees or changing insurer policies.

Some patients may decide not to use our tests because of price, all or part of which may be payable directly by the patient if the patient's insurer denies reimbursement in full or in part. There is a growing trend among insurers to shift more of the cost of healthcare to patients in the form of higher co-payments or premiums, and this trend is accelerating which puts patients in the position of having to pay more for our tests. In addition, rising interest rates and ongoing inflation in the U.S. and globally may put further pressure on insurers and other providers to raise prices or reduce reimbursement, increasing the cost to the patient. We expect to continue to see pressure from payers to limit the utilization of tests, generally, and we believe more payers are deploying costs containment tactics, such as pre-authorization and employing laboratory benefit managers to reduce utilization rates. Implementation of provisions of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, collectively the ACA, has also resulted in increases in premiums and reductions in coverage for some patients. These events may result in patients delaying or forgoing medical checkups or treatment due to their inability to pay for our tests, which could have an adverse effect on our revenue. Many patients have been deferring elective procedures and medical visits as a result of the COVID-19 pandemic, and we have experienced, and may continue to experience, a significant reduction in patient demand, which has and may continue to adversely affect our business.

If we fail to comply with federal and state licensing requirements, we could lose the ability to perform our tests or experience disruptions to our business.

We are subject to CLIA, 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. CLIA regulations mandate specific personnel qualifications, facilities administration, quality systems, inspections, and proficiency testing. CLIA certification is also required for us to be eligible to bill state and federal healthcare programs, as well as many private third-party payers. To renew these certifications, we are subject to survey and inspection every two years. Moreover, CLIA inspectors may conduct random inspections of our clinical reference laboratories. If we fail to maintain CLIA certificates in our

South San Francisco, California, San Diego, California, Austin, Texas or Richmond, Virginia laboratory locations, we would be unable to bill for services provided by state and federal healthcare programs, as well as many private third-party payers, which may have an adverse effect on our business, financial condition and results of operations.

We are also required to maintain state licenses to conduct testing in our laboratories. California, New York, and Texas, among other states' laws, require that we maintain a license and comply with state regulation as a clinical laboratory. Other states may have similar requirements or may adopt similar requirements in the future. In addition, all of our clinical laboratories are required to be licensed on a test-specific basis by New York. We have received approval for the Afirma, Decipher Prostate, Envisia and Decipher Bladder tests. We will be required to obtain approval for other tests we may offer in the future. If we were to lose our CLIA certificate or California license for our South San Francisco or San Diego laboratories, whether as a result of revocation, suspension, limitation or otherwise, we would no longer be able to perform our molecular tests, which would eliminate our primary source of revenue and harm our business. If we fail to meet the state licensing requirements for our Austin laboratory, whether as a result of revocation, suspension, limitation or otherwise, it could result in a delay in processing tests during that transition and increased costs. If we were to lose our licenses issued by New York or by other states where we are required to hold licenses, we would not be able to test specimens from those states. New tests we may develop may be subject to new approvals by regulatory bodies such as the New York State Department of Health, and we may not be able to offer our new tests until such approvals are received.

Our quarterly operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts for various reasons, including in response to the way we recognize revenue and/or the amount of cash we generate, which may cause our stock price to fluctuate or decline.

Our quarterly financial and operating results depend on sales of our products in the markets we operate and are sensitive to a number of factors, including patient and clinician demand, market conditions in the US and globally, and the prevalence of the indications we seek to address. In addition, we cannot be sure that we will be able to successfully complete development of or commercialize any of our planned future products, or that they will prove to be capable of reliably being used. Before we can successfully develop and commercialize any of our currently planned or other new diagnostic solutions, we will need to:

- conduct substantial research and development;
- obtain the necessary testing samples and related data;
- conduct analytical and clinical validation studies, as well as clinical utility studies;
- expend significant funds;
- expand and scale-up our laboratory processes;
- expand and train our sales force;
- gain acceptance from ordering clinicians at a larger number of hospitals;
- gain acceptance from ordering laboratories; and
- seek and obtain regulatory clearances, approvals or certifications of our new solutions, as required by applicable regulatory bodies.

This process involves a high degree of risk and may take up to several years or more. Our test development and commercialization efforts may be delayed or fail for many reasons, including:

- failure of the test at the research or development stage;
- difficulty in accessing suitable testing samples, especially testing samples with known clinical results;
- lack of analytical and clinical validation data to support the effectiveness of the test, or lack of clinical utility data to support the value of the test;
- delays resulting from the failure of third-party suppliers or contractors to meet their obligations in a timely and cost-effective manner;
- failure to obtain or maintain necessary clearances, approvals or certifications to market the test;
- manufacturing constraints due to limited energy supply in Europe or other supply constraints; or
- lack of commercial acceptance by patients, clinicians or third-party payers.

Few research and development projects result in commercial products, and success in early clinical studies often is not replicated in later studies. At any point, we may abandon development of new diagnostic tests, or we may be required to expend considerable resources repeating clinical studies, which would adversely impact the timing for generating potential revenue from those new diagnostic tests. In addition, as we develop diagnostic tests, we will have to make additional investments in our sales and marketing operations, which may be prematurely or unnecessarily incurred if the commercial launch of a test is abandoned or delayed. If a clinical validation study fails to demonstrate the prospectively defined endpoints of the study, we would likely abandon the development of the test or test feature that was the subject of the clinical study, which could harm our business. If a clinical utility study fails to demonstrate the value of a particular test, we may not be able to obtain reimbursement for the test.

In addition, we recognize test revenue upon delivery of the patient report to the prescribing physician based on the amount we expect to ultimately realize. We determine the amount we expect to ultimately realize based on payer reimbursement history, contracts, and coverage. Upon ultimate collection, the amount received is compared to the estimates and the amount accrued is adjusted accordingly. We cannot be certain as to when we will receive payment for our diagnostic tests, and we must appeal negative payment decisions, which delays collections. Should judgments underlying estimated reimbursement change or be incorrect at the time we accrued such revenue, our financial results could be negatively impacted in future quarters. Furthermore, most of our European sales are denominated in Euros, and as the U.S. dollar has strengthened in recent periods relative to the Euro, our results of operations may be adversely affected even where our underlying business is performing as anticipated. As a result, comparing our operating results on a period-to-period basis may not be meaningful. You should not rely on our past results as an indication of our future performance. In addition, these fluctuations in revenue may make it difficult for us, for securities analysts and for investors to accurately forecast our revenue and operating results. If our revenue or operating results fall below expectations, the price of our common stock would likely decline.

If our general strategy of seeking growth through acquisitions and collaborations is not successful, or if we do not successfully integrate companies or assets that we acquire into our business, our prospects and financial condition will suffer.

As an element of our growth strategy, we may pursue opportunities to license assets or purchase companies or assets that we believe would complement our current business or help us expand into new markets. For example, we acquired the nCounter Analysis System and Prosigna test from NanoString; we also acquired Decipher Biosciences and HalioDx. We may pursue additional acquisitions of complementary businesses or assets as part of our business strategy. There can be no assurance that we will successfully integrate the assets acquired from such acquisitions into our existing business, in general, or that our exclusive worldwide license to the nCounter Analysis System for in vitro diagnostic use granted by NanoString will allow us to expand our international reach as anticipated. This and any future acquisitions made by us also could result in significant write-offs or the incurrence of debt and contingent liabilities, any of which could harm our operating results. Integration of acquired companies or businesses we may acquire in the future also may require management resources that otherwise would be available for ongoing development of our existing business. We may not identify or complete these transactions in a timely manner, on a cost-effective basis, or at all, and we may not realize the anticipated benefits of any acquisition, technology license, strategic alliance, joint venture or investment.

To finance any acquisitions or investments, we have previously issued and may choose in the future to issue shares of our stock as consideration, which would dilute the ownership of our stockholders. If the price of our common stock is low or volatile, we may not be able to acquire other companies for stock. Alternatively, it may be necessary for us to raise additional funds for these activities through public or private financings. Additional funds may not be available on terms that are favorable to us, or at all. If these funds are raised through the sale of equity or convertible debt securities, dilution to our stockholders could result.

Our future success and international growth depends, in part, on our ability to adapt and manufacture select tests to be performed on the nCounter Analysis System.

Our strategy to expand into international markets depends on our ability to successfully acquire and distribute the nCounter Analysis System, adapt our menu of diagnostic tests for the platform, and secure necessary regulatory approvals. Currently, the Prosigna breast cancer assay is the only commercially-available test on the platform. If we are not able to adapt our other current or future genetic tests to be performed on the nCounter Analysis System, or if the nCounter Analysis System fails to be competitive against other diagnostic platforms, our prospects for growth could suffer. In addition, to the extent

international markets have existing practices and standards of care that are different than those in the United States, we may face challenges with the adoption of the nCounter Analysis System in international markets.

The growth that we are expecting in our biopharma services business may not transpire.

We have previously entered into technology licensing and collaboration arrangements, such as our collaborations with Johnson & Johnson in December 2018, with Acerta Pharma, the hematology research and development arm of AstraZeneca, in December 2019 and with CareDx in May 2020, which reflect an important element of our business strategy. With the acquisition of Decipher Biosciences and HalioDx, we continue to seek to expand the range of our biopharma services offerings to pharmaceutical partners with services such as clinically relevant biomarker identification, patient stratification for clinical trials, and development of companion diagnostics. The success of our biopharma services business depends in part on our ability to identify and successfully negotiate with appropriate pharma partners. We cannot guarantee that we will be successful in the identification of appropriate pharma partners or the successful and timely negotiation with such partners.

The COVID-19 pandemic has had, and may continue to have, an adverse effect on certain of our business, results of operations and financial condition.

The COVID-19 pandemic and the ongoing emergence of new variants has caused, and continues to cause, significant volatility in global financial markets. Public health problems resulting from COVID-19 and precautionary measures instituted by governments and businesses to mitigate its spread, including travel restrictions and quarantines, have contributed to a general slowdown in the global economy, adversely impacted patients, physicians, customers, suppliers, third-party contract manufacturers, and collaboration partners, and disrupted our operations. The global COVID-19 pandemic continues to evolve. Certain jurisdictions have begun re-opening only to return to restrictions due to increases in new COVID-19 cases and the emergence of new variant strains of COVID-19. Changes in our operations in response to COVID-19 or employee illnesses resulting from the pandemic may result in inefficiencies or delays, including in sales and product development efforts, timing to receive patient sample shipments and additional costs related to business continuity initiatives, that cannot be fully mitigated through succession planning, employees working remotely or teleconferencing technologies. To date, the FDA has approved several vaccines, certain of which are subject to an Emergency Use Authorization, or EUA, for certain uses. Although vaccines are increasingly available in the United States and Europe, and certain countries in South America, Asia and Oceania, there can be no guarantee that the vaccines will be effective against new strains of the virus or that the vaccines will be broadly accepted. Also there can be no guarantee that federal, state, local and foreign agencies will not continue to take other cautionary steps to combat the virus to reduce the incidence of new cases, which could negatively impact our volumes and revenue and limit our ability to reliably forecast our test volumes and levels of revenue.

COVID-19 and related governmental reactions have had and may continue to have a negative impact on our business, liquidity, results of operations, and stock price due to the occurrence of some or all of the following events or circumstances among others:

- Inability of healthcare providers to deliver anticipated total test volumes due to temporary or permanent staff attrition.
- We may not be able to manage our business effectively due to key employees becoming ill, working from home inefficiently and being unable to travel to our facilities.
- We and our customers, suppliers, third-party contract manufacturers, and collaboration partners may be prevented from operating worksites, including manufacturing facilities, due to employee illness, reluctance to appear at work or “stay-at-home” regulations.
- Interruptions in manufacturing (including the sourcing of reagents or supplies) and shipment of our products. We believe the rapid increase in daily testing volumes is consuming reagents and supplies otherwise available to genomic testing companies like ours across the United States. When not limited by the expiration date of products and when we feel it reasonable and feasible to do so, we are taking steps to increase our level of supplies and inventory reserves, to develop alternative sources of supply and to implement procedures to mitigate the impact on our supply chain or our ability to process samples in our laboratories. Though we are in regular contact with our key suppliers, we do not have, nor expect to have, the necessary insight into our vendors’ supply chain issues that we may need to know to effectively mitigate the impact to our business. Though we attempt to mitigate the impact to our business, these interruptions in manufacturing (including the sourcing of reagents or supplies) may negatively impact our total test volumes or levels of revenue.

- Reduced patient demand for, or provider capacity to deliver, diagnostic testing and elective procedures generally (which may impact our ability to deliver to our revenue estimates).
- Disruptions of the operations of our third-party contract manufacturers and suppliers, which could impact our ability to purchase components at efficient prices and in sufficient amounts.
- We may need to raise capital, and if we raise capital by issuing equity securities, our common stock may be diluted.
- The market price of our common stock may drop or remain volatile.
- We may incur significant employee health care costs under our insurance programs.
- Inability or delay of regulatory bodies to conduct inspections/surveys, review or clear/approve our regulatory filings and submissions, and perform other activities necessary for us to conduct our business.

The extent of the impact of COVID-19 on our business and financial results will depend largely on future developments, including the deployment, efficacy, availability and utilization of vaccines, the emergence of new variant strains of COVID-19, the impact on capital and financial markets and the related impact on the financial circumstances of patients, physicians, suppliers, third-party contract manufacturers, and collaboration partners, all of which are highly uncertain and cannot be predicted. This situation is changing rapidly, and additional impacts may arise that we are not aware of at this time.

We rely on sole suppliers for some of the reagents, equipment and other materials used to perform our tests, and we may not be able to find replacements or transition to alternative suppliers.

We rely on sole suppliers for critical supply of reagents, equipment and other materials and services that we use to perform our tests, for the manufacture of the nCounter Analysis System for diagnostic use and Prosigna test kits sold to customers. We also purchase components used in our sample collection kits from sole-source suppliers. Some of these items are unique to these suppliers and vendors.

We rely on NanoString for the supply of the nCounter Analysis System for diagnostic use and Prosigna test kits. As part of the HalioDx Acquisition we intended to, and have begun to migrate manufacture of the test kits for the nCounter from NanoString to HalioDx. In the future, we may need to transition the manufacture of the nCounter Analysis System for diagnostic use from NanoString to Veracyte. While we are preparing for such transition, we cannot be certain that we will be successful in effectively manufacturing the system or acquiring or retaining the talent, skillset, or suppliers required to manufacture the system.

While we have developed alternate sourcing strategies for these materials and vendors, we cannot be certain whether these strategies will be effective or the alternative sources will be available when we need them. Moreover, the supply of key reagents and testing materials has been severely challenged by the COVID-19 pandemic. Periodically, as a result of the COVID-19 pandemic and other challenges to global supply chains, we experienced supply chain disruptions in the supply of plastic materials used in the processing of samples, although this has not resulted in delays in our ability to timely return test results. If suppliers can no longer provide us with the materials we need to perform the tests and for our sample collection kits, if the materials do not meet our quality specifications or are otherwise unusable, if we cannot obtain acceptable substitute materials, or if we elect to change suppliers, an interruption in test processing or system and test kit deliveries could occur, we may not be able to deliver tests to physicians or deliver patient reports and we may incur higher one-time switching costs. Carriers responsible for transporting samples to us are currently operating at lower than usual capacity because of COVID-19, causing delays in the timeliness of our receipt of samples. Any such interruption may significantly affect our future revenue, cause us to incur higher costs, and harm our customer relationships and reputation. In addition, in order to mitigate these risks, we maintain inventories of these supplies at higher levels than would be the case if multiple sources of supplies were available. If our total test volume decreases or we switch suppliers, we may hold excess supplies with expiration dates that occur before use which would adversely affect our losses and cash flow position. As we introduce any new test, we may experience supply issues as we ramp test volume. Moreover, the COVID-19 pandemic has disrupted supply chains globally, and could adversely affect our ability to source essential reagents, equipment and other materials in a timely manner or at all.

We depend on a specialized cytopathology practice to perform the cytopathology component of our Afirma test, and our ability to perform our diagnostic solution would be harmed if we were unexpectedly unable to secure a replacement.

We rely on TCP to provide cytopathology professional diagnoses on thyroid FNA samples pursuant to a pathology services agreement. Pursuant to this agreement, as amended, TCP has the exclusive right to provide our cytopathology diagnoses on FNA samples at a fixed price per test. Until February 2019, TCP also previously subleased a portion of our

facility in Austin, Texas. Our agreement with TCP is effective through October 31, 2023, and automatically renews every year unless either party provides notice of intent not to renew at least 12 months prior to the end of the then-current term.

If TCP were unexpectedly unable to support our current test volume or future increases in total test volume or to provide the quality of services we require, or if we were unable to agree on commercial terms and our relationship with TCP were to terminate, our business could be harmed until we were able to secure the services of another cytopathology provider. There can be no assurance that we would be successful in finding a replacement that would be able to conduct cytopathology diagnoses at the same volume or with the same high-quality results as TCP. Locating another suitable cytopathology provider could be time consuming and would result in delays in processing Afirma tests until a replacement was fully integrated with our test processing operations.

We may be unable to manage our future growth effectively, which could make it difficult to execute our business strategy.

In addition to the need to scale our testing capacity, future growth, including our transition to a multi-product company with international operations, will impose significant added responsibilities on management, including the need to identify, recruit, train and integrate additional employees with the necessary skills to support the growing complexities of our business. Rapid and significant growth may place strain on our administrative, financial and operational infrastructure. Our ability to manage our business and growth will require us to continue to improve our operational, financial and management controls, reporting systems and procedures. We have implemented an internally-developed data warehouse, which is critical to our ability to track our diagnostic services and patient reports delivered to physicians, as well as to support our financial reporting systems. The time and resources required to optimize these systems is uncertain, and failure to complete optimization in a timely and efficient manner could adversely affect our operations. If we are unable to manage our growth effectively, it may be difficult for us to execute our business strategy and our business could be harmed.

If we are unable to support demand for our commercial tests, services or products, our business could suffer.

As demand for our tests, services and products grow, we will need to continue to scale our capacity, processing technology, expand customer service, billing and systems processes, enhance our internal quality assurance program and expand our manufacturing capacity. We will also need additional certified laboratory scientists as well as other scientific and technical personnel to process higher volumes. We cannot assure you that any increases in scale, related improvements and quality assurance will be successfully implemented or that appropriate personnel will be available and able to be hired. Failure to implement necessary procedures, transition to new processes or hire the necessary personnel could result in higher costs of processing tests, quality control issues or inability to meet demand. There can be no assurance that we will be able to perform our testing or fulfill our product, testing, or service commitments on a timely basis at a level consistent with demand, or that our efforts to scale our operations will not negatively affect the quality of test results. If we encounter difficulty meeting market demand or quality standards, our reputation could be harmed and our future prospects and our business could suffer.

Changes in healthcare policy, including legislation reforming the U.S. healthcare system, may have a material adverse effect on our financial condition and operations.

The ACA, enacted in March 2010, made changes that significantly affected the pharmaceutical and medical device industries and clinical laboratories. Along with the now-repealed 2.3% excise tax on the sale of certain medical devices sold outside of the retail setting, other significant measures contained in the ACA include, for example, coordination and promotion of research on comparative clinical effectiveness of different technologies and procedures, initiatives to revise Medicare payment methodologies, such as bundling of payments across the continuum of care by providers and physicians, and initiatives to promote quality indicators in payment methodologies. The ACA also includes significant new fraud and abuse measures, including required disclosures of financial arrangements with physician customers, lower thresholds for violations and increasing potential penalties for such violations. In addition, various efforts to amend the ACA are ongoing. We cannot predict if, or when, the ACA will be amended, and cannot predict the impact that an amendment of the ACA will have on our business.

In addition to the ACA, various healthcare reform proposals have also periodically emerged from federal and state governments. For example, in February 2012, Congress passed the Middle Class Tax Relief and Job Creation Act of 2012, which in part reset the clinical laboratory payment rates on the Medicare Clinical Laboratory Fee Schedule, or CLFS, by 2% in 2013. In addition, under the Budget Control Act of 2011, which is effective for dates of service on or after April 1, 2013, Medicare payments, including payments to clinical laboratories, are subject to a reduction of 2% due to the automatic expense reductions (sequester) until fiscal year 2024. In March 2020, Congress passed the CARES Act, which suspended the 2%

reduction in Medicare fee-for-service payments from May 1, 2020 through December 31, 2020. To account for this temporary suspension, the legislation also extends the effect of sequestration by a year (now through fiscal year 2031). Reductions resulting from the Congressional sequester are applied to total claims payment made; however, they do not currently result in a rebasing of the negotiated or established Medicare or Medicaid reimbursement rates. In December 2020, Congress passed the Consolidated Appropriations Act of 2021, or CAA, which extended the suspension through March 31, 2021. Legislation enacted April 14, 2021 further extended the suspension through December 31, 2021. The Protecting Medicare and American Farmers from Sequester Cuts Act, enacted on December 10, 2021, extends the suspension through March 31, 2022, after which a 1.0% sequestration would apply for Medicare payments made between April 1, 2022 and June 30, 2022. The legislation also applies a 2.25% sequestration to Medicare payments made during the first six months of fiscal year 2030, and a 3% reduction to payments made during the last six months of fiscal year 2030.

State legislation on reimbursement applies to Medicaid reimbursement and managed Medicaid reimbursement rates within that state. Some states have passed or proposed legislation that would revise the reimbursement methodology for clinical laboratory payment rates under those Medicaid programs. For example, effective July 2015, California's Department of Health Care Services implemented a new rate methodology for clinical laboratories and laboratory services. This methodology involved the use of a range of rates that fell between zero and 80% of the calculated California-specific Medicare rate and the calculation of a weighted average (based on units billed) of such rates. Effective for dates of service on or after July 1, 2022, the cap at 80% of the Medicare rate has been replaced with a cap at 100% of the lowest maximum allowance established by the federal Medicare program for the same or similar services.

We cannot predict whether future healthcare initiatives will be implemented at the federal or state level or in countries outside of the United States in which we do or may do business, or the effect any future legislation or regulation will have on us. The taxes imposed by the new federal legislation, cost reduction measures and the expansion in the role of the U.S. government in the healthcare industry may result in decreased revenue, lower reimbursement by payers for our tests or reduced medical procedure volumes, all of which may adversely affect our business, financial condition and results of operations. In addition, sales of our tests outside the United States subject our business to foreign regulatory requirements and cost-reduction measures, which may also change over time.

Ongoing calls for deficit reduction at the federal government level and reforms to programs such as the Medicare program to pay for such reductions may affect the pharmaceutical, medical device and clinical laboratory industries. Currently, clinical laboratory services are excluded from the Medicare Part B co-insurance and co-payment as preventative services. Any requirement for clinical laboratories to collect co-payments from patients may increase our costs and reduce the amount ultimately collected.

CMS bundles payments for clinical laboratory diagnostic tests together with other services performed during hospital outpatient visits under the Hospital Outpatient Prospective Payment System. CMS currently maintains an exemption for molecular pathology tests and "Criterion A" ADLTs from this bundling provision. It is possible that this exemption could be removed by CMS in future rule making, which might result in lower reimbursement for tests performed in this setting.

PAMA includes a substantial new payment system for clinical laboratory tests under the CLFS. Under PAMA, laboratories that receive the majority of their Medicare revenue from payments made under the CLFS and the Physician Fee Schedule would report on a triennial basis (or annually for ADLTs), private payer rates and volumes for their tests with specific CPT codes based on final payments made during a set data collection period (the first of which was January 1 through June 30, 2016). We believe that PAMA and its implementing regulations are generally favorable to us. We reported to CMS the data required under PAMA before the March 31, 2017 deadline. The new payment rate for the Afirma genomic classifier based on the volume-weighted median of private payer rates took effect January 1, 2018, increasing from $3,220 to $3,600 through December 31, 2020. In December 2019, through the Further Consolidated Appropriations Act of 2020, Congress delayed the next data reporting period from 2020 to 2021 for final payments made between January 1 and June 30, 2019, extending the applicability of the current rate for Afirma through December 31, 2021. In March 2020, through the CARES Act, Congress further delayed the next reporting period to 2022 for final payments made between January 1 and June 30, 2019, extending the applicability of the payment rates based on 2017 reporting through December 31, 2022. In December 2021, through the Protecting Medicare and American Farmers from Sequester Cuts Act, Congress further delayed the next reporting period to 2023. In December 2022, through the Consolidated Appropriations Act of 2023, Congress further delayed the next reporting period to 2024. There can be no assurance that the payment rate for Afirma or Prosigna will not decrease in the future or that the payment rates for Decipher Prostate Biopsy, Decipher Prostate RP or Decipher Bladder will not be adversely affected by the PAMA law and regulations.

Our Envisia classifier was approved by CMS as a New ADLT on September 17, 2020. The initial payment rate (for a period not to exceed nine months) under PAMA for a New ADLT (an ADLT for which payment has not been made under the CLFS prior to January 1, 2018) will be set at the "actual list charge" for the test as reported by the laboratory. Effective July 1, 2021, Envisia is priced based on private payer rates collected and reported annually. We can determine whether to seek ADLT status for our tests, but there can be no assurance that our tests will be designated ADLTs or that the payment rates for our tests, including Envisia, will not be adversely affected by such designation.

There have also been substantial changes to the payment structure for physicians, including those passed as part of the Medicare Access and CHIP Reauthorization Act of 2015, or MACRA, which was signed into law on April 16, 2015. MACRA created the Merit-Based Incentive Payment System which, beginning in 2019, more closely aligns physician payments with composite performance on performance metrics similar to three existing incentive programs (i.e., the Physician Quality Reporting System, the Value-based modifier program and the Electronic Health Record Meaningful Use program) and incentivizes physicians to enroll in alternative payment methods. At this time, we do not know whether these changes to the physician payment systems will have any impact on orders or payments for our tests.

In December 2016, Congress passed the 21st Century Cures Act, which, among other things, revised the process for LCDs. Additionally, effective June 11, 2017, a MAC is required to, among other things, publish a summary of the evidence that it considered when developing an LCD, including a list of sources, and an explanation of the rationale that supports the MAC's determinations. In October 2018, CMS issued additional guidance revising the requirements for the development of LCDs. We cannot predict whether these revisions will delay future LCDs and result in impeded coverage for our test products, which could have a material negative impact on revenue.

In December 2020, in its enactment of the CAA, Congress enacted the No Surprises Act. This law, which takes effect January 1, 2022, prohibits an out-of-network provider from billing a patient at an amount in excess of the in-network cost sharing for services furnished with respect to a visit at certain in-network health-care facilities. The law establishes an independent dispute resolution process between the provider and the payer to determine the appropriate payment rate to the provider. As written, the No Surprises Act may apply to laboratory tests furnished by an independent laboratory with respect to a hospital visit. The law establishes a notice and consent exception that generally does not apply to laboratory tests, although it allows for the Secretary of the Department of Health and Human Services, or HHS, to apply the exception to certain advanced tests. HHS, the Department of Labor, and the Department of the Treasury have implemented the No Surprises Act through rulemakings issued on July 1, 2021, September 30, 2021, and August 19, 2022. The No Surprises Act, and regulations and subregulatory guidance promulgated thereunder, could limit our ability to achieve payment in full for our testing services.

Because of Medicare billing rules, we may not receive reimbursement for all tests provided to Medicare patients.

Under previous Medicare billing rules, hospitals were required to bill for our molecular pathology tests when performed on Medicare beneficiaries who were hospital outpatients at the time of tissue specimen collection when these tests were ordered less than 14 days following the date of the patient's discharge.

Effective January 1, 2018, CMS revised its billing rules to allow the performing laboratory to bill Medicare directly for molecular pathology tests and Criterion A ADLTs performed on specimens collected from hospital outpatients, even when those tests are ordered less than 14 days after the date of discharge, if certain conditions are met. We believe that our Afirma, Decipher Prostate Biopsy, Decipher Prostate RP, Envisia, and Decipher Bladder classifiers, along with Prosigna, should be covered by this policy. Accordingly, we bill Medicare for these tests when we perform them on specimens collected from hospital outpatients and meet the conditions set forth in CMS's revised billing rules.

This change does not apply to tests performed on specimens collected from hospital inpatients. We will continue to bill hospitals for tests performed on specimens collected from hospital inpatients when the test was ordered less than 14 days after the date of discharge.

In the CY 2020 Hospital Outpatient Prospective Payment System Proposed Rule, CMS solicited comments on potential revisions to these billing rules that could have impacted our ability to bill Medicare directly for our Afirma, Decipher Prostate Biopsy, Decipher Prostate RP, Envisia, and Decipher Bladder classifiers, as well as for Prosigna, when performed on specimens collected from hospital outpatients. Although these changes were not finalized, if CMS makes similar changes in the future, it could negatively impact our business.

In addition, we must maintain CLIA compliance and certification to sell our tests and be eligible to bill for diagnostic services provided to Medicare beneficiaries.

If the FDA or foreign authorities were to begin regulating those of our tests that they do not currently regulate, we could incur substantial costs and delays associated with trying to obtain premarket clearance, approval or certification.

Clinical laboratory tests have long been subject to comprehensive regulations under CLIA, as well as by applicable state laws. Most clinical diagnostic tests developed and run within a single CLIA-certified clinical laboratory (known as “laboratory developed tests” or “LDTs”), are not currently subject to regulation under the FDA's enforcement discretion policy concerning LDTs. While the FDA maintains its authority to regulate LDTs, it continues to exercise enforcement discretion not to enforce the premarket review, quality system/current Good Manufacturing Practices regulations, and other applicable medical device requirements against most LDT developers and users. Certain reagents, instruments, software or components manufactured and sold by third parties and used by their customers to manufacture or perform diagnostic tests may be subject to regulation under certain circumstances. We believe that the Afirma, Decipher Prostate Biopsy, Decipher Prostate RP, Envisia, and Decipher Bladder classifiers, have been developed and are performed in a manner consistent with FDA’s enforcement discretion policy concerning LDTs.

In October 2014, the FDA issued two draft guidance documents stating that the FDA intended to modify its policy of enforcement discretion with respect to LDTs in a risk-based manner consistent with the existing classification of medical devices. Although the FDA halted finalization of the guidance in November 2016 to allow for further public discussion on an appropriate oversight approach to LDTs and to give Congressional authorizing committees the opportunity to develop a legislative solution, it is unclear if Congress or the FDA will modify the current approach to the regulation of LDTs in a way that would subject our current or future services marketed as LDTs to FDA regulatory requirements. The FDA Commissioner and the Director of the Center for Devices and Radiological Health, or CDRH, have expressed significant concerns regarding disparities between some LDTs and in vitro diagnostics that have been reviewed, cleared, authorized or approved by the FDA. If the FDA were to determine that Afirma, Decipher Prostate Biopsy, Decipher Prostate RP, Envisia and Decipher Bladder classifiers are not within the scope of FDA's enforcement discretion policy for LDTs for any reason, including new rules, policies or guidance, or due to changes in statute, our tests may become subject to extensive FDA requirements, or our business may otherwise be adversely affected. If the FDA were to disagree with our LDT status or modify its approach to regulating LDTs, we could experience reduced revenue or increased costs, which could adversely affect our business, prospects, results of operations and financial condition.

In March 2017, a draft bill on the regulation of LDTs, entitled "The Diagnostics Accuracy and Innovation Act", or DAIA, was released for discussion. In December 2018, the sponsors of DAIA released a new version of the legislation called the “Verifying Accurate, Leading-edge IVCT Development Act", or VALID Act. The VALID Act proposes a risk-based approach to regulate LDTs and creates a new in vitro clinical test category, which includes LDTs, and a new regulatory structure under the FDA. Similar versions of the VALID Act have since been introduced. The most recent version was included in the Food and Drug Administration (FDA) Safety and Landmark Advancements Act (FDASLA) reported to the Senate on July 13, 2022. As proposed, the bill would create a precertification program for lower risk tests not otherwise required to go through premarket review. It would grandfather certain existing tests from some requirements but would allow the FDA to subject otherwise grandfathered tests to premarket review under certain conditions. Similarly, the Verified Innovative Testing in American Laboratories (VITAL) Act was introduced in December 2020 and re-introduced in May 2021. In contrast with the VALID Act, the VITAL Act would prevent FDA from regulating LDTs and would instead assign regulatory authority over LDTs entirely to CMS. We cannot predict whether either of these or other draft bills governing LDTs will become legislation and cannot quantify the effect of such draft bills on our business.

In addition, changes in the way the European Union, or EU, regulates LDTs could result in additional expenses for offering our current and any future tests or possibly delay or suspend development, or commercialization of such tests. The EU Regulation (EU) 2017/746 of April 5, 2017, repealing the IVDD, referred to as the IVD Medical Devices Regulation, or IVDR, became applicable on May 26, 2022 (subject to certain transition provisions). Under the IVDR, the general safety and performance requirements set out in Annex I are also applicable to devices that are not placed on the market but used in the context of a commercial activity. If our tests do not qualify for an exemption, we may be subject to the full application of the IVDR with respect to some or all of our existing, as well as future, tests, and we would be required to expend additional time and resources to complying with the requirements of the IVDR. Following Brexit, the IVDR will not be applicable in Great Britain (although it will apply in Northern Ireland), but the UK government is currently undertaking a consultation on the

regime applicable to in vitro diagnostics in the UK, and it is anticipated that similar provisions will be introduced as under the IVDR.

