2019 Annual Report

Dear Shareholders,

2019 was a transformational year in our mission to improve diagnosis and treatment decisions throughout the patient journey. Key highlights included strong revenue and volume growth; advancing our first-of-its-kind, non-invasive nasal swab test for early lung cancer detection; and completing a strategic acquisition that positions us for global expansion on our own distributed platform with an expanding menu of advanced genomic tests in oncology and other diseases.

We are particularly excited about the December 2019 acquisition of the exclusive global diagnostic rights to the NanoString nCounter FLEX Analysis System. This move positions us to deliver our current and pipeline advanced genomic tests to physicians and their patients via hospital and clinical laboratories throughout the European Union and other parts of the world – enabling us to access an estimated $40 billion global market. Our test menu was also expanded with the addition of the Prosigna breast cancer test and the in-development LymphMark lymphoma subtyping test, which were included in the acquisition.

Our key accomplishments in 2019 and early 2020 include:

Strong Commercial Growth

- Achieved strong revenue growth across our genomic testing and product portfolio, delivering $108.3 million for the year, with total revenue – including from biopharma collaborations – of $120.4 million.
- Grew total genomic volume (for the Afirma, Percepta and Envisia classifiers) by 25% to 39,612 tests for the year.
- Received final Medicare coverage for Envisia and published strong clinical validation and utility data in *The Lancet Respiratory Medicine*, which together fueled the test's successful nationwide expansion for improved diagnosis of idiopathic pulmonary fibrosis and other interstitial lung diseases.
- Strengthened the clinical evidence for all of our genomic tests, including 11 abstracts for the Prosigna breast cancer test, which were presented at the San Antonio Breast Cancer Symposium in December 2019.

Biopharmaceutical Collaborations

- Announced a long-term strategic collaboration with Johnson & Johnson Innovation LLC in January 2019 to advance development of novel diagnostic tests for early lung cancer detection.
- In March 2020, formed a multi-year collaboration with Acerta Pharma, the hematology research development arm of AstraZeneca plc, to support the biopharmaceutical company's development of oncology therapeutics in lymphoma.

Pipeline Advancement

- Presented compelling preliminary data at the American College of Chest Physicians (CHEST) annual meeting for the first noninvasive nasal swab classifier for improved lung cancer diagnosis.
- Launched the second-generation Percepta Genomic Sequencing Classifier, completing the transition of our core classifiers to our RNA whole-transcriptome sequencing platform.

Responding to the evolving COVID-19 pandemic, Veracyte took swift action to protect our employees and the broader community, while ensuring our ability to deliver our genomic test results to physicians and their patients who need them. Our CLIA lab is running and most of our employees are working remotely. We believe we will emerge strong over the long-term due to the fundamental strength and diversification of our business and our strong cash position. Importantly, our focus on improving diagnosis and treatment decisions, while reducing unnecessary procedures, aligns with critical healthcare system priorities.

Looking ahead, we remain focused in 2020 on advancing our global vision as we prepare to launch three significant new products in 2021: our nasal swab test for lung cancer in the United States, the Envisia classifier on the nCounter system in international markets and the Percepta Atlas to inform treatment decisions at the time of lung cancer diagnosis. We look forward to keeping you apprised of our progress throughout the year.

In closing, I would like to thank our employees, whose positive attitudes, drive and focus are key to our success and inspire me each day. And, finally, thank you to you, our shareholders, for your ongoing support of our mission and our team.

Warm Regards,

Bonnie H. Anderson
Chairman and Chief Executive Officer

April 15, 2020

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, 2019 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, Including 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 is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of June 30, 2019, the aggregate market value of common stock held by non-affiliates of the registrant was approximately $1.3 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 20, 2020 was 49,738,822.

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 2020 Annual Meeting of Stockholders to be held on or about June 5, 2020 are incorporated herein by reference in Part III of this Annual Report on Form 10-K to the extent stated herein. Such proxy statement will be filed with the Securities and Exchange Commission within 120 days of the registrant's fiscal year ended December 31, 2019.

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PART I

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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; our beliefs with respect to the optimization of our processes for the analysis of ribonucleic acid, or RNA, samples; our integration of the assets acquired from NanoString Technologies, Inc.; our ability to deploy the nCounter FLEX Analysis System successfully and run our tests on this platform worldwide; our collaboration with Johnson & Johnson Services, Inc., or Johnson & Johnson; our belief in the importance of maintaining libraries of clinical evidence; 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 obtain Medicare coverage for 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 size of the global markets for our tests; the estimated number of patients who receive uncertain diagnoses 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 strategic relationships, and the success of those relationships; our beliefs regarding our laboratory capacity; 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.

Veracyte, Afirma, Percepta, Envisia, Prosigna, LymphMark, and Know by Design, and the Veracyte, Afirma, Percepta, Envisia and Prosigna logos are our trademarks. We also refer to trademarks of other corporations or organizations in this report that are the property of their respective owners.

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

We are a leading genomic diagnostics company that is creating value through innovation. We were founded in 2008 with a mission of improving diagnostic accuracy. Today, our growing menu of tests leverage advances in genomic science and technology to improve care throughout the patient journey, enabling more confident diagnostic, prognostic and treatment decisions in cancer and other challenging diseases. We are creating new standards of care by enabling more patients to avoid risks of unnecessary invasive procedures and removing costs from the healthcare system, while expediting the time to diagnosis and treatment decisions.

We perform our genomic tests for thyroid cancer, lung cancer and idiopathic pulmonary fibrosis, or IPF, in our CLIA-certified laboratory in South San Francisco, California. In December 2019, we announced our acquisition from NanoString Technologies, Inc., or NanoString, of an exclusive global diagnostics license to the nCounter® FLEX Analysis System, as well as the Prosigna® breast cancer prognostic gene signature assay, which is commercially available, and the LymphMark™ lymphoma subtyping assay, which is in development. Both tests are designed for use on the nCounter system. We believe this strategic transaction positions us to expand our business globally with a broad menu of advanced genomic tests that may be offered as distributed kits and performed in local laboratories worldwide. We believe our current and pipeline products address a collective $40 billion global market.

We develop our genomic tests to answer specific clinical questions, providing patients and physicians with a clear path forward in their diagnostic and treatment journey. We use advanced scientific methods, such as RNA whole-transcriptome sequencing and machine learning, to develop our tests and optimize the assay and classifier results for the platform on which the test will be performed. Historically, that platform has been RNA sequencing, performed in our CLIA lab. In the future, we expect this to also include the nCounter platform for international distribution of our tests.

Our classifiers are designed to improve diagnostic and prognostic clarity for cancer and other diseases. In its 2015 report, "Improving Diagnostic Errors in Medicine," the Institute of Medicine concluded that most people will experience at least one diagnostic error in their lifetime, sometimes with devastating consequences. Annually, of the hundreds of thousands of patients who are evaluated for suspected disease in our thyroid and lung indications, diagnosis can be ambiguous in 15-70% of cases. This diagnostic uncertainty can lead to additional, invasive procedures that are often unnecessary, delayed or incorrect treatment, increased healthcare costs and patient anxiety.

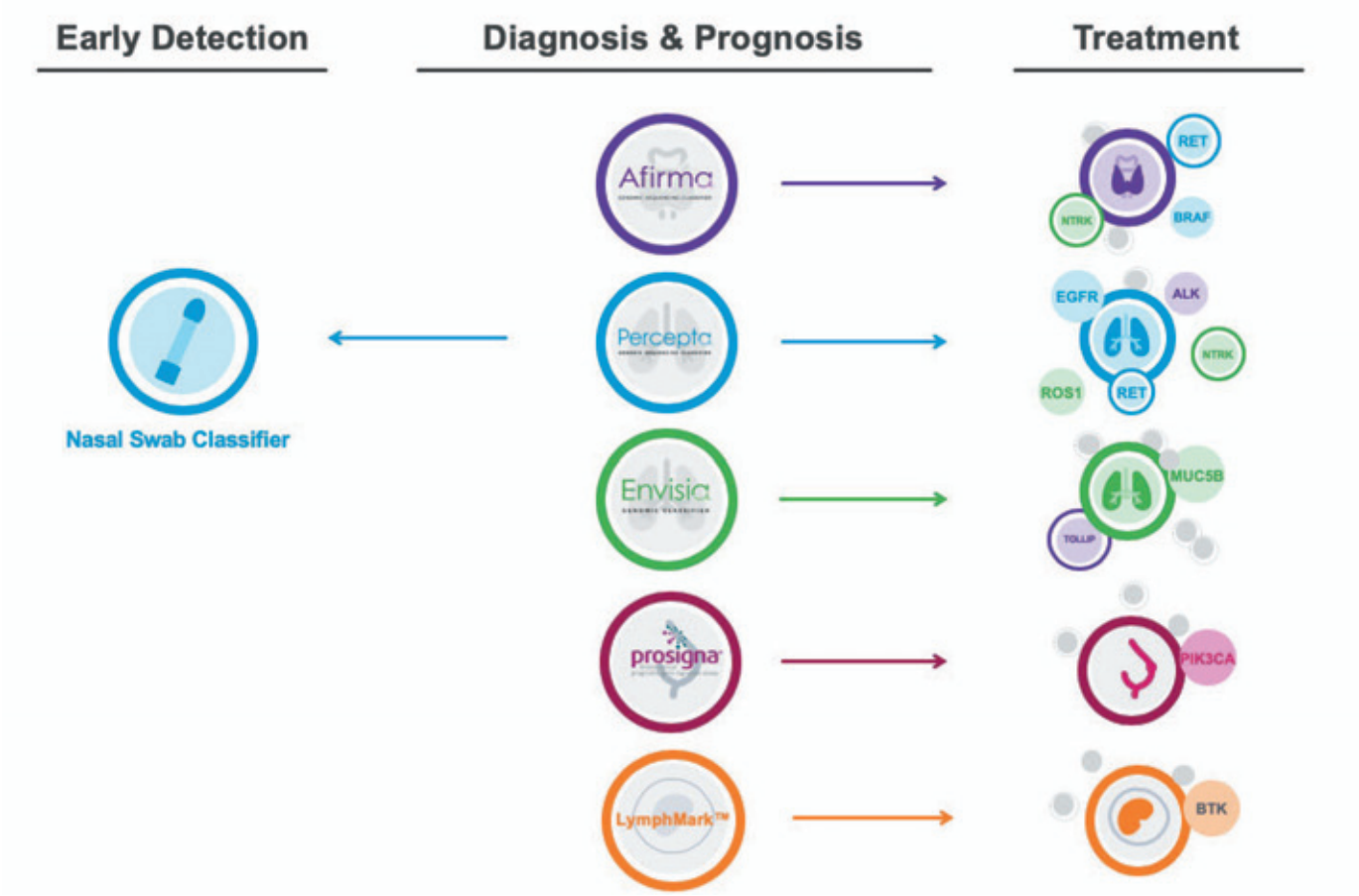
We position our tests to fit into the way physicians currently evaluate patients in order to facilitate adoption. We also design our tests to improve patient care and outcomes, while delivering clinical and economic utility to physicians, payers and the healthcare system in general.

We believe our powerful scientific platform provides multiple vectors to create value for patients, providers and payers, as well as stockholders, and to help advance precision medicine:

- Unique Biorepositories - When we develop new tests, we build extensive, robust biorepositories of patient-consented samples and well-curated clinical, radiological, outcome and other information from Institutional Review Board-approved clinical trials to inform our discovery efforts. Our biorepositories are designed to encompass the broad spectrum of disease that our tests may encounter when used in clinical practice, as well as the wide range of conditions associated with patients who are suspected of having a particular disease. We extract extensive genomic information from these patient samples using our RNA whole-transcriptome sequencing platform.

- Proprietary Technology and Bioinformatics - 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 enables us to develop high-performing genomic classifiers that can answer specific clinical questions. In addition, our bioinformatics pipelines are built to extract genomic variant content from the same assay to inform therapeutic selection.

- High-Performing Commercial Genomic Tests - With the exception of Prosigna, which competes with a first-to-market test in a highly competitive environment, our genomic tests generally serve large, untapped markets where they are changing the diagnostic and treatment paradigm for patients. We believe the nCounter platform affords us the opportunity to extend our business model on a global basis by enabling the development of a broad menu of tests. The platform is expected to be applicable to laboratories worldwide. Separately, we expect the nCounter platform may provide increased efficiency in our United States-based CLIA lab.



We currently offer five commercialized genomic tests that are changing disease diagnosis and patient care. All five tests are available in the United States and one is available internationally. These include the Afirma® Genomic Sequencing Classifier, or GSC (its predecessor was the Afirma Gene Expression Classifier, or GEC) for thyroid cancer; the Percepta® GSC (its predecessor was the Percepta Bronchial Genomic Classifier) for lung cancer; the Envisia® Genomic Classifier for IPF; the Afirma Xpression Atlas, which provides information on the most common and emerging gene alterations associated with thyroid cancer, enabling physicians to confidently tailor surgical and treatment decisions at time of diagnosis; and the Prosigna breast cancer test for assessing risk of distant recurrence, which is available for use on the nCounter platform in the United States and internationally.

We further believe our ability to leverage RNA whole-transcriptome sequencing data in large biorepositories of patient-consented samples in oncology and other indications presents an opportunity for biopharmaceutical companies to enhance their research and development capabilities. In April 2018, we announced a collaboration with Loxo Oncology (now a wholly owned subsidiary of Eli Lilly and Company) to advance its development of highly selective medicines for patients with genetically defined cancers, including thyroid cancer. In December 2018, we entered into a long-term strategic collaboration with Johnson & Johnson Innovation and the Lung Cancer Initiative at Johnson & Johnson to advance the development and commercialization of novel diagnostic tests to detect lung cancer at its earliest stages, when the disease is most treatable. The collaboration builds upon foundational "field of injury" science whereby genomic changes associated with lung cancer can be identified with a simple brushing of a person's airway to develop new interventions that can save lives. Additionally, in January 2020, we announced an agreement with Acerta Pharma, the hematology research and development arm of AstraZeneca, to provide genomic information that will support its development of oncology therapeutics in lymphoma.

Our collaboration with the Lung Cancer Initiative at Johnson & Johnson has helped accelerate two of our key lung cancer programs: (i) commercialization of the Percepta GSC on our RNA whole-transcriptome sequencing platform, and (ii) development of the first non-invasive nasal swab test for early lung cancer detection. We began making the Percepta GSC available to customers in June 2019. In October 2019, we announced preliminary data for our nasal swab classifier, which demonstrated the test's potential to identify patients at low risk of lung cancer so they can potentially avoid unnecessary procedures and those at high risk so they can receive prompt diagnosis and treatment.

The published evidence supporting our tests demonstrates the robustness of our science and clinical studies, which we believe is key to driving adoption and reimbursement. Patients and physicians can access our full list of publications on our website. Over 45 clinical studies covering our products have been published, including three landmark clinical validation papers published in *The New England Journal of Medicine* for the Afirma and Percepta classifiers, respectively, and in *The Lancet Respiratory Medicine* for the Envisia classifier. We continue to build upon our extensive library of clinical evidence.

We believe our focus on developing clinically useful tests that change patient care is enabling the company to set new standards in genomic test reimbursement. Our genomic classifiers in thyroid cancer, lung cancer and IPF, as well as the Prosigna breast cancer assay are covered by Medicare. Our Afirma classifier, for use in thyroid cancer diagnosis, is now covered by every major health plan in the United States, which collectively insure more than 275 million people. We are contracted as an in-network service provider to health plans representing over 225 million people in the United States. We believe that our in-network status with private payers will help facilitate private insurer reimbursement for our Percepta and Envisia classifiers. The Prosigna test is covered by leading private payers in the United States and is widely reimbursed by government and private payers in the countries where it is available.

We also expect to continue expanding our offerings in thyroid cancer, lung cancer, interstitial lung diseases such as IPF, breast cancer and lymphoma, as well as other indications that we believe will benefit from our technology and approach. Our product development pipelines address what we believe to be significant market opportunities for addressing clinical questions in early detection, diagnosis, staging/prognosis, therapy selection/surgery and disease monitoring across the aforementioned indications.

Patients access our tests through their physician. Our Afirma, Percepta and Envisia tests are used as part of the diagnostic process and genomic testing services are performed in our CLIA laboratory located in San Francisco, California. We perform slide preparation and staining for cytopathology on fine needle aspiration samples, for use with Afirma testing, in our reference laboratory in Austin, Texas. The Prosigna test is an *in vitro* diagnostic test that is performed on the nCounter FLEX Analysis System in laboratories worldwide, as well as in the United States.

Company Background

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 telephone number is (650) 243-6300. Our website address is www.veracyte.com. Our website and the information contained therein or connected thereto are not intended to be incorporated into this Annual Report on Form 10-K.

We make available free of charge on our website our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports as soon as reasonably practicable after we electronically file or furnish such materials to the Securities and Exchange Commission, or SEC. The reports are also available at www.sec.gov.

Fourth Quarter and Full-Year 2019 Financial Results

For the three months ended December 31, 2019, compared to the prior year:

- *Total Revenue* was $29.7 million, an increase of 15%;
- *Gross Margin* was 66%, unchanged;
- *Operating Expenses, Excluding Cost of Revenue,* were $27.8 million, an increase of 38%;
- *Net Loss and Comprehensive Loss* was ($7.5) million, an increase of 140%;
- *Basic and Diluted Net Loss Per Common Share* was ($0.15), an increase of 88%;
- *Net Cash Provided by Operating Activities* was $1.8 million, compared to $1.2 million used; and
- *Cash and Cash Equivalents* was $159.3 million at December 31, 2019.

For the year ended December 31, 2019, compared to the prior year:

- *Total Revenue* was $120.4 million, an increase of 31%;
- *Gross Margin* was 70%, an increase of six percentage points;
- *Operating Expenses, Excluding Cost of Revenue,* were $99.0 million, an increase of 22%;
- *Net Loss and Comprehensive Loss* was ($12.6) million, an improvement of 45%;
- *Basic and Diluted Net Loss Per Common Share* was ($0.27), an improvement of 56%; and
- *Net Cash Used in Operating Activities* was $3.2 million, an improvement of 76%.

2019 Full-Year and Recent Business Highlights

Commercial Growth:

- Achieved strong total revenue growth across our testing and product portfolio delivering $29.5 million in the fourth quarter and $108.3 million for 2019, an increase of 16% and 19%, respectively, compared to the prior year.
- Accelerated pulmonology testing revenue to $2.0 million and $5.5 million for the fourth quarter and full year, respectively, a 123% and 174% increase compared to prior year.
- Grew total genomic volume (Afirma, Percepta and Envisia) by 18% to 10,846 tests in the fourth quarter of 2019 and by 25% to 39,612 tests in 2019, compared to prior year.
- Increased genomic volume for our pulmonology products by 136% in 2019 compared to prior year, achieving growth targets for both the Percepta and Envisia classifiers.
- Received final Medicare coverage in March 2019 for the Envisia classifier and published strong clinical validation and clinical utility data in *The Lancet Respiratory Medicine*, propelling nationwide commercial expansion of the test in the second half of 2019.
- Expanded payer contracts by 14.4 million lives, making Veracyte an in-network genomic testing provider to health plans representing over 225 million members.
- Continued to build an extensive library of clinical data across our portfolio in 2019, including 8 publications and 11 presentations at leading medical meetings, demonstrating our Afirma and pulmonology tests' performance and clinical utility.
- Eleven abstracts were presented at the San Antonio Breast Cancer Symposium in December 2019, including data showing a benefit of Prosigna® over other genomic testing to identify patients' long-term risk of developing distant metastases. In addition, data were presented showing the test's ability to identify patients with intrinsic breast cancer subtypes that may potentially benefit from CDK4/6 inhibitors in place of standard chemotherapy.

Biopharmaceutical Collaborations/Pipeline Advancement:

- In January 2019, announced a long-term strategic collaboration with Johnson & Johnson Innovation LLC to advance the development and commercialization of novel diagnostic tests to detect lung cancer at its earliest stages, when the disease is most treatable.
- Presented preliminary data at the American College of Chest Physicians (CHEST) annual meeting for our first-of-its-kind noninvasive nasal swab classifier for improved lung cancer diagnosis. The test, being developed through our Johnson & Johnson collaboration, is expected to launch in early 2021.
- Launched the second-generation Percepta GSC, completing the transition of our core classifiers to our RNA whole-transcriptome sequencing platform.
- Announced a multi-year collaboration with Acerta Pharma, the hematology research and development arm of AstraZeneca plc, to provide genomic information that will support the biopharmaceutical company's development of oncology therapeutics in lymphoma.

Global Expansion:

- Acquired the exclusive global diagnostic rights to the NanoString nCounter FLEX Analysis System, as well as the Prosigna breast cancer assay and the in-development LymphMark lymphoma subtyping test. We believe this transaction positions us to access a $40 billion global market for our current and pipeline products, by offering a broad menu of advanced genomic tests in oncology and other indications using a distributed-kit model.

Our Products

We believe our focus on answering clinical questions that produce actionable results; our comprehensive scientific approach to product development, including our use of RNA whole-transcriptome sequencing; and our development of rigorous clinical evidence to establish our tests' performance and facilitate their reimbursement play critical roles in our ability to develop diagnostic tests that change clinical care. We offer genomic tests in thyroid cancer, lung cancer, IPF and breast cancer:

- ***Afirma Genomic Sequencing Classifier and Xpression Atlas.*** Our Afirma offerings include the Afirma GSC and Xpression Atlas. Our offerings are intended to provide physicians with clinically actionable results from a single fine needle aspiration, or FNA, biopsy. The Afirma GSC was developed with RNA whole-transcriptome sequencing and machine learning, and is used to identify patients with benign thyroid nodules among those with indeterminate cytopathology results in order to rule

out unnecessary thyroid surgery. The Afirma product is the first of its kind to market, and we believe the market leader. Since Afirma testing became available in 2011, we estimate that we have helped more than 75,000 patients avoid having all or part of their thyroids removed.

We commercially launched the Afirma Xpression Atlas in 2018 to complement the Afirma GSC. The Xpression Atlas provides physicians with genomic alteration content from the same FNA samples that are used in Afirma GSC testing and may help physicians decide with greater confidence on the surgical or therapeutic pathway for their patients. The Afirma Xpression Atlas includes 761 DNA variants and 130 RNA fusion partners in over 500 genes that are associated with thyroid cancer.

- ***Percepta Genomic Sequencing Classifier.*** The Percepta classifier improves lung cancer diagnosis by enhancing the performance of diagnostic bronchoscopies, thus identifying more patients with lung nodules who are at low risk of cancer and may avoid further, invasive procedures. This second-generation test, developed on our RNA whole-transcriptome sequencing platform and commercially introduced in June 2019, provides expanded clinical utility by identifying not only low risk patients, but also those with a high risk of lung cancer, so they may obtain faster diagnosis and treatment. The test is built upon foundational "field of injury" science - through which genomic changes associated with lung cancer in current and former smokers can be identified with a simple brushing of a person's airway - without the need to sample the often hard-to-reach nodule directly. The Percepta classifier is the first product of its kind to be available commercially and the first to obtain Medicare coverage for improved lung cancer diagnosis.

- ***Envisia Genomic Classifier.*** The Envisia classifier improves diagnosis of IPF by helping physicians better differentiate IPF from other interstitial lung diseases, or ILDs, without the need for surgery. The test identifies the genomic pattern of usual interstitial pneumonia, or UIP, a hallmark of IPF, with high accuracy on patient samples that are obtained through transbronchial biopsy, a nonsurgical procedure that is commonly used in lung evaluation. 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. IPF is often difficult to distinguish from other ILDs, even with the most advanced imaging technologies. Further, diagnostic surgery is risky, expensive and may not be viable for some patients. The Envisia classifier is the first product of its kind to market. We announced a final Medicare coverage policy for the Envisia classifier in March 2019, which was followed by the online publication of positive clinical validation and clinical utility data in *The Lancet Respiratory Medicine* in May 2019. Following these milestones, we initiated nationwide expansion for the test, beyond the limited Early Access Program begun in 2018.

- ***Prosigna Breast Cancer Prognostic Gene Signature Assay*.** The Prosigna test uses advanced genomic technology to inform next steps for patients with early-stage breast cancer, based on the genomic make-up of their disease. The test leverages a collection of 50 genes known as the PAM50 gene signature, and can provide a breast cancer patient and physician with prognostic score indicating the probability of cancer recurrence during the next ten years. Outside of the United States, it is also utilized to provide cancer subtype classification information.

  Physicians can use Prosigna to help guide therapeutic decisions so that patients receive therapeutic interventions, such as chemotherapy, only if clinically warranted. The *in vitro* diagnostic test is indicated in female breast cancer patients who have undergone surgery in conjunction with locoregional treatment consistent with standard of care, either as:

  1. A prognostic indicator for distant recurrence-free survival at ten years in post-menopausal women with Hormone Receptor-Positive (HR+), lymph node-negative, Stage I or II breast cancer to be treated with adjuvant endocrine therapy alone, when used in conjunction with other clinicopathological factors; or
  2. A prognostic indicator for distant recurrence-free survival at ten years in post-menopausal women with Hormone Receptor-Positive (HR+), lymph node-positive (1-3 positive nodes), Stage II breast cancer to be treated with adjuvant endocrine therapy alone, when used in conjunction with other clinicopathological factors. The device is not intended for patients with 4 or more positive nodes.

  The Prosigna test is cleared by the FDA for marketing in the United States for use on the nCounter Dx Analysis System and is available for use when ordered by a physician. The test is performed on formalin-fixed and paraffin-embedded, or FFPE, tissue. The Prosigna test has been CE-marked, 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 test is covered by Medicare and leading private payers in the United States and is widely covered by government and private payers in the countries where it is available.

