VERACYTE, INC.
Form 10-K
March 14, 2016

Use these links to rapidly review the document

Table of Contents

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, 2015

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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post 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, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer o	Accelerated filer ý	Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company 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, 2015, the aggregate market value of voting and non-voting common stock held by non-affiliates of the registrant was approximately $151.4 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 March 4, 2016 was 27,854,567.

DOCUMENTS INCORPORATED BY REFERENCE

Item 10 (as to directors and Section 16(a) Beneficial Ownership Reporting Compliance), 11, 12, 13 and 14 of Part III incorporate by reference information from 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 2016 Annual Meeting of Stockholders to be held on June 17, 2016.

Table of Contents

TABLE OF CONTENTS

Table of Contents

PART I

ITEM 1. BUSINESS

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 expectations regarding capital expenditures; our anticipated cash needs and our estimates regarding our capital requirements; 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; the estimated size of the global markets for our tests and our future tests; the 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, including tests for interstitial lung disease, 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 agreements with Genzyme and 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, including entering new international markets and the timing thereof; 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 ability to compete with potential competitors; our compliance with federal, state and international regulations; the potential impact of regulation of our tests by the FDA or other regulatory bodies; the impact of new or changing policies, regulation or legislation, or of judicial decisions, on our business; our ability to comply with the requirements of being a public company; the impact of seasonal fluctuations and economic conditions on our business; our belief that we have taken reasonable steps to protect our intellectual property; 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.

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, as well as risks and uncertainties related to: our limited operating history and history of losses since inception; our ability to increase usage of and reimbursement for our tests and any other tests we may develop; our dependence on a limited number of payers for a significant portion of our revenue; the complexity, time and expense associated with billing and collecting for our test; current and future laws, regulations and judicial decisions applicable to our business, including potential regulation by the FDA or by regulatory bodies outside of the United States; changes in legislation related to the U.S. healthcare system; our dependence on strategic relationships, collaborations and co-promotion arrangements; unanticipated delays in research and development efforts; our ability to develop and commercialize new products and the timing of commercialization; our ability to successfully enter new product or geographic markets; our ability to conduct clinical studies and the outcomes of such clinical studies; the applicability of clinical results to actual outcomes; trends and challenges in our business; our ability to compete against other companies and products; our ability to protect our intellectual property; and our ability to obtain capital when needed. 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

Table of Contents

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, the Veracyte logo and the Afirma logo are our trademarks. We also refer to trademarks of other corporations or organizations in this report.

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.

Overview

We are a molecular diagnostics company that uses novel genomics to resolve the critical healthcare problem of diagnostic ambiguity. We believe that diagnostic ambiguity results in hundreds of thousands of patients undergoing unnecessary, invasive procedures and wasting billions of healthcare dollars each year. We target diseases in which large numbers of patients undergo invasive and costly diagnostic procedures that could be avoided with a more accurate diagnosis from a cytology sample taken preoperatively. By improving diagnosis preoperatively, we help patients avoid such unnecessary invasive procedures and surgeries while reducing healthcare costs. Since Veracyte's founding in 2008, we have evolved this concept into an enterprise with two commercialized products and a third scheduled to launch in the fourth quarter of 2016, with approximately $50 million in annual revenue in 2015 and a near-term addressable market of over $2 billion. In 2016, we are focused on the continued growth of our endocrinology franchise and further expansion into pulmonology, our second clinical indication, using our proven approach to genomic test development and commercialization.

We launched our first commercial solution, the Afirma® Thyroid FNA Analysis, in 2011 for use in thyroid cancer diagnosis. Our offering centers on our proprietary Afirma Gene Expression Classifier, or GEC, which is used to resolve diagnostic ambiguity among the more than 525,000 patients who undergo fine needle aspiration, or FNA, biopsies each year in the United States to assess potentially cancerous thyroid nodules. The Afirma GEC helps physicians reduce the number of unnecessary surgeries by employing a proprietary 142-gene signature to preoperatively determine whether thyroid nodules previously classified by cytopathology as indeterminate can be reclassified as benign. An additional 25 genes are used to differentiate uncommon neoplasm subtypes. As of March 2016, we have received more than 225,000 FNA samples and have performed more than 50,000 Afirma GEC tests to resolve indeterminate cytopathology results, helping over 20,000 patients potentially avoid unnecessary surgery and reducing healthcare costs by an estimated $400 million. We estimate that our market penetration has doubled in the last two years, to approximately 25%, based on the number of Afirma GEC tests performed relative to an 18% rate of indeterminate results among the estimated 525,000 FNAs performed each year in the United States. We launched our first product extension the Afirma Malignancy Classifiers in 2014, which comprise genomic tests for medullary thyroid cancer, or MTC, and BRAF V600E mutation status. These genomic tests are intended to preoperatively inform physicians' choice of thyroid surgery when surgery is needed. We believe Afirma offers the most comprehensive, proven solution for the assessment and management of patients with thyroid nodules. We estimate our addressable thyroid market opportunity today is approximately $500 million per year in the United States, and we believe that there is an estimated $300 million additional market opportunity for the Afirma GEC internationally.

The Afirma GEC is now supported by nearly 20 peer-reviewed, published scientific studies and we believe it is becoming a new standard of care in thyroid cancer diagnosis. A prospective, multicenter,

Table of Contents

double-blind clinical validation study was published in *The New England Journal of Medicine* in 2012 and suggested that the test can reduce the number of unnecessary surgeries by 50%. As of March 2016, the Afirma GEC is included in all of the recently updated thyroid-focused clinical practice guidelines and is covered by positive medical policies for nearly 180 million patient lives in the United States, including through Medicare and many commercial insurance plans. Additionally, we have established contracts with numerous health plans, making the Afirma GEC an in-network service for nearly 130 million lives. These include Medicare, UnitedHealthcare, Cigna, Aetna and several Blue Cross Blue Shield plans.

We market our Afirma solution through our dedicated specialty sales force and, until mid-September 2016, under a co-promotion agreement with Genzyme, a subsidiary of Sanofi, which targets the same endocrinologist customers with Thyrogen®. In March 2016, we notified Genzyme that we will conclude our co-promotion agreement with them and assume full responsibility for Afirma sales and marketing, while ending our payments of 15% of all U.S. Afirma sales. We believe our growing sales force enables us to further drive market penetration and expansion for Afirma, in the physician office, or ambulatory practice setting, as well as in regional laboratories, which we believe allows us to further penetrate the community physician market. Our customers also include radiology clinics and institutional accounts, including integrated delivery networks, or IDNs. We now offer sales models that meet the needs of our diverse customer base, and we believe we are positioned to continue to drive growth in all of these markets. To date, substantially all of our revenue has been derived from customers we serve in the United States. Our revenue has increased from $11.6 million in 2012, to $21.9 million in 2013, $38.2 million in 2014 and $49.5 million in 2015.

In April 2015, we accelerated our entry into pulmonology, our second clinical area, with the launch of the Percepta® Bronchial Genomic Classifier. The Percepta test is designed to improve the preoperative diagnosis of lung cancer, thus helping to reduce unnecessary invasive, risky and costly procedures among patients with suspicious lung nodules and lesions that were initially found on CT scans. Lung nodules are often difficult to diagnose without invasive biopsies. Bronchoscopy, however, offers a nonsurgical way to diagnose such suspicious lung nodules and lesions and is performed on approximately 250,000 patients in the United States each year for this purpose. However, approximately 40% of bronchoscopy procedures produce inconclusive results, leaving physicians with a diagnostic dilemma of whether to subject patients to invasive and potentially unnecessary procedures or just monitor them, with the chance that they may have cancer. Our initial focus is on building our library of clinical evidence, including clinical utility, for the Percepta classifier, while we secure coverage from Medicare and private payers. As of March 2016, we have expanded the number of thought-leading academic and other institutions to 40 that are now offering Percepta to their patients during this initial stage of commercialization.

We believe the market opportunity for the Percepta Bronchial Genomic Classifier is between $350 million and $400 million in the United States, depending on the value we can extract for our test. We estimate that the number of bronchoscopies and inconclusive results could expand significantly in the next two to three years as, beginning in early 2015, more than eight million Americans at high risk for lung cancer have become eligible for annual screening through the Affordable Care Act and Medicare coverage.

Clinical validation data from two multicenter, prospective studies AEGIS I and II were published in July 2015 in *The New England Journal of Medicine* and showed that the Percepta classifier had a negative predictive value, or NPV, of 91%, demonstrating the test's ability to reclassify patients as low risk, with a high degree of accuracy, following an inconclusive bronchoscopy result. The authors concluded that these patients could potentially be monitored with CT scans, rather than face invasive diagnostic procedures. The AEGIS data also showed that use of the Percepta classifier increased the sensitivity of bronchoscopy from 75% to 97%, suggesting that it could potentially improve the clinical utility of this nonsurgical procedure. Clinical validation data from a third study were published in May 2015 in *BMC Medical Genomics* and similarly showed an NPV for the Percepta test of greater than 90%. Additionally, initial clinical utility data, derived from the AEGIS trials, were published in February 2016 online in *CHEST*, the

Table of Contents

official journal of the American College of Chest Physicians. These data suggest that use of the Percepta test could have decreased unnecessary, invasive procedures by 50% in the evaluated patient population. Also in February 2016, analytical verification data for the Percepta classifier were published online in *BMC Cancer,* establishing the quality and reproducibility of our testing processes. We expect to expand the library of clinical evidence supporting the adoption and reimbursement of the Percepta test in 2016.

We also plan to expand our footprint in pulmonology in 2016 with the launch of a product designed to preoperatively identify idiopathic pulmonary fibrosis, or IPF, among patients presenting with a suspected interstitial lung disease, or ILD. Our IPF test will target pulmonologists, the same physicians with the Percepta test, and will also test cytology samples obtained through bronchoscopy. IPF is the most common form of ILD, a group of diseases characterized by chronic, progressive scarring of the lungs, and is often difficult to distinguish from other ILDs. Currently, many of the estimated 175,000 to 200,000 patients in the United States and Europe who present with suspected ILDs each year may endure months of incorrect or missed diagnoses, undergoing invasive, risky and expensive diagnostic surgeries, or receiving suboptimal treatment. The need for improved IPF diagnosis is increasingly important given the availability of new therapies to halt or slow progression of this often-fatal disease, which were approved by the Food and Drug Administration, or FDA, in late 2014. We estimate the addressable market for our IPF test to be over $500 million in the United States and Europe.

We presented data at the American Thoracic Society International Conference in May 2015 and at the Pulmonary Fibrosis Foundation, or PFF, Summit 2015: From Bench to Bedside in November demonstrating the ability of our in-development molecular classifier to help distinguish IPF from other ILDs on samples obtained through bronchoscopy. In May 2015, *The Lancet Respiratory Medicine* also published an article online, which detailed foundational work in the test's development and results from an independent test set, demonstrating the classifier's performance using patient samples obtained through surgery. We are working with key leading thought leaders and more than 25 sites across the United States and Europe to finalize development of our classifier test and unveil validation results from multicenter, prospective clinical validation studies. We expect to initiate commercialization in the fourth quarter of 2016.

We believe additional clinical areas offer opportunities for future expansion of our molecular cytology franchise beyond endocrinology and pulmonology. In determining new clinical areas to enter, we will focus on diseases in which a large number of patients undergo invasive and costly diagnostic procedures that could be avoided with a more accurate diagnosis from a cytology sample taken preoperatively.

Our Strategy

We believe the market opportunities are significant and have focused our strategic objectives around these four growth vectors:

Accelerate the Growth of Afirma in Endocrinology. We expect to continue to invest in driving the adoption of Afirma and expanding our base of prescribing physicians, both in the community physician office market as well as in institutional settings, offering flexible models that address our customers' diverse needs. We plan to continue to leverage and expand our sales force, comprised of endocrine product specialists, account managers and institutional channel managers in the U.S. market, as we transition from our co-promotion relationship with Genzyme. We also intend to pursue select international markets for entry where attractive regulations and reimbursement exists. We plan to use our inclusion in clinical practice guidelines and the extensive library of published evidence on Afirma to date, coupled with our core expertise in managed care, claims adjudication, and billing, to drive even broader coverage determinations and to convert coverage determinations into additional in-network contracts with payers, in order to expand adoption and reimbursement.

Broaden the Launch of Percepta. We believe our molecular cytology strategy could address several unmet clinical needs in pulmonology. We commercially launched our Percepta Bronchial Genomic

Table of Contents

Classifier, designed to improve lung cancer diagnosis, in April 2015 and plan to continue to secure adoption by leading institutions as we build our library of clinical evidence, including additional clinical utility data, and work to secure Medicare and private-payer reimbursement. Upon obtaining Medicare reimbursement, we plan to scale our sales and marketing efforts, to secure customers nationwide, beyond the approximately 50 thought-leader sites originally targeted for the first phase of our launch.

Expand Pulmonology Offering with Launch of Our IPF Test. We plan to further expand our molecular cytology platform within the pulmonology vertical with the introduction of a test to improve the diagnosis of patients suspicious for ILD, specifically IPF. To support the IPF test's introduction, we plan to complete clinical validation work demonstrating its performance on patient samples collected prospectively from more than 25 clinical sites around the United States and Europe. We plan to commercially introduce the test in the fourth quarter of 2016. Similar to our approach with Afirma and Percepta, we plan to focus on initial adoption among leading sites as we further build out the clinical evidence, including clinical utility data, for the test and work to secure reimbursement from Medicare and private payers.

Expand Our Franchise into Additional Indications with Diagnostic Ambiguity. We intend to leverage our demonstrated core capabilities in research and development, clinical development, and managed care and reimbursement to expand our business into other clinical areas of unmet need, where we can resolve diagnostic ambiguity, either through internal development or through acquisition. For each clinical area we target, we deploy a proven strategy comprised of four key pillars:

Inform the Right Clinical Question. We focus on developing genomic tests that answer a relevant clinical question and that, when used at the optimal point in the diagnostic pathway, provide physicians with information that can significantly alter physician decision-making, enabling patients to avoid unnecessary invasive and costly procedures. We then work with key opinion leaders and other clinicians to understand the performance criteria that will be needed for a new test to give physicians confidence to change clinical-care decisions. Only when we have pinpointed this information do we then deploy the appropriate science to develop the test.

Develop Proprietary Science and Validate in Well-designed Clinical Trials. Once we know the parameters of the test we need to develop to change patient care, we apply rich, broad-based genomic science based on our expertise in biomarker discovery and algorithm development. We utilize proprietary technology, intellectual property and scientific know-how to extract rich genomic information from tiny cytology samples, sometimes with only nanogram quantities of biological material, to answer our target clinical question. We then conduct prospective, blinded, multicenter clinical validation studies and seek to obtain publication in peer-reviewed journals to establish the clinical performance of our test.

Demonstrate Clear Value. We build into our commercialization strategy the steps that will be needed to prove that our tests do indeed change clinical practice and provide healthcare cost savings. To do this, we design and initiate clinical utility and cost-effectiveness studies early in the process so that we will be able to quickly and efficiently demonstrate value to physicians and payers.

