VERACYTE, INC.
Form 10-K
March 20, 2014

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, 2013

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)

7000 Shoreline Court, Suite 250
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 Global 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 o	Non-accelerated filer ý (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

The registrant's common stock was not publicly traded on The NASDAQ Global Market as of the last business day of the registrant's most recently completed second fiscal quarter.

The number of shares of the registrant's Common Stock outstanding as of March 1, 2014 was 21,143,313.

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 2014 Annual Meeting of Stockholders to be held on May 19, 2014.

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 expectation that our research and development, general and administrative and selling and marketing expenses will increase and our anticipated uses of those 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; our belief that our published evidence provides a basis for inclusion of our test in treatment guidelines; the estimated size of the global market for Afirma; the potential benefits of the Afirma solution and any future products 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 the Afirma Malignancy Classifiers and a test for interstitial lung disease, and the timeframes for development or commercial launch; our dependence on 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 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 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 Afirma and any new 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 third parties; 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

Table of Contents

forward-looking statements contained herein to reflect any change in our expectations with regard thereto or any change in events, conditions or circumstances on which any such statement is based.

When used in this report, all references to "Veracyte," the "company," "we," "our" and "us" refer to Veracyte, Inc.

Veracyte, Afirma, the Veracyte logo and the Afirma logo are our registered 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 diagnostics company pioneering the field of molecular cytology to improve patient outcomes and lower healthcare costs. We specifically target diseases that often require invasive procedures for an accurate diagnosis diseases where many patients undergo costly interventions that ultimately prove unnecessary. We improve the accuracy of diagnosis at an earlier stage of patient care by deriving clinically actionable genomic information from minimally invasive nonsurgical samples. Our first commercial solution, the Afirma Thyroid FNA Analysis, includes as its centerpiece our Gene Expression Classifier, which we refer to as the GEC. The 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. We have demonstrated the clinical utility and cost effectiveness of the GEC in studies published in peer-reviewed journals and established the clinical validity of the GEC in a study published in *The New England Journal of Medicine* in 2012.

Since we commercially launched Afirma in January 2011, we have processed over 80,000 fine needle aspiration, or FNA, samples for evaluation using Afirma and performed approximately 16,000 GECs in order to resolve indeterminate cytopathology results. We have received positive coverage decisions from Aetna, Cigna, Humana, Medicare and UnitedHealthcare, as well as other regional payers. Collectively, these payers represent more than 120 million covered lives. Additionally, we have entered into a global co-promotion agreement with Genzyme Corporation, a subsidiary of Sanofi. To date, substantially all of our revenue has been derived from delivery of patient reports to physicians in the United States. Our revenue has increased from $2.6 million in 2011 to $11.6 million in 2012 and $21.9 million in 2013.

For decades, pathologists have diagnosed complex diseases by evaluating cells taken from a surgical tissue sample. More recently, molecular diagnostic tests that analyze the genomic material in these samples have emerged as an important complement to surgical pathology by helping to predict outcomes and guide treatment decisions. Both approaches, however, typically require relatively large quantities of tissue that must be obtained through an invasive surgical procedure. Cytopathology, which relies on small samples such as FNAs, collected in an outpatient setting, is often the first step in the diagnostic process because it offers a minimally invasive and cost effective alternative to surgery. However, cytology samples tend to be small and non-uniform, which contributes to a relatively high rate of diagnostic ambiguity, resulting in many patients undergoing surgery to obtain an accurate diagnosis. Molecular diagnostics broadly used today are not designed to reduce this ambiguity.

We are building our molecular cytology business by developing molecular diagnostics that yield clinically actionable genomic information from cytology samples, as opposed to surgical tissue samples. Molecular cytology identifies genomic signatures from cytology samples to inform clinical decisions prior

Table of Contents

to surgery. We believe molecular cytology has the potential to improve patient care while simultaneously lowering costs to the healthcare system in a broad range of areas including thyroid, pulmonology, dermatology and reproductive endocrinology. We estimate that the use of molecular diagnostic solutions in thyroid and in three potential expansion areas could represent an approximately $4.0 billion opportunity. This estimate is based on our internal market assessment, from which we estimated the number of patients with ambiguous diagnostic results that we believe could benefit from using genomic tests, and the estimated price of such tests, which price takes into account the estimated cost savings to payers from avoidance of surgery.