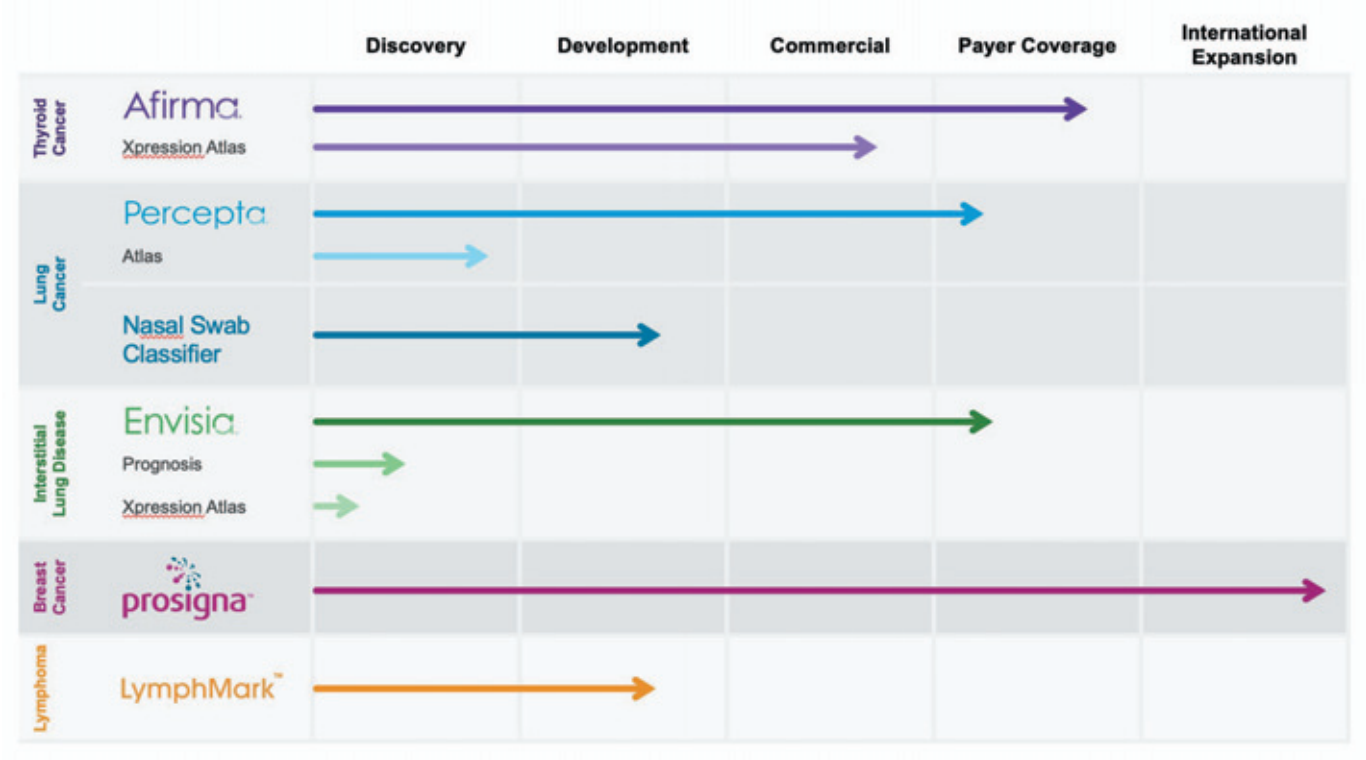
Our Pipeline

Our product pipeline reflects our strategy of answering clinical questions in our indications across the clinical care continuum. We develop new products using our RNA whole-transcriptome sequencing and machine learning platform and also strategically acquire complementary products through collaborations and acquisitions. In December 2019, we acquired the exclusive global rights to the nCounter® diagnostics platform, positioning us to make our genomic tests available to physicians and patients worldwide through a distributed platform in which customers perform the tests in their local laboratories. This transaction also expands our existing genomic test offerings into new oncology indications of breast cancer and lymphoma. We believe the global market opportunity for our current and future pipeline products is over $40 billion annually.

- **Nasal Swab Test for Early Lung Cancer Detection** - In October 2019, we announced preliminary clinical data showing that our noninvasive nasal swab test - the first of its kind - may enable early lung cancer detection and diagnosis. The preliminary findings specifically show that our novel genomic test has the potential to accurately classify lung cancer risk in patients with lung nodules so that these patients may obtain the prompt diagnosis and potential treatment they need or may be monitored noninvasively. The in-development test uses "field of injury" technology to determine the likelihood that a lung nodule is cancerous by measuring gene expression patterns in cells collected from the nose. We plan to introduce the nasal swab test commercially in the United States in early 2021 and internationally on the nCounter platform in 2022.

- **LymphMark Lymphoma Subtyping Test** - The LymphMark test is in development for use on the nCounter platform. The test uses the gene expression profile of cells found in Diffuse Large B-cell Lymphoma, or DLBCL, FFPE tissue for the classification of Cell-of-Origin subtype of DLBCL into Activated B-Cell-like or Germinal Center B-Cell-like or an unclassified result. DLBCL is a heterogeneous group of cancers that represents the most common and one of the most aggressive forms of Non-Hodgkin Lymphoma. According to the National Cancer Institute, there were approximately 70,000 new cases of Non-Hodgkin Lymphoma in the United States in 2015.

- **Product Extensions** - We are expanding our portfolio of tests across our indications - lung cancer, IPF, breast cancer and lymphoma - to inform treatment decisions at the time of diagnosis, similar to what we have done with the Afirma Xpression Atlas in thyroid cancer. Because our diagnostic and prognostic tests are positioned early in the clinical care continuum, we have a unique opportunity to inform downstream decisions without the patient having to undergo further procedures to obtain additional tissue samples.



Platform for Global Expansion

In December 2019, we acquired from NanoString an exclusive worldwide license to the nCounter FLEX Analysis System for *in vitro* diagnostic use and for the development and commercialization of *in vitro* diagnostic tests. We expect this instrument platform to enable a broad range of testing through its ability to simultaneous conduct multiplex testing of up to 800 RNA, DNA

and protein targets. The nCounter system is simple to use and requires less than two hours of hands-on time, which is an up to 80 percent reduction compared to sequencing technology, making advanced genomic testing more accessible to patients through laboratories that previously may not have had the resources or expertise to perform such complex testing.

As of December 31, 2019, several hundred nCounter instruments have been installed in more than 20 countries where they are used for research as well as diagnostic testing in clinical laboratories and medical centers. The Prosigna breast cancer prognostic gene signature assay is already offered on the system internationally and in the United States. We plan to begin offering the Envisia classifier, for use in IPF diagnosis, to international customers in 2021 as a kit-based test that runs on the nCounter system. We expect our in-development nasal swab classifier, for use in lung cancer diagnosis, to follow on the nCounter system in 2022, after the test becomes available in our CLIA laboratory in the United States in early 2021. Over time, we plan to offer additional genomic tests on the nCounter platform, including tests developed by potential diagnostics or biopharmaceutical partners seeking access to global markets. For testing in the United States, we plan to incorporate the nCounter FLEX Analysis System into our CLIA lab, as appropriate, to realize increased efficiency and margin expansion.

Biopharmaceutical Collaborations

We believe the powerful clinical and scientific platform we use in the discovery and development of new products also provides multiple opportunities to monetize our assets through collaborations with biopharmaceutical companies. In developing our products, we have built or gained access to unique biorepositories that include extensive clinical cohorts and whole genome RNA sequencing data, which we believe are important to the development of new targeted therapies, determining clinical trial eligibility and guiding treatment selection. Further, we believe our expanded global footprint and move into new clinical areas in oncology, enabled by the nCounter FLEX Analysis System acquired from NanoString, will prove highly attractive to biopharmaceutical companies, which need access to patients worldwide for their targeted therapies.

As of December 31, 2019, we had established biopharmaceutical collaborations with Loxo Oncology, Inc., or Loxo, a wholly-owned subsidiary of Eli Lilly and Company, and Johnson & Johnson. In January 2020, we announced a new collaboration with Acerta Pharma, the hematology research and development arm of AstraZeneca plc.

Through the research collaboration with Loxo Oncology, the biopharmaceutical company gained access to data derived from our Afirma Xpression Atlas platform for use in its development of highly selective medicines for patients with genetically defined cancers, including thyroid cancer.

We also collaborate with the Lung Cancer Initiative at Johnson & Johnson to advance the development and commercialization of novel diagnostic tests to detect lung cancer at its earliest stages, when the disease is most treatable. The collaboration with Johnson & Johnson, announced in January 2019, was formed to accelerate two key lung cancer programs for us: the commercialization of our Percepta GSC on our RNA whole-transcriptome sequencing platform, which was achieved in June 2019, and the development of the first noninvasive nasal swab test for early lung cancer detection. Under terms of the agreement, we and Johnson & Johnson have combined clinical study cohorts involving more than 5,000 patients with multiple years of clinical outcome data.

Through our collaboration with Acerta Pharma, we will provide genomic information that will support the biopharmaceutical company's development of oncology therapeutics in lymphoma. The Acerta Pharma collaboration followed the announcement of our expansion into new oncology indications and global markets through our strategic transaction with NanoString.

Market Opportunity

The majority of our current business is focused on developing and commercializing genomic classifiers that help resolve diagnostic uncertainty. We believe this is a critical healthcare issue that leads to hundreds of thousands of unnecessary surgeries, delayed or potentially harmful treatments and billions of wasted healthcare dollars each year. We also offer genomic tests designed to answer important questions at other points along the care continuum - often from the same patient samples used in diagnosis - to further help improve patient outcomes and the use of healthcare resources. We believe the total addressable market for our current tests - in thyroid cancer, lung cancer, IPF and breast cancer - is over $3.4 billion in the United States and Europe. We believe the global market opportunity for our current and pipeline products is over $40 billion annually.

Thyroid Market Opportunity for Our Afirma Solution

Each year in the United States, we estimate that more than 525,000 FNA biopsies are performed to assess patients with potentially cancerous thyroid nodules. Cytopathology is performed on each biopsy and we estimate that up to 30 percent of the results are indeterminate (not clearly benign or malignant). Physicians have traditionally recommended thyroid surgery to obtain a more definitive diagnosis. Following surgery, however, 70% to 80% of patients' nodules are diagnosed as benign, meaning the surgery was unnecessary. Such surgery is invasive, costly and often leads to the need for lifelong daily thyroid hormone replacement drugs. The Afirma classifier is included in most leading medical guidelines.

We believe the addressable market opportunity for our Afirma solution is $720 million in the United States and approximately $100 million in the European Union. We currently do not have meaningful operations or sales outside the United States.

In January 2012, we obtained Medicare coverage for our Afirma classifier. The test is covered by every major health plan in the United States, which collectively insure more than 275 million people. We are contracted as an in-network service provider to health plans representing over 225 million people in the United States. We estimate that approximately 20% of patients evaluated for thyroid cancer in the United States are covered by Medicare and the remaining 80% are covered by commercial plans or Medicaid or they are self-insured.

Lung Cancer Market Opportunity for Our Percepta Classifier

Lung cancer is often difficult to diagnose without invasive, risky and costly surgeries. Nearly 230,000 people are diagnosed with lung cancer each year in the United States and more than 140,000 people die annually from the disease. We estimate that approximately 1.8 million to 2.0 million lung nodules are identified in patients in the United States each year and that doctors perform approximately 545,000 bronchoscopies on these patients in order to obtain a diagnosis. A bronchoscopy is a non-surgical procedure that is often used to evaluate patients with potentially cancerous lung nodules, but produces inconclusive results in up to 70% of cases. We estimate that the number of bronchoscopies performed would potentially increase - in lieu of more invasive procedures - if physicians had more confidence in the bronchoscopy procedure's ability to provide clear results. Currently, we estimate that approximately 230,000 patients undergoing bronchoscopy have inconclusive results and could potentially benefit from our test.

We believe the addressable market opportunity for our Percepta product is approximately $490 million in the United States and over $200 million in Europe. We anticipate the market will expand significantly over the coming years as lung cancer screening programs are implemented in the United States and physicians embrace bronchoscopy as a standard, less-invasive diagnostic modality for evaluating lung nodules and lesions.

In May 2017, we obtained Medicare coverage for Percepta, making it the first genomic test to be covered for use in lung cancer screening and diagnosis. The test is available to nearly 60 million Medicare enrollees. We estimate that half of the patients evaluated for lung cancer in the United States are covered by Medicare.

IPF Market Opportunity for Our Envisia Classifier

Each year in the United States and Europe, up to 220,000 patients are suspected of having an ILD, including IPF, which is among the most common and deadly of these lung-scarring diseases. IPF is notoriously difficult to diagnose, often leading to treatment delays, repeated misdiagnoses, patient distress and added healthcare expense. Physicians routinely use high-resolution computed tomography imaging to identify UIP, the pattern whose presence is essential to IPF diagnosis. This approach, however, frequently provides inconclusive results, leading many patients to require surgery to secure a more definitive diagnosis using surgical histopathology. These surgeries are risky and expensive, and many patients are too frail to undergo the procedure. Of the approximate 250,000 patients evaluated for ILD annually, we estimate that approximately 87%, or 191,000 patients receive an uncertain diagnosis and are candidates for our Envisia test.

We believe the addressable market opportunity for our Envisia product is approximately $435 million in the United States and up to $300 million in Europe.

In March 2019, we obtained final Medicare coverage for the Envisia classifier through the MolDX program, administered by Palmetto GBA. The Envisia classifier is the first genomic test to be covered by Medicare for use in IPF diagnosis, with the test available to the government health program's nearly 60 million Medicare enrollees. We estimate that half of the patients evaluated for ILDs/IPF in the United States are covered by Medicare.

Breast Cancer Market Opportunity for Our Prosigna Test

Breast cancer is the most common cancer and the leading cause of cancer-related death in women worldwide. It impacts 2.1 million women and causes 627,000 deaths each year. Following diagnosis, physicians have traditionally used clinical factors - tumor size, grade and nodal status - to help determine the risk of cancer recurrence and thus to help inform whether adjuvant chemotherapy should be added to endocrine treatment. We believe that historically this subjective approach led to women unnecessarily being exposed to toxic chemotherapy or to being undertreated.

The Prosigna assay measures RNA expression levels of 50 genes that provide a breast cancer patient and physician with a prognostic score indicating the probability of cancer recurrence over ten years, as well as information on the patient's breast cancer genetic subtypes [Luminal A and B, Basal and HER2-Enriched (in ex-United States markets and CLIA)], which can further inform treatment.

We estimate that the global early stage breast cancer recurrence market is significant, with over 500,000 patients potentially eligible for Prosigna annually. This is comprised of approximately 115,000 patients in the United States and 400,000 in the rest of the world. The Prosigna test is clinically validated in studies published in *Annals of Oncology* and the *Journal of Clinical Oncology*. The test is recommended in guidelines from the National Comprehensive Cancer Network and the American Society of Clinical Oncology in the United States. Medicare coverage for Prosigna through the MolDX program has been in effect since October 2015. 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, which in 2019 recommended use of the test. We estimate that the addressable market for Prosigna is approximately $700 million in the United States and $500 million in the European Union.

Scientific Background

In the past, clinicians made diagnoses from biopsy samples by looking at them under a microscope. Technology has advanced far beyond this, and scientists now have the ability to decipher genomic patterns that reside in the DNA and RNA of such biopsies. We search for patterns that tell us whether or not the biopsy contains the disease in question. We do this by using a whole-genome approach. This means we look at all of the human genes, including their expression patterns and their variants and mutations, rather than just looking at a few selected genes that we think may be important. This comprehensive measurement of the human genome allows us to detect signals from genes we may not have previously suspected to be involved in disease.

We use machine learning-based algorithms to match genomic patterns with clinical truth, or the true diagnosis. For example, when we train an algorithm on RNA sequencing data, we teach it to associate a set of expression patterns with disease and a different set of patterns with lack of disease. When algorithms are trained on enough examples with clinical truth, they learn to find that pattern in samples they have never encountered, thus allowing the algorithm to predict disease in a clinical setting.

Our core products are built around algorithms that help either rule in or rule out disease. Due to the complex, sometimes rare, subtypes of various diseases like cancer, we develop and train our machine learning algorithms using a diverse set of patient samples so that they are equipped to recognize patterns across the whole spectrum of conditions that may be encountered in the clinic.

Our process uses commercially available reagents and instruments with our own proprietary process and protocols, which results in RNA extraction from the range of small, minimally invasive biopsies used in our clinical development studies and our commercial laboratory tests.

Our recently-acquired Prosigna breast cancer prognostic test similarly utilizes machine learning-based algorithms to provide prognostic information for certain early-stage breast cancer patients. The RNA-based test uses a "PAM50" signature, comprised of 50 genes, to compare the gene expression profile of a patient's tumor - from a surgically removed sample - with each of four intrinsic tumor subtypes to determine the degree of similarity. The results, in combination with a proliferation score and tumor size, produce an individualized Prosigna risk-of-recurrence score. The Prosigna test was adapted to be performed using the nCounter Analysis System so that it can be performed in local laboratories.

In addition to our primary tests in each of our clinical indications, our RNA sequencing platform also enables us to identify gene alterations such as variants and fusions, copy number and other information - from samples utilized in initial testing - that may inform next steps in patient care. We currently offer this capability in our thyroid cancer offerings as the Afirma Xpression Atlas, which is used to help inform surgical strategy and treatment options for patients whose thyroid nodules are confirmed or suspicious for cancer. We believe this capability may be especially useful in oncology and other diseases that are increasingly treated using therapies that target specific gene alterations.

Technology

Genomic Testing

Our technology approach for our genomic tests is comprised of a number of key attributes:

- *Core Expertise in Broad-based Genomic Analysis.* Our team of bioinformatics and computational scientists possess extensive knowledge of both existing computational methods as well as the capacity to develop proprietary methods as needed for algorithm design. We demonstrated our ability to utilize large amounts of genomic data with machine learning algorithms in the development of the Afirma GEC on microarrays and substantially extended this capability in the development of the Afirma GSC by accessing genomic features through deep RNA sequencing. Our expertise allows us to use a combination of expression analysis as well as mutations and variants to build our sophisticated machine learning algorithms, all on the same platform. Additionally, we believe our technological capabilities enable us to adapt our genomic tests to other platforms, including the nCounter FLEX Analysis System for distribution to global markets.

- *Platform-Agnostic Approach.* We are not reliant on any one technology platform to measure genomic signals; in fact, we may take advantage of a multitude of genomic methodologies to develop future tests. When we developed the Afirma GEC in 2008, microarray technologies were a cost-effective discovery technology compared to other approaches that were nascent at the time. More recently, the rapid cost reductions achieved in next generation sequencing platforms have allowed us to pursue our whole genome approach to biomarker discovery using a range of genomic features obtained through both DNA and RNA sequencing. From this vast array of sequence data, our algorithms select those genomic signals that inform on the disease in question, in the relevant biopsy sample. We continue to evaluate potential opportunities to use new genomic discoveries and technologies to further improve patient care.

- *Proprietary Capabilities in Analyzing Small, Heterogeneous Cytology Samples.* We have developed proprietary technology, intellectual property and know-how for optimized methods for extraction and analysis of nanogram quantities of RNA from small biopsy samples. Our focus is on redefining clinical truth, using patient samples obtained through less-invasive techniques, thereby increasing access to our technology by a larger patient population. While others can extract RNA from these small biopsies, we believe our process is optimized and scaled for high-throughput clinical testing and large-scale clinical development studies, such as those involving high-density microarrays and next-generation sequencing.

- *Precision and Reproducibility.* We have in place standard operating procedures governing reagents, materials, instruments and controls and extensive experience from numerous verification studies performed for our tests. We apply the same high-quality control methods that were developed for our reagents and processes, along with our proprietary software for automation, sample tracking, data quality control and statistical analysis, to our development process.

nCounter Platform

In December 2019, we acquired from NanoString an exclusive worldwide license to the nCounter FLEX Analysis System for *in vitro* diagnostic use and for the development and commercialization of *in vitro* diagnostic tests. Currently, the Prosigna breast cancer assay is the only commercially-available test on the platform.

The nCounter system can simultaneously analyze RNA, DNA or protein targets, as well as gene mutations, fusions and copy number variations, in up to 800 genes. The system utilizes proprietary chemistry that allows the measurement of subtle changes in the activity of multiple genes from minute amounts of a biological sample, with high sensitivity and precision. This chemistry also obviates the need for amplification or other steps that can be cumbersome and time-consuming or may introduce the possibility of measurement errors. As a result, the nCounter system enables easy-to-use genomic testing with simple workflow that requires less than two hours of hands-on time - an up to 80 percent reduction compared to sequencing technology - making advanced genomic testing more accessible to patients through laboratories that previously may not have had the resources or expertise to perform such complex testing.

We believe the nCounter system's sensitivity and multiplexing capabilities will provide a robust platform for our genomic classifiers, enabling us to offer them in a kit format that can be performed locally in laboratories worldwide where the nCounter system is installed. Additionally, we believe that we can perform our genomic classifiers on the nCounter system in our own CLIA lab, enabling other, smaller-volume labs in the United States to offer our tests without the need to invest in an nCounter instrument, while also enabling us to enhance our margins.

We expect to begin offering the Envisia classifier, for use in IPF diagnosis, to international customers in 2021 as a kit-based test that runs on the nCounter system. We expect our in-development nasal swab classifier, for use in lung cancer diagnosis, to follow on the nCounter system in 2022, after the test becomes available in our CLIA lab in the United States in early 2021. The nCounter system can also run additional tests developed by us, as well as by potential diagnostics or biopharmaceutical partners seeking access to global markets.

Studies Validating Test Performance and Clinical Utility

In 2010, the Centers for Disease Control and Prevention published the "ACCE" model as a paradigm for establishing evidence to confirm the safety and effectiveness of molecular diagnostic tests. ACCE derives its name from the main criteria for evaluating such tests, including analytic validity, clinical validity and clinical utility. This model has been adopted by most technology assessment groups, professional societies and payers. We fully embrace this paradigm of evidence development and we strive to provide the highest level of scientific evidence to support our test claims.

We believe that developing an extensive library of rigorous clinical evidence to support our tests is critical to driving inclusion in clinical guidelines, securing reimbursement and gaining physician adoption. We make our published research, abstracts from medical conferences and other product information available on our website at www.veracyte.com. Our website and the information contained therein or connected thereto are not intended to be incorporated into this Annual Report on Form 10-K.

Our Afirma classifiers are supported by more than 30 published scientific studies. These include a prospective, multicenter clinical validation study published in *The New England Journal of Medicine*, which suggested that the test can significantly reduce the number of unnecessary surgeries, compared to traditional diagnostic approaches. They also include a clinical validation study with patients from this same cohort, which was published in *JAMA Surgery* and show that the next-generation Afirma GSC can identify 30 percent more patients who may potentially avoid unnecessary surgery. The Afirma classifier is recommended in leading practice guidelines and is covered for over 275 million lives in the United States, including through Medicare and all major commercial insurance plans in the United States.

Our Percepta test is supported by six published scientific studies, including data published in *The New England Journal of Medicine*, which demonstrate the test's accuracy in identifying patients who are at low risk of cancer following inconclusive results from bronchoscopy. These patients may then be monitored with CT scans in lieu of undergoing surgery - a frequent next step at this juncture of the clinical pathway. A clinical utility study published in the *CHEST* journal showed that use of the test reduced unnecessary surgeries in the target patient population, compared to physicians' plans prior to Percepta testing.

Our Envisia classifier is supported by clinical data published in six peer-reviewed journals. These include a prospective clinical validation study published in *The Lancet Respiratory Medicine*, which showed that the Envisia test achieved high specificity, meaning it would be expected to identify more than two-thirds of patients with usual interstitial pneumonia, or UIP, the hallmark of IPF, while minimizing the number of false positive results. In comparison, data show that high-resolution CT (HRCT) imaging, which is typically used in IPF diagnosis, has a sensitivity of just 43 percent for UIP.

The Prosigna breast cancer prognostic test is supported by multiple clinical studies involving thousands of female patients with early-stage breast cancer. These include a large clinical validation study published in *Annals of Oncology*. In this study of 1,478 patients, researchers found that the Prosigna risk of recurrence score added a "highly significant further increase in prognostic information" compared to a clinical linear predictor alone. Data demonstrating the test's clinical performance, clinical utility, cost-effectiveness and analytical validation have been published in over a dozen peer-reviewed journals including *the Journal of Clinical Oncology*, *Journal of the National Cancer Institute* and *JAMA Oncology* among others.

Commercial Operations

United States

Our commercial infrastructure, including our sales, marketing, managed care, and customer care functions, is critical to our ongoing success. We have built a strong domestic sales, marketing and reimbursement capability that interacts directly with users of our products, as well as payers and other stakeholders involved in the diagnostic workup of a patient.

Our sales team is structured to sell all of our tests; we do not maintain a separate sales force for each product. Currently, our sales force is comprised of our product specialists, who are accountable for select geographic territories; pulmonary product specialists, who maintain and grow our relationships with key regional institutions; account managers, who manage existing client relationships; and medical science specialists, who focus on addressing medical and clinical education in the field.

We continued to expand our domestic field sales team in 2019 and we expect to continue to invest in sales and marketing to support our commercial expansion efforts in the United States. Additionally, through the strategic transaction with NanoString, we hired a small number of personnel to support Prosigna laboratory customers in the United States.

To date, substantially all of our revenue has been derived from customers we serve in the United States. Through December 31, 2019, we derived most of our revenue from our Afirma solution, including cytopathology services and the Afirma assays.

In addition to direct sales, industry trade shows or events provide us with an opportunity to share important product and research updates and to interact with key opinion leaders who impact our business. We typically have a presence at a number of select industry conferences, including the Annual Scientific and Clinical Congress of the American Association of Clinical Endocrinologists, or AACE, and the Endocrine Society's Annual Meeting, or ENDO; key pulmonology conferences such as the American Thoracic Society's International Conference, or ATS, and the American College of Chest Physician's CHEST Annual Meeting. With our expansion into breast cancer, we plan to also attend the annual San Antonio Breast Cancer Symposium.

Our other marketing efforts encompass a range of tools and channels, including product websites, digital marketing tactics such as search engine optimization and online advertising, direct-to-customer communications and advertising in trade media outlets read by our customers.

International

With our acquisition of the exclusive worldwide *in* vitro diagnostic rights for the nCounter platform, we hired several key international members of NanoString's global diagnostics sales, marketing, medical affairs and distribution teams, providing a foundation for our international expansion efforts.

Prosigna is currently our only product generating revenue in global markets. Commercialization efforts for Prosigna involve securing reimbursement, selling test kits to institutions and medical centers that already own or lease nCounter instruments, and driving physician demand for the test.

Laboratory Operations

We perform all genomic testing in thyroid cancer, lung cancer and IPF in South San Francisco, California. For Afirma testing, we perform slide preparation and staining for cytopathology on FNA samples in Austin, Texas. Our South San Francisco facility is responsible for quality assurance oversight, licensing and regulatory compliance and maintenance for both of our laboratories to ensure data integrity and consistent, validated processes.

