VERACYTE, INC.
Form 10-K
February 25, 2019
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-K

(Mark One)
ý ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2018 or
o 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	Name of Each Exchange on Which Registered
Common Stock, par value $0.001 per share	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 o No ý

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

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 ý No o

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 ý No o

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ý

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	o	Accelerated filer	ý
Non-accelerated filer	o	Smaller reporting company	ý
		Emerging growth company	o

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. o

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes o No ý

As of June 30, 2018, the aggregate market value of common stock held by non-affiliates of the registrant was approximately $291.6 million, 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 21, 2019 was 41,108,741.

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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 2019 Annual Meeting of Stockholders to be held on or about June 11, 2019 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, 2018.
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PART I

ITEM 1. BUSINESS

This report contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. When used in this report, the words "expects," "anticipates," "intends," "estimates," "plans," "believes," "continuing," "ongoing," and similar expressions are intended to identify forward-looking statements. These are statements that relate to future events and include, but are not limited to, the factors that may impact our financial results; our expectations regarding revenue; our expectations with respect to our future research and development, general and administrative and selling and marketing expenses and our anticipated uses of our funds; our beliefs with respect to the optimization of our processes for the analysis of ribonucleic acid, or RNA, samples; 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 agreement with TCP, and on other 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, Know by Design, the Veracyte logo and the Afirma logo 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 foundational science is enabling us to serve this critical medical need and

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expand our offerings further along the clinical continuum of care so that we can advance early detection of disease and inform treatment decisions at the same time as diagnosis.

We have three leading, first-to-market tests that are transforming care in large, untapped clinical areas-thyroid cancer, lung cancer and idiopathic pulmonary fibrosis, or IPF. We develop tests that answer specific clinical questions, providing patients and physicians with a clear path forward without the need for risky or costly procedures that are often unnecessary. Our RNA whole-transcriptome sequencing platform enables us to maximize the amount of genomic content that we extract from each nonsurgical patient sample. We utilize our machine learning expertise to develop genomic classifiers that provide actionable information at the time of diagnosis. At the same time, our approach enables us to provide information that can guide treatment decisions such as surgery strategy and therapy selection.

We design our tests for each clinical indication to improve diagnostic 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.

For each clinical indication, our approach to product development is to identify the clinical question and the inefficiency that we can solve with genomics. We aim to create a new clinical paradigm that benefits patients through better outcomes. We do this by partnering with physicians to ensure we provide them with clinically relevant data that help them make better treatment decisions. We design 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, and to help advance precision medicine:

- Unique Biorepositories - When we develop new tests, we build extensive, robust biorepositories of patient-consented samples and 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 typically assemble hundreds of samples that are paired with clinical truth labels, as well as a range of clinical, pathology and/or imaging data. 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 genes and gene features in 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 - Our genomic tests serve largely untapped markets where they are changing the diagnostic paradigm for patients. Further, because every sample is run on our RNA whole-transcriptome sequencing platform, we can provide physicians with gene alteration information that may help guide surgical strategy or therapy selection.

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To date, we have commercialized three genomic tests that are changing disease diagnosis: the Afirma Genomic Sequencing Classifier, or GSC, and its predecessor, the Afirma Gene Expression Classifier, or GEC, for thyroid cancer; the Percepta Bronchial Genomic Classifier for lung cancer; and the Envisia Genomic Classifier for IPF. In 2018, we unveiled our 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. Collectively, we believe these three tests address a $2 billion global market opportunity.

We announced in 2018 that we intend to run all of our diagnostic classifiers and Xpression Atlas tests on the same RNA whole-transcriptome sequencing platform, using what we call our Unified Assay, by the middle of 2019. We believe this will give us a comprehensive set of genomic data with which to answer a wide range of clinical questions as accurately as possible - at the time of diagnosis using nonsurgical patient samples.

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 is expected to build 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.

The collaboration is expected to accelerate two of our key lung cancer programs, including the development of the first non-invasive nasal swab test for early lung cancer detection as well as the commercialization of the Percepta classifier on our RNA whole-transcriptome sequencing platform. With the acceleration of our product pipeline, we believe this collaboration expands our addressable lung cancer diagnostic market to a more than $30 billion global opportunity.