Our strategy is to 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. In prioritizing our opportunities, we develop a detailed understanding of the unmet clinical need and the shortcomings of the current standard of care. We precisely define the clinical question in these diseases that, if informed by genomic information, would alter the standard of care in a way that improves patient outcomes while reducing costs in both the short- and long-term. Only then do we deploy our expertise in biomarker discovery and algorithm development to derive a genomic signature that provides meaningful diagnostic information. We position our diagnostic solution as an alternative to an invasive procedure and attempt to efficiently validate the accuracy of our diagnostic tests during product development by comparing our results to those obtained using the more invasive approach.

We developed our first commercial offering, Afirma, to address a significant unmet need in thyroid nodule diagnosis. Thyroid nodules, or bumps under the skin of the neck around the thyroid gland, are usually benign, however, patients with thyroid nodules larger than one centimeter are often referred to an endocrinologist for evaluation. Endocrinologists typically collect cells from the nodule for cytopathology with an FNA and send these samples to a cytopathologist for analysis. According to Sosa et al. in a study published in *Surgery* in 2013, FNAs performed on thyroid nodules are growing at a significant rate. They estimate that there were over 525,000 thyroid FNAs performed in the United States in 2011, more than double the number of FNAs performed in 2006. The American Thyroid Association, or ATA, guidelines indicate that 15% to 30% of FNAs yield indeterminate results, meaning they cannot be diagnosed as definitively benign or malignant by cytopathology alone. Because the risk of malignancy ranges from 20% to 30%, as referenced in the ATA guidelines for an indeterminate diagnosis, clinical practice guidelines have historically recommended that patients with indeterminate cytopathology results undergo surgery to remove part or all of their thyroid to obtain an accurate pathology diagnosis. Accordingly, in 70%-80% of these cases, the thyroid nodule proves to be benign. We estimate the average cost of surgery to be $15,000, and surgery can result in complications and leave a patient in need of thyroid hormone replacement therapy for life.

Afirma is a comprehensive solution that consists of cytopathology and the GEC. According to a clinical validity study published in *The New England Journal of Medicine* in 2012, the GEC reduces the number of unnecessary diagnostic surgeries by analyzing the genomic signature of FNA samples judged to be indeterminate by cytopathology and reclassifies approximately 50% as benign. The study authors concluded that the GEC could be useful to physicians in making important patient care decisions, such as recommending watchful waiting in lieu of diagnostic surgery for patients who receive a GEC benign result following indeterminate cytopathology findings. A subsequent clinical utility study published in *Thyroid* in 2012 covered 368 patients from 51 different endocrinologists. Each of these patients had both a cytopathology indeterminate result and a GEC-benign result. This study found that physicians recommended surgery in only 7.6% of these cases, compared with a historical surgery rate of 74% for patients with indeterminate cytopathology results alone, representing an approximate 90% reduction in surgeries for the 52% of patients receiving a GEC benign result. In other words, approximately 90% of the 52% of patients receiving a GEC benign result make the decision to avoid a surgery. A recent multicenter clinical utility study published in *The Journal of Clinical Endocrinology and Metabolism* in 2013 confirmed earlier findings of a 90% relative reduction in the decision to operate on cytologically indeterminate

Table of Contents

nodules that also had a GEC benign result. The study followed patients a mean of 8.5 months post-diagnosis, thereby demonstrating the durability of a GEC benign result to change patient care. We believe the GEC is currently the only diagnostic test that meets the criteria of the National Comprehensive Cancer Network, or NCCN, for safely monitoring patients with indeterminate cytopathology results in lieu of surgery.

The graphic below illustrates how Afirma changes the traditional method of thyroid nodule diagnosis:

In addition to thyroid cancer, there are many other complex diseases in which cytology samples play a critical role in clinical decision making. As with thyroid nodule diagnosis, inherent ambiguity in evaluation of cytopathology samples often results in unnecessary costs and procedures that would be avoidable if a molecular diagnostic test could refine diagnoses reached by cytopathology alone. We are currently developing Afirma Malignancy Classifiers which we plan to introduce in the second quarter of 2014 to identify rare or potentially aggressive forms of thyroid cancer or metastases to the thyroid that are intended to better inform surgical strategy. We are also in late biomarker discovery in interstitial lung disease, or ILD, a group of lung diseases affecting the tissue and space around the microscopic air sacs of the lungs that are often difficult to diagnose without a surgical lung biopsy. Specifically, we intend to improve the accuracy of diagnosis of idiopathic pulmonary fibrosis, or IPF, a rapidly progressive ILD manifested by lung scarring that is often fatal, as well as other difficult to diagnose ILDs, without subjecting patients to an invasive surgical lung biopsy and enabling them to participate in clinical studies or other avenues of treatment would benefit their diagnosis.