Achieve Coverage and Reimbursement Success. By developing the clinical evidence for our tests, which is then published in peer-reviewed journals, we create compelling evidence for our tests to be included in clinical practice guidelines, helping to establish a new routine standard of care. We believe guideline inclusion, along with the capabilities we have built in managed care and claims adjudication, is key to obtaining successful payer coverage, contracts and reimbursement. Our team combines expertise in advocating for positive coverage decisions

Table of Contents

with specific insights into what tactical steps will maximize reimbursement from each payer. As a result, we have developed detailed knowledge of the intricacies of specific payer practices and requirements, which informs and allows us to leverage our strategy across indication selection, clinical study design, marketing and sales.

Limitations of Disease Diagnosis Today

Surgical pathology has long been part of the standard of care for diagnosis of numerous complex diseases, including many types of cancer and lung diseases. Patient samples collected from surgeries allow multiple slices, or sections, of the tissue to be stained, permitting a pathologist to use a microscope to evaluate the shape and structure of the cells in question to diagnose the sample. However, surgical pathology by definition requires an invasive procedure. Cytopathology, or the analysis of small numbers of cells using minimally invasive methods (which we refer to as cytology samples), is designed to provide a pathologic diagnosis using a small biopsy. It is often the first step in the diagnostic process because it offers a less-invasive and cost-effective alternative to surgery. However, because cytology samples are often small and non-uniform, definitive diagnoses can be difficult. In some cases, physicians may forego less-invasive procedures to obtain cytology samples because they do not believe they will yield diagnostic results. Moreover, the high rate of ambiguity in diagnosis using cytology samples today results in many patients undergoing other subsequent invasive procedures, often including surgery, to obtain an accurate diagnosis.

The role of genomic information in medical practice is evolving rapidly and has affected the diagnosis of disease as well as treatment decisions. Over the past decade, molecular diagnostic tests that analyze genomic material from surgical tissue samples have emerged as an important complement to evaluations performed by pathologists. Information at the molecular level enables one to understand more fully the makeup and specific subtype of disease to improve diagnosis. In many cases, the genomic information derived from these samples can help guide treatment decisions as part of the standard of care. However, due to limitations of available technologies, many of these molecular tests require relatively large quantities of tissue with specific levels of cellularity, which most often must be obtained through an invasive surgical procedure.

Cytology samples offer a more attractive alternative for early, less invasive and less costly diagnosis. These samples are commonly obtained using minimally invasive methods, such as FNA biopsies, washings, brushings, lavages or bronchoscopy biopsies, from which to diagnose various diseases. Physicians typically collect these samples without performing surgery, and therefore have the potential to offer a lower cost and less invasive approach to disease diagnosis. Cytology samples, however, are challenging for both traditional cytopathology, as well as molecular cytology, due to the small amount of cellular material obtained in the collection process and the often non-uniform nature of the collected tissue.

Extracting clinically meaningful genomic information from these small, heterogeneous cytology samples offers the potential to reduce ambiguity in diagnosis prior to surgery and inform treatment decisions at a much lower cost to the healthcare system.

Our Solutions

We are developing and delivering genomic solutions that resolve diagnostic ambiguity and enable physicians to make more informed treatment decisions at an early stage in patient care. We target diseases in which a large number of patients undergo invasive and costly diagnostic procedures that could be avoided with a more accurate diagnosis from a cytology sample taken preoperatively. In contrast to molecular diagnostics developed for surgical tissue, our solutions solve many of the technical challenges associated with generating analytically valid and clinically relevant genomic information from very small, heterogeneous cytology samples. By improving diagnosis before surgery, we help patients avoid unnecessary invasive procedures while reducing healthcare costs.

Table of Contents

Our molecular cytology solutions are designed to deliver a number of benefits to physicians, payers and patients, including a reduction of unnecessary surgeries, lower healthcare costs, and actionable information by integrating our genomic tests into the diagnostic clinical pathway that is the standard of care today.

Our initial focus is on the clinical areas of endocrinology, where we have made significant inroads to date, and pulmonology, which we entered in mid-2015. Together, we believe these two market opportunities offer a near-term estimated addressable market of over $2 billion.

Our Endocrinology Solution

We entered the endocrinology market in January 2011 with our Afirma Thyroid FNA Analysis, which is now included in leading practice guidelines and gaining market share in thyroid cancer diagnosis. Our offering centers on our proprietary Afirma GEC, which is used to resolve diagnostic ambiguity among the more than 525,000 patients who undergo FNA procedures each year to assess thyroid nodules that are potentially cancerous. We launched our first product extension the Afirma Malignancy Classifiers in May 2014, comprising tests for MTC and BRAF V600E gene mutation status to provide results that might preoperatively inform surgery selection for those patients who need surgery.

As of March 2016, we have received more than 225,000 FNA samples and have performed more than 50,000 GEC tests to resolve indeterminate cytopathology results, helping over 20,000 patients avoid unnecessary surgery and reducing healthcare costs by an estimated $400 million. The Afirma GEC is covered as a medically necessary test for nearly 180 million lives, including through Medicare and many commercial payers including UnitedHealthcare, Cigna, Aetna, Humana, Health Care Services Corporation, or HCSC, and other leading Blue Cross and/or Blue Shield plans such as Highmark, Horizon Blue Cross, and Blue Shield of California, for a total of more than 45 million covered Blues plan members. Afirma is contracted for nearly 130 million lives, making us an in-network provider for payers including Medicare, UnitedHealthcare, Cigna, Aetna and more than seven million Blues plan members, which facilitates adoption. On March 1, 2015, a separate CPT code, or Current Procedural Terminology code, for the Afirma GEC, was issued which we believe will continue to facilitate our progress with payer coverage and contracts, and reimbursement. The new code became effective January 1, 2016.

We estimate that our market penetration has doubled in the last two years, to approximately 25%, based on the number of Afirma GEC tests performed relative to an 18% rate of indeterminate results among the estimated 525,000 FNAs performed each year in the United States.

Our Pulmonology Solution

We launched our first pulmonology product for improved lung cancer diagnosis in April 2015. The Percepta Bronchial Genomic Classifier is designed to help resolve diagnostic ambiguity among the approximately 250,000 patients each year who undergo bronchoscopy to determine if lung nodules or lesions are benign or cancerous. Our solution is intended to identify patients with inconclusive bronchoscopy results whose nodules or lesions, initially found on CT scans, are at low risk of being cancerous, so these patients can potentially avoid unnecessary invasive, risky and costly diagnostic procedures and be monitored with low-dose computed tomography, or LDCT, instead. Early adoption of the Percepta classifier in April 2015 was supported by the subsequent publication in July 2015 of clinical validation data in *The New England Journal of Medicine*. Our initial commercialization focus is on securing adoption among leading institutions as we build our library of clinical evidence, including additional clinical utility data, and secure Medicare and private-payer reimbursement. As of March 2016, 40 thought-leading academic and other customers across the country are offering Percepta to their patients, and we are on track to secure the approximately 50 active sites we are initially targeting by mid-2016.

We believe our introduction of Percepta will facilitate the subsequent launch in the fourth quarter of 2016 of our IPF test, which will target the same customers, pulmonologists, and will similarly be run on

Table of Contents

cytology samples obtained through bronchoscopy. Our IPF test is intended to preoperatively identify, using deep RNA sequencing, patients with IPF among those presenting with a suspected ILD, so that these patients can obtain an accurate diagnosis and proper treatment sooner without the need for invasive surgery. We have collaborated with more than 25 clinical sites in the United States and Europe to develop our IPF test and to prospectively collect patient samples for use in its subsequent clinical validation, which we expect to complete this year. We plan to launch the test in the fourth quarter of 2016 and to then begin assembling the evidence to demonstrate the test's clinical utility. In addition to our collaboration with clinical thought leaders, we partnered with the Pulmonary Fibrosis Foundation on a patient survey designed to quantify and qualify the extensive challenges that ILD/IPF patients face in obtaining a timely, accurate diagnosis. Findings from the survey were presented at the PFF 2015 Summit: From Bench to Bedside in November 2015.

The Endocrinology Market

Our Afirma solution addresses the large and growing thyroid market, which is burdened with significant ambiguity in cytopathology results, offering the potential to reduce the rate of surgery needed to diagnose and subsequently treat thyroid cancers.

Thyroid cancer is the fastest growing cancer in the United States, according to the American Cancer Society, and evaluation of thyroid nodules the most common indicator of thyroid cancer is rapidly increasing the number of thyroid FNAs conducted. Approximately 525,000 thyroid FNAs were performed in the United States in 2011, which is more than double the number of FNAs performed in 2006. We estimate our addressable thyroid market opportunity today is approximately $500 million per year in the United States, consisting of an estimated $100 million in cytopathology testing, $350 million in Afirma GEC tests performed on indeterminate cytopathology samples and an additional $40 million related to our Afirma Malignancy Classifiers. Our estimates are based on the product of FNA volumes and the estimated reimbursement per test for both cytology and the Afirma GEC, not our list price at which we bill. We believe that there is an estimated $300 million additional market opportunity for the Afirma GEC internationally.

Table of Contents

The biology of thyroid cells is complex. Approximately 15% to 30% of thyroid nodule FNAs performed in the United States are deemed indeterminate following cytopathology review, meaning they cannot be diagnosed as definitively benign or malignant by cytopathology alone. Because the risk of malignancy in such patients ranges from 20% to 30%, clinical practice guidelines have traditionally recommended that most of these patients undergo surgery to remove all or part of the thyroid for a definitive diagnosis. Following surgery, however, 70% to 80% of these patients prove to have benign nodules, meaning the surgery was unnecessary. We estimate each surgery costs $15,000 to over $20,000 on average. Additionally, such surgeries have a complication rate of 2% to 10%, and most patients subsequently require lifelong thyroid hormone replacement therapy.

We estimate that approximately 3,500 endocrinologists specialize in thyroid disease and perform FNAs. We also serve other specialists, including radiologists and ear, nose and throat, or ENT, physicians who similarly perform FNAs. Approximately 60% of FNAs are performed in ambulatory, or community-based, practices, with the remaining 40% conducted in institutional settings, comprised of both academic centers and integrated delivery networks, which are networks of facilities and providers that work together to offer a continuum of care to a specific geographic area or market. While endocrinologists generally diagnose patients and refer them to surgery when necessary, endocrinologists do not perform the surgeries themselves. Institutions, which influence standard of care, typically have cytopathology laboratories on-site, to which the institutions' endocrinologists submit patient samples for review. Additional stakeholders that may be involved in the decision-making process in institutions include radiologists, pathologists and, occasionally, administration. We offer Afirma to institutional customers as an option following their internal cytopathology testing, and receive orders for the Afirma GEC only and/or the Malignancy Classifiers from these customers. We refer to this as our Afirma Diagnostic Partner model. We similarly offer this model to a number of regional laboratories, which perform the cytopathology testing and send the indeterminate samples to us for Afirma GEC testing only, which enables us to further penetrate the local-physician market. This approach represents a higher margin opportunity versus in settings where we also conduct the lower margin cytopathology assessment.

Afirma Thyroid FNA Analysis

Launched in 2011, the Afirma Thyroid FNA Analysis is our comprehensive offering for thyroid nodule assessment. The solution centers on our proprietary Afirma GEC to resolve indeterminate FNA results, based on cytopathology, so that patients whose nodules are benign can avoid unnecessary diagnostic surgery and undergo routine monitoring instead. The Afirma GEC is a 142-gene signature that is proven in multiple peer-reviewed, published studies to identify benign nodules with a high level of accuracy among those deemed indeterminate by cytopathology. An additional 25 genes are used to differentiate uncommon neoplasm subtypes. Data suggest the Afirma GEC can enable unnecessary surgeries to be reduced by approximately 50%. Our comprehensive solution also includes our Afirma Malignancy Classifiers comprised of tests for medullary thyroid cancer, a rare and aggressive form of thyroid cancer, and BRAF V600E gene mutational status, which is often predictive for papillary thyroid cancer which were launched in May 2014 to preoperatively help inform selection of surgery when surgery is needed, minimizing the need for patients to undergo an additional "completion surgery." The MTC test result is included as part of the patient report when an Afirma GEC is performed on any FNA that is indeterminate by cytopathology. Physicians can also order it separately for use on FNAs that are malignant by cytopathology. The BRAF test is performed when ordered specifically by the physician on either GEC suspicious or malignant by cytopathology FNAs.

The Afirma Thyroid FNA Analysis includes initial cytopathology to optimize utilization of the Afirma GEC, ensuring that the test is used appropriately and without the need for patients to return for a repeat

Table of Contents

FNA procedure. We offer the Afirma GEC through two models, designed to meet the needs of both our community-practice and institutional and regional laboratory customers.

Our Total Solution Model

This model allows community-based physicians to implement Afirma in their practice without any meaningful changes to their workflow. Samples for both cytopathology and the Afirma GEC are collected during one FNA procedure using well-accepted and widely-used techniques. Customers send both the cytopathology and the Afirma GEC samples overnight to our CLIA-certified laboratory in Austin, Texas. After we accession the samples into our laboratory information system, the Afirma GEC samples are stored in a freezer while the cytopathology samples are prepared and stained for review by Thyroid Cytopathology Partners, or TCP, a specialized cytopathology practice in Austin, Texas that provides professional diagnoses on these samples. When cytopathology results are indeterminate, we send the stored sample to our CLIA-certified laboratory in South San Francisco, California, where we perform the Afirma GEC and/or Malignancy Classifiers. Results are provided to the ordering physician via a comprehensive report that provides cytopathology results and identifies the Afirma GEC results as either "benign" or "suspicious" for malignancy and the Afirma Malignancy Classifiers as "positive" or "negative."

Approximately 14% to 17% of thyroid FNA biopsies from TCP have been classified as indeterminate and have been reflexed to the GEC. This rate is at the low end of the 15% to 30% range cited in the 2009

Table of Contents

American Thyroid Association Guidelines, suggesting TCP's specialized focus on thyroid cytopathology offers results that are more consistent with those of academic settings. Through our relationship with TCP, the high quality of care historically only accessible to patients in academic settings is now broadly available. By using a large, high-volume, thyroid-specialized pathology practice to offer consistent cytopathology analysis, we can optimize quality and manage appropriate utilization, helping to ensure that the Afirma GEC is not run on cytologically benign or malignant samples, or where the FNA contains insufficient cellular material for diagnosis. We believe this ability to manage utilization is attractive to payers looking to capture the value we promise in patient care. In the fourth quarter of 2015, approximately 87% of the FNAs we received were for the Afirma total solution model.

Afirma Diagnostic Partner Model

In this model, academic and hospital-based customers as well as integrated delivery networks typically perform their own cytopathology analysis and then only send us samples for Afirma GEC testing when the cytopathology result is indeterminate. We also receive samples to perform the Afirma Malignancy Classifiers either in addition to the GEC or for patients with a suspicious for malignancy result by cytopathology. In this scenario, the physician collects the FNA sample for GEC testing at the same time the FNA sample is collected for cytopathology review. The GEC test sample is preserved until the cytopathology results are processed. When the cytopathology result is reported, the preserved FNA sample is sent overnight to our CLIA-certified laboratory for testing, using the Afirma GEC when the result is indeterminate and/or using the Malignancy Classifier analysis for suspicious samples.