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 38 clinical studies covering our products have been published, including two landmark clinical validation papers published in The New England Journal of Medicine for the Afirma and Percepta classifiers, respectively. We continue to build upon our extensive library of clinical evidence.

We also expect to continue expanding our offerings in thyroid cancer, lung cancer and interstitial lung diseases such as IPF, 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 and address clinical questions in early detection, diagnosis, staging/prognosis, therapy selection/surgery and disease monitoring across the aforementioned indications.

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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 Afirma classifier is now covered by every major health plan in the United States, which collectively insure more than 275 million people, for use in thyroid cancer diagnosis. We are now contracted as an in-network service provider to health plans representing over 200 million people in the United States. Our second commercial product, the Percepta classifier, is the first genomic test to gain Medicare coverage for improved lung cancer screening and diagnosis, making it a covered benefit for more than 60 million people. In August 2018, the Centers for Medicaid and Medicare Services, or CMS, issued a draft coverage policy for the Envisia Classifier. We expect that the coverage policy will become final in early 2019. We believe that our in-network status with private payers will facilitate private insurer reimbursement for our Percepta and Envisia classifiers.

Patients typically access our tests through their physician during the diagnostic process. All of our testing services are made available through our clinical reference laboratories located in San Francisco, California and Austin, Texas.

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 2018 Financial Results

For the three- and twelve-month periods ended December 31, 2018, compared to the prior year:

- Revenue was $25.8 million and $92.0 million, respectively, an increase of 31% and 28%;
- Gross Margin was 66% and 64%, respectively, an increase of 6% and 3%;
- Operating Expenses, Excluding Cost of Revenue, were $20.1 million and $81.2 million, respectively, an increase of 12% and 15%;
- Net Loss and Comprehensive Loss was ($3.1) million and ($23.0) million, respectively, an improvement of 63% and 26%;
- Basic and Diluted Net Loss Per Common Share was ($0.08) and ($0.62), respectively, an improvement, of 67% and 32%;
- Net Cash Used in Operating Activities was $1.2 million and $13.5 million, respectively, an improvement of 79% and 44%;
- Cash Burn[(1)] was $1.7 million and $15.4 million, respectively, an improvement of 73% and 39%; and
- Cash and Cash Equivalents was $78.0 million at December 31, 2018.

(1) Cash burn is a financial measure that is not calculated in accordance with generally accepted accounting principles in the United States, or U.S. GAAP. See “Management’s Discussion and Analysis of Financial Condition and Results of Operations-Fourth Quarter and Full-Year 2018 Financial Results” in Part II. Item 7 of this Annual Report on Form 10-K for information regarding cash burn and a reconciliation of cash burn to net cash used in operating activities.

2018 Full-Year and Recent Business Highlights

Commercial Expansion:

- Grew total genomic test volume to 9,154 tests in the fourth quarter of 2018, representing 28% growth over 2017, which resulted in full-year 2018 growth of 22% over 2017, or 31,710 tests.
- Transitioned all Afirma customers to the second-generation Afirma Genomic Sequencing Classifier (GSC) platform and launched the Afirma Xpression Atlas to provide a comprehensive solution that informs both thyroid cancer diagnosis and treatment decisions. Notably, 30% of Afirma GSC orders included Xpression Atlas in 2018, ahead of the company's expectations.
- Grew Percepta Bronchial Genomic Classifier volume to nearly 1,550 tests in its first full year of commercialization, with genomic volume accelerating 74% sequentially from the third quarter to the fourth quarter of 2018.

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- Established 20 leading Early Access Program (EAP) sites across the United States for Envisia in 2018, addressing physician demand for patient access to the classifier which improves idiopathic pulmonary fibrosis (IPF) diagnosis and builds a solid foundation for the company to commercially expand it in 2019.