If the FDA or foreign authorities were to require us to seek clearance, approval or certification for our existing tests that are not currently cleared, approved, or certified or any of our future products for clinical use, we may not be able to obtain such clearances, approvals or certifications on a timely basis, or at all. While it is possible that our Afirma, Decipher Prostate Biopsy, Decipher Prostate RP, Envisia, and Decipher Bladder classifiers, would be "grandfathered" and therefore exempted from some new regulatory requirements, there can be no assurance of what the FDA might ultimately require if it issues a rule or if legislative reforms are enacted. If premarket reviews or certifications are required, our business could be negatively impacted if we are required to stop selling our products pending their clearance, approval or certification. In addition, the launch of any new products that we develop or modifications we make to existing products could be delayed by the implementation of future FDA or foreign regulations. The cost of complying with premarket review or certification requirements, including obtaining clinical data, could be significant. In addition, any future regulation by the FDA or foreign authorities could subject our business to further regulatory risks and costs. For example, our sample collection kits are listed as Class I devices with the FDA. If the FDA were to determine that they are not Class I devices or otherwise not exempt from 510(k) clearance requirements, we would be required to file 510(k) premarket notifications and obtain FDA clearance to use the containers, which could be time consuming and expensive.

The FDA has raised potential concerns where companies manufacture and label finished clinical test kits or clinical testing components as "research use only", or RUO, or "investigational use only", or IUO, and either knowingly use them or sell them for use in patient care. The FDA has taken the position that if evidence demonstrates that a product which otherwise meets the definition of a regulated medical device is inappropriately labeled as RUO or IUO, the distribution, sale, or use of the product could violate the misbranding or adulteration provisions of the Federal Food, Drug, and Cosmetic Act, or the FDC Act. In the EU, under the IVDD, RUO products which are intended to be used for research purposes, without any medical objective, are not regarded as devices for performance evaluation used in diagnostic procedures. More importantly, the IVDR expressly provides that products intended for RUO are excluded from the scope of the regulation. A material intended for RUO, without any medical purpose or objective, is therefore not considered as an IVD MD and is not subject to compliance with the IVD MDs requirements. Depending on the product in question, other regulations may be applicable to the RUO products. Some of the reagents, instruments, software or components obtained by us from suppliers for use in our products are currently labeled by those suppliers as "RUO" or "IUO". If the FDA or foreign bodies were to determine that any of these reagents, instruments, software or components are improperly labeled as RUO or IUO and undertake enforcement actions, some of our suppliers might cease selling these reagents, instruments, software or components to us or be forced to recall them, and any failure to obtain an acceptable substitute could significantly and adversely affect our business, financial condition and results of operations, including increasing the cost of testing or delaying, limiting or prohibiting the purchase of reagents, instruments, software or components necessary to perform testing. Such actions could also lead FDA to investigate our purchase and use of supplier products and for the Agency to question whether or not Veracyte has violated the FDC Act.

Failure to comply with applicable regulatory requirements of the FDA or foreign authorities could result in enforcement action, including receiving untitled or warning letters, fines, injunctions, or civil or criminal penalties. Any such enforcement action would have a material adverse effect on our business, financial condition and operations.

Obtaining marketing authorization or certification by the FDA and foreign regulatory authorities or notified regulatory bodies for our diagnostic tests will take significant time and require significant research, development and clinical study expenditures and ultimately may not succeed.

Before we begin to label and market some of our products for use as clinical diagnostics in the United States, unless an exemption applies, we are required to obtain clearance from the FDA by submitting a premarket notification under section 510(k) of the FDC Act or 510(k), or approval from the FDA by submitting a premarket approval, or PMA. Alternatively, we may be able to obtain marketing authorization through a *De Novo* classification process rather than through a PMA for class I or class II devices if the 510(k) pathway is not available. In September 2013, Prosigna was granted FDA 510(k) clearance as a prognostic indicator for distant recurrence-free survival at ten years in post-menopausal women with Stage I/II lymph node-negative or Stage II lymph node-positive (1-3 positive nodes), hormone receptor-positive breast cancer to be treated with adjuvant endocrine therapy alone, when used in conjunction with other clinicopathological factors after they have undergone surgery in conjunction with locoregional treatment and consistent with the standard of care.

The FDA issued guidance titled "In Vitro Companion Diagnostic Devices" that defined an IVD companion diagnostic device as an in vitro diagnostic device that provides information that is essential for the safe and effective use of a corresponding therapeutic product. The use of an IVD companion diagnostic device with a therapeutic product is stipulated in the instructions for use in the labeling of both the diagnostic device and the corresponding therapeutic product, including the labeling of any generic equivalents of the therapeutic product. The FDA stated that an IVD companion diagnostic should be submitted for review and cleared or approved through an appropriate device submission contemporaneously with the review and approval of the therapeutic product to facilitate concurrent review. The FDA guidance also stated that while there may be cases when a companion diagnostic could come to market through the 510(k) pathway, the FDA expects that most companion diagnostics will be Class III devices. An IVD diagnostic device that is not a companion diagnostic device, because it is not essential for the safe and effective use of a corresponding therapeutic product, may still be beneficial for use with a therapeutic product, but may not be identified in the labeling of the therapeutic product. It is possible that revenue from a cleared or approved beneficial or complementary IVD diagnostic device may be less than revenue from a cleared or approved IVD companion diagnostic device.

The FDA issued another draft guidance in December 2018 specific to oncology companion diagnostic tests, which it finalized in April 2020. The guidance explained that some oncology companion diagnostic tests can be developed in a way that results in labeling for a specific group of oncology therapeutic products, rather than a single therapeutic product. However, there is no assurance that we would be able to obtain clearance or approval for any of our diagnostic devices in development as a companion diagnostic device or that any such clearance or approval will occur without significant delay.

Any marketing authorization we obtain for any future device product would be subject to regulatory requirements that would affect how we are able to market and sell the device. The FDC Act and FDA regulations place considerable requirements on medical devices, including, but not limited to, compliance with the quality system regulation, or QSR, establishment registration and product listing with the FDA, and compliance with labeling, marketing, complaint handling, medical device reporting requirements, and reporting certain corrections and removals. Obtaining FDA clearance or approval for diagnostics can be expensive and uncertain, generally may take several months to several years, and generally requires detailed and comprehensive scientific and clinical data, as well as compliance with FDA regulations for investigational devices. In addition, we have limited experience in obtaining PMA, 510(k) clearance, or De Novo authorization approval from the FDA and are therefore supplementing our operational capabilities to manage the more complex processes needed to obtain and maintain marketing authorization. Notwithstanding the expense, these efforts may never result in FDA clearance or approval. Even if we were to obtain marketing authorization, it may not be for the uses we believe are important or commercially attractive, in which case we would not market our product for those uses.

Sales of our diagnostic tests outside the United States are subject to foreign regulatory requirements governing clinical studies, vigilance reporting, marketing approval, manufacturing, regulatory inspections, product licensing, pricing and reimbursement. These regulatory requirements vary greatly from country to country. As a result, the time required to obtain approvals or certifications outside the United States may differ from that required to obtain FDA marketing authorization, and we may not be able to obtain foreign regulatory approvals on a timely basis or at all. Marketing authorization from the FDA does not ensure approval or certification by regulatory authorities in other countries, and approval or certification by any foreign regulatory authority does not ensure marketing authorization or certifications by regulatory authorities in other countries or by the FDA. Foreign regulatory authorities could require additional testing beyond what the FDA requires. In addition, the FDC Act imposes requirements on the export of medical devices, such as labeling requirements, and foreign governments impose requirements on the import of medical devices from the United States. Failure to comply with these regulatory requirements or to obtain required approvals, clearances, and export certifications could impair our ability to commercialize our diagnostic products outside of the United States.

For instance, in order to sell some of our products in the EU, those products must comply with the General Safety and Performance Requirements of the IVDR. Compliance with these requirements is a prerequisite to place IVD products on the EU market. All medical devices placed on the market in the EU must meet the General Safety and Performance Requirements laid down in Annex I to the IVDR, including the requirement that an IVD MD must be designed and manufactured in such a way that it will not compromise the clinical condition or safety of patients, or the safety and health of users and others. In addition, the device must achieve the performances intended by the manufacturer and be designed, manufactured, and packaged in a suitable manner. To demonstrate compliance with the General Safety and Performance Requirements we must undergo a conformity assessment procedure, which varies according to the type of medical device and its (risk) classification. As a general rule, demonstration of conformity of IVD MDs and their manufacturers with the essential requirements must be based, among other things, on the evaluation of clinical data supporting the safety and performance of the products during normal conditions

of use. Specifically, a manufacturer must demonstrate that the device achieves its intended performance during normal conditions of use, that the known and foreseeable risks, and any adverse events, are minimized and acceptable when weighed against the benefits of its intended performance, and that any claims made about the performance and safety of the device are supported by suitable evidence.

The EU regulatory landscape concerning medical devices has significantly changed, and the new IVDR governing IVD MDs became applicable on May 26, 2022 (subject to certain transitional provisions meaning that were such transitional provisions apply, the products can continue to be placed on the market under the IVDD for a certain period of time). The new requirements in the IVDR have a significant effect on the way we conduct our business in the EU and the EEA. In particularly, substantially more IVDs require the involvement of a notified body to be able to affix a CE Mark to the product, which may lead to delay in being able to place such products on the market.

On April 5, 2017, the IVDR was adopted to establish a modernized and more robust EU legislative framework, with the aim of ensuring better protection of public health and patient safety. Unlike directives, the IVDR does not need to be transposed into national law and therefore reduces the risk of discrepancies in interpretation across the different European markets. The IVDR increases the regulatory requirements applicable to IVD MDs in the EU and would require that we re-classify and obtain new certificates of conformity for our existing CE-marked IVD MDs by May 25, 2022, unless a transitional provision applies to the product, meaning that where such transitional provisions apply, the products can continue to be placed on the market under the IVDD for a certain period of time. For most IVD MDs, the manufacturer used to self-declare the conformity of its products with the essential requirements of the IVDD. Under the IVDR, the majority of IVD MDs require now the intervention of a notified body for conformity assessment. Notified bodies are independent organizations designated by EU member states to assess the conformity of devices before being placed on the market. The notified body audits and examines the product's technical documentation and the manufacturer's quality system. If satisfied that the relevant product conforms to the General Safety and Performance Requirements, the notified body issues a certificate of conformity. The manufacturer may then apply the CE Mark to the device, which allows the device to be placed on the market throughout the EU. If we fail to remain in compliance with applicable EU laws and directives, we would be unable to continue to affix the CE mark to our products, which would prevent us from selling them within the EU and European Economic Area, or EEA (which consists of the 27 EU member states plus Norway, Liechtenstein and Iceland).

The IVDR will not be implemented in Great Britain, and since January 1, 2021, the Medicines and Healthcare products Regulatory Agency, or MHRA, has become the sovereign regulatory authority responsible for the Great Britain (i.e., England, Wales and Scotland) medical device market according to the requirements provided in the Medical Devices Regulations 2002 (SI 2002 No 618, as amended). The UK regulation implemented the three pre-existing EU directives, including the IVDD. Following the end of the Brexit transitional period on January 1, 2021, new regulations require medical devices to be registered with the MHRA before being placed on the Great Britain market. The MHRA only registers devices where the manufacturer or their United Kingdom, or UK, Responsible Person has a registered place of business in the UK. Manufacturers based outside the UK need to appoint a UK Responsible Person that has a registered place of business in the UK to register devices with the MHRA. By July 1, 2023, in Great Britain, all medical devices will require a UK Conformity Assessed, or UKCA, mark but CE marks issued by EU notified regulatory bodies will remain valid until this time. Manufacturers may choose to use the UKCA mark on a voluntary basis until June 30, 2023.

For the time being, the regulatory regime for medical devices and IVD MDs in Great Britain (England, Scotland and Wales) continues to be based on the requirements derived from current EU legislation. An MHRA public consultation was opened until end of November 2021 on the post-Brexit regulatory framework for medical devices and diagnostics. The MHRA seeks to amend the UK Medical Devices Regulations 2002, in particular to create a new access pathway to support innovation, create an innovative framework for regulating software and artificial intelligence as medical devices, reform IVD MD regulation, and foster sustainability through the reuse and remanufacture of medical devices. The regime is expected to come into force in July 2023, coinciding with the end of the acceptance period for EU CE marks in Great Britain, subject to appropriate transitional arrangements. The consultation indicated that the MHRA will publish guidance in relation to the changes to the regulatory framework and may rely more heavily on guidance to add flexibility to the regime.

Subject to the outcome of the MHRA public consultation on the post-Brexit regulatory framework for medical devices and diagnostics, the UK may choose to retain regulatory flexibility or align with the EU Medical Devices Regulation and the IVDR going forward. EU CE markings will continue to be recognized in the UK, and certificates issued by EU-registered notified regulatory bodies will be valid in the UK, until June 30, 2023. For medical devices, including IVD MDs, placed on the

market in Great Britain after this period, the UKCA marking will be mandatory. In contrast, UKCA marking and certificates issued by UK notified regulatory bodies are not recognized on the EU market.

The rules for placing medical devices on the Northern Ireland market differ from those in Great Britain, and the IVDR will apply in Northern Ireland. Under the terms of the Northern Ireland Protocol of the Withdrawal Agreement between the EU and UK, Northern Ireland follows EU rules on medical devices, including the IVDR when applicable. Therefore, devices marketed in Northern Ireland will require assessment according to the EU regulatory regime. Such assessment may be conducted by an EU notified body, in which case a CE mark is required before placing the device on the market in the EU or Northern Ireland. Alternatively, if a UK notified body conducts such assessment, a 'UKNI' mark is applied and the device may only be placed on the market in Northern Ireland and not the EU.

A mutual recognition agreement (MRA) aligning in vitro diagnostic (IVD) regulations between the European Union and Switzerland has officially expired following the In Vitro Diagnostic Medical Devices Regulation's (IVDR) May 26, 2022 date of application, impacting certification and authorized representation requirements for manufacturers. The Swiss government has issued its own Ordinance on In Vitro Diagnostic Medical Devices (IvDO). The Swiss regulation aligns closely with the IVDR in terms of requirements for manufacturers, and follows the IVDR's transitional timelines regarding compliance deadlines according to IVD risk classifications as well as designations of Swiss Authorized Representatives.

These modifications may have an effect on the way we intend to conduct our business in these countries.

If we are unable to obtain marketing authorizations or certifications, approvals, clearances or certifications to market Prosigna or our other assays on the nCounter Analysis System in additional countries or if regulatory limitations are placed on our diagnostic kit products, our business and growth will be harmed.

The FDA cleared the Prosigna test for marketing in the United States. Prosigna is CE marked which permits us to market the test in the EU and Prosigna received marketing authorizations in selected other jurisdictions. We intend to seek regulatory authorizations or certifications for Prosigna in other jurisdictions and, potentially, for other indications.

In addition, pursuant to our collaborations with pharmaceutical companies for the development of companion diagnostic tests for use with their drugs, we are responsible for obtaining regulatory authorizations or certifications to use the companion diagnostic tests in clinical studies as well as the authorizations or certifications to sell the companion diagnostic tests following completion of such studies. Some of the compensation we expect to receive pursuant to these collaborations is based on the receipt of authorizations or certifications. Any failure to obtain authorizations or certifications for our diagnostic kits in a particular jurisdiction may also reduce sales of the nCounter Analysis System for clinical use in that jurisdiction, as the lack of a robust menu of available diagnostic tests would make those systems less attractive to testing laboratories.

In the EU, the IVDR has introduced a new classification system for companion diagnostics which are now specifically defined as a device which is essential for the safe and effective use of a corresponding medicinal product to: (a) identify, before and/or during treatment, patients who are most likely to benefit from the corresponding medicinal product; or (b) identify, before and/or during treatment, patients likely to be at increased risk of serious adverse reactions as a result of treatment with the corresponding medicinal product. Companion diagnostics have to undergo a conformity assessment by a notified body. Before it can issue a certificate of conformity, the notified body will have to seek a scientific opinion from the European Medicines Agency or the relevant national competent authority on the suitability of the companion diagnostic to the medicinal product concerned.

We cannot assure investors that we will be successful in obtaining or maintaining regulatory clearances, certifications, approvals, or marketing authorizations. If we do not obtain or maintain regulatory clearances, certifications, approvals, or marketing authorizations for future diagnostic kit products or expand future indications for diagnostic purposes, if additional regulatory limitations are placed on our diagnostic kit products or if we fail to successfully commercialize such products, the market potential for our diagnostic kit products would be constrained, and our business and growth prospects would be adversely affected.

We are subject to ongoing and increasingly extensive regulatory requirements, which may be subject to change, and our failure to comply with these requirements could substantially harm our business.

Certain of our products are regulated as IVD MDs, including Prosigna and the nCounter Analysis System. Accordingly, we and certain of our contract manufacturers are subject to ongoing International Organization for Standardization, or ISO, obligations as well as requirements under CLIA and state laboratory quality statutes and regulations, the FDC Act and related FDA regulations, and other statutory and regulatory requirements enforced by other government authorities. These may include routine inspections by notified bodies, FDA, CMS, and other health authorities, of our manufacturing facilities and our records for compliance with standards such as ISO 13485 and the QSR, which establish extensive requirements for quality assurance and control as well as manufacturing and change control procedures, among other things. These inspections may include the manufacturing facilities of any suppliers. In the event that a supplier fails to maintain compliance with regulatory or our quality requirements, we may have to qualify a new supplier and could experience manufacturing delays as a result. We are also subject to other regulatory obligations, such as registration of our company offices and facilities and the listing of our devices with the FDA (and similar listings and certifications in certain other countries); continued adverse event and malfunction reporting; reporting certain corrections and removals; and labeling and promotional requirements.

The IVDR increases the regulatory requirements applicable to in vitro diagnostics in the EU and would require that we re-classify and obtain new certificates of conformity for our existing CE-marked IVD products by May 25, 2022, unless a transitional provision applies to the product. Failure to secure these re-certifications in time will halt our ability to commercialize our products in relevant countries. Currently Prosigna is our only test that will require recertification. Moreover, complying with the stricter regulatory requirements of the IVDR, including with respect to clinical evaluation requirements, quality systems, and post-market surveillance, may require us to incur significant expenditures. Failure to meet these requirements could adversely impact our business in the EU and EEA and other regions that tie their product registrations or regulations to the EU requirements.

The IVDR became applicable five years after publication on May 26, 2022 and once applicable to a particular product, the IVDR will among other things:

- strengthen the rules on placing devices on the market and reinforce surveillance once they are available;
- establish explicit provisions on manufacturers' responsibilities for the follow-up of the quality, performance and safety of devices placed on the market;
- establish explicit provisions on importers' and distributors' obligations and responsibilities;
- impose an obligation to identify a responsible person who is ultimately responsible for all aspects of compliance with the requirements of the new regulation;
- improve the traceability of medical devices throughout the supply chain to the end-user or patient through the introduction of a unique identification number, to increase the ability of manufacturers and regulatory authorities to trace specific devices through the supply chain and to facilitate the prompt and efficient recall of medical devices that have been found to present a safety risk;
- set up a central database (Eudamed) to provide patients, healthcare professionals and the public with comprehensive information on products available in the EU;
- establish recourse for damage caused by a defective device; and
- strengthen rules for the assessment of certain high-risk devices that may have to undergo an additional check by experts before they are placed on the market.

Other regulatory bodies may also issue guidelines and regulations that could impact the development of our products, including companion diagnostic tests. For example, the European Medicines Agency recently launched an initiative to determine guidelines for the use of genomic biomarkers in the development and lifecycle of drugs. The guidelines may impose greater requirements for demonstrating the clinical validity and utility of our biomarker-based tests and may interfere with our ability to develop companion diagnostics or otherwise obtain or maintain marketing authorization or certifications for our diagnostic tests.

We may also be subject to additional FDA or foreign regulatory authority post-marketing obligations or requirements by the FDA or foreign regulatory authority to change our current product classifications which would impose additional regulatory obligations on us. For example, FDA has issued a proposed rule to revise the QSR to more closely align with ISO 13485:2016

but that also includes proposed clarifications and additional definitions and requirements. The promotional claims we can make for Prosigna in the United States are limited to the indications for use as cleared by the FDA or outside the United States as authorized or certified by the applicable regulatory authority. If we are not able to maintain regulatory compliance, we may not be permitted to market our medical device products and/or may be subject to enforcement actions by the FDA or other governmental authorities such as the issuance of warning or untitled letters, fines, injunctions, and civil penalties; recall or seizure of products; operating restrictions; and criminal prosecution. In addition, we may be subject to similar regulatory regimes of foreign jurisdictions as we continue to commercialize our products in new markets outside of the United States and Europe. Adverse notified body, EU competent authority or FDA or global regulatory authority action in any of these areas could significantly increase our expenses and limit our revenue and profitability.

If we are unable to compete successfully, we may be unable to increase or sustain our revenue or achieve profitability.

For our Afirma genomic classifier we face competition from companies and academic institutions that use next generation sequencing technology or other methods to measure mutational markers such as BRAF and KRAS, along with numerous other mutations. These organizations include, Interpace Diagnostics Group, Inc., CBLPath, Inc./University of Pittsburgh Medical Center and others who are developing new products or technologies that may compete with our tests. In the future, we may also face competition from companies developing new products or technologies.

Our Decipher Prostate test faces competition from Myriad Genetics and MDx Health, which offer genomic testing for prognostic purposes within localized prostate cancer. Additionally, traditional methods used by pathologists and clinicians to estimate risk of disease progression pose competitive threats to our business in addition to new technologies such as artificial intelligence and digital pathology. In bladder cancer, we are not currently aware of a direct competitor offering genomic testing for prognostic purposes that match the intended use population for the Decipher Bladder test. However, DNA mutational analysis and traditional clinical methods and nomograms are currently in use by physicians for similar purposes.

We believe our primary competition in pulmonology with our Envisia classifiers will similarly come from traditional methods used by physicians to diagnose the related diseases. For the Percepta Nasal Swab test, we expect competition from companies focused on lung cancer such as Biodesix, Inc. We believe our principal competitor in the breast cancer diagnostics market is Exact Sciences, Inc., which currently commands a substantial majority of the market. Other competitors in the breast cancer diagnostics market include Myriad Genetics, Inc. and Agendia, Inc.

As we expand our portfolio of tests, we may also face competition from companies informing treatment decisions such as Guardant Health or Foundation Medicine, Inc. Competition could also emerge using alternative samples, such as blood, urine or sputum.

In general, we also face competition from commercial laboratories, such as Laboratory Corporation of America Holdings and Sonic Healthcare USA, with strong infrastructure to support the commercialization of diagnostic services. We face potential competition from companies such as Illumina, Inc. and Thermo Fisher Scientific Inc., both of which have entered the clinical diagnostics market. Other potential competitors include companies that develop diagnostic products, such as Roche Diagnostics, a division of Roche Holding Ltd, Siemens AG and Qiagen N.V., and we also may face competition from competitors of our biopharma services such as Neogenomics, Adapative, Tempus and Akoya.

In addition, competitors may develop their own versions of our solutions in countries we may seek to enter where we do not have patents or where our intellectual property rights are not recognized, and compete with us in those countries, including encouraging the use of their solutions by physicians in other countries.

To compete successfully, we must be able to demonstrate, among other things, that our diagnostic test results are accurate and cost effective, and we must secure a meaningful level of reimbursement for our products.

Many of our potential competitors have widespread brand recognition and substantially greater financial, technical and research and development resources, and selling and marketing capabilities than we do. Others may develop products with prices lower than ours that could be viewed by physicians and payers as functionally equivalent to our solutions or offer solutions at prices designed to promote market penetration, which could force us to lower the list price of our solutions and affect our ability to achieve profitability. If we are unable to change clinical practice in a meaningful way or compete successfully against current and future competitors, we may be unable to increase market acceptance and sales of our products,

which could prevent us from increasing our revenue or achieving profitability and could cause the market price of our common stock to decline. As we add new tests, products and services, we will face many of these same competitive risks.

We depend on our senior management team, and the loss of one or more of our executive officers, or any inability to attract and retain highly-skilled employees and other key personnel could adversely affect our business.

Our success depends in part on the skills, experience and performance of members of our executive management team and others in key management positions. We have in the past and may in the future experience changes in our executive management, which may be disruptive to our business. Executive transitions may impact our ability to implement our business strategy and could have a material adverse effect on our business.

In addition, our research and development programs and commercial laboratory operations depend on our ability to attract and retain highly skilled scientists. We may not be able to attract or retain qualified scientists and technicians in the future due to the intense competition for qualified personnel among life science businesses. Our success in the development and commercialization of advanced diagnostics requires a significant medical and clinical staff to conduct studies and educate physicians and payers on the merits of our tests in order to achieve adoption and reimbursement. We are in a highly competitive industry to attract and retain this talent, and the labor market in our industry is becoming increasingly competitive. Additionally, our success depends on our ability to attract and retain qualified salespeople.

There can be no assurance that we will be successful in maintaining and growing our business. Additionally, as we increase our sales channels for new tests we commercialize, we may have difficulties recruiting and training additional sales personnel or retaining qualified salespeople, which could cause a delay or decline in the rate of adoption of our tests.

Our business requires specialized capabilities in reimbursement, billing, and other areas and there may be a shortage of qualified individuals. If we are not able to attract and retain the necessary personnel to accomplish our business objectives, we may experience constraints that could adversely affect our ability to support our research and development, clinical laboratory, sales and reimbursement, billing and finance efforts. All of our U.S. employees are at will, which means that either we or the employee may terminate their employment at any time. We do not carry key person insurance for any of our employees.

Finally, we rely, in part, on equity awards to compensate and incentivize our employees to drive our further growth. As the equity capital markets have been highly volatile in recent periods and the price of our common stock has declined, certain of our employees' equity awards have lost some or all of their value, which may limit their effectiveness as retention tools and, in the event we fail to retain such employees, may adversely affect our business, results of operations and financial condition.

Billing for our diagnostic tests is complex, and we must dedicate substantial time and resources to the billing process to be paid.

Billing for clinical laboratory testing services is complex, time-consuming and expensive. Depending on the billing arrangement and applicable law, we bill various payers, including Medicare, commercial insurance companies and patients, all of which have different billing requirements. We generally bill third-party payers for our diagnostic tests and pursue reimbursement on a case-by-case basis where pricing contracts are not in place. To the extent laws or contracts require us to bill patient co-payments or co-insurance, we must also comply with these requirements. We may also face increased risk in our collection efforts, including potential write-offs of accounts receivable and long collection cycles, which could adversely affect our business, results of operations and financial condition including cash collections. Furthermore, third-party payers may reduce or refuse to pay for our tests, with or without notice.

Several factors make the billing process complex, including:

- differences between the list price for our tests and the reimbursement rates of payers;
- compliance with complex federal and state regulations related to billing government payers, such as Medicare and Medicaid, including requirements to have an active CLIA certificate;
- risk of government audits related to billing Medicare and other government payers;
- disputes among payers as to which party is responsible for payment;

- differences in coverage and in information and billing requirements among payers, including the need for prior authorization and/or advanced notification;
- the effect of patient co-payments or co-insurance;
- individual payers may argue technical contract noncompliance and withhold payment;
- changes to billing codes used for our tests;
- incorrect or missing billing information; and
- the resources required to manage the billing and claims appeals process.

We use standard industry billing codes, known as CPT codes, to bill for our tests, including cytopathology. Through December 31, 2020, we used the CPT code 81545 to bill for our Afirma classifier. Effective January 1, 2021, we began using the new CPT code 81546 to bill for our Afirma classifier, and code 81545 was retired. Effective January 1, 2020, we began using CPT code 81542 to bill for Decipher Prostate Biopsy and Decipher Prostate RP tests. Effective January 1, 2021, we began using the new CPT code 81554 to bill for our Envisia classifier. Effective October 1, 2020, we began using CPT code 0016M to bill for our Decipher Bladder test.

CPT codes can change over time. When codes change, there is a risk of an error being made in the claim adjudication process. These errors can occur with claims submission, third-party transmission or in the processing of the claim by the payer. Claim adjudication errors may result in a delay in payment processing or a reduction in the amount of the payment received. Coding changes, therefore, may have an adverse effect on our total revenue. Even when we receive a designated CPT code specific to our tests, there can be no assurance that payers will recognize these codes in a timely manner or that the process of transitioning to such a code and updating their billing systems and ours will not result in errors, delays in payments and a related increase in accounts receivable balances.

As we introduce new tests, we will need to add new codes to our billing process as well as our financial reporting systems. Failure or delays in effecting these changes in external billing and internal systems and processes could negatively affect our collection rates, revenue and cost of collecting.

Correct coding is subject to the coding policies of the American Medical Association CPT Editorial Panel, or AMA CPT. With respect to claims submitted to Medicare and Medicaid, it is also subject to coding policies developed through the National Correct Coding Initiative, or NCCI. Other payers may develop their own payer-specific coding policies. The broader coding policies of the AMA CPT, NCCI, and other payers are subject to change. For instance, the NCCI adopted an update to its Coding Policy Manual effective January 1, 2019, to limit instances when multiple codes may be billed for molecular pathology testing. Although the NCCI appears to have moderated this change in its updates effective January 1, 2020, such coding policy changes may negatively affect our total revenue and cash flow.

Additionally, our billing activities require us to implement compliance procedures and oversight, train and monitor our employees, challenge coverage and payment denials, assist patients in appealing claims, and undertake internal audits to evaluate compliance with applicable laws and regulations as well as internal compliance policies and procedures. Payers also conduct external audits to evaluate payments, which adds further complexity to the billing process. If the payer makes an overpayment determination, there is a risk that we may be required to return some portion of prior payments we have received. Additionally, the ACA established a requirement for providers and suppliers to report and return any overpayments received from government payers under the Medicare and Medicaid programs within 60 days of identification. Failure to identify and return such overpayments exposes the provider or supplier to liability under federal false claims laws. These billing complexities, and the related uncertainty in obtaining payment for our tests, could negatively affect our revenue and cash flow, our ability to achieve profitability, and the consistency and comparability of our results of operations.

We rely on a third-party provider to transmit claims to payers, and any delay in transmitting claims could have an adverse effect on our revenue.

While we manage the overall processing of claims, we rely on a third-party provider to transmit the actual claims to payers based on the specific payer billing format. We have previously experienced delays in claims processing when our third-party provider made changes to its invoicing system, and again when it did not submit claims to payers within the timeframe we require. Additionally, coding for diagnostic tests may change, and such changes may cause short-term billing errors that may take significant time to resolve. If claims are not submitted to payers on a timely basis or are erroneously submitted, or if we are required to switch to a different provider to handle claim submissions, we may experience delays in our ability to process these claims and receipt of payments from payers, or possibly denial of claims for lack of timely submission, which would have an adverse effect on our revenue and our business.

If our internal sales force is less successful than anticipated, our business expansion plans could suffer and our ability to generate revenue could be diminished. In addition, we have limited history selling our molecular diagnostics tests on a direct basis and our limited history makes forecasting difficult.

If our internal sales force is not successful or new additions to our sales team fail to gain traction among our customers, we may not be able to increase market awareness and sales of our molecular diagnostic tests and products. If we fail to establish our molecular diagnostic tests and products in the marketplace, it could have a negative effect on our ability to sell subsequent molecular diagnostic tests and products, thereby hindering the desired expansion of our business. We have growing, however limited, historical experience forecasting the direct sales of our molecular diagnostics tests and products. Our ability to produce total test volumes that meet customer demand is dependent upon our ability to forecast accurately and plan production capacities accordingly.

Developing new products involves a lengthy and complex process, and if we do not achieve our projected development and commercialization goals in the time frames we announce and expect, our business will suffer and our stock price may decline.

From time to time, we expect to estimate and publicly announce the anticipated timing of the accomplishment of various clinical and other product development goals. The actual timing of accomplishment of these targets could vary dramatically compared to our estimates, in some cases for reasons beyond our control, including the impact of the COVID-19 pandemic. We cannot be certain that we will meet our projected targets and if we do not meet these as publicly announced, the commercialization of our tests may be delayed or may not occur at all and, as a result, our business will suffer and our stock price may decline.

We continually seek to develop enhancements to our test offerings and additional diagnostic tests that requires us to devote considerable resources to research and development. We may face challenges obtaining sufficient numbers of samples to validate a genomic signature for our products. We must provide sufficient clinical and analytical validity, as well as clinical utility studies that meet individual payer evidence requirements to obtain reimbursement. Even after launching new products, we must complete additional studies that meet the clinical evidence required by individual payers to obtain reimbursement. Moreover, we may experience delays in the development and introduction of new products due to the effects of the current COVID-19 pandemic.

In order to develop and commercialize diagnostic tests to be run in our CLIA lab, we need to:

- expend significant funds to conduct substantial research and development;
- conduct successful analytical and clinical studies;
- scale our laboratory processes to accommodate new tests; and
- build the commercial, regulatory, and compliance infrastructure to market and sell new products.

Our product development process involves a high degree of risk and may take several years. Our test and product development efforts may fail for many reasons, including:

- failure to identify a genomic signature in biomarker discovery;

- inability to secure sufficient numbers of samples at an acceptable cost and on an acceptable timeframe to conduct analytical and clinical studies; or
- failure of clinical validation studies to support the effectiveness of the test.