Similarly, we offer the Afirma Diagnostic Partner model to regional laboratories that serve community-based physicians, which allows us to further penetrate this market. With this approach, the physician collects the FNA sample for Afirma GEC testing at the same time the FNA sample is collected for cytopathology review. The physician sends both samples to the regional laboratory, which preserves the Afirma GEC test sample until the cytopathology results are processed. If the cytopathology results are indeterminate, the laboratory sends via overnight service the preserved FNA sample for Afirma GEC testing in our CLIA laboratory. Similarly, samples with suspicious cytopathology results are sent to our South San Francisco-CLIA laboratory for Malignancy Classifier analysis. In the fourth quarter of 2015, approximately 13% of the FNAs we received were from the Afirma Diagnostic Partner.

Whether the final result is rendered by cytopathology alone or a combination of cytopathology and genomic testing, physicians receive an actionable answer based on samples collected in a single patient visit.

Our Afirma Growth Strategy

Our business growth is predominantly driven by growth of the Afirma GEC. Key initiatives include:

Continue to Drive Afirma as the Leading, Comprehensive Solution for Managing Patients with Thyroid Nodules. We believe that Afirma offers a unique, market-leading solution that enables patients to avoid unnecessary surgeries and provides cost savings. Our service models fit the needs of multiple specialties that perform or evaluate FNAs, in a variety of settings, providing a comprehensive assessment, preoperatively, on a single FNA collected on the first patient visit. We are advancing this value proposition by reinforcing our market-leadership position and through patient-centered marketing messages and content.

Expand and Deepen Our Penetration through our Diagnostic Partner Model. We believe that, in addition to community endocrinologist and ENT customers, radiology practices, hospital-based laboratories, integrated delivery networks, and regional pathology laboratories present an opportunity to conduct more Afirma GEC tests at the local level. Community physicians often refer their thyroid nodule patients to radiology centers or hospital-based radiologists for FNA procedures, which are often performed using ultrasound-guided techniques. Additionally, regional

Table of Contents

pathology laboratories often perform cytopathology for community physicians. We believe that partnering with these diverse clients provides us with an opportunity to further grow our Afirma GEC business, while also enabling these practices to enhance their offerings to their referring physician customers.

Expanded our Sales Force. We grew our internal sales force in 2015, enabling us to further drive market penetration and expansion for Afirma, in both the ambulatory physician practice setting as well as in institutional accounts and integrated delivery networks. We expect to continue growing this dedicated sales force to position us to further penetrate the market and to transition as we exit our co-promotion agreement with Genzyme.

Strengthen Marketing Programs. We support our sales efforts with comprehensive marketing initiatives that include medical education, speaker programs for physicians to share their experience with Afirma, as well as more traditional promotional campaigns targeting endocrinologists and other physicians and patients who have been diagnosed with a thyroid nodule. We also provide marketing materials and tools for referral practices, enabling them to promote their use of Afirma to their physician customers.

Drive Payer Coverage and Contracts. Many physicians typically require a test to have broad coverage and be offered by a service provider that has in-network status before they will offer it to their patients. We will continue our efforts to advance payer coverage decisions and contracts to facilitate rapid adoption of Afirma among ordering physicians. With Medicare and most of the leading commercial payers covering Afirma, including large Blue Cross and Blue Shield plans, we intend to focus our efforts on obtaining coverage from remaining "Blues" plans. Additionally, we are expanding our resources to negotiate and secure in-network contracts which we believe will facilitate adoption as well as provide more predictable reimbursement and revenue.

Development of the Afirma Gene Expression Classifier and Malignancy Classifiers

We used a whole-genome approach to develop the Afirma GEC, identifying gene expression patterns that we believed could best identify a benign thyroid nodule signature in thyroid FNA samples diagnosed as indeterminate by cytopathology. We utilized microarray technology to perform whole-genome analyses on hundreds of thyroid samples, producing a rich database of more than one billion genomic measurements of thyroid biology. We initially measured mRNA expression in over 247,000 transcripts before selecting the target genes to be measured. We acquired large numbers of FNA samples taken at endocrinology practices across the United States in the early development of the Afirma GEC. Because thyroid cancer is a complex disease with multiple, sometimes rare, subtypes, this approach provided the diversity of clinical samples that would be encountered both during clinical validation and in commercial practice. Our scientists then developed machine-learning algorithms using sophisticated statistical approaches to distill the large amount of genomic data and to address FNA sample variability, dilution effects and RNA quantity and quality challenges. The development of the Afirma GEC first on thyroid surgical tissue and then on thyroid FNA samples was first published in 2010 in the *Journal of Clinical Endocrinology and Metabolism.* Using our extensive thyroid-genomic database derived from the whole-genome discovery work that led to the GEC, which we believe to be the largest single data set for thyroid conditions, we developed the Afirma Malignancy Classifiers as an extension to the GEC.

Additionally, our research and development team continues to evaluate potential opportunities to use new genomic discoveries and technologies to further improve patient care. For example, data presented in October 2015 at the International Thyroid Congress and Annual Meeting of the American Thyroid Association and subsequently published in *BMC BioInformatics* in January 2016 contributed to the scientific understanding of the role that gene variant and fusion data, derived from deep RNA sequencing, can potentially play in thyroid cancer diagnosis.

Table of Contents

Published Evidence for Afirma

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. To this end, nearly 20 scientific studies supporting Afirma have been published in peer-reviewed journals. These include two clinical validation, one analytical verification, 15 clinical utility including two long-term durability and two cost-effectiveness studies. Following is an overview of some of the key studies.

Clinical Validation

Preoperative Diagnosis of Benign Thyroid Nodules with Indeterminate Cytology (Alexander, The New England Journal of Medicine, 2012)

In this study, which was sponsored by us and conducted with the support of institutional research grants from us, our Afirma GEC exhibited a negative predictive value, or NPV, of 95% for indeterminate results in the atypia or follicular lesion of undetermined significance category (AUS/FLUS) and 94% for indeterminate results in the suspicious for follicular or Hürthle cell neoplasm category (SFN/SHN) and reclassified as benign over half of the true benign FNA samples that had indeterminate cytopathology diagnoses, which the authors defined to include any results suspicious for malignancy in addition to AUS/FLUS and SFN/SHN. This pivotal validation study employed a prospective, multicenter, double-blind study design to validate the accuracy of preoperative Afirma GEC benign results compared to post-operative expert pathology review. It was the second prospective multicenter study validating the Afirma GEC approach. The study supported the consideration of a more conservative approach than surgery for most patients with thyroid nodules that are cytologically indeterminate but benign according to Afirma GEC results.

This large multicenter study included 49 academic and community practices across 26 states over 19 months. The study involved patients with ultrasonographically confirmed thyroid nodules one centimeter or larger in diameter. 4,812 thyroid FNA samples were prospectively collected from 3,789 patients. In the independent validation set of 265 nodules that were indeterminate by cytopathology, 85 were subsequently determined malignant by surgical pathology, equivalent to a 32% risk of malignancy. The Afirma GEC correctly identified 78 of the 85 malignant nodules as suspicious, a 92% sensitivity (95% confidence interval, or CI, 84 to 97). The Afirma GEC achieved a 52% specificity (95% CI 44 to 59) and reclassified as benign over half of the true benign FNA samples that had indeterminate cytopathology diagnoses. The authors concluded that a benign Afirma GEC result has a post-test probability of malignancy that is similar to the probability for operated nodules with cytologically benign features on an FNA, making watchful waiting a safe and effective clinical option for these patients.

Molecular Classification of Thyroid Nodules using High-Dimensionality Genomic Data (Chudova, Journal of Clinical Endocrinology and Metabolism, 2010)

In this study, which we sponsored, our FNA trained classifier exhibited an NPV of 96% on a modest sized test set of FNA samples, demonstrating an NPV similar to operated nodules with benign FNA cytology. In this study, the authors defined indeterminate results to include any cytological results suspicious for malignancy in addition to AUS/FLUS and SFN/SHN. This prospective, multicenter, double-blind study was the first study on an independent modest-sized set of FNA samples to clinically validate the gene expression classifier approach. In addition, this study demonstrated that even with substantial degradation of RNA and in the presence of blood, in some cases with dilution of up to 80%, the GEC correctly recognized benign nodules and did not miss malignancy in the majority of FNA samples.

The GEC was prospectively validated on an independent test set of 48 FNA samples, one-half of which had indeterminate cytopathology. The GEC exhibited an NPV of 96% and a specificity of 84%. The reference gold standard in this outcome study was the post-operative determination of whether the thyroid

Table of Contents

nodule was benign or malignant by expert endocrine surgical pathologists who were blinded to the GEC results. The authors concluded that the GEC performance and validation conducted on an independent validation set demonstrated a high enough specificity to reclassify over half of indeterminate FNAs as benign and that the observed NPV indicated that those nodules classified as benign by the GEC carry a similar risk of malignancy as a benign diagnosis by thyroid nodule FNA cytopathology alone.

Clinical Utility/Long-term Durability

The Impact of Benign Gene Expression Classifier Test Results on the Endocrinologist-patient Decision to Operate in Patients with Thyroid Nodules with Indeterminate Fine Needle Aspiration Cytopathology (Duick, Thyroid, 2012)

This study, which was sponsored by us and supported with institutional research grants, found that approximately one surgery was avoided for every two GECs run on thyroid FNAs with indeterminate cytopathology, which the authors defined to include any results suspicious for malignancy in addition to AUS/FLUS and SFN/SHN. This study evaluated the clinical utility of the Afirma GEC in a multicenter, cross-sectional survey of the endocrinologists' decision to operate on patients with a cytopathology indeterminate FNA and a benign Afirma GEC result. The study reviewed the first 2,040 GEC tests performed on samples that were classified as indeterminate by cytopathology, of which the Afirma GEC reclassified 52.3% of these results as benign. In the study, a cohort of 51 endocrinologists (46 community based; five academic based) at 21 practice sites in 11 states completed case report forms on whether surgery was recommended for their Afirma benign patients. Of 368 unique patients (395 cytopathology indeterminate FNAs) for whom data was collected, physicians and patients opted for watchful waiting in lieu of diagnostic thyroid surgery 92.4% of the time when the Afirma GEC result reclassified the patient's indeterminate nodule as benign. Surgery was performed on only 7.6% (95% CI 5.1 to 10.8) of patients, compared to the 74% historic rate of surgery on indeterminate thyroid nodules previously reported by *Thyroid* in 2011, a 90% relative reduction in the decision to operate ($p < 0.001$). Additionally, this 7.6% rate of surgery is similar to the 9.0% rate of surgery associated with cytology benign FNA results and reflects other factors considered by physicians, including the size and growth rate of the nodule, the presence of other suspicious or malignant nodules, and other symptoms. The study demonstrates the effect of the GEC on clinical decision making for patients with indeterminate thyroid nodules.

*Multicenter Clinical Experience with the Afirma Gene Expression Classifier (Alexander, Journal of Clinical Endocrinology and Metabolism, 2014)**

This study sought to determine how use of the Afirma GEC affects clinical practice in a real-world environment. Researchers at five academic centers followed all thyroid nodule patients who were tested with the Afirma GEC following indeterminate biopsy results based on cytopathology between 2010 and 2013. Among the 339 patients with indeterminate thyroid nodules, the Afirma GEC identified 174 (51%) as benign and, of these, 71 patients were followed clinically for an average of nine months. Of these 71 patients, only one cancer was identified over the course of the study, confirming a high NPV for the Afirma GEC of over 95%, which is similar to the malignancy risk of a benign cytopathology result. These findings reaffirm data from the initial validation trial published previously in *The New England Journal of Medicine*. The study also supports previous findings regarding the clinical utility of the Afirma GEC, as only 6% of patients with nodules identified as benign by our test underwent surgery.

---

* A co-author of this study was a consultant and member of our clinical advisory board, and owned shares of our common stock at the time of the study.

Table of Contents

Afirma Benign Thyroid Nodules Show Similar Growth to Cytologically Benign Nodules During Follow-Up (Angell, Journal of Clinical Endocrinology and Metabolism, 2015)

This independent, long-term durability study found that thyroid nodules classified as benign by the Afirma GEC had similar rates of growth during extended follow-up as nodules that were benign by cytopathology, which suggests comparable clinical behavior. Researchers at Brigham and Women's Hospital evaluated 90 patients whose thyroid nodule FNAs were deemed benign by the Afirma GEC (following indeterminate cytopathology) between 2010 and 2014. Using ultrasound data available for 58 nodules in 56 of the patients, they compared rates of growth an indicator of potential cancer over a median of 13 months (range of 4 to 40 months) to those of 1,224 thyroid nodules with benign cytopathology results. The latter were from 873 patients who underwent FNA procedures over a ten-year period prior to the introduction of the Afirma GEC and who were followed with ultrasound for a similar period of time. They found that Afirma GEC-benign nodules showed similar growth as the cytopathology-benign cases using either of two criteria: ≥20% in two dimensions (8.6% vs. 8.3%) or ≥50% in volume (17.2% vs. 13.8%). The authors noted that they report on change in Afirma-benign nodules during a clinically relevant monitoring period, as cytologically benign thyroid nodules are typically followed with ultrasound at six to 18 months. They concluded that the findings suggest that physicians may monitor patients with benign Afirma GEC results, just as they would with patients whose cytopathology results are benign.

Cost-effectiveness

*Cost-effectiveness of a Novel Molecular Test for Cytologically Indeterminate Thyroid Nodules (Li, Journal of Clinical Endocrinology and Metabolism, 2011) ©The Endocrine Society**

This clinical study was conducted by researchers from the Johns Hopkins University School of Medicine. Supported with a research grant from us, the authors found that use of the GEC can potentially avoid almost three-fourths of currently performed surgeries in patients with benign nodules but indeterminate cytopathology results, which the authors defined to include any results suspicious for malignancy in addition to AUS/FLUS and SFN/SHN.

Researchers modeled the direct cost savings of utilizing the Afirma GEC in clinical practice. They developed a 16-state Markov decision model based upon the 2009 American Thyroid Association Guidelines for the treatment of adult patients with thyroid nodules with an FNA cytopathology indeterminate diagnosis. The decision model was based on clinical validation study results and expert opinion though model variables necessarily require a substantial degree of judgment. One million patient simulations were run through the decision model to represent five years of treatment and follow-up for patients who first presented with cytologically indeterminate thyroid nodules. Utilization of the Afirma GEC yielded an estimated direct cost savings of $1,453 and an increase of 0.07 quality adjusted life years, or QALYs, per patient, a modest increase in the quality of life. A Monte Carlo simulation of 10,000 trials testing the sensitivity of all variables across a range of values resulted in the Afirma GEC being both less costly and more effective in improving care quality 92.5% of the time. A Monte Carlo simulation is the repeated sampling of random outcomes to predict likely outcomes. Additionally, the authors found no difference in cancers left untreated between the current care paradigm of sending patients with indeterminate nodules to surgery versus clinical observation following a benign Afirma GEC result. The authors concluded that if the GEC were to be universally adopted in routine clinical practice in the United States, every year 74% fewer surgeries would be performed on patients with benign nodules that cytopathology would have classified as indeterminate.