Biopharmaceutical Collaborations

- Executed a long-term strategic collaboration with Johnson & Johnson, LLC and Johnson & Johnson's Lung Cancer Initiative to advance diagnostics, including a nasal swab test, for early lung cancer detection. Veracyte estimates the combined monetary and non-monetary value of the collaboration to be more than $50 million. The company believes this collaboration expands its addressable lung cancer diagnostic market to a more than $30 billion global opportunity.
- Entered into a research collaboration with Loxo Oncology, through which Loxo has access to data from Veracyte's Afirma Xpression Atlas platform to help in its development of therapies for patients with genetically defined cancers, including thyroid cancer.

Reimbursement Progress:

- Received draft Medicare coverage for the Envisia Genomic Classifier through the MolDX program, with a final positive coverage decision expected in early 2019.
- Achieved in-network status as a service provider with the last of the major commercial health plans, which Veracyte believes will facilitate coverage and reimbursement for its Percepta and Envisia classifiers.

Evidence Development:

- Afirma - Published clinical validation data for the Afirma GSC in JAMA Surgery, demonstrating the next-generation test's ability to help approximately 70% of patients with indeterminate thyroid nodules avoid unnecessary surgery.
- Presented 12 Afirma studies at three endocrinology conferences, including real-world data showing that the Afirma GSC is helping even more patients avoid unnecessary surgery than is suggested by the clinical validation study findings.
- Percepta - Presented early, interim results at the 2018 CHEST Annual Meeting from the ongoing registry clinical utility study showing the test changed clinical decision-making and reduced invasive procedures at every evaluation time point up to 12 months post-testing.
- Envisia - Published a study quantifying and qualifying the challenges in obtaining timely, accurate diagnosis of IPF and other interstitial lung diseases, thus underscoring the clinical need for the Envisia classifier. Presented data at a leading pulmonology conference demonstrating the test's ability to improve the diagnosis of IPF without the need for surgery.

Financing and Debt Facility:

- In July 2018, we issued and sold 5,750,000 shares of common stock in a registered public offering, including the underwriters' exercise in full of their option to purchase an additional 750,000 shares, at a price to the public of $10.25 per share. Net proceeds from the offering were approximately $55.0 million.
- In January 2019, we used $12.5 million of cash and cash equivalents to reduce our principal debt balance from $25.0 million to $12.5 million.

Our Products

We are a leading genomic diagnostics company that is creating value through innovation. We believe our comprehensive scientific approach to product development, including our early adoption of and transition to RNA whole-transcriptome sequencing, as well as our focus on being first-to-market in each targeted indication, play critical roles in our ability to develop diagnostic tests that change clinical care. Since our founding in 2008, we have commercialized three leading products in large, untapped clinical areas: thyroid cancer; lung cancer; and IPF:

- Afirma Genomic Sequencing Classifier and Xpression Atlas. Our Afirma offering, consisting of the Afirma GSC and the Afirma Xpression Atlas, provides physicians with a comprehensive solution for a complex landscape in thyroid nodule diagnosis. The combined offering is 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.

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Since Afirma testing became available in 2011, we have performed more than 130,000 genomic tests and estimate that we have helped over 50,000 patients avoid having all or part of their thyroids removed.

We commercially launched the Afirma Xpression Atlas in 2018 as part of this comprehensive offering. The Afirma 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 Bronchial Genomic 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. 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. In 2018, we launched an Early Access Program to begin making the Envisia classifier available to physicians and patients in advance of nationwide expansion. As of December 31, 2018, 20 sites were participating in the program. In August 2018, we obtained draft positive Medicare coverage for the Envisia classifier. We expect to receive final positive Medicare coverage in early 2019.

Our Pipeline

We believe early detection and improved diagnosis are key to saving lives in pulmonary diseases, specifically in lung cancer and IPF, which on a combined basis address a global market opportunity of over $30 billion annually. We believe we can use minimally invasive techniques, such as nasal swabs, airway brushings and samples taken during a bronchoscopy, to improve diagnosis, without the need for patients to undergo surgery to obtain an accurate diagnosis. Our product pipeline expands upon our founding strategy of improving diagnostic accuracy to answering clinical questions in our indications across the clinical care continuum, including early detection and informing treatment decisions. We also continue to evaluate acquisitions of intellectual property and corporate acquisitions that we believe answer clinically meaningful questions to enable better patient outcomes.