Typically, few research and development projects result in commercial products, and success in early clinical studies often is not replicated in later studies. At any point, we may abandon development of a product candidate, or we may be required to expend considerable resources repeating clinical studies, which would adversely affect the timing for generating potential revenue from a new product and our ability to invest in other products in our pipeline. If a clinical validation study fails to demonstrate the prospectively defined endpoints of the study or if we fail to sufficiently demonstrate analytical validity, we might choose to abandon the development of the product, which could harm our business. If a clinical utility study fails to demonstrate the value of a particular test, we may not be able to obtain reimbursement for the test. In addition, competitors may develop and commercialize competing products or technologies faster than us or at a lower cost.

If we are unable to develop products to keep pace with rapid technological, medical and scientific change, our operating results and competitive position could be harmed.

In recent years, there have been numerous advances in technologies relating to diagnostics, particularly diagnostics that are based on genomic information. These advances require us to continuously develop our technology and to work to develop new solutions to keep pace with evolving standards of care. Our solutions could become obsolete unless we continually innovate and expand our product offerings to include new clinical applications. If we are unable to develop new products or to demonstrate the applicability of our products for other diseases, our sales could decline, and our competitive position could be harmed.

Complying with numerous statutes and regulations pertaining to our business is an expensive and time-consuming process, and any failure to comply could result in substantial penalties.

Our operations are subject to other extensive federal, state, local, and foreign laws and regulations, all of which are subject to change. These laws and regulations currently include, among others:

- the Federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which established comprehensive federal standards with respect to the privacy and security of protected health information and requirements for the use of certain standardized electronic transactions, and amendments made to those standards in 2013 pursuant to the Health Information Technology for Economic and Clinical Health Act, or HITECH Act, which strengthened and expanded HIPAA privacy and security compliance requirements, increased penalties for violators, extended enforcement authority to state attorneys general, and imposed new requirements for breach notification;

- Medicare billing and payment regulations applicable to clinical laboratories, including requirements to have an active CLIA certificate;

- the Federal Anti-kickback Statute (and state equivalents), which prohibits knowingly and willfully offering, paying, soliciting, or receiving remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing, arranging for, or recommending of an item or service that is reimbursable, in whole or in part, by a federal healthcare program;

- the Eliminating Kickbacks in Recovery Act of 2018, which prohibits the solicitation, receipt, payment or offering of any remuneration in return for referring a patient or patronage to a recovery home, clinical treatment facility, or laboratory for services covered by both government and private payers;

- the Federal Stark physician self-referral law (and state equivalents), which prohibits a physician from making a referral for certain designated health services covered by the Medicare program, including laboratory and pathology services, if the physician or an immediate family member has a financial relationship with the entity providing the designated health services, unless the financial relationship falls within an applicable exception to the prohibition;

- the Federal Civil Monetary Penalties Law, which prohibits, among other things, the offering or transfer of remuneration to a Medicare or state health-care 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 health-care program, unless an exception applies;

- the Federal False Claims Act, which imposes liability on any person or entity who knowingly presents, or causes to be presented, a false, fictitious, or fraudulent claim for payment to the federal government;

- the Physician Payments Sunshine Act, enacted as part of the ACA, which imposes annual reporting requirements on manufacturers of certain devices, drugs and biologics for certain payments and transfers of value by them and in some cases their distributors to covered recipients, including physicians, as defined by such law, teaching hospitals, and certain healthcare providers as well as ownership or investment interests that physicians or physicians' immediate family members hold with the reporting entity;

- other federal and state fraud and abuse laws, such as anti-kickback laws, prohibitions on self-referral, fee-splitting restrictions, prohibitions on the provision of products at no or discounted cost to induce physician or patient adoption, and false claims acts, which may extend to services reimbursable by any third-party payer, including private insurers;

- the prohibition on reassignment of Medicare claims, which, subject to certain exceptions, precludes the reassignment of Medicare claims to any other party;

- the Protecting Access to Medicare Act of 2014, which requires us to report private payer rates and test volumes for specific CPT codes on a triennial basis and imposes penalties for failures to report, omissions, or misrepresentations;

- the No Surprises Act and its implementing regulations (effective January 1, 2022), which prohibit an out-of-network provider from billing a patient at an amount in excess of the in-network cost sharing for services furnished with respect to a visit at certain in-network health-care facilities, as well as various state laws restricting balance billing of patients;

- the rules regarding billing for diagnostic tests reimbursable by the Medicare program, which prohibit a physician or other supplier from marking up the price of the technical component or professional component of a diagnostic test ordered by the physician or other supplier and supervised or performed by a physician who does not "share a practice" with the billing physician or supplier;

- state laws that prohibit other specified practices related to billing such as billing physicians for testing that they order, waiving co-insurance, co-payments, deductibles, and other amounts owed by patients, and billing a state Medicaid program at a price that is higher than what is charged to other payers;

- the Foreign Corrupt Practices Act of 1977, and other similar laws, which apply to our international activities;

- unclaimed property (escheat) laws and regulations, which may require us to turn over to governmental authorities the property of others held by us that has been unclaimed for a specified period of time;

- enforcing our intellectual property rights; and

- foreign laws and regulations equivalent to the above.

We have adopted policies and procedures designed to comply with applicable laws and regulations. In the ordinary course of our business, we conduct internal reviews of our compliance with these laws. Our compliance with some of these laws and regulations is also subject to governmental review. The growth of our business, sales organization and our expansion outside of the United States may increase the potential of violating these laws or our internal policies and procedures. We believe that we are in material compliance with all statutory and regulatory requirements, but there is a risk that one or more government agencies could take a contrary position.

In recent years U.S. Attorneys' Offices have increased scrutiny of the healthcare industry, as have Congress, the Department of Justice, the Department of Health and Human Services' Office of the Inspector General and the Department of Defense. These bodies have all issued subpoenas and other requests for information to conduct investigations of, and commenced civil and criminal litigation against, healthcare companies based on financial arrangements with health-care providers, regulatory compliance, product promotional practices and documentation, and coding and billing practices.

Whistleblowers have filed numerous qui tam lawsuits against healthcare companies under the federal and state False Claims Acts in recent years, in part because the whistleblower can receive a portion of the government's recovery under such suits.

Many member states in the EU have adopted specific anti-gift statutes that further limit commercial practices for medical devices (including IVD MDs), in particular vis-à-vis healthcare professionals and organizations. Additionally, there has been a recent trend of increased regulation of payments and transfers of value provided to healthcare professionals or entities and many EU member states have adopted national "Sunshine Acts" which impose reporting and transparency requirements (often on an annual basis), similar to the requirements in the United States, on medical device manufacturers.

These laws and regulations are complex and are subject to interpretation by the courts and by government agencies. If one or more such agencies alleges that we may be in violation of any of these requirements, regardless of the outcome, it could damage our reputation and adversely affect important business relationships with third parties, including managed care organizations and other commercial third-party payers. Any action brought against us for violation of these or other laws or regulations, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. If our operations are found to be in violation of any of these laws and regulations, we may be subject to any applicable penalty associated with the violation, including civil and criminal penalties, damages and fines, we could be required to refund payments received by us, and we could be required to curtail or cease our operations. Any of the foregoing consequences could seriously harm our business and our financial results.

If we use hazardous materials in a manner that causes contamination or injury, we could be liable for resulting damages.

We are subject to federal, state and local laws, rules and regulations governing the use, discharge, storage, handling and disposal of biological material, chemicals and waste. We cannot eliminate the risk of accidental contamination or injury to employees or third parties from the use, storage, handling or disposal of these materials. In the event of contamination or injury, we could be held liable for any resulting damages, remediation costs and any related penalties or fines, and any liability could exceed our resources or any applicable insurance coverage we may have. The cost of compliance with these laws and regulations may become significant, and our failure to comply may result in substantial fines or other consequences, and either could negatively affect our operating results.

We must successfully integrate the HalioDx and Decipher Biosciences businesses to realize the financial goals that we currently anticipate.

Risks we face in connection with the ongoing integration of HalioDx and Decipher Biosciences include:

- We may have difficulties managing acquired products and tests or retaining key personnel from the acquired businesses;
- We may not successfully integrate the acquired businesses as planned (including, for example, systems integration), there could be unanticipated adverse impacts on the acquired businesses, or we may otherwise not realize the expected return on our investments, which could adversely affect our business or operating results and potentially cause impairment to assets that we record as a part of an acquisition including intangible assets and goodwill;
- Our operating results or financial condition may be adversely impacted by (i) claims or liabilities related to the acquired businesses including, among others, claims from U.S. or international regulatory or other governmental agencies, terminated employees, current or former customers or business partners, or other third parties; (ii) pre-existing contractual relationships of the acquired businesses that we would not have otherwise entered into, the termination or modification of which may be costly or disruptive to our business; (iii) unfavorable accounting treatment as a result of the acquired businesses' practices; and (iv) intellectual property claims or disputes;
- Neither HalioDx nor Decipher Biosciences was required to maintain an internal control infrastructure that would meet the standards of a public company, including the requirements of the Sarbanes-Oxley Act of 2002. The costs that we may incur to implement such controls and procedures may be substantial and we could encounter unexpected delays and challenges in this implementation. In addition, we may discover significant deficiencies or material weaknesses in the quality of HalioDx's or Decipher Biosciences' respective financial and disclosure controls and procedures;
- We may experience a failure of development activities on behalf of a HalioDx customer where HalioDx bears development risk resulting in a refund of development fees;

- We may fail to transition manufacturing of the test kits for the nCounter, currently produced by NanoString, to HalioDx's manufacturing facility in Marseille, France in a timely manner or at all, or we may experience manufacturing irregularities or challenges in connection with the transition, including rolling blackouts due to energy shortages in Europe;
- We may not realize the anticipated accretion to our gross margins as a result of transitioning manufacturing of test kits to HalioDx;
- We may experience disagreements with the French employee work council; and
- We may have failed to identify or assess the magnitude of certain liabilities, shortcomings or other circumstances prior to acquiring either of the acquired businesses, which could result in unexpected litigation or regulatory exposure, unfavorable accounting treatment, a diversion of management's attention and resources, and other adverse effects on our business, financial condition, and operating results.

We are exposed to risks associated with transactions denominated in foreign currency.

Changes in the value of the relevant currencies may affect the cost of certain items required in our operations and contractual agreements. Changes in currency exchange rates, such as the recent strengthening of the U.S. dollar relative to the Euro, may also affect the relative prices at which we are able to sell products in the same market. Our revenue from international customers may be negatively impacted as increases in the U.S. dollar relative to our international customers local currency could make our products more expensive, impacting our ability to compete. Our costs of materials from international suppliers may increase if, in order to continue doing business with us, they raise their prices as the value of the U.S. dollar decreases relative to their local currency. Foreign policies and actions regarding currency valuation could result in actions by the United States and other countries to offset the effects of such fluctuations. Recent global financial conditions have led to a high level of volatility in foreign currency exchange rates and that level of volatility may continue, which could adversely affect our business, financial condition, or results of operations.

Aspects of our international business expose us to business, regulatory, political, operational, financial and economic risks associated with doing business outside of the United States.

Our business strategy currently includes international presence and expansion in select countries and may include developing and maintaining physician outreach and education capabilities outside of the United States, establishing agreements with laboratories, and expanding our relationships with international payers. In 2021, we acquired HalioDx, an immuno-oncology diagnostics company that is based in Marseille, France, and operates globally. Doing business internationally involves a number of risks, including:

- multiple, conflicting and changing laws and regulations such as tax laws, privacy laws, export and import restrictions, employment laws, regulatory requirements and other governmental approvals, permits and licenses;
- difficulties in maintaining the manufacturing output we anticipate at the Marseille, France facility as a result of rolling blackouts due to energy shortages in Europe resulting from the Russian invasion of Ukraine;
- failure by us to obtain regulatory approvals or certifications where required for the use of our solutions in various countries;
- complexities associated with managing multiple payer reimbursement regimes, government payers or patient self-pay systems, including payers mandating additional evidence requirements for reimbursement consideration;
- logistics and regulations associated with shipping tissue samples, including infrastructure conditions and transportation delays;
- challenges associated with establishing laboratory partners, including proper sample collection techniques, management of supplies, sample logistics, billing and promotional activities;
- limits on our ability to penetrate international markets if we are not able to process tests locally;

- financial risks, such as longer payment cycles, difficulty in collecting from payers, the effect of local and regional financial crises, and exposure to foreign currency exchange rate fluctuations;

- natural disasters, political and economic instability, including wars, terrorism, and political unrest, outbreak of disease, including COVID-19, boycotts, curtailment of trade and other business restrictions (including as a direct or indirect result of the conflict in Ukraine); and

- regulatory and compliance risks that relate to maintaining accurate information and control over activities that may fall within the purview of the Foreign Corrupt Practices Act of 1977, including both its books and records provisions and its anti-bribery provisions.

Any of these factors could significantly harm our future international expansion and operations and, consequently, our revenue and results of operations.

Our operating results may be adversely affected by unfavorable macroeconomic and market conditions.

Our business or financial results may be adversely impacted by uncertain economic conditions, including: the impact of the COVID-19 pandemic, adverse changes in interest rates, foreign currency exchange rates, tax laws or tax rates; inflation; a recession; contraction in the availability of credit in the marketplace due to legislation or other economic conditions, which may potentially impair our ability to access the capital markets on terms acceptable to us or at all; and the effects of government initiatives to manage economic conditions. Many of the countries in which we operate, including the U.S. and those in Europe, have experienced and continue to experience uncertain economic conditions, including increased inflation rates, resulting from global as well as local factors. For example, in February 2022, Russia launched a significant military action against Ukraine, the short and long-term implications of which are difficult to predict at this time. The impact to Ukraine as well as actions taken by other countries, including new and stricter sanctions imposed by the U.S. and the European Union, and other countries and companies and organizations, could adversely affect the global economy and financial markets and thus could affect our business and results of operations, as well as the price of our common stock and our ability to raise additional capital when needed on acceptable terms.

Moreover, we cannot predict how future economic conditions will affect our customers, suppliers and distributors and any negative impact on our critical customers, suppliers or distributors may also have an adverse impact on our results of operations or financial condition. A severe or prolonged economic downturn, as result of a global pandemic such as the COVID-19 pandemic or otherwise, could result in a variety of risks to our business, including weakened demand for our products and services and our ability to raise additional capital when needed on favorable terms, if at all. A weak or declining economy could strain our collaborators, possibly resulting in supply disruption, or cause delays in their payments to us. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

Our reliance on distributors for sales of our products outside of the United States, and on clinical laboratories for delivery of Prosigna testing services, could limit or prevent us from selling our products and impact our revenue.

We have established distribution agreements for the nCounter Analysis System for diagnostic use and related diagnostic kit products in certain countries where we do not sell directly. We intend to continue to grow our business internationally, and to do so we must attract additional distributors and retain existing distributors to maximize the commercial opportunity for our products. There is no guarantee that we will be successful in attracting or retaining desirable sales and distribution partners or that we will be able to enter into such arrangements on favorable terms. Distributors may not commit the necessary resources to market and sell our products to the level of our expectations or may choose to favor marketing the products of our competitors. If current or future distributors do not perform adequately, or we are unable to enter into effective arrangements with distributors in particular geographic areas, we may not realize long-term international revenue growth.

Similarly, we or our distributors have entered into agreements with clinical laboratories globally to provide Prosigna testing services. We do not provide testing services directly and, thus, we are reliant on these clinical laboratories to actively promote and sell Prosigna testing services. These clinical laboratories may take longer than anticipated to begin offering Prosigna testing services and may not commit the necessary resources to market and sell Prosigna testing services to the level of our expectations. Furthermore, we intend to contract with additional clinical laboratories to offer Prosigna testing services, including physician-owned laboratories, and we may be unsuccessful in attracting and contracting with new clinical laboratory

providers. If current or future Prosigna testing service providers do not perform adequately, or we are unable to enter into contracts with additional clinical laboratories to provide Prosigna testing services, we may not be successful selling Prosigna and our future revenue prospects may be adversely affected.

Errors or defects in our products or services could harm our reputation, decrease market acceptance of our products or services or expose us to product liability claims, and we could face substantial liabilities that exceed our resources.

We are creating new tests, products and services, many of which are initially based on novel technologies. Our new tests and products may contain undetected errors or defects that are not identified until after they are first introduced to the market. As all of our tests, products and services progress, we or others may determine that we made unintended scientific or technological mistakes or omissions. Furthermore, the testing processes utilize a number of complex and sophisticated biochemical, informatics, optical and mechanical processes, many of which are highly sensitive to external factors and variation between testing runs. Refinements to our processes may initially result in unanticipated issues that reduce efficiency or increase variability. In particular, sequencing, which is a key component of these processes, could be inefficient with higher-than-expected variability. This could increase total sequencing costs and reduce the number of samples we can process in a given time period, which may negatively impact customer turnaround time. Additionally, our laboratory operations could result in any number of errors or defects. Our quality assurance system or product development processes may fail to prevent us from inadvertent problems with samples, sample quality, lab processes including sequencing, software, data upload or analysis, raw materials, reagent manufacturing, assay quality or design, or other components or processes. Moreover, our assays may have quality or design errors, and we may have inadequate procedures or instrumentation to process samples, assemble our proprietary primer mixes and commercial materials, upload and analyze data, or otherwise conduct our laboratory operations. Additionally, the marketing, sale and use of our current or future tests could lead to product liability claims if someone were to allege that the tests failed to perform as they were designed. We may also be subject to liability for errors in the results we provide to physicians or for a misunderstanding of, or inappropriate reliance upon, the information we provide. Our Afirma classifiers are performed on FNA samples that are diagnosed as indeterminate by standard cytopathology review. We report results as benign or suspicious to the prescribing physician. Under certain circumstances, we might report a result as benign that later proves to have been malignant. This could be the result of the physician having poor nodule sampling in collecting the FNA, performing the FNA on a different nodule than the one that is malignant or failure of the classifier to perform as intended. We may also be subject to similar types of claims related to our Decipher Prostate, Prosigna, Envisia, and Decipher Bladder tests, as well as tests we may develop or acquire in the future.

Any of the foregoing defects or errors could harm our reputation, decrease market acceptance of our products or services or expose us to product liability claims. A product liability or errors and omissions liability claim could further result in substantial damages and be costly and time consuming for us to defend. Although we maintain product liability and errors and omissions insurance, we cannot assure you that our insurance would fully protect us from the financial impact of defending against these types of claims or any judgments, fines or settlement costs arising out of any such claims. Any product liability or errors and omissions 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 lawsuit could cause injury to our reputation, decrease market acceptance of our products or cause us to recall or suspend sales of our products and solutions. The occurrence of any of these events could have an adverse effect on our business and results of operations.

Our business and the operations of our laboratories are subject to the risk of disruptions caused by pandemics, political events, war, terrorism, earthquakes, fire, power outages, severe weather, floods, and other catastrophic events.

War, terrorism, geopolitical uncertainties, including any developments or consequences of the conflict in Ukraine or related sanctions, trade restrictions, public health issues, natural disasters and other catastrophic events may cause damage or disruption to the economy and commerce on a global, regional or country-specific basis, and could disrupt supply or delivery of, or demand for, our products. For example, the COVID-19 outbreak has had, and may continue to have, a negative effect on consumer confidence and spending, and other impacts, which could adversely affect our business.

In addition, we perform all of the Afirma and Envisia genomic classifier testing at our laboratory in South San Francisco, California, near major earthquake faults known for seismic activity and in a region affected by wildfires. We perform our urology tests in our laboratory in San Diego, California. Our laboratory in Austin, Texas accepts and stores the majority of our Afirma FNA samples pending transfer to our California laboratory for genomic test processing. Our manufacturing facility in Marseille, France, produces many of our Prosigna tests, as well as products for our IVD manufacturing business, and is subject to the risk of power outages resulting from constrained European energy supply.

The laboratories and equipment we use to perform our tests would be costly to replace and could require substantial lead time to replace and qualify for use if they became inoperable. Either of our facilities may be harmed or rendered inoperable by natural or man-made disasters, including earthquakes, flooding and power outages, which may render it difficult or impossible for us to perform our testing services for some period of time or to receive and store samples. The inability to perform our tests for even a short period of time may result in the loss of customers or harm our reputation, and we may be unable to regain those customers in the future. Although we maintain insurance for damage to our property 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, if at all.

Our inability to raise additional capital on acceptable terms in the future may limit our ability to develop and commercialize new solutions and technologies and expand our operations.

We expect continued capital expenditures and operating losses over the next few years as we expand our infrastructure, commercial operations and research and development activities. We may seek to raise additional capital through equity offerings, debt financings, collaborations or licensing arrangements. Additional funding may not be available to us on acceptable terms, or at all. If we raise funds by issuing equity securities, dilution to our stockholders could result. Any equity securities issued also may provide for rights, preferences or privileges senior to those of holders of our common stock. The terms of debt securities issued or borrowings could impose significant restrictions on our operations. The incurrence of additional indebtedness or the issuance of certain equity securities could result in increased fixed payment obligations and could also result in restrictive covenants, such as limitations on our ability to incur debt or issue additional equity, limitations on our ability to acquire or license intellectual property rights, and other operating restrictions that could adversely affect our ability to conduct our business. In addition, the issuance of additional equity securities by us, or the possibility of such issuance, may cause the market price of our common stock to decline. In the event that we enter into collaborations or licensing arrangements to raise capital, we may be required to accept unfavorable terms. These agreements may require that we relinquish or license to a third-party on unfavorable terms our rights to technologies or product candidates that we otherwise would seek to develop or commercialize ourselves, or reserve certain opportunities for future potential arrangements when we might be able to achieve more favorable terms. The trading prices for our common stock and other companies have been highly volatile as a result of the COVID-19 pandemic, which may reduce our ability to access capital on favorable terms or at all. In addition, a recession, depression or other sustained adverse market event resulting from the spread of COVID-19 could materially and adversely affect our business and the value of our common stock. If we are not able to secure additional funding when needed, we may have to delay, reduce the scope of or eliminate one or more research and development programs or selling and marketing initiatives. In addition, we may have to work with a partner on one or more of our products or development programs, which could lower the economic value of those programs to our company.

Security breaches, loss of data and other disruptions to our or our third-party service providers' data systems could compromise sensitive information related to our business or prevent us from accessing critical information and expose us to liability, which could adversely affect our business and our reputation.

In the ordinary course of our business, we and our third-party service providers collect and store sensitive data, including legally protected health information, other personally identifiable information, credit card information, intellectual property, and our proprietary business and financial information. We manage and maintain our applications and data utilizing a combination of on-site systems, managed data center systems and cloud-based data center systems. We face a number of risks related to our protection of, and our service providers’ protection of, this critical information, including loss of access, inappropriate disclosure and inappropriate access, as well as risks associated with our ability to identify and audit such events. System failures or outages, including any potential disruptions due to significantly increased global demand on certain cloud-based systems during the COVID-19 pandemic, could compromise our ability to protect sensitive information and prevent business interference, which could harm our ability to conduct business and/or delay our financial reporting. Such failures could materially adversely affect our operating results and financial condition.

The secure processing, storage, maintenance and transmission of this critical information is vital to our operations and business strategy, and we devote significant resources to protecting such information. Although we take measures to protect sensitive information from unauthorized access or disclosure, our information technology and infrastructure may be vulnerable to attacks by hackers or viruses or otherwise breached due to employee error, malfeasance or other activities. While we are not currently aware of any such attack or breach having occurred, if such an event were to occur and cause interruptions in our operations, our networks would be compromised and the information we store on those networks could potentially be accessed

by unauthorized parties, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information could result in legal claims or proceedings, liability, and penalties under federal, state, and international laws and regulations that protect the privacy and security of personal information, such as the HIPAA regulations and the EU General Data Protection Regulation, or GDPR. Unauthorized access, loss or dissemination of such data also could disrupt our operations, including our ability to process tests, provide test results, bill payers or patients, process claims and appeals, provide customer assistance services, conduct research and development activities, collect, process, and prepare company financial information, provide information about our tests and other patient and physician education and outreach efforts through our website, and manage the administrative aspects of our business, any of which could adversely affect our business, including by materially damaging our reputation.

In addition, the interpretation and application of consumer, health-related and data protection laws in the United States, Europe and elsewhere are often uncertain, contradictory, and in flux. It is possible that these laws may be interpreted and enforced in a manner that we have not anticipated in designing our practices and compliance policies. If so, this could result in government-imposed fines or orders requiring that we change our practices, which could adversely affect our business. Certain health-related and data protection requirements have been modified under section 319 of the Public Health Service Act during the Public Health Emergency, or PHE, first declared January 31, 2020, which was most recently extended effective January 11, 2023. The Biden Administration has announced that it intends to lift the PHE declaration on May 11, 2023. In addition, we are subject to various state laws, including the California Consumer Privacy Act, or CCPA, which, among other things, requires covered companies to provide disclosures to California consumers concerning the collection and sale of personal information, and gives such consumers the right to opt out of certain sales of personal information. Amendments to the CCPA have been made since its enactment in 2018, most significantly in the form of amendments and expansions pursuant to the California Privacy Rights Act adopted by ballot measure in November 2020, and it remains unclear what, if any, further amendments will be made to this legislation or how it will be interpreted. We cannot yet predict the impact of the CCPA or similar laws on our business or operations, but they may require us to modify our data processing practices and policies and to incur substantial costs and expenses in an effort to comply.

Risks associated with data privacy issues, including evolving laws, regulations and associated compliance efforts, may adversely impact our business and financial results.

Legislation in various countries around the world with regard to cybersecurity, privacy and data protection is rapidly expanding and creating a complex compliance environment. We are subject to many federal, state, and foreign laws and regulations, including those related to privacy, rights of publicity, data protection, content regulation, intellectual property, health and safety, competition, protection of minors, consumer protection, employment, and taxation.

Recent developments in Europe have created compliance uncertainty regarding the processing of personal data from Europe. For example, the GDPR, which became effective in the EU on May 25, 2018, applies to our activities conducted from an establishment in the EU or related to products and services that we offer to EU users. The GDPR imposed new compliance obligations applicable to our business, including accountability obligations requiring data controllers and processors to maintain a record of their data processing and implement policies as part of its mandated privacy governance framework. It also requires data controllers to be transparent and to disclose to data subjects how their personal data is to be used, protected, and shared; imposes limitations on retention of personal data; introduces mandatory data breach notification requirements; and sets higher standards for data controllers to demonstrate that they have obtained valid consent for certain data processing activities. Continued compliance with these obligations could cause us to change our business practices, and we risk financial penalties for noncompliance (including possible fines of up to 4% of global annual turnover for the preceding financial year or €20 million (whichever is higher) for the most serious infringements). In addition, the GDPR prohibits the transfer of personal data from the EEA to the United States and other jurisdictions that the European Commission does not recognize as having “adequate” data protection laws unless a data-protective transfer mechanism has been put in place. On July 16, 2020, the Court of Justice of the European Union, or CJEU, issued a decision undermining the validity of the data-protective transfer mechanisms previously relied on, creating widespread uncertainty about compliance with the GDPR rules on data transfers to non-“adequate” jurisdictions. The EU Commission announced in December 2022 that it had begun the process of adopting an adequacy decision that would apply to the United States based on an executive order issued by President Biden in October 2022; even if the EU Commission approves the adequacy decisions, however, it is widely expected that the new data transfer framework may be challenged before the CJEU.

While the CJEU generally confirmed the validity of the European Commission-approved “Standard Contractual Clauses”, or SCCs, as a personal data-protective transfer mechanism, it made clear that reliance on the SCCs alone may not necessarily be

sufficient in all circumstances. Use of the SCCs must now be assessed on a case-by-case basis taking into account the legal regime applicable in the destination country, in particular applicable surveillance laws and rights of individuals and additional measures and/or contractual provisions may need to be put in place, however, the nature of these additional measures is currently uncertain. In response to the CJEU decision, the European Commission has published revised SCCs; existing SCC arrangements were required to be migrated to the revised SCCs by December 27, 2022. We were required to implement the revised SCCs, in relation to relevant existing contracts and certain additional contracts and arrangements, by that date. In addition, the revised SCCs are not to be relied on for data transfers to non-EEA entities subject to the GDPR, and we are waiting for further guidance on valid mechanisms for data transfers from the EEA to such entities.

Following the United Kingdom's withdrawal from the EEA and the EU, and the expiry of the transition period, companies processing the information of EU data subjects have to comply with both the GDPR and the GDPR as incorporated into United Kingdom national law, the latter regime having the ability to separately fine up to the greater of £17.5 million or 4% of global turnover. The European Commission has adopted an adequacy decision in favor of the United Kingdom, enabling data transfers from EU member states to the United Kingdom without additional safeguards. However, the UK adequacy decision will automatically expire in June 2025 unless the European Commission re-assesses and renews/ extends that decision, and remains under review by the Commission during this period. The relationship between the United Kingdom and the EU in relation to certain aspects of data protection law remains unclear, and it is unclear how UK data protection laws and regulations will develop in the medium to longer term, and how data transfers to and from the United Kingdom will be regulated in the long term. These developments may lead to additional costs and increase our overall risk exposure.

In the United States, numerous federal and state laws and regulations, including federal health information privacy laws, state data breach notification laws, state health information privacy laws and federal and state consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), that govern the collection, use, disclosure and protection of health-related and other personal information could apply to our operations or the operations of our collaborators. In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under HIPAA, as amended by HITECH. Depending on the facts and circumstances, we could be subject to civil and criminal penalties if we obtain, use, or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.

The CCPA established individual privacy rights for California consumers and places increased privacy and data security obligations on entities handling personal information of consumers or households. The CCPA was amended several times after its enactment, most recently by the California Privacy Rights Act, or the CPRA, which, as of its effective date of January 1, 2023, gives California residents expanded privacy rights, including the right to opt out of certain personal information sharing, the use of "sensitive personal information," and the use of personal information for automated decision-making or targeted advertising. The CCPA and CPRA provide for civil penalties and a private right of action for data breaches that is expected to increase data breach litigation. The CCPA and CPRA may increase our compliance costs and potential liability. Following the lead of California, several other states, including Colorado, Utah, Virginia and Connecticut have each enacted laws similar to the CCPA/CPRA and other states are considering enacting privacy laws as well. The multiple layers of privacy law within the United States could increase our potential liability, increase our compliance costs, and adversely affect our business.

Other countries outside of the United States and Europe have enacted or are considering enacting similar cross-border data transfer restrictions and laws requiring local data residency and restricting cross-border data transfer, which could increase the cost and complexity of delivering our services and operating our business. For example, Brazil recently enacted the General Data Protection Law (Lei Geral de Proteção de Dados Pessoais or LGPD) (Law No. 13,709/2018), and effective November 1, 2021 was China's Personal Information Protection Law (, PIPL), both of which broadly regulate the processing of personal information and impose compliance obligations and penalties comparable to those of the GDPR.

These recent developments are likely to require us to review and amend the legal mechanisms by which we make and/ or receive personal data transfers to/in the United States and other countries outside of the EEA. As supervisory authorities issue further guidance on personal data export mechanisms, including circumstances where the SCCs cannot be used, and/or commence enforcement actions, we could suffer additional costs, complaints and/or regulatory investigations or fines, and/or if we are otherwise unable to transfer personal data between and among countries and regions in which we operate, it could affect the manner in which we provide our services and/or the geographical location or segregation of our relevant systems and operations, and could adversely affect our financial results.

If we cannot license rights to use technologies on reasonable terms, we may not be able to commercialize new products in the future.

In the future, we may license third-party technology to develop or commercialize new products. In return for the use of a third-party's technology, we may agree to pay the licensor royalties based on sales of our solutions. Royalties are a component of cost of revenue and affect the margins on our solutions. We may also need to negotiate licenses to patents and patent applications after introducing a commercial product. Our business may suffer if we are unable to enter into the necessary licenses on acceptable terms, or at all, if any necessary licenses are subsequently terminated, if the licensors fail to abide by the terms of the license or fail to prevent infringement by third parties, or if the licensed patents or other rights are found to be invalid or unenforceable.

If we are unable to protect our intellectual property effectively, our business would be harmed.

We rely on patent protection as well as trademark, copyright, trade secret and other intellectual property rights protection and contractual restrictions to protect our proprietary technologies, all of which provide limited protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage. If we fail to protect our intellectual property, third parties may be able to compete more effectively against us and we may incur substantial litigation costs in our attempts to recover or restrict use of our intellectual property.

We apply for and in-license patents covering our products and technologies and uses thereof, as we deem appropriate, however we may fail to apply for patents on important products and technologies in a timely fashion or at all, or we may fail to apply for patents in potentially relevant jurisdictions.

It is possible that none of our pending patent applications will result in issued patents in a timely fashion or at all, and even if patents are granted, they may not provide a basis for intellectual property protection of commercially viable products, may not provide us with any competitive advantages, or may be challenged and invalidated by third parties. It is possible that others will design around our current or future patented technologies. We may not be successful in defending any challenges made against our patents or patent applications. Any successful third-party challenge to our patents could result in the unenforceability or invalidity of such patents and increased competition to our business. The outcome of patent litigation can be uncertain and any attempt by us to enforce our patent rights against others may not be successful, or, if successful, may take substantial time and result in substantial cost, and may divert our efforts and attention from other aspects of our business.