---

* A co-author of this study was a consultant and member of our clinical advisory board, and owned shares of our common stock at the time of the study. This study was conducted with the support of institutional research grants by us.

Table of Contents

The cost savings estimate in the Johns Hopkins model was based on an estimated 14% rate of surgery on a benign Afirma GEC nodule, which is almost double the 7.6% and 6.3% rates subsequently reported in studies published in *Thyroid* (Duick, 2012) and the *Journal of Clinical Endocrinology and Metabolism* (Alexander, 2014). Based on the rate of surgery on GEC benign nodules reported in *Thyroid*, this study found that each Afirma GEC test would save approximately $2,600.

Analytical Validity

Analytical Performance Verification of a Molecular Diagnostic for Cytology-Indeterminate Thyroid Nodules (Walsh, Journal of Clinical Endocrinology and Metabolism, 2012)

This study evaluated the Afirma GEC's ability to provide a robust, accurate and reproducible assay result on patient samples. The findings showed that the RNA content in an FNA sample that is preserved in our proprietary FNAProtect is stable for up to six days at room temperature with no changes in RNA yield or quality. Additionally, the Afirma GEC results were found to be stable over the range of shipping conditions expected in clinical practice. Analytic sensitivity studies demonstrated tolerance to variation in RNA input (5-25ng) and to the dilution of malignant FNA material down to 20%. Analytic specificity studies using malignant samples mixed with blood up to 83% and genomic DNA up to 30% demonstrated negligible assay interference with respect to false-negative results, although benign FNA samples mixed with relatively high proportions of blood demonstrated a potential for false-positive results. The Afirma GEC results were shown to be reproducible across operators, runs, reagent lots, and in inter-laboratory comparisons (standard deviation of 0.158 for scores on a >6 unit scale), demonstrating the highest level of evidence for analytic validity based on the Evaluation of Genomic Applications in Practice and Prevention, or EGAPP, criteria. Analytical sensitivity, analytical specificity, robustness, and quality control of the Afirma GEC were successfully demonstrated.

Afirma Malignancy Classifiers

Machine Learning from Concept to Clinic: Reliable Detection of BRAF V600E DNA Mutations in Thyroid Nodules Using High-Dimensional RNA Expression Data (Diggans, Pacific Symposium on Biocomputing, 2015)

This study, which was sponsored by us and supported with institutional research grants, demonstrated the analytical and clinical validity of the Afirma BRAF test, one of our Afirma Malignancy Classifiers, and confirms that the RNA-based classifier detects the BRAF V600E gene mutation with high diagnostic accuracy. In the study, researchers evaluated 535 FNA samples using both the Afirma RNA-based classifier and a sensitive, standard PCR DNA-based test. The Afirma BRAF RNA-based classifier accurately determined the presence or absence of the BRAF V600E gene mutation with equal performance, but with a lower non-diagnostic rate, than the DNA-based test (7.6% vs. 24.5%).

Additionally, strong clinical validation data demonstrating the ability of the Afirma MTC test to accurately identify cases of medullary thyroid cancer, which were missed by cytopathology alone, were presented at the American Association of Clinical Endocrinologists, or AACE, 23rd Annual Scientific & Clinical Congress in May 2014.

Table of Contents

Afirma in Practice Guidelines

We believe the inclusion of diagnostic tests in clinical practice guidelines is essential to drive their broad adoption and reimbursement. In October 2015, the American Thyroid Association, or ATA, updated its guidelines for managing thyroid nodules and included the recommendation that the Afirma GEC may be used in lieu of diagnostic surgery to rule out cancer in patients whose thyroid nodules are indeterminate following traditional cytopathology. The Afirma GEC is the only molecular test with a high enough sensitivity and negative predictive value, demonstrated in rigorous clinical trials, to be recommended as an option for such use. Prior to this, in January 2013, the National Comprehensive Cancer Network, or NCCN, similarly modified its thyroid cancer guidelines to recommend that physicians consider molecular testing in lieu of diagnostic surgery for patients with cytopathology indeterminate thyroid nodules, provided that the molecular test predicts a risk of malignancy comparable to the risk of malignancy of a benign cytopathology result. Based on published evidence, the Afirma GEC meets these criteria. In July 2014, the NCCN further modified its guidelines to include the Afirma GEC by name. Additionally, UpToDate, a leading evidence-based clinical decision support resource for physicians, recommended the Afirma GEC in its February 2013 review. The American Association of Clinical Endocrinologists is expected to issue new guidelines for thyroid nodule management in 2016.

Afirma Marketing and Sales

Marketing

We employ diverse marketing programs to inform key stakeholders of the value of our Afirma solution in order to drive adoption and reimbursement. As part of our marketing strategy, we educate physicians, healthcare professionals and managed care executives about our unique value proposition, which is supported by numerous peer-reviewed publications demonstrating the analytical and clinical validity, clinical utility and long-term durability of a benign Afirma GEC result, as well as cost-effectiveness of Afirma. We primarily achieve this through national and regional clinical meetings focused on thyroid and endocrine disease and disorders. We also sponsor physician speaker programs and continuing medical education where both academic and community physicians educate their peers on the benefits of Afirma. In addition, we provide marketing materials and tools to physician practices and regional labs, enabling them to promote to their referring physicians the fact that they offer Afirma.

We also continue to employ a comprehensive promotional campaign targeting endocrinologists and other physicians who perform FNAs and/or manage patients with thyroid nodules. The campaign highlights the patient benefits of Afirma primarily its ability to help avoid unnecessary surgeries using information derived from a single FNA procedure. We expanded this campaign to focus on a patient audience while still highlighting the patient experience for physicians. The campaign's centerpiece, www.afirma.com, serves as the digital home for an inbound marketing campaign for patients diagnosed with a thyroid nodule that includes paid search, search engine optimization, advertising in physician offices, and outreach to patient advocacy organizations. To support the consumer campaign, a robust physician campaign includes sales aids, medical conference promotion, print and online advertising and direct mail promotion.

Sales

We market our Afirma solution through our dedicated specialty sales force and through mid-September 2016 through a co-promotion agreement with Genzyme Corporation, which targets the same endocrinologist customers with Thyrogen. We estimate that approximately 3,500 endocrinologists specialize in thyroid disease and perform FNAs to determine whether a thyroid nodule is malignant for cancer or benign. We also serve other specialists, including radiologists and ENT physicians, who also perform FNAs. We estimate that 60% of FNAs are collected in the physician office ambulatory setting and 40% in institutions and integrated delivery networks. In the early years of commercialization of Afirma,

Table of Contents

our success was attributed to our ability to gain adoption in the ambulatory setting where the physician alone can make a decision to use Afirma. As our market share and brand awareness for Afirma have grown, we now offer our Afirma Diagnostic Partner model to institutions, which involve a more complex sales process due to the multiple stakeholders within the institutions that participate in the decision to adopt Afirma, as well as to regional laboratories that serve community physicians. We believe servicing both models continues to be important to our future growth.

We continue to expand our team of sales professionals, which as of December 31, 2015, comprised 28 associates, versus eight associates two years ago. Our team focuses on driving Afirma adoption and GEC test volume among both community-based and institutional customers, as well as the regional laboratories, with the continued engagement of the Genzyme sales force through mid-September 2016. To accommodate the transition away from Genzyme, we plan to hire approximately ten new dedicated sales associates. We aim to have the expanded sales team in place by mid-September 2016 when we assume full sales and marketing responsibility for Afirma.

We entered two new international markets in 2015. In July, we signed an exclusive agreement with Pronto Diagnostics to promote the Afirma GEC in Israel, where Pronto distributes several leading U.S. diagnostics brands. In April, we entered into an exclusive agreement with NewBridge Pharmaceuticals, which distributes our test in the Middle East and North Africa. Prior to that, in 2014, we entered Brazil, our first international market, through a partnership with Fleury Health and Medicine, one of the largest diagnostics organizations in Brazil. All of these actions reflect our strategy of entering international markets where the adoption opportunity and reimbursement landscape are attractive and our partners have a strong local track record for commercializing novel molecular diagnostics. We do not expect meaningful revenue from international sales in the near future.

The Pulmonology Market: Lung Cancer Diagnostic Market

Pulmonology represents a significant opportunity for our approach, given the inherent challenges in diagnosing lung cancer and lung diseases, which are difficult to access without invasive procedures.

Lung cancer is the leading cause of cancer deaths in the United States, where more than 220,000 new diagnoses and nearly 160,000 deaths were expected in 2015. Approximately 250,000 patients with suspected lung cancer currently undergo bronchoscopy each year in the United States to assess lung nodules or lesions that are suspicious for lung cancer. Bronchoscopy, a procedure typically performed in an outpatient setting, enables the physician to visualize and collect cells from the patient's lung airways and is considered safer than other, more invasive sampling methods, such as transthoracic needle biopsy, or TTNB, or surgical lung biopsy, and is also less expensive. TTNB, for example, is associated with a 15% to 25% risk of collapsed lung; estimated costs for surgical lung biopsy exceed $20,000.

Approximately 40% of bronchoscopies produce inconclusive results, meaning that malignancy was not found but cannot be ruled out in approximately 100,000 patients each year in the United States. This results from difficulty in accessing small and/or peripheral nodules with bronchoscopy devices. This leaves physicians with the dilemma of whether to direct these patients to surgery or other invasive procedures to obtain a diagnosis, or to actively monitor the patients with imaging techniques, with the potential that cancer may be present.

An estimated 1.6 million pulmonary nodules are discovered incidentally from CT scanning as a part of routine medical care in the United States. Approximately 1.5 million of these patients do not have cancer, though these patients are recommended to be followed up with imaging surveillance or biopsies. Beginning in early 2015, more than eight million Americans at high-risk for lung cancer became eligible for annual screening with LDCT through new coverage requirements for private insurers as part of the Affordable Care Act, and through Medicare. This screening requirement resulted from the National Lung Screening Trial, a landmark 2011 government study, which found that annual screening using newer LDCT scans reduced lung cancer deaths by 20% among older current and former smokers. These findings had

Table of Contents

subsequently prompted the U.S. Preventive Services Task Force to recommend annual LDCT screening for people at high risk of lung cancer due to their age (from 55 to 80 years old) and history of smoking the equivalent of a pack a day for 30 years. While annual screening is expected to save many lives through early detection, it is anticipated to also find many lung nodules that prove to be benign, which has raised concerns that many patients will be unnecessarily subjected to invasive, risky and expensive procedures just to get a diagnosis.

We believe the market opportunity for our Percepta test is between $350 million and $400 million in the United States, based on the current number of bronchoscopies performed to evaluate lung nodules that are suspicious for cancer. This does not include the potential for the number of bronchoscopies to increase, given that use of the Percepta classifier could make bronchoscopy a more attractive option for nonsurgical evaluation of lung nodules or lesions. Specifically, clinical validation data for the Percepta classifier showed that, when used with bronchoscopy, the combined sensitivity was 97%, compared to 75% for bronchoscopy alone. Further, the number of patients screened for lung cancer and the number of inconclusive bronchoscopies could expand significantly as screening programs are implemented.

Percepta Bronchial Genomic Classifier

We launched the Percepta Bronchial Genomic Classifier in April 2015 to improve lung cancer diagnosis. The gene expression test is designed to identify patients with lung nodules who are at low risk of cancer following an inconclusive bronchoscopy, helping to determine which patients may be monitored with CT surveillance and avoid unnecessary invasive procedures or surgery.

The Percepta test comprises a 23-gene molecular classifier that measures the "field of injury," detecting molecular changes that occur in the epithelial cells lining the lung's respiratory tract in response to smoking the cause of approximately 85% to 90% of lung cancers. These changes can be detected in cytologically normal airway cells and have been shown to correlate with the presence of malignancy or disease processes from distant sites in the lung. This field of injury genomic technology plays a key role in our positioning of Percepta at the point in the clinical pathway following a bronchoscopy procedure that yields inconclusive results. By resolving ambiguity following a bronchoscopy, we believe our test results can potentially help physicians and patients avoid an invasive surgical procedure as the next step in achieving diagnostic results. The Percepta test is also designed to fit easily into physicians' existing clinical workflow. During a normal bronchoscopy procedure, in addition to collecting the standard patient samples,

Table of Contents

physicians use tiny brushes to collect two cytology samples from the mainstem bronchus for potential molecular testing. These samples are then placed in a collection tube and sent to our CLIA-certified laboratory in South San Francisco for Percepta testing if the initial bronchoscopy is inconclusive. Percepta test results are typically provided to physicians within ten days of order.

We estimate that approximately 4,000 physicians perform bronchoscopies in the United States, of which approximately 80% are pulmonologists. The remaining bronchoscopies are performed by thoracic surgeons, general surgeons and other subspecialty physicians. Most bronchoscopies are performed in hospitals and the majority of those for lung cancer diagnosis take place in the hospital outpatient setting. The primary decision maker for Percepta is the pulmonologist, although other physicians involved in the diagnostic work-up for lung cancer are also involved, including the pathologist, thoracic surgeon, oncologist and radiologist.

Development of Percepta Bronchial Genomic Classifier

We gained Percepta and its underlying technology and intellectual property through the acquisition of Allegro Diagnostics Corp. Early work published in *Nature Medicine* in 2007 demonstrated how gene expression alterations in cytologically normal large-airway epithelial cells of current and former smokers could serve as a lung cancer diagnostic. Percepta was developed using a training set of 299 patients, a subset of patients enrolled in the AEGIS, or Airway Epithelium Gene Expression in the Diagnosis of Lung Cancer, trials, designed as prospective, observational, cohort studies of current and former cigarette smokers with lung nodules suspicious for cancer, who were undergoing bronchoscopy as part of their diagnostic work-up. Samples were collected at medical centers around the country using standard cytopathology brushings during bronchoscopy. The microarray-based gene expression algorithm was derived using genes associated with lung cancer and with three clinical covariates, including gender, tobacco use and smoking history, as well as patient age, and then applying logistical regression modeling techniques to lock a classifier that could accurately predict cancer status.

Clinical Evidence for Percepta

Clinical Validation

The performance of the Percepta test has been demonstrated in studies enrolling over 1,000 patients from more than 30 domestic and international sites in three clinical validation studies. Results from two large, prospective, multicenter clinical validation studies (AEGIS I and II) were published in *The New England Journal of Medicine* in July 2015 and demonstrated the ability of the genomic test to identify patients at low risk of lung cancer, which could support a more conservative diagnostic approach. The studies involved 639 patients at 28 sites in the United States, Canada and Ireland who were undergoing bronchoscopy to evaluate their lung nodules. Among patients with an inconclusive bronchoscopy result, the Percepta test had a negative predictive value of 91%, demonstrating its ability to identify patients at low risk of cancer with a high degree of accuracy. The Percepta test and bronchoscopy had a combined sensitivity of 97%, compared to 75% for bronchoscopy alone. Additionally, clinical validation data published online in *BMC Medical Genomics* in May 2015 also found the test to have an NPV of greater than 90% in ruling out cancer among 123 patients with inconclusive bronchoscopy results.