Limitations of Disease Diagnosis Today

Surgical pathology has long been part of the standard of care for diagnosis in many complex diseases, including the diagnosis of many kinds of cancer and lung diseases. Samples collected from surgeries allow multiple slices, or sections, of the tissue to be stained, permitting a pathologist to evaluate the shape and structure of the cells in question, or cellular morphology, that diagnostically classify the sample. However, surgical pathology by definition requires an invasive procedure. Cytopathology, or the analysis of small numbers of cells obtained by minimally invasive needle biopsies, scrapings or smears, what we refer to as cytology samples, is designed to provide a pathologic diagnosis using a small biopsy, obviating the need for surgery. However, cytology samples often have small numbers of cells for microscopic analysis which can make it difficult to make a definitive diagnosis. Even when tissue samples are obtained through a

Table of Contents

diagnostic surgery, there are limitations of microscopic review to guide patient care and treatment decisions. Cells that structurally appear the same by pathology review under a microscope may function differently over the course of disease progression. Predicting aggressiveness of disease, the likelihood of recurrence, which patients are likely to respond to treatment and which therapies would be most likely to improve outcomes is difficult. Even in cases in which pathology provides a definitive benign diagnosis, patient care would be meaningfully improved with lower costs if that diagnosis could be provided without surgery.

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 known levels of cellularity that 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 in an outpatient setting, without 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. The high rate of ambiguity in diagnosis on cytology samples today results in many patients undergoing other subsequent invasive procedures, often including surgery, to obtain an accurate diagnosis.

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 Solution

We are pioneering the field of molecular cytology by developing molecular diagnostics that yield clinically actionable genomic information from cytology samples. Molecular cytology combines the screening benefits of a minimally invasive cytology sample with genomic information to inform disease diagnosis or treatment decisions preoperatively. Our approach begins by developing a detailed understanding of the unmet clinical need and the current standard of care. We precisely define the clinical question in a disease area that, if informed by genomic information, would alter the standard of care in a way that reduces costs and improves patient outcomes. Only then do we deploy our scientific expertise in biomarker discovery and algorithm development to derive a genomic signature that provides meaningful diagnostic information. We 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. Positioning our test as an alternative to an invasive procedure allows us to efficiently validate the accuracy of our test by comparing our test results to those obtained using the more invasive approach. Armed with clinical data that supports the use of molecular cytology in lieu of a more invasive or costly procedure, we believe we are well-positioned to support clinical studies that demonstrate how our products change the standard of care, improve patient outcomes and reduce costs.

We take an integrated team approach in identifying a large, unmet need and carefully defining the relevant clinical question and performance specifications we believe must be achieved to alter patient care. We then leverage the expertise we have developed in biomarker discovery and algorithm development to

Table of Contents

derive a genomic signature that provides an answer to that clinical question. In contrast to molecular diagnostics developed for surgical tissue, our solution solves many of the technical challenges associated with generating analytically valid and clinically relevant genomic information from smaller, heterogeneous cytology samples. To this end, we use a whole-genome approach for gene selection and machine-learning algorithms with statistical methods to identify the genomic signature that achieves the desired performance. Once we have a feasible genomic signature to move forward in product development, we partner with key opinion leaders to design and execute clinical studies that specifically validate the key attributes we believe will be required for broad adoption and reimbursement of our products.