The patent positions of life sciences companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in such companies' patents has emerged to date in the United States or elsewhere. Courts frequently render opinions in the biotechnology field that may affect the patentability of certain inventions or discoveries, including opinions that may affect the patentability of methods for analyzing or comparing nucleic acids.

In particular, the patent positions of companies engaged in the development and commercialization of genomic diagnostic tests are particularly uncertain. Various courts, including the U.S. Supreme Court, have rendered decisions that affect the scope of patentability of certain inventions or discoveries relating to certain diagnostic tests and related methods. These decisions state, among other things, that patent claims that recite laws of nature (for example, the relationship between blood levels of certain metabolites and the likelihood that a dosage of a specific drug will be ineffective or cause harm) are not themselves patentable. What constitutes a law of nature is uncertain, and it is possible that certain aspects of genomic diagnostics tests would be considered natural laws. Accordingly, the evolving case law in the United States may adversely affect our ability to obtain patents and may facilitate third-party challenges to any owned and licensed patents.

The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States, and we may encounter difficulties protecting and defending such rights in foreign jurisdictions. The legal systems of many other countries do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biotechnology, which could make it difficult for us to stop the infringement of our patents in such countries. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business.

Changes in either the patent laws or in interpretations of patent laws in the United States or other countries may diminish the value of our intellectual property. We cannot predict the breadth of claims that may be allowed or enforced in our patents or in third-party patents. We may not develop additional proprietary products, methods and technologies that are patentable.

In addition to pursuing patents on our technology, we take steps to protect our intellectual property and proprietary technology by entering into agreements, including confidentiality agreements, non-disclosure agreements and intellectual property assignment agreements, with our employees, consultants, academic institutions, corporate partners and, when needed, our advisors. Such agreements may not be enforceable or may not provide meaningful protection for our trade secrets or other proprietary information in the event of unauthorized use or disclosure or other breaches of the agreements, and we may not be able to prevent such unauthorized disclosure. If we are required to assert our rights against such party, it could result in significant cost and distraction.

Monitoring unauthorized disclosure is difficult, and we do not know whether the steps we have taken to prevent such disclosure are, or will be, adequate. If we were to enforce a claim that a third-party had illegally obtained and was using our trade secrets, it would be expensive and time consuming, and the outcome would be unpredictable. In addition, courts outside the United States may be less willing to protect trade secrets.

We may also be subject to claims that our employees have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers, or to claims that we have improperly used or obtained such trade secrets. Litigation may be necessary to defend against these claims. If we fail in defending such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights and face increased competition to our business. A loss of key research personnel work product could hamper or prevent our ability to commercialize potential products, which could harm our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

Further, competitors could attempt to replicate some or all of the competitive advantages we derive from our development efforts, willfully infringe our intellectual property rights, design around our protected technology or develop their own competitive technologies that fall outside of our intellectual property rights. Others may independently develop similar or alternative products and technologies or replicate any of our products and technologies. If our intellectual property does not adequately protect us against competitors' products and methods, our competitive position could be adversely affected, as could our business.

We have not registered certain of our trademarks in all of our potential geographic markets. If we apply to register these trademarks, our applications may not be allowed for registration in a timely fashion or at all, and our registered trademarks may not be maintained or enforced. In addition, opposition or cancellation proceedings may be filed against our trademark applications and registrations, and our trademarks may not survive such proceedings. If we do not secure registrations for our trademarks, we may encounter more difficulty in enforcing them against third parties than we otherwise would. If some other business in one of these markets already owns a trademark that is confusingly similar to one of our trademarks, we may be prohibited from entering that market under our trademark unless we re-brand our product in that location. Similarly, if we develop a new product line, there is no guarantee that one of our existing trademarks will be available as the brand for that new product line. Under those circumstances, we may incur the cost of developing a new trademark for this new product line.

To the extent our intellectual property offers inadequate protection, or is found to be invalid or unenforceable, we would be exposed to a greater risk of direct competition. If our intellectual property does not provide adequate coverage of our competitors' products, our competitive position could be adversely affected, as could our business. Both the patent application process and the process of managing patent disputes can be time consuming and expensive.

We may be involved in litigation related to intellectual property, which could be time-intensive and costly and may adversely affect our business, operating results or financial condition.

We may receive notices of claims of direct or indirect infringement or misappropriation or misuse of other parties' proprietary rights from time to time. Some of these claims may lead to litigation. We cannot assure you that we will prevail in such actions, or that other actions alleging misappropriation or misuse by us of third-party trade secrets, infringement by us of third-party patents and trademarks or other rights, or the validity of our patents, trademarks or other rights, will not be asserted or prosecuted against us.

We might not have been the first to make the inventions covered by each of our pending patent applications and we might not have been the first to file patent applications for these inventions. To determine the priority of these inventions, we may have to participate in interference proceedings, derivation proceedings, or other post-grant proceedings declared by the U.S. Patent and Trademark Office that could result in substantial cost to us. No assurance can be given that other patent applications will not have priority over our patent applications. In addition, the patent laws of the United States allow for various post-grant opposition proceedings, and their outcome can be difficult to predict. Furthermore, if third parties bring these proceedings against our patents, we could experience significant costs and management distraction.

Litigation may be necessary for us to enforce our patent and proprietary rights or to determine the scope, coverage and validity of the proprietary rights of others. The outcome of any litigation or other proceeding is inherently uncertain and might not be favorable to us, and we might not be able to obtain licenses to technology that we require on acceptable terms or at all. Further, we could encounter delays in product introductions, or interruptions in product sales, as we develop alternative methods or products. In addition, if we resort to legal proceedings to enforce our intellectual property rights or to determine the validity, scope and coverage of the intellectual property or other proprietary rights of others, the proceedings could be burdensome and expensive, even if we were to prevail. Any litigation that may be necessary in the future could result in substantial costs and diversion of resources and could have a material adverse effect on our business, operating results or financial condition.

As we move into new markets and applications for our products, incumbent participants in such markets may assert their patents and other proprietary rights against us as a means of slowing our entry into such markets or as a means to extract substantial license and royalty payments from us. Our competitors and others may now and, in the future, have significantly larger and more mature patent portfolios than we currently have. In addition, future litigation may involve patent holding companies or other adverse patent owners who have no relevant product revenue and against whom our own patents may provide little or no deterrence or protection. Therefore, our commercial success may depend in part on our non-infringement of the patents or proprietary rights of third parties. Numerous significant intellectual property issues have been litigated, and will likely continue to be litigated, between existing and new participants in our existing and targeted markets and competitors may assert that our products infringe their intellectual property rights as part of a business strategy to impede our successful entry into or growth in those markets. Third parties may assert that we are employing their proprietary technology without authorization. In addition, our competitors and others may have patents or may in the future obtain patents and claim that making, having made, using, selling, offering to sell or importing our products infringes these patents. We could incur substantial costs and divert the attention of our management and technical personnel in defending against any of these claims. Parties making claims against us may be able to obtain injunctive or other relief, which could block our ability to develop, commercialize and sell products, and could result in the award of substantial damages against us. In the event of a successful claim of infringement against us, we may be required to pay damages and ongoing royalties, and obtain one or more licenses from third parties, or be prohibited from selling certain products. We may not be able to obtain these licenses on acceptable terms, if at all. We could incur substantial costs related to royalty payments for licenses obtained from third parties, which could negatively affect our financial results. In addition, we could encounter delays in product introductions while we attempt to develop alternative methods or products to avoid infringing third-party patents or proprietary rights. Defense of any lawsuit or failure to obtain any of these licenses could prevent us from commercializing products, and the prohibition of sale of any of our products could materially affect our business and our ability to gain market acceptance for our products. With respect to trademarks, infringement litigation or threats of infringement litigation may require us to re-brand our product in order to enter into the new mark.

Furthermore, 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 this type of litigation. In addition, during the course of this kind of litigation, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

In addition, our agreements with some of our customers, suppliers or other entities with whom we do business require us to defend or indemnify these parties to the extent they become involved in infringement claims, including the types of claims described above. We could also voluntarily agree to defend or indemnify third parties in instances where we are not obligated to do so if we determine it would be important to our business relationships. If we are required or agree to defend or indemnify third parties in connection with any infringement claims, we could incur significant costs and expenses that could adversely affect our business, operating results, or financial condition.

Our ability to use our net operating loss carryforwards may be limited and may result in increased future tax liability to us.

We have incurred net losses since our inception and may never achieve profitability. As of December 31, 2022, we had net operating loss, or NOL, carryforwards of approximately $402.0 million, $78.8 million and $126.1 million available to reduce future taxable income, if any, for federal, California and other state income tax purposes, respectively. The U.S. federal NOL carryforwards will begin to expire in 2031 while for state purposes, the NOL carryforwards begin to expire in 2023. In addition, as of December 31, 2022, we had foreign net operating loss carryforwards of approximately $69.9 million and $44.2 million available to reduce future taxable income, if any, for Canadian and French income tax purposes, respectively. The Canada net operating loss carryforwards will begin to expire in 2034, while for French purposes, the net operating losses will carryforward indefinitely. These NOL carryforwards could expire unused and be unavailable to offset future income tax liabilities. Under the Tax Cuts and Jobs Acts, or Tax Act, which was enacted in December 2017, federal NOLs incurred in tax years beginning after December 31, 2017 may be carried forward indefinitely, but the deductibility of such federal NOLs is limited.

To the extent that we continue to generate taxable losses, unused losses will carry forward to offset future taxable income, if any, until such unused losses expire. We may be limited in the portion of NOL carryforwards that we can use in the future to offset taxable income for U.S. federal and state income tax purposes, and federal tax credits to offset federal tax liabilities. Sections 382 and 383 of Internal Revenue Code limit the use of NOLs and tax credits after a cumulative change in corporate ownership of more than 50% occurs within a three-year period. The limitation could prevent a corporation from using some or all its NOL and tax credits before they expire within their normal 20-year lifespan, as it places a formula limit of how much NOL and tax credits a loss corporation can use in a tax year. In the event we have undergone an ownership change under Section 382 of the Internal Revenue Code, if we earn net taxable income, our ability to use our pre-change NOL carryforwards to offset U.S. federal taxable income may become subject to limitations, which could potentially result in increased future tax liability to us.

On March 27, 2020, the CARES Act was signed into law. The CARES Act changes certain provisions of the 2017 Tax Act. Under the CARES Act, NOLs arising in taxable years beginning after December 31, 2017 and before January 1, 2021 may be carried back to each of the five taxable years preceding the tax year of such loss, but NOLs arising in taxable years beginning after December 31, 2020 may not be carried back. In addition, the CARES Act eliminates the limitation on the deduction of NOLs to 80% of current year taxable income for taxable years beginning before January 1, 2021, and increases the amount of interest expense that may be deducted to 50% of adjusted taxable income for taxable years beginning in 2019 or 2020. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the Tax Act, as modified by the CARES Act, is uncertain and our business, financial conditions, results of operations and growth prospects could be materially and adversely affected.

Changes to Internal Revenue Code Section 174 under the 2017 Tax Cuts and Jobs Act went into effect in 2022. The revised code no longer permits a deduction for research and development expenditures in the tax year that such costs are incurred. Instead, such costs must be capitalized and amortized over five or 15 years for U.S. and foreign costs, respectively. The new rules will change the utilization of our NOLs and it is uncertain whether the new rules will be repealed or modified in the future.

Impairment in the value of our goodwill or other intangible assets could have a material adverse effect on our operating results and financial condition.

We record goodwill and intangible assets at fair value upon the acquisition of a business. Goodwill represents the excess of amounts paid for acquiring businesses over the fair value of the net assets acquired. Goodwill and indefinite-lived intangible assets are evaluated for impairment annually, or more frequently if conditions warrant, by comparing the carrying value of a reporting unit to its estimated fair value. Intangible assets with definite lives are reviewed for impairment when events or circumstances indicate that their carrying value may not be recoverable. Declines in operating results, divestitures, sustained market declines and other factors that impact the fair value of our reporting unit could result in an impairment of goodwill or intangible assets and, in turn, a charge to net income. Any such charges could have a material adverse effect on our results of operations or financial condition.

Our effective tax rate may fluctuate and we may incur obligations in tax jurisdictions in excess of amounts that have been accrued.

We are subject to income taxes in the United States and various foreign jurisdictions. Our effective tax rate may be lower or higher than experienced in the past due to numerous factors, including a change in the mix of our revenue from country to country, the establishment or release of valuation allowances against our deferred tax assets, and changes in tax laws. In addition, we have recorded gross unrecognized tax benefits in our consolidated financial statements that, if recognized, would impact our effective tax rate. We are subject to tax audits in various jurisdictions, including the United States, and tax authorities may disagree with certain positions we have taken and assess additional taxes. There can be no assurance that we will accurately predict the outcomes of these audits, and the actual outcomes could have a material impact on our net income or financial condition. Any of these factors could cause us to experience an effective tax rate significantly different from previous periods or our current expectations, which could have an adverse effect on our business and results of operations. The recognition of deferred tax assets is reduced by a valuation allowance if it is more likely than not that the tax benefits will not be realized. We regularly review our deferred tax assets for recoverability and establish a valuation allowance based on historical income, projected future income, the expected timing of the reversals of existing temporary differences, and the implementation of tax-planning strategies.

Changes in financial accounting standards or practices may cause adverse, unexpected financial reporting fluctuations and affect our reported operating results.

U.S. GAAP is subject to interpretation by the Financial Accounting Standards Board, the Securities and Exchange Commission, or the SEC, and various bodies formed to promulgate and interpret appropriate accounting principles. A change in accounting standards or practices can have a significant effect on our reported results and may even affect our reporting of transactions completed before the change is effective. New accounting pronouncements and varying interpretations of accounting pronouncements have occurred and may occur in the future. Changes to existing rules or the questioning of current practices may adversely affect our reported financial results or the way we conduct our business.

Our consolidated financial statements are subject to change and if our estimates or judgments relating to our critical accounting policies prove to be incorrect, our operating results could be adversely affected.

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in our consolidated financial statements and related notes. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, as provided in the section titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in this Annual Report on Form 10-K. The results of these estimates form the basis for making judgments about the carrying values of assets, liabilities, and equity, and the amount of revenue and expenses that are not readily apparent from other sources. Critical accounting policies and estimates used in preparing our consolidated financial statements include those related to: revenue recognition; write-down of supplies; the useful lives of property and equipment; the recoverability of long-lived assets; the incremental borrowing rate for leases; the estimation of the fair value of intangible assets and contingent consideration; variable interest entity assessment; impairment of equity investment, at cost; stock options; income tax uncertainties, including a valuation allowance for deferred tax assets; reserve on accounts receivable and contingencies. Our operating results may be adversely affected if our assumptions change or if actual circumstances differ from those in our assumptions, which could cause our operating results to fall below the expectations of securities analysts and investors, resulting in a decline in the price of our common stock.

Risks Related to Being a Public Company

We will continue to incur increased costs and demands on management as a result of compliance with laws and regulations applicable to public companies, which could harm our operating results.

As a public company, we will continue to incur significant legal, accounting, consulting and other expenses that we did not incur as a private company, including costs associated with public company accounting and reporting requirements. In addition, the Sarbanes-Oxley Act of 2002 and the Dodd-Frank Act of 2010, as well as rules implemented by the SEC, and The Nasdaq Stock Market LLC, impose a number of requirements on public companies, including with respect to corporate governance practices. Our management and other personnel need to devote a substantial amount of time to these compliance and disclosure obligations. Moreover, these rules and regulations have and will continue to increase our legal, accounting and

financial compliance costs and make some activities more complex, time-consuming and costly. We also expect that it will continue to be expensive for us to maintain director and officer liability insurance.

If we are unable to implement and maintain effective internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our reported financial information and the market price of our common stock may be negatively affected.

As a public company, we are required to maintain internal control over financial reporting and to report any material weaknesses in such internal control. Section 404 of the Sarbanes-Oxley Act of 2002 requires that we evaluate and determine the effectiveness of our internal control over financial reporting and provide a management report on our internal controls on an annual basis. If we have material weaknesses in our internal control over financial reporting, we may not detect errors on a timely basis and our consolidated financial statements may be materially misstated. We will need to maintain and enhance the systems, processes and documentation necessary to comply with Section 404 of the Sarbanes-Oxley Act as we grow, and we will require additional management and staff resources to do so. Additionally, even if we conclude our internal controls are effective for a given period, we may in the future identify one or more material weaknesses in our internal controls, in which case our management will be unable to conclude that our internal control over financial reporting is effective. We are also required to include an attestation report from our independent registered public accounting firm on the effectiveness of our internal control over financial reporting annually. Further, our recent acquisitions of Decipher Biosciences and HalioDx, both of which were previously private companies and were not subject to audits of internal controls, require or will require us to incorporate additional controls to such businesses, which may be difficult, costly and time-consuming. Even if our management concludes that our internal control over financial reporting is effective, our independent registered public accounting firm may conclude that there are material weaknesses with respect to our internal controls or the level at which our internal controls are documented, designed, implemented or reviewed.

If we are unable to conclude that our internal control over financial reporting is effective, or if our auditors were to express an adverse opinion on the effectiveness of our internal control over financial reporting because we had one or more material weaknesses, investors could lose confidence in the accuracy and completeness of our financial disclosures, which could cause the price of our common stock to decline. Irrespective of compliance with Section 404, any failure of our internal control over financial reporting could have a material adverse effect on our reported operating results and harm our reputation. Internal control deficiencies could also result in a restatement of our financial results.

Investors' expectations of our performance relating to environmental, social and governance factors may impose additional costs and expose us to new risks.

There is an increasing focus from certain investors, employees, regulators and other stakeholders concerning corporate responsibility, specifically related to environmental, social and governance, or ESG, matters. Some investors may use these non-financial performance factors to guide their investment strategies and, in some cases, may choose not to invest in us if they believe our policies and actions relating to corporate responsibility are inadequate. We may face reputational damage in the event that we do not meet the ESG standards set by various constituencies.

Furthermore, if our competitors' corporate social responsibility performance is perceived to be better than ours, potential or current investors may elect to invest with our competitors instead. In addition, in the event that we communicate certain initiatives and goals regarding environmental, social and governance matters, we could fail, or be perceived to fail, in our achievement of such initiatives or goals, or we could be criticized for the scope of such initiatives or goals. If we fail to satisfy the expectations of investors, employees and other stakeholders or our initiatives are not executed as planned, our reputation and business, results of operations, and financial condition could be adversely affected.

Risks Related to Our Common Stock

Our stock price may be volatile, and you may not be able to sell shares of our common stock at or above the price you paid.

The trading price of our common stock is likely to continue to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. These factors include:

- actual or anticipated variations in our and our competitors' results of operations;
- the global macroeconomic impact of the current COVID-19 outbreak, rising interest rates or inflationary pressures;

- announcements by us or our competitors of new products, commercial relationships or capital commitments;
- changes in reimbursement by current or potential payers, including governmental payers;
- issuance of new securities analysts' reports or changed recommendations for our stock;
- fluctuations in our revenue, due in part to the way in which we recognize revenue;
- actual or anticipated changes in regulatory oversight of our products;
- developments or disputes concerning our intellectual property or other proprietary rights;
- commencement of, or our involvement in, litigation;
- announced or completed acquisitions of businesses or technologies by us or our competitors, including the effect of additional equity we or our competitors issue as consideration for such acquisitions;
- any major change in our management; and
- general economic conditions, including inflation and changes in interest rates, and slow or negative growth of our markets.

In addition, the stock market in general, and the market for stock of life sciences companies in particular, has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. Broad market and industry factors may seriously affect the market price of our common stock, regardless of our actual operating performance. These fluctuations may cause the trading volume of our stock to decrease. In addition, in the past, following periods of volatility in the overall market and the market price of a particular company's securities, securities class action litigation has often been instituted against these companies. This litigation, if instituted against us, could result in substantial costs and a diversion of our management's attention and resources.

Anti-takeover provisions in our charter documents and under Delaware law could discourage, delay or prevent a change in control and may affect the trading price of our common stock.

Provisions in our restated certificate of incorporation and our amended and restated bylaws may have the effect of delaying or preventing a change of control or changes in our management. Our restated certificate of incorporation and amended and restated bylaws include provisions that:

- authorize our board of directors to issue, without further action by the stockholders, up to 5.0 million shares of undesignated preferred stock;
- require that any action to be taken by our stockholders be effected at a duly called annual or special meeting and not by written consent;
- specify that special meetings of our stockholders can be called only by our board of directors, our chairman of the board, or our chief executive officer;
- establish an advance notice procedure for stockholder approvals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to our board of directors;
- establish that our board of directors is divided into three classes, Class I, Class II and Class III, with each class serving staggered terms;
- provide that our directors may be removed only for cause;
- provide that vacancies on our board of directors may, except as otherwise required by law, be filled only by a majority of directors then in office, even if less than a quorum;
- provide that the federal district courts of the United States shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act of 1933, as amended;
- specify that no stockholder is permitted to cumulate votes at any election of directors; and
- require a super-majority of votes to amend certain of the above-mentioned provisions.

In addition, we are subject to the provisions of Section 203 of the Delaware General Corporation Law regulating corporate takeovers. Section 203 generally prohibits us from engaging in a business combination with an interested stockholder subject to certain exceptions.

We have never paid dividends on our capital stock, and we do not anticipate paying dividends in the foreseeable future.

We have never paid dividends on any of our capital stock and currently intend to retain any future earnings to fund the growth of our business. We may enter into credit agreements or other borrowing arrangements in the future that will restrict our ability to declare or pay cash dividends on our common stock. Any determination to pay dividends in the future will be at the discretion of our board of directors and will depend on our financial condition, operating results, capital requirements, general business conditions and other factors that our board of directors may deem relevant. As a result, capital appreciation, if any, of our common stock will be the sole source of gain for the foreseeable future.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

We lease office and laboratory facilities in South San Francisco (approximately 59,000 square feet) and San Diego (approximately 28,400 square feet), California; Austin, Texas (approximately 10,400 square feet); Marseille, France (approximately 31,400 square feet); and Richmond, Virginia (approximately 8,200 square feet). We believe our facilities are in good condition and adequate for their current use. We may expand or improve our current facilities or add additional facilities as appropriate to meet the needs of our operations.

ITEM 3. LEGAL PROCEEDINGS

We are not currently a party to any material legal proceedings. We may from time to time become involved in legal proceedings arising in the ordinary course of business.

ITEM 4. MINE SAFETY DISCLOSURE

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

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

Holders of Record

As of February 24, 2023, there were 14 holders of record of our common stock. Because many of our shares of common stock are held in street name by brokers and other nominees on behalf of stockholders, we are unable to estimate the total number of beneficial owners of our commons stock represented by these holders of record.

Dividend Policy

We have never declared or paid dividends on our common stock and do not expect to pay dividends on our common stock for the foreseeable future. Instead, we anticipate that all of our earnings in the foreseeable future will be used for the operation and growth of our business. Any future determination to declare dividends will be subject to the discretion of our board of directors and will depend on various factors, including applicable laws, our results of operations, financial condition, future prospects, and any other factors deemed relevant by our board of directors. In addition, the terms of our credit agreement restrict our ability to pay dividends on our common stock, and we may also enter into credit agreements or other borrowing arrangements in the future that will further restrict our ability to declare or pay dividends on our common stock.

Recent Sale of Unregistered Securities and Use of Proceeds

None.

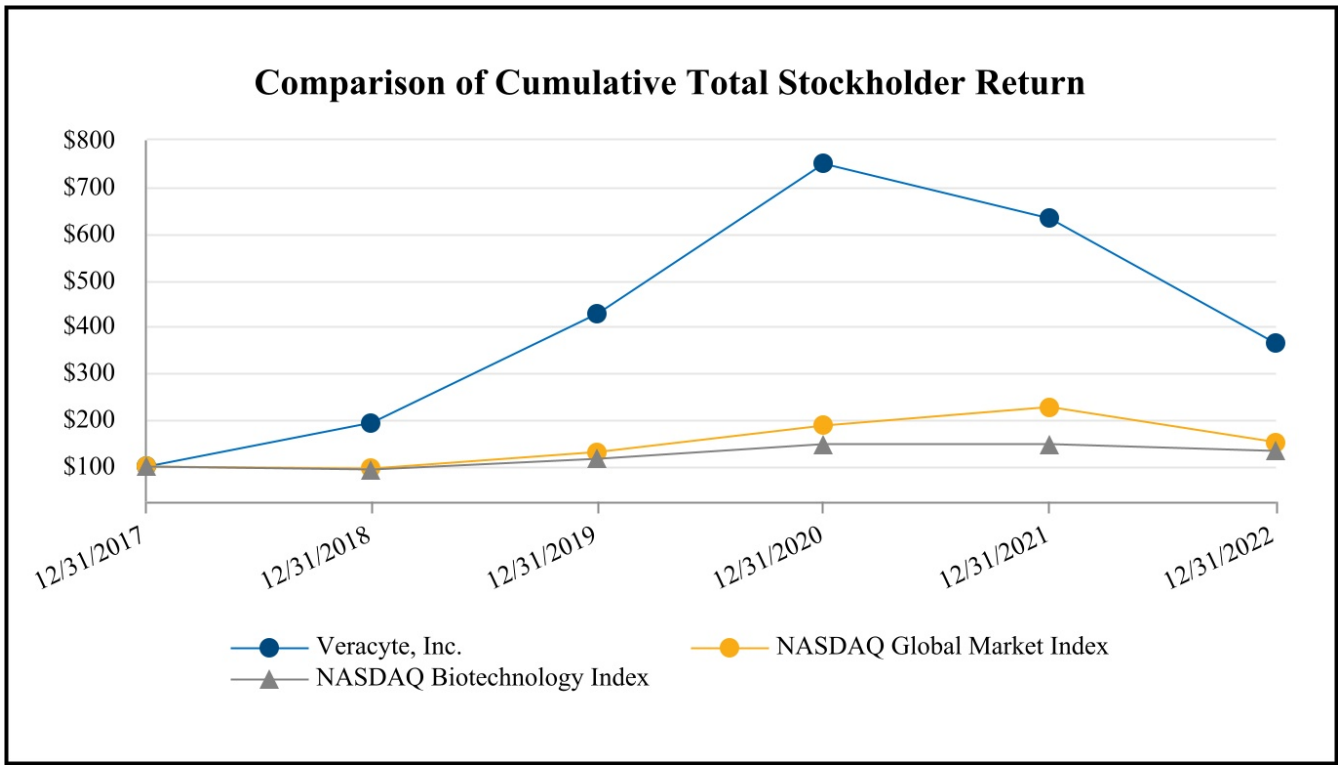
Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

Stock Performance Graph

The following information is not deemed to be "soliciting material" or to be "filed" with the Securities and Exchange Commission or subject to Regulation 14A or 14C under the Securities Exchange Act of 1934, as amended, or the Exchange Act, or to the liabilities 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, except to the extent we specifically incorporate it by reference into such a filing.

The graph below compares the cumulative total stockholder return of our common stock to the Nasdaq Global Market Index and the Nasdaq Biotechnology Index. The graph and table below assume that $100 was invested on the starting date and dividends, if any, were reinvested on the date of payment without payment of any commissions. The comparisons in the table are required by the SEC and are not intended to forecast or be indicative of future performance of our common stock.



	December 31, 2017	December 31, 2018	December 31, 2019	December 31, 2020	December 31, 2021	December 31, 2022
Veracyte, Inc.	$ 100.00	$ 193.00	$ 428.00	$ 749.00	$ 631.00	$ 363.00
Nasdaq Global Market Index	$ 100.00	$ 96.00	$ 130.00	$ 187.00	$ 227.00	$ 152.00
Nasdaq Biotechnology Index	$ 100.00	$ 94.00	$ 117.00	$ 148.00	$ 148.00	$ 133.00

ITEM 6. [RESERVED]

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of financial condition and results of operations should be read together with the consolidated financial statements and the related notes included in Item 8 of Part II of this Annual Report on Form 10-K. This discussion and analysis contains certain forward-looking statements that involve risks and uncertainties. Our actual results may differ materially from those discussed below. Factors that could cause or contribute to such differences include, but are not limited to, those identified below and those set forth under the section entitled "Risk Factors" in Item 1A, and other documents we file with the Securities and Exchange Commission. Historical results are not necessarily indicative of future results.

Overview

We are a global diagnostics company that empowers clinicians with the high-value insights they need to guide and assure patients at pivotal moments in the race to diagnose and treat cancer. Our high-performing tests enable clinicians to make more confident diagnostic, prognostic and treatment decisions, helping patients avoid unnecessary procedures and interventions, and speed time to appropriate treatment, thereby improving outcomes for patients all over the world.

We currently offer tests in thyroid cancer (Afirma); prostate cancer (Decipher Prostate); breast cancer (Prosigna); interstitial lung diseases (Envisia); and bladder cancer (Decipher Bladder). Our Percepta Nasal Swab test is being run in our CLIA lab in support of clinical studies and our tests for kidney cancer and lymphoma are in development, the latter as a companion diagnostic.

We serve global markets with two complementary models. In the United States, we offer LDTs through our centralized CLIA certified laboratories in South San Francisco and San Diego, California, supported by our cytopathology expertise in Austin, Texas. Additionally, primarily outside of the United States, we provide tests to patients through distribution to laboratories and hospitals that can perform the tests locally. Today, this includes our Prosigna test, and in the future, we intend to offer the Envisia, Decipher Prostate and Percepta Nasal Swab tests as in IVD tests that run on the nCounter Analysis System. We believe our broad menu of advanced diagnostic tests, combined with our ability to deliver them globally, uniquely positions us in the diagnostics industry.

In March 2021, we acquired Decipher Biosciences, expanding our genomic testing menu into urologic cancers. The acquisition also provided us with Decipher GRID (Genomics Resource for Intelligent Discovery), a platform and database that helps drive biopharmaceutical partnerships, KOL engagement and pipeline development in urologic cancers.

In August 2021, we acquired HalioDx SAS and HalioDx Inc., historically a wholly owned subsidiary of HalioDx SAS, (collectively referred to as “HalioDx”), giving us the capabilities and expertise to manufacture our own IVD test kits for use on the nCounter Analysis System. The acquisition also deepened our scientific expertise and capabilities in the rapidly growing area of immuno-oncology further strengthening our offerings to biopharmaceutical and other partners.

COVID-19 and Macroeconomic Factors

We believe the COVID-19 outbreak, including its numerous variants, impacted our total test volumes primarily during 2020 and 2021. Our customers, third-party contract manufacturers, carriers, suppliers and collaboration partners have been affected by the closure of hospitals, doctors' offices, manufacturing sites, or country borders, among other measures put in place around the world. Layoffs, furloughs and unplanned loss of staff in the medical industry and otherwise during the pandemic have had, and will continue to have, negative impacts on the demand for and supply of medical care and diagnostic tests, which affects the frequency with which tests are ordered, and the ability of doctors and hospitals to administer such tests. Further the inability to travel and conduct face-to-face meetings can also make it more difficult to expand utilization of our products into new geographies and to drive awareness of our products.

Our Decipher Prostate test has been least impacted by the pandemic because our customers are mostly community-based urology practices, which generally remained more accessible to patients and our sales reps. Our Afirma thyroid cancer test was impacted by COVID-19 in 2020 and portions of 2021 as a majority of our samples come from large institutions which are less accessible to patients and our reps. We believe our pulmonology businesses were the most impacted since the bronchoscopy procedures used to collect samples for our Envisia test are considered elective procedures and are performed in hospital settings, which have been more restrictive. Further these tests are ordered by pulmonologists who could be largely preoccupied with caring for COVID-19 patients.

In addition, ongoing interest rate increases and inflation in the U.S. and other markets globally may heighten the risk of an economic downturn or recession and volatility and dislocation in the capital or credit markets in the U.S. or globally. Moreover, the continued strengthening of the U.S. dollar compared to other currencies (including the Euro, in which a material portion of our European sales and costs are denominated), has impacted and may continue to impact our results of operations. We intend to continue to monitor macroeconomic conditions closely and may determine to take certain financial or operational actions in response to such conditions as appropriate. Finally, the measures taken by Russia in response to European support for Ukraine have increased the risk of disruptions to energy supplies in Europe, which may impact our ability to manufacture tests from our facility in Marseille, France.

The extent of the impact of COVID-19 and other macroeconomic factors on our future liquidity and operational performance will depend on certain developments, including the deployment and long-term efficacy of vaccines; the duration and spread of the outbreak particularly in the form of more transmissible variants; the impact on our customers' operations; the impact to our sales and renewal cycles; changes in central bank policies and interest rates; rates of inflation; and changes in foreign currency exchange rates. See Risk Factors for further discussion.