Additional Evidence Development

In February 2016, initial clinical utility study data for the Percepta classifier were published online in *CHEST*, the official journal of the American College of Chest Physicians. Using data from the AEGIS trials, the researchers determined the number of patients with inconclusive bronchoscopy results who underwent invasive procedures on lung nodules and lesions that turned out to be benign. Based on the Percepta test performance, they concluded that use of the test could reduce unnecessary invasive procedures by 50% among patients with benign disease and inconclusive bronchoscopy results. This

Table of Contents

publication follows the presentation of findings, also derived from the AEGIS trials, which were presented in October 2015 at the CHEST 2015 Annual Meeting. Additionally, we published an analytical verification study in February 2016 in the journal *BMC Cancer*, establishing the quality and reproducibility of our testing processes. Additional clinical utility, as well as cost-effectiveness data, are expected to be presented at scientific meetings in 2016 and are intended to demonstrate the test's value to payers.

Practice Guidelines

Several existing guidelines cover the management of patients undergoing a diagnostic workup for lung cancer. In 2013, the American College of Chest Physicians, or ACCP, released comprehensive guidelines for the diagnosis and management of lung cancer, updating their 2007 guidelines. NCCN also publishes guidelines for lung cancer screening and management of non-small cell lung cancer and small cell lung cancer. Both organizations' recommendations advise on when to proceed to a biopsy. However, there is little guidance on what to do after an inconclusive bronchoscopy. Our internal research suggests that physicians vary widely in how they proceed with these patients. For example, some physicians take all of these patients to surgery, or TTNB, while others are more conservative and place them under CT surveillance. ACCP guidelines place patients with an inconclusive bronchoscopy at an intermediate risk of malignancy, thus implying that pulmonologists should treat these patients as they would any other intermediate-risk patient. Current guidelines, however, do not provide definitive guidance on what to do for this group. We believe that Percepta can change this diagnostic paradigm by offering evidence-based medicine to further guide how to manage "intermediate-risk" patients, identifying those who are at low risk for lung cancer so they can be followed with CT surveillance rather than moving on to additional invasive diagnostic procedures.

Percepta Marketing and Sales

We entered the market with a small, targeted pulmonary product specialist sales force, offering the Percepta Bronchial Genomic Classifier to a limited number of thought-leading academic and community-based sites as we complete the remaining studies we believe will be needed to build out our library of evidence to support reimbursement. As of March 2016, 40 institutions are offering the Percepta test to their patients who have inconclusive bronchoscopy results, and we expect to have approximately 50 sites using Percepta by mid-2016. We intend to seek reimbursement from Medicare in 2016. Upon receiving Medicare reimbursement, we expect to ramp our sales and marketing efforts as we seek to commercialize the test more broadly. We plan for this to include increasing our sales force and expanding our marketing efforts through such activities as physician speaker programs, increased participation in regional medical conferences, and patient education resources and materials to which physicians can refer and/or provide patients. Our strategy follows a similar approach as used to commercialize Afirma.

Our Product Pipeline

By the end of 2016, we plan to have three commercialized products in our first two targeted clinical areas: endocrinology and pulmonology.

In addition, we are continuously evaluating opportunities to expand our genomic testing approach to other areas of substantial unmet clinical need, all with a focus on the problem of diagnostic ambiguity. We seek large, addressable markets where we can leverage our molecular cytology platform to commercialize comprehensive solutions that improve quality of life for patients by reducing unnecessary surgeries and costs. Today, minimally invasive cytology biopsies or imaging studies are routinely collected from or performed on numerous organs such as breast, cervix, endometrium and others. Similar to thyroid and lung, these often generate ambiguous results that lead to invasive procedures including surgery. We aim to continue to grow our business through internal test development or acquisition.

Table of Contents

Interstitial Lung Diseases

The market for an ILD diagnostic, and particularly IPF, represents another large opportunity to resolve preoperative diagnostic ambiguity, helping to reduce the need for invasive procedures and associated costs. The physician specialist for our IPF product is also the pulmonologist, enabling us to leverage our pulmonology channel, which we have already entered with Percepta.

IPF is one of the most common and most deadly forms of ILD, a diagnostic category comprising more than 200 diverse lung disorders characterized by progressive scarring of the lungs. An estimated 175,000 to 200,000 patients in the United States and major European countries present with suspected ILDs each year. IPF and other ILDs are often similar in symptoms and appearance, making them challenging for physicians to distinguish from each other.

This uncertainty can result in incorrect or missed diagnoses; invasive, risky and expensive diagnostic surgeries costing over $40,000 per surgery; and/or suboptimal treatment. A recent survey of ILD patients further quantifies the significant challenges that patients face in obtaining a diagnosis. The survey, commissioned by the Pulmonary Fibrosis Foundation, with support from Veracyte, found that 42% of respondents endured a year or more between the time they first experienced symptoms and the time they obtained a diagnosis; 25% endured two years or more. Fifty-five percent (55%) of survey respondents were misdiagnosed at least once and, among those who were misdiagnosed, the misdiagnoses persisted for nearly a year (11 months). Nearly half of survey participants underwent a surgical lung biopsy as part of their diagnostic process. In addition, patients diagnosed with IPF who actually have another, less-serious ILD could be erroneously told that they have a deadly disease with a very poor prognosis and may be subjected to inadequate and/or potentially harmful treatment. The need for improved IPF diagnosis is increasingly important with the recent availability of new therapies for IPF in the United States and Europe, pirfenidone and nintedanib, that slow IPF progression, and with other drugs under development with the potential to slow or reverse IPF-related lung damage.

IPF diagnosis is typically made by a multidisciplinary team, or MDT, comprised of a pulmonologist, radiologist and pathologist, based on a thorough clinical work-up combined with the presence of a specific pattern called usual interstitial pneumonia, or UIP, from high-resolution computed tomography, or HRCT, or from a pathology diagnosis made from a tissue sample collected from a surgical procedure. These UIP patterns are often difficult to distinguish, and even experienced radiologists and pathologists may not agree on the diagnosis. Additionally, many patients live in areas where an MDT is not available. When an IPF diagnosis is uncertain by HRCT, diagnostic surgery is considered the best approach; however, lung surgery is invasive, risky and expensive and many patients are too sick to undergo surgery.

A genomic test that could resolve diagnostic ambiguity found in patients presenting with potential IPF or another ILD could enable many patients to be diagnosed and treated appropriately, sooner, and without the need for diagnostic surgery. Our research suggests that clinicians see the need for a genomic test that could provide greater confidence in making an IPF or other ILD diagnosis. Additionally, in data presented at the PFF Summit in November 2015, which we sponsored, pulmonologists reported that the availability of a genomic test that could accurately distinguish UIP patterns would reduce their use of surgical lung biopsy by more than half in ambiguous cases, based on imaging and clinical history. We estimate the addressable market for our IPF test to be over $500 million in the United States and Europe.

Our IPF Test

We are developing a molecular test to enable less-invasive, more accurate and less costly diagnosis of IPF using cytology samples obtained through bronchoscopy. Our IPF test is intended to replace the need for diagnostic surgery by providing valuable, objective information that will enable the MDT to make more accurate diagnoses earlier. We plan to launch our test in the fourth quarter of 2016.

Table of Contents

Our molecular classifier is designed to identify patients with pathology patterns that correspond with IPF versus those typically associated with other ILDs and is being developed using whole-genome, deep RNA sequencing. In May at the ATS 2015 International Conference and in November at the PFF Summit 2015: From Bench to Bedside, we presented data demonstrating the potential of our molecular classifier to accurately distinguish IPF from other ILDs on patient samples obtained through bronchoscopy. Additionally, in May 2015, *The Lancet Respiratory Medicine* published results from key original proof-of-concept research involving our development of classifiers that could distinguish UIP from other ILD pathology patterns using tissue samples obtained through surgery.

We continue to work with more than 25 clinical sites in the United States and internationally to prospectively collect hundreds of patient samples for use in developing and later, in validating our test under our BRAVE protocols. Our intent is to obtain samples that represent all types of cases and associated clinical annotations, which we believe our classifier will be exposed to once commercialized. We have formed a "virtual" MDT of world-renowned experts in pulmonology, radiology and pathology to establish "clinical truth" against which we are developing and measuring our test's performance. We expect to present clinical validation data demonstrating the performance of our IPF test on bronchoscopy samples at a scientific meeting in 2016.

Third-party Relationships

Genzyme

We began our co-promotion partnership with Genzyme, a subsidiary of Sanofi, in January 2012 by executing a co-promotion agreement. Genzyme is an established leader in endocrinology globally, developing and commercializing Thyrogen (thyrotropin alfa for injection) in the United States and over 42 countries worldwide. Thyrogen is an adjunctive diagnostic agent used in follow up of patients with well differentiated thyroid cancer, and an adjunctive treatment for ablation or destruction of thyroid remnants in patients who have had their thyroid removed for the treatment of well-differentiated thyroid cancer. We manage the relationship through a steering committee that oversees certain tactical and strategic planning activities.

Under the 2012 agreement, Genzyme paid us a $10.0 million upfront fee and we are required to pay Genzyme a co-promotion fee that was equal to a percentage of our U.S. cash receipts from the sale of the Afirma GEC test, which fee varied over time. We record the Genzyme co-promotion fees, net of amortization related to the upfront fee, within selling and marketing expense in our statements of operations.

In November 2014, we signed an Amended and Restated U.S. Co-Promotion Agreement, or Amended Agreement. Under the Amended Agreement, the co-promotion fees payable to Genzyme as a percentage of U.S. cash receipts from the sale of the Afirma GEC test were reduced from 32% to 15% beginning January 1, 2015. The earliest either party may terminate the Amended Agreement for convenience is July 1, 2016 and our Amended Agreement with Genzyme expires in January 2027. On March 9, 2016, we formalized the decision to conclude the Amended Agreement with Genzyme effective September 9, 2016.

In February 2015, we entered into an Ex-U.S. Co-Promotion Agreement, or Ex-U.S. Agreement, with Genzyme for the co-exclusive promotion of the Afirma GEC test in two countries outside the United States: Brazil and Singapore. We also granted Genzyme, for a limited period of time, an exclusive right of first negotiation to enter into an agreement with us for the promotion of the Afirma GEC test in three additional countries: Canada, the Netherlands and Italy. Further, upon mutual agreement, the parties may add additional countries (other than the United States) to the Ex-U.S. Agreement. The term of the Ex-U.S. Agreement commenced January 1, 2015 and continues until December 31, 2019 with extension of the agreement possible upon agreement of the parties. Country-specific terms have been established under the Ex-U.S. Agreement for Brazil and Singapore. Pursuant to these terms, we will pay Genzyme 25% of cash receipts from the sale of the Afirma GEC test in Brazil and Singapore over a five-year period commencing January 1, 2015. Beginning in the fourth year of the agreement, if we terminate the agreement for convenience with respect to Brazil, we may be required to pay a termination fee contingent on the number of GEC billable results generated.

Table of Contents

TCP

We rely on Thyroid Cytopathology Partners, P.A. to provide cytopathology professional diagnoses on thyroid FNA samples pursuant to a pathology services agreement. We originally entered into the pathology services agreement in November 2010 with Brazos Valley Pathology, P.A. D/B/A Reitpath, which assigned the contract to TCP in May 2011. In December 2012, we further amended the pathology services agreement. Pursuant to the agreement, as amended in full, TCP has the exclusive right to provide the cytopathology diagnoses on FNA samples that are referred to us as part of the Afirma solution at a fixed price per test with volume discounts. TCP can terminate the agreement upon our failure to pay any amounts due under the contract, and either we or TCP can terminate the agreement upon the insolvency of the other party, breach of the agreement by the other party, termination or breach of the service terms or the suspension or termination of the necessary regulatory licenses and approvals needed to perform the FNA diagnoses. TCP is co-located in a portion of our facilities in Austin, Texas and reimburses us for a portion of our actual out-of-pocket rental and related operating expense costs. Our agreement with TCP was effective until December 31, 2015 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.

Reimbursement

Revenue for the Afirma Thyroid FNA Analysis 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. We believe that reimbursement for our lung products will be derived from similar sources but with a greater proportion coming from Medicare and potentially Medicaid due to the age of the target patient population.

Payer Landscape

For the Afirma GEC, reimbursement is comprised of cytopathology, the Afirma GEC and/or the Malignancy Classifiers when these tests are performed as part of our comprehensive solution. To date, a high percentage of FNA samples received are accessioned for cytopathology, for which we bill both the technical and professional component using established CPT codes. Under our Afirma Diagnostic Partner model, which is used predominantly by our institutional and regional laboratory customers, reimbursement is sought for the Afirma GEC and/or the Malignancy Classifiers. We bill payers directly for the Afirma GEC and the Malignancy Classifiers using either a unique code or a miscellaneous code.

Effective January 2012, Palmetto GBA, the regional Medicare administrative contractor, or MAC, that handled claims processing for Medicare services with jurisdiction at that time, issued coverage and payment determinations for the Afirma GEC. Their review determined that the Afirma GEC met their criteria for analytical and clinical validity, and clinical utility as a reasonable and necessary Medicare benefit. This coverage decision provided approximately 50 million Medicare participants with access to the Afirma GEC. In mid-September 2013, Noridian Administrative Services succeeded Palmetto as the MAC for our region and continued to reimburse under our unique Z code originally established by Palmetto. 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 GEC or for future products could result in a change in the coverage or reimbursement rates for such products, or the loss of coverage. On March 1, 2015, a separate CPT code, or Current Procedural Terminology code, for the Afirma GEC was issued, which we believe will continue to facilitate our progress with payer coverage and contracts, and reimbursement. The new code became effective January 1, 2016.

Collectively, as of March 2016, we have nearly 180 million lives under positive medical coverage policies for the Afirma GEC including from Medicare (January 2012) and leading commercial insurers, including UnitedHealthcare (April 2013), Aetna (June 2013), Humana (July 2013), Cigna (December 2013) and several leading Blue Cross and/or Blue Shield plans, including Health Care Services

Table of Contents

Corporation (December 2015) and Highmark, Horizon Blue Cross, and Blue Shield of California (all 2014). We have nearly 130 million lives under contract for the Afirma GEC, which establishes us as an in-network provider and helps facilitate adoption. However, 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. Any such actions could have a negative effect on our revenue.

We plan to seek Medicare reimbursement for the Percepta Bronchial Genomic Classifier from the Centers for Medicare & Medicaid Services, or CMS, in 2016, using a unique Z code, which we believe would be priced by our local CMS contractor, similar to our early approach with the Afirma GEC.

Dependence on Certain Third-party Payers

We rely on a small number of third-party payers for a significant portion of our revenue. Reimbursement on behalf of patients covered by Medicare accounted for 26%, 26%, and 32% of our revenue for the years ended December 31, 2015, 2014, and 2013, respectively. UnitedHealthcare accounted for 14%, 18%, and 18% of our revenue for the years ended December 31, 2015, 2014, and 2013, respectively. Aetna accounted for 9%, 11%, and 9% of our revenue for the years ended December 31, 2015, 2014, and 2013, respectively. The loss of one or more of these payers would have a negative effect on our business and our revenue.