In order to achieve broad clinical adoption and consistent reimbursement, we believe stakeholders in the healthcare system are increasingly demanding that a molecular diagnostic not only meet a rigorous standard of evidence supporting a test's ability to detect disease, but also provide information to physicians that affects clinical decisions, improves patient outcomes and favorably affects cost. Our clinical studies are designed to demonstrate that by deploying our solutions, physicians can safely avoid or delay a more invasive diagnostic procedure for a meaningful proportion of a patient population. Our studies are also designed to confirm that our diagnostic solution materially affects the standard of care and to quantify the resulting costs savings and benefits to patient care. The clinical evidence supporting the GEC is sufficiently robust to reduce diagnostic surgery on patients with cytology indeterminate results by approximately 90% as measured by our published clinical utility and clinical validity data.

We drive physician adoption and retention by marketing Afirma as the centerpiece of a comprehensive solution for improved disease diagnosis, which allows our solution to seamlessly integrate into a physician's practice workflow. We offer Afirma to physicians as a turnkey solution that combines cytopathology for every patient with the GEC when cytopathology yields ambiguous results. Our solution includes a complete patient report that helps guide decision making. By integrating disparate diagnostic procedures into one comprehensive offering, we can simplify and improve the diagnostic process for physicians and their patients while optimizing utilization of our molecular diagnostics to maximize clinical benefits and cost savings. We intend to duplicate this model with solutions we develop for other diseases.

Our capabilities in managed care and claims adjudication are essential to our success in obtaining positive coverage decisions and reimbursement. Our integrated team combines expertise in advocating for positive coverage decisions 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 our strategy across disease selection, clinical study design, marketing and sales.

Thyroid Nodule Diagnostic Market

Afirma addresses a large and growing thyroid nodule diagnostic market where significant ambiguity in cytopathology offers the potential to reduce the rate of surgery needed to diagnose or treat thyroid cancers. These dynamics offer an attractive opportunity for diagnostic improvement:

Large, growing market. Thyroid cancer is the fastest growing cancer in the United States according to the American Cancer Society, and screening of nodules suspicious for cancer is rapidly increasing the number of thyroid FNAs performed. Approximately 525,000 thyroid FNAs were performed in the United States in 2011. We estimate our addressable thyroid nodule diagnostic market opportunity today is approximately $500 million per year in the United States, consisting of an estimated $100 million of cytopathology testing, $350 million of GECs performed on indeterminate cytopathology samples and an additional $40 million related to a molecular cytology test for malignant thyroid FNA samples. Our estimates are based on the product of FNA volumes and the estimated reimbursement per test for both cytology and the GEC, not our list price at which we bill. Based on our research of our primary international target markets, we believe that there is an estimated $300 million market opportunity for the GEC internationally. Because Afirma represents

Table of Contents

a significant innovation for an underserved and relatively concentrated base of physicians, we believe we can effectively market Afirma with a small specialty sales force.

High costs of unnecessary surgery for patients and payers. The biology of thyroid cells is complex. Microscopic analysis by a cytopathologist typically results in 15% to 30% of diagnoses being deemed indeterminate, meaning they cannot be diagnosed as definitively benign or malignant by cytopathology alone. This ambiguity results in confusion for doctors and patients. The 2011 NCCN Guidelines recommend these patients undergo a diagnostic surgery, which we estimate costs $15,000 on average. Post-surgical diagnosis indicates a benign condition in 70% to 80% of these surgeries but surgery can result in complications and leave a patient in need of hormone replacement therapy for life.

Concentrated base of customers. We estimate that approximately 3,500 endocrinologists specialize in thyroid disease and influence the standard of care. We also serve other specialists, including radiologists and Ear, Nose and Throat, or ENT, physicians who also perform FNAs. While endocrinologists generally diagnose patients and refer them to surgery when necessary, endocrinologists do not perform the surgeries themselves. Afirma represents a new solution that endocrinologists can employ to better identify patients with benign results, where watchful waiting is the appropriate standard of care rather than referral to a surgeon.

Highly fragmented thyroid FNA cytopathology market. We believe the analysis of thyroid FNAs is highly fragmented among local cytopathologists and a number of local, regional and national laboratories. As a result, turnaround times and analysis quality can vary between laboratories and cytopathologists. Because an ambiguous diagnosis often leads patients to opt for thyroid surgery, cytopathology practices that meet standards comparable to those found in leading academic settings have the potential to reduce the frequency of indeterminate diagnoses and subsequent thyroid surgeries.