We receive samples for testing directly from the following sources:

- ***FNAs for Afirma Genomic Testing Only.*** Institutions and other clients, such as laboratories, that perform their own cytopathology may send us FNA samples from indeterminate results to perform Afirma genomic testing. We receive over 70% of our Afirma test volume from this source and it is the fastest-growing segment of our business.

- ***FNAs for Cytopathology and Reflexed Afirma Genomic Testing.*** We receive FNA samples from ordering physicians for cytopathology assessment and if results are indeterminate, Afirma genomic testing is to be performed. We partner with Thyroid Cytopathology Partners, or TCP, to perform the cytopathology review.

- ***Bronchoscopy Samples for Percepta Classifier.*** Institutions send us samples collected during the bronchoscopy procedure and order genomic testing with the Percepta classifier when bronchoscopy results are inconclusive.

- ***Bronchoscopy Samples for Envisia Classifier.*** Institutions send us samples to help better differentiate IPFs from other ILDs without the need for surgery. These samples are collected using transbronchial biopsy.

We rely on TCP to provide professional cytopathology diagnoses on thyroid FNA samples pursuant to a pathology services agreement. Our agreement with TCP is effective until October 31, 2022 and thereafter automatically renews every year unless either party provides notice of intent not to renew at least twelve months prior to the end of the then-current term.

Our Prosigna breast cancer test is performed on the nCounter FLEX Analysis System in laboratories internationally and in the United States. We believe that our state-of-the-art laboratory space in South San Francisco, California, has sufficient laboratory capacity to accommodate volume growth for our existing and pipeline products, as well as for Prosigna testing on the nCounter instrumentation system.

Our quality assurance function oversees the quality of our laboratories as well as the quality systems used in research and development, client services, billing operations and sales and marketing. We have an established quality management system compliant with federal and state regulations and standards that we believe achieves excellence in operations across the entire business. We continuously monitor and strive to improve our quality program and believe our implementation of these processes has supported our achievement of product performance, customer satisfaction and retention and a philosophy of continuous improvement.

Reimbursement Strategy

We employ a multi-pronged strategy designed to achieve broad coverage and reimbursement for our tests in the United States and internationally:

- ***Compile a Growing Library of Peer-reviewed Studies that Demonstrate the Test Is Effective.*** To date, several peer-reviewed articles and review papers have been published and have helped support our efforts aimed at widespread adoption and reimbursement of our genomic tests. In each disease area we pursue, we intend to conduct studies in order to develop robust library of evidence.

- ***Meet the Evidence Standards Necessary to Be Consistent with Leading Clinical Guidelines.*** We believe inclusion in leading clinical practice guidelines plays an important role in payers' coverage decisions. For example, the data published on Afirma to date is consistent with the recommendations of the widely-recognized American Thyroid Association and National Comprehensive Cancer Network clinical practice guidelines.

- ***Execute an Internal Managed Care and Claims Adjudication Function as Part of Our Core Business Operations.*** We believe that obtaining adequate and widespread reimbursement is a critical factor in our long-term success. We employ a team of in-house claims processing and reimbursement specialists who work with payers, physician practices and patients to obtain maximum reimbursement.

- ***Collaborate with Network of Key Opinion Leaders.*** Key opinion leaders are able to impact clinical practice by publishing research and determining whether new tests should be integrated into practice guidelines. We collaborate with key opinion leaders early in the development process to ensure our clinical studies are designed and executed in a way that clearly demonstrates the benefits of our tests to patients, physicians and payers. Ongoing studies to support real world experience with our tests are also a key component of our efforts to collaborate with physician thought leaders.

- ***Established Payer Relationships and In-network Contracts.*** We believe that positive engagement with payers leads to coverage decisions and facilitates our efforts on coverage and contract decisions for subsequent tests.

Coverage, Coding and 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. The Centers for Medicare & Medicaid Services, or CMS, administers the Medicare and Medicaid programs, which provide health care to almost one in every three Americans. For any particular geographic region, Medicare claims are processed at the local level by Medicare Administrative Contractors, or MACs.

Medicare generally covers molecular diagnostic tests through the MolDX program, administered by the MAC, Palmetto GBA. Medicare has covered our Afirma classifier testing since 2012 and Percepta classifier testing since 2017. We received Medicare coverage for our Envisia classifier testing in 2019. The Prosigna test achieved Medicare coverage in 2015. We estimate that Medicare covers approximately 20% of patients evaluated for thyroid cancer and approximately 50% of patients evaluated for lung cancer, IPF and breast cancer, respectively.

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, added section 1834A to the SSA. The statute required extensive revisions to the Medicare CLFS coding, rate setting processes, and laboratory payment reporting for CDLTs, and creates a new subcategory of CDLTs called Advanced Diagnostic Laboratory Tests, or ADLTs, with separate reporting and payment requirements.

In 2016, CMS issued the final rule to implement the requirements of PAMA, which significantly revised the Medicare payment system for clinical diagnostic laboratory tests. 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 CDLT.

Prior to the implementation on January 1, 2018, the allowable Medicare rate for our Afirma GSC was $3,200. From January 1, 2018 through December 31, 2020, the allowable Medicare rate for our Afirma test under PAMA increased to $3,600.

In December 2019, through the Further Consolidated Appropriations Act of 2020, Congress delayed the next data reporting period under PAMA 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. Afirma will continue to be paid at $3,600 through that date. The 2020 Medicare payment rate for Prosigna based on the volume-weighted median of private payer rates under PAMA will be $2,510.21. In 2021, Prosigna's rate will decrease by 15% to approximately $2,134. The volume-weighted median of these private payer rates for final payments made from January through June 2019 (and now reported January through March 2021) will now set the Medicare payment rate for the Afirma classifier and for Prosigna from January 1, 2022 through December 31, 2024.

We submit claims to payers directly for the Afirma GSC, using a unique American Medical Association Current Procedural Terminology code, or CPT code 81545. FNA samples are also received for cytopathology, for which we bill both the technical and professional component using established CPT codes.

We bill payers directly for the Percepta and Envisia classifiers using an "unlisted" CPT code until we obtain specific codes for the tests. Currently, labs in the United States that perform Prosigna testing on their own nCounter instruments bill payers directly using the CPT code that is specific to the Prosigna test, 81520. We expect that, when we perform Prosigna testing in our own CLIA certified lab that we will bill payers directly for Prosigna testing.

State Medicaid programs typically make their own decisions with respect to coverage for our tests, as do private payers. We rely on a small number of third-party payers for a significant portion of our revenue, the loss of one or more of which would have a negative effect on our business. For the years ended December 31, 2019, 2018, and 2017, respectively, revenue was represented by the indicated percent for each payer:

- Medicare accounted for 29%, 26% and 27% of our revenue; and
- UnitedHealthcare accounted for 12%, 14% and 12% of our revenue.

Outside the United States

Outside of the United States, we bill hospital and laboratory customers directly for test kits they order, which currently consist of Prosigna test kits. 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 reimbursement efforts in Europe and other global markets through the development of clinical and other evidence to support Prosigna's inclusion in guidelines and coverage programs.

Competition

We believe the principal competitive factors in the markets we target with our advanced genomic tests include:

- the ability of the test to answer the appropriate clinical question at the right point in the clinical pathway;
- the quality and strength of clinical validation and utility data;
- confidence in diagnostic results backed by analytical verification data;
- the extent of reimbursement and in-network payer contracts;
- inclusion in practice guidelines;
- cost-effectiveness; and
- local testing near the patient and ease of use.

We believe we compete favorably on the factors described above with our Afirma solution and are positioning ourselves to compete effectively on these factors with our first-to-market Percepta and Envisia classifiers. Another competitive factor that we believe will become increasingly important for advanced genomic tests offered within and outside of the United States is that they be available as distributed kits on an instrument platform with broad functionality to justify the capital expense. We believe our plans to adapt our genomic tests to the nCounter platform, which already can run the Prosigna test, will further enhance our tests' attractiveness to hospitals and laboratories globally.

Our principal competition for the Afirma solution comes from traditional methods used by physicians to diagnose thyroid cancer. Physicians in the United States have historically recommended that patients with indeterminate diagnoses from cytopathology results be considered for surgery to remove all or part of the thyroid to rule out cancer. This practice has been the standard of care in the United States, as well as in many international markets, for many years, and we continue to educate physicians about the benefits of our test in order to change clinical practice.

We also 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.

With the Percepta and Envisia tests, we believe our primary competition will similarly come from traditional methods used by physicians to diagnose the related diseases. For the Percepta test, we expect competition from companies focused on lung cancer such as Oncocyte Corporation and Biodesix, Inc. We also anticipate facing potential competition from companies offering or developing approaches for assessing malignancy risk in patients with lung nodules using alternative samples such as blood, urine or sputum, including Biodesix, Inc. and Guardant Health, Inc. However, such "liquid biopsies" are predominantly used later in the diagnostic paradigm; for example, to inform treatment decisions for cancer or to gauge risk of recurrence or response to treatment.

In the breast cancer diagnostics market, the Prosigna test competes with Exact Sciences Corporation's Oncotype Dx, a service for gene expression analysis performed in a central laboratory in Redwood City, California. We also face competition from companies such as Agendia, Inc. and bioTheranostics, Inc., which also offer centralized laboratories that profile gene or protein expression in breast cancer. Outside the United States, we also face regional competition from Myriad Genetics, Inc., and its product EndoPredict, a distributed test for breast cancer recurrence.

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.

Competitors may develop their own versions of our solution in countries in which 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 solution by physicians in other countries.

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, which could be viewed by physicians and payers as functionally equivalent to our solution, 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 and services, we will face many of these same competitive risks for these new tests.

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 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 for diagnostic services provided to Medicare beneficiaries.

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. If we were to be found out of compliance with CLIA requirements and subjected to sanctions, our business could be harmed.

We have historically held CLIA certifications to perform testing at our South San Francisco 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 make random inspections of our clinical reference laboratories. If we in the future fail to maintain CLIA certificates in our South San Francisco or Austin, Texas 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 clinical reference laboratory 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 laboratory is 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 laboratory, assess substantial civil money penalties, or impose specific corrective action plans. Any such actions could materially affect our business. We maintain a current license 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 State. The license establishes 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 state 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 the laboratory developed tests, or LDTs, before the test is offered in New York; approval has been received for the Afirma GEC and the Percepta classifier. 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 Austin 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 out-of-state laboratories under certain circumstances. Pennsylvania, Maryland and Rhode Island require licenses to test specimens from patients in those states and Florida requires a license to receive specimens from a clinical laboratory in that state. 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 out-of-state laboratories to obtain licensure in order to accept specimens from the state, and it is possible that other states do have such requirements or 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: Diagnostic Kits

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 the device is of a type exempted 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 under that Act. Entities that fail to comply with FDA requirements may be subject to 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 for 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 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. For most 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 a legally marketed device, referred to as a predictive 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 as safe and effective as 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 illness or injury 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. Class III devices require 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 not to 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 distribute FDA-related medical devices, including manufacturers, repackagers and relabelers, specification developers, and initial importers, are required to register and list their device products with the FDA.

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, or MDR (which requires manufacturers to report to the FDA), and the Reports of Corrections and Removals regulation (which requires manufacturers to report certain recalls and 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 that is not labeled or otherwise represented as sterile is classified as a Class I exempt device, which means that the device is exempt from the 510(k) premarket notification requirement and the QSR, except for recordkeeping and complaint handling requirements. These 510(k) exempt devices are still subject to MDR requirements, the reporting of corrections and removals, and establishment registration and product listing.

In our FDA registration, we have registration, we have listed the containers we provide for collection and transport of Afirma GEC or GSC and Percepta 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 . We also plan to list our sample collection containers for Envisia samples with the FDA as Class I devices. If the FDA were to determine that our sample collection containers are not Class I devices, we would be required to file 510(k) applications 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 validated by a laboratory are referred to as laboratory developed tests, or LDTs, by the FDA. Currently, FDA believes these tests meet the definition of a device under the FDC Act; however, the FDA is currently exercising enforcement discretion for LDTs, meaning that FDA is not enforcing the device regulations that FDA has stated apply to clinical laboratories performing a LDT , although FDA may continue to enforce device regulations with respect to reagents, instruments, software or components provided by third parties and used to perform LDTs. We believe that the Afirma, Percepta and Envisia classifiers are LDTs for which FDA is currently exercising its enforcement discretion. 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, 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. However, FDA's enforcement discretion policy is expected to remain in place unless and until FDA announces and implements a different approach to the regulation of LDTs.

Some of the materials we use for our tests and that we may use for future tests are in vitro diagnostic 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 in vitro diagnostic 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 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 in vitro diagnostic 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, 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 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, most recently the Verifying Accurate Leading-edge IVCT Development (VALID) Act of 2018 in December 2018, 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, 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 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 FDA a premarket notification to obtain clearance or a 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.

Privacy and Fraud and Abuse Compliance

Health Insurance Portability and Accountability Act

Under the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, the 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 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.

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 Consumer Privacy Act, or CCPA, which was enacted in California in 2018 and components of which went into effect on January 1, 2020. 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. Amendments to the CCPA have been made since its enactment, and it remains unclear what, if any, further amendments will be made to this legislation or how it will be interpreted.

Recent developments in Europe have created compliance uncertainty regarding the processing of personal data from Europe. For example, the General Data Protection Regulation, or GDPR, which became effective in the European Union 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 European Union users. The GDPR creates new compliance obligations applicable to our business, which could cause us to change our

business practices, and increases 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).

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. 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 Law makes it a felony for a person or entity, including a laboratory, to knowingly and willfully offer, pay, solicit or receive remuneration, directly or indirectly, in order to induce business that is reimbursable under any federal health care program. A violation of the Anti-kickback Law may result in imprisonment for up to five years and fines of up to $250,000 in the case of individuals and $500,000 in the case of organizations. Convictions under the Anti-kickback Law 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 Law also incur 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.

Although the Anti-kickback Law applies only to federal health care programs, a number of states, including California, have passed statutes substantially similar to the Anti-kickback Law 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 Anti-kickback Law. 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 Law, holding that the statute may be violated if merely one purpose of a payment arrangement is to induce referrals or purchases.

The federal Anti-kickback Law includes statutory exceptions and provides for a number of safe harbors. If an arrangement meets the provisions of a safe harbor, it is deemed not to violate the Anti-kickback Law. 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 Law. These state anti-kickback statutes have generally been interpreted consistently with the Anti-kickback Law.

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 Law. California does not have a discount safe harbor. However, as noted above, Section 650 has generally been interpreted consistent with the Anti-kickback Law.

The personal services safe harbor to the Anti-kickback Law provides that remuneration paid to a referral source for personal services will not violate the Anti-kickback Law provided all of the elements of that safe harbor are met. One element is that if the agreement is intended to provide for the services of the physician on a periodic, sporadic or part-time basis, rather than on a full-time basis for the term of the agreement, the agreement specifies exactly the schedule of such intervals, their precise length, and the exact charge for such intervals. Our personal services arrangements with some physicians may not meet the specific requirement of this safe harbor that the agreement specify exactly the schedule of the intervals of time to be spent on the services because the nature of the services, such as speaking engagements, does not lend itself to exact scheduling and therefore meeting this element of the personal services safe harbor is impractical. Failure to meet the terms of the safe harbor does not 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 Law, Section 650, and Section 14107.2, there can be no assurance that our relationships with physicians, academic institutions and other customers will not be subject to investigation or challenge under such laws. If imposed for any reason, sanctions under the Anti-kickback Law, 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 Department of Health and Human Services' Office of the Inspector General 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 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 aware of the action. If the government is ultimately successful in obtaining redress in the matter or if the plaintiff succeeds in obtaining redress without the government's involvement, then the plaintiff will receive a percentage of the recovery. 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 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.

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 the Department of Health and Human Services has issued guidance further interpreting or implementing EKRA.

Finally, under 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 2021 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. 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 the 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 $100,000 and imprisonment for up to five years. Other countries, including the United Kingdom and other OECD Anti-Bribery Convention members, have similar anti-corruption regulations, such as the United Kingdom Anti-bribery Act.

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.

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. Our issued patents expire between 2029 and 2035 and are related to methods used in the Afirma thyroid diagnostic platform, lung diagnostics, breast cancer diagnostics, and the nCounter analysis platform.

We intend to file additional patent applications in the United States and abroad to strengthen our intellectual property rights; however, our patent applications (including the patent applications listed above) 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 registered trademarks in the United States for "Veracyte," "Afirma," "Percepta," "Know By Design," the Afirma logo, and the current and former Veracyte logos, and we have a pending federal trademark application for "Envisia". We also hold registered trademarks in various jurisdictions outside of the United States.

We require all employees and technical consultants working for us to execute confidentiality agreements, which provide that all confidential information received by them during the course of the employment, consulting or business relationship be kept confidential, except in specified circumstances. Our agreements with our research 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.

Employees

At December 31, 2019, we had 354 employees, of which 60 work in laboratory operations, 33 in research and development and clinical development, 175 in selling and marketing, and 86 in general and administrative, including 59 in billing and client services, 10 in information technology and 9 in finance. None of our employees are the subject of collective bargaining arrangements, and our management considers its relationships with employees to be good.

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.

Raw Materials and Suppliers

We procure reagents, equipment, chips 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 a sole source 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, 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.

ITEM 1A. RISK FACTORS

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, 2019, we had a net loss of $12.6 million and as of December 31, 2019, we had an accumulated deficit of $246.7 million. We expect to incur additional losses in the future, and we may never achieve revenue sufficient to offset our expenses. Over the next couple of years, we expect to continue to devote substantially all of our resources to increase adoption of, and reimbursement for our Afirma, Percepta and Envisia classifiers and Prosigna test, 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 tests, and we will need to generate sufficient revenue from this and other diagnostic solutions 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. Over the next few years, we expect to continue to derive a substantial portion of our revenue from sales of our Afirma tests. In the third quarter of 2017, we began recognizing revenue from the sale of our Percepta test, used in the diagnosis of lung cancer. We also launched our Envisia test to help improve the diagnosis of interstitial lung disease, specifically IPF, and began recognizing revenue from Envisia in the second quarter of 2019. In December 2019, we acquired the rights to the Prosigna test from NanoString Technologies, Inc. and commenced marketing and selling Prosigna test kits to U.S. and international customers. Once genomic 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 solutions 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, Percepta, Envisia and Prosigna tests, or develop and commercialize other solutions, 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 not able to successfully transition to our next-generation Percepta GSC, our business, operating results and competitive position could be harmed.

We are in the process of transitioning our customers to our next-generation Percepta Genomic Sequencing Classifier, or GSC, that uses the same technology platform as the Afirma and Envisia classifiers. There are risks associated with this transition that include, but are not limited to, operational implementation, reimbursement, and customer adoption risks. If we are unable to effectively transition to the new platform, our business, financial condition and results of operations could be adversely effected and our reputation and competitive position could be harmed.

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.

Revenue for tests performed on patients covered by Medicare and UnitedHealthcare was 26% and 11%, respectively, of our revenue for the twelve months ended December 31, 2019, compared with 29% and 12%, respectively, for the twelve months ended December 31, 2018. 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 Molecular Diagnostics Services Program, or MolDX program, administered by Palmetto GBA, under a Local Coverage Determination, or LCD.

Noridian Healthcare Solutions issued an LCD for Percepta effective for services performed on or after May 2017. This coverage policy requires us to establish and maintain a Certification and Training Registry program and make Percepta available only to certain Medicare patients through physicians who participate in this program. Failure by us or physicians to comply with the requirements of the Certification and Training Registry program could lead to loss of Medicare coverage for Percepta, which could have an adverse effect on our revenue.

We submitted the dossier of clinical evidence needed to obtain Medicare coverage for the Envisia Genomic Classifier through the MolDX technical assessment process in 2018, and received final Medicare coverage for the classifier in the first quarter of 2019, with an effective date of April 1, 2019.

An LCD was issued for Prosigna by Palmetto GBA in August 2015, which has been in effect since October 1, 2015.

On a five-year rotational basis, Medicare requests bids for its regional MAC services. Any future changes in the MAC processing or coding for Medicare claims for the Afirma, Percepta or Envisia classifiers, or for Prosigna, could result in a change in the coverage or reimbursement rates for such products, or the loss of coverage, and could also result in increased difficulties in obtaining and maintaining coverage for future products.

On March 1, 2015, an American Medical Association Current Procedural Terminology code, or 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 rates based on final payments made between January 1 and June 30, 2016, which we reported to the Centers for Medicare & Medicaid Services, or CMS, 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. Afirma will continue to be paid at $3,600 through that date. The volume-weighted median of private payer rates for final payments made from January through June 2019 (and now reported January through March 2021) will set the Medicare payment rate for the Afirma classifier from January 1, 2022 through December 31, 2024. There can be no assurance that the Afirma or Prosigna rates will not decrease during this or a subsequent reporting cycle under PAMA.

We submit claims to Medicare for Percepta and Envisia using unlisted codes under the MolDX program. Specific CPT codes assigned to Percepta and Envisia may be required to go through the national payment determination process, and there can be no assurance that the Medicare payment rates the tests receive through this process will not be lower than their current payment rates. There can also be no assurance that the Medicare payment rates for the tests will not be reduced when they are set based on the volume-weighted medians of private payer rates when we are required to report those rates under PAMA.

If there is a decrease in the Medicare payment rate for our tests, our revenue from Medicare 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.

Although we have entered into contracts with certain third-party payers that establish in-network allowable rates of reimbursement for our Afirma tests, payers may suspend or discontinue reimbursement at any time, 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 do not have a contracted rate of reimbursement with some payers for our tests. Without a contracted rate 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 there is no contracted rate for reimbursement, there is typically a greater patient co-insurance or co-payment requirement which may result in further delay 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, Percepta and Envisia classifiers, Prosigna, 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. However, 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 benefits 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.

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. 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. Because our Afirma, Percepta and Envisia testing services are performed by our certified laboratory 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.

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. 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. In addition, Congressional efforts to repeal the ACA could result in an increase in uninsured 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.

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 make random inspections of our clinical reference laboratories. If we in the future fail to maintain CLIA certificates in our South San Francisco or Austin, Texas 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, both of our clinical laboratories are required to be licensed on a test-specific basis by New York State. We have received approval for the Afirma, Percepta and Envisia 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 laboratory, whether as a result of revocation, suspension or limitation, 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, we would need to move the receipt and storage of FNAs, as well as the slide preparation for cytopathology, to South San Francisco, which 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 New York State, and we may not be able to offer our new tests until such approvals are received.

If we are not successful in integrating the assets acquired from NanoString or if our general strategy of seeking growth through such acquisitions and collaborations is not successful, our prospects and financial condition will suffer.

We have recently acquired assets, such as the nCounter FLEX Analysis System and Prosigna in December 2019, and we may pursue additional acquisitions of complementary businesses or assets as part of our business strategy. To date, we have limited experience with respect to acquisitions and the formation of strategic alliances and joint ventures. There can be no assurance that we will successfully integrate the assets acquired from NanoString successfully into our existing business, or that our exclusive worldwide license to the nCounter system for *in vitro* diagnostic use 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 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 Loan and Security Agreement with Silicon Valley Bank contains covenants that could limit our ability to sell debt securities or obtain additional debt financing arrangements, which could affect our ability to finance acquisitions or investments other than through the issuance of stock.

If we are not successful in advancing our collaborations with Johnson & Johnson and others, or if our general strategy of seeking growth through such collaborations is not successful, our prospects and financial condition will suffer.

We have previously entered into technology licensing and collaboration arrangements, such as our collaboration with Johnson & Johnson in December 2018 and with Acerta Pharma, the hematology research and development arm of AstraZeneca, in December 2019, reflecting important elements of our business strategy. We also may pursue additional strategic alliances that leverage our core technology and industry experience to expand our offerings or distribution, or make investments in other companies. However, we have limited experience with respect to the formation of strategic alliances and joint ventures. There can be no assurance that we will successfully 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 technology license, strategic alliance, joint venture or investment.

We rely on sole suppliers for some of the reagents, equipment, chips 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, chips and other materials that we use to perform our tests and for the manufacture of the nCounter FLEX Dx systems and Prosigna test kits sold to customers. 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 a sole source to assemble and distribute our sample collection kits. We rely on NanoString for the supply of the nCounter FLEX Dx System and Prosigna test 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, 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 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 supplies were available. If our 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.

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 required 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, 2022, and thereafter 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 not able to support our current test volume or future increases in 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 would 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.

Due to how we recognize revenue, our quarterly operating results are likely to fluctuate.

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 were incorrect at the time we accrued such revenue, our financial results could be negatively impacted in future quarters. 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 research 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.

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, our business could suffer.

As demand for our tests grows, we will need to continue to scale our testing capacity and processing technology, expand customer service, billing and systems processes and enhance our internal quality assurance program. We will also need additional certified laboratory scientists and other scientific and technical personnel to process higher volumes of our tests. 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. 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 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 the beginning of 2017, the U.S. Congress and the Administration took actions to repeal the ACA and indicated an intent to replace it with another act and efforts to repeal or amend the ACA are ongoing. We cannot predict if, or when, the ACA will be repealed or amended, and cannot predict the impact that an amendment or repeal 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. 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.

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 involves 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.

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 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 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 revenues from payments made under the CLFS and the Physician Fee Schedule would report on triennial bases (or annually for advanced diagnostic laboratory tests, or 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. The volume-weighted median of the private payer rates between January 1 and June 30, 2019 will now set the Medicare payment rate for the Afirma classifier from January 1, 2022 through December 31, 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 Percepta or Envisia will not be adversely affected by the PAMA law and regulations.

We believe our Afirma genomic classifier as well as our Percepta and Envisia classifiers would be considered ADLTs under PAMA. 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. Insofar as the actual list charge substantially exceeds private payer rates (by more than 30%), CMS will have the ability to recoup excess payments made during the initial nine-month payment period. 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 will not be adversely affected by such designation.

There have also been recent and 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.

Congress is considering legislation to limit balance billing of patients who receive services from out-of-network providers (including laboratories) at in-network facilities and to set a methodology for payment of the out-of-network provider in such circumstances. This legislation, if enacted, 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 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 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, Percepta, and Envisia 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, Percepta, and Envisia 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 were to begin regulating those of our tests that are not currently regulated, we could incur substantial costs and delays associated with trying to obtain premarket clearance or approval.