Reimbursement Strategy

We employ a multi-pronged strategy designed to achieve broad coverage and reimbursement for our tests:

Meet the Evidence Standards Necessary to Be Consistent with Leading Clinical Guidelines. We believe inclusion in leading clinical practice guidelines plays a critical role in payers' coverage decisions. For example, the data published on the Afirma GEC to date is consistent with the recommendations of the widely-recognized American Thyroid Association and National Comprehensive Cancer Network clinical practice guidelines. We intend to pursue a similar strategy with the Percepta test and our future tests.

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. In parallel, a managed care team collaborates with our reimbursement specialists to ensure our payer outreach strategy reacts to and anticipates the changing needs of our customer base. Our customer service team is an integral part of our reimbursement strategy, working with physician practices and patients to navigate the claims process.

Cultivate a Network of Key Opinion Leaders. Key opinion leaders are able to influence 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 physicians and payers. Ongoing studies to support real world experience with our tests are a key component of our efforts to collaborate with physician influencers.

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 Afirma. In each disease area we pursue, we intend to conduct studies in order to develop similar supporting literature as we are currently doing with the Percepta test.

Table of Contents

Established Payer Relationships and In-network Contracts. We believe that positive engagement with payers for Afirma, which has led to coverage decisions, will facilitate our efforts as we approach these same payers for coverage of Percepta and subsequent tests. Additionally, we believe that once we achieve in-network provider status with payers for Afirma, the process for converting Percepta from a covered test to an in-network offering will be streamlined.

Research and Development

Our technology platform offers a number of key attributes, which are applicable to Afirma, Percepta and products we may develop in the future:

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 GEC.

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. Although others can extract RNA from these small biopsies, we believe their process has not been optimized and scaled for high-throughput clinical testing and large-scale clinical development studies involving amplification and hybridization to high-density microarrays. Our process uses commercially available reagents and instruments with our own proprietary process and protocols, which results in RNA extraction from the range of FNAs used in our clinical development studies and our commercial laboratory test.

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 both the Afirma GEC and the Percepta test. We are applying 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 in interstitial lung disease and expect to do so for other diseases in the future.

Technology Agnostic Discovery Platform. We are not reliant on specific formats and are able to take advantage of a multitude of genomic technologies in developing 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 has allowed us to pursue our whole genome approach to biomarker discovery using a range of features obtained through both DNA and RNA sequencing.

Laboratory Operations

Our laboratory operations are headquartered at our CLIA-certified laboratory in South San Francisco, California, where we perform all molecular testing. For our Afirma solution, customers ship samples for cytopathology assessment to our CLIA-registered laboratory in Austin, Texas. Once received, samples are processed through our automated accessioning system, prepared for cytopathology review, and delivered to TCP for cytopathology diagnosis. If cytopathology results are indeterminate, the sample is transferred to South San Francisco where we perform Afirma GEC testing. Institutions and other clients using our Afirma Diagnostic Partner model ship the samples for the Afirma GEC and/or the Afirma Malignancy Classifiers directly to our South San Francisco laboratory. Percepta samples are also shipped directly to South San Francisco. Our South San Francisco facility is responsible for quality assurance

Table of Contents

oversight, licensing and regulatory compliance and maintenance for both of our laboratories to ensure data integrity and consistent, validated processes.

We have recently moved into expanded state-of-the-art laboratory space in South San Francisco, California and believe we have sufficient laboratory capacity to accommodate volume growth for our Afirma, Percepta and IPF tests.

Quality Assurance

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 established a quality system implementation and maintenance, document control, supplier qualification, corrective or preventive actions oversight, and employee training processes that we believe achieves excellence in operations across the entire business. We continuously monitor and improve our quality over time and believe our implementation of these processes has supported our achievement of product performance, customer satisfaction and retention and a philosophy of continuous improvement.

Competition

We believe the principal competitive factors in the markets we target with our products include:

- the ability of the test to answer the appropriate clinical question at the right point in the clinical pathway;
- 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
- 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 Percepta Bronchial Genomic Classifier.

Our principal competition for Afirma 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 are educating 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. The organizations include Interpace Diagnostics Group, Inc., Rosetta Genomics Ltd., Integrated Diagnostics, Inc. 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 that are able to compete with Afirma's high negative predictive value to rule out cancer.

With the Percepta test, we believe our primary competition will similarly come from traditional methods used by physicians to diagnose lung cancer. We also anticipate facing potential competition from companies offering or developing approaches for assessing malignancy risk in

patients with lung nodules

Table of Contents

using alternative samples, such as blood, urine or sputum. However, such "liquid biopsies" are often used earlier in the diagnostic paradigm for instance, to screen for cancer or to gauge risk of recurrence or response to treatment.

In general, we also face competition from commercial laboratories, such as Laboratory Corporation of America Holdings, Quest Diagnostics Incorporated 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 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 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 that 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.

Intellectual Property

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 have eight issued patents which expire between 2029 and 2032 related to methods used in the Afirma diagnostic platform, in addition to eight pending U.S. utility patent applications and six U.S. provisional applications. Some of these U.S. utility patent applications have pending foreign counterparts. We also exclusively licensed intellectual property, including rights to two issued patents that will expire between 2030 and 2032, and three pending U.S. utility patent applications in the thyroid space that would expire between 2030 and 2033 once issued, related to methods that are used in the Afirma diagnostic test, some of which have foreign counterparts.

In the lung diagnostic space, we exclusively license intellectual property rights to seven pending patent applications and one issued patent in the United States and abroad. Patents issuing from the licensed portfolio will expire between 2024 and 2028. In addition, we own a PCT application and a pending U.S. application related to our Percepta test. We also own two applications related to other lung diseases, and a PCT application, a pending U.S. application, and two ex-U.S. applications related to our interstitial lung disease test under development. Any patents granted from the current lung cancer patent applications will expire no earlier than 2035 and those from the interstitial lung disease patent applications will expire no earlier than from 2034 to 2035.

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

Table of Contents

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," and "Percepta" and for the Veracyte and Afirma logos. 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.

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. Under CLIA, we are required to hold a certificate applicable to the type of laboratory examinations we perform and to comply with standards covering personnel, facilities administration, quality systems and proficiency testing.

We have current certificates under CLIA to perform testing at each of our locations. To renew our CLIA certificates, we are subject to survey and inspection every two years to assess compliance with program standards. The regulatory and compliance standards applicable to the testing we perform may change over time, and any such changes could have a material effect on our business.

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. We must maintain CLIA compliance and certification to be eligible to bill for diagnostic services provided to Medicare beneficiaries. If we were to be found out of compliance with CLIA requirements and subjected to sanction, our business could be harmed.

U.S. Food and Drug Administration: Diagnostic Kits

Diagnostic kits, including collection systems, which are sold and distributed through interstate commerce 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 notice of observations, untitled or warning letters, and can be liable for criminal or civil penalties, such as recalls, import detentions, seizures, or injunctions, including orders to cease manufacturing.

The FDC Act classifies medical devices into one of three categories based on the risks associated with the device and the level of control necessary to provide reasonable assurance of safety and effectiveness. Class I devices are deemed to be low risk and are subject to the fewest regulatory controls. Many Class I devices are exempt from FDA premarket review requirements. For Class II devices, the FDA generally requires clearance through the premarket notification, or 510(k) clearance process. Class III devices are

Table of Contents

generally the highest risk devices and are subject to the highest level of regulatory control to provide reasonable assurance of the device's safety and effectiveness. Class III devices must typically be approved by the FDA before they are marketed.

Generally, establishments that manufacture or distribute devices, including manufacturers, repackagers and relabelers, specification developers, and initial importers, are required to register their establishments with the FDA and provide the FDA a list of the devices that they handle at their facilities.

After a device is placed on the market, numerous regulatory requirements apply. These include: all of the relevant elements of the Quality System Regulation, or QSR, labeling regulations, restrictions on promotion and advertising, the Medical Device Reporting regulation (which requires that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur), and the Reports of Corrections and Removals regulation (which requires manufacturers to report certain recalls and field actions to the FDA).

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 used effectively for diagnostic examination. A specimen transport and storage container is a Class I device. It is subject to MDR requirements, the reporting of corrections and removals, registration and listing. It is exempt from premarket review and from QSR requirements, except for recordkeeping and complaint handling requirements, so long as no sterility claims are made. Our facility is registered with the FDA as a specification developer, which means that we can sell the collection system under our own name and outline the specifications used to make the collection system, but a third party assembles the collection system for us. The containers we provide for collection and transport of Afirma GEC and Percepta samples from a physician to our clinical reference laboratory are listed as Class I devices with the FDA. We also plan to list our sample collection containers for use with IPF 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 use 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 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 the Afirma GEC 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 for its own use, which are referred to as laboratory developed tests, or LDTs, currently are generally not subject to FDA regulation, although reagents, instruments, software or components provided by third parties and used to perform LDTs may be subject to regulation. We believe that the Afirma GEC and the Percepta test are LDTs. FDA currently exercises its enforcement discretion for LDTs. In October 2014, the FDA published draft guidance documents describing the framework by which they might regulate LDTs. The framework is similar to the guidance they issued previously. The comment period ended in February 2015. There is no timeframe in which the FDA must issue final guidance documents.

Table of Contents

Some of the materials we use for Afirma and Percepta and that we may use for future products are for research use only, or RUO. An RUO product is not intended for human clinical use and must be labeled "For Research Use Only. Not for use in diagnostic procedures." RUOs are a separate regulatory category and are not considered medical devices. They are therefore not subject to the FDA regulatory requirements discussed above. They cannot make any claims related to safety, effectiveness, or diagnostic utility or be intended for human clinical diagnostic or prognostic use. In November 2013, the FDA issued guidance regarding "Commercially Distributed In-Vitro Diagnostic Products Labeled for Research Use Only or Investigational Use Only."

We cannot predict the ultimate form or impact of any such RUO, 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 regulation, including premarket review, will not be required 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, 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 diagnostic services or to develop and introduce new services.

If premarket review, including approval, is required, our business could be negatively affected until such review is completed and clearance to market or approval is obtained, and the FDA could require that we stop selling our diagnostic services pending premarket clearance or approval. If our diagnostic services 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 labeling claims the FDA allows us to make are limited, 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 a premarket notification or filing a PMA application with the FDA. If premarket review is required by the FDA, there can be no assurance that our diagnostic services will be cleared or approved on a timely basis, if at all, nor can there any be assurance that labeling claims will be consistent with our current claims or adequate to support continued adoption of and reimbursement for our solution. 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 diagnostic services if we determine that doing so would be appropriate.

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. Penalties for violations of HIPAA regulations include civil and criminal penalties.

Table of Contents

We have developed and implemented policies and procedures designed to comply with these regulations. The requirements under these regulations may change periodically and could have an effect on our business operations if compliance becomes substantially more costly 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. The U.S. Department of Commerce, the European Commission and the Swiss Federal Data Protection and Information Commissioner have agreed on a set of data protection principles and frequently asked questions, referred to as the Safe Harbor Principles, to enable U.S. companies to satisfy the requirement under European Union and Swiss law that adequate protection is given to personal information transferred from the European Union or Switzerland to the United States. The European Commission and Switzerland have also recognized the Safe Harbor Principles as providing adequate data protection.

New laws governing privacy may be adopted in the future as well. 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.

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 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. 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.

Table of Contents

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 health care program 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 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. Both California's fee-splitting 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.

In addition to statutory exceptions to the Anti-kickback Law, regulations provide 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. There are no regulatory safe harbors to California's Section 650.

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.

Table of Contents

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, taking into account all facts and circumstances.

While we believe that we are in compliance with the Anti-kickback Law and Section 650, 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 and Section 650 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.

Further, the Federal False Claims Act prohibits a person from knowingly submitting a claim, making a false record or statement in order to secure payment 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 fines, imprisonment or both, 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.

International

Many countries in which we may offer Afirma 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 violate local laws. In

Table of Contents

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 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.

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 Health Services, or DHS, 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 DHS. However, we cannot provide assurance that DHS 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 NYDOH, 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

Table of Contents

being found guilty of a misdemeanor under New York law. NYDOH also must approve the LDT before the test is offered in New York; approval has been received for Afirma and conditional approval has been received for Percepta. 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 NYDOH for our South San Francisco and Austin laboratories. We cannot provide assurance that the NYDOH 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 including Florida, Maryland, Pennsylvania and Rhode Island, require licensing of out-of-state laboratories under certain circumstances. 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.

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 Thyroid Cytopathology Partners, 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 Afirma. TCP is managed by Pathology Resources Consultants, or PRC, which provides management and other services to medical practitioners. We have entered into a services agreement with PRC in connection with our arrangement with TCP, pursuant to which we engaged PRC exclusively to manage the pathology services being provided by TCP. Our agreement with PRC was effective until December 31, 2015 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.

Employees

At December 31, 2015, we had 192 employees, of which 38 work in laboratory operations, 27 in research and development and clinical development, 49 in selling and marketing, 78 in general and administrative, including 46 in billing and client services, 12 in information technology and 11 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

Table of Contents

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 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 whether 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, if we cannot obtain acceptable substitute materials, or if we elect to change suppliers, an interruption in test processing could occur and we may not be able to deliver patient reports and 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 sales.

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.

Available Information

We were incorporated in Delaware as Calderome, Inc. in August 2006. Calderome operated as an incubator until early 2008. We changed our name to Veracyte, Inc. in March 2008. Our principal executive offices are located at 6000 Shoreline Court, Suite 300, South San Francisco, California 94080 and our telephone number is (650) 243-6300. Our website address is www.veracyte.com. The information contained on, or that can be accessed through, our website is not part of 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 such material with, or furnish it to, the Securities and Exchange Commission, or SEC. The reports are also available at *www.sec.gov*.

Table of Contents

ITEM 1A. RISK FACTORS

Risks Related to Our Business

We are an early-stage company with 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, 2015, we had a net loss of $33.7 million and we expect to incur additional losses in 2016 and in future years. As of December 31, 2015, we had an accumulated deficit of $148.7 million. We may never achieve revenue sufficient to offset our expenses. Over the next several years, we expect to continue to devote substantially all of our resources to increase adoption of, and reimbursement for, Afirma, as well as our lung cancer test, Percepta, which we launched in April 2015, and the development of additional tests we plan to commercialize, including our test for Idiopathic Pulmonary Fibrosis, or IPF. 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 depend solely on sales of Afirma, and we will need to generate sufficient revenue from this and other diagnostic solutions to grow our business.

All of our revenues have been derived from the sale of Afirma, which we commercially launched in January 2011. For the foreseeable future, we expect to derive substantially all of our revenue from sales of Afirma. We launched our first product in pulmonology for lung cancer, Percepta, in April 2015, and our efforts may not be successful. 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 with our molecular cytology platform or, if we are able to identify such diseases, whether or when we will be able to successfully commercialize these solutions. If we are unable to increase sales and expand reimbursement for Afirma, or successfully commercialize Percepta and 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.