Afirma Thyroid FNA Analysis

Afirma Thyroid FNA Analysis is our comprehensive laboratory-developed solution for thyroid nodule diagnosis. Our customers, primarily endocrinologists, radiologists and head and neck specialists, can implement Afirma in their practice without any meaningful changes to their workflow. Samples for both cytology and the GEC are collected during one FNA procedure on the patient using well accepted techniques.

The majority of our customers practice in the community setting. Our community-based customers send both the cytopathology and the GEC samples overnight to our CLIA-certified laboratory for analysis. After we receive samples and accession them into our laboratory information system, the 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 practice that provides cytopathology professional diagnoses on these samples. When cytopathology results are indeterminate, we perform the GEC on the patient's sample collected from the same FNA procedure. Approximately 14% to 17% of thyroid FNA biopsies to date 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 American Thyroid Association Guidelines, suggesting TCP's specialized focus on thyroid cytopathology offers results more consistent with academic settings. Through our relationship with TCP, the high quality of care historically only accessible to patients in academic settings is now broadly available.

Table of Contents

In addition to our customers in community practices, we serve academic and hospital-based customers who perform their own cytopathology analyses and send us only the GEC when the cytopathology result is indeterminate. This customer base, though smaller, is important since these physicians often influence the standard of care as thought leaders.

By using a large, high volume, thyroid specialized pathology practice to offer consistent cytopathology analysis, we can optimize quality and manage appropriate utilization, ensuring that the GEC is not run on cytologically benign or malignant samples, or where the FNA contains insufficient cellular material for diagnosis. Our ability to manage utilization is attractive to payers looking to capture the value we promise in patient care.

Physicians based in academic settings generally conduct cytopathology in their own laboratory. With Afirma, the GEC sample is preserved until they have processed the cytopathology results. The GEC samples from patients with a cytopathology indeterminate diagnosis are then sent overnight to our laboratory for analysis.

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

The graphic below illustrates the Afirma workflow:

Advantages of Afirma for Stakeholders

Patients

With the GEC, approximately half of the patients with indeterminate cytology results that are reclassified to benign may avoid invasive diagnostic surgery. Patients who obtain an Afirma benign result avoid the potential for surgery-related complications, the effects of life-long hormone replacement therapy and the associated costs. Of the approximately 525,000 FNAs performed in the United States in 2011, we estimate that approximately 115,000 yielded an indeterminate result. With Afirma, patients benefit from access to high-quality cytopathology services delivered as part of our comprehensive solution. Samples for both cytopathology and the GEC can be collected during one routine FNA procedure, delivering to patients a comprehensive assessment of their health status from the first office visit.

Table of Contents

Physicians

Afirma enables every physician, regardless of practice setting, to offer his or her patients access to advanced technology for the diagnosis and management of thyroid nodules. We believe the GEC is the only test available today to reclassify an indeterminate thyroid diagnosis as benign with a risk of malignancy similar to that of a benign diagnosis by cytopathology alone. Afirma does not introduce any new steps into the physician's patient-care routine and eliminates the step of preparing slides for cytopathology. In addition, TCP, our cytopathology provider, is a specialized practice focused solely on performing thyroid FNAs and meets high quality standards with short turnaround times. According to a market research study conducted by Sermo, a third party, and commissioned by us and Genzyme, a survey of 229 endocrinologists indicated that over 96% of 102 Afirma users reported that they were either somewhat satisfied, very satisfied or extremely satisfied with the services of TCP.

Payers

Payers differentiate themselves by offering their insured the most advanced care available in medicine, however, payers are also under increased pressure to contain rising healthcare costs. Afirma allows payers to provide advanced care at a cost lower than the current standard of care. The first peer-reviewed and independent economic impact study, published in the *Journal of Clinical Endocrinology and Metabolism* in 2011, concluded that routine use of the GEC in the United States would prevent tens of thousands of surgeries each year. Based on our estimate of the average costs of surgery of $15,000 as well as the findings from this study and the clinical utility study published in *Thyroid* in 2012, we believe full adoption of Afirma would result in over $500 million in direct cost savings to the healthcare system over five years.

Our Strategy

Our goal is to resolve diagnostic ambiguity preoperatively, allowing patients to avoid unnecessary procedures and generate significant cost savings for the healthcare system.