Clinical laboratory tests have long been subject to comprehensive regulations under CLIA, as well as by applicable state laws. Most laboratory developed tests, or LDTs, are not currently subject to regulation under the FDA's enforcement discretion policy, although reagents, instruments, software or components provided by third parties and used to perform LDTs may be subject to regulation. While the FDA maintains its authority to regulate LDTs, it has chosen to exercise its enforcement discretion not to enforce the premarket review and other applicable medical device requirements for LDTs. We believe that the Afirma, Percepta and Envisia classifiers are LDTs that fall under the FDA's enforcement discretion policy. In October 2014, the FDA issued draft guidance, entitled "Framework for Regulatory Oversight of LDTs," proposing a risk-based framework of oversight and a phased-in enforcement of premarket review requirements for most LDTs. In 2016, the FDA announced that it would not be finalizing the guidance.

In January 2017, the FDA issued a "Discussion Paper on Laboratory Developed Tests" following input it received from multiple stakeholders who had commented on its 2014 draft guidance. The FDA specifically states in its Discussion Paper that the proposals contained in the document do not represent a final version of the LDT draft guidance documents and are only designed to provide a possible approach to spark further dialogue. The suggested LDT framework could grandfather many types of LDTs without requiring new premarket review or quality management requirements. It also suggests a four-year phased implementation of the premarket review requirements for some types of tests. 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." The FDA listed key principles of an approach it would support.

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 regulatory structure under the FDA. As proposed, the bill would create a precertification program for lower risk tests not otherwise required to go through premarket review. It would grandfather existing tests but would allow the FDA to subject otherwise grandfathered tests to premarket review under certain conditions. We cannot predict whether this draft bill will become legislation and cannot quantify the effect of this draft bill on our business.

If the FDA were to require us to seek clearance or approval for our existing tests or any of our future products for clinical use, we may not be able to obtain such approvals on a timely basis, or at all. While we believe our Afirma, Percepta and Envisia classifiers would likely qualify for the "grandfathered" tests treatment, there can be no assurance of what the FDA might ultimately require if it issued final guidance. If premarket reviews were required, our business could be negatively impacted if we were required to stop selling our products pending their clearance or approval. In addition, the launch of any new products that we develop could be delayed by the implementation of future FDA guidance. The cost of complying with premarket review requirements, including obtaining clinical data, could be significant. In addition, future regulation by the FDA could subject our business to further regulatory risks and costs. Failure to comply with applicable regulatory requirements of the FDA 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. In addition, our sample collection containers are listed as Class I devices with the FDA. If the FDA were to determine that they are not Class I devices, we would be required to file 510(k) applications and obtain FDA clearance to use the containers, which could be time consuming and expensive.

Some of the materials we use for our tests and that we may use for future tests are labeled for research use only, or RUO, or investigational use only, or IUO. In November 2013, the FDA finalized guidance regarding the sale and use of products labeled RUO or IUO. Among other things, the guidance advises that the FDA continues to be concerned about distribution of research or investigational use only products intended for clinical diagnostic use and that the manufacturer's objective intent for the 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. 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 Federal Food, Drug and Cosmetic Act. Some of the reagents, instruments, software or components obtained by us from suppliers for use in our products are currently labeled as RUO or IUO. If the FDA were to determine that any of these reagents, instruments, software or components are improperly labeled RUO or IUO and undertake enforcement actions, some of our suppliers might cease selling these reagents, instruments, software or components to us, 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.

Obtaining marketing authorization by the FDA and foreign regulatory authorities 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 FDA by submitting a premarket notification under section 510(k) of the FDC Act, or 510(k), or approval from FDA by submitting a PMA. We may also be able to obtain marketing authorization through a de novo classification process rather than through a PMA if the 510(k) pathway is not available. In September 2013, Prosigna obtained 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.

In August 2014, the FDA issued a final guidance document titled In Vitro Companion Diagnostic Devices. In the guidance, FDA 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. FDA stated that an IVD companion diagnostic should be submitted for review and approved or cleared 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, FDA expects that most companion diagnostics will be Class III devices. Class III devices generally require the approval of a PMA before they can be marketed. 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. 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.

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 our products, including, but not limited to, compliance with the 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 approval from the FDA and are therefore supplementing our operational capabilities to manage the more complex processes needed to obtain and maintain PMAs. 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 products 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 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 by regulatory authorities in other countries, and approval by any foreign regulatory authority does not ensure marketing authorization 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.

If we are unable to obtain marketing authorizations to market Prosigna in additional countries or if regulatory limitations are placed on our diagnostic kit products, our business and growth will be harmed.

FDA cleared the Prosigna test for marketing in the United States; Prosigna also has a CE mark which permits us to market the test in the European Union; and Prosigna received marketing authorizations in selected other jurisdictions. We intend to seek regulatory authorizations 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 to use the companion diagnostic tests in clinical trials as well as the marketing authorizations to sell the companion diagnostic tests following completion of such trials. Some of the compensation we expect to receive pursuant to these collaborations is based on the receipt of marketing authorizations. Any failure to obtain marketing authorizations for our diagnostic kits in a particular jurisdiction may also reduce sales of our

nCounter systems 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.

We cannot assure investors that we will be successful in obtaining regulatory clearances, approvals, or marketing authorizations. If we do not obtain regulatory clearances, approvals, or marketing authorizations for future kit products or expand future indications for diagnostic purposes, if additional regulatory limitations are placed on our 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 extensive regulatory requirements, and our failure to comply with these requirements could substantially harm our business.

Certain of our products are regulated as *in vitro* diagnostic medical devices, including Prosigna and the nCounter FLEX 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 the FDC Act and device regulations enforced by the FDA and other statutory and regulatory requirements enforced by other government authorities. These may include routine inspections by Notified Bodies, FDA, and other health authorities, of our manufacturing facilities and our records for compliance with standards such as ISO 13485 and QSR regulations, which establish extensive requirements for quality assurance and control as well as manufacturing and change control procedures, among other things. 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; continued adverse event and malfunction reporting; reporting certain corrections and removals; and labeling and promotional requirements. 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, a European Union agency which is responsible for the scientific evaluation of medicines used in the European Union, recently launched an initiative to determine guidelines for the use of genomic biomarkers in the development and life-cycle of drugs. On April 5, 2017, the European Union Parliament passed Regulation (EU) 2017/746, referred to as the IVD Device Regulation, or IVDR, which increases the regulatory requirements applicable to *in vitro* diagnostics in the EU and would require that we re-classify and obtain approval, registration, or clearance for our existing CE-marked IVD products within a five-year grace period (by May 25, 2022).

We may also be subject to additional FDA or global regulatory authority post-marketing obligations or requirements by the FDA or global regulatory authority to change our current product classifications which would impose additional regulatory obligations on us. The promotional claims we can make for Prosigna are limited to the indications for use in the United States as cleared by FDA or outside the United States as authorized 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.

Our principal competition for our tests comes from traditional methods used by physicians to diagnose and manage patient care decisions. For example, with our Afirma genomic classifier, practice guidelines in the United States have historically recommended that patients with indeterminate diagnoses from cytopathology results be considered for surgery to remove all or part of the thyroid to rule out cancer. This practice has been the standard of care in the United States for many years, and we need to continue to educate physicians about the benefits of the Afirma genomic classifier to change clinical practice.

We also 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.

We believe our primary competition in pulmonology with our Percepta and Envisia classifiers will similarly come from traditional methods used by physicians to diagnose the related diseases. For the Percepta test, we expect competition from companies

focused on lung cancer such as Oncocyte Corporation and Biodesix, Inc. We believe our principal competitor in the breast cancer diagnostics market is Exact Sciences, Inc. (having combined with Genomic Health, Inc.), which currently commands a substantial majority of the market. As we expand our portfolio of tests to address clinical questions across the clinical care continuum, we may also face competition from companies focused on screening at-risk patients for cancer or companies informing treatment decisions such as Guardant Health or GRAIL. Competition could also emerge using alternative samples, such as blood, urine or sputum. However, such "liquid biopsies" are currently being used to gauge risk of recurrence or response to treatment in patients already diagnosed with lung cancer.

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.

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 and services, we will face many of these same competitive risks for these new tests.

The loss of members of our senior management team or our inability to attract and retain key personnel could adversely affect our business.

Our success depends largely on the skills, experience and performance of key members of our executive management team and others in key management positions. The efforts of each of these persons together will be critical to us as we continue to develop our technologies and test processes and focus on our growth. If we were to lose one or more of these key employees, we may experience difficulties in competing effectively, developing our technologies and implementing our business strategy.

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, particularly in the San Francisco Bay Area. 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. Additionally, our success depends on our ability to attract and retain qualified sales people. We recently significantly expanded our sales force as we invest in our multi-product sales strategy, which includes assignment of a single contact to successfully develop and implement relationships with our customers. 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, including the Percepta and Envisia tests, or acquire, such as Prosigna, 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. As a public company located in the San Francisco Bay Area, we also face intense competition for highly skilled finance and accounting personnel. If we are unable to attract and retain finance and accounting personnel experienced in public company financial reporting, we risk being unable to close our books and file our public documents on a timely basis. Finally, 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 employees are at will, which means that either we or the employee may terminate their employment at any time. We do not carry key man insurance for any of our employees.

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, 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.

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;
- 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 cytopathology. In addition, we use the CPT code 81545 to bill for our Afirma classifier. CPT codes do not exist for our other proprietary molecular diagnostic tests. Therefore, until such time that we are assigned and are able to use a designated CPT code specific to Percepta and Envisia, we use "unlisted" codes for claim submissions, which can lead to delays in payers adjudicating our claims or denying payment altogether. Moreover, these 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 revenues. Even when we receive a designated CPT code specific to our tests, such as the 81545 code for the Afirma GEC that became effective January 1, 2016, 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 recently 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 revenues 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 add 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 revenues 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.

We acquired several international sales employees from NanoString, and expect to build upon this team as we offer additional tests internationally in the future. If our internal sales force is not successful, however, 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. If we fail to establish our molecular diagnostic tests in the marketplace, it could have a negative effect on our ability to sell subsequent molecular diagnostic tests and hinder the desired expansion of our business. We have growing, however limited, historical experience forecasting the direct sales of our molecular diagnostics products. Our ability to produce 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 we may not be able to commercialize on a timely basis, or at all, other products we are developing.

We continually seek to develop enhancements to our current test offerings and additional diagnostic solutions that requires us to devote considerable resources to research and development. There can be no assurance that we will be able to identify other diseases that can be effectively addressed with our molecular cytology platform. In addition, if we identify such diseases, we may not be able to develop products with the diagnostic accuracy necessary to be clinically useful and commercially successful. We may face challenges obtaining sufficient numbers of samples to validate a genomic signature for a molecular diagnostic product. After launching new products, we still must complete studies that meet the clinical evidence required to obtain reimbursement.

In order to develop and commercialize diagnostic tests, 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 infrastructure to market and sell new products.

Our product development process involves a high degree of risk and may take several years. Our 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. In addition, competitors may develop and commercialize competing products or technologies faster than us or at a lower cost.

If we cannot enter into new clinical study collaborations, our product development and subsequent commercialization could be delayed.

In the past, we have entered into clinical study collaborations, and our success in the future depends in part on our ability to enter into additional collaborations with highly regarded institutions. This can be difficult due to internal and external constraints placed on these organizations. Some organizations may limit the number of collaborations they have with any one company so as to not be perceived as biased or conflicted. Organizations may also have insufficient administrative and related infrastructure to enable collaboration with many companies at once, which can extend the time it takes to develop, negotiate and implement a collaboration. Moreover, it may take longer to obtain the samples we need which could delay our trials, publications, and product launches and reimbursement. Additionally, organizations often insist on retaining the rights to publish the clinical data resulting from the collaboration. The publication of clinical data in peer-reviewed journals is a crucial step in commercializing and obtaining reimbursement for our diagnostic tests, and our inability to control when and if results are published may delay or limit our ability to derive sufficient revenue from them.

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.

Our Loan and Security Agreement provides our lenders with a first-priority lien against substantially all of our assets, excluding our intellectual property, and contains financial covenants and other restrictions on our actions, which could limit our operational flexibility and otherwise adversely affect our financial condition.

Our Loan and Security Agreement restricts our ability to, among other things, incur liens, make investments, incur indebtedness, merge with or acquire other entities, dispose of assets, make dividends or other distributions to holders of its equity interests, engage in any new line of business, or enter into certain transactions with affiliates, in each case subject to certain exceptions. It also requires us to achieve certain revenue levels tested quarterly on a trailing twelve-month basis. However, failure to maintain the revenue levels will not be considered a default if the sum of our unrestricted cash and cash equivalents maintained

with Silicon Valley Bank and amount available under the revolving line of credit is at least $40.0 million. Our ability to comply with these and other covenants is dependent upon a number of factors, some of which are beyond our control.

Our failure to comply with the financial covenants, or the occurrence of other events specified in our Loan and Security Agreement, could result in an event of default under the Loan and Security Agreement, which would give our lenders the right to terminate their commitments to provide additional loans under the Loan and Security Agreement and to declare all borrowings outstanding, together with accrued and unpaid interest and fees, to be immediately due and payable. In addition, we have granted our lenders a first-priority lien against all of our assets, excluding our intellectual property, as collateral. Failure to comply with the covenants or other restrictions in the Loan and Security Agreement could result in a default. If the debt under our Loan and Security Agreement was to be accelerated, we may not have sufficient cash on hand or be able to sell sufficient collateral to repay it, which would have an immediate adverse effect on our business and operating results. This could potentially cause us to cease operations and result in a complete loss of your investment in our common stock.

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 in 2013 to HIPAA under the Health Information Technology for Economic and Clinical Health Act, or HITECH, which strengthen and expand HIPAA privacy and security compliance requirements, increase penalties for violators, extend enforcement authority to state attorneys general, and impose 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;

- 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 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; and

- enforcing our intellectual property rights.

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 and 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.

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.

International expansion of our business exposes us to business, regulatory, political, operational, financial and economic risks associated with doing business outside of the United States.

Our business strategy includes international 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. 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;
- failure by us to obtain regulatory approvals 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;
- 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, boycotts, curtailment of trade and other business restrictions; 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 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 our nCounter FLEX Analysis System and related consumable 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.

If we are sued for product liability or errors and omissions liability, we could face substantial liabilities that exceed our resources.

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 Percepta, Envisia and Prosigna tests, as well as tests we may develop or acquire in the future. A product liability or errors and omissions liability claim could 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 or cause us to 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.

If a catastrophe strikes either of our laboratories or if either of our laboratories becomes inoperable for any other reason, we will be unable to perform our testing services and our business will be harmed.

We perform all of the Afirma, Percepta and Envisia genomic classifier testing at our laboratory in South San Francisco, California, near major earthquake faults known for seismic activity. 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. 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 additional 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. Our Loan and Security Agreement imposes restrictions on our operations, increases our fixed payment obligations, and has restrictive covenants. 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. 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 us or our third-party service providers 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, personally identifiable information about our patients, 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.

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 aware of any such attack or breach, if such event would occur and cause interruptions in our operations, our networks would be compromised and the information we store on those networks could 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 under federal, state, and international laws that protect the privacy of personal information, such as HIPAA, and regulatory penalties. Unauthorized access, loss or dissemination could also 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, manage the administrative aspects of our business and damage our reputation, any of which could adversely affect our business.

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 applied in a manner that is inconsistent with our practices. If so, this could result in government-imposed fines or orders requiring that we change our practices, which could adversely affect our business. In addition, we are subject to various state laws, including the California Consumer Privacy Act, or CCPA, which was enacted in California in 2018 and components of which went into effect on January 1, 2020. 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. Amendments to the CCPA have been made since its enactment, 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 on our business or operations, but it may require us to modify our data processing practices and policies and to incur substantial costs and expenses in an effort to comply.

Recent developments in Europe have created compliance uncertainty regarding the processing of personal data from Europe. For example, the General Data Protection Regulation, or GDPR, which became effective in the European Union 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 European Union users. The GDPR creates new compliance obligations applicable to our business, which could cause us to change our business practices, and increases 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). As a result, we may need to modify the way we treat such information.

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. Our issued patents expire between 2029 and 2035 and are related to methods used in thyroid diagnostics, lung diagnostics, breast cancer diagnostics, and the nCounter FLEX analysis platform.

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 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.

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, recent changes to the patent laws of the United States allow for various post-grant opposition proceedings that have not been extensively tested, and their outcome is therefore uncertain. 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.

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, 2019, we had net operating loss, or NOL, carryforwards of approximately $236.9 million, $58.3 million and $45.2 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 2026 while for state purposes, the NOL carryforwards begin to expire in 2028. 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. It is uncertain if and to what extent various states will conform to the newly enacted federal tax law.

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.

If our goodwill or intangible assets become impaired, we may be required to record a significant charge to earnings.

We review our goodwill and intangible assets for impairment when events or changes in circumstances indicate the carrying value may not be recoverable, such as declines in stock price, market capitalization, or cash flows and slower growth rates in our industry. Goodwill is required to be tested for impairment at least annually. If we are required to record a significant charge in our financial statements during the period in which any impairment of our goodwill or intangible assets is determined, that would negatively affect our operating results.

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 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 financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in our 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 financial statements include those related to revenue recognition, finite-lived intangible assets, goodwill, and stock-based compensation expense. 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 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, impose a number of requirements on public companies, including with respect to corporate governance practices. Our management and other personnel will 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 financial statements may be materially misstated. We have only recently compiled the systems, processes and documentation necessary to comply with Section 404 of the Sarbanes-Oxley Act. We will need to maintain and enhance these processes and controls 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 now required to include an attestation report from our independent registered public accounting firm on the effectiveness of our internal control over financial reporting annually. 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.

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;
- 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;
- any major change in our management; and
- general economic conditions and slow or negative growth of our markets.

In addition, the stock market in general, and the market for stock of life sciences companies and other emerging growth 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 be even more pronounced if the trading volume of our stock remains low. 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.

If securities or industry analysts issue an adverse opinion regarding our stock or do not publish research or reports about our company, our stock price and trading volume could decline.

The trading market for our common stock will depend in part on the research and reports that equity research analysts publish about us, our business and our competitors. We do not control these analysts or the content and opinions or financial models included in their reports. Securities analysts may elect not to provide research coverage of our company, and such lack of research coverage may adversely affect the market price of our common stock. The price of our common stock could also decline if one

or more equity research analysts downgrade our common stock or if those analysts issue other unfavorable commentary or cease publishing reports about us or our business. If one or more equity research analysts cease coverage of our company, we could lose visibility in the market, which in turn could cause our stock price to decline.

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;
- 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. In addition, our Loan and Security Agreement restricts our ability to pay cash dividends on our common stock and we may also 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

On April 29, 2015, we signed a non-cancelable lease agreement for approximately 59,000 square feet to serve as our South San Francisco, California headquarters and laboratory. The lease began in June 2015 and ends in March 2026, and contains extension of lease term and expansion options. Certain expansion options were waived by us on February 8, 2017 in exchange for consideration of $500,000. We also lease approximately 10,400 square feet of office and laboratory space in Austin, Texas, under a lease that expires in January 2029 and includes options for expansion and early termination in 2025.

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".

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

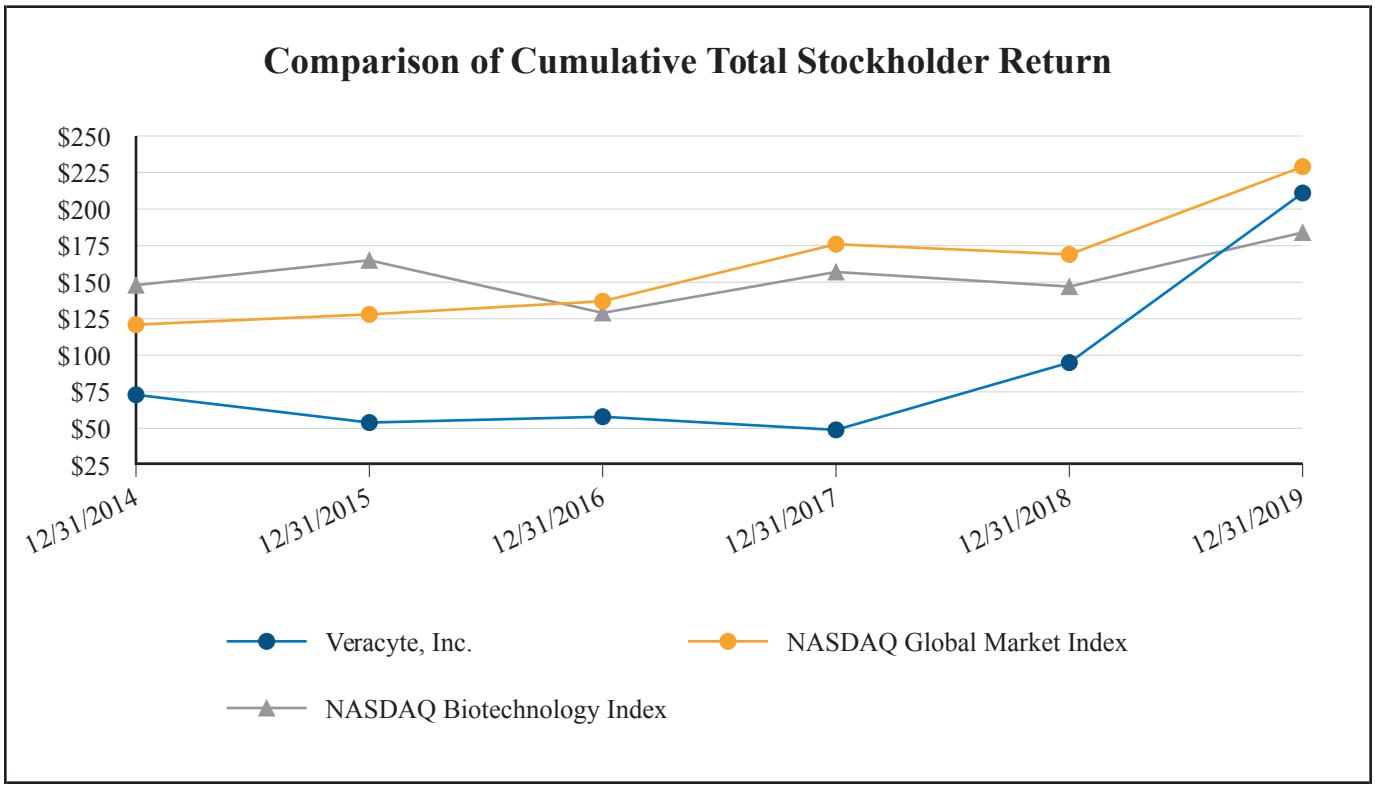
Recent Sale of Unregistered Securities

On December 3, 2019, we issued 376,732 shares of our common stock as consideration to NanoString Technologies, Inc. in connection with our acquisition of certain of its assets. The sales of these securities were exempt from registration under the Securities Act of 1933, as amended, or the Securities Act, in reliance upon Section 4(a)(2) of the Securities Act.

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 shows the cumulative total stockholder return (change in stock price plus reinvested dividends) assuming the investment of $100.00 on the date specified in each of our common stock, the Nasdaq Global Market Index, and the Nasdaq Biotechnology Index for the period commencing on October 30, 2013 (the first day of trading of our common stock) and ending on December 31, 2019. 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, 2014	December 31, 2015	December 31, 2016	December 31, 2017	December 31, 2018	December 31, 2019
Veracyte, Inc.	$ 73.00	$ 54.00	$ 58.00	$ 49.00	$ 95.00	$ 211.00
Nasdaq Global Market Index	$ 121.00	$ 128.00	$ 137.00	$ 176.00	$ 169.00	$ 229.00
Nasdaq Biotechnology Index	$ 148.00	$ 165.00	$ 129.00	$ 157.00	$ 147.00	$ 184.00

ITEM 6. SELECTED FINANCIAL DATA

The information set forth below should be read in conjunction with "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations" and our audited consolidated financial statements and related notes included elsewhere in this annual report. The selected consolidated balance sheet data at December 31, 2019 and 2018 and the selected consolidated statements of operations data for each of the years ended December 31, 2019, 2018 and 2017 have been derived from our audited consolidated financial statements that are included elsewhere in this report. The selected consolidated balance sheet data at December 31, 2017, 2016 and 2015 and the selected consolidated statements of operations data for the years ended December 31, 2016 and 2015 have been derived from our audited consolidated financial statements not included in this report. The financial data are historical and are not necessarily indicative of results to be expected in any future period (in thousands, except share and per share data and genomic classifiers reported):

	Year Ended December 31,				
	2019	2018	2017	2016	2015
Consolidated Statements of Operations Data:					
Revenue:					
Testing revenue	$ 107,355	$ 91,058	$ 71,953	$ 65,085	$ 49,503
Product revenue	923	—	—	—	—
Biopharmaceutical revenue	8,090	950	—	—	—
Collaboration revenue	4,000	—	—	—	—
Total revenue	$ 120,368	$ 92,008	$ 71,953	$ 65,085	$ 49,503
Operating expenses:					
Cost of testing revenue[(1)]	36,077	33,078	28,195	25,462	21,497
Cost of product revenue	446	—	—	—	—
Research and development[(1)]	14,851	14,820	13,881	15,324	12,796
Selling and marketing[(1)]	53,691	41,313	32,260	28,248	25,293
General and administrative[(1)]	29,029	23,963	23,088	23,787	22,583
Intangible asset amortization	1,401	1,067	1,067	1,067	800
Total operating expenses[(1)]	135,495	114,241	98,491	93,888	82,969
Loss from operations	(15,127)	(22,233)	(26,538)	(28,803)	(33,466)
Interest expense	(677)	(1,963)	(4,941)	(2,757)	(378)
Other income, net	3,205	1,197	476	202	140
Net loss and comprehensive loss	$ (12,599)	$ (22,999)	$ (31,003)	$ (31,358)	$ (33,704)
Net loss per common share, basic and diluted	$ (0.27)	$ (0.62)	$ (0.91)	$ (1.09)	$ (1.30)
Shares used in computing net loss per common share, basic and diluted	46,138,177	37,020,246	33,925,617	28,830,472	25,994,193
Other Operating Data:					
Reported genomic test volume	39,612	31,710	26,026	23,237	19,421

(1) Includes stock-based compensation as follows:

	Year Ended December 31,				
	2019	2018	2017	2016	2015
Cost of testing revenue	$ 277	$ 130	$ 133	$ 126	$ 100
Research and development	1,856	1,018	1,495	1,322	1,178
Selling and marketing	2,938	1,866	1,899	1,594	1,326
General and administrative	4,736	2,944	3,090	3,336	2,998
Total stock-based compensation	$ 9,807	$ 5,958	$ 6,617	$ 6,378	$ 5,602

Consolidated Balance Sheets Data:

	As of December 31,				
	2019	2018	2017	2016	2015
Cash and cash equivalents	$ 159,317	$ 77,995	$ 33,891	$ 59,219	$ 39,084
Working capital	170,218	83,893	41,900	62,093	33,192
Total assets	275,212	120,638	78,669	101,034	75,247
Accumulated deficit	(246,685)	(234,086)	(211,087)	(180,084)	(148,726)
Total stockholders' equity	239,455	79,755	37,225	59,581	51,252

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 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 leading genomic diagnostics company that is creating value through innovation. We were founded in 2008 with a mission of improving diagnostic accuracy. Today, our growing menu of tests leverage advances in genomic science and technology to improve care throughout the patient journey, enabling more confident diagnostic, prognostic and treatment decisions in cancer and other challenging diseases. We are creating new standards of care by enabling more patients to avoid risks of unnecessary invasive procedures and removing costs from the healthcare system, while speeding the time to diagnosis and treatment decisions.