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, UnitedHealthcare and Aetna was 26%,14% and 9%, respectively, of our revenue for the year ended December 31, 2015, compared with 26%, 18% and 11%, respectively, in the year ended December 31, 2014. The percentage of our revenue derived from significant payers is expected to fluctuate from period to period as our revenue increases, 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 with jurisdiction at that time, issued coverage and payment determinations for the Gene Expression Classifier, or GEC. 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 GEC could result in a change in the coverage or reimbursement rates for such products, or the loss of coverage.

On March 1, 2015, a separate CPT code, or Current Procedural Terminology code, for the Afirma GEC was issued. The new code became effective January 1, 2016. In November 2015, the Centers for Medicare & Medicaid Services, or CMS, issued a final determination for the 2016 Clinical Lab Fee Schedule, or CLFS, to establish a national limitation amount for this new CPT code under the gapfill process through the regional MACs during calendar year 2016. We do not yet know whether the gapfill process for our new CPT code for Afirma will impact the current Medicare payment rate. Approximately 20% of our GEC patients are covered by Medicare. Additionally, if commercial payers tie their

Table of Contents

reimbursement rates to Medicare rates, the rates at which these payers reimbursement for our test could be negatively affected.

Although we have entered into contracts with certain third-party payers which 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. Any such actions 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 may 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 many payers for Afirma, and we do not have any contracted reimbursement with respect to Percepta. 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 not a 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 Afirma GEC, Afirma Malignancy Classifiers, launched in May 2014, Percepta, launched in 2015, as well as 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, commercial payers may tie their allowable rates to Medicare rates, and should Medicare reduce their rates, we may be negatively impacted. 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.

Table of Contents

Several existing guidelines and historical practices in the United States regarding indeterminate thyroid nodule fine needle aspiration, or FNA, results recommend a full or partial surgical thyroidectomy in most cases. Accordingly, physicians may be reluctant to order a diagnostic solution that may suggest surgery is unnecessary where some current guidelines and historical practice have typically led to such procedures. Moreover, our diagnostic services often are performed at a specialized clinical reference laboratory rather than by a pathologist in a local laboratory, so pathologists may be reluctant to support our services. In addition, guidelines for the diagnosis and treatment of thyroid nodules may subsequently be revised to recommend another type of treatment protocol, and these changes may result in medical practitioners deciding not to use Afirma. These facts may make physicians reluctant to convert to using or continuing to use Afirma, which could limit our ability to generate revenue and our ability to 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 Afirma outside the United States.

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

We recognize a large portion of our revenue upon the earlier of receipt of third-party payer notification of payment or when cash is received. We have little visibility as to when we will receive payment for our diagnostic test, and we must appeal negative payment decisions, which delays collections. We may receive a large number of past payments from a payer all at once which might cause a one-time increase in revenues. For tests performed where we have an agreed upon reimbursement rate or we are able to estimate the amount that will ultimately be realized at the time delivery is complete, such as in the case of Medicare and certain other payers, we recognize the related revenue upon delivery of a patient report to the prescribing physician based on the established billing rate less contractual and other adjustments to arrive at the amount that we expect to realize. We determine the amount we expect to realize based on a per payer, per contract or agreement basis. In the first period in which revenue is accrued for a particular payer, there generally is a one-time increase in revenue. In situations where we cannot estimate the amount that will ultimately be collected, we recognize revenue upon the earlier of receipt of third-party notification of payment or when cash is received. Upon ultimate collection, the amount received from Medicare and other payers where reimbursement was estimated is compared to previous estimates and the contractual allowance is adjusted accordingly. These factors will likely result in fluctuations in our quarterly revenue. Should we recognize revenue from payers on an accrual basis and later determine the 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, research analysts and 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 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. 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, 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

Table of Contents

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 sales.

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

We rely on Thyroid Cytopathology Partners, P.A., or TCP, to provide cytopathology professional diagnoses on thyroid FNA samples pursuant to a pathology services agreement. Pursuant to this agreement, TCP has the exclusive right to provide the cytopathology diagnoses on FNA samples at a fixed price per test. We have also agreed to allow TCP to co-locate in a portion of our facilities in Austin, Texas. Our agreement with TCP is effective through December 31, 2015 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.

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

As demand for Afirma and Percepta 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 Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, collectively the ACA, enacted in March 2010, makes changes that are expected to significantly affect the pharmaceutical and medical device industries and clinical laboratories. Effective January 1, 2013, the ACA includes a 2.3% excise tax on the sale of certain medical devices sold outside of the retail setting. Although a moratorium has been imposed on this excise tax for 2016 and 2017, the excise tax is scheduled to be restored in 2018. Although the FDA has issued draft guidance that, if finalized, would regulate certain laboratory developed tests, or LDTs, as medical devices, our tests are not currently listed as medical devices with the FDA. We cannot assure you that the tax will not be extended to services such as ours in the future if our tests were to be regulated as devices.

Table of Contents

Other significant measures contained in the ACA include, for example, coordination and promotion of research on comparative clinical effectiveness of different technologies and procedures, initiatives to revise Medicare payment methodologies, such as bundling of payments across the continuum of care by providers and physicians, and initiatives to promote quality indicators in payment methodologies. The ACA also includes significant new fraud and abuse measures, including required disclosures of financial arrangements with physician customers, lower thresholds for violations and increasing potential penalties for such violations. In addition, the ACA establishes an Independent Payment Advisory Board, or IPAB, to reduce the per capita rate of growth in Medicare spending. The IPAB has broad discretion to propose policies to reduce expenditures, which may have a negative effect on payment rates for services. The IPAB proposals may affect payments for clinical laboratory services beginning in 2016 and for hospital services beginning in 2020. We are monitoring the effect of the ACA to determine the trends and changes that may be necessitated by the legislation, any of which may potentially affect our business.

In addition to the ACA, the effect of which on our business cannot presently be fully quantified, various healthcare reform proposals have also 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 resets the clinical laboratory payment rates on the Medicare 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 reimbursement methodology for clinical laboratory payment rates under those Medicaid programs. 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 announced plans to bundle payments for clinical laboratory diagnostic tests together with other services performed during hospital outpatient visits under the Hospital Outpatient Prospective Payment System. For calendar year 2016, CMS maintained an exemption for molecular pathology tests from this packaging 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.

On March 1, 2015, a separate CPT code, or Current Procedural Terminology code, for the Afirma GEC was issued. The new code became effective January 1, 2016. In November 2015, the Centers for Medicare & Medicaid Services, or CMS, issued a final determination for the 2016 CLFS to establish a national limitation amount for this new CPT code under the gapfill process through the regional MACs during calendar year 2016. We do not yet know whether the gapfill process for our new CPT code for Afirma will impact the current Medicare payment rate.

Table of Contents

The recently enacted Protecting Access to Medicare Act of 2014, or 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 would report, beginning January 1, 2016, and then on an every three year basis thereafter (or annually for advanced diagnostic laboratory tests, or ADLTs), private payer payment rates and volumes for their tests. CMS will use the rates and volumes reported by laboratories to develop Medicare payment rates for the tests equal to the volume-weighted median of the private payer payment rates for the tests. The payment rates calculated under PAMA will be effective starting January 1, 2017. Although CMS has not yet issued regulations to implement PAMA, we believe our Afirma GEC as well as our Percepta test, once covered, would be considered ADLTs. We cannot assure you that reimbursement rates under the final regulation for tests like ours will not be adversely affected.

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

Under current Medicare billing rules, payment for our tests performed on Medicare beneficiaries who were hospital inpatients at the time the tissue samples were obtained and whose tests were ordered less than 14 days from discharge must be bundled into the payment that the hospital receives for the inpatient services provided. Medicare billing rules also require hospitals to bill for our tests when ordered for hospital outpatients less than 14 days following the date of the hospital procedure where the tissue samples were obtained. Accordingly, we are required to bill individual hospitals for tests performed on Medicare beneficiaries during these time frames. We cannot ensure that hospitals will pay us for tests performed on patients falling under these rules. We cannot assure you that Medicare will not change this limitation in the future.

If the FDA were to begin regulating our tests, we could incur substantial costs and delays associated with trying to obtain premarket clearance or approval.

Clinical laboratory tests like our tests are regulated under the Clinical Laboratory Improvement Amendments of 1988, or CLIA, as well as by applicable state laws. Most laboratory developed tests are not currently subject to FDA regulation, although reagents, instruments, software or components provided by third parties and used to perform LDTs may be subject to regulation. We believe that the Afirma GEC and Percepta tests are LDTs. FDA currently exercises its enforcement discretion for LDTs. In October 2014, the FDA published draft guidance documents describing the framework by which they might regulate LDTs. The framework is similar to the guidance they issued previously. There is no timeframe in which the FDA must issue final guidance documents.

If the FDA requires us to seek clearance or approval to offer 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. If premarket review is required, our business could be negatively impacted if we are required to stop selling our products pending their clearance or approval or the launch of any new products that we develop could be delayed by new requirements. The cost of conducting clinical trials and otherwise developing data and information to support premarket applications may be significant. Further, if the FDA were to issue guidance requiring our ILD test to obtain FDA approval prior to commercial availability, our LDT launch could be delayed. 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. In addition, we could be subject to a recall or seizure of current or future products, operating restrictions, partial suspension or total shutdown of production. 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.

Table of Contents

Some of the materials we use for the Afirma and Percepta tests and that we may use for future products are labeled for research use only. In November 2013, the FDA finalized guidance regarding the sale and use of products labeled for research or investigational use only. 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 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 investigational or research-use only products. If the FDA were to undertake enforcement actions, some of our suppliers might cease selling investigational or research-use only products 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.

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 test, 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 test 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. The organizations include Interpace Diagnostics Group, Inc., Rosetta Genomics Ltd., Integrated Diagnostics, Inc. 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 that are able to compete with Afirma's high negative predictive value to rule out cancer.

With the Percepta test, we believe our primary competition will similarly come from traditional methods used by physicians to diagnose lung cancer. 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. However, such "liquid biopsies" are often used earlier in the diagnostic paradigm for instance, to screen for cancer or to gauge risk of recurrence or response to treatment.

In general, we also face competition from commercial laboratories, such as Laboratory Corporation of America Holdings, Quest Diagnostics Incorporated 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 solution in countries 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 solution 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.

Table of Contents

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 solution, or offer solutions at prices designed to promote market penetration, which could force us to lower the list price of our solution 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. As a public company located in the San Francisco Bay Area, we 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. Additionally, our success depends on our ability to attract and retain qualified sales people. We plan to significantly expand our sales force for Afirma in 2016. There can be no assurance that they will be successful in maintaining and growing the business. As we plan to further increase our sales channels for new tests we commercialize, we may have difficulties locating and recruiting additional sales personnel or retaining qualified salespeople, which could cause a delay or decline in the rate of adoption of our tests. 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.

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. In addition, 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

Table of Contents

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. The move of our laboratory facility to a new location in South San Francisco requires us to notify appropriate regulatory agencies, which may result in an inspection or audit of the new facility. This disrupts our business, including the provision of Afirma GEC and Percepta test reports, and requires the continued investment of resources. 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.

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 doubtful accounts 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 Medicare;
- risk of government audits related to billing Medicare;
- 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.

Standard industry billing codes, known as CPT codes, that we use to bill for cytopathology do not generally exist for our proprietary molecular diagnostic tests. Therefore, until such time that we are awarded and are able to use a designated CPT code specific to our tests, we use "miscellaneous" codes for claim submissions. 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, there can be no assurance that payers will recognize these codes in a timely manner or that the process to transitioning to such a code and updating their billing systems will not result in errors, delays in payments and a related increase in accounts receivable balances. The separate CPT code for the Afirma GEC test became effective January 1, 2016. There can be no assurance that we or our customers who bill will not face issues as the new code is utilized, which could have an adverse effect on our collection rates, revenue, and cost of collecting.

Table of Contents

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 revenue and cash flow.

In October 2015, CMS replaced the ICD-9 code set with the ICD-10 code set. The transition requires ordering physicians to submit ICD-10 codes along with their requisitions for our tests with FNA samples. If physicians do not send proper coding with requisitions, electronic billing systems are not prepared for the transition, or payers have not upgraded their systems to appropriately pay claims with the new codes, we may experience delays in collecting payments, which would impact our revenue recognized on a cash basis, and our cash position.

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. 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 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, which would have an adverse effect on our revenue and our business.

The success of our relationship with Genzyme to co-promote Afirma may have a significant effect on our business.

We sell Afirma in the United States through our internal sales team and through our Amended and Restated U.S. Co-promotion Agreement with Genzyme Corporation, or the Amended Agreement. Under the Amended Agreement, we are required to pay Genzyme a co-promotion fee that is currently 15% of our cash receipts from the sale of the Afirma GEC test. We have also granted Genzyme a right of first offer to co-promote any future thyroid cancer product that we commercialize. On March 9, 2016, we formalized the decision to conclude the Amended Agreement with Genzyme effective September 9, 2016. We intend to hire additional sales personnel to support the growth of Afirma GEC and our other thyroid tests we had previously co-promoted with Genzyme. If we are unsuccessful in transitioning sales and marketing of Afirma from Genzyme soley to our internal sales and marketing personnel, we may experience declining test volumes and associated revenue.

In February 2015, we entered into an Ex-U.S. Co-promotion Agreement with Genzyme for the promotion of the Afirma GEC test with exclusivity in five countries outside the United States initially and in other countries agreed to from time to time. The term of the agreement is January 1, 2015 and continues until December 31, 2019, with extension of the agreement possible upon agreement of the parties. Country-specific terms have been established under this agreement for Brazil and Singapore and a right of first negotiation has been established for Canada, the Netherlands and Italy. We pay Genzyme 25% of net

Table of Contents

revenue from the sale of the Afirma GEC test in Brazil and Singapore over a five-year period commencing January 1, 2015. Beginning in the fourth year of the agreement, if we terminate the agreement for convenience, we may be required to pay a termination fee contingent on the number of GEC billable results generated outside the United States. If Genzyme does not commit the necessary resources to market and sell the Afirma GEC test outside the United States to the level of our expectations, or if they terminate the agreement, we may not realize the benefits of this relationship and our ability to generate revenue in the future may be harmed.

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. We have recently launched the Percepta test and are in the process of developing a test for interstitial lung disease, specifically IPF. We still must complete studies that meet the clinical evidence required to obtain reimbursement, which studies are currently underway. Our product for interstitial lung diseases may not be fully developed and introduced as planned in 2016.

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.

Table of Contents

We may acquire businesses or assets, form joint ventures or make investments in other companies or technologies that could harm our operating results, dilute our stockholders' ownership, increase our debt or cause us to incur significant expense.

We acquired Allegro Diagnostics Corp. in September 2014, and we may pursue additional acquisitions of complementary businesses or assets, as well as technology licensing arrangements as part of our business strategy. We also may pursue strategic alliances that leverage our core technology and industry experience to expand our offerings or distribution, or make investments in other companies. To date, we have limited experience with respect to acquisitions and the formation of strategic alliances and joint ventures. We may not be able to integrate acquisitions successfully into our existing business, and we could assume unknown or contingent liabilities. In addition, we may not realize the expected benefits of our acquisition of Allegro or any businesses we may acquire in the future. Any 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 may choose 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 current loan and security agreement contains covenants that could limit our ability to sell debt securities or obtain additional debt financing arrangements.