Key initiatives driving our strategy include:

Accelerate the growth of Afirma. We will continue to drive rapid adoption of Afirma by expanding our base of prescribing physicians and achieving broader reimbursement. We plan to selectively grow our sales force in high-volume geographies domestically and leverage our marketing relationship with Genzyme to accelerate Afirma growth both in the United States and internationally. We intend to increase the body of clinical and pharmacoeconomic evidence to support Afirma's inclusion in additional clinical practice guidelines. We will use our inclusion in guidelines and the extensive data published on Afirma to date, coupled with our core expertise in managed care, claims adjudication, and billing to drive broader reimbursement.

Market our novel molecular diagnostic tests as the centerpiece of a comprehensive patient care solution. In each disease area we pursue, we intend to offer one comprehensive solution that integrates our tests with the disparate diagnostic procedures recommended by clinical practice guidelines. By applying a consistent, evidenced-based diagnostic framework to every patient that fits seamlessly within the physician's practice workflow, we reduce complexity for our customers and optimize utilization of our molecular diagnostics to maximize patient benefit and cost savings.

Drive cost and capital efficiencies by offering turnkey solutions to physicians in specialty markets. The infrastructure we have built to make Afirma commercially available is designed to support a rapid acceleration in patient volumes as we drive broader adoption. Because we market Afirma in a specialty market as part of a turnkey solution, our targeted sales force is able to devote fewer resources to maintaining business with our existing base of prescribing physicians and instead focus on driving adoption of Afirma among new customers. As a result, we believe we are well-positioned

Table of Contents

to achieve scale in Afirma with only incremental capital investments. We intend to target diseases that are well suited to this sales model whenever possible.

Broaden our addressable market in endocrinology. Our product development pipeline includes additional genomic tests to complement Afirma that will serve our current base of physician customers. The large volumes of thyroid FNA samples we receive in the course of performing Afirma provides us with access to patient FNAs from rare malignancies or cancers that have metastasized to the thyroid gland. For example, we are preparing to launch in the second quarter of 2014 our Afirma Malignancy Classifiers, our first product extension to help guide surgical strategy for the treatment of medullary thyroid cancer and other rare or potentially aggressive forms of thyroid cancer.

Expand molecular cytology to additional diseases. We intend to apply our core competencies we have developed in disease selection, genomic discovery, clinical development, and managed care strategy to additional areas of unmet need. For example, we are pursuing a solution for ILD diagnosis that will offer an alternative to surgery by developing genomic signatures derived from cytology samples collected through less invasive bronchoscopy techniques. We intend to commercialize our first lung product in 2016 and believe this product will serve as the foundational application to expand our molecular cytology platform within the pulmonology vertical.

The Afirma Gene Expression Classifier

Development

For the GEC, we used a whole-genome approach to identify gene expression patterns that 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 from endocrinology practices across the United States in the early development of the 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 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.*

Clinical Validation

We collaborated with clinicians across the country to demonstrate the clinical validity of the GEC in a range of practice settings. Clinical validity refers to the accuracy of the results from the GEC against diagnosis from expert pathological review of surgical tissue samples.

Preoperative Diagnosis of Benign Thyroid Nodules with Indeterminate Cytology (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 gene expression classifier exhibited a negative predictive value, or NPV, of 95% for indeterminate results in the atypia or follicular lesion of undetermined clinical 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,

Table of Contents

double-blind study design to validate the accuracy of preoperative GEC benign results compared to post-operative expert pathology review. It was the second prospective multicenter study validating the 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 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 GEC correctly identified 78 of the 85 malignant nodules as suspicious, a 92% sensitivity (95% confidence interval, or CI, 84 to 97). The 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 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 (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 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 and Cost Effectiveness

We collaborated with clinicians to demonstrate the clinical utility of the GEC, which refers to the effect of the GEC result on treatment decision-making and patient outcomes. The clinical utility of the GEC is based on preventing surgery on cytologically indeterminate but benign thyroid nodules that would otherwise be referred for a diagnostic thyroid surgery. Because thyroid nodules with indeterminate FNA cytopathology have a 20% to 30% risk of malignancy when resected, approximately 70% to 80% of these operations will likely be on nodules determined to be benign post-operatively. According to a study published in *PloS Currents: Evidence of Genomic Tests* in 2013, thyroid surgery is associated with potential complications, including temporary and permanent hypocalcemia, recurrent laryngeal nerve injury (with voice change, dysphagia, and potentially airway compromise), and bleeding, with an incidence as high as approximately 2% to 10%. Hypothyroidism is an expected consequence of thyroid surgery, with patients requiring life-long thyroid hormone supplementation or replacement therapy. We believe the most appropriate metric for evaluating the clinical utility of the GEC is the reduction of surgeries performed on