We perform our genomic tests for thyroid cancer, lung cancer and idiopathic pulmonary fibrosis, or IPF, in our CLIA-certified laboratory in South San Francisco, California. In December 2019, we announced our acquisition from NanoString Technologies, Inc., or NanoString, of the exclusive global diagnostics license to the nCounter FLEX Analysis System, as well as the Prosigna breast cancer prognostic gene signature assay, which is commercially available, and the LymphMark lymphoma subtyping assay, which is in development. Both tests are designed for use on the nCounter system. We believe this strategic transaction positions us to expand our business globally with a broad menu of advanced genomic tests that may be offered as distributed kits and performed in local laboratories worldwide. We believe our current and pipeline products address a collective $40 billion global market.

We currently offer five commercialized genomic tests that are changing disease diagnosis and patient care. All five tests are available in the United States and one is available internationally. These include the Afirma Genomic Sequencing Classifier, or GSC (its predecessor was the Afirma Gene Expression Classifier, or GEC) for thyroid cancer; the Percepta GSC (its predecessor was the Percepta Bronchial Genomic Classifier) for lung cancer; the Envisia Genomic Classifier for IPF; the Afirma Xpression Atlas, which provides information on the most common and emerging gene alterations associated with thyroid cancer, enabling physicians to confidently tailor surgical and treatment decisions at time of diagnosis; and the Prosigna breast cancer test for assessing risk of distant recurrence, which is available for use on the nCounter platform in the United States and internationally.

Our ability to leverage RNA whole-transcriptome sequencing data in large biorepositories of patient-consented samples in oncology and other indications presents an opportunity for biopharmaceutical companies to enhance their research and development capabilities. In April 2018, we announced a collaboration with Loxo Oncology (now a wholly owned subsidiary of Eli Lilly and Company) to advance our development of highly selective medicines for patients with genetically defined cancers, including thyroid cancer. In December 2018, we entered into a long-term strategic collaboration with Johnson & Johnson Innovation and the Lung Cancer Initiative at Johnson & Johnson to advance the development and commercialization of novel diagnostic tests to detect lung cancer at its earliest stages, when the disease is most treatable. The collaboration builds upon foundational "field of injury" science where genomic changes associated with lung cancer can be identified with a simple brushing of a person's airway to develop new interventions that can save lives. Additionally, in January 2020, we announced an agreement with Acerta Pharma, the hematology research and development arm of AstraZeneca, to provide genomic information that will support its development of oncology therapeutics in lymphoma.

Patients access our tests through their physician. Our Afirma, Percepta and Envisia tests are used as part of the diagnostic process and genomic testing services are performed in our CLIA laboratory located in San Francisco, California. Cytopathology services for Afirma testing are performed in our reference laboratory in Austin, Texas. The Prosigna test is indicated in female breast cancer patients who have undergone surgery in conjunction with locoregional treatment consistent with standard of care. This in vitro diagnostic test is performed on the nCounter Flex Analysis System in laboratories worldwide, as well as in the United States.

Fourth Quarter and Full-Year 2019 Financial Results

For the three months ended December 31, 2019, compared to the prior year:

- *Total Revenue* was $29.7 million, an increase of 15%;
- *Gross Margin* was 66%, unchanged;
- *Operating Expenses, Excluding Cost of Revenue,* were $27.8 million, an increase of 38%;
- *Net Loss and Comprehensive Loss* was ($7.5) million, an increase of 140%;
- *Basic and Diluted Net Loss Per Common Share* was ($0.15), an increase of 88%;
- *Net Cash Provided by Operating Activities* was $1.8 million, compared to $1.2 million used; and
- *Cash and Cash Equivalents* was $159.3 million at December 31, 2019.

For the year ended December 31, 2019, compared to the prior year:

- *Total Revenue* was $120.4 million, an increase of 31%;
- *Gross Margin* was 70%, an increase of six percentage points;
- *Operating Expenses, Excluding Cost of Revenue,* were $99.0 million, an increase of 22%;
- *Net Loss and Comprehensive Loss* was ($12.6) million, an improvement of 45%;
- *Basic and Diluted Net Loss Per Common Share* was ($0.27), an improvement of 56%; and
- *Net Cash Used in Operating Activities* was $3.2 million, an improvement of 76%.

2019 Full-Year and Recent Business Highlights

Commercial Growth:

- Achieved strong total revenue growth across our testing and product portfolio delivering $29.5 million in the fourth quarter and $108.3 million for 2019, an increase of 16% and 19%, respectively, compared to the prior year.
- Accelerated pulmonology testing revenue to $2.0 million and $5.5 million for the fourth quarter and full year, respectively, a 123% and 174% increase compared to prior year.
- Grew total genomic volume (Afirma, Percepta and Envisia) by 18% to 10,846 tests in the fourth quarter of 2019 and by 25% to 39,612 tests in 2019, compared to prior year.
- Increased genomic volume for our pulmonology products by 136% in 2019 compared to prior year, achieving growth targets for both the Percepta and Envisia classifiers.
- Received final Medicare coverage in March 2019 for the Envisia classifier and published strong clinical validation and clinical utility data in *The Lancet Respiratory Medicine*, propelling nationwide commercial expansion of the test in the second half of 2019.
- Expanded payer contracts by 14.4 million lives, making Veracyte an in-network genomic testing provider to health plans representing over 225 million members.
- Continued to build an extensive library of clinical data across our portfolio in 2019, including 8 publications and 11 presentations at leading medical meetings, demonstrating our Afirma and pulmonology tests' performance and clinical utility.
- Eleven abstracts were presented at the San Antonio Breast Cancer Symposium in December 2019, including data showing a benefit of Prosigna® over other genomic testing to identify patients' long-term risk of developing distant metastases. In addition, data were presented showing the test's ability to identify patients with intrinsic breast cancer subtypes that may potentially benefit from CDK4/6 inhibitors in place of standard chemotherapy.

Biopharmaceutical Collaborations/Pipeline Advancement:

- In January 2019, announced a long-term strategic collaboration with Johnson & Johnson Innovation LLC to advance the development and commercialization of novel diagnostic tests to detect lung cancer at its earliest stages, when the disease is most treatable.
- Presented preliminary data at the American College of Chest Physicians (CHEST) annual meeting for our first-of-its-kind noninvasive nasal swab classifier for improved lung cancer diagnosis. The test, being developed through our Johnson & Johnson collaboration, is expected to launch in early 2021.
- Launched the second-generation Percepta GSC, completing the transition of our core classifiers to our RNA whole-transcriptome sequencing platform.

- Announced a multi-year collaboration with Acerta Pharma, the hematology research and development arm of AstraZeneca plc, to provide genomic information that will support the biopharmaceutical company's development of oncology therapeutics in lymphoma.

Global Expansion:

- Acquired the exclusive global diagnostic rights to the NanoString nCounter FLEX Analysis System, as well as the Prosigna breast cancer assay and the in-development LymphMark lymphoma subtyping test. We believe this transaction positions us to access a $40 billion global market for our current and pipeline products, by offering a broad menu of advanced genomic tests in oncology and other indications using a distributed-kit model.

Factors Affecting Our Performance

Reported Genomic Test Volume

Our performance depends on the number of genomic tests that we perform and report as completed in our CLIA laboratories. Factors impacting the number of tests that we report as completed include, but are not limited to:

- 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.

We generate substantially all our revenue from genomic testing services, including the rendering of a cytopathology diagnosis as part of the Afirma solution. For the Afirma classifier, we do not accrue revenue for approximately 5% - 10% of the tests that we perform and report as complete due principally to insufficient RNA from which to render a result and tests performed for which we do not reasonably expect to be paid.

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. To drive increased adoption of our products, we increased our sales force and marketing efforts over the last several years. Our sales team is structured to sell all of our products; we do not maintain a separate sales force for each product. 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, 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.

Integrating acquired assets and advances to our collaborations

Revenue growth, operational results and advances to our business strategy depends on our ability to integrate the assets acquired into our existing business. The integration of acquired assets may impact our revenue growth, increase the cost of operations, cause significant write-offs of intangible assets, or may require management resources that otherwise would be available for ongoing development of our existing business. The integration of assets acquired from NanoString in December 2019 may

impact our revenue and operating results through integration of a sales force, development of a product supply operation and the expansion of our business internationally with a broad menu of advanced genomic tests that may be offered.

Revenue growth or reimbursement from our collaborations depends on our ability to deliver services or information and achieve milestones required from our collaborative partners. Our collaboration parters pay us for the provision of data, other services and the achievement of milestones. Under a collaboration with Johnson & Johnson in 2018, we provided data services required under this agreement for $7.0 million in 2019, however, there remains $9.0 of revenue associated with development and commercialization milestones yet to be achieved.

How We Recognize Revenue

Testing Revenue

We commenced recognizing revenue in accordance with the provisions of ASC 606, *Revenue from Contracts with Customers* starting January 1, 2018. Prior to January 1, 2018, we recognized revenue in accordance with the provisions of ASC 954-605, *Health Care Entities - Revenue Recognition*.

Most of our revenue is generated from the provision of diagnostic services. These services are completed upon the delivery of test results to the prescribing physician, at which time we bill for the services. We recognize revenue related to billings 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 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.

As of December 31, 2019, cumulative amounts billed at list price for tests processed which were not recognized as revenue upon delivery of a patient report because our accrual revenue recognition criteria were not met and for which we have not collected cash or written off as uncollectible, totaled approximately $159.3 million. Of this amount, we did not collect any amounts in the year ended December 31, 2019 and we have no expectation of future collection because we began accruing for substantially all revenue upon delivery of a patient report in the third quarter of 2016.

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 calculate the average reimbursement from our products from all payers, for tests that are on average a year old, since it can take a significant period of time to collect from some payers. Except in situations where we believe the rate we reasonably expect to collect to vary due to a coverage decision, contract, more recent reimbursement data or evidence to the contrary, we use an average of reimbursement for tests provided over four quarters as it reduces the effects of temporary volatility and seasonal effects. Thus, the average reimbursement per product represents the total cash collected to date against genomic classifier tests, including variants, performed during the relevant period divided by the number of these tests performed during that same period.

The average genomic classifier reimbursement rate 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. For the year ended December 31, 2019, we accrued, on average, between $2,800 and $2,900 for the Afirma genomic classifier tests, including variants, that met our revenue recognition standard, which was between 90% - 95% of the reported Afirma classifier test volume.

From the fourth quarter of 2018 to the fourth quarter of 2019, we accrued between $1.0 million and $2.4 million in revenue per quarter from providing cytopathology services associated with our Afirma solution.

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

We began recognizing product revenue in December 2019 in accordance with the provisions of ASC 606, *Revenue from Contracts with Customers,* when we executed an agreement with NanoString for the exclusive worldwide license to the nCounter platform for *in vitro* diagnostic use.

We recognize product revenue when control of the promised goods or services is transferred to our customers, in an amount that reflects the consideration expected to be received in exchange for those products and services. 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 or service to the customer, meaning the customer has the ability to use and obtain the benefit of the product or service. 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.

Our products consist of the nCounter Analysis System and related consumables. Services consist of instrument service contracts and service fees for assay processing. Revenues are presented net of the taxes that are collected from customers and remitted to governmental authorities.

Biopharmaceutical and Collaboration Revenues

From time to time, we enter into arrangements for research and development and/or commercialization services. Such arrangements may require us to deliver various rights, services and/or samples, including intellectual property rights/licenses, R&D services, and/or commercialization services. The underlying terms of these arrangements generally provide for consideration to us in the form of nonrefundable upfront license fees, development and commercial performance milestone payments, royalty payments, and/or profit sharing.

The terms of the Company's collaborative arrangements typically include one or more of the following: (i) up-front fees; (ii) milestone payments related to the achievement of development, regulatory, or commercial goals; and (iii) royalties on net sales of licensed products. Each of these payments may result in collaboration revenues or an offset against research and development expense.

Arrangements with partners may fall under the scope of ASC Topic 808, *Collaborative Arrangements* ("ASC 808"). While these arrangements are in the scope of ASC 808, we may analogize to ASC 606 for some aspects of these arrangements. We analogize to ASC 606 for certain activities within the collaborative arrangement for the delivery of a good or service (i.e., a unit of account) that is part of our ongoing major or central operations.

In arrangements involving more than one performance obligation, each required performance obligation 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 selling price on a stand-alone basis is not available.

The consideration allocated to each distinct performance obligation is recognized as revenue when control of the related goods is transferred or services are performed. 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 revenues generated from royalties or profit sharing as the underlying sales occur.

Net sales of data or other services to our customers are classified under biopharmaceutical revenue and collaboration revenue, such as milestones, are classified under collaboration revenue in our consolidated statements of operations and comprehensive loss. Payments made to us that are not net sales of data or other services to our customers are recorded as an offset against research and development expense in our consolidated statements of operations and comprehensive loss.

Development of Additional Tests

We continue to advance our portfolio of diagnostic tests that leverage innovations in genomic science, sequencing technology and machine learning methodologies to further improve patient care. In May 2017, we introduced the Afirma GSC, supported by rigorous clinical validation data showing that the RNA sequencing-based test can help significantly more patients avoid unnecessary surgery in thyroid cancer diagnosis, compared to the original Afirma classifier. In March 2018, we unveiled our Afirma Xpression Atlas, which uses the same RNA sequencing data from the platform as the Afirma GSC and enables us to extract rich genomic content - including gene expression, DNA variants and RNA fusions in over 500 genes that are associated with thyroid cancer - from thyroid FNA samples. We believe that this offering will provide clinicians with valuable genomic information that may inform surgery strategy and treatment options for patients with suspected thyroid cancer.

Together with our Afirma GSC and our tests for the BRAF v600E mutation and medullary thyroid cancer, or Malignancy Classifiers, the Afirma Xpression Atlas rounds out a comprehensive solution for physicians evaluating thyroid nodules. This innovation also enables us to enter into research collaboration with biopharmaceutical companies, which is intended to support their development of targeted therapies for genetically defined cancers, including thyroid cancer.

We have also expanded our ability to provide important clinical answers - without the need for surgery - into pulmonology. Our Percepta Bronchial Genomic Classifier, introduced in April 2015, is the first genomic test to receive Medicare coverage for use in lung cancer diagnosis, where it improves the performance of diagnostic bronchoscopy. In June 2019, we began making our "next-generation" Percepta Genomic Sequencing Classifier available to physicians, providing them with expanded lung cancer risk information that can further guide next steps for patients with suspicious lung nodules, as compared to the Percepta Bronchial Genomic Classifier.

Additionally, our Envisia Genomic Classifier, launched in October 2016, is the first commercial test to improve the diagnosis of IPF among patients with a suspected interstitial lung disease. In March 2019, we received final Medicare coverage for the Envisia classifier through the MolDX program, with an effective date of April 1, 2019.

We also believe our Xpression Atlas platform can be transferred to our pulmonology indications, to further improve patient care and advance precision medicine in lung cancer and IPF.

We are currently exploring opportunities to utilize the same "field of injury" technology that powers our Percepta classifier to develop a nasal swab test that can enable earlier lung cancer detection - and ultimately help reduce lung cancer deaths. In October 2019, we announced preliminary clinical data showing for our noninvasive nasal swab classifier - the first test of its kind. The findings show that the novel genomic test can accurately classify lung cancer risk in patients with lung nodules so that these patients can obtain the prompt diagnosis and potential treatment they need or may be monitored noninvasively.

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 to secure clinical samples that can be used in discovery and product development as well as clinical validation studies. The timing of these research and development activities is difficult to predict, as is the timing of 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

Testing Revenue

Through December 31, 2019, we derived a substantial majority of our revenue from the sale of Afirma 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,		
	2019	2018	2017
Medicare	26%	29%	26%
UnitedHealthcare	11%	12%	14%
	37%	41%	40%

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 revenue are laboratory expenses, kit costs, sample collection expenses, compensation expense, license fees and royalties, depreciation and amortization, 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 revenue as a percentage of 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 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 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 revenue until we achieve efficiencies in processing these new tests.

Cost of Product Revenue

Cost of product revenue consists primarily of costs of purchasing instruments and consumables from third-party contract manufacturers, installation, warranty, service and packaging and delivery costs. In addition, cost of product includes royalty costs for licensed technologies included in our products, provisions for slow-moving and obsolete inventory and stock-based compensation expense. Cost of product revenue for instruments and consumables 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.

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 prototype materials, 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 expect to incur significant research and development expenses as we continue to invest in research and development activities related to developing additional products and evaluating various platforms. We incurred research and development expenses on ongoing evidence development for our Afirma, Percepta and Envisia classifiers in 2019 . We believe a majority of our research and development expenses in and after 2020 will be predominantly in support of our pipeline products.

Selling and Marketing

Selling and marketing expenses consist of compensation expenses, direct marketing expenses, professional fees, other expenses such as travel and communications costs and allocation of facility and information technology expenses. We have expanded our internal sales force as we invest in our multi-product sales strategy to assign a single point of contact to successfully develop and implement relationships with our customers and increased our marketing spending. We have also incurred increased selling and marketing expense as a result of investments in our lung product portfolio and believe total selling and marketing expenses will continue to increase as we launch and promote our new tests.

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. For the year ended December 31, 2019, approximately 67% of the average headcount classified as general and administrative encompass our billing and customer care teams. We expect general and administrative expenses to continue to increase as we build our general and administration infrastructure and to stabilize thereafter.

Intangible Asset Amortization

Our finite-lived intangible assets, acquired in business combinations, are being amortized over 5 to15 years, using the straight-line method. Amortization expense is expected to be approximately $5.1 million per year through 2024 and decrease thereafter.

Interest Expense

Interest expense is attributable to our borrowings under debt agreements and capital leases as well as costs associated with the pre-payment of debt.

Other Income, Net

Other income, net consists primarily of sublease rental income and interest income from our cash held in interest bearing accounts.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our audited financial statements, which have been prepared in accordance with United States generally accepted accounting principles, or U.S. GAAP. The preparation of the financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the 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 recognize revenue related to billings 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 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 based on the average reimbursement from payers for tests that are on average a year old, since it can take a significant period of time to collect from some payers. Except in situations where we believe the rate we reasonably expect to collect to vary due to a coverage decision, contract, more recent reimbursement data or evidence to the contrary, we use an average of reimbursement for tests provided over four quarters as it reduces the effects of temporary volatility and seasonal effects.

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

Biopharmaceutical and Collaboration Revenue

From time to time, we enter into arrangements for the research and development and/or commercialization of services. Such arrangements may require us to deliver various rights, services and/or samples, including intellectual property rights/licenses, research and development services, and/or commercialization of services. The underlying terms of these arrangements generally provide for consideration to us in the form of nonrefundable upfront license fees, development and commercial performance milestone payments, royalty payments and/or profit sharing.

In arrangements involving more than one performance obligation, each required performance obligation 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 selling price on a stand-alone basis is not available.

Arrangements with partners may fall under the scope of ASC Topic 808, *Collaborative Arrangements* ("ASC 808"). While these arrangements are in the scope of ASC 808, we may analogize to ASC 606 for some aspects of these arrangements. We analogize to ASC 606 for certain activities within the collaborative arrangement for the delivery of a good or service (i.e., a unit of account) that is part of our ongoing major or central operations.

The consideration allocated to each distinct performance obligation is recognized as revenue when control of the related goods or services is transferred. 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 revenues generated from royalties or profit sharing as the underlying sales occur.

Net sales of data or other services to our customers are classified under biopharmaceutical revenue and collaboration revenue, such as milestones, are classified under collaboration revenue in our consolidated statements of operations and comprehensive loss. Payments made to us that are not net sales of data or other services to our customers are recorded as an offset against research and development expense in our consolidated statements of operations and comprehensive loss.

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.

Finite-lived Intangible Assets

Finite-lived intangible assets consist of intangible assets acquired as part of business combinations. We amortize finite-lived intangible assets using the straight-line method over their estimated useful lives of five to 15 years, based on management's estimate of the period over which their economic benefits will be realized, product life and patent life. We test these finite-lived intangible assets for impairment when events or circumstances indicate a reduction in the fair value below their carrying amounts. There was no impairment recognized during the years ended December 31, 2019, 2018, or 2017.

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, 2019, 2018, or 2017.

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. 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.

Results of Operations

Comparison of the Years Ended December 31, 2019 and 2018 (in thousands of dollars, except percentages)

	Year Ended December 31,			
	2019	Change	%	2018
Revenue:				
Testing revenue	$ 107,355	16,297	18 %	$ 91,058
Product revenue	923	923	— %	—
Biopharmaceutical revenue	8,090	7,140	752 %	950
Collaboration revenue	4,000	4,000	— %	—
Total revenue	120,368	$ 28,360	31 %	$ 92,008
Operating expense:				
Cost of testing revenue	36,077	2,999	9 %	33,078
Cost of product revenue	446	446	— %	—
Research and development	14,851	31	— %	14,820
Selling and marketing	53,691	12,378	30 %	41,313
General and administrative	29,029	5,066	21 %	23,963
Intangible asset amortization	1,401	334	31 %	1,067
Total operating expenses	135,495	21,254	19 %	114,241
Loss from operations	(15,127)	7,106	32 %	(22,233)
Interest expense	(677)	1,286	(66)%	(1,963)
Other income, net	3,205	2,008	168 %	1,197
Net loss and comprehensive loss	$ (12,599)	$ 10,400	45 %	$ (22,999)
Other Operating Data:				
Genomic classifiers reported	39,612	7,902	25 %	31,710

Revenue

Revenue increased $28.4 million, or 31%, for the year ended December 31, 2019 compared to 2018, primarily due to an increase in testing revenue from a 25% increase in genomic classifiers reported. We had a $15.8 million increase in testing revenue for our Afirma, Percepta, and Envisia classifiers in the year ended December 31, 2019 compared to 2018. We also make adjustments, as necessary, for testing revenue accrued in prior periods as collections are made if the amount we expect to collect changes. The adjustment for testing revenue accrued in prior periods was $1.0 million and $2.0 million for the years ended December 31, 2019 and 2018, respectively, a net decrease of $1.0 million between the years. We also recognized $0.9 million from sales of Prosigna, a product that we acquired from NanoString in December 2019. We recognized $8.1 million of biopharmaceutical revenue compared to $1.0 million in 2018 primarily due to the performance of data sequencing services for Johnson & Johnson. We also recognized $4.0 million of collaboration revenue in 2019 due to the achievements of milestones under the agreement we signed with Johnson & Johnson in December 2018.

Comparison of revenue for the years ending December 31, 2018 and 2017 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 25, 2019. There was no product revenue, biopharmaceutical revenue or collaboration revenue in 2017.

Cost of revenue

Comparison of the years ended December 31, 2019 and 2018 was as follows (in thousands of dollars, except percentages):

	Year Ended December 31,			
	2019	Change	%	2018
Cost of testing revenue:				
Laboratory expense	$ 20,166	$ 1,108	6 %	$ 19,058
Sample collection expense	4,801	635	15 %	4,166
Compensation expense	6,013	1,492	33 %	4,521
License fees and royalties	10	(795)	(99)%	805
Depreciation and amortization	1,020	220	28 %	800
Other expenses	1,749	18	1 %	1,731
Allocations	2,318	321	16 %	1,997
Total	$ 36,077	$ 2,999	9 %	$ 33,078
Cost of product revenue	$ 446	$ 446	— %	$ —

Cost of testing revenue increased $3.0 million, or 9%, for the year ended December 31, 2019 compared to 2018. The increase in laboratory costs was primarily due to a 25% increase in reported genomic classifiers volume, partially offset by lower pricing on supplies and improved efficiencies following the completion of the transition from the Afirma GEC to Afirma GSC in the third quarter of 2018. The increase in sample collection costs was primarily related to the increase in the overall volume of samples received, partially offset by lower shipping costs from modifications to our collection kits. The increase in compensation expense was primarily due to an average laboratory headcount increase of 16%. The decrease in license fees and royalties was due to the completed transition to the Afirma GSC in the third quarter of 2018, for which we do not pay license fees as we did in connection with the Afirma GEC. The increase in depreciation and amortization was from more equipment being placed into service. The increase in allocations was due to higher allocated costs from the increased headcount. Cost of product revenue was $0.4 million from sales of Prosigna in 2019, a product that we acquired from NanoString in December 2019.

Comparison of cost of testing revenue for the years ending December 31, 2018 and 2017 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 25, 2019. There was no cost of product revenue in 2017.

Research and development

Comparison of the years ended December 31, 2019 and 2018 was as follows (in thousands of dollars, except percentages):

	Year Ended December 31,			
	2019	Change	%	2018
Research and development expense				
Compensation expense	$ 9,444	$ 1,209	15 %	$ 8,235
Direct research and development expense	2,924	(792)	(21)%	3,716
Professional fees	548	(242)	(31)%	790
Depreciation and amortization	287	(113)	(28)%	400
Other expenses	443	38	9 %	405
Allocations	1,205	(69)	(5)%	1,274
Total	$ 14,851	$ 31	— %	$ 14,820

Research and development expense was flat in the year ended December 31, 2019 compared to 2018. Compensation expense increased $1.2 million, primarily due to higher stock-based compensation expense from the increase in our stock price and incentive compensation, partially offset by severance costs incurred in 2018 that were not incurred in 2019. The decrease in direct research and development expense was due to one-time sequencing costs and materials and supplies purchased for research and development projects in 2018. The decrease in professional fees was due to lower consulting costs.

Comparison of research and development expense for the years ending December 31, 2018 and 2017 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 25, 2019.