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.

If we fail to comply with federal, state and foreign laboratory 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 quality standards or personnel qualifications and responsibilities, facility administration, general laboratory systems, quality assessment, quality control, pre-analytic, analytic, and post-analytic systems and proficiency testing. CLIA certification is also required in order 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. With our recent relocation of our South San Francisco CLIA laboratory to our new building, we may be subject to additional inspections or audits by federal or state regulatory agencies to maintain our CLIA certificate. If we relocate our Texas facility, we may be subject to the same inspections or audits at our new facility.

Table of Contents

We are also required to maintain state licenses to conduct testing in our laboratories. California, New York, Texas, among other states' laws, require that we maintain a license and comply with state regulation as a clinical laboratory; including the training and skills required of personnel and quality control matters. 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 tests as well as conditional approval for the Percepta test, and will be required to obtain approval for any other tests we may offer in the future. 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. Several other states require that we hold licenses to test samples from patients in those states. Other states may have similar requirements or may adopt similar requirements 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 the GEC, which would eliminate our primary source of revenue and harm our business. If we were to lose our CLIA certificate 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.

Finally, we may be subject to regulation in foreign jurisdictions as we pursue offering our tests internationally. Other limitations, such as 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 may constrain our ability to offer tests internationally in the future.

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. Implementation of provisions of the ACA has also resulted in increases in premiums and reductions in coverage for some patients. These events may result in patients delaying or forgoing medical checkups or treatment due to their inability to pay for our tests, which could have an adverse effect on our revenue.

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;

- the Federal Anti-Kickback Statute, 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 health care program;

Table of Contents

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 that, among other things, knowingly presents, or causes to be presented, a false 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 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; and

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

We have adopted policies and procedures designed to comply with these laws and regulations. In the ordinary course of our business, we conduct internal reviews of our compliance with these laws. Our compliance 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. 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.

Table of Contents

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 solution 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, inventory management, 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.

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 GEC is 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 GEC to perform as intended. We may also be subject to similar types of claims related to our Afirma Malignancy Classifiers and our Percepta test, as well as tests we may develop 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.

Table of Contents

If our laboratory in South San Francisco becomes inoperable due to an earthquake or 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 GEC and Percepta testing at our laboratory in South San Francisco, California. Our laboratory in Austin, Texas accepts and stores substantially all FNA samples pending transfer to our California laboratory for Afirma GEC 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.

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 collaborations with many companies at once, which can extend the time it takes to develop, negotiate and implement a collaboration. 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 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.

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 several 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

Table of Contents

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. 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 relative 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 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, in October 2015, the European Court of Justice invalidated a safe-harbor agreement between the United States and European Union member-states, which addressed how U.S. companies handle personal information of European customers, as a result, we may need to

Table of Contents

modify the way we treat such information. Complying with these various laws could cause us to incur substantial costs or require us to change our business practices, systems and compliance procedures in a manner adverse to our business.

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. We have eight issued patents that expire between 2029 and 2032 related to methods used in the Afirma diagnostic platform, in addition to eight pending U.S. utility patent applications and six U.S. provisional applications. Some of these U.S. utility patent applications have pending foreign counterparts. We also exclusively licensed intellectual property, including rights to two issued patents that will expire between 2030 and 2032, and three pending U.S. utility patent applications in the thyroid space that would expire between 2030 and 2033 once issued, related to methods that are used in the Afirma diagnostic test, some of which have foreign counterparts. In the lung diagnostic space, we exclusively license intellectual property rights to seven pending patent applications and one issued patent in the United States and abroad. Patents issuing from the licensed portfolio will expire between 2024 and 2028. In addition, we own a PCT application and a pending U.S. application related to our Percepta test. We also own two applications related to other lung diseases, and a PCT application, a pending U.S. application, and two ex-U.S. applications related to our interstitial lung disease test under development. Any patents granted from the current lung cancer patent applications will expire no earlier than 2035 and those from the interstitial lung disease patent applications will expire no earlier than from 2034 to 2035. 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.

Table of Contents

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, like the Afirma GEC, Malignancy Classifiers and Percepta, 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.

Table of Contents

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

Table of Contents

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.

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 Securities and Exchange Commission, or 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

Table of Contents

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, beginning with the annual report for the year ending December 31, 2014, 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. Moreover, when we are no longer an emerging growth company, our independent registered public accounting firm will be required to issue an attestation report on the effectiveness of our internal control over financial reporting. 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 when we are no longer an emerging growth company, 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.

We are an emerging growth company and may elect to comply with reduced public company reporting requirements applicable to emerging growth companies, which could make our common stock less attractive to investors.

We are an emerging growth company, as defined under the Securities Act of 1933, or the Securities Act. We will remain an emerging growth company until December 31, 2018, although if our revenue exceeds $1 billion in any fiscal year before that time, we would cease to be an emerging growth company as of the end of that fiscal year. In addition, if the market value of our common stock that is held by non-affiliates exceeds $700 million as of the last business day of our second fiscal quarter of any fiscal year before the end of that five-year period, we would cease to be an emerging growth company as of December 31 of that year. As an emerging growth company, we may choose to take advantage of exemptions from various reporting requirements applicable to certain other public companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, reduced financial statement and financial-related disclosures, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirement of holding a nonbinding advisory vote on executive compensation and obtaining stockholder approval of any golden parachute payments not previously approved by our stockholders. If some investors find our common stock less attractive as a result of any choices to reduce

Table of Contents

future disclosure we may make, there may be a less active trading market for our common stock and our stock price may be more volatile.

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.

Prior to our initial public offering in October 2013, there was no public market for our common stock, and an active and liquid public market for our stock may not develop or be sustained. In addition, 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;
- 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 and our business. 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.

Table of Contents

Insiders have substantial control over us and will be able to influence corporate matters.

As of March 4, 2016, directors and executive officers and their affiliates beneficially owned, in the aggregate, 42% of our outstanding capital stock. As a result, these stockholders will be able to exercise significant influence over all matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions, such as a merger or other sale of our company or its assets. This concentration of ownership could limit stockholders' ability to influence corporate matters and may have the effect of delaying or preventing a third-party from acquiring control over us.

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.

Table of Contents

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 new 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. We also lease 24,000 square feet of office and laboratory space in South San Francisco under a lease that expires in March 2016 and approximately 10,400 square feet of office and laboratory space in Austin, Texas, under a lease that expires in July 2018, with an option for us to extend the lease for an additional five years.

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.

EXECUTIVE OFFICERS OF THE REGISTRANT

Our executive officers and their ages and positions as of March 4, 2016, are as set forth below:

Name	Age	Position
Bonnie H. Anderson	58	President, Chief Executive Officer and Director
Julie A. Brooks	70	General Counsel and Secretary
Shelly D. Guyer	55	Chief Financial Officer
Christopher M. Hall	47	Chief Operating Officer

Bonnie H. Anderson has served as our Chief Executive Officer and as a member of our board of directors since February 2008. In August 2013, she was appointed as our President. Prior to joining us, Ms. Anderson was an independent strategic consultant from April 2006 to January 2008, including as a strategic consultant for us from July 2007 to January 2008. Ms. Anderson was a Vice President at Beckman Coulter, Inc., a manufacturer of biomedical testing instrument systems, tests and supplies, from September 2000 to March 2006. She currently serves as a trustee emeritus of the Keck Graduate Institute of Applied Life Sciences. Ms. Anderson holds a B.S. in Medical Technology from Indiana University of Pennsylvania.

Julie A. Brooks has served as our General Counsel and Secretary since March 2014. Prior to joining us, Ms. Brooks was a legal consultant for Auxogyn, Inc., a women's health company, from September 2013 to December 2013. From June 2013 to September 2013, Ms. Brooks served as Vice President, General Counsel for Bayer HealthCare LLC, which acquired Conceptus, Inc., a medical device company, in June 2013, where she served as Executive Vice President, General Counsel and Secretary from November 2009 through June 2013. Previously, from November 2007 through October 2009, Ms. Brooks was Senior Vice President, General Counsel and Secretary of Perlegen Sciences, a genomics company. Ms. Brooks has also held executive roles with a number of medical device, healthcare IT, eCommerce and healthcare services companies, including Virgin HealthCare, Access Health and Westmark International. Ms. Brooks holds a B.A. in Comparative Literature and an M.B.A. from the University of Washington, a J.D. from Santa Clara University and a Masters of Law in Taxation from Georgetown University Law Center.

Shelly D. Guyer has served as our Chief Financial Officer since April 2013 and served as our Secretary from April 2013 to March 2014. Prior to joining us, Ms. Guyer served as Chief Financial Officer and Executive Vice President of Finance and Administration of iRhythm Technologies, Inc., a medical device

Table of Contents

and service company, from April 2008 to December 2012. From March 2006 to August 2007, Ms. Guyer served as Vice President of Business Development and Investor Relations of Nuvelo Inc., a biopharmaceutical company. Prior to joining Nuvelo, Ms. Guyer worked at J.P. Morgan Securities and its predecessor companies for over 17 years, serving in a variety of roles including in healthcare investment banking. Ms. Guyer holds an A.B. in Politics from Princeton University and an M.B.A. from the Haas School of Business at the University of California, Berkeley.

Christopher M. Hall has served as our Chief Operating Officer since September 2014. Mr. Hall served as our Chief Commercial Officer from March 2010 to September 2014. Prior to joining us, Mr. Hall served as Chief Business Officer of Celera Corporation, a diagnostics company focusing on personalized disease management, from October 2008 to February 2010. From August 2002 to February 2010, Mr. Hall served in various executive and senior positions at Berkeley HeartLab, Inc., a cardiovascular disease management company that was acquired by Celera in October 2007, including Chief Clinical Operations Officer and Vice President of Marketing. Mr. Hall holds a B.A. in Economics and Political Science from DePauw University and an M.B.A. from Harvard Business School.

Table of Contents

PART II

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

Market Information

Our common stock commenced trading under the symbol "VCYT" on The NASDAQ Global Market under the symbol "VCYT" on October 30, 2013. Prior to that time, there was no public market for our common stock. The following table sets forth the high and low sales prices of our common stock, on a per share basis, as reported by The NASDAQ Global Market, for the periods indicated:

	High	Low
2015		
Fourth Quarter	$ 8.15	$ 4.69
Third Quarter	$ 12.47	$ 4.59
Second Quarter	$ 12.20	$ 7.24
First Quarter	$ 9.74	$ 6.50
2014		
Fourth Quarter	$ 9.85	$ 6.01
Third Quarter	$ 17.92	$ 9.22
Second Quarter	$ 18.01	$ 12.24
First Quarter	$ 19.00	$ 13.76

As of March 4, 2016, there were approximately 24 holders of record of our common stock. However, because many of our outstanding shares are held in accounts with brokers and other institutions, we have more beneficial owners.

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 loan and security agreement restricts 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.

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 or to the liabilities of Section 18 of the Securities Exchange Act of 1934, and will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933 or the Securities Exchange Act of 1934, 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, 2015. The

Table of Contents

comparisons in the table are required by the Securities and Exchange Commission and are not intended to forecast or be indicative of future performance of our common stock.

	October 30, 2013	December 31, 2013	March 31, 2014	June 30, 2014	September 30, 2014
Veracyte, Inc.	$ 100.00	$ 109.00	$ 129.00	$ 129.00	$ 74.00
NASDAQ Global Market Index	$ 100.00	$ 107.00	$ 107.00	$ 112.00	$ 115.00
NASDAQ Biotechnology Index	$ 100.00	$ 111.00	$ 115.00	$ 125.00	$ 133.00

	December 31, 2014	March 31, 2015	June 30, 2015	September 30, 2015	December 31, 2015
Veracyte, Inc.	$ 73.00	$ 55.00	$ 84.00	$ 35.00	$ 54.00
NASDAQ Global Market Index	$ 121.00	$ 125.00	$ 127.00	$ 118.00	$ 128.00
NASDAQ Biotechnology Index	$ 148.00	$ 229.00	$ 180.00	$ 148.00	$ 165.00

Sales of Unregistered Securities

In April 2015, we completed a private placement of 4,907,975 shares of our common stock to certain accredited investors, or Investors, at a purchase price of $8.15 per share. Gross proceeds to us were $40.0 million and we received $37.3 million in net proceeds, after deducting placement agent fees and other expenses payable by us of $2.7 million. The shares of common stock issued in the private placement were sold in reliance on the exemption from registration provided by Section 4(a)(2) of the Securities Act of 1933. We relied on this exemption from registration based in part on representations made by the investors.

Table of Contents

Equity Compensation Plan Information

Information pertaining to our equity compensation plans is set forth in Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters Equity Compensation Plan Information, and is incorporated herein by reference.

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 financial statements and related notes included elsewhere in this annual report. The selected balance sheet data at December 31, 2015 and 2014 and the selected statements of operations data for each of the years ended December 31, 2015, 2014 and 2013 have been derived from our audited financial statements that are included elsewhere in this report. The selected balance sheet data at December 31, 2013, 2012 and 2011 and the selected statements of operations data for the years end December 31, 2012 and 2011 have been derived from our audited financial statements not included in this report. The financial data included in

Table of Contents

this report are historical and are not necessarily indicative of results to be expected in any future period (in thousands of dollars, except share and per share data and FNAs received):

	Year Ended December 31,				
	2015	2014	2013	2012	2011
Statements of Operations Data:					
Revenue	$ 49,503	$ 38,190	$ 21,884	$ 11,628	$ 2,645
Operating expenses:					
Cost of revenue(1)	21,497	16,606	12,607	7,584	2,925
Research and development(1)	12,796	9,804	7,810	6,608	6,680
Selling and marketing(1)	25,293	21,932	12,540	8,447	2,934
General and administrative(1)	22,583	18,854	12,100	7,918	5,372
Intangible asset amortization	800				
Total operating expenses(1)	82,969	67,196	45,057	30,557	17,911
Loss from operations	(33,466)	(29,006)	(23,173)	(18,929)	(15,266)
Interest expense	(378)	(439)	(233)		
Other income (expense), net	140	72	(2,174)	280	821
Net loss	$ (33,704)	$ (29,373)	$ (25,580)	$ (18,649)	$ (14,445)
Net loss per common share, basic and diluted	$ (1.30)	$ (1.36)	$ (6.15)	$ (28.68)	$ (24.90)
Shares used in computing net loss per common share, basic and diluted	25,994,193	21,639,374	4,158,664	650,333	580,061
Other Operating Data:					
FNAs received	78,548	65,848	49,670	25,890	6,402

(1) Includes employee stock-based compensation as follows:

	Year Ended December 31,				
	2015	2014	2013	2012	2011
Cost of revenue	$ 100	$ 51	$ 34	$ 26	$ 32
Research and development	1,178	790	250	131	130
Selling and marketing	1,326	707	169	111	77
General and administrative	2,998	2,000	794	407	