Factors Affecting Our Performance

Reported Total Test Volume

Our performance depends on the number of tests that we perform and report as completed in our CLIA-certified laboratories and Prosigna tests processed on the nCounter Analysis System. Factors impacting the number of tests that we report as completed include, but are not limited to:

- the impact of COVID-19 on patients seeking to have tests performed;
- the availability of hospital staff to perform and support procedures needed to collect samples for our tests;
- the number of samples that we receive that meet the medical indication for each test performed;
- the quantity and quality of the sample received;
- receipt of the necessary documentation, such as physician order and patient consent, required to perform, bill and collect for our tests;
- the patient's ability to pay or provide necessary insurance coverage for the tests performed;
- the time it takes us to perform our tests and report the results;
- the seasonality inherent in our business, such as the impact of work days per period, timing of industry conferences and the timing of when patient deductibles are exceeded, which also impacts the reimbursement we receive from insurers; and
- our ability to obtain prior authorization or meet other requirements instituted by payers, benefit managers, or regulators necessary to be paid for our tests.

Continued Adoption of and Reimbursement for our Products

Revenue growth depends on our ability to secure coverage decisions, achieve broader reimbursement at increased levels from third-party payers, expand our base of prescribing physicians and increase our penetration in existing accounts. Because some payers consider our products experimental and investigational, we may not receive payment for tests and payments we receive may not be at acceptable levels. We expect our revenue growth to increase if more payers make a positive coverage decision and as payers enter into contracts with us, which should enhance our revenue and cash collections. Our sales teams are aligned under our general manager-based structure to focus on specific products and global markets. If we are unable to expand the base of prescribing physicians and penetration within these accounts at an acceptable rate, or if we are not able to execute our strategy for increasing reimbursement and associated collections, we may not be able to effectively increase our revenue. We expect to continue to see pressure from payers to limit the utilization of tests, generally, and we believe more payers are deploying cost containment tactics, such as pre-authorization, reduction of the payer portion of reimbursement and employing laboratory benefit managers to reduce utilization rates.

How We Recognize Revenue

We recognize revenue in accordance with the provisions of ASC 606, *Revenue from Contracts with Customers*, or ASC 606. This process involves identifying the contract with a customer, determining the performance obligations in the contract,

determining the contract price, allocating the contract price to the distinct performance obligations in the contract, and recognizing revenue when the performance obligations have been satisfied.

Testing Revenue

We bill for testing services at the time of test completion as defined by the delivery of test results. We recognize revenue based on estimates of the amount that will ultimately be realized. In determining the amount to accrue for a delivered test, we consider factors such as payment history, payer coverage, whether there is a reimbursement contract between the payer and us, payment as a percentage of agreed upon rate (if applicable), amount paid per test and any current developments or changes that could impact reimbursement. These estimates require significant judgment by management. Actual results could differ from those estimates and assumptions.

Generally, cash we receive is collected within 12 months of the date the test is billed. We cannot provide any assurance as to when, if ever, or to what extent any of these amounts will be collected. Notwithstanding our efforts to obtain payment for these tests, payers may deny our claims, in whole or in part, and we may never receive payment for these tests.

We bill list price regardless of contract rate, but only recognize revenue from amounts that we estimate are collectible and meet our revenue recognition criteria. Revenue may not be equal to the billed amount due to a number of factors that we consider when determining revenue accrual rates, including differences in reimbursement rates, the amounts of patient co-payments and co-insurance, the existence of secondary payers, claims denials and the amount we expect to ultimately collect. Finally, when we increase our list price, it will increase the cumulative amounts billed but may not positively impact accrued revenue. In addition, payer contracts generally include the right of offset and payers may offset payments prior to resolving disputes over tests performed.

Generally, we determine accrual rates by calculating an average of reimbursement from all payers for tests performed over a four-quarter period as it reduces the effects of temporary volatility and seasonality. The periods selected to determine accrual rates typically are at least six months old because it takes a significant period of time to collect from some payers. We may also determine accrual rates based on other factors such as coverage decisions, contracts, or more recent reimbursement data as appropriate.

The average test reimbursement rates will change over time due to a number of factors, including medical coverage decisions by payers, the effects of contracts signed with payers, changes in allowed amounts by payers, our ability to successfully win appeals for payment, and our ability to collect cash payments from third-party payers and individual patients. Historical average reimbursement is not necessarily indicative of future average reimbursement.

We incur expense for tests in the period in which the test is conducted and recognize revenue for tests in the period in which our revenue recognition criteria are met.

Product Revenue

Our products consist of the Prosigna breast cancer assay, the nCounter Analysis System and related diagnostic kits. We recognize product revenue when control of the promised goods is transferred to our customers, in an amount that reflects the consideration expected to be received in exchange for those products. This process involves identifying the contract with a customer, determining the performance obligations in the contract, determining the contract price, allocating the contract price to the distinct performance obligations in the contract, and recognizing revenue when the performance obligations have been satisfied. A performance obligation is considered distinct from other obligations in a contract when it provides a benefit to the customer either on its own or together with other resources that are readily available to the customer and is separately identified in the contract. Performance obligations are considered satisfied once we have transferred control of a product to the customer, meaning the customer has the ability to use and obtain the benefit of the product. We recognize product revenue for satisfied performance obligations only when there are no uncertainties regarding payment terms or transfer of control. Shipping and handling costs incurred for product shipments are charged to our customers and included in product revenue. Revenue is presented net of the taxes that are collected from customers and remitted to governmental authorities.

Biopharmaceutical and Other Revenue

We enter into arrangements to license or provide access to our assets or services, including testing services, clinical services, research and development, contract manufacturing and development, as well as other services. Such arrangements may require us to deliver various rights, data, services, manufactured diagnostic test kits, access and/or testing services to partner biopharmaceutical companies. One such arrangement is a collaborative arrangement that falls under the scope of ASC Topic 808, *Collaborative Arrangements*, or ASC 808. The underlying terms of these arrangements generally provide for consideration paid to us in the form of nonrefundable fees; payments on delivery of data, test results or manufactured products; costs of service plus margin; performance milestone payments; expense reimbursements and possibly royalty and/or other payments. Net sales of data or other services to our customers are recognized in accordance with ASC 606 and are classified under biopharmaceutical and other revenue. Milestone payments which fall under the scope of ASC 808, are recognized in the same manner as milestone payments from customers and are considered to be collaboration revenue. Payments received that are not related to sales or services to a customer or collaboration revenue are recorded as offsets against research and development expense or cost of biopharmaceutical and other revenue in our consolidated statements of operations.

In arrangements involving more than one good or service delivered to a customer, each good or service is evaluated to determine whether it qualifies as a distinct performance obligation based on whether (i) the customer can benefit from the good or service either on its own or together with other resources that are readily available and (ii) the good or service is separately identifiable from other promises in the contract. The consideration under the arrangement is then allocated to each separate distinct performance obligation based on its respective relative stand-alone selling price. The estimated selling price of each deliverable reflects our best estimate of what the selling price would be if the deliverable was regularly sold by us on a stand-alone basis or using an adjusted market assessment approach if the selling price on a stand-alone basis is not available.

The consideration allocated to each distinct performance obligation is recognized as revenue when control is transferred which may be at a point in time or over time. Consideration associated with at-risk substantive performance milestones is recognized as revenue when it is probable that a significant reversal of the cumulative revenue recognized will not occur. Should there be royalties, we utilize the sales and usage-based royalty exception in arrangements that resulted from the license of intellectual property, recognizing revenue generated from royalties or profit sharing as the underlying sales occur.

Timing of Our Research and Development Expenses

We deploy state-of-the-art and costly genomic technologies in our biomarker discovery experiments, and our spending on these technologies may vary substantially from quarter to quarter. We also spend a significant amount on activities to secure clinical trial results in support of our testing and product development portfolio and on-market tests, as well as clinical validation and utilization studies. The timing of these research and development activities is difficult to predict, as is the timing of clinical trial enrollments and sample acquisitions. If a substantial number of clinical samples are acquired in a given quarter or if a high-cost experiment is conducted in one quarter versus the next, the timing of these expenses can affect our financial results. We conduct clinical studies to validate our new products, as well as on-going clinical studies to further the published evidence to support our commercialized tests. As these studies are initiated, start-up costs for each site can be significant and concentrated in a specific quarter. Spending on research and development, for both experiments and studies, may vary significantly by quarter depending on the timing of these various expenses.

Financial Overview

Revenue

Through December 31, 2022, we had derived most of our revenue from the sale of Decipher and Afirma tests, delivered primarily to physicians in the United States. We generally invoice third-party payers upon delivery of a patient report to the prescribing physician. As such, we take the assignment of benefits and the risk of cash collection from the third-party payer and

individual patients. Third-party payers and other customers in excess of 10% of total revenue and their related revenue as a percentage of total revenue were as follows:

	Year Ended December 31,		
	2022	2021	2020
Medicare	31 %	30 %	24 %
UnitedHealthcare	10 %	10 %	11 %
	41 %	40 %	35 %

For tests performed, we recognize the related revenue upon delivery of a patient report to the prescribing physician based on the amount that we expect to ultimately receive. In determining the amount to accrue for a delivered test, we consider factors such as payment history, payer coverage, whether there is a reimbursement contract between the payer and us, payment as a percentage of agreed upon reimbursement rate (if applicable), amount paid per test and any current development or changes that could impact reimbursement. Upon ultimate collection, the amount received is compared to previous estimates and the amount accrued is adjusted accordingly. Our ability to increase our revenue will depend on our ability to penetrate the market, obtain positive coverage policies from additional third-party payers, obtain reimbursement and/or enter into contracts with additional third-party payers for our current and new tests, and increase reimbursement rates for tests performed. Finally, should the judgments underlying our estimated reimbursement change, our accrued revenue and financial results could be negatively impacted in future periods.

Cost of Testing Revenue

The components of our cost of testing revenue are laboratory expenses, sample collection kit costs, sample collection expenses, compensation expense, license fees and royalties, depreciation, other expenses such as equipment and laboratory supplies, and allocations of facility and information technology expenses. Costs associated with performing tests are recorded as the test is processed regardless of whether and when revenue is recognized with respect to that test. As a result, our cost of testing revenue as a percentage of testing revenue may vary significantly from period to period because we may not recognize all revenue in the period in which the associated costs are incurred. We expect cost of testing revenue in absolute dollars to increase as the number of tests we perform increases. However, we expect that the cost per test will decrease over time due to leveraging fixed costs, efficiencies we may gain as test volume increases and from automation, process efficiencies and other cost reductions. As we introduce new tests, initially our cost of testing revenue will be high as we expect to run suboptimal batch sizes, run quality control batches, test batches, registry samples, and generally incur costs that may suppress or reduce gross margins. This will disproportionately increase our aggregate cost of testing revenue until we achieve efficiencies in processing these new tests.

Cost of Product Revenue

Our cost of product revenue consists primarily of costs of purchasing instruments and diagnostic kits from third-party contract manufacturers, installation, warranty, service and packaging and delivery costs. In addition, cost of product revenue includes royalty costs for licensed technologies included in our products and labor expenses. As our Prosigna test kits are sold in various configurations with different number of tests, our product cost per test will vary based on the specific kit configuration purchased by customers.

Cost of Biopharmaceutical and Other Revenue

Our cost of biopharmaceutical and other revenue are the costs of performing activities under arrangements that require us to perform research and development, commercialization, contract manufacturing and development, and contract testing services on behalf of a customer. This cost is mainly composed of compensation expense, laboratory supplies and pass-through costs.

Research and Development

Research and development expenses include expenses incurred to develop our technology, collect clinical samples and conduct clinical studies to develop and support our products and pipeline. These expenses consist of compensation expenses, direct research and development expenses such as laboratory supplies and costs associated with setting up and conducting

clinical studies at domestic and international sites, professional fees, depreciation and amortization, other miscellaneous expenses and allocation of facility and information technology expenses. We expense all research and development costs in the periods in which they are incurred. We incurred a majority of our research and development expenses in years ended December 31, 2022 and December 31, 2021 in support of our early-stage products, including Percepta Nasal Swab. Going forward, we expect to incur significant expense as we invest in the development of our innovation engine, early-stage products, including required clinical studies, the development of current tests for the nCounter instrument and the transition of manufacturing to our Veracyte SAS facility.

Selling and Marketing

Selling and marketing expenses consist of compensation expenses, direct marketing expenses, professional fees, other expenses such as travel and communications costs, as well as allocation of facility and information technology expenses. Our sales team of approximately 120 representatives is organized by business unit, with separate teams calling on thyroid cancer, urologic cancers, and pulmonology physicians. The business units have dedicated marketing support, as well as a marketing operations team that serves the commercial organization broadly. Prosigna sales outside of the U.S. are led by country managers that call on laboratories and breast cancer oncologists and have dedicated marketing support.

General and Administrative

General and administrative expenses include compensation expenses for executive officers and administrative, billing and client service personnel, professional fees for legal and audit services, occupancy costs, depreciation and amortization, and other expenses such as information technology and miscellaneous expenses offset by allocation of facility and information technology expenses to other functions. General and administrative expenses include costs related to the acquisitions of Decipher Biosciences and HalioDx, which were included in general and administrative compensation expense and professional fees. We expect general and administrative expenses to continue to increase as we build our infrastructure to scale revenue growth, and to stabilize thereafter.

Intangible Asset Amortization

Our finite-lived intangible assets, acquired in business combinations, are being amortized over 4 to 15 years, using the straight-line method. Amortization expense is expected to be approximately $21.3 million per year through 2024 and decrease thereafter.

Interest Expense

Interest expense is attributable to our borrowings under debt agreements and costs associated with the prepayment of debt.

Other Income, Net

Other income, net consists primarily of realized and unrealized gains and losses on foreign currency transactions, French research tax credits, interest expense on our debt and interest income from our cash held in interest bearing accounts. The French research tax credits (crédit d’impôt recherche or CIR) are generated by our wholly owned subsidiary, Veracyte SAS, in connection with its research efforts performed in Marseille, France.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our audited consolidated financial statements, which have been prepared in accordance with United States generally accepted accounting principles, or U.S. GAAP. The preparation of the consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent liabilities at the date of the consolidated financial statements, as well as the reported revenue generated and expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions and any such differences may be material. We believe that the accounting policies discussed below are critical to

understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

Testing Revenue

We bill for testing services at the time of test completion as defined by the delivery of test results. We recognize revenue on an accrual basis based on estimates of the amount that will ultimately be realized. In determining the amount to accrue for a delivered test, we consider factors such as payment history, payer coverage, whether there is a reimbursement contract between the payer and us, payment as a percentage of the agreed upon rate (if applicable), amount paid per test and any current developments or changes that could impact reimbursement. These estimates require significant judgment by management.

Generally, we determine accrual rates by calculating an average of reimbursement from all payers for tests performed over a four-quarter period as it reduces the effects of temporary volatility and seasonality. The periods selected to determine accrual rates tend to be at least six months old because it takes a significant period of time to collect from some payers. We may also determine accrual rates based on other factors such as coverage decisions, contracts, or more recent reimbursement data as appropriate.

We use judgment in determining accrual rates and our judgments will continue to evolve in the future as we continue to gain reimbursement experience.

Product Revenue

Our products consist of the Prosigna breast cancer assay, the nCounter Analysis System and related diagnostic kits. We recognize product revenue when control of the promised goods is transferred to our customers, in an amount that reflects the consideration expected to be received in exchange for those products. Shipping and handling costs incurred for product shipments are charged to our customers and included in product revenue. Revenues are presented net of the taxes that are collected from customers and remitted to governmental authorities.

Biopharmaceutical and Other Revenues

For biopharmaceutical and other revenue, we develop estimates and assumptions that require judgment to determine the underlying stand-alone selling price for each performance obligation which determines how the transaction price is allocated among the performance obligations. The estimation of the stand-alone selling price may include independent evidence of market price, forecasted revenues or costs, development timelines, discount rates, and probabilities of technical and regulatory success. We evaluate each performance obligation to determine if they can be satisfied at a point in time or over time, and we measure the services delivered to the collaborative partner which are periodically reviewed based on the progress of the related program. For licenses that are bundled with other promises, we utilize judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time. The effect of any change made to an estimated input component and, therefore revenue or expense recognized, would be recorded as a change in estimate. In addition, variable consideration must be evaluated to determine if it is constrained and, therefore, excluded from the transaction price.

At the inception of each arrangement that includes milestone payments (variable consideration), we evaluate whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price. Milestone payments that are not within either party’s control, such as non-operational developmental and regulatory approvals, are generally not considered probable of being achieved until those approvals are received. At the end of each reporting period, we re-evaluate the probability of achievement of milestones that are within either party’s control, such as operational developmental milestones and any related constraint, and if necessary, adjusts our estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenues and earnings in the period of adjustment. Revisions to our estimate of the transaction price may also result in negative revenues and earnings in the period of adjustment. One collaboration arrangement with milestone payments falls under the scope of ASC 808. These milestone payments are recognized in the same manner as milestone payments from customers and are classified under biopharmaceutical and other revenue.

Other Significant Accounting Policies

Acquisitions

We first determine whether a set of assets acquired and liabilities assumed constitute a business and should be accounted for as a business combination. If the assets acquired are not a business, we account for the transaction as an asset acquisition. Business combinations are accounted for by using the acquisition method of accounting. Under the acquisition method, assets acquired, and liabilities assumed are recorded at their respective fair values as of the acquisition date in our consolidated financial statements. The excess of the fair value of consideration transferred over the fair value of the net assets acquired is recorded as goodwill. Contingent consideration obligations incurred in connection with a business combination are recorded at fair value on the acquisition date and remeasured at each subsequent reporting period until the related contingencies are resolved, with the resulting changes in fair value recorded in earnings. The estimation of the fair value of the contingent consideration is based on the present value of the expected payments calculated by assessing the likelihood of when the related milestones would be achieved, discounted using our estimated borrowing rate.

Intangible Asset Amortization

We have acquired finite-lived and indefinite-lived intangible assets in business combinations. These intangible assets are measured at their respective fair values as of the acquisition date and are subject to potential adjustments within the measurement period, which may be up to one year from the acquisition dates. The fair values of the intangible assets are generally determined using income approaches such as the multi-period excess earnings method, the with-and-without method and the relief from royalty method. These income approaches are based on various estimates for each asset including the estimate of future cash flows including, revenue assumptions (such as projected testing volumes, growth rates), discount rates and the expected economic life/obsolescence factors of the respective assets. Our finite-lived intangible assets are being amortized using the straight-line method over their estimated useful lives of 4 to 15 years, based on management's estimate of the period over which their economic benefits will be realized, product life and patent life. Our in-process research and development, or IPR&D, is not amortized until it becomes commercially viable and placed in service. At the time when the IPR&D is placed in service, we will determine a useful life. We test these intangible assets for impairment on an annual basis or when events or circumstances indicate a reduction in the fair value below their carrying amounts.

Goodwill

Goodwill is reviewed for impairment on an annual basis or more frequently if events or circumstances indicate that it may be impaired. Our goodwill evaluation is based on both qualitative and quantitative assessments regarding the fair value of goodwill relative to its carrying value. We have determined that we operate in a single segment and have a single reporting unit associated with the development and commercialization of diagnostic products. In the event we determine that it is more likely than not the carrying value of the reporting unit is higher than its fair value, quantitative testing is performed comparing recorded values to estimated fair values. If impairment is present, the impairment loss is measured as the excess of the recorded goodwill over its implied fair value. We perform our annual evaluation of goodwill during the fourth quarter of each fiscal year. There was no impairment recognized during the years ended December 31, 2022, 2021, or 2020.

Stock-based Compensation

We recognize stock-based compensation expense for only those shares underlying stock options and restricted stock units that we expect to vest on a straight-line basis over the requisite service period of the award. We estimate the fair value of stock options using a Black-Scholes option-pricing model, which requires the input of highly subjective assumptions, including the option's expected term and stock price volatility. In addition, judgment is also required in estimating the number of stock-based awards that are expected to be forfeited. Forfeitures are estimated based on historical experience at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Performance-based stock units, which vest upon the achievement of certain performance conditions, are subject to the employees’ continued service with us. The probability of vesting is assessed at each reporting period and compensation cost is adjusted based on this probability assessment. The assumptions used in calculating the fair value of share-based payment awards represent management's best estimates, but these estimates involve inherent uncertainties and the application of management's judgment. As a result, if factors change and we use different assumptions, our stock-based compensation expense could be materially different in the future.

Supplies and Inventory

Supplies consists of materials and reagents consumed in the performance of testing services. Inventory consists of raw materials consumed in the contract manufacturing process as well as finished and semi-finished components used in the assembly of diagnostic kits related to product sales. Inventory is stated at the lower of cost or net realizable value on a weighted average basis. We periodically analyze supply and inventory levels and expiration dates, and write down supply or inventory that has become obsolete, that has a cost basis in excess of its net realizable value, or in excess of expected sales requirements as cost of revenue. We record an allowance for excess or obsolete supplies and inventory using an estimate based on historical trends and evaluation of near-term expirations.

Leases

We determine if an arrangement is, or contains, a lease at inception. Operating leases are included in right-of-use assets - operating leases and operating lease liabilities in our consolidated balance sheets, representing our right to use an underlying asset for the lease term and the obligation to make lease payments arising from the lease. Right-of-use, or ROU, assets and lease liabilities are recognized at commencement based on the present value of lease payments over the lease term. We use our incremental borrowing rate based on the estimated rate of interest for collateralized borrowing over a similar term of the lease payments. The ROU assets also includes any lease payments made and is adjusted for lease incentives. Lease terms may include options to extend or terminate the lease which are recognized when it is reasonably certain that we will exercise that option. Lease expense is recognized on a straight-line basis over the lease terms. Lease and non-lease components are accounted for as a single lease component. Financing leases are immaterial and are included in property and equipment, net and other liabilities in the consolidated balance sheets. Leases with terms of 12 months or less are not recorded on our balance sheet.

Foreign Currency Translation

The functional currency of our foreign subsidiary, Veracyte SAS, is the Euro. Assets and liabilities denominated in foreign currencies are translated to U.S. dollars using the exchange rates at the balance sheet date. Foreign currency translation adjustments are recorded as a component of accumulated other comprehensive loss within stockholders' equity. Revenue and expenses from our foreign subsidiaries are translated using the monthly average exchange rates in effect during the period in which the transactions occur. Foreign currency transaction gains and losses are recorded in other income, net, on the consolidated statements of operations.

Comprehensive Loss

Comprehensive loss is the change in stockholders' equity from transactions and other events and circumstances other than those resulting from investments by stockholders and distributions to stockholders. Our comprehensive loss includes our net loss and gains and losses from the foreign currency translation of the assets and liabilities of our foreign subsidiaries.

Results of Operations

Comparison of the Years Ended December 31, 2022 and 2021 (in thousands of dollars, except percentages and test volume)

	Year Ended December 31,			
	2022	Change	%	2021
Revenue:				
Testing revenue	$ 250,544	$ 62,362	33 %	$ 188,182
Product revenue	12,632	1,168	10 %	11,464
Biopharmaceutical and other revenue	33,360	13,492	68 %	19,868
Total revenue	296,536	77,022	35 %	219,514
Operating expense:				
Cost of testing revenue	75,317	16,457	28 %	58,860
Cost of product revenue	7,820	1,933	33 %	5,887
Cost of biopharmaceutical and other revenue	18,445	8,792	91 %	9,653
Research and development	40,603	10,760	36 %	29,843
Selling and marketing	97,560	17,720	22 %	79,840
General and administrative	76,518	(24,835)	(25)%	101,353
Intangible asset amortization	21,354	5,373	34 %	15,981
Total operating expenses	337,617	36,200	12 %	301,417
Loss from operations	(41,081)	40,822	50 %	(81,903)
Other income, net	4,654	4,400	1,732 %	254
Loss before income tax benefit	(36,427)	45,222	(55)%	(81,649)
Income tax provision (benefit)	133	6,219	(102)%	(6,086)
Net loss	$ (36,560)	$ 39,003	52 %	$ (75,563)
Other Operating Data:				
Diagnostic tests reported	93,340	22,891	32 %	70,449
Product tests sold	9,184	1,068	13 %	8,116
Total test volume	102,524	23,959	30 %	78,565
Depreciation and amortization expense	$ 25,928	$ 6,335	32 %	$ 19,593
Stock-based compensation expense	$ 27,456	$ 4,937	22 %	$ 22,519

Revenue

Revenue increased $77.0 million, or 35%, for the year ended December 31, 2022 compared to 2021. This was primarily due to a $62.4 million increase in testing revenue driven by a 32% volume increase, as well as a $13.5 million increase in our Biopharmaceutical and other revenue. Testing revenue and volume reported for the year ended December 31, 2022 increased primarily due to Decipher Prostate tests, which contributed $56.6 million of the increase and was partially impacted by the closing of the Decipher Bioscience acquisition on March 12, 2021. The remaining increase was driven by growth in our Afirma test volume. Product revenue increased $1.2 million for the year ended December 31, 2022 compared to 2021, driven primarily by product tests kits as well as sales of the nCounter Analysis System. This growth was partially offset by a decline in currency exchange rates, which negatively impacted product revenue by $1.1 million. Biopharmaceutical and other revenue increased by $13.5 million for the year ended December 31, 2022 driven primarily by the contribution of the HalioDx acquisition and partially offset by a $4.0 million milestone payment received in the prior year period that did not repeat. Currency exchange rates negatively impacted our total revenue by $4.7 million when compared to prior year rates, primarily related to our Biopharmaceutical and other revenue.

Comparison of revenue for the years ended December 31, 2021 and 2020 is included in Item 8 of Part II of the Annual Report on Form 10-K filed with the Securities and Exchange Commission dated February 28, 2022.

Cost of revenue

Comparison of the years ended December 31, 2022 and 2021 was as follows (in thousands of dollars, except percentages):

	Year Ended December 31,			
	2022	Change	%	2021
Cost of testing revenue:				
Laboratory expense	$ 37,502	$ 5,312	17 %	$ 32,190
Sample collection expense	9,633	4,210	78 %	5,423
Compensation expense	17,018	5,243	45 %	11,775
License fees and royalties	75	(856)	(92)%	931
Depreciation and amortization	1,247	106	9 %	1,141
Other expenses	4,080	1,170	40 %	2,910
Allocations	5,762	1,272	28 %	4,490
Total	$ 75,317	$ 16,457	28 %	$ 58,860
Cost of product revenue:				
Product costs	$ 5,879	$ 1,128	24 %	$ 4,751
License fees and royalties	1,089	28	3 %	1,061
Depreciation and amortization	151	76	101 %	75
Other expenses	620	620	NM	—
Allocations	81	81	NM	—
Total	$ 7,820	$ 1,933	33 %	$ 5,887
Cost of biopharmaceutical and other revenue:				
Compensation expense	$ 8,935	$ 4,678	110 %	$ 4,257
License fees and royalties	170	69	68 %	101
Depreciation and amortization	400	166	71 %	234
Other expenses	8,732	3,638	71 %	5,094
Allocations	208	241	(730)%	(33)
Total	$ 18,445	$ 8,792	91 %	$ 9,653

Cost of testing revenue increased $16.5 million, or 28.0%, for the year ended December 31, 2022 compared to 2021. The increase in cost of testing revenue is due to increased volume in testing, primarily related to Afirma and Decipher Prostate as well as approximately $1.3 million of costs related to sample collection kits that were classified as marketing expense in the prior year.

Cost of product revenue is related to sales of Prosigna and nCounter Analysis Systems. Cost of product revenue increased $1.9 million, or 33%, for the year ended December 31, 2022 compared to the same period in 2021, driven by increased test volume, system sales and transitional costs related to in-sourcing the manufacturing of the product line to our facilities in Marseille, France. This was partially offset by a $0.3 million currency exchange impact.

Cost of biopharmaceutical and other revenue includes labor costs incurred by our employees working on customer projects and laboratory supplies and pass-through expenses incurred on these projects. Cost of biopharmaceutical and other

revenue increased by $8.8 million driven by the operations of HalioDx following its acquisition on August 2, 2021, including a $1.9 million favorable currency exchange impact when compared to prior year rates.

Comparison of cost of revenue for the years ended December 31, 2021 and 2020 are included in Item 8 of Part II of the Annual Report on Form 10-K filed with the Securities and Exchange Commission dated February 28, 2022.

Research and development

Comparison of the years ended December 31, 2022 and 2021 was as follows (in thousands of dollars, except percentages):

	Year Ended December 31,			
	2022	Change	%	2021
Research and development expense				
Compensation expense	$ 27,383	$ 6,276	30 %	$ 21,107
Direct research and development expense	5,675	1,171	26 %	4,504
Depreciation and amortization	524	212	68 %	312
Other expenses	4,146	2,389	136 %	1,757
Allocations	2,875	712	33 %	2,163
Total	$ 40,603	$ 10,760	36 %	$ 29,843

Research and development expense increased $10.8 million or 36% for the year ended December 31, 2022 compared to 2021. The increase in compensation expense and other expenses were primarily due to an increase in headcount, including the additions of new personnel from the acquisitions of Decipher Biosciences and HalioDx. The increase in direct research and development expense was primarily related to our on-going clinical studies including but not limited to furthering the support and evidence of our Percepta Nasal Swab test. We recognized a $0.9 million favorable impact from foreign currency exchange when compared to the prior year rates.

Comparison of research and development expense for the years ended December 31, 2021 and 2020 are included in Item 8 of Part II of the Annual Report on Form 10-K filed with the Securities and Exchange Commission dated February 28, 2022.

Selling and marketing

Comparison of the years ended December 31, 2022 and 2021 was as follows (in thousands of dollars, except percentages):

	Year Ended December 31,			
	2022	Change	%	2021
Selling and marketing expense:				
Compensation expense	$ 72,258	$ 14,847	26 %	$ 57,411
Direct marketing expense	6,138	(1,073)	(15)%	7,211
Other expenses	13,485	3,045	29 %	10,440
Allocations	5,679	901	19 %	4,778
Total	$ 97,560	$ 17,720	22 %	$ 79,840

Selling and marketing expense increased $17.7 million, or 22%, for the year ended December 31, 2022 compared to 2021. The increase in compensation expense was primarily due to additional employees and commissions to support the growth of Decipher test volume. Following our acquisition of HalioDx in August 2021, HalioDx's operations contributed to the increase in compensation expenses, inclusive of a $1.0 million favorable impact from foreign currency exchange rates when compared to the prior year rates. The increase in other expenses was primarily due to increased travel and entertainment to also support

the Decipher test volume. The reduction in direct marketing expense is related to the reclassification of sample collection kit expense to cost of revenue for the year ended December 31, 2022.

Comparison of selling and marketing expense for the years ended December 31, 2021 and 2020 are included in Item 8 of Part II of the Annual Report on Form 10-K filed with the Securities and Exchange Commission dated February 28, 2022.

General and administrative

Comparison of the years ended December 31, 2022 and 2021 was as follows (in thousands of dollars, except percentages):

	Year Ended December 31,			
	2022	Change	%	2021
General and administrative expense:				
Compensation expense	$ 51,357	$ (13,585)	(21)%	$ 64,942
Occupancy costs	5,816	761	15 %	5,055
Depreciation and amortization	2,245	398	22 %	1,847
Other expenses	31,705	(9,202)	(22)%	40,907
Allocations	(14,605)	(3,207)	28 %	(11,398)
Total	$ 76,518	$ (24,835)	(25)%	$ 101,353

General and administrative expense decreased $24.8 million, or 25%, for the year ended December 31, 2022 compared to 2021. This decrease is driven by expenses recognized for the year ended December 31, 2021 related to the acquisitions of Decipher Biosciences and HalioDx, including $27.0 million of stock-based compensation and $20.1 million of professional fees and other costs associated with the transactions. Following the acquisitions of Decipher Biosciences in March 2021 and HalioDx in August 2021, their operations contributed to an increase in general and administrative expenses. Additionally, we recorded expense of $3.3 million for the year ended December 31, 2022 related to the impairment of an intangible asset. The remaining increase was primarily due to annual compensation adjustments and investments in infrastructure. General and administrative expenses related to occupancy costs and information technology costs are allocated monthly to general and administrative expense, selling and marketing expense, research and development expense, and cost of revenue based on the headcount and employee location. Foreign currency exchange had a $1.8 million favorable impact on general and administrative expense when compared to prior year rates.

Comparison of general and administrative expense for the years ended December 31, 2021 and 2020 are included in Item 8 of Part II of the Annual Report on Form 10-K filed with the Securities and Exchange Commission dated February 28, 2022.

Other income, net

Other income, net, increased $4.4 million for the year ended December 31, 2022 compared to 2021, primarily due to an increase of $0.9 million from the CIR related to operations in France, an increase of $1.8 million of interest and dividend income and an increase of $1.3 million of unrealized foreign currency gain (loss). The CIR are generated by our wholly owned subsidiary, Veracyte SAS, in connection with its research efforts performed in Marseille, France. We recognize other income from the CIR over time based on when the research and development expenses are incurred.

Comparison of Other income, net, for the years ended December 31, 2021 and 2020 are included in Item 8 of Part II of the Annual Report on Form 10-K filed with the Securities and Exchange Commission dated February 28, 2022.

Liquidity and Capital Resources

From inception through December 31, 2022, we have been financed primarily through net proceeds from the sale of our equity securities. We have incurred net losses since our inception. For the years ended December 31, 2022, 2021 and 2020, we had net losses of $36.6 million, $75.6 million and $34.9 million, respectively, and we expect to incur additional losses in 2023 and potentially in future years. As of December 31, 2022, we had an accumulated deficit of $393.7 million.