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Biopharmaceutical Partnerships

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 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 that we believe are important to the development of new targeted therapies, determining clinical trial eligibility and guiding treatment selection.

In April 2018, we entered into a research collaboration with Loxo Oncology, Inc. through which Loxo Oncology gained access to data derived from our Afirma Xpression Atlas platform in its development of highly selective medicines for patients with genetically defined cancers, including thyroid cancer.

In December 2018, we entered into an agreement with 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, using novel “field of injury” science. The terms of the collaboration are described in greater detail on our Current Report on Form 8-K filed on January 3, 2019.

Market Opportunity

We believe diagnostic uncertainty 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 believe the total addressable market for our three existing commercial tests exceed $2 billion globally and our pipeline of non-invasive lung cancer products has the potential to expand our total addressable market to over $30 billion.

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Thyroid Market Opportunity for Our Afirma Solution

Each year in the United States, more than 525,000 FNA biopsies are performed to assess patients with potentially cancerous thyroid nodules. Up to 30 percent of the results are indeterminate (not clearly benign or malignant) and physicians have traditionally recommended thyroid surgery for 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 and is covered as medically necessary by Medicare and all of the major U.S. insurance companies.

We believe the addressable market opportunity for our Afirma solution is approximately $800 million globally -- $500 million in the United States and $300 million internationally. We currently do not have meaningful operations or sales outside 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, Medicaid or self-insured.

Lung Cancer Market Opportunity for Our Percepta Classifier

Lung cancer is often difficult to diagnose without invasive, risky and costly surgeries. Approximately 235,000 people are diagnosed with lung cancer each year in the United States and nearly 160,000 people die annually from lung cancer. 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 350,000 bronchoscopies on these patients. 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 bronchoscopy’s ability to provide clear results. Currently, we estimate that approximately 140,000 patients undergoing bronchoscopy have inconclusive results and could potentially benefit from our test. We believe our Percepta product can improve the diagnostic performance of bronchoscopy and classify approximately 40% of these patients as low risk or very low risk for lung cancer, saving approximately 60,000 patients from potentially having to undergo diagnostic surgeries.

We believe the addressable market opportunity for our Percepta product is approximately $425 million to $525 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 positive Medicare coverage for Percepta through the Molecular Diagnostics Services Program, or MolDX program, administered by the Medicare Administrative Contractor, or MAC, Palmetto GBA, making it the first genomic test to be covered for use in lung cancer screening and diagnosis. The effect of these coverage decisions is that 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 200,000 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 200,000 patients evaluated for ILD

annually, we estimate that approximately 75%, or 150,000 patients receive an uncertain diagnosis and are candidates for our Envisia test.

We believe the addressable market opportunity for our Envisia product is approximately $350 million to $400 million in the United States and over $200 million in Europe.

In August 2018, we obtained draft positive Medicare coverage for the Envisia classifier through the MolDX program, administered by Palmetto GBA. Upon expected finalization, the Envisia classifier will be the first genomic test to be covered by Medicare for use in IPF diagnosis, making 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. We believe the Envisia Genomic Classifier will receive final positive Medicare coverage in early 2019.

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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 the biopsies we test. Ultimately, 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 complex information requires computer-based algorithms to make sense of the patterns. 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 computer-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 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.

Technology

Our technology approach 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. We have extended this capability substantially by accessing genomic features through deep RNA sequencing for the development of Afirma GSC. 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.

- 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.

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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.

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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 28 published scientific studies, including 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. 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 journal CHEST showed that use of the test reduced unnecessary surgeries in the target patient population, compared to physicians’ plans prior to Percepta testing.

We continue to build our library of clinical evidence to support our Envisia product. Our test is supported by two clinical validation studies with a third validation (manuscript)combined with clinical utility in process, one analytical validation study, and one clinical utility study that demonstrate the unmet clinical need and potential utility of the test when used by subspecialty physicians.

Commercial Operations

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 products; 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.

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