Selling and marketing

Comparison of the years ended December 31, 2019 and 2018 was as follows (in thousands of dollars, except percentages):

	Year Ended December 31,			
	2019	Change	%	2018
Selling and marketing expense:				
Compensation expense	$ 33,239	$ 7,346	28%	$ 25,893
Direct marketing expense	6,015	1,148	24%	4,867
Professional fees	2,234	727	48%	1,507
Other expenses	9,008	2,459	38%	6,549
Allocations	3,195	698	28%	2,497
Total	$ 53,691	$ 12,378	30%	$ 41,313

Selling and marketing expense increased $12.4 million, or 30%, for the year ended December 31, 2019 compared to 2018. The increase in compensation expense was due to a 41% increase in average headcount, higher incentive compensation and higher stock-based compensation expense. The increase in direct marketing expense was due to higher general marketing expenditures. The increase in professional fees was due to higher consulting expenses. The increase in other expenses was primarily due to higher travel and entertainment expenses related to the increase in headcount, which also increased allocated costs.

Comparison of selling and marketing expense for the years ending December 31, 2018 and 2017 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 25, 2019.

General and administrative

Comparison of the years ended December 31, 2019 and 2018 was as follows (in thousands of dollars, except percentages):

	Year Ended December 31,			
	2019	Change	%	2018
General and administrative expense:				
Compensation expense	$ 18,537	$ 2,479	15 %	$ 16,058
Professional fees	8,854	2,652	43 %	6,202
Occupancy costs	2,518	143	6 %	2,375
Depreciation and amortization	1,408	(245)	(15)%	1,653
Other expenses	4,430	987	29 %	3,443
Allocations	(6,718)	(950)	16 %	(5,768)
Total	$ 29,029	$ 5,066	21 %	$ 23,963

General and administrative expense increased $5.1 million, or 21%, for the year ended December 31, 2019 compared to 2018. The increase in compensation expense was primarily due to higher stock-based compensation expense from the increase in our stock price. The increase in professional fees was mainly due to $1.5 million of expenses associated with our acquisition of NanoString Technologies. Inc.'s diagnostics business, $0.6 million in other increases in legal spend, and $0.3 million higher investor relations costs. The increase in other expenses was mainly from higher IT expenses to support the higher company headcount. The increase in expenses allocated to other departments was due to higher headcount in departments associated with selling and marketing and cost of revenue.

Comparison of general and administrative expense for the years ending December 31, 2018 and 2017 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 25, 2019.

Interest expense

Interest expense decreased $1.3 million, or 66%, for the year ended December 31, 2019 compared to 2018, primarily due to the prepayments of $12.5 million and $12.4 million of the principal amount of our Term Loan Advance in January 2019 and May 2019, respectively. The average Term Loan Advance interest rate was 6.70% and 6.14% for the years ended December 31, 2019 and 2018, respectively.

Comparison of interest expense for the years ending December 31, 2018 and 2017 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 25, 2019.

Other income, net

Other income, net, increased $2.0 million for the year ended December 31, 2019 compared to 2018, primarily due to higher interest income from our cash and cash equivalents, which had higher balances in 2019 following our public offering of common stock in July 2018 and May 2019.

Comparison of Other income, net, for the years ending December 31, 2018 and 2017 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 25, 2019.

Liquidity and Capital Resources

From inception through December 31, 2019, we have been financed primarily through net proceeds from the sale of our equity securities and borrowings under our credit facilities. We have incurred net losses since our inception. For the years ended December 31, 2019, 2018 and 2017, we had net losses of $12.6 million, $23.0 million and $31.0 million, respectively, and we expect to incur additional losses in 2020 and potentially in future years. As of December 31, 2019, we had an accumulated deficit of $246.7 million.

We believe our existing cash and cash equivalents of $159.3 million as of December 31, 2019, our available revolving line of credit, and 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, costs to service our Loan and Security Agreement (See Note 8 to our audited consolidated financial statements included in this Annual Report on Form 10-K for more information about our Loan and Security Agreement), capital expenditures 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 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.

Public Offering of Common Stock

On May 7, 2019, we issued and sold 6,325,000 shares of common stock in a registered public offering, including 825,000 shares issued and sold upon the underwriters' exercise in full of their option to purchase additional shares, at a price to the public of $23.25 per share. Our net proceeds from the offering were approximately $137.8 million, after deducting underwriting discounts and commissions and offering expenses of $9.2 million.

In July 30, 2018, we issued and sold 5,750,000 shares of common stock in a registered public offering, including 750,000 shares issued and sold upon the underwriters' exercise in full of their option to purchase additional shares, at a price to the public of $10.25 per share. Our net proceeds from the offering were approximately $55.0 million, after deducting underwriting discounts and commissions and estimated offering expenses of $3.9 million.

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 allows 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. The Term Loan was advanced upon the closing of the Loan and Security Agreement. Borrowings under the Loan and Security Agreement mature in October 2022. The Term Loan bears 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. We are also required to pay an annual facility fee on the Revolving Line of Credit of $25,000. The average Term Loan Advance interest rate for the year ended December 31, 2019 was 6.70%.

We may prepay the outstanding principal amount under the Term Loan plus accrued and unpaid interest and, if the Term Loan is repaid in full, a prepayment premium. The prepayment premium will equal (i) $750,000, if the prepayment is made on or before November 3, 2018, (ii) $500,000, if the prepayment is made after November 3, 2018 and on or prior to November 3, 2019 and (iii) $250,000, if the prepayment is made after November 3, 2019. In addition, a final payment on the Term Loan in the amount of $1.2 million is due upon the earlier of the maturity date of the Term Loan or its payment in full. In January 2019 and May 2019, we prepaid $12.5 million and $12.4 million of the principal amount of the Term Loan Advance, respectively, and did not incur any prepayment premium as we did not repay the Term Loan Advance in full. These prepayments cover scheduled principal payments from November 2019 to September 2022.

The Loan and Security Agreement contains customary representations, warranties, and events of default such as a material adverse change in our business, operations or financial conditions, as well as affirmative and negative covenants. The negative covenants include, among other provisions, covenants that limit or restrict our ability to incur liens, make investments, incur indebtedness, merge with or acquire other entities, dispose of assets, make dividends or other distributions to holders of our equity interests, engage in any new line of business, or enter into certain transactions with affiliates, in each case subject to certain exceptions. As of December 31, 2019, the principal balance outstanding was $0.1 million and we were in compliance with debt covenants.

The Loan and Security Agreement also requires us to comply with certain financial covenants, including achieving certain revenue levels tested quarterly on a trailing twelve-month basis. However, failure to maintain the revenue levels will not be considered a default if the sum of our unrestricted cash and cash equivalents maintained with Silicon Valley Bank and amount available under the Revolving Line of Credit is at least $40.0 million.

Our obligations under the Loan and Security Agreement are secured by substantially all of our assets (excluding intellectual property), subject to certain customary exceptions.

Cash Flows

The following table summarizes our cash flows for the years ended December 31, 2019, 2018 and 2017 (in thousands of dollars):

	Years Ended December 31,		
	2019	2018	2017
Cash used in operating activities	$ (3,232)	$ (13,521)	$ (23,915)
Cash used in investing activities	(42,733)	(1,874)	(1,315)
Cash provided by (used in) financing activities	127,287	59,499	(218)

Cash Flows from Operating Activities

Cash used in operating activities for the year ended December 31, 2019 was $3.2 million. The net loss of $12.6 million includes non-cash charges of $9.8 million of stock-based compensation expense and $4.1 million of depreciation and amortization, which includes $1.4 million of intangible asset amortization, and $0.2 million of end-of-term debt obligation accruals. Cash used as a result of changes in operating assets and liabilities was $4.8 million, primarily comprised of an increase in accounts receivable of $6.2 million, increase in supplies of $3.4 million and increase in other assets of $0.4 million, partially offset by an increase in accrued liabilities and deferred rent of $5.2 million.

Cash used in operating activities for the year ended December 31, 2018 was $13.5 million. The net loss of $23.0 million includes non-cash charges of $6.0 million of stock-based compensation expense and $3.9 million of depreciation and amortization, which includes $1.1 million of intangible asset amortization. It also includes $0.3 million of end-of-term debt obligation accruals. Cash used as a result of changes in operating assets and liabilities of $0.7 million was primarily due to a decrease in accounts payable of $1.6 million, an increase in other assets of $0.8 million and increases in prepaid expenses and other current assets and accounts receivable of $0.9 million, partially offset by a decrease in supplies of $1.9 million and an increase in accrued liabilities and deferred rent of $0.7 million.

Cash used in operating activities for the year ended December 31, 2017 was $23.9 million. The net loss of $31.0 million includes non-cash charges of $6.6 million of stock-based compensation expense and $3.8 million of depreciation and amortization, which includes $1.1 million of intangible asset amortization. It also includes a $1.5 million prepayment penalty for exiting our previous credit agreement which is a financing cash flow, and the amortization and write-off of $0.5 million of debt issuance costs. Cash used as a result of changes in operating assets and liabilities of $5.4 million was primarily due to an increase in accounts receivable of $4.0 million, an increase in supplies inventory of $1.8 million and a decrease in accrued liabilities and deferred rent of $1.2 million, partially offset by an increase in accounts payable of $1.7 million.

Cash Flows from Investing Activities

Cash used in investing activities for the year ended December 31, 2019 was $42.7 million, consisting of $40.0 million for the acquisition of NanoString Technologies, Inc.'s diagnostics business, and $2.7 million for the acquisition of property and equipment, net of proceeds from the disposal of property and equipment.

Cash used in investing activities for the year ended December 31, 2018 was $1.9 million for the acquisition of property and equipment.

Cash used in investing activities for the year ended December 31, 2017 was $1.2 million, mainly comprising $1.8 million for the acquisition of property and equipment, partially offset by $0.4 million of proceeds from the sale of property and equipment.

Cash Flows from Financing Activities

Cash provided by financing activities for the year ended December 31, 2019 was $127.3 million, consisting of $137.8 million in net proceeds from the issuance of common stock in a public offering in May 2019 and $14.6 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, during the year, partially offset by $24.9 million of loan principal repayments and finance lease payments of $0.3 million.

Cash provided by financing activities for the year ended December 31, 2018 was $59.5 million, consisting of $55.0 million in net proceeds from the issuance of common stock in a public offering in the second quarter of 2018, $4.4 million in proceeds from the exercise of options to purchase our common stock and purchases under our ESPP and $0.4 million in proceeds from a legal settlement, partially offset by capital lease payments of $0.3 million during the period.

Cash used in financing activities for the year ended December 31, 2017 was $0.2 million, consisting of a $25.4 million payment of the principal on prior credit agreement, $1.5 million payment for the prepayment premium for terminating the prior credit agreement and $0.3 million of capital lease payments, partially offset by $24.9 million of net proceeds from our new loan and security agreement, $1.9 million in proceeds from the purchase of stock under our ESPP and exercise of options to purchase our common stock.

Contractual Obligations

The following table summarizes certain contractual obligations as of December 31, 2019 (in thousands of dollars):

	Payments Due by Period				
	Fiscal Year 2020	Fiscal Year 2021 to 2022	Fiscal Year 2023 to 2024	Fiscal Year 2025 and Beyond	Total
Operating lease obligations (1)	$ 2,332	$ 4,873	$ 5,157	$ 4,161	$ 16,523
Long-term debt obligations (2)	—	1,288	—	—	1,288
Supplies purchase commitments	5,693	1,913	—	—	7,606
Capital lease obligation	—	—	—	—	—
Total	$ 8,025	$ 8,074	$ 5,157	$ 4,161	$ 25,417

(1) Represents minimum operating lease payments under operating leases for facilities.
(2) Debt obligations include principal, estimate of variable rate interest and end-of-term debt obligation. In January 2019 and May 2019, we paid off $12.5 million and $12.4 million of principal from our Loan and Security Agreement, respectively.

Off-balance Sheet Arrangements

We have not entered into any off-balance sheet arrangements.

Recent Accounting Pronouncements

In February 2016, the FASB issued ASU No. 2016-2, *Leases (Topic 842)*. This ASU is aimed at making leasing activities more transparent and comparable, and requires substantially all leases be recognized by lessees on their balance sheet as a right-of-use asset and corresponding lease liability, including leases currently accounted for as operating leases. The ASU was effective for interim and annual periods beginning after December 15, 2018. Additionally, the FASB issued ASU No. 2018-11, *Leases (Topic 842): Targeted Improvements*, which offers an additional transition method whereby entities may apply the new leases standard at the adoption date and recognize a cumulative-effect adjustment to the opening balance of retained earnings rather than application of the new leases standard at the beginning of the earliest period presented in the financial statements. We elected this transition method and adopted ASC 842 on January 1, 2019 and as a result, recorded operating lease right-of-use ("ROU") assets of $9.8 million, including offsetting deferred rent of $4.3 million, along with the associated operating lease liabilities of $14.1 million. On January 1, 2019, we had finance lease ROU assets of $0.8 million and associated finance lease liabilities of $0.3 million for leases classified as finance leases prior to the adoption of ASC 842. The adoption of ASC 842 had an immaterial impact on the our consolidated statement of operations and comprehensive loss, consolidated statement of stockholders' equity and consolidated statement of cash flows for the year ended December 31, 2019. In addition, we elected the package of practical expedients permitted under the transition guidance within the new standard which allowed it to carry forward the historical lease

classification. Additional information and disclosures required by this new standard are contained in Note 7, Commitments and Contingencies.

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments-Credit Losses: Measurement of Credit Losses on Financial Instruments*. This ASU requires measurement and recognition of expected credit losses for financial assets. This guidance will become effective for us beginning January 1, 2020 with early adoption permitted. We are currently evaluating the potential effect of this standard on its financial statements. We do not expect to have a material impact on our financial statements and related disclosures from the adoption of this guidance.

In November 2018, the FASB issued ASU No. 2018-18, *Collaborative Arrangements (Topic 808)*. Under this ASU, transactions in collaborative arrangements are to be accounted for under ASC 606 if the counterparty is a customer for a good or service (or bundle of goods and services) that is a distinct unit of account. Also, entities are precluded from presenting consideration from transactions with a counterparty that is not a customer together with revenue recognized from ASC 606. This ASU is effective for all interim and annual reporting periods beginning on or after December 15, 2019, with early adoption permitted. We adopted the ASU in 2019 with no cumulative-effect adjustments or retrospective impact.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET 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 of $159.3 million as of December 31, 2019 which consisted of bank deposits, money market funds and overnight reverse repurchase agreements. Such interest-bearing instruments carry a degree of risk; however, a hypothetical 10% change in interest rates during any of the periods presented would not have had a material impact on our consolidated financial statements.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Veracyte, Inc.
Index to Consolidated Financial Statements

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, 2019 and 2018, the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2019, 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, 2019 and 2018, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2019, 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, 2019, 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 25, 2020 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 matters communicated below are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of critical audit matters 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 matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Revenue from diagnostic services

Description of the Matter

During the year ended December 31, 2019, the Company's revenue from diagnostic services was approximately $107.4 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.

Valuation of intangible assets and contingent consideration

Description of the Matter

On December 3, 2019, the Company entered into an agreement to acquire a license and certain assets for consideration of $60 million, including up to $10 million of contingent consideration upon achievement of certain milestones. As discussed in Note 4 to the consolidated financial statements, the Company accounted for this transaction as a business combination.

Auditing the accounting for this business combination was complex due to the significant estimation uncertainty in determining the fair value of identified intangible assets and contingent consideration. The significant estimation uncertainty was primarily due to the sensitivity of the fair value estimates to the significant underlying assumptions about the forecasted results of the acquired business. The significant assumptions used to form the basis of the forecasted results included revenue growth rates, profit margins, timing of cash flows, and the discount rate. These significant assumptions are forward-looking and could be affected by future economic and market conditions.

How We Addressed the Matter in Our Audit

We obtained an understanding, evaluated the design, and tested the operating effectiveness of the Company's controls over the valuation of intangible assets and contingent consideration related to the business combination. This included testing controls over the estimation process supporting the recognition and measurement of identified intangible assets and contingent consideration and management's judgment and evaluation of underlying assumptions and estimates with regards to these fair values.

To test these fair values, our audit procedures included, among others, involvement of a specialist to assist us in the evaluation of the Company's valuation methodology and testing of the discount rate, evaluating prospective financial information, and testing the completeness and accuracy of underlying data. For example, we compared the significant assumptions to current industry and market trends, historical results and other relevant factors.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2014.
Redwood City, California
February 25, 2020

VERACYTE, INC.

Consolidated Balance Sheets

(in thousands, except share and per share amounts)

	As of December 31,	
	2019	2018
Assets		
Current assets:		
Cash and cash equivalents	$ 159,317	$ 77,995
Accounts receivable	19,329	13,168
Supplies	6,806	3,402
Prepaid expenses and other current assets	2,235	2,387
Total current assets	187,687	96,952
Property and equipment, net	8,933	8,940
Right-of-use assets - operating lease	8,808	—
Finite-lived intangible assets, net	65,019	12,000
Goodwill	2,725	1,057
Restricted cash	603	603
Other assets	1,437	1,086
Total assets	$ 275,212	$ 120,638
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,328	$ 2,516
Accrued liabilities	13,734	9,186
Current portion of long-term debt	—	1,357
Current portion of operating lease liability	1,407	—
Total current liabilities	17,469	13,059
Long-term debt	694	23,925
Deferred rent, net of current portion	—	3,899
Acquisition related contingent consideration	6,088	—
Operating lease liability, net of current portion	11,506	—
Total liabilities	35,757	40,883
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, 2019 and 2018	—	—
Common stock, $0.001 par value; 125,000,000 shares authorized, 49,625,341 and 40,863,202 shares issued and outstanding as of December 31, 2019 and 2018, respectively	50	41
Additional paid-in capital	486,090	313,800
Accumulated deficit	(246,685)	(234,086)
Total stockholders' equity	239,455	79,755
Total liabilities and stockholders' equity	$ 275,212	$ 120,638

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

VERACYTE, INC.

Consolidated Statements of Operations and Comprehensive Loss

(in thousands, except share and per share amounts)

	Year Ended December 31,		
	2019	2018	2017
Revenue:			
Testing revenue	$ 107,355	$ 91,058	$ 71,953
Product revenue	923	—	—
Biopharmaceutical revenue	8,090	950	—
Collaboration revenue	4,000	—	—
Total revenue	120,368	92,008	71,953
Operating Expenses:			
Cost of testing revenue	36,077	33,078	28,195
Cost of product revenue	446	—	—
Research and development	14,851	14,820	13,881
Selling and marketing	53,691	41,313	32,260
General and administrative	29,029	23,963	23,088
Intangible asset amortization	1,401	1,067	1,067
Total operating expenses	135,495	114,241	98,491
Loss from operations	(15,127)	(22,233)	(26,538)
Interest expense	(677)	(1,963)	(4,941)
Other income, net	3,205	1,197	476
Net loss and comprehensive loss	$ (12,599)	$ (22,999)	$ (31,003)
Net loss per common share, basic and diluted	$ (0.27)	$ (0.62)	$ (0.91)
Shares used to compute net loss per common share, basic and diluted	46,138,177	37,020,246	33,925,617

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

VERACYTE, INC.

Consolidated Statements of Stockholders' Equity

(in thousands, except shares)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance at December 31, 2016	33,762,278	$ 34	$ 239,631	$ (180,084)	$ 59,581
Issuance of common stock on exercise of stock options and vesting of restricted stock units	295,059	—	1,374	—	1,374
Issuance of common stock under employee stock purchase plan (ESPP)	153,051	—	656	—	656
Stock-based compensation expense (employee)	—	—	6,352	—	6,352
Stock-based compensation expense (non-employee)	—	—	19	—	19
Stock-based compensation expense (ESPP)	—	—	246	—	246
Net loss and comprehensive loss	—	—	—	(31,003)	(31,003)
Balance at December 31, 2017	34,210,388	34	248,278	(211,087)	37,225
Issuance of common stock on exercise of stock options and vesting of restricted stock units	756,231	1	3,432	—	3,433
Issuance of common stock under employee stock purchase plan (ESPP)	146,583	—	790	—	790
Sale of common stock in a public offering, net of issuance costs of $3,890	5,750,000	6	55,032	—	55,038
Stock-based compensation expense (employee)	—	—	5,602	—	5,602
Stock-based compensation expense (non-employee)	—	—	24	—	24
Stock-based compensation expense (ESPP)	—	—	332	—	332
Legal settlement from short-swing profits, net of tax	—	—	310	—	310
Net loss and comprehensive loss	—	—	—	(22,999)	(22,999)
Balance at December 31, 2018	40,863,202	41	313,800	(234,086)	79,755
Issuance of common stock on exercise of stock options and vesting of restricted stock units	1,924,156	2	13,376	—	13,378
Issuance of common stock under employee stock purchase plan (ESPP)	136,251	—	1,266	—	1,266
Sale of common stock in a public offering, net of issuance costs of $9,208	6,325,000	6	137,842	—	137,848
Issuance of common stock for acquisition	376,732	1	9,999	—	10,000
Stock-based compensation expense (employee)	—	—	8,883	—	8,883
Stock-based compensation expense (non-employee)	—	—	181	—	181
Stock-based compensation expense (ESPP)	—	—	743	—	743
Net loss and comprehensive loss	—	—	—	(12,599)	(12,599)
Balance at December 31, 2019	49,625,341	$ 50	$ 486,090	$ (246,685)	$ 239,455

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,		
	2019	**2018**	**2017**
Operating activities			
Net loss	$ (12,599)	$ (22,999)	$ (31,003)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	4,117	3,920	3,841
(Gain) loss on disposal of property and equipment	(23)	—	12
Stock-based compensation	9,807	5,958	6,617
Other income	—	(93)	—
Amortization and write-off of debt discount and issuance costs	83	32	472
Interest on end-of-term debt obligation and prepayment penalty	229	312	1,589
Changes in operating assets and liabilities:			
Accounts receivable	(6,161)	(452)	(3,960)
Supplies	(3,404)	1,922	(1,849)
Prepaid expenses and other current assets	154	(517)	(7)
Right-of-use assets - operating lease and operating lease liability	(171)	—	—
Other assets	(351)	(760)	(192)
Accounts payable	(141)	(1,568)	1,728
Accrued liabilities and deferred rent	5,228	724	(1,163)
Net cash used in operating activities	(3,232)	(13,521)	(23,915)
Investing activities			
Cash paid for acquisition	(40,000)	—	—
Purchases of property and equipment	(2,756)	(1,874)	(1,755)
Proceeds from the sale of property and equipment	23	—	440
Net cash used in investing activities	(42,733)	(1,874)	(1,315)
Financing activities			
Proceeds from the issuance of long-term debt, net of debt issuance costs	—	—	24,880
Proceeds from issuance of common stock in a public offering, net of issuance costs	137,848	55,038	200
Payment of long-term debt	(24,900)	—	(25,385)
Payment of end-of-term debt obligation and prepayment penalty	—	—	(1,536)
Proceeds from legal settlement regarding short-swing profits	—	403	—
Payment of financial lease liability	(308)	(292)	(274)
Proceeds from the exercise of common stock options and employee stock purchases	14,647	4,350	1,897
Net cash provided by (used in) financing activities	127,287	59,499	(218)
Net increase (decrease) in cash, cash equivalents and restricted cash	81,322	44,104	(25,448)
Cash, cash equivalents and restricted cash at beginning of year	78,598	34,494	59,942
Cash, cash equivalents and restricted cash at end of year	$ 159,920	$ 78,598	$ 34,494
Supplementary cash flow information of non-cash investing and financing activities:			
Operating lease liability arising from obtaining right-of-use assets - operating lease at beginning of period	$ 14,118	$ —	$ —
Shares issued for purchase consideration for a business combination	10,000	—	—
Deferred purchase consideration for a business combination	6,088	—	—
Purchases of property and equipment included in accounts payable and accrued liabilities	226	273	42
Supplementary cash flow information:			
Cash paid for interest on debt	332	1,547	2,718
Cash paid for tax	35	79	21

Cash, Cash Equivalents and Restricted Cash:

	December 31,		
	2019	2018	2017
Cash and cash equivalents	$ 159,317	$ 77,995	$ 33,891
Restricted cash	603	603	603
Total cash, cash equivalents and restricted cash	$ 159,920	$ 78,598	$ 34,494

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

1. Organization and Description of Business

Veracyte, Inc. ("Veracyte" or the "Company") is a leading genomic diagnostics company that is creating value through innovation. The Company was founded in 2008 with a mission to improve diagnostic accuracy. Today, the Company's growing menu of tests leverage advances in genomic science and technology to improve care throughout the patient journey, enabling more confident diagnostic, prognostic and treatment decisions in cancer and other challenging diseases. The Company is creating new standards of care by enabling more patients to avoid risks of unnecessary invasive procedures and removing costs from the healthcare system, while speeding the time to diagnosis and treatment decisions.

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 operations are based in South San Francisco, California and Austin, Texas, and it operates in one segment.

The Company performs its genomic tests for thyroid cancer, lung cancer and idiopathic pulmonary fibrosis, or IPF, in our CLIA-certified laboratory in South San Francisco, California. In December 2019, we announced our acquisition of the exclusive global diagnostics license to the NanoString nCounter FLEX Analysis System, as well as the Prosigna breast cancer prognostic gene signature assay, which is commercially available, and the LymphMark lymphoma subtyping assay, which is in development. Both tests are designed for use on the nCounter system.

The Company offers genomic tests in thyroid cancer; lung cancer; IPF and breast cancer:

Afirma Genomic Sequencing Classifier and Xpression Atlas. The Company's Afirma offerings include the Afirma GSC and Xpression Atlas, to help guide next steps for patients with potentially cancerous thyroid nodules. The offerings are intended to provide physicians with clinically actionable results from a single fine needle aspiration, or FNA biopsy. The Afirma GSC was developed with RNA whole-transcriptome sequencing and machine learning, and is used to identify patients with benign thyroid nodules among those with indeterminate cytopathology results in order to rule out unnecessary thyroid surgery.

The Company commercially launched the Afirma Xpression Atlas in 2018 to complement the Afirma GSC. The Xpression Atlas provides physicians with genomic alteration content from the same FNA samples that are used in Afirma GSC testing and may help physicians decide with greater confidence on the surgical or therapeutic pathway for their patients.