We believe our existing cash and cash equivalents and short-term investments of $178.9 million as of December 31, 2022, and cash flows generated by our revenue during the next 12 months will be sufficient to meet our anticipated cash requirements for at least the next 12 months. We expect that our near- and longer-term liquidity requirements will continue to consist of costs to run our laboratories, research and development expenses, selling and marketing expenses, general and administrative expenses, working capital, capital expenditures, lease obligations and general corporate expenses associated with the growth of our business. However, we may also use cash to acquire or invest in complementary businesses, technologies, services or products that would change our cash requirements. If we are not able to generate cash flows from our revenue to finance our cash requirements, we will need to finance future cash needs primarily through public or private equity offerings, debt financings, borrowings or strategic collaborations or licensing arrangements. If we raise funds by issuing equity securities, dilution to stockholders could result. Any equity securities issued also may provide for rights, preferences or privileges senior to those of holders of our common stock. The terms of debt securities issued or borrowings could impose significant restrictions on our operations. The incurrence of indebtedness or the issuance of certain equity securities could result in increased fixed payment obligations and could also result in restrictive covenants, such as limitations on our ability to incur additional debt or issue additional equity, limitations on our ability to acquire or license intellectual property rights, restrictions on our cash and other operating restrictions that could adversely affect our ability to conduct our business. In addition, the issuance of additional equity securities by us, or the possibility of such issuance, may cause the market price of our common stock to decline. In the event that we enter into collaborations or licensing arrangements to raise capital, we may be required to accept unfavorable terms. These agreements may require that we relinquish or license to a third-party on unfavorable terms our rights to technologies or product candidates that we otherwise would seek to develop or commercialize ourselves, or reserve certain opportunities for future potential arrangements when we might be able to achieve more favorable terms. If we are not able to secure additional funding when needed, we may have to delay, reduce the scope of or eliminate one or more research and development programs or selling and marketing initiatives, or forgo potential acquisitions or investments. In addition, we may have to work with a partner on one or more of our products or development programs, which could lower the economic value of those programs to us.

Public Offering of Common Stock

In February 2021, we issued and sold 8,547,297 shares of common stock in a registered public offering, including 1,114,864 shares issued and sold upon the underwriters' exercise in full of their option to purchase additional shares, at a price to the public of $74.00 per share. Our net proceeds from the offering were approximately $593.8 million, after deducting underwriting discounts and commissions and offering expenses of $38.7 million.

In August 2020, we issued and sold 6,900,000 shares of common stock in a registered public offering, including 900,000 shares issued and sold upon the underwriters' exercise in full of their option to purchase additional shares, at a price to the public of $30 per share. Our net proceeds from the offering were approximately $193.8 million, after deducting underwriting commissions and offering expenses of $13.2 million.

Operating Leases

We lease office and laboratory facilities in South San Francisco and San Diego, California; Austin, Texas; Marseille, France; and Richmond, Virginia, and lease certain equipment under various non-cancelable lease agreements. The lease terms extend to October 2030 and contain extension of lease term and expansion options. As of December 31, 2022, the leases have a weighted average remaining lease term of 3.9 years and total future minimum lease payments of $16.6 million.

As of December 31, 2022, Veracyte SAS has signed a lease agreement for facilities which will be constructed in Marseille, France. The lease will commence upon completion of the construction of the office building which we currently expect to occur in the fourth quarter of 2023 at which time we will record a lease liability and a corresponding right-of-use asset. The initial term of the lease will be twelve years with annual rent of approximately $1.4 million, which is subject to change based on final construction.

Supplies Purchase Commitments

We had non-cancelable purchase commitments with suppliers to purchase a minimum quantity of supplies for approximately $10.1 million at December 31, 2022.

Acquisition-Related Contingent Consideration

In December 2019, we acquired from NanoString the exclusive global diagnostics license to the nCounter Analysis System, the Prosigna breast cancer prognostic gene signature assay, and the LymphMark lymphoma subtyping assay. Pursuant to the terms of the agreement, we paid NanoString $40.0 million in cash and $10.0 million in Veracyte common stock, and may pay up to an additional $10.0 million in cash, contingent upon first achievement or occurrence, by or on behalf of Veracyte, of the commercial launch of the first, second and third diagnostic tests for use on the nCounter multiplex analysis system. As of December 31, 2022, the achievement of two of the milestones is forecasted to occur within the next 12 months, requiring payments totaling $7.0 million.

HalioDx Acquisition-Related Payments

In connection with the HalioDx Acquisition, 11,031 unvested HalioDx free ordinary share awards, or free shares, were modified to provide us the right to purchase the vested free shares (call option) from the holders and the holders the right to sell the vested free shares to us (put option) from time to time through late 2023. As a result of the call and put options, the free shares are liability classified. Additionally, in connection with the HalioDx Acquisition, all of HalioDx's equity-classified options that were outstanding prior to the HalioDx Acquisition were terminated and cancelled at the acquisition date. We committed to pay cash consideration of $1.5 million to holders of unvested options on the date the employee satisfies the original service requirement.

As part of the agreement, we held back $16.8 million of the cash consideration, or the holdback, which will be payable to the founders of HalioDx based on their continuous employment with us. Fifty percent of the holdback was placed in escrow on the founders' behalf on the first anniversary of the closing date and the remainder will be paid directly to the founders on the second anniversary.

As of December 31, 2022, the remaining amount to be paid for all HalioDx related items was $9.6 million subject to holders continued service, excluding any potential associated social charges.

Loan and Security Agreement

On November 3, 2017, we entered into the Loan and Security Agreement with Silicon Valley Bank. The Loan and Security Agreement allowed us to borrow up to $35.0 million, with a $25.0 million term loan, or Term Loan, and a revolving line of credit of up to $10.0 million, or the Revolving Line of Credit, subject to, with respect to the Revolving Line of Credit, a borrowing base of 85% of eligible accounts receivable. In October 2022, the Loan and Security Agreement matured, and we repaid the outstanding principal and final payment totaling $1.2 million.

Cash Flows

The following table summarizes our cash flows for the years ended December 31, 2022, 2021 and 2020 (in thousands of dollars):

	Years Ended December 31,		
	2022	**2021**	**2020**
Net cash provided by (used in) operating activities	$ 7,535	$ (31,621)	$ (9,711)
Net cash used in investing activities	(29,387)	(739,206)	(3,837)
Net cash provided by financing activities	3,494	596,320	203,595

Cash Flows from Operating Activities

Cash provided by operating activities for the year ended December 31, 2022 was $7.5 million. The net loss of $36.6 million includes non-cash charges of $26.7 million of stock-based compensation expense, $25.9 million of depreciation and amortization, including $21.4 million of intangible asset amortization, $3.3 million of impairment of intangible asset, noncash lease expense of $3.3 million, and $0.5 million of foreign currency loss. Cash used as a result of changes in operating assets and liabilities was $16.4 million, primarily comprising an increase in accounts receivable of $4.5 million, a decrease in accrued liabilities of $3.9 million, a decrease in operating lease liability of $3.4 million, an increase in supplies and inventory of

$3.0 million, and an increase in other assets of $3.0 million, partially offset by a decrease in prepaid expense and other current assets of $1.4 million.

Cash used in operating activities for the year ended December 31, 2021 was $31.6 million. The net loss of $75.6 million includes non-cash charges of $22.5 million of stock-based compensation expense, $19.6 million of depreciation and amortization, including $16.0 million of intangible asset amortization, $6.3 million of deferred income taxes, noncash lease expense of $1.6 million, $1.2 million of foreign currency loss, and a $0.8 million expense for the revaluation of the contingent consideration related to the NanoString transaction. Cash provided by changes in operating assets and liabilities was $4.2 million, primarily comprised of an increase in accrued liabilities of $14.4 million and an increase in accounts payable of $5.2 million, partially offset by an increase in accounts receivable of $8.6 million, an increase in prepaid expense and other current assets of $3.3 million, an increase in supplies of $1.5 million and a decrease in operating lease liability of $1.8 million.

Cash used in operating activities for the year ended December 31, 2020 was $9.7 million. The net loss of $34.9 million includes non-cash charges of $13.0 million of stock-based compensation expense, $7.9 million of depreciation and amortization, including $5.1 million of intangible asset amortization, a $1.1 million write-down of supplies, noncash lease expense of $1.0 million, an impairment loss of $1.0 million and a $1.5 million expense for the revaluation of the contingent consideration related to the NanoString transaction. Cash used as a result of changes in operating assets and liabilities was $0.5 million, primarily comprised of a decrease in accrued liabilities of $0.9 million, a decrease in operating lease liability of $1.4 million, and an increase in prepaid expense and other current assets of $1.0 million, partially offset by a decrease in accounts receivable of $1.0 million, an increase in accounts payable of $0.7 million and a decrease in supplies of $1.1 million.

Cash Flows from Investing Activities

Cash used in investing activities for the year ended December 31, 2022 was $29.4 million for the purchase and maturity of short-term investments and acquisition of property and equipment.

Cash used in investing activities for the year ended December 31, 2021 was $739.2 million consisting of $574.4 million for the acquisition of Decipher Biosciences, $162.4 million for the acquisition of HalioDx and $5.4 million for the acquisition of property and equipment partially offset by $3.0 million of proceeds from the sale of an equity investment.

Cash used in investing activities for the year ended December 31, 2020 was $2.8 million for the acquisition of property and equipment and $1.0 million for the purchase of equity securities of MAVIDx, Inc.

Cash Flows from Financing Activities

Cash provided by financing activities for the year ended December 31, 2022 was $3.5 million, consisting of $7.9 million in proceeds from the exercise of options to purchase our common stock and purchase of stock under our Employee Stock Purchase Plan, or ESPP, partially offset by $3.2 million in tax payments during the period related to the vesting of restricted stock units granted to employees and $1.3 million in payment of long-term debt.

Cash provided by financing activities for the year ended December 31, 2021 was $596.3 million, consisting of $593.8 million in net proceeds from the issuance of common stock in a public offering in February 2021, $11.5 million in proceeds from the exercise of options to purchase our common stock and purchase of stock under our ESPP partially offset by $9.0 million in tax payments during the period related to the vesting of restricted stock units granted to employees.

Cash provided by financing activities for the year ended December 31, 2020 was $203.6 million, consisting of $193.8 million in net proceeds from the issuance of common stock in a public offering in August 2020, $13.7 million in proceeds from the exercise of options to purchase our common stock and purchase of stock under our ESPP partially offset by $3.8 million in tax payments during the period related to the vesting of restricted stock units granted to employees.

Recent Accounting Pronouncements

In October 2021, the FASB issued ASU 2021-08, *Business Combinations (Topic 805): Accounting for Contract Assets and Contract Liabilities from Contracts with Customers*, which requires entities to recognize and measure contract assets and contract liabilities acquired in a business combination in accordance with ASC 2014-09, Revenue from Contracts with Customers (Topic 606). The update will generally result in an entity recognizing contract assets and contract liabilities at

amounts consistent with those recorded by the acquiree immediately before the acquisition date rather than at fair value. The new standard is effective on a prospective basis for fiscal years beginning after December 15, 2022, with early adoption permitted. We do not expect to have a material impact on our consolidated financial statements and related disclosures from the adoption of this guidance.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Risk

We are exposed to market risks in the ordinary course of our business. These risks primarily relate to interest rates. We had cash and cash equivalents and short-term investments of $178.9 million as of December 31, 2022 which consisted of bank deposits, money market funds and U.S. treasury securities. Such interest-bearing instruments carry a degree of risk; however, As of December 31, 2022, a hypothetical 10% change in interest rates would not have had a material impact on our consolidated financial statements.

Foreign Currency Risk

As of December 31, 2022, we held $3.6 million of bank deposits denominated in Euros. Such Euro denominated deposits carry a degree of risk from changes in currency exchange rates as the gains or losses from changes in exchange rates are included in our net loss and comprehensive loss. As of December 31, 2022 a hypothetical 10% appreciation or depreciation of the U.S. dollar relative to the Euro would not have had a material impact on our consolidated financial statements.

Inflation Risk

We are facing inflation headwinds in compensation, travel, supply and inventory costs, however we do not believe that inflation has had a material effect on our business, financial condition, or operating results to date.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Veracyte, Inc.
Index to Consolidated Financial Statements

	Page No.
REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM (PCAOB ID: 42)	82
Consolidated Balance Sheets as of December 31, 2022 and 2021	84
Consolidated Statements of Operations for the Years Ended December 31, 2022, 2021, and 2020	85
Consolidated Statements of Comprehensive Loss for the Years Ended December 31, 2022, 2021, and 2020	86
Consolidated Statements of Stockholders' Equity for the Years Ended December 31, 2022, 2021, and 2020	87
Consolidated Statements of Cash Flows for the Years Ended December 31, 2022, 2021, and 2020	88
Notes to Consolidated Financial Statements	90

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and the Board of Directors of Veracyte, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Veracyte, Inc. (the Company) as of December 31, 2022 and 2021, the related consolidated statements of operations, comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2022, and the related notes (collectively referred to as the “consolidated financial statements”). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2022 and 2021, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2022, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2022, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 Framework), and our report dated February 28, 2023 expressed an unqualified opinion thereon.

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 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. 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.

Critical Audit Matters

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Revenue from diagnostic services

Description of the Matter

During the year ended December 31, 2022, the Company's revenue from diagnostic services was approximately $250.5 million. As discussed in Note 2, the Company's diagnostic services revenue is recognized upon the delivery of test results to the prescribing physician, at which time the Company bills for its services. The Company recognizes revenue related to billings based on estimates of the amount that will ultimately be realized.

Auditing the measurement of the Company's diagnostic services revenue was complex due to the judgments used in estimating the amount to be realized per test. In determining the amount to recognize for a delivered test the Company considers factors such as payment history, amount collected per test, payer coverage, and whether there is a reimbursement contract between the payer and the Company. The Company also considers whether historical collections per test are indicative of future collections or if there are any current or expected developments or changes that could affect reimbursement rates, which is an estimate that requires significant judgment by the Company.

How We Addressed the Matter in Our Audit

We obtained an understanding, evaluated the design, and tested the operating effectiveness of controls used by management in making this estimate. For example, we tested controls over management's review of changes in collection trends, payer rates, contract terms, and payer behavior and expectations of how those changes are expected to impact future collections and the amount of revenue to be recognized per test.

To test management's estimate of the amount of revenue to be recognized per test delivered our audit procedures included, among others, evaluating the methodology used, understanding and testing the significant assumptions discussed above, and testing the underlying data used by the Company (including the completeness and accuracy of historical data). We tested payment history and amount collected per test on a sample basis, including agreeing selections to supporting documentation such as physician requisition, cash collected, write-offs of receivables, and proof of delivery, as applicable. We evaluated and tested management's assessment of changes in payer trends, behaviors, and contract terms and how those changes will impact future cash collections as well as management's consideration of any contrary factors. We also assessed and tested management's review of differences between prior period accrual rates and actual cash collections and how those differences were factored into management's estimate of current period accrual rates.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2014.

San Diego, California
February 28, 2023

VERACYTE, INC.

Consolidated Balance Sheets

(in thousands, except share and par value amounts)

	As of December 31,	
	2022	2021
Assets		
Current assets:		
Cash and cash equivalents	$ 154,247	$ 173,197
Short-term investments	24,605	3,964
Accounts receivable	44,021	41,461
Supplies and inventory	14,294	11,225
Prepaid expenses and other current assets	11,469	13,255
Total current assets	248,636	243,102
Property and equipment, net	17,702	15,098
Right-of-use assets - operating leases	13,160	16,043
Intangible assets, net	174,866	202,731
Goodwill	695,891	707,904
Restricted cash	749	749
Other assets	5,418	2,198
Total assets	$ 1,156,422	$ 1,187,825
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 11,911	$ 12,360
Accrued liabilities	37,774	39,475
Current portion of long-term debt	—	1,127
Current portion of deferred revenue	2,613	4,646
Current portion of acquisition-related contingent consideration	6,060	2,682
Current portion of operating lease liabilities	4,070	3,630
Current portion of other liabilities	186	231
Total current liabilities	62,614	64,151
Deferred revenue, net of current portion	—	343
Deferred tax liability	4,531	5,592
Acquisition-related contingent consideration, net of current portion	2,498	5,722
Operating lease liabilities, net of current portion	10,648	14,096
Other liabilities	931	1,407
Total liabilities	81,222	91,311
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized, no shares issued and outstanding as of December 31, 2022 and 2021	—	—
Common stock, $0.001 par value; 125,000,000 shares authorized, 71,959,454 and 71,123,108 shares issued and outstanding as of December 31, 2022 and 2021, respectively	72	71
Additional paid-in capital	1,500,191	1,468,683
Accumulated deficit	(393,717)	(357,157)
Accumulated other comprehensive loss	(31,346)	(15,083)
Total stockholders' equity	1,075,200	1,096,514
Total liabilities and stockholders' equity	$ 1,156,422	$ 1,187,825

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

VERACYTE, INC.

Consolidated Statements of Operations

(in thousands, except share and per share amounts)

	Year Ended December 31,		
	2022	2021	2020
Revenue:			
Testing revenue	$ 250,544	$ 188,182	$ 101,970
Product revenue	12,632	11,464	9,845
Biopharmaceutical and other revenue	33,360	19,868	5,668
Total revenue	296,536	219,514	117,483
Operating expenses:			
Cost of testing revenue	75,317	58,860	35,913
Cost of product revenue	7,820	5,887	4,921
Cost of biopharmaceutical and other revenue	18,445	9,653	621
Research and development	40,603	29,843	17,204
Selling and marketing	97,560	79,840	52,389
General and administrative	76,518	101,353	36,729
Intangible asset amortization	21,354	15,981	5,095
Total operating expenses	337,617	301,417	152,872
Loss from operations	(41,081)	(81,903)	(35,389)
Other income, net	4,654	254	480
Loss before income tax benefit	(36,427)	(81,649)	(34,909)
Income tax provision (benefit)	133	(6,086)	—
Net loss	$ (36,560)	$ (75,563)	$ (34,909)
Net loss per common share, basic and diluted	$ (0.51)	$ (1.11)	$ (0.66)
Shares used to compute net loss per common share, basic and diluted	71,549,204	67,890,328	53,239,231

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

VERACYTE, INC.

Consolidated Statements of Comprehensive Loss

(in thousands)

	Year Ended December 31,		
	2022	2021	2020
Net loss	$ (36,560)	$ (75,563)	$ (34,909)
Other comprehensive loss:			
Change in currency translation adjustments	(16,263)	(15,083)	—
Net comprehensive loss	$ (52,823)	$ (90,646)	$ (34,909)

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

VERACYTE, INC.

Consolidated Statements of Stockholders' Equity

(in thousands)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2019	49,625	$ 50	$ 486,090	$ (246,685)	$ —	$ 239,455
Sale of common stock in a public offering, net of offering costs of $13,169	6,900	7	193,824	—	—	193,831
Issuance of common stock on exercise of stock options and vesting of restricted stock units	1,573	1	11,667	—	—	11,668
Issuance of common stock under employee stock purchase plan (ESPP)	103	—	2,037	—	—	2,037
Tax portion of vested restricted stock units	—	—	(3,845)	—	—	(3,845)
Stock-based compensation expense (employee)	—	—	12,017	—	—	12,017
Stock-based compensation expense (non-employee)	—	—	51	—	—	51
Stock-based compensation expense (ESPP)	—	—	927	—	—	927
Net loss	—	—	—	(34,909)	—	(34,909)
Balance at December 31, 2020	58,201	58	702,768	(281,594)	—	421,232
Sale of common stock in a public offering, net of offering costs of $38,677	8,547	9	593,812	—	—	593,821
Issuance of common stock for acquisition	3,347	3	147,086	—	—	147,089
Issuance of common stock on exercise of stock options and vesting of restricted stock units	947	1	9,174	—	—	9,175
Issuance of common stock under ESPP	81	—	2,353	—	—	2,353
Tax portion of vested restricted stock units	—	—	(9,029)	—	—	(9,029)
Stock-based compensation expense (employee)	—	—	20,795	—	—	20,795
Stock-based compensation expense (non-employee)	—	—	61	—	—	61
Stock-based compensation expense (ESPP)	—	—	1,663	—	—	1,663
Net loss	—	—	—	(75,563)	—	(75,563)
Comprehensive loss	—	—	—	—	(15,083)	(15,083)
Balance at December 31, 2021	71,123	71	1,468,683	(357,157)	(15,083)	1,096,514
Issuance of common stock on exercise of stock options and vesting of restricted stock units	681	1	4,193	—	—	4,194
Issuance of common stock under ESPP	155	—	3,748	—	—	3,748
Tax portion of vested restricted stock units	—	—	(3,167)	—	—	(3,167)
Stock-based compensation expense (employee)	—	—	24,781	—	—	24,781
Stock-based compensation expense (non-employee)	—	—	11	—	—	11
Stock-based compensation expense (ESPP)	—	—	1,942	—	—	1,942
Net loss	—	—	—	(36,560)	—	(36,560)
Comprehensive loss	—	—	—	—	(16,263)	(16,263)
Balance at December 31, 2022	71,959	$ 72	$ 1,500,191	$ (393,717)	$ (31,346)	$ 1,075,200

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

VERACYTE, INC.

Consolidated Statements of Cash Flows

(in thousands of dollars)

	Year Ended December 31,		
	2022	2021	2020
Operating activities			
Net loss	$ (36,560)	$ (75,563)	$ (34,909)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	25,928	19,593	7,944
Loss on disposal of property and equipment	206	—	—
Stock-based compensation	26,734	22,519	12,995
Provision for (benefit from) income taxes	133	(6,258)	—
Interest on end-of-term debt obligation	161	216	216
Write-down of excess supplies	—	—	1,088
Noncash lease expense	3,320	1,632	964
Revaluation of acquisition-related contingent consideration	154	810	1,506
Impairment loss	3,318	—	1,000
Effect of foreign currency on operations	522	1,211	(34)
Changes in operating assets and liabilities:			
Accounts receivable	(4,495)	(8,571)	955
Supplies and inventory	(3,011)	(1,464)	1,061
Prepaid expenses and other current assets	1,390	(3,316)	(970)
Other assets	(3,049)	(216)	37
Operating lease liability	(3,448)	(1,794)	(1,407)
Accounts payable	152	5,155	711
Accrued liabilities and deferred revenue	(3,920)	14,425	(868)
Net cash provided by (used in) operating activities	7,535	(31,621)	(9,711)
Investing activities			
Purchase of short-term investments	(33,519)	—	—
Proceeds from maturity of short-term investments	12,681	—	—
Acquisition of Decipher Biosciences, net of cash acquired	—	(574,411)	—
Acquisition of HalioDx, net of cash acquired	—	(162,419)	—
Proceeds from sale of equity securities	—	3,000	—
Purchase of equity securities	—	—	(1,000)
Purchases of property and equipment	(8,549)	(5,376)	(2,837)
Net cash used in investing activities	(29,387)	(739,206)	(3,837)
Financing activities			
Proceeds from issuance of common stock in a public offering, net of issuance costs	—	593,821	193,831
Payment of long-term debt	(1,281)	—	(100)
Payment of taxes on vested restricted stock units	(3,167)	(9,029)	(3,845)
Proceeds from the exercise of common stock options and employee stock purchases	7,942	11,528	13,709
Net cash provided by financing activities	3,494	596,320	203,595
(Decrease) increase in cash, cash equivalents and restricted cash	(18,358)	(174,507)	190,047
Effect of foreign currency on cash, cash equivalents and restricted cash	(592)	(1,514)	—
Net (decrease) increase in cash, cash equivalents and restricted cash	(18,950)	(176,021)	190,047
Cash, cash equivalents and restricted cash at beginning of year	173,946	349,967	159,920
Cash, cash equivalents and restricted cash at end of year	$ 154,996	$ 173,946	$ 349,967
Supplementary cash flow information of non-cash investing and financing activities:			
Shares issued for purchase consideration for a business combination	$ —	$ 147,089	$ —
Purchases of property and equipment included in accounts payable and accrued liabilities	—	392	294
Supplementary cash flow information:			
Cash paid for interest on debt	9	9	13
Cash paid for tax	570	112	112

Cash, Cash Equivalents and Restricted Cash:

	December 31,		
	2022	**2021**	**2020**
Cash and cash equivalents	$ 154,247	$ 173,197	$ 349,364
Restricted cash	749	749	603
Total cash, cash equivalents and restricted cash	$ 154,996	$ 173,946	$ 349,967

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

VERACYTE, INC.

Notes to Consolidated Financial Statements

1. Organization and Description of Business

Veracyte, Inc., or Veracyte, or the Company, is a global diagnostics company that empowers clinicians with the high-value insights they need to guide and assure patients at pivotal moments in the race to diagnose and treat cancer. Veracyte's high-performing tests enable clinicians to make more confident diagnostic, prognostic and treatment decisions, helping patients avoid unnecessary procedures and interventions, and speed time to appropriate treatment, thereby improving outcomes for patients all over the world.

Veracyte was incorporated in the state of Delaware on August 15, 2006, as Calderome, Inc. Calderome operated as an incubator until early 2008. On March 4, 2008, the Company changed its name to Veracyte, Inc. The Company’s headquarters are in South San Francisco, California, and it also has operations in San Diego, California; Austin, Texas; Richmond, Virginia; and Marseille, France.

The Company currently offers tests in thyroid cancer (Afirma); prostate cancer (Decipher Prostate); breast cancer (Prosigna); interstitial lung diseases (Envisia); and bladder cancer (Decipher Bladder). The Company’s Percepta Nasal Swab test is being run in its CLIA lab in support of clinical studies and its tests for kidney cancer and lymphoma are in development, the latter as a companion diagnostic.

The Company serves global markets with two complementary models. In the United States, it offers laboratory developed tests, or LDTs, through its centralized, Clinical Laboratory Improvement Amendments of 1988, or CLIA, certified laboratories in South San Francisco and San Diego, California, supported by its cytopathology expertise in Austin, Texas. Additionally, primarily outside of the United States, the Company provides its Prosigna test to patients through distribution to laboratories and hospitals that can perform the tests locally as an in vitro diagnostic, or IVD, test that runs on the nCounter Analysis System.

In March 2021, the Company acquired Decipher Biosciences, expanding the Company's genomic testing menu into urologic cancers. The acquisition also provided it with Decipher GRID (Genomics Resource for Intelligent Discovery), a platform and database that helps drive biopharmaceutical partnerships, key opinion leaders engagement and pipeline development in urologic cancers.

In August 2021, the Company acquired HalioDx SAS and HalioDx Inc., historically a wholly owned subsidiary of HalioDx SAS, collectively referred to as HalioDx, giving it the capabilities and expertise to manufacture the Company's own IVD test kits for use on the nCounter Analysis System. The acquisition also deepened its scientific expertise and capabilities in the rapidly growing area of immuno-oncology further strengthening its offerings to biopharmaceutical and other partners.

2. Summary of Significant Accounting Policies

Basis of Presentation

The Company's consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States, or U.S. GAAP. The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. All intercompany accounts and transactions have been eliminated in consolidation.

Reclassifications

Certain prior period balances have been reclassified to conform to current period presentation of the Company’s consolidated financial statements and accompanying notes. Such reclassifications have no effect on previously reported results of operations, accumulated deficit, subtotals of operating, investing or financing cash flows or consolidated balance sheet totals; however, for the period December 31, 2021, the Company reclassified $4.0 million of short-term investments from the prepaid expenses and other current assets caption in the consolidated balance sheets.

Use of Estimates

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent liabilities as of the date of the consolidated financial statements and the reported amounts of revenue and expenses during the reporting period. Significant items subject to such estimates include: revenue recognition; write-down of supplies; useful lives of property and equipment; the recoverability of long-lived assets; the incremental borrowing rates for leases; accounting for acquisitions; the estimation of the fair value of intangible assets and contingent consideration; stock based compensation; income tax uncertainties, including a valuation allowance for deferred tax assets; credit related losses on investments; and allowance for credit losses and contingencies. The Company bases these estimates on historical and anticipated results, trends, and various other assumptions that the Company believes are reasonable under the circumstances, including assumptions as to future events. These estimates form the basis for making judgments about the carrying values of assets and liabilities and recorded revenue and expenses that are not readily apparent from other sources. Actual results could differ from those estimates and assumptions.

Liquidity

The Company has incurred net losses since its inception and as of December 31, 2022, the Company had an accumulated deficit of $393.7 million. The Company believes its cash and cash equivalents and short-term investments of $178.9 million as of December 31, 2022, and its revenue from sales in 2023 will be sufficient to meet its anticipated cash requirements through at least February 2024.

In February 2021, the Company issued and sold 8,547,297 shares of common stock in a registered public offering, including 1,114,864 shares issued and sold upon the underwriters' exercise in full of their option to purchase additional shares, at a price to the public of $74.00 per share. The Company's net proceeds from the offering were approximately $593.8 million, after deducting underwriting commissions and offering expenses of $38.7 million.

In August 2020, the Company issued and sold 6,900,000 shares of common stock in a registered public offering, including 900,000 shares issued and sold upon the underwriters' exercise in full of their option to purchase additional shares, at a price to the public of $30 per share. The Company's net proceeds from the offering were approximately $193.8 million, after deducting underwriting commissions and offering expenses of $13.2 million.

If the Company is not able to generate cash proceeds from revenue sufficient to satisfy its cash obligations, the Company will need to finance future cash needs primarily through public or private equity offerings, debt financings, borrowings or strategic collaborations or licensing arrangements. If the Company is not able to secure additional funding when needed, on acceptable terms, it may have to delay, reduce the scope of or eliminate one or more research and development programs or selling and marketing initiatives which may have a material adverse effect on the Company's business, results of operations, financial condition and/or its ability to fund its scheduled obligations on a timely basis or at all.

Concentrations of Credit Risk and Other Risks and Uncertainties

The worldwide spread of coronavirus, or COVID-19, has created significant uncertainty in the global economy. There have been no comparable recent events that provide guidance as to the effect the spread of COVID-19 as a global pandemic may have. As a result, the ultimate impact of COVID-19 and the extent to which COVID-19 impacts the Company’s business, results of operations and financial condition will depend on future developments, which are highly uncertain and difficult to predict. If the financial markets or the overall economy are impacted for an extended period, the Company’s liquidity, revenue, supplies, goodwill and intangibles may be adversely affected. The Company considers the effects, to the extent knowable, of the COVID-19 pandemic in developing its estimates.

The majority of the Company’s cash and cash equivalents are deposited with one major financial institution in the United States. Deposits in this institution may exceed the amount of insurance provided on such deposits. The Company has not realized any losses on its deposits of cash and cash equivalents other than exchange rate losses related to foreign currency denominated accounts.

Several of the components of the Company's sample collection kits and test reagents, and the nCounter Analysis system and related diagnostic kits, are obtained from single-source suppliers. If these single-source suppliers fail to satisfy the Company's requirements on a timely basis, the Company could suffer delays in being able to deliver its diagnostic solutions, suffer a possible loss of revenue, or incur higher costs, any of which could adversely affect its operating results.

Through December 31, 2022, the Company has derived most of its revenue from the sale of Decipher and Afirma testing. To date, Decipher and Afirma testing have been delivered primarily to physicians in the United States.

The Company is also subject to credit risk from its accounts receivable related to its sales. Credit risk for accounts receivable from testing revenue is incorporated in testing revenue accrual rates as the Company assesses historical collection rates and current developments to determine accrual rates and amounts the Company will ultimately collect. The Company generally does not perform evaluations of customers' financial condition for testing revenue and generally does not require collateral. The Company assesses credit risk and the amount of accounts receivable the Company will ultimately collect for product, biopharmaceutical and other revenue based on collection history, current developments and credit worthiness of the customer. The estimate of credit losses is not material at December 31, 2022.

The Company's total third-party payers and other customers in excess of 10% of total revenue and their related revenue as a percentage of total revenue were as follows:

	Year Ended December 31,		
	2022	2021	2020
Medicare	31 %	30 %	24 %
UnitedHealthcare	10 %	10 %	11 %
	41 %	40 %	35 %

The Company's significant third-party payers in excess of 10% of total accounts receivable and their related accounts receivable balance as a percentage of total accounts receivable were as follows:

	As of December 31,	
	2022	2021
Medicare	14 %	12 %
UnitedHealthcare	10 %	9 %

Cash Equivalents

The Company considers demand deposits in a bank, money market funds and highly liquid investments with an original maturity of 90 days or less to be cash equivalents.

Short-Term Investments

The Company's short-term investments consist of U.S. treasury securities and time deposits with a bank with maturities at the time of purchase that were between 90 days and one year. The Company classifies these investments as held-to-maturity debt securities, which are reported at amortized cost. Discounts or premiums from the purchase of the securities are recognized as a component of interest income in other income (loss), net in the consolidated statements of operations. Investments are initially recorded net of an allowance for expected credit losses, if any, which are remeasured each period and any impairments are recognized as an expense. Unrealized gains and losses are not recognized in income. As of both December 31, 2022 and December 31, 2021, no allowances for expected credit losses had been recorded and there have been no impairment or credit losses on the Company's short term investments.

Restricted Cash

The Company had deposits of $0.7 million included in long-term assets as of both December 31, 2022 and December 31, 2021, restricted from withdrawal and held by banks in the form of collateral for irrevocable standby letters of credit held as security for the Company's leases.