Percepta Genomic Sequencing Classifier. The Percepta classifier improves lung cancer diagnosis by enhancing the performance of diagnostic bronchoscopies, thus identifying more patients with lung nodules who are at low risk of cancer and may avoid further, invasive procedures. This second-generation test was developed on our RNA whole-transcriptome sequencing platform and commercially introduced in June 2019, provides expanded clinical utility by also identifying patients as high risk of cancer so they may obtain faster diagnosis and treatment. The test is built upon foundational "field of injury" science - through which genomic changes associated with lung cancer in current and former smokers can be identified with a simple brushing of a person's airway - without the need to sample the often hard-to-reach nodule directly.

Envisia Genomic Classifier. The Envisia classifier improves diagnosis of IPF by helping physicians better differentiate IPF from other interstitial lung diseases, or ILDs, without the need for surgery. The test identifies the genomic pattern of usual interstitial pneumonia, or UIP, a hallmark of IPF, with high accuracy on patient samples that are obtained through transbronchial biopsy, a nonsurgical procedure that is commonly used in lung evaluation.

Prosigna Breast Cancer Prognostic Gene Signature Assay. The Prosigna test, acquired in December 2019 through our strategic transaction with NanoString, uses advanced genomic technology to inform next steps for patients with early-stage breast cancer, based on the genomic make-up of their disease. The test leverages a collection of 50 genes known as the PAM50 gene signature and can provide a breast cancer patient and physician with prognostic score that indicates the probability of cancer recurrence over ten years. Physicians use Prosigna to help guide therapeutic decisions so that patients receive a therapeutic intervention, such as chemotherapy, only if clinically warranted.

The Company's approach also provides multiple opportunities for partnerships with biopharmaceutical companies. In developing the Company's products, the Company has built or gained access to unique biorepositories, proprietary technology and bioinformatics that it believes are important to the development of new targeted therapies, determining clinical trial eligibility and guiding treatment selection.

All of the Company's testing services are made available through its clinical reference laboratories located in South San Francisco, California and Austin, Texas.

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 ("U.S. GAAP"). The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary, which was created in 2019 to process certain administrative functions associated with the business combination in Note 4, Business Combination. All intercompany accounts and transactions have been eliminated in consolidation. Certain amounts have been reclassified on the consolidated statements of operations for presentation purposes.

Use of Estimates

The preparation of 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 assets and liabilities as of the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. Significant items subject to such estimates include: revenue recognition; the useful lives of property and equipment; the recoverability of long-lived assets; the estimation of the fair value of intangible assets; stock options; income tax uncertainties, including a valuation allowance for deferred tax assets; 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 recognized 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, 2019, the Company had an accumulated deficit of $246.7 million. The Company believes its cash and cash equivalents of $159.3 million as of December 31, 2019 and its revenue from sales in 2020 will be sufficient to meet its anticipated cash requirements through at least February 2021.

On May 7, 2019, the Company issued and sold 6,325,000 shares of common stock in a registered public offering, including 825,000 shares issued and sold upon the underwriters' exercise in full of their option to purchase additional shares, at a price to the public of $23.25 per share. The Company's net proceeds from the offering were approximately $137.8 million, after deducting underwriting discounts and commissions and offering expenses of $9.2 million.

In July 2018, the Company issued and sold 5,750,000 shares of common stock in a registered public offering, including 750,000 shares issued and sold upon the underwriters' exercise in full of their option to purchase additional shares, at a price to the public of $10.25 per share. The Company's net proceeds from the offering were approximately $55.0 million, after deducting underwriting commissions and offering expenses of $3.9 million.

In November 2017, the Company entered into a Loan and Security Agreement and drew down a term loan advance of $25.0 million of which the entire amount was used to pay the outstanding balance of the Company's previous long-term debt as discussed in Note 8 - Debt.

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 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 experienced any losses on its deposits of cash and cash equivalents.

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

The Company is also subject to credit risk from its accounts receivable related to its sales. The Company does not perform evaluations of customers' financial condition and does not require collateral.

Through December 31, 2019, most of the Company's revenue have been derived from the sale of Afirma. To date, Afirma has been delivered primarily to physicians in the United States. The Company's third-party payers and other customers in excess of 10% of revenue and their related revenue as a percentage of total revenue were as follows:

	Year Ended December 31,		
	2019	2018	2017
Medicare	26%	29%	26%
UnitedHealthcare	11%	12%	14%
	37%	41%	40%

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

	As of December 31,	
	2019	2018
Medicare	15%	20%
Johnson and Johnson Services, Inc.	10%	—%
UnitedHealthcare	9%	11%

Cash Equivalents

Cash equivalents consist of short-term, highly liquid investments with original maturities of three months or less from the date of purchase. Cash equivalents consist of amounts invested in a money market account primarily consisting of U.S. Treasury reserves, and overnight reverse repurchase agreements which are tri-party repurchase agreements and are collateralized by U.S. Treasury and agency securities of at least 102% of the principal amount. In a tri-party repurchase agreement, a third-party custodian bank functions as an independent intermediary to facilitate transfer of cash and holding the collateral on behalf of the underlying investor for the term of the agreement thereby minimizing risk and exposure to both parties. These overnight reverse repurchase agreements are included within cash equivalents due to their high liquidity and relatively low risk.

Restricted Cash

The Company had deposits of $603,000 included in long-term assets as of December 31, 2019 and December 31, 2018, restricted from withdrawal and held by a bank in the form of collateral for an irrevocable standby letter of credit held as security for the lease of the Company's South San Francisco facility.

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 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.

Accounts Receivable and Allowance for Doubtful Accounts for Product Sales

Accounts receivable are stated at the amount management expects to collect from customers based on their outstanding invoices. Management reviews accounts receivable regularly to determine if any receivable will potentially be uncollectible and to estimate the amount of allowance for doubtful accounts necessary to reduce accounts receivable to its estimated net realizable value by analyzing the status of significant past due receivables. Product sales commenced in December 2019 and there was no allowance for doubtful accounts at either December 31, 2019 or 2018.

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 and comprehensive loss in the period realized.

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 5 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. There was no impairment for the years ended December 31, 2019, 2018 or 2017.

Goodwill

Goodwill, derived from the Company's acquisition of Allegro Diagnostics Corp. in September 2014 and the exclusive global diagnostics license to the NanoString nCounter FLEX Analysis System and Prosigna and LymphMark assays in December 2019, 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 done annually on October 31 and 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 for the years ended December 31, 2019, 2018 or 2017.

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

Testing Revenue

The Company commenced recognizing testing revenue in accordance with the provisions of ASC 606, *Revenue from Contracts with Customers*, or ASC 606, starting January 1, 2018. Prior to January 1, 2018, the Company recognized testing revenue in accordance with the provisions of ASC 954-605, *Health Care Entities - Revenue Recognition*, or ASC 954.

Most of the Company's revenue is generated from the provision of testing services. These services are completed upon the delivery of test results to the prescribing physician, at which time the Company bills for the services. The Company recognizes revenue related to billings 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.

The Company adopted ASC 606 on January 1, 2018 using the modified retrospective method, which requires a cumulative catch-up adjustment as if the Company had recognized revenue under ASC 606 from January 1, 2016. Prior to January 1, 2018, the Company recognized revenue in accordance with ASC 954 and recognized revenue for tests delivered on an accrual basis when amounts that will ultimately be realized could be reasonably estimated, and on the cash basis when there was insufficient information to estimate revenue accruals. There was sufficient payment history for the Company to substantially accrue all revenue upon delivery of test results starting July 1, 2016 and the Company continued to recognize revenue in 2017 upon cash receipt for unaccrued tests that were delivered prior to July 1, 2016.

Testing revenue recognized for the years ended December 31, 2019, 2018 and 2017 was as follows (in thousands of dollars):

	Year Ended December 31,					
	2019		2018		2017	
Testing revenue recognized on the accrual basis	$ 107,355	100%	$ 91,058	100%	$ 69,274	96%
Testing revenue recognized on the cash basis	—	—%	—	—%	2,679	4%
Total	$ 107,355	100%	$ 91,058	100%	$ 71,953	100%

As noted above, on July 1, 2016 the Company began recognizing testing revenue from substantially all its tests on the accrual basis of accounting at an amount equal to management's best estimate of the cash to ultimately be collected. For tests delivered prior to July 1, 2016, substantially all the related cash had been collected by December 31, 2017. Thus, at January 1, 2018, the cumulative impact of adopting ASC 606 was not material and no adjustment was recorded. Since the Company commenced recognizing revenue from substantially all of its tests on the accrual basis of accounting commencing on July 1, 2016, and continued to do so after the adoption of ASC 606, the adoption of ASC 606 did not have a material impact on the Company's statement of operations for the year ended December 31, 2019.

During 2019, the Company changed its testing revenue estimates due to actual and anticipated cash collections for tests delivered in 2018 or prior years and recognized additional revenue of $1.6 million, which resulted in a decrease in the Company's loss from operations of $1.6 million and a decrease in loss per share of $0.04 for the year ended December 31, 2019.

During 2018, the Company changed its testing revenue estimates due to actual and anticipated cash collections for tests delivered in 2017 or prior years and recognized additional revenue of $1.4 million, which resulted in a decrease in the Company's loss from operations of $1.4 million and a decrease in loss per share of $0.04 for the year ended December 31, 2018.

Product Revenue

The Company began recognizing product revenue in December 2019, when the Company executed an agreement with NanoString for the exclusive global license to the nCounter platform for diagnostic use. More details on this agreement are in Note 4 - Business Combination.

Product revenue from instruments, consumables and in vitro diagnostic kits is recognized generally upon shipment or when the instrument is ready for use by the end customer, which is when title of the product has been transferred to the customer. 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 transferred control of a product to the customer, meaning the customer has the ability to use and obtain the benefit of the product. The Company recognizes 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 the Company's customers and included in product revenue. Revenues are presented net of the taxes that are collected from customers and remitted to governmental authorities. There was no revenue from instrument sales for the years ended December 31, 2019, 2018 or 2017.

Biopharmaceutical and Collaboration Revenue

From time to time, the Company enters into arrangements for research and development and/or commercialization services. Such arrangements may require the Company to deliver various rights, services and/or samples, including intellectual property rights/licenses, R&D services, and/or commercialization services. The underlying terms of these arrangements generally provide for consideration to the Company in the form of nonrefundable upfront license fees, development and commercial performance milestone payments, royalty payments, and/or profit sharing.

In arrangements involving more than one performance obligation, each required performance obligation 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 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 of the related goods is transferred or services are performed. 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, the Company utilizes the sales and usage-based royalty exception in arrangements that resulted from the license of intellectual property, recognizing revenues generated from royalties or profit sharing as the underlying sales occur.

Collaborative Arrangements

The Company enters into collaborative arrangements with partners that fall under the scope of ASC Topic 808, *Collaborative Arrangements* (“ASC 808”). While these arrangements are in the scope of ASC 808, the Company may analogize to ASC 606 for some aspects of these arrangements. The Company analogizes to ASC 606 for certain activities within the collaborative arrangement for the delivery of a good or service (i.e., a unit of account) that is part of its ongoing major or central operations.

The terms of the Company’s collaborative arrangements typically include one or more of the following: (i) up-front fees; (ii) milestone payments related to the achievement of development, regulatory, or commercial goals; and (iii) royalties on net sales

of licensed products. Each of these payments may result in collaboration revenues or an offset against research and development expense.

Net sales of data or other services to our customers are classified under biopharmaceutical revenue and collaboration revenue, such as milestones, are classified under collaboration revenue in our consolidated statements of operations and comprehensive loss.

As part of the accounting for these arrangements, the Company must 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. Generally, the estimation of the stand-alone selling price may include such estimates as independent evidence of market price, forecasted revenues or costs, development timelines, discount rates, and probabilities of technical and regulatory success. The Company evaluates each performance obligation to determine if they 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. 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 (e.g., milestone payments) must be evaluated to determine if it is constrained and, therefore, excluded from the transaction price.

Up-front Fees: If a license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenues from the transaction price allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. 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.

Milestone Payments: 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 using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the Company's or the collaborative partner'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 its or the collaborative partner'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 collaboration revenues and earnings in the period of adjustment. Revisions to the Company's estimate of the transaction price may also result in negative collaboration revenues and earnings in the period of adjustment.

Services Agreement with Loxo Oncology

On April 9, 2018, the Company entered into an agreement with Loxo Oncology, Inc. ("Loxo") whereby the Company agreed to provide certain tissue samples and other services in exchange for agreed-upon fees. During the quarter ended June 30, 2018, the Company recognized $450,000 of revenue upon deliveries of tissue samples and the Company received $500,000 for other services, which was recognized ratably during the quarters ended September 30 and December 31, 2018 as the services were performed. Thereafter, the Company expects to receive approximately $250,000 per quarter as services are performed and may also recognize revenue related to the deliveries of additional tissue samples as long as the agreement is not terminated. The agreement has a one-year term with an automatic renewal of one year and Loxo may terminate the agreement at any time with at least 90 days' notice. As of December 31, 2019, the agreement had not been terminated. The Company evaluated the accounting for this agreement under ASC 606 and concluded that the performance obligations thereunder are the deliveries of tissue samples and performance of services, both of which are distinct. For the year ended December 31, 2019, the Company recognized revenue of $90,000 for deliveries of tissue samples and $1,000,000 for the performance of services and is classified under biopharmaceutical revenue in the Consolidated Statement of Operations and Comprehensive Loss. There was no deferred revenue related to this agreement at December 31, 2019.

Diagnostic Development Agreement with Johnson & Johnson

On December 28, 2018, the Company entered into a diagnostics development agreement with Johnson and Johnson Services, Inc. ("JJSI") (i) to cooperate on a program to enable the Company to use JJSI samples and clinical data to develop a next generation

bronchial genomic classifier diagnostic for lung cancer diagnosis ("Percepta v.2") and a nasal genomic classifier diagnostic for lung cancer ("NasaRISK") and (ii) for JJSI to use Veracyte data generated in two Veracyte development programs for therapeutic purposes and for purposes of developing a companion diagnostic product used in conjunction with a JJSI therapeutic. The Company granted a license to JJSI with the right to use data and under the Company's intellectual property rights for JJSI's therapeutic purposes, including the development and commercialization of a companion diagnostic for its products, from the Percepta v.2 and NasaRISK programs. The license granted to JJSI is not distinct from other performance obligations as JJSI receives benefit only when other performance obligations are met.

Under the terms of the agreement, the Company will provide data from its RNA whole-transcriptome sequencing platform to JJSI in exchange for $7.0 million in payments from JJSI. The Company is also entitled to additional payments from JJSI of up to $13.0 million, conditioned upon the achievement of certain milestones relating to the development and reimbursement of Percepta v.2 and NasaRISK. For a period of ten years commencing with the first commercial sale of Percepta v.2 and NasaRISK, respectively, the Company will make payments to JJSI of one percent of net cash collections for Percepta v.2 and in the low-single digits of net cash collections for NasaRISK, depending on the number and timing of JJSI samples and associated clinical data the Company receives from JJSI.

The JJSI agreement is considered to be within the scope of ASC 808, as the parties are active participants and exposed to the risks and rewards of the collaborative activity. The Company evaluated the terms of the JJSI agreement and has analogized to ASC 606 for the delivery of data from its RNA whole-transcriptome sequencing platform to JJSI under the collaborative arrangement, which the Company believes is a distinct service for which JJSI meets the definition of a customer. Using the concepts of ASC 606, the Company has identified the delivery of data as its only performance obligation. The Company further determined that the transaction price under the arrangement was the $7.0 million in payments which was allocated to the obligation to deliver data. The $13.0 million in future potential payments is considered variable consideration because the Company determined that the potential payments are contingent upon regulatory and commercialization milestones that are uncertain to occur and, as such, were not included in the transaction price, and will be recognized accordingly as each potential payment becomes probable.

The Company recognized revenue of $7.0 million and $4.0 million during 2019 for the provision of data and fulfillment of obligations relating to Percepta v.2 and NasaRISK development milestones, respectively. This revenue is classified under biopharmaceutical revenue and collaboration revenue, respectively, in the consolidated statement of operations and comprehensive loss. Accounts receivable from JJSI was $2.0 million at December 31, 2019. The cost of biopharmaceutical revenue recognized under the agreement with JJSI is not significant and recorded in research and development in the statement of operations and comprehensive loss. There was no deferred revenue related to this agreement at December 31, 2019.

Collaboration Agreement with AstraZeneca Group

On December 23, 2019, the Company entered into an agreement with Acerta Pharma B.V. ("Acerta"), a member of AstraZeneca Group whereby the Company agreed to provide genomic information that will support Acerta's development of oncology therapeutics. Acerta will reimburse the Company for certain development costs and pay milestones to the Company for the achievement of development milestones. As of December 31, 2019, there was no performance of obligations under the agreement or consideration paid. The agreement will be accounted for in accordance with the policy on collaborative arrangements, as mentioned in this footnote.

Cost of Testing Revenue

The components of our cost of testing services are laboratory expenses, sample collection expenses, compensation expense, license fees and royalties, depreciation and amortization, 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 consumables from third-party contract manufacturers, installation, warranty, service and packaging and delivery costs. In addition, cost of product includes royalty costs for licensed technologies included in the Company's products and labor expenses. Cost of product revenue for instruments and

consumables 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.

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. These expenses consist of compensation expenses, direct research and development expenses such as prototype materials, 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.

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 is measured based on the grant-date fair value of the award. The fair value of each employee stock option is estimated on the date of grant using the Black-Scholes option-pricing model. Stock-based compensation expense for stock units 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 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 required to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

Following the adoption of ASU No. 2018-07, *Compensation - Stock Compensation (Topic 718): Improvements to Nonemployee Share Based Payment Accounting* by the Company on October 1, 2018, stock-based compensation expense for equity instruments issued to non-employees is also measured based on the grant-date fair value of the awards using the Black-Scholes option-pricing model. Prior to this, the fair value of such awards was subject to re-measurement as the underlying equity awards vest.

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, restricted stock units and shares subject to purchase under our 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.

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. Substantially all the Company's revenue for the years ended December 31, 2019, 2018 and 2017 was derived in the United States. All of the Company's long-lived assets were located in the United States as of December 31, 2019 and 2018.

Recent Accounting Pronouncements

In February 2016, the FASB issued ASU No. 2016-2, *Leases (Topic 842)*. This ASU is aimed at making leasing activities more transparent and comparable, and requires substantially all leases be recognized by lessees on their balance sheet as a right-of-use asset and corresponding lease liability, including leases currently accounted for as operating leases. The ASU was effective for interim and annual periods beginning after December 15, 2018. Additionally, the FASB issued ASU No. 2018-11, *Leases (Topic 842): Targeted Improvements*, which offers an additional transition method whereby entities may apply the new leases standard at the adoption date and recognize a cumulative-effect adjustment to the opening balance of retained earnings rather than application of the new leases standard at the beginning of the earliest period presented in the financial statements. The Company elected this transition method and adopted ASC 842 on January 1, 2019 and as a result, recorded operating lease right-of-use ("ROU") assets of $9.8 million, including offsetting deferred rent of $4.3 million, along with the associated operating lease liabilities of $14.1 million. On January 1, 2019, the Company had finance lease ROU assets of $0.8 million and associated finance lease liabilities of $0.3 million for leases classified as finance leases prior to the adoption of ASC 842. The adoption of ASC 842 had an immaterial impact on the Company's consolidated statement of operations and comprehensive loss, consolidated statement of stockholders' equity and consolidated statement of cash flows for the year ended December 31, 2019. In addition, the Company elected the package of practical expedients permitted under the transition guidance within the new standard which allowed it to carry forward the historical lease classification. Additional information and disclosures required by this new standard are contained in Note 7, Commitments and Contingencies.

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments-Credit Losses: Measurement of Credit Losses on Financial Instruments*. This ASU requires measurement and recognition of expected credit losses for financial assets. This guidance will become effective for the Company beginning January 1, 2020 with early adoption permitted. The Company does not expect to have a material impact on its financial statements and related disclosures from the adoption of this guidance.

In November 2018, the FASB issued ASU No. 2018-18, *Collaborative Arrangements (Topic 808)*. Under this ASU, transactions in collaborative arrangements are to be accounted for under ASC 606 if the counterparty is a customer for a good or service (or bundle of goods and services) that is a distinct unit of account. Also, entities are precluded from presenting consideration from transactions with a counterparty that is not a customer together with revenue recognized from ASC 606. This ASU is effective for all interim and annual reporting periods beginning on or after December 15, 2019, with early adoption permitted. The Company adopted this ASU in 2019 with no cumulative-effect adjustments or retrospective impact.

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, 2019, 2018 and 2017 because their inclusion would be anti-dilutive:

	Year Ended December 31,		
	2019	2018	2017
Shares of common stock subject to outstanding options	5,394,944	5,998,163	6,163,734
Employee stock purchase plan	26,124	34,869	34,559
Restricted stock units	712,122	384,691	63,425
Total common stock equivalents	6,133,190	6,417,723	6,261,718

4. Business Combination

Exclusive License to NanoString Diagnostics Platform

On December 3, 2019, the Company executed an agreement with NanoString for the exclusive global diagnostics license to the nCounter FLEX Analysis System, the Prosigna breast cancer prognostic gene signature assay, and the LymphMark lymphoma subtyping assay. The strategic transaction positions the Company to expand its genomic diagnostics business globally, with the ability to deliver its advanced genomic tests to physicians and their patients via hospital and clinical laboratories throughout the European Union and other parts of the world. The Company has accounted for this agreement under Accounting Standards Codification 805, *Business Combinations*. 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 the commercial launch of Veracyte diagnostic tests for use on the platform. This contingency was valued at $6.1 million as of the acquisition date, recorded as a liability, and will be remeasured to fair value at each reporting date until the contingent consideration is settled.

Assets acquired are recorded based on valuations derived from estimated fair value assessments and assumptions used by the Company. While the Company believes that its estimates and assumptions underlying the valuations are reasonable, different estimates and assumptions could result in different valuations assigned to the individual assets acquired and the resulting amount of goodwill. The following table summarizes the fair values of assets acquired and liabilities assumed at the date of acquisition (in thousands):

Prosigna product technology	$	4,120
Prosigna customer relationships		2,430
nCounter FLEX Dx license		46,880
LymphMark product technology		990
Total identifiable intangible assets acquired		54,420
Goodwill		1,668
Net assets acquired	$	56,088

Identifiable acquisition-related intangibles included in the above table are finite-lived and are being amortized on a straight-line basis over their estimated lives, which approximates the pattern in which the economic benefits of the intangible assets are expected to be realized, as follows:

	Estimated Useful life (In Years)
Prosigna product technology	15
Prosigna customer relationships	5
nCounter FLEX Dx license	15
LymphMark product technology	7

Goodwill represents the excess of the purchase price over the fair value of the net tangible and intangible assets acquired. This acquisition includes $1.7 million of goodwill which the Company believes consists principally of the organized workforce

that will help the Company execute its strategic plans in relation to the assets acquired. In accordance with ASC 350, goodwill will not be amortized but will be tested for impairment at least annually. As of December 31, 2019, goodwill is not deductible for tax purposes, however, if contingent consideration is paid at a future date, the portions of contingent consideration paid and allocated to the intangible assets for tax purposes will be tax deductible. The accounting for this acquisition is preliminary and will be finalized upon completion of the analysis of certain contracts acquired and executed as part of this acquisition along with the impact on goodwill, should there be any.

The unaudited pro forma financial information in the table below summarizes the combined revenue for the Company and acquired business from NanoString as though the acquisition had been executed as of January 1, 2018. The pro forma amounts have been adjusted in the table below. NanoString's historical books and records did not contain the operating expense information to prepare the financial disclosures required in the pro forma table below. Thus, the pro forma financial disclosures are limited to revenue only. The unaudited pro forma revenue information is for informational purposes only and is not necessarily indicative of the revenue that would have been achieved if the acquisition had taken place as of January 1, 2018 (in thousands):

	Year Ended December 31,	
	2019	2018
Product revenue	$ 11,040	$ 11,482

5. Balance Sheet Components

Property and Equipment, Net

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

	December 31,	
	2019	2018
Leasehold improvements	$ 5,926	$ 5,825
Laboratory equipment	9,655	8,895
Computer equipment	1,709	1,615
Software, including software developed for internal use	3,226	2,450
Furniture and fixtures	1,482	1,435
Construction-in-process	1,015	726
Total property and equipment, at cost	23,013	20,946
Accumulated depreciation and amortization	(14,080)	(12,006)
Total property and equipment, net	$ 8,933	$ 8,940

Depreciation and amortization expense was $2.7 million, $2.9 million and $2.8 million for the years ended December 31, 2019, 2018 and 2017, respectively.

The Company had a capital lease for laboratory equipment that went into service in 2017. The lease was paid off in 2019 and the cost of $1.2 million was included in Property and Equipment as of December 31, 2019. The laboratory equipment had accumulated depreciation of $600,000 and $367,000 at December 31, 2019 and 2018, respectively and depreciation of $233,000, $232,000, and $135,000 for the years ended December 31, 2019, 2018 and 2017, respectively.

Finite-lived Intangible Assets, Net

Finite-live intangible assets consisted of the following (in thousands of dollars):

	December 31, 2019			December 31, 2018			Weighted Average Amortization Period (Years)
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	
Percepta product technology	$ 16,000	$ (5,067)	$10,933	$16,000	$ (4,000)	$12,000	15
Prosigna product technology	4,120	(17)	4,103	—	—	—	15
Prosigna customer relationships	2,430	(42)	2,388	—	—	—	5
nCounter FLEX Dx license	46,880	(263)	46,617	—	—	—	15
LymphMark product technology	990	(12)	978	—	—	—	7
Total	$ 70,420	$ (5,401)	$65,019	$16,000	$ (4,000)	$12,000	14.5

Amortization of the Percepta product technology, which was acquired from the acquisition of Allegro in September 2014, began in April 2015 when research and development activities were deemed to be completed and is recognized on a straight-line basis. Amortization of the Prosigna product technology, Prosigna customer relationships, nCounter FLEX Dx license and LymphMark product technology, which were acquired under an agreement with NanoString, see Note 4 - Business Combination, began in December 2019 and is recognized on a straight-line basis. Amortization of $1.4 million, $1.1 million and $1.1 million was recognized for the years ended December 31, 2019, 2018, and 2017, respectively.

The estimated future aggregate amortization expense as of December 31, 2019 is as follows (in thousands of dollars):

Year Ending December 31,	Amounts
2020	$ 5,095
2021	5,094
2022	5,094
2023	5,094
2024	5,054
Thereafter	39,588
Total	$ 65,019

Accrued Liabilities

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

	December 31,	
	2019	2018
Accrued compensation expense	$ 10,100	$ 6,412
Accrued other	3,634	2,774
Total accrued liabilities	$ 13,734	$ 9,186

6. Fair Value Measurements

The Company records its financial assets and liabilities at fair value. 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 carrying value of the Company's debt approximates its fair value because the interest rate approximates market rates that the Company could obtain for debt with similar terms. The fair value of the Company's debt is estimated using the net present value of the payments, discounted at an interest rate that is consistent with market interest rates, which is a Level II input. The accounting guidance for fair value provides a framework for measuring fair value, clarifies the definition of fair value, and expands disclosures regarding fair value measurements. 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 fair value of the Company's financial assets includes money market funds, overnight reverse repurchase agreements and a deposit for the lease of the Company's South San Francisco facility. Money market funds, included in cash and cash equivalents in the accompanying consolidated balance sheets, was $57.6 million and $76.6 million as of December 31, 2019 and 2018, respectively, and are Level I assets as described above. Overnight reverse repurchase agreements, included in cash and cash equivalents in the accompanying consolidated balance sheets, were $100.0 million and zero as of December 31, 2019 and 2018, respectively, and are Level II assets as described above. There were no unrealized gains or losses from overnight reverse repurchase agreements at December 31, 2019 and 2018. The deposit for the lease, included in restricted cash in the accompanying consolidated balance sheets, was $603,000 as of December 31, 2019 and 2018, and is a Level I asset as described above.

The contingent consideration in Note 4, Business Combination, associated with the agreement with NanoString on December 3, 2019, is a Level III financial liability. As of December 31, 2019, the contingent consideration of $6.1 million is dependent on the achievement of certain milestones and is payable in cash of up to $10.0 million. Estimation of the fair value of the contingent consideration is based 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 value of the contingent consideration that are not readily apparent from other sources. Actual results could differ from those estimates and assumptions. Changes to the forecasts for the achievement of milestones can significantly affect the estimated fair value of the contingent consideration. There has been no change to the estimated fair value of the contingent consideration from the date of the agreement with NanoString to December 31, 2019 and the Company will assess the fair value of the contingent liability on a quarterly basis.

7. Commitments and Contingencies

Operating Leases

The Company leases its headquarters and laboratory facilities in South San Francisco, California under a non-cancelable lease agreement for approximately 59,000 square feet. The lease began in June 2015 and ends in March 2026 and contains extension of lease term and expansion options. In February 2017, the Company relinquished certain expansion rights for a nominal fee. The Company had deposits of $603,000 included in long-term assets as of December 31, 2019 and 2018, restricted from withdrawal and held by a bank in the form of collateral for an irrevocable standby letter of credit held as security for the lease of the South San Francisco facility.

The Company also leases laboratory and office space in Austin, Texas under a lease that expires in January 2029 and includes options for expansion and early termination in 2025. The Company provided a cash security deposit for this lease of $139,000, included in other assets in the Company's balance sheets as of December 31, 2019 and 2018.

The Company determined its operating lease liabilities for the two operating leases mentioned above using a discount rate of 7.53% based on the rate that the Company would have to pay to borrow on a collateralized basis for a similar lease an amount equal to the lease payments in a similar economic environment. Operating lease liabilities along with the associated right-of-use assets as of December 31, 2019 are disclosed in the accompanying consolidated balance sheets. After the adoption of ASC 842, the Company classified its deferred rent for tenant improvements with its operating lease right-of-use assets on the consolidated balance sheets.

Future minimum lease payments under non-cancelable operating leases as of December 31, 2019 are as follows (in thousands of dollars):

Year Ending December 31,	Amounts
2020	$ 2,332
2021	2,401
2022	2,472
2023	2,543
2024	2,614
Thereafter	4,226
Total future minimum lease payments	16,588
Less: amount representing interest	3,675
Present value of future lease payments	12,913
Less: short-term lease liabilities	1,407
Long-term lease liabilities	$ 11,506

The Company recognizes rent expense on a straight-line basis over the non-cancelable lease period. Rent expense was $1.9 million, $1.9 million, and $1.9 million for the years ended December 31, 2019, 2018 and 2017, respectively.

Supplies Purchase Commitments

The Company had non-cancelable purchase commitments with suppliers to purchase a minimum quantity of supplies for approximately $7.6 million at December 31, 2019.

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 financial statements.

8. Debt

Loan and Security Agreement

On November 3, 2017, the Company entered into a loan and security agreement (the "Loan and Security Agreement") with Silicon Valley Bank. The Loan and Security Agreement allows the Company to borrow up to $35.0 million, with a $25.0 million advance term loan (the "Term Loan Advance") and a revolving line of credit of up to $10.0 million (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. The Company had not drawn on the Revolving Line of Credit as of December 31, 2019. Borrowings under the Loan and Security Agreement mature on October 1, 2022. Amounts may be borrowed and repaid under the Revolving Line of Credit up until the earliest of full repayment or maturity of the Loan and Security Agreement, termination of the Loan and Security Agreement, or October 1, 2022.

The Term Loan Advance bears interest at a variable rate equal to (i) the thirty-day U.S. London Interbank Offer Rate ("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. The average Term Loan Advance interest rate for the year ended December 31, 2019 was 6.70%.

The Company may prepay the outstanding principal amount under the Term Loan Advance plus accrued and unpaid interest and, if the Term Loan Advance is repaid in full, a prepayment premium. The prepayment premium will be (i) $750,000 if prepayment is made prior to November 3, 2018, (ii) $500,000 if the prepayment is made after November 3, 2018 but on or before November 3, 2019, or (iii) $250,000 if the prepayment is made after November 3, 2019. In January 2019 and May 2019, the Company prepaid $12.5 million and $12.4 million, respectively, of the principal amount of the Term Loan Advance. These prepayments did not trigger any prepayment premium because they were partial, not full, repayments of the principal amount.

In addition, a final payment on the Term Loan Advance in the amount of $1.2 million is due upon the earlier of the maturity date of the Term Loan Advance or its payment in full. The Loan and Security Agreement contains customary representations, warranties, and events of default such as a material adverse change in our business, operations or financial condition, as well as affirmative and negative covenants. The negative covenants include, among other provisions, covenants that limit or restrict the Company's ability to incur liens, make investments, incur indebtedness, merge with or acquire other entities, dispose of assets, make dividends or other distributions to holders of its equity interests, engage in any new line of business, or enter into certain transactions with affiliates, in each case subject to certain exceptions. The Company's obligations under the Loan and Security Agreement are secured by substantially all of its assets (excluding intellectual property), subject to certain customary exceptions. The Loan and Security Agreement also requires the Company to achieve certain revenue levels tested quarterly on a trailing twelve-month basis. However, failure to maintain the revenue levels will not be considered a default if the Company maintains liquidity of at least $40.0 million. As of December 31, 2019, the Company was in compliance with the loan covenants.

As of December 31, 2019 and 2018, the net debt obligation for borrowings made under the Loan and Security Agreement was as follows (in thousands of dollars):

	December 31,	
	2019	2018
Debt principal	$ 100	$ 25,000
End-of-term debt obligation	594	365
Unamortized debt issuance costs	—	(83)
Net debt obligation	$ 694	$ 25,282

Future principal and end-of-term debt obligation payments due under the Loan and Security Agreement are $1.3 million in 2022.

The end-of-term debt obligation accretes over the term of the Loan and Security Agreement until maturity and is included in interest expense in the Company's consolidated statement of operations and comprehensive loss.

Credit Agreement

In March 2016, the Company entered into a credit agreement (the "Credit Agreement") with Visium Healthcare Partners, LP ("Visium"). Under the Credit Agreement, two term loans were available to the Company with an aggregate principal amount of up to $40.0 million. The Company drew down the initial $25.0 million term loan (the "Initial Term Loan") on March 30, 2016, of which $5.0 million was used to pay the outstanding balance of the Company's previous long-term debt, which was canceled at that date.

The Term Loans bore interest at a fixed rate of 12.0% per annum and no principal payments were due through March 31, 2020. The Company was obligated to repay the outstanding principal amounts under the Term Loans in eight equal installments during the final two years under the Credit Agreement. Prepayment of the outstanding principal amount under the Term Loans prior to March 31, 2018 was subject to a prepayment premium equal to 24.0% of the outstanding principal balance, less the aggregate amount of all interest payments in cash. For any quarterly interest payment through and including the 16th interest payment date after the Initial Borrowing Date, so long as no event of default had occurred and was then continuing, the Company could have elected to pay interest in cash on the outstanding principal amounts of the Term Loans at a fixed rate of 9.0%, with the remaining 3.0% of the 12.0% interest paid-in-kind by adding such paid-in-kind interest to the outstanding principal amounts of the Term Loans. The Company elected to pay interest in-kind for the quarters ended June 30, 2016 and September 30, 2016, totaling $385,000.

As noted above, upon entering into the Loan and Security Agreement, the Credit Agreement was paid in full and terminated on November 3, 2017, wherein all commitments were terminated, all liens were released and all outstanding principal, interest and fees accrued thereunder were repaid in the aggregate amount of $27.3 million, including a prepayment premium of $1.5 million.

Interest Expense

Interest expense was recognized as follows (in thousands of dollars):

	Year Ended December 31,		
	2019	2018	2017
Nominal debt interest	$ 332	$ 1,568	$ 2,838
Amortization and write-off of debt discount and issuance costs	107	57	472
End-of-term debt obligation interest	229	312	53
Debt prepayment penalty	—	—	1,536
Interest on capital lease	9	26	42
Total	$ 677	$ 1,963	$ 4,941

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, 2019.

As of December 31, 2019 and 2018, the Company had reserved shares of common stock for issuance as follows:

	December 31,	
	2019	2018
Stock options and restricted stock units issued and outstanding	5,562,484	6,235,258
Stock options and restricted stock units available for grant under stock option plans	1,954,804	1,571,658
Common stock available for the Employee Stock Purchase Plan	173,168	309,419
Total	7,690,456	8,116,335

On May 7, 2019, the Company issued and sold 6,325,000 shares of common stock in a registered public offering, including 825,000 shares issued and sold upon the underwriters' exercise in full of their option to purchase additional shares, at a price to the public of $23.25 per share. The Company's net proceeds from the offering were approximately $137.8 million, after deducting underwriting discounts and commissions and offering expenses of $9.2 million.

In July 2018, the Company issued and sold 5,750,000 shares of common stock in a registered public offering, including 750,000 shares issued and sold upon the underwriters' exercise in full of their option to purchase additional shares, at a price to the public of $10.25 per share. The Company's net proceeds from the offering were $55.0 million, after deducting underwriting commissions and offering expenses of $3.9 million.

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 ("ISOs"), non-statutory stock options ("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 ("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, 2019, 1,954,799 shares were available for future issuance under the 2013 Plan.

Pursuant to the 2013 Plan, stock options, restricted shares, stock units, including restricted stock units 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.

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 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 (1/3) 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 will be automatically granted an option to purchase 10,000 shares of common stock, provided that the outside director has served on the Board of Directors for at least six months. Each annual option will vest and become 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 occurs prior to the first anniversary date. The options granted to outside directors will have a per share exercise price equal to 100% of the fair market value of the underlying shares on the date of grant and will become fully vested in the event of a change of 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 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, 2018	1,571,658	6,235,258	$ 7.95	6.95	$ 27,340
Additional shares authorized	1,634,528	—			
Granted - stock options	(969,500)	969,500	21.16		
Granted - restricted stock units	(505,965)	505,965			
Canceled	180,017	(180,017)	9.40		
Exercised	—	(1,846,222)	7.77		
Restricted stock units vested	—	(122,000)			
Tax portion of restricted stock units vested	44,066	—			
Balance—December 31, 2019	1,954,804	5,562,484	$ 10.66	6.97	$ 79,760
Options vested and exercisable—December 31, 2019		2,651,858	$ 8.13	5.90	$ 52,469
Options vested and expected to vest—December 31, 2019		4,442,275	$ 10.48	6.91	$ 77,453

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 $27.92 and $12.58 per share as of December 31, 2019 and 2018, respectively.

The weighted average fair value of options to purchase common stock granted was $11.07, $3.62 and $4.49 for the years ended December 31, 2019, 2018 and 2017, respectively.

The aggregate estimated grant date fair value of employee options to purchase common stock vested during the years ended December 31, 2019, 2018 and 2017 was $4.4 million, $4.1 million and $3.1 million, respectively.

The intrinsic value of stock options exercised was $31.3 million, $4.9 million and $0.7 million for the years ended December 31, 2019, 2018 and 2017, respectively.

The weighted average fair value of restricted stock units granted was $21.90 and $6.17 for the years ended December 31, 2019 and 2018, respectively. The intrinsic value of restricted stock units vested was $2,720,000 and $184,000 for the years ended December 31, 2019 and 2018, respectively.

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.

Stock-based Compensation

The following table summarizes stock-based compensation expense related to stock options, restricted stock units and the ESPP for the years ended December 31, 2019, 2018 and 2017, and are included in the consolidated statements of operations and comprehensive loss as follows (in thousands of dollars):

	Year Ended December 31,		
	2019	2018	2017
Cost of testing revenue	$ 277	$ 130	$ 133
Research and development	1,856	1,018	1,495
Selling and marketing	2,938	1,866	1,899
General and administrative	4,736	2,944	3,090
Total stock-based compensation expense	$ 9,807	$ 5,958	$ 6,617

As of December 31, 2019, the Company had $18.4 million of unrecognized compensation expense related to unvested stock options and restricted stock units, which is expected to be recognized over an estimated weighted-average period of 2.20 years.

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

	Year Ended December 31,		
	2019	2018	2017
Weighted-average volatility	52.90 - 53.40%	50.40 - 52.70%	50.40 - 52.40%
Weighted-average expected term (years)	5.50 - 6.08	5.50 - 6.08	5.50 - 6.08
Risk-free interest rate	1.90 - 2.60%	2.40 - 3.10%	1.80 - 2.33%
Expected dividend yield	—	—	—

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

	Year Ended December 31,		
	2019	2018	2017
Weighted-average volatility	—%	43.60 - 50.50%	50.40 - 51.10%
Weighted-average expected term (years)	—	0.25 - 6.75	6.80 - 7.75
Risk-free interest rate	—%	1.84 - 2.87%	2.16 - 2.37%
Expected dividend yield	—	—	—

There were no non-employee stock options outstanding as of December 31, 2019.

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,		
	2019	2018	2017
Weighted-average volatility	53.38 - 71.77%	42.88 - 47.74%	37.00 - 43.86%
Weighted-average expected term (years)	0.50 - 1.00	0.50 - 1.00	0.50 - 1.00
Risk-free interest rate	1.88 - 2.56%	1.64 - 2.45%	0.65 - 1.22%
Expected dividend yield	—	—	—

11. Thyroid Cytopathology Partners

The Company has an agreement with a specialized pathology practice, Thyroid Cytopathology Partners, ("TCP"), to provide testing services to the Company (the "TCP Agreement"). The TCP Agreement is effective through October 31, 2022, and thereafter 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. Under the TCP Agreement, the Company pays TCP based on a fixed price per test schedule which is reviewed periodically for changes in market pricing, and the TCP Agreement included a clause allowing TCP to sublease a portion of the Company's facility in Austin, Texas. The Company does not have an ownership interest in or provide any form of financial or other support to TCP. The Company previously concluded that TCP represented a variable interest entity as a result of the facility arrangement clause, but that the Company was not the primary beneficiary as it did not have the ability to direct the activities that most significantly impacted TCP's economic performance, and therefore did not consolidate TCP. On February 14, 2019, the TCP Agreement was amended to remove the facility clause. Accordingly, the Company believes TCP was no longer a variable interest entity as of that date.

TCP's portion of rent and related operating expenses reimbursed to the Company for the shared space at the Austin, Texas facility was $11,000, $128,000 and $114,000 for the years ended December 31, 2019, 2018 and 2017 and is included other income, net in the Company's consolidated statements of operations and comprehensive loss.

12. Income Taxes

The Company generated a pretax loss of $12.5 million, $23.0 million and $31.0 million in the United States for the years ended December 31, 2019, 2018 and 2017, respectively. Since inception, the Company has not generated any pretax income or loss outside of the United States. The Company recorded no provision for income taxes during the years ended December 31, 2019, 2018 or 2017.

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,		
	2019	2018	2017
U.S. federal taxes at statutory rate	$ (2,632)	$ (4,825)	$ (10,541)
State tax (net of federal benefit)	(828)	—	15
Non deductible officers' compensation	439	409	—
Stock based compensation - PSU/RSU/NQSQ	628	—	—
Permanent differences	221	285	198
Incentive stock options	(4,994)	(256)	994
Tax credits	(996)	(777)	(588)
Change in valuation allowance	8,162	5,164	(14,552)
Rate differential impact - *Tax Cuts and Jobs Act*	—	—	24,474
Total	$ —	$ —	$ —

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,		
	2019	2018	2017
Deferred tax assets:			
Net operating loss carryforwards	$ 56,506	$ 50,410	$ 47,177
Research and development credits	5,579	4,584	4,034
Stock-based compensation	2,246	1,032	2,068
NanoString intangibles and goodwill	380	—	—
Operating lease liability	3,068	—	—
Accruals and other	2,610	2,918	2,375
Gross deferred tax assets	70,389	58,944	55,654
Valuation allowance	(65,228)	(55,366)	(51,657)
Net deferred tax assets	5,161	3,578	3,997
Deferred tax liabilities:			
Property and equipment	(471)	(695)	(983)
In-process research and development	(2,597)	(2,883)	(3,014)
ROU assets	(2,093)	—	—
Gross deferred tax liabilities	(5,161)	(3,578)	(3,997)
Net deferred tax liabilities	(5,161)	(3,578)	(3,997)
Net deferred taxes	$ —	$ —	$ —

The Company has established a full valuation allowance against its net deferred tax assets due to the uncertainty surrounding realization of such assets. The valuation allowance increased $9.9 million during the year ended December 31, 2019, increased $3.7 million during the year ended December 31, 2018 and decreased $14.3 million during the year ended December 31, 2017.

As of December 31, 2019, the Company had net operating loss carryforwards of approximately $236.9 million, $58.3 million and $45.2 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 2026 while for state purposes, the net operating losses began to expire in 2028.

As of December 31, 2019, the Company had net research and development credit carryforwards of approximately $4.9 million and $4.7 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 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, 2019, the Company had unrecognized tax benefits of $3.3 million, none of which would currently 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, 2019 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,		
	2019	2018	2017
Unrecognized tax benefits, beginning of period	$ 2,799	$ 2,523	$ 2,222
Gross increases—tax position in prior period	—	—	—
Gross decreases—tax position in prior period	—	(97)	—
Gross increases—current period tax position	479	373	301
Lapse of statute of limitations	—	—	—
Unrecognized tax benefits, end of period	$ 3,278	$ 2,799	$ 2,523

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, 2019.

The Company's major tax jurisdictions are the United States 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.

13. 401(k) Plan

The Company sponsors a 401(k) defined contribution plan covering all employees. Employer contributions to the plan were $509,000, $448,000 and $324,000 for the years ended December 31, 2019, 2018, and 2017, respectively.

14. Selected Quarterly Financial Data (Unaudited)

The following table presents selected unaudited financial data for each of the eight quarters in the two-year period ended December 31, 2019. The Company believes this information reflects all recurring adjustments necessary to fairly present this information when read in conjunction with the Company's financial statements and the related notes. Net loss per common share, basic and diluted, for the four quarters of each fiscal year may not sum to the total for the fiscal year because of the different number of shares outstanding during each period. The results of operations for any quarter are not necessarily indicative of the results to be expected for any future period (in thousands of dollars, except for share and per share data):

Quarter Ended	March 31	June 30	September 30	December 31
2019:				
Revenue	$ 29,529	$ 30,136	$ 30,973	$ 29,730
Net loss	(1,917)	(2,494)	(730)	(7,458)
Net loss per common share, basic and diluted	(0.05)	(0.05)	(0.02)	(0.15)
Shares used to compute net loss per common share, basic and diluted	41,168,593	45,586,081	48,588,296	49,095,703
2018:				
Revenue	$ 20,041	$ 22,751	$ 23,466	$ 25,750
Net loss	(9,177)	(6,248)	(4,469)	(3,105)
Net loss per common share, basic and diluted	(0.27)	(0.18)	(0.12)	(0.08)
Shares used to compute net loss per common share, basic and diluted	34,271,254	34,314,234	38,620,036	40,731,334

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 such term is defined in Rule 13a-15(e) under the Exchange Act, that are designed to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is 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. In designing and evaluating our disclosure controls and procedures, management recognized that disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the disclosure controls and procedures are met. Our disclosure controls and procedures have been designed to meet reasonable assurance standards. Additionally, in designing disclosure controls and procedures, our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible disclosure controls and procedures. The design of any disclosure controls and procedures also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions.

Based on their evaluation as of the end of the period covered by this Annual Report on Form 10-K, our Chief Executive Officer and Chief Financial Officer have concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rule 13a-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, 2019 using the criteria established in *Internal Control Integrated Framework* ("2013 Framework") issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO").

Based on our evaluation using those criteria, our management has concluded that, as of December 31, 2019, our internal control over financial reporting was effective 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.

In accordance with guidance issued by the Securities and Exchange Commission, companies are permitted to exclude acquisitions from their final assessment of internal control over financial reporting for the first fiscal year in which the acquisition occurred. Our management's evaluation of internal control over financial reporting excluded the internal control activities of the diagnostics business which we acquired from NanoString Technologies, Inc. on December 3, 2019, as discussed in Note 4 to our consolidated financial statements. We have included the financial results of the acquired business in the consolidated financial statements from the date of acquisition. Revenue from the acquired business comprised less than 1% of our total revenue for the year ended December 31, 2019 and approximately 5% of our accounts receivable as of December 31, 2019.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as such term is defined in Rule 13a-15(f) under the Exchange Act) identified in connection with the evaluation identified above that occurred during the quarter ended December 31, 2019 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, 2019, 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, 2019, based on the COSO criteria.

As indicated in the accompanying Management's Report on Internal Control over Financial Reporting, management's assessment of and conclusion on the effectiveness of internal control over financial reporting did not include the internal control activities of the diagnostics business acquired from NanoString Technologies, Inc. on December 3, 2019, which is included in the 2019 consolidated financial statements of the Company and constituted less than 1% of the Company's total revenue, for the year ended December 31, 2019, and approximately 5% of its accounts receivable as of December 31, 2019. Our audit of internal control over financial reporting of the Company also did not include an evaluation of the internal control over financial reporting of the diagnostic business acquired from NanoString Technologies, Inc.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the 2019 consolidated financial statements of the Company and our report dated February 25, 2020 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

Redwood City, California
February 25, 2020

ITEM 9B. OTHER INFORMATION

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, 2019 in connection with the solicitation of proxies for our 2020 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 (to be updated)

Exhibit Number	Description	Incorporated by Reference				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
3.1	Restated Certificate of Incorporation of the Registrant	8-K	001-36156	3.1	11/8/2013	
3.2	Restated Bylaws of the Registrant	8-K	001-36156	3.2	11/8/2013	
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					X
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#	Employee Stock Purchase Plan	10-Q	001-36156	10.1	8/13/2015	
10.5	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	
10.6	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	
10.7	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	

		Incorporated by Reference				
10.8	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	
10.9	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	
10.10	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	
10.11#	Employment Agreement, dated as of February 15, 2008, between Bonnie Anderson and the Registrant	S-1	333-191282	10.10	9/20/2013	
10.12#	Amendment to Bonnie Anderson Employment Agreement, dated as of December 22, 2008, between Bonnie Anderson and the Registrant	S-1	333-191282	10.11	9/20/2013	
10.13#	Amendment No. 2 to Bonnie Anderson Employment Agreement, effective as of March 11, 2009, between Bonnie Anderson and the Registrant	S-1	333-191282	10.12	9/20/2013	
10.14#	Services and Separation Agreement, effective April 22, 2019, between Christopher M. Hall and the Registrant	10-Q	001-36156	10.1	7/30/2019	
10.15#	Offer Letter dated as of March 5, 2008 with Giulia Kennedy					X
10.16#	Offer Letter dated as of August 9, 2011 with John Hanna					X
10.17†	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	
10.18	Loan and Security Agreement dated as of November 3, 2017 between Silicon Valley Bank and the Registrant	10-K	001-36156	10.19	2/27/2018	
10.19#	Offer Letter dated as of November 17, 2016 with Keith Kennedy	10-K	001-36156	10.20	2/27/2018	
10.20	Form of Performance Stock Unit	10-Q	001-36156	10.1	5/1/2018	
10.21#	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	
10.22#	Amended and Restated Change in Control and Severance Agreement, effective July 1, 2019 between Keith Kennedy and the Registrant	10-Q	001-36156	10.3	7/30/2019	
10.23#	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	
10.24#	Amended and Restated Change in Control and Severance Agreement, effective July 1, 2019 between John Hanna and the Registrant	10-Q	001-36156	10.5	7/30/2019	
10.25†	Diagnostic Development Agreement, dated December 28, 2018, between Johnson & Johnson Services, Inc. and the Registrant	10-K	001-36156	10.22	2/25/2019	

		Incorporated by Reference				
10.26†	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	
10.27	Registration Rights Schedule, dated December 3, 2019	8-K	001-36156	4.1	12/3/2019	
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	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/ BONNIE H. ANDERSON

Bonnie H. Anderson
Chairman and Chief Executive Officer

Date: February 25, 2020

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENT, that each person whose signature appears below constitutes and appoints Bonnie H. Anderson and Keith Kennedy, and each of them, his 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/ BONNIE H. ANDERSON Bonnie H. Anderson	Chairman and Chief Executive Officer (Principal Executive Officer)	February 25, 2020
/s/ KEITH KENNEDY Keith Kennedy	Chief Financial Officer (Principal Financial Officer)	February 25, 2020
/s/ JOHN L. BISHOP John L. Bishop	Lead Independent Director	February 25, 2020
/s/ FRED E. COHEN, M.D., D.PHIL. Fred E. Cohen, M.D., D.Phil.	Director	February 25, 2020
/s/ KARIN EASTHAM Karin Eastham	Director	February 25, 2020
/s/ ROBERT S. EPSTEIN Robert S. Epstein	Director	February 25, 2020
/s/ KEVIN K. GORDON Kevin K. Gordon	Director	February 25, 2020
/s/ EVAN JONES Evan Jones	Director	February 25, 2020
/s/ TINA S. NOVA, PH.D. Tina S. Nova, Ph.D.	Director	February 25, 2020