Acquisitions

The Company first determines whether a set of assets acquired and liabilities assumed constitute a business and should be accounted for as a business combination. If the assets acquired are not a business, the Company accounts for the transaction as an asset acquisition. Business combinations are accounted for by using the acquisition method of accounting. Under the acquisition method, assets acquired, and liabilities assumed are recorded at their respective fair values as of the acquisition date in the Company's consolidated financial statements. The estimated fair value of intangible assets acquired are based on discounted cash flows utilizing certain assumptions including revenues (such as projected testing volumes, growth rates), discount rates and expected economic life/obsolescence factors of the respective assets. The excess of the fair value of consideration transferred over the fair value of the net assets acquired is recorded as goodwill. Contingent consideration obligations incurred in connection with a business combination are recorded at fair value on the acquisition date and remeasured at each subsequent reporting period until the related contingencies are resolved, with the resulting changes in fair value recorded in general and administrative expense in the consolidated statements of operations.

Equity Investment

In July 2020, the Company invested $1.0 million in the preferred stock of MAVIDx, Inc., or MAVIDx, a company developing a diagnostic platform for infectious diseases testing. MAVIDx is a variable interest entity, or VIE, and the Company's investment is a variable interest. The Company has determined that it is not the primary beneficiary of the VIE due to the fact that the Company does not have the power to direct the activities that impact the economic performance of MAVIDx or the obligation to fund its operations with ongoing financial support or contributions. MAVIDx is a private company and its equity securities are not traded or quoted in any securities exchange or in the over-the-counter market, and therefore does not have a readily determinable fair value. As such, the Company has elected to measure its investment in the preferred stock at cost, less any impairment, plus or minus changes resulting from observable price changes in orderly transactions for an identical or similar equity financings of MAVIDx, in accordance with Accounting Standards Codification, or ASC 321, *Investments—Equity Securities*. Based on the fourth quarter of 2020 operating performance of MAVIDx and the volatile nature of the market in which it operates, the Company determined that the investment in MAVIDx was fully impaired as of December 31, 2020. As a result, an impairment loss of $1.0 million was recorded in the fourth quarter of 2020 and is included in general and administrative expense in the consolidated statements of operations.

Supplies and Inventory

Supplies consists of materials and reagents consumed in the performance of testing services. Inventory consists of raw materials consumed in the contract manufacturing process as well as finished and semi-finished components used in the assembly of diagnostic kits related to product sales. Inventory is stated at the lower of cost or net realizable value on a weighted average basis. The Company periodically analyzes supply and inventory levels and expiration dates, and writes down supply or inventory that has become obsolete, that has a cost basis in excess of its net realizable value, or in excess of expected sales requirements as cost of revenue. The Company records an allowance for excess or obsolete supplies and inventory using an estimate based on historical trends and evaluation of near-term expirations.

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation and amortization. Depreciation is computed using the straight-line method over the estimated useful lives of the assets, generally between three and five years. Leasehold improvements are amortized using the straight-line method over the shorter of the estimated useful life of the asset or the term of the lease. Maintenance and repairs are charged to expense as incurred, and improvements and betterments are capitalized. When assets are retired or otherwise disposed of, the cost and accumulated depreciation are removed from the balance sheet and any resulting gain or loss is reflected in the statements of operations in the period realized.

Leases

The Company determines if an arrangement is, or contains, a lease at inception. Operating leases are included in right-of-use assets - operating leases and operating lease liabilities in the consolidated balance sheets, representing the right to use an underlying asset for the lease term and the obligation to make lease payments arising from the lease. Right-of-use, or ROU, assets and lease liabilities are recognized at commencement based on the present value of lease payments over the lease term. The Company uses its incremental borrowing rate based on the estimated rate of interest for collateralized borrowing over a similar term of the lease payments. The ROU assets also includes any lease payments made and is adjusted for lease incentives. Lease terms may include options to extend or terminate the lease which are recognized when it is reasonably certain that the Company will exercise that option. Lease expense is recognized on a straight-line basis over the lease terms. Lease and non-lease components are accounted for as a single lease component. Financing leases are immaterial and are included in property and equipment, net and other liabilities in the consolidated balance sheets. Leases with terms of 12 months or less are not recorded on our balance sheet.

Finite-lived Intangible Assets

Finite-lived intangible assets consist of intangible assets acquired as part of business combinations. The Company amortizes finite-lived intangible assets using the straight-line method over their estimated useful lives of 4 to 15 years, based on management's estimate of the period over which their economic benefits will be realized, product life and patent life. The Company tests these finite-lived intangible assets for impairment when events or circumstances indicate a reduction in the fair value below their carrying amounts. The Company recorded a $3.3 million impairment charge for the year ended December 31, 2022 and no impairment charge for the years ended December 31, 2021 or 2020. See Note 5 Balance Sheet Components for more information on the 2022 impairment testing.

Indefinite-lived Intangible Assets

Indefinite-lived intangible assets consist of in-process research and development, or IPR&D, acquired as part of business combinations. The IPR&D is not amortized until it becomes commercially viable and placed in service. At the time when the intangible assets are placed in service the Company will determine a useful life. The Company also tests these indefinite-lived intangible assets for impairment when events or circumstances indicate a reduction in the fair value below their carrying amounts. There was no impairment of indefinite-lived intangible assets for the years ended December 31, 2022, 2021 or 2020.

Goodwill

Goodwill, is reviewed for impairment on an annual basis or more frequently if events or circumstances indicate that it may be impaired. The Company's goodwill evaluation is based on both qualitative and quantitative assessments regarding the fair value of goodwill relative to its carrying value. The Company has determined that it operates in a single segment and has a single reporting unit associated with the development and commercialization of diagnostic products. In the event the Company determines that it is more likely than not the carrying value of the reporting unit is higher than its fair value, quantitative testing is performed comparing recorded values to estimated fair values. If impairment is present, the impairment loss is measured as the excess of the recorded goodwill over its implied fair value. There was no impairment of goodwill for the years ended December 31, 2022, 2021 or 2020.

Fair Value of Financial Instruments

The carrying amounts of certain financial instruments including cash and cash equivalents, accounts receivable, prepaid expenses and other current assets, accounts payable and accrued liabilities approximate fair value due to their relatively short maturities.

See Note 6. Fair Value Measurements for further information on the fair value of the Company’s financial instruments.

Revenue Recognition

The Company recognizes revenue in accordance with the provisions of ASC 606, *Revenue from Contracts with Customers*, or ASC 606. This process involves identifying the contract with a customer, determining the performance obligations in the contract, determining the contract price, allocating the contract price to the distinct performance obligations in the contract, and recognizing revenue when the performance obligations have been satisfied. A performance obligation is considered distinct from other obligations in a contract when it provides a benefit to the customer either on its own or together with other resources that are readily available to the customer and is separately identified in the contract. Performance obligations are considered satisfied once the Company has completed a service or transferred control of a product to the customer.

In arrangements involving more than one service or good, each required service or good is evaluated to determine whether it qualifies as a distinct performance obligation based on whether (i) the customer can benefit from the service or good either on its own or together with other resources that are readily available and (ii) the service or good is separately identifiable from other promises in the contract. The consideration under the arrangement is then allocated to each separate distinct performance obligation based on its respective relative stand-alone selling price. The estimated selling price of each deliverable reflects the Company's best estimate of what the selling price would be if the deliverable was regularly sold by the Company on a stand-alone basis or using an adjusted market assessment approach if selling price on a stand-alone basis is not available. The consideration allocated to each distinct performance obligation is recognized as revenue when control is transferred which may be at a point in time or over time.

Testing Revenue

The Company bills for testing services at the time of test completion as defined by the delivery of test results. The Company recognizes revenue based on estimates of the amount that will ultimately be realized. In determining the amount to accrue for a delivered test, the Company considers factors such as payment history, payer coverage, whether there is a reimbursement contract between the payer and the Company, payment as a percentage of agreed upon rate (if applicable), amount paid per test and any current developments or changes that could impact reimbursement. These estimates require significant judgment by management. Actual results could differ from those estimates and assumptions.

The Company has changed its revenue estimates due to actual and anticipated cash collections for tests delivered in prior years and recognized immaterial changes in revenue, loss from operations and basic and diluted net loss per share for the years ended December 31, 2022, 2021 and 2020.

Product Revenue

The Company's products consist of the Prosigna breast cancer assay, the nCounter Analysis System and related diagnostic kits. Product revenue from diagnostic kits is generally recognized upon shipment. Product revenue from instruments is generally recognized when the instrument is ready for use by the end customer. Shipping and handling costs incurred for product shipments are included in product revenue. Revenue is presented net of the taxes that are collected from customers and remitted to governmental authorities.

Biopharmaceutical and Other Revenue

The Company enters into arrangements for biopharmaceutical research and development, commercialization, contract manufacturing and development, and testing services which are classified under biopharmaceutical and other revenue. Such arrangements may require the Company to deliver various rights, manufactured diagnostic test kits, services and/or samples, including intellectual property rights/licenses, biopharmaceutical research and development services, and/or commercialization services. The Company receives consideration in the form of upfront license fees; payments on delivery of data, test results or manufactured products; costs of service plus margin; and development and commercial performance milestone payments.

The Company develops estimates and assumptions that require judgment to determine the underlying stand-alone selling price for each performance obligation which determines how the transaction price is allocated among the performance obligations. The estimation of the stand-alone selling price may include independent evidence of market price, forecasted

revenue or costs, development timelines, discount rates, and probabilities of technical and regulatory success. The Company evaluates each performance obligation to determine if the obligation can be satisfied at a point in time or over time, and it measures the services delivered to the collaborative partner which are periodically reviewed based on the progress of the related program. For licenses that are bundled with other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time. The effect of any change made to an estimated input component and, therefore revenue or expense recognized, would be recorded as a change in estimate. In addition, variable consideration must be evaluated to determine if it is constrained and, therefore, excluded from the transaction price.

At the inception of each arrangement that includes milestone payments (variable consideration), the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price. Milestone payments that are not within either party's control, such as non-operational developmental and regulatory approvals, are generally not considered probable of being achieved until those approvals are received. At the end of each reporting period, the Company re-evaluates the probability of achievement of milestones that are within either party's control, such as operational developmental milestones and any related constraint, and if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenue and earnings in the period of adjustment. Revisions to the Company's estimate of the transaction price may also result in negative revenue and earnings in the period of adjustment. One collaboration arrangement with milestone payments falls under the scope of ASC Topic 808, *Collaborative Arrangements*, or ASC 808. These milestone payments are recognized in the same manner as milestone payments from customers and are classified under biopharmaceutical and other revenue.

Accounts receivable from biopharmaceutical and other revenue was $9.3 million and $11.6 million at December 31, 2022 and 2021, respectively. There was $2.6 million and $5.0 million of deferred revenue related to these agreements at December 31, 2022 and 2021, respectively.

Revenue included in biopharmaceutical and other revenue for the years ended December 31, 2022, 2021 and 2020 was as follows (in thousands of dollars):

	Year Ended December 31,		
	2022	2021	2020
Biopharmaceutical revenue	$ 26,341	$ 12,613	$ 5,668
Contract manufacturing and testing	7,019	3,255	—
Collaboration milestones	—	4,000	—
Total	$ 33,360	$ 19,868	$ 5,668

Cost of Testing Revenue

The components of the Company's cost of testing services are laboratory expenses, sample collection expenses, compensation expense, license fees and royalties, depreciation, other expenses such as equipment and laboratory supplies, and allocations of facility and information technology expenses. Costs associated with performing tests are expensed as the test is processed regardless of whether and when revenue is recognized with respect to that test.

Cost of Product Revenue

Cost of product revenue consists primarily of costs of purchasing instruments and diagnostic kits from third-party contract manufacturers, installation, service and packaging and delivery costs, and the Company's internal labor expenses. In addition, cost of product includes royalty costs for licensed technologies included in the Company's products. Cost of product revenue for instruments and diagnostic kits is recognized in the period the related revenue is recognized. Shipping and handling costs incurred for product shipments are included in cost of product in the consolidated statements of operations.

Cost of Biopharmaceutical and Other Revenue

Cost of biopharmaceutical and other revenue consists of costs of performing activities under arrangements that require the Company to perform biopharmaceutical research and development, commercialization, contract manufacturing and contract testing services on behalf of a customer.

Research and Development

Research and development expenses include expenses incurred to develop the Company's technology, collect clinical samples and conduct clinical studies to develop and support its products. These expenses consist of compensation expenses, direct research and development expenses such as laboratory supplies and costs associated with setting up and conducting clinical studies at domestic and international sites, professional fees, depreciation and amortization, other miscellaneous expenses and allocation of facility and information technology expenses. The Company expenses all research and development costs in the periods in which they are incurred.

Income Taxes

The Company accounts for income taxes under the liability method. Under this method, deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to affect taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amounts expected to be realized.

The Company assesses all material positions taken in any income tax return, including all significant uncertain positions, in all tax years that are still subject to assessment or challenge by relevant taxing authorities. The Company's assessment of an uncertain tax position begins with the initial determination of the position's sustainability and is measured at the largest amount of benefit that is more-likely-than-not of being realized upon ultimate settlement. As of each balance sheet date, unresolved uncertain tax positions must be reassessed, and the Company will determine whether (i) the factors underlying the sustainability assertion have changed and (ii) the amount of the recognized tax benefit is still appropriate. The recognition and measurement of tax benefits requires significant judgment. Judgments concerning the recognition and measurement of a tax benefit may change as new information becomes available.

Stock-based Compensation

Stock-based compensation expense for stock options issued to employees and non-employees is measured based on the grant-date fair value of the award. The fair value of each stock option is estimated on the date of grant using the Black-Scholes option-pricing model. Stock-based compensation expense for restricted stock units, or RSUs, is measured based on the fair value of the award, which is determined based upon the closing price of the Company’s common stock on the date of the grant. The Company grants performance-based stock units, or PSUs, to certain employees which vest upon the achievement of certain performance conditions, subject to the employees’ continued service with the Company. The probability of vesting is assessed at each reporting period and compensation cost is adjusted based on this probability assessment.

The Company recognizes compensation costs on a straight-line basis for all employee stock-based compensation awards that are expected to vest over the requisite service period of the awards, which is generally the awards' vesting period. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

Net Loss per Common Share

Basic net loss per common share is calculated by dividing net loss attributable to common stockholders by the weighted-average number of common shares outstanding during the period, without consideration of common stock equivalents. Diluted net loss per common share is computed by dividing net loss attributable to common stockholders by the weighted-average number of common share equivalents outstanding for the period determined using the treasury stock method. Potentially dilutive securities consisting of options to purchase common stock, RSUs, PSUs and shares subject to purchase under the

Company's employee stock purchase plan are considered to be common stock equivalents and were excluded from the calculation of diluted net loss per common share because their effect would be anti-dilutive for all periods presented.

French Research Tax Credits

The French research tax credits (crédit d'impôt recherche or CIR) are generated by the Company's wholly owned subsidiary, Veracyte SAS, in connection with its research efforts performed in Marseille, France. The Company recognizes other income from the CIR over time based on when the research and development expenses are incurred. As of December 31, 2022, $4.8 million of CIR are recorded in prepaids and other current assets on the consolidated balance sheets and $3.5 million is included in other assets.

Foreign Currency Translation

The functional currency of the Company's foreign subsidiary, Veracyte SAS, is the Euro. Assets and liabilities denominated in foreign currencies are translated to U.S. dollars using the exchange rates at the balance sheet date. Foreign currency translation adjustments are recorded as a component of accumulated other comprehensive income (loss) within stockholders' equity. Revenues and expenses from the Company's foreign subsidiaries are translated using the monthly average exchange rates in effect during the period in which the transactions occur. Foreign currency transaction gains and losses are recorded in other income, net, on the consolidated statements of operations.

Comprehensive Loss

Comprehensive loss is the change in stockholders' equity from transactions and other events and circumstances other than those resulting from investments by stockholders and distributions to stockholders. The Company's comprehensive loss includes our net loss and gains and losses from the foreign currency translation of the assets and liabilities of our foreign subsidiaries.

Segment Reporting

The chief operating decision maker for the Company is the Chief Executive Officer, who reviews financial information presented on a consolidated basis for purposes of allocating resources and assessing financial performance. The Company has a single reporting unit associated with the development and commercialization of diagnostic products and biopharmaceutical services.

Revenue by geographic region based on the customer billing address was as follows (in thousands):

	Year Ended December 31,		
	2022	2021	2020
United States	$ 262,923	$ 200,982	$ 109,614
International	33,613	18,532	7,869
Total revenue	$ 296,536	$ 219,514	$ 117,483

Substantially all of the Company's long-lived assets were located in the United States as of December 31, 2022 and 2021.

Recent Accounting Pronouncements

In October 2021, the FASB issued ASU 2021-08, *Business Combinations (Topic 805): Accounting for Contract Assets and Contract Liabilities from Contracts with Customers*, which requires entities to recognize and measure contract assets and contract liabilities acquired in a business combination in accordance with ASC 2014-09, Revenue from Contracts with Customers (Topic 606). The update will generally result in an entity recognizing contract assets and contract liabilities at amounts consistent with those recorded by the acquiree immediately before the acquisition date rather than at fair value. The new standard is effective on a prospective basis for fiscal years beginning after December 15, 2022, with early adoption

permitted. The Company does not expect to have a material impact on its consolidated financial statements and related disclosures from the adoption of this guidance.

3. Net Loss Per Share

The following outstanding common stock equivalents have been excluded from diluted net loss per common share for the years ended December 31, 2022, 2021 and 2020 because their inclusion would be anti-dilutive:

	Year Ended December 31,		
	2022	2021	2020
Shares of common stock subject to outstanding options	3,923,882	3,754,807	4,564,777
Employee stock purchase plan	42,733	21,158	21,006
Restricted stock units	2,003,509	1,106,938	913,562
Total common stock equivalents	5,970,124	4,882,903	5,499,345

4. Business Combinations

HalioDx

On August 2, 2021, the Company acquired 100% of the equity interests of HalioDx, or the HalioDx Acquisition. The HalioDx Acquisition gave the Company the capabilities and expertise to manufacture its own IVD test kits for use on the nCounter Analysis System. The acquisition also deepened the Company's scientific expertise and capabilities in the rapidly growing area of immuno-oncology, further strengthening its offerings for biopharmaceutical and other partners. The consideration to acquire HalioDx was $319.6 million, comprised of $147.1 million in the form of 3.3 million shares of the Company’s common stock based on the Company's share price on the closing date, $4.2 million in liabilities, and the remainder in cash. Since the acquisition, the Company has recorded certain measurement period adjustments, which were recorded as net increases to goodwill totaling $0.2 million and did not impact the consolidated statements of operations.

Decipher Biosciences

On March 12, 2021, the Company acquired 100% of the equity interests of Decipher Biosciences, a privately-held company developing diagnostic tests in urologic cancers, for approximately $594.7 million, or the Decipher Acquisition. The Decipher Acquisition advanced the Company's objective to improve the lives of patients through innovations in genomic technology tailored for diagnostic, prognostic, and treatment decisions related to urologic cancers. The measurement period concluded in March 2022, and no adjustments were recorded during the year ended December 31, 2022

Related Party Transactions

Dr. Robert S. Epstein, M.D., M.S., a member of the Company’s board of directors, and Dr. Tina S. Nova, Ph.D., formerly a member of the Company’s board of directors, served on the board of directors of Decipher Biosciences prior to the acquisition, with Dr. Nova additionally serving as President and Chief Executive Officer of Decipher Biosciences. Pursuant to Veracyte's related party transactions policy, Dr. Nova and Dr. Epstein recused themselves from all discussions of its board of directors related to the Decipher Acquisition, and the Decipher Acquisition was approved by each of the non-interested members of the board of directors. In connection with the Decipher Acquisition, certain Decipher Biosciences equity awards held by Dr. Nova and Dr. Epstein were fully-accelerated and certain incentive bonus payments were made to Dr. Nova pursuant to a management incentive plan established by the Decipher Biosciences board of directors, resulting in payments of approximately $26.5 million and $1.4 million to each of them, respectively. Dr. Nova resigned from Veracyte’s board of directors and now serves as Veracyte's General Manager, Urology. Dr. Epstein continues to serve on Veracyte’s board of directors.

5. Balance Sheet Components

Supplies and Inventory

As of December 31, 2022 and 2021, supplies and inventory consisted of $10.2 million and $8.2 million, respectively, of lab supplies and reagents consumed in the performance of testing services, and $4.1 million and $3.0 million, respectively, of inventory related to raw materials consumed in contract manufacturing process, as well as finished and semi-finished components used in the assembly of diagnostic kits related to product sales.

Property and Equipment, Net

Property and equipment consisted of the following (in thousands of dollars):

	December 31,	
	2022	2021
Leasehold improvements	$ 9,740	$ 8,607
Laboratory equipment	21,159	17,533
Computer equipment	2,245	2,311
Software, including software developed for internal use	6,647	4,627
Furniture and fixtures	3,306	2,502
Construction-in-process	587	999
Total property and equipment, at cost	43,684	36,579
Accumulated depreciation	(25,982)	(21,481)
Total property and equipment, net	$ 17,702	$ 15,098

Depreciation expense was $4.6 million, $3.6 million and $2.8 million for the years ended December 31, 2022, 2021 and 2020, respectively.

VERACYTE, INC.

Notes to Consolidated Financial Statements (Continued)

Intangible Assets, Net

Intangible assets include finite-lived product technology, customer relationships, licenses and trade names and indefinite-lived in-process research and development. Intangible assets consisted of the following (in thousands of dollars):

	December 31, 2022			December 31, 2021			Weighted Average Remaining Amortization Period (Years)
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	
Percepta product technology	$ 16,000	$ (8,267)	$ 7,733	$ 16,000	$ (7,200)	$ 8,800	7
Prosigna product technology	4,120	(847)	3,273	4,120	(572)	3,548	11
Prosigna customer relationships	2,430	(1,499)	931	2,430	(1,013)	1,417	1
nCounter Dx license	46,880	(9,636)	37,244	46,880	(6,511)	40,369	11
LymphMark product technology	990	(436)	554	990	(295)	695	4
Decipher product technology	90,000	(16,234)	73,766	90,000	(7,234)	82,766	8
Decipher trade names	4,000	(1,443)	2,557	4,000	(643)	3,357	3
HalioDx developed technology	39,724	(5,899)	33,825	45,640	(1,877)	43,763	9
HalioDx customer relationships	4,602	(1,144)	3,458	4,870	(352)	4,518	5
HalioDx customer backlog	6,528	(2,303)	4,225	6,908	(710)	6,198	2
Total finite lived intangibles	215,274	(47,708)	167,566	221,838	(26,407)	195,431	8.7
In-process research and development	7,300	—	7,300	7,300	—	7,300	
Total intangible assets	$ 222,574	$ (47,708)	$ 174,866	$ 229,138	$ (26,407)	$ 202,731	

During the three months ended June 30, 2022, the Company concluded it had a triggering event requiring assessment of impairment for certain of its long-lived assets in conjunction with management's decision to cease commercialization efforts related to the Company's stand-alone Immunoscore Colon Dx commercial offering. As a result, the Company reviewed the long-lived assets for impairment and recorded a $3.3 million impairment charge associated with its HalioDx Immunoscore Colon Dx developed technology finite-lived intangible asset. The impairment is recorded within general and administrative expense on the consolidated statement of operations for the year ended December 31, 2022. The impairment was assessed under an income approach estimating forecasted discounted cash flows. This method is consistent with the methods the Company employed in prior periods to value other long-lived assets.

Amortization of the finite-lived intangible assets is recognized on a straight-line basis. Amortization of $21.4 million, $16.0 million and $5.1 million was recognized for the years ended December 31, 2022, 2021, and 2020, respectively.

The estimated future aggregate amortization expense as of December 31, 2022 is as follows (in thousands of dollars):

Year Ending December 31,	Amounts
2023	$ 21,275
2024	21,234
2025	20,117
2026	18,282
2027	17,680
Thereafter	68,978
Total	$ 167,566

Goodwill

Goodwill was $695.9 million and $707.9 million as of December 31, 2022 and 2021, respectively. The changes in the carrying amounts of goodwill during the year ended December 31, 2022 were due to foreign currency translation of $13.1 million and measurement period adjustments. The Company has not recorded any impairment related to goodwill.

Accrued Liabilities

Accrued liabilities consisted of the following (in thousands of dollars):

	December 31,	
	2022	2021
Accrued compensation expense	$ 30,637	$ 30,792
Accrued other	7,137	8,683
Total accrued liabilities	$ 37,774	$ 39,475

6. Fair Value Measurements

The Company records certain of its financial assets and liabilities at fair value. The accounting guidance for fair value provides a framework for measuring fair value and clarifies the definition of fair value. Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability (an exit price) in an orderly transaction between market participants at the reporting date. The accounting guidance establishes a three-tiered hierarchy, which prioritizes the inputs used in the valuation methodologies in measuring fair value as follows:

- Level I: Inputs which include quoted prices in active markets for identical assets and liabilities;
- Level II: Inputs other than Level I that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities; and
- Level III: Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The carrying amounts of certain financial instruments of the Company, including cash and cash equivalents, prepaid expenses and other current assets, accounts payable and accrued liabilities, approximate fair value due to their relatively short maturities. The fair value of the Company’s financial assets includes money market funds and deposits for leases of the Company's facilities. Money market funds, included in cash and cash equivalents in the accompanying consolidated balance sheets, was $131.2 million and $159.2 million as of December 31, 2022 and 2021, respectively, and are Level I assets as described above. The deposits for the leases, included in restricted cash, was $0.7 million as of both December 31, 2022 and 2021 and are Level I assets as described above. There were no transfers between Levels 1, 2 or 3 for the years ended December 31, 2022, 2021, and 2020.

On December 3, 2019, the Company acquired from NanoString the exclusive global diagnostics license to the nCounter Analysis System, the Prosigna breast cancer prognostic gene signature assay, and the LymphMark lymphoma subtyping assay. Pursuant to the terms of the agreement, Veracyte paid NanoString $40.0 million in cash and $10.0 million in Veracyte common stock, and may pay up to an additional $10.0 million in cash, contingent upon first achievement or occurrence, by or on behalf of Veracyte, of the commercial launch of the first, second and third diagnostic tests for use on the nCounter multiplex analysis system. This contingency was valued at $6.1 million as of the acquisition date and is remeasured to fair value at each reporting date until the contingent consideration is settled. As of December 31, 2022 and 2021, this contingency was remeasured to $8.6 million and $8.4 million, respectively. with the corresponding changes included in general and administrative expense. For the years ended December 31, 2022, 2021, and 2020 expenses of $0.2 million, $0.8 million and $1.5 million, respectively, were

recorded in general and administrative expense for the changes in carrying value. As of December 31, 2022, the achievement of two of the milestones is forecasted to occur within the next 12 months. As a result, $6.1 million of the contingent consideration is included in short term liabilities at December 31, 2022. The fair value of the contingent consideration includes inputs that are not observable in the market and thus represents a Level III financial liability. The estimation of the fair value of the contingent consideration is based on the present value of the expected payments calculated by assessing the likelihood of when the related milestones would be achieved and estimating the Company's borrowing rate. These estimates form the basis for making judgments about the carrying value of the contingent consideration that are not readily apparent from other sources. Changes to the forecasts for the achievement of the milestones and the borrowing rate can significantly affect the estimated fair value of the contingent consideration. As of December 31, 2022 and 2021, the Company calculated the estimated fair value of the milestones using the following significant unobservable inputs:

	Value or Range (Weighted-Average)	
Unobservable input	December 31, 2022	December 31, 2021
Discount rate	8.3%	5.9%
Probability of achievement	80% - 100% (94%)	80% - 100% (94%)

Short-Term Investments Held-to-Maturity

The Company's short-term investments consist of U.S. treasury securities and time deposits with a bank with maturities at the time of purchase that were between 90 days and one year. The Company classifies these investments as held-to-maturity debt securities, which are reported at amortized cost, and are Level I assets as described above. As of December 31, 2022, short-term investments comprised U.S. treasury bills recorded at amortized cost of $24.6 million, with fair values of approximately $24.6 million. As of December 31, 2021, short-term investments comprised time deposits recorded at amortized cost of $4.0 million, with fair values of approximately $4.0 million. As of December 31, 2022 and 2021, gross unrealized gains on short-term investments were insignificant.

7. Commitments and Contingencies

Operating Leases

The Company leases office and laboratory facilities in South San Francisco and San Diego, California; Austin, Texas; Marseille, France; and Richmond, Virginia, and leases certain equipment under various non-cancelable lease agreements. The lease terms extend to October 2030 and contain extension of lease term and expansion options. The leases have a weighted average remaining lease term of 3.9 years as of December 31, 2022. The Company had deposits of $0.7 million included in long-term assets as of both December 31, 2022 and 2021 restricted from withdrawal and held by banks in the form of collateral for irrevocable standby letters of credit held as security for the leases

The Company determined its operating lease liabilities using payments through their current expiration dates and a weighted average discount rate of 6.4% based on the rate that the Company would have to pay to borrow, on a collateralized basis, an amount equal to the lease payments in a similar economic environment. Operating lease liabilities along with the associated ROU assets are disclosed in the accompanying consolidated balance sheets. After the adoption of ASC 842, *Leases*, the Company classified its deferred rent for tenant improvements with its operating lease ROU assets on the consolidated balance sheets. In connection with the acquisition of Decipher Biosciences in March 2021, the Company identified certain off-market rate leases and has estimated an intangible asset of $1.8 million which is included in operating lease assets and will be amortized over the remaining lease term. See Note 4 Business Combinations for more information on the acquisition of Decipher Biosciences.

Future minimum lease payments under non-cancelable operating leases as of December 31, 2022 are as follows (in thousands of dollars):

Year Ending December 31,	Amounts
2023	$ 4,718
2024	4,446
2025	4,489
2026	1,403
2027	697
Thereafter	879
Total future minimum lease payments	16,632
Less: amount representing interest	1,914
Present value of future lease payments	14,718
Less: short-term lease liabilities	4,070
Long-term lease liabilities	$ 10,648

The Company recognizes operating lease expense on a straight-line basis over the non-cancelable lease period. The following table summarizes operating lease expense and cash paid for amounts included in the measurement of lease liabilities (in thousands of dollars):

	Year Ended December 31,		
	2022	2021	2020
Operating lease expense	$ 4,392	$ 3,503	$ 1,889
Cash paid for amounts included in the measurement of lease liabilities	$ 4,527	$ 3,650	$ 2,332

The company has leased laboratory equipment under various financing leases. As of December 31, 2022 and 2021, the total ROU assets and total financing lease liabilities for these financing leases were $0.4 million and $0.4 million and $0.7 million and $0.6 million, respectively, and are included in property and equipment, net and other liabilities in the accompanying consolidated balance sheets.

The Company’s wholly-owned foreign subsidiary has entered into an arrangement under which it expects to sign a lease agreement for facilities which will be constructed in Marseille, France. The lease will commence upon completion of the construction of the office building which the Company currently expects to occur in the fourth quarter of 2023 at which time the Company will record a lease liability and a corresponding ROU asset. The initial term of the lease will be twelve years with annual rent of approximately $1.4 million, which is subject to change based on final construction.

Supplies Purchase Commitments

The Company had non-cancelable purchase commitments with suppliers to purchase a minimum quantity of supplies for approximately $10.1 million at December 31, 2022.

Contingencies

From time to time, the Company may be involved in legal proceedings arising in the ordinary course of business. The Company believes there is no litigation pending that could have, either individually or in the aggregate, a material impact on the Company's consolidated financial statements.

8. Debt

Loan and Security Agreement

On November 3, 2017, the Company entered into a loan and security agreement, or the Loan and Security Agreement, with Silicon Valley Bank. The Loan and Security Agreement allowed the Company to borrow up to $35.0 million, with a $25.0 million advance term loan, or the Term Loan Advance, and a revolving line of credit of up to $10.0 million, or the Revolving Line of Credit. The Term Loan Advance was advanced upon the closing of the Loan and Security Agreement and was used to pay the outstanding balance of the Company's existing long-term debt, which was canceled at that date. In October 2022, the Loan and Security Agreement matured, and the outstanding principal and final payment, totaling $1.2 million, was repaid in full.

The Term Loan Advance bore interest at a variable rate equal to (i) the thirty-day U.S. London Interbank Offer Rate. or LIBOR, plus (ii) 4.20%, with a minimum rate of 5.43% per annum. Principal amounts outstanding under the Revolving Line of Credit bear interest at a variable rate equal to (i) LIBOR plus (ii) 3.50%, with a minimum rate of 4.70% per annum.

A final payment on the Term Loan Advance in the amount of $1.2 million was due upon the earlier of the maturity date of the Term Loan Advance or its payment in full. The end-of-term debt obligation accreted over the term of the Loan and Security Agreement until maturity and is included in interest expense in the Company's consolidated statements of operations. As of December 31, 2021, the principal balance outstanding was one dollar and the accreted balance of the end-of-term debt obligation was $1.0 million.

9. Stockholders' Equity

Common Stock

The Company's Restated Certificate of Incorporation authorizes the Company to issue 125,000,000 shares of common stock with a par value of $0.001 per share. The holder of each share of common stock shall have one vote for each share of stock. The common stockholders are also entitled to receive dividends whenever funds and assets are legally available and when declared by the Board of Directors, subject to the prior rights of holders of all series of convertible preferred stock outstanding. No dividends have been declared as of December 31, 2022.

As of December 31, 2022 and 2021, the Company had reserved shares of common stock for issuance as follows:

	December 31,	
	2022	2021
Stock options and restricted stock units issued and outstanding	5,881,906	4,892,164
Stock options and restricted stock units available for grant under stock option plans	5,591,977	4,418,364
Common stock available for the Employee Stock Purchase Plan	1,335,353	1,490,130
Total	12,809,236	10,800,658

10. Stock Incentive Plans

Stock Plans

In February 2008, the Company adopted the 2008 Stock Plan (the "2008 Plan"). The 2008 Plan provides for the granting of options to purchase common stock and common stock to employees, directors and consultants of the Company. The Company may grant incentive stock options, or ISOs, non-statutory stock options, or NSOs, or restricted stock under the 2008 Plan. ISOs may only be granted to Company employees (including directors who are also considered employees). NSOs and restricted stock may be granted to Company employees, directors and consultants. Options may be granted for terms of up to ten years from the date of grant, as determined by the Board of Directors, provided however, that with respect to an ISO granted

to a person who owns stock representing more than 10% of the voting power of all classes of stock of the Company, the term shall be for no more than five years from the date of grant. The exercise price of options granted must be at a price no less than 100% of the estimated fair value of the shares on the date of grant, as determined by the Board of Directors, provided however, that with respect to an ISO granted to an employee who at the time of grant of such option owns stock representing more than 10% of the voting power of all classes of stock of the Company, the exercise price shall not be less than 110% of the estimated fair value of the shares on the date of grant.

In October 2013, the Company adopted the 2013 Stock Incentive Plan (the "2013 Plan"). The 2013 Plan was subsequently approved by the Company's stockholders and became effective on November 4, 2013, immediately before the closing of the Company's initial public offering, or IPO. Following the effectiveness of the 2013 Plan, no additional options were granted under the 2008 Plan. An aggregate of 1,700,000 shares were initially reserved for issuance under the 2013 Plan. In addition, to the extent that any awards outstanding or subject to vesting restrictions under the 2008 Plan are subsequently forfeited or terminated for any reason before being exercised or settled, the shares of common stock reserved for issuance pursuant to such awards as of the closing of the IPO will become available for issuance under the 2013 Plan. The remaining shares available for grant under the 2008 Plan became available for issuance under the 2013 Plan upon the closing of the IPO. On the first day of each year from 2014 to 2023, the 2013 Plan authorizes an annual increase of the lesser of 4% of outstanding shares on the last day of the immediately preceding fiscal year or a lesser amount as determined by the Company's Board of Directors. As of December 31, 2022, 5,591,977 shares were available for future issuance under the 2013 Plan.

Pursuant to the 2013 Plan, stock options, restricted shares, stock units, including RSUs and stock appreciation rights may be granted to employees, consultants, and outside directors of the Company. Options granted may be either ISOs or NSOs.

Stock options are governed by stock option agreements between the Company and recipients of stock options. ISOs and NSOs may be granted under the 2013 Plan at an exercise price of not less than 100% of the fair market value of the common stock on the date of grant, determined by the Compensation Committee of the Board of Directors. Options become exercisable and expire as determined by the Compensation Committee, provided that the term of ISOs may not exceed ten years from the date of grant. Stock option agreements may provide for accelerated exercisability in the event of an optionee's death, disability, or retirement or other events.

Stock units are governed by stock unit agreements between the Company and recipients of stock units. Stock units may be granted under the 2013 Plan and the number of stock units awarded are determined by the Compensation Committee of the Board of Directors. Stock units vest and expire as determined by the Compensation Committee. Stock unit agreements may provide for accelerated vesting in the event of a stock unit holder's death, disability, or retirement or other events.

Beginning in 2021, any outside director who was not previously an employee and who first joins the Company's Board of Directors on or after the effective date of the 2013 Plan will be automatically granted RSUs, or Initial RSUs, valued on the grant date at $600,000. The RSUs will vest as to one-third of those shares on each of the first, second and third annual anniversaries of the date of grant. On the first business day after each annual meeting of stockholders, each non-employee director who continues to serve on the Company's board of directors and who has served as a director for at least six months will be automatically granted RSUs, or Annual RSUs, valued on the grant date at $300,000. The RSUs will vest in full on the first anniversary of the date of grant or, if earlier, the date of the next annual meeting of stockholders. In February 2022, the value of the Initial RSUs was reduced to $500,000 and the value of the Annual RSUs was reduced to $250,000. In 2020 and prior years, any outside director who was not previously an employee and who first joined the Company's Board of Directors on or after the effective date of the 2013 Plan was automatically granted an initial NSO to purchase 35,000 shares of common stock upon first becoming a member of the Board of Directors. The shares subject to the initial option will vest and become exercisable one-third each of the first, second and third annual anniversaries of the date of grant. On the first business day after each regularly scheduled annual meeting of stockholders, each outside director who was not elected to the Board of Directors for the first time at such meeting and who will continue serving as a member of the Board of Directors thereafter was automatically granted an option to purchase 10,000 shares of common stock, provided that the outside director had served on the Board of Directors for at least six months. Each annual option vested and became exercisable on the first anniversary of the date of grant, or immediately prior to the next regular annual meeting of the Company's stockholders following the date of grant if the meeting occurred prior to the first anniversary date. The options granted to outside directors have a per share exercise price equal to 100% of the fair market value of the underlying shares on the date of grant. These RSUs and options will become fully vested in the event of a change in control. In addition, such options will terminate on the earlier of (i) the day before the

10th anniversary of the date of grant or (ii) the date 12 months after the termination of the outside director's service for any reason.

The following table summarizes activity under the Company's stock incentive plans (aggregate intrinsic value in thousands):

	Shares Available for Grant	Stock Options Outstanding and Unvested Restricted Stock Units	Weighted Average Exercise Price of Stock Options	Weighted Average Remaining Contractual Life of Stock Options (Years)	Aggregate Intrinsic Value of Stock Options
Balance—December 31, 2021	4,418,364	4,892,164	$ 19.87	6.16	$ 78,914
Additional shares authorized	2,844,924	—			
Granted - stock options	(1,132,620)	1,132,620	25.81		
Granted - restricted stock units	(1,746,249)	1,746,249			
Canceled	1,074,896	(1,074,896)	14.98		
Exercised	—	(401,015)	10.46		
Restricted stock units vested	—	(413,216)			
Tax portion of restricted stock units vested	132,662	—			
Balance—December 31, 2022	5,591,977	5,881,906	$ 21.10	6.30	$ 23,450
Options vested and exercisable—December 31, 2022		2,391,902	$ 16.29	4.84	$ 22,939
Options vested and expected to vest—December 31, 2022		3,541,604	$ 20.64	6.14	$ 23,359

The aggregate intrinsic value was calculated as the difference between the exercise price of the options to purchase common stock and the fair market value of the Company's common stock, which was $23.73 and $41.20 per share as of December 31, 2022 and 2021, respectively.

The weighted average fair value of options to purchase common stock granted was $14.61, $23.45 and $12.97 for the years ended December 31, 2022, 2021 and 2020, respectively.

The aggregate estimated grant date fair value of employee options to purchase common stock vested during the years ended December 31, 2022, 2021 and 2020 was $6.8 million, $7.8 million and $7.3 million, respectively.

The intrinsic value of stock options exercised was $6.3 million, $24.0 million and $32.9 million for the years ended December 31, 2022, 2021 and 2020, respectively.

The weighted average fair value of RSUs granted was $24.37 and $46.41 for the years ended December 31, 2022, and 2021, respectively. The intrinsic value of RSUs vested was $9.6 million and $21.7 million for the years ended December 31, 2022 and 2021, respectively.

Included in RSUs granted for 2022 and 2021 are PSUs with a grant date fair value for remaining participants of $2.2 million and $3.3 million, respectively, or the 2022 PSUs and 2021 PSUs. These PSUs vest based on the achievement of certain performance conditions, subject to the employees' continued service with the Company. The service period for the 2021 PSUs began in 2022 and ends in February 2024. As of December 31, 2022, the Company assessed the probability of the achievement of the performance conditions related to the 2021 PSUs was less than likely, and no expense was recognized in 2022. Any expense related to the 2021 PSUs will continue through 2023 based on the Company's assessment of the probability of the achievement of the 2021 PSUs performance conditions. The service period for the 2022 PSUs begins in 2023 and any expense related to the 2022 PSUs will begin in 2023 and will be based on the Company's assessment of the probability of the achievement of the 2022 PSUs performance conditions.

Employee Stock Purchase Plan

In May 2015, the Company's stockholders approved the Company's ESPP. The ESPP provides eligible employees with an opportunity to purchase common stock from the Company and to pay for their purchases through payroll deductions. The ESPP will be implemented through a series of offerings of purchase rights to eligible employees. Under the ESPP, the Compensation Committee of the Company's Board of Directors may specify offerings with a duration of not more than 12 months and may specify shorter purchase periods within each offering. During each purchase period, payroll deductions will accumulate, without interest. On the last day of the purchase period, accumulated payroll deductions will be used to purchase common stock for employees participating in the offering.

The purchase price will be specified pursuant to the offering, but cannot, under the terms of the ESPP, be less than 85% of the fair market value per share of the Company's common stock on either the offering date or on the purchase date, whichever is less.

The Company's Board of Directors has determined that the purchase periods initially shall have a duration of six months, that the first purchase period began on August 3, 2015, and that the purchase price will be 85% of the fair market value per share of the Company's common stock on either the offering date or the purchase date, whichever is less. The length of the purchase period applicable to U.S. employees and the purchase price may not be changed without the approval of the independent members of the Compensation Committee of the Company's Board of Directors. The Compensation Committee has determined that if the fair market value of a share of the Company's common stock on any purchase date within a particular offering period is less than the fair market value on the start date of that offering period, then the offering period will automatically terminate and the employees in that offering period will automatically be transferred and enrolled in a new offering period which will begin on the next day following such purchase date.

No employee is permitted to accrue, under the ESPP, a right to purchase stock of the Company having a value in excess of $25,000 of the fair market value of such stock (determined at the time the right is granted) for each calendar year. As of December 31, 2022, 1,335,353 shares of common stock were reserved for issuance under the ESPP.

Stock-based Compensation

The following table summarizes stock-based compensation expense related to stock options, RSUs and the ESPP for the years ended December 31, 2022, 2021 and 2020, and are included in the consolidated statements of operations as follows (in thousands of dollars):

	Year Ended December 31,		
	2022	2021	2020
Cost of revenue	$ 1,053	$ 640	$ 369
Research and development	6,004	4,636	2,690
Selling and marketing	5,936	4,390	3,474
General and administrative	13,741	12,853	6,462
Total stock-based compensation expense	$ 26,734	$ 22,519	$ 12,995

As of December 31, 2022, the Company had $57.4 million of unrecognized compensation expense related to unvested stock options and RSUs, which is expected to be recognized over an estimated weighted-average period of 2.7 years.

The estimated grant-date fair value of stock options was calculated using the Black-Scholes option-pricing model, based on the following assumptions.

- *Expected Term*: The expected term represents the period that the options granted are expected to be outstanding, and is determined using the Company's historical data.
- *Expected Volatility*: The Company uses the historical volatility of its common stock.
- *Risk-Free Interest Rate*: The Company based the risk-free interest rate over the expected term of the options based on the constant maturity rate of U.S. Treasury securities with similar maturities as of the date of the grant.

- *Expected Dividend Yield*: The Company has not paid and does not anticipate paying any dividends in the near future. Therefore, the expected dividend yield was zero.

The estimated grant-date fair value of employee stock options using the Black-Scholes option-pricing model was based on the following assumptions:

	Year Ended December 31,		
	2022	2021	2020
Weighted-average volatility	62.64 - 67.66%	56.83 - 60.48%	54.40 - 58.20%
Weighted-average expected term (years)	5.26 - 5.27	5.05 - 5.25	5.24 - 5.42
Risk-free interest rate	1.72 - 4.21%	0.40 - 1.21%	0.24 - 0.92%
Expected dividend yield	—	—	—

The estimated grant date fair value of the ESPP shares was calculated using the Black-Scholes option-pricing model, based on the following assumptions:

	Year Ended December 31,		
	2022	2021	2020
Weighted-average volatility	75.04 - 88.59%	62.03 - 80.70%	54.16 - 85.01%
Weighted-average expected term (years)	0.50 - 1.00	0.50 - 1.00	0.50 - 1.00
Risk-free interest rate	0.47 - 2.96%	0.06 - 0.08%	0.11 - 1.56%
Expected dividend yield	—	—	—

11. Income Taxes

The Company generated a pre-tax loss of $36.4 million, $81.6 million and $34.9 million in the United States for the years ended December 31, 2022, 2021 and 2020, respectively. Starting in 2020, the Company began generating pre-tax loss outside the United States. Pre-tax loss has been recorded in the following jurisdictions for the years ended December 31, 2022, 2021 and 2020 (in thousands of dollars):

	Year Ended December, 31,		
	2022	2021	2020
United States	$ (16,816)	$ (68,707)	$ (34,909)
Foreign	(19,611)	(12,942)	—
Total	$ (36,427)	$ (81,649)	$ (34,909)

The Company recorded an income tax provision in 2022 of $0.1 million primarily due to foreign and state income taxes offset partially by reductions in deferred tax liabilities from acquired entities. The Company recorded an income tax benefit in 2021 of $6.1 million primarily due to the release of certain valuation allowances on the Company's deferred tax assets upon recording of the deferred tax liabilities upon acquisition of Decipher Biosciences and a provision benefit recorded on the 2021 year loss of HalioDx French entity. The Company recorded no provision for income taxes during the year ended December 31,

2020. The components of the provision (benefit) for income taxes are as follows for the years ended December 31, 2022, 2021 and 2020 (in thousands of dollars):

	Year Ended December, 31,		
	2022	2021	2020
Current:			
Federal	$ —	$ —	$ —
State	426	63	—
Foreign	134	54	—
Total current	560	117	—
Deferred:			
Federal	—	(3,526)	—
State	118	(508)	—
Foreign	(545)	(2,169)	—
Total deferred	(427)	(6,203)	—
Total income tax provision (benefit)	$ 133	$ (6,086)	$ —

The Company follows FASB ASC No. 740, *Income Taxes* for the Computation and Presentation of its Tax Provision. The following table presents a reconciliation of the income tax expense computed at the statutory federal rate and the Company's income tax expense for the periods presented (in thousands of dollars):

	Year Ended December, 31,		
	2022	2021	2020
U.S. federal taxes at statutory rate	$ (7,573)	$ (17,146)	$ (7,302)
State tax (net of federal benefit)	720	(1,609)	(1,794)
Foreign rate differential	3,726	674	1
Non-deductible officers' compensation	729	3,055	1,443
Transaction costs	—	2,255	—
Permanent differences	79	59	131
Stock based compensation - excess benefit	1,874	(5,687)	(4,881)
Tax credits	(936)	(714)	(588)
Change in valuation allowance	1,514	13,027	12,990
Total	$ 133	$ (6,086)	$ —

VERACYTE, INC.

Notes to Consolidated Financial Statements (Continued)

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 (in thousands of dollars):

	Year Ended December 31,		
	2022	2021	2020
Deferred tax assets:			
Net operating loss carryforwards	$ 126,225	$ 133,492	$ 68,113
Research and development credits	8,907	7,926	6,167
Section 174 capitalization	6,719	—	—
Stock-based compensation	4,080	3,760	2,696
NanoString intangibles and goodwill	1,447	1,244	908
Operating lease liability	3,622	4,327	2,826
Accruals and other	6,596	7,099	2,623
Gross deferred tax assets	157,596	157,848	83,333
Valuation allowance	(125,378)	(120,586)	(78,650)
Net deferred tax assets	32,218	37,262	4,683
Deferred tax liabilities:			
Property and equipment	(235)	(219)	(334)
Other acquired intangibles	(29,457)	(34,823)	—
In-process research and development	(3,702)	(3,892)	(2,423)
ROU assets	(3,355)	(3,920)	(1,926)
Gross deferred tax liabilities	(36,749)	(42,854)	(4,683)
Net deferred tax liabilities	(36,749)	(42,854)	(4,683)
Net deferred taxes	$ (4,531)	$ (5,592)	$ —

The Company records net deferred tax assets to the extent it is more likely than not that the assets will be realized. In making such determination, the Company considered all available positive and negative evidence, including future reversals of existing taxable temporary differences, projected future taxable income, tax planning strategies and recent financial operations. The Company has established a valuation allowance against its net deferred tax assets due to the uncertainty surrounding realization of such assets. The valuation allowance increased $4.8 million, $41.9 million and $13.4 million during the years ended December 31, 2022, 2021 and 2020, respectively.

As of December 31, 2022, the Company had net operating loss carryforwards of approximately $402.0 million, $78.8 million and $126.1 million available to reduce future taxable income, if any, for federal, California and other state income tax purposes, respectively. The U.S. federal net operating loss carryforwards will begin to expire in 2031 while for state purposes, the net operating losses begin to expire in 2023.

As of December 31, 2022, the Company had foreign net operating loss carryforwards of approximately $69.9 million and $44.2 million available to reduce future taxable income, if any, for Canadian and French income tax purposes, respectively. The Canada net operating loss carryforwards will begin to expire in 2034, while for French purposes, the net operating losses will carryforward indefinitely.

As of December 31, 2022, the Company had net research and development credit carryforwards of approximately $6.7 million and $6.3 million available to reduce future taxable income, if any, for federal and state income tax purposes, respectively. The federal credit carryforwards begin to expire in 2028. California credits have no expiration date. Other state credit carryforwards begin to expire in 2023.

The Company also had scientific net research and development credit carryforwards of approximately $1.4 million available to reduce future taxable income, if any, for Canadian income tax purposes. The credit carryforwards begin to expire in 2025.

The Internal Revenue Code of 1986, as amended, imposes restrictions on the utilization of net operating losses and tax credits in the event of an "ownership change" of a corporation. Accordingly, a company's ability to use net operating losses and tax credits may be limited as prescribed under Internal Revenue Code Section 382 and 383 ("IRC Section 382"). Events which may cause limitations in the amount of the net operating losses or tax credits that the Company may use in any one year include, but are not limited to, a cumulative ownership change of more than 50% over a three-year period. Utilization of the federal and state net operating losses may be subject to substantial annual limitation due to the ownership change limitations provided by the IRC Section 382 rules and similar state provisions. In the event the Company has any changes in ownership, net operating losses and research and development credit carryovers could be limited and may expire unutilized.

Uncertain Tax Positions

As of December 31, 2022, the Company had unrecognized tax benefits of $4.9 million, none of which currently would affect the Company's effective tax rate if recognized due to the Company's deferred tax assets being fully offset by a valuation allowance. The Company does not anticipate that the amount of unrecognized tax benefits relating to tax positions existing at December 31, 2022 will significantly increase or decrease within the next 12 months.

A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows (in thousands of dollars):

	Year Ended December 31,		
	2022	2021	2020
Unrecognized tax benefits, beginning of period	$ 4,452	$ 3,563	$ 3,278
Gross increases—tax position in prior period	—	515	—
Gross decreases—tax position in prior period	(31)	—	—
Gross increases—current period tax position	467	374	285
Lapse of statute of limitations	—	—	—
Unrecognized tax benefits, end of period	$ 4,888	$ 4,452	$ 3,563

It is the Company's policy to include penalties and interest expense related to income taxes as a component of other income (expense), net, and interest expense, respectively, as necessary. There was no interest expense or penalties related to unrecognized tax benefits recorded through December 31, 2022.

The Company's major tax jurisdictions are the United States, France, Canada, and California. All of the Company's tax years will remain open for examination by the Federal and state tax authorities for three and four years, respectively, from the date of utilization of the net operating loss or research and development credit. The Company does not have any tax audits pending in the United States. There is an audit of Veracyte SAS ongoing in France.

The Inflation Reduction Act of 2022 was signed into law August 16, 2022, and includes significant legislation addressing taxes, inflation, climate change and renewable energy incentives, and healthcare. Key tax provisions include a 15% corporate minimum tax, clean energy incentives, and a 1% excise tax on stock buybacks. The Company does not expect the provisions of such legislation to have any impact on the effective tax rate of the Company but will continue to evaluate the tax effects should any provisions become applicable to the Company.

Changes to Internal Revenue Code Section 174 under the 2017 Tax Cuts and Jobs Act went into effect during 2022. The revised code no longer permits a deduction for research and development expenditures in the tax year that such costs are incurred. Instead, such costs must be capitalized and amortized over five or 15 years for U.S. and foreign costs, respectively. The Company capitalized such costs in its 2022 income tax provision, resulting in an increase in deferred tax assets.

12. Employee Benefit Plans

401(k) plan

The Company sponsors a 401(k) defined contribution plan covering all employees. Under the plan, participants are entitled to make pre-tax contributions up to the annual maximums established by the Internal Revenue Service. The Company, at its discretion, may make matching contributions to the 401(k) plan. Employer contributions to the plan were $1.4 million, $1.3 million and $0.6 million for the years ended December 31, 2022, 2021, and 2020, respectively.

Pension plan

The Company also maintains a defined benefit plan for certain non-U.S. employees of its HalioDx subsidiary. The pension liability is included in other long-term liabilities on the Company's consolidated balance sheets and totaled $0.7 million and $1.1 million as of December 31, 2022 and 2021, respectively.

13. Components of Other Income, net

Other income, net consists of the following (in thousands of dollars):

	Year Ended December 31,		
	2022	2021	2020
French research tax credits	$ 2,423	$ 1,535	$ —
Interest and dividend income	1,972	135	594
Interest expense	(198)	(241)	(229)
Gain (loss) on currency revaluation	197	(1,081)	56
Other	260	(94)	59
Total	$ 4,654	$ 254	$ 480

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

Not applicable.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We maintain "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, as amended, which are designed to provide reasonable assurance that information required to be disclosed by us in reports that we file or submit under the Exchange Act are recorded, processed, summarized, and reported within the time periods specified in Securities and Exchange Commission rules and forms and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. Management recognizes that disclosure controls and procedures, no matter how well designed and operated, can provide only reasonable, not absolute, assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible disclosure controls and procedures. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of December 31, 2022.

Management's Annual Report on Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of the effectiveness of internal control to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with policies or procedures may deteriorate. Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2022, using the criteria established in *Internal Control Integrated Framework* ("2013 Framework") issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"). Our management has concluded that, as of December 31, 2022, our internal control over financial reporting was effective to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external purposes in accordance with generally accepted accounting principles.

The effectiveness of our internal control over financial reporting as of December 31, 2022 has been audited by Ernst & Young LLP, an independent registered public accounting firm, as stated in their report, which is included herein.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting as defined in Rule 13a-15(f) under the Exchange Act, during the quarter ended December 31, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and the Board of Directors of Veracyte, Inc.

Opinion on Internal Control over Financial Reporting

We have audited Veracyte, Inc.'s internal control over financial reporting as of December 31, 2022, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, Veracyte, Inc. (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2022, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the 2022 consolidated financial statements of the Company and our report dated February 28, 2023 expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Annual Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the 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 effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ Ernst & Young LLP

San Diego, California
February 28, 2023

ITEM 9B. OTHER INFORMATION

None.

ITEM 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this item with respect to directors is incorporated by reference from the information contained in our proxy statement to be filed with the Securities and Exchange Commission no later than 120 days from the end of our fiscal year ended December 31, 2022 in connection with the solicitation of proxies for our 2023 Annual Meeting of Stockholders, or the Proxy Statement.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item is incorporated by reference to our Proxy Statement.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this item is incorporated by reference to our Proxy Statement.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this item is incorporated by reference to our Proxy Statement.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this item is incorporated by reference to our Proxy Statement.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) Documents filed as part of this report

1. Financial Statements:

Reference is made to the Index to Financial Statements of Veracyte, Inc. included in Item 8 of Part II hereof.

2. Financial Statement Schedules

All schedules have been omitted because they are not required, not applicable, or the required information is included in the financial statements or notes thereto.

3. Exhibits

See Item 15(b) below. Each management contract or compensating plan or arrangement required to be filed has been identified.

(b) Exhibits

		Incorporated by Reference				
Exhibit Number	Description	Form	File No.	Exhibit	Filing Date	Filed Herewith
3.1	Restated Certificate of Incorporation of the Registrant	8-K	001-36156	3.1	11/8/2013	
3.2	Amended and Restated Bylaws of the Registrant	8-K	001-36156	3.1	2/10/2023	
4.1	Form of Common Stock Certificate	S-1/A	333-191282	4.1	10/15/2013	
4.2	Description of Securities Registered under Section 12 of the Securities Exchange Act of 1934, as amended	10-K	001-36156	4.2	2/22/2021	
10.1#	Form of Indemnification Agreement between the Registrant and its officers and directors	S-1/A	333-191282	10.1	10/7/2013	
10.2#	2008 Stock Plan and forms of agreements thereunder	S-1	333-191282	10.2	9/20/2013	
10.3#	2013 Stock Incentive Plan, as amended, and forms of stock option award agreement, stock option exercise agreement, restricted stock agreement and restricted stock unit agreement	10-K	001-36156	10.3	2/27/2018	
10.4#	Form of stock option award under 2013 Stock Incentive Plan	10-Q	001-36156	10.1	11/2/2020	
10.5#	Form of stock unit award under 2013 Stock Incentive Plan	10-Q	001-36156	10.1	11/2/2020	
10.6#	Amended and Restated Employee Stock Purchase Plan	10-Q	001-36156	10.1	7/30/2020	
10.7	Lease Agreement between Riata Holdings, L.P., as landlord, and the Registrant, as tenant, dated November 28, 2012	S-1	333-191282	10.6	9/20/2013	
10.8	Second Amendment to Lease Agreement dated as of August 14, 2017 by and between BRI 1868 RIATA, LLC and the Registrant	10-Q	001-36156	10.1	11/7/2017	

Exhibit Number	Description	Incorporated by Reference				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
10.9	First Amendment to Lease Agreement dated as of January 7, 2014 by and between Riata Holdings, L.P. and the Registrant	10-K	001-36156	10.7	3/20/2014	
10.10	Office Building Lease by and between American Fund US Investments LP and the Registrant dated April 29, 2015	10-Q	001-36156	10.2	8/13/2015	
10.11	First Amendment to Office Building Lease dated May 3, 2016 by and between American Fund US Investments LP and the Registrant	10-K	001-36156	10.9	2/27/2018	
10.12	Second Amendment to Office Building Lease dated February 8, 2017 by and between CRP 6000 Shoreline, L.L.C. and the Registrant	10-K	001-36156	10.10	3/1/2017	
10.14†	Amended and Restated Pathology Services Agreement dated as of February 14, 2019 between Thyroid Cytopathology Partners, P.A. and the Registrant	10-Q	001-36156	10.1	4/30/2019	
10.16#	Form of Performance Stock Unit	10-Q	001-36156	10.1	5/1/2018	
10.17#	Amended and Restated Change in Control and Severance Agreement, effective July 1, 2019 between Bonnie Anderson and the Registrant	10-Q	001-36156	10.2	7/30/2019	
10.18†	Diagnostic Development Agreement, dated December 28, 2018, between Johnson & Johnson Services, Inc. and the Registrant	10-K	001-36156	10.22	2/25/2019	
10.19†	License and Asset Purchase Agreement, dated December 3, 2019, between NanoString Technologies, Inc. and the Registrant	8-K	001-36156	2.1	12/3/2019	
10.20	Registration Rights Schedule, dated December 3, 2019	8-K	001-36156	4.1	12/3/2019	
10.21	Memorandum of Understanding between the Shareholders of HalioDx and the Registrant	10-Q	001-36156	10.4	7/29/2021	
10.22	Securities Purchase and Contribution Agreement, dated July 13, 2021, between the registrant and HalioDx SAS	10-Q	001-36156	10.5	7/29/2021	
10.23#	Employment Agreement, dated as of May 7, 2021, between Marc Stapley and the Registrant	10-Q	001-36156	10.2	7/29/2021	
10.24#	Change in Control and Severance Agreement, effective June 1, 2021 between Marc Stapley and the Registrant	10-Q	001-36156	10.3	7/29/2021	
10.25	Agreement and Plan of Merger between Decipher Biosciences, Inc., the Registrant, and the parties thereto, dated as of February 2, 2021	10-Q	001-36156	10.1	5/10/2021	
10.26#	Amended and Restated Offer Letter, dated August 15, 2021, between the Registrant and Rebecca Chambers	10-Q	001-36156	10.1	11/9/2021	
10.27#	Change in Control and Severance Agreement, effective July 19, 2021 between Rebecca Chambers and the Registrant	10-Q	001-36156	10.2	11/9/2021	

Exhibit Number	Description	Incorporated by Reference				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
10.28#	Separation Agreement dated December 13, 2022 between Giulia Kennedy and the Registrant					X
10.29#	Amended and Restated Change in Control and Severance Agreement, effective July 1, 2019 between Giulia Kennedy and the Registrant	10-Q	001-36156	10.4	7/30/2019	
10.30#	Offer Letter, dated as of February 2, 2021, between Tina S. Nova and the Registrant	10-Q	001-36156	10.1	5/4/2022	
10.31#	Change of Control and Severance Agreement, effective February 2, 2021, between Tina S. Nova and the Registrant	10-Q	001-36156	10.2	5/4/2022	
10.32#	Offer Letter, dated as of January 9, 2023, between Annie McGuire and the Registrant					X
10.33#	Change of Control and Severance Agreement, effective January 1, 2023, between Annie McGuire and the Registrant					X
10.34#	Amended and Restated Employment Agreement, dated as of April 20, 2022, between Bonnie Anderson and the Registrant	10-Q	001-36156	10.6	5/4/2022	
21.1	List of Subsidiaries					X
23.1	Consent of Independent Registered Public Accounting Firm					X
24.1	Power of Attorney (see the signature page of this Annual Report on Form 10-K)					X
31.1	Principal Executive Officer’s Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					X
31.2	Principal Financial Officer’s Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					X
32.1*	Certification Pursuant to 18 U.S.C. § 1350 (Section 906 of the Sarbanes-Oxley Act of 2002)					X
32.2*	Certification Pursuant to 18 U.S.C. § 1350 (Section 906 of the Sarbanes-Oxley Act of 2002)					X
101.INS	Inline XBRL Instance Document					X
101.SCH	Inline XBRL Taxonomy Extension Schema					X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase					X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase					X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase					X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase					X
104	Cover Page Interactive Data File (embedded within the Inline XBRL document and included in Exhibit 101)					X

#	Indicates management contract or compensatory plan or arrangement.
*	In accordance with Item 601(b)(32)(ii) of Regulation S-K and SEC Release No. 34-47986, the certifications furnished in Exhibits 32.1 and 32.2 hereto are deemed to accompany this Form 10-K and will not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") or deemed to be incorporated by reference into any filing under the Exchange Act or the Securities Act of 1933, as amended, except to the extent that the registrant specifically incorporates it by reference.
†	Registrant is requesting or has previously been granted confidential treatment with respect to certain portions of this Exhibit.

Copies of the above exhibits not contained herein are available to any stockholder, upon payment of a reasonable per page fee, upon written request to: Chief Financial Officer, Veracyte, Inc., 6000 Shoreline Court, Suite 300, South San Francisco, California 94080.

(c) Financial Statement Schedules

Reference is made to Item 15(a) 2 above.

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.

VERACYTE, INC.

By: /s/ MARC STAPLEY

Marc Stapley

Chief Executive Officer and Director

Date: February 28, 2023

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENT, that each person whose signature appears below constitutes and appoints Marc Stapley and Rebecca Chambers, and each of them, his or her true and lawful attorneys-in-fact, each with full power of substitution, for him or her in any and all capacities, to sign any amendments to this annual report on Form 10-K and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that each of said attorneys-in-fact or their substitute or substitutes may do or cause to be done by virtue hereof.

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

Signature	Title	Date
/s/ MARC STAPLEY Marc Stapley	Chief Executive Officer and Director (Principal Executive Officer)	February 28, 2023
/s/ REBECCA CHAMBERS Rebecca Chambers	Chief Financial Officer (Principal Financial Officer)	February 28, 2023
/s/ JONATHAN WYGANT Jonathan Wygant	Chief Accounting Officer (Principal Accounting Officer)	February 28, 2023
/s/ JOHN L. BISHOP John L. Bishop	Lead Independent Director	February 28, 2023
/s/ BONNIE H. ANDERSON Bonnie H. Anderson	Director	February 28, 2023
/s/ ELIAV BARR, M.D. Eliav Barr, M.D.	Director	February 28, 2023
/s/ MUNA BHANJI Muna Bhanji	Director	February 28, 2023
/s/ KARIN EASTHAM Karin Eastham	Director	February 28, 2023
/s/ ROBERT S. EPSTEIN, M.D., M.S. Robert S. Epstein, M.D., M.S.	Director	February 28, 2023
/s/ JENS HOLSTEIN Jens Holstein	Director	February 28, 2023
/s/ EVAN JONES Evan Jones	Director	February 28, 2023