Table of Contents

patients with benign nodules that are diagnosed as cytologically indeterminate. We believe the impact of the GEC on the physician and patient decision making is immediate and measurable from both the perspective of avoidance of unnecessary surgery and cost savings.

Clinical utility

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 (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 GEC in a multicenter, cross-sectional survey of the endocrinologists' decision to operate on patients with a cytopathology indeterminate FNA and a benign GEC result. The study reviewed the first 2,040 GEC tests performed on samples that were classified as indeterminate by cytopathology, of which the GEC reclassified 52.3% of these results as benign. In the study, a cohort of 51 endocrinologists (46 community based; 5 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 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,

Table of Contents

and other symptoms. The study demonstrates the effect of the GEC on clinical decision making for patients with indeterminate thyroid nodules. The graph below sets forth the results of the study:

Afirma Gene Expression Classifier:
Proven Clinical Utility

In addition, such results were consistent with results from an earlier unpublished study, which reported the results of a web- and mail-based opinion survey of 32 physician practices, with a mean of 89% of physicians reporting that they recommended watchful waiting for patients with cytologically indeterminate FNAs but benign GEC results. The study, entitled *Clinical Practice Impact of a Novel mRNA-based Gene Expression Classifier in Thyroid Nodules with Indeterminate Fine Needle Aspiration Cytopathology*, was presented at the American Thyroid Association annual scientific meeting in 2011.

Health economics

*Cost-effectiveness of a Novel Molecular Test for Cytologically Indeterminate Thyroid Nodules (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 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

*

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

Table of Contents

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 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 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 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.

The cost savings estimate in the Johns Hopkins model was based on an estimated 14% rate of surgery on a GEC benign nodule, which rate is almost double the 7.6% and 6.3% subsequently reported in the studies published in *Thyroid* and the *Journal of Clinical Endocrinology and Metabolism* described above. Based on the rate of surgery on GEC benign nodules reported in *Thyroid*, this study found that each GEC test would save approximately $2,600. The graph below sets forth the results of the Johns Hopkins study:

Impact on Patient Quality-Adjusted Life Years (QALY) and Cost Effectiveness of Incorporating GEC into Practice

Analytical Validity

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

We conducted extensive analytical performance studies to validate the performance of the GEC to ensure our ability to offer a robust, accurate and reproducible assay result on patient samples. Over 40 sub-studies were performed on a large number of FNA samples. In the above study, the GEC was subjected to an analytical verification study in our clinical laboratory.

This study found 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 GEC results were found to be stable over the range of shipping conditions expected in community practice. Analytic sensitivity studies demonstrated tolerance to variation in RNA input

Table of Contents

(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 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 GEC were successfully verified, indicating its suitability for clinical use.

Table of Contents

The table below summarizes the Afirma clinical studies that have been performed to date:

Study	Publication/ Presentation	Main Findings
Clinical Validity		
Preoperative Diagnosis of Benign Thyroid Nodules with Indeterminate Cytology(1)(2)(3)	*The New England Journal of Medicine* (August 2012)	Pivotal clinical validation study (prospective, multicenter, double-blind)
		A GEC benign result is comparable in accuracy to a benign cytology result
Molecular Classification of Thyroid Nodules Using High-Dimensionality Genomic Data(1)(2)(3)	*Journal of Clinical Endocrinology and Metabolism* (December 2010)	First prospective, multicenter, double-blind validation study
		Even in the presence of degraded RNA, bloody samples, or malignant samples diluted up to 80% with aspirate material from benign nodules, the GEC correctly recognizes benign nodules and does not miss malignancy in the majority of FNA samples
Clinical Utility		
Multicenter Clinical Experience with the Afirma Gene Expression Classifier(3)(4)	*The Journal of Clinical Endocrinology and Metabolism* (October 2013)	The study followed patients a mean of 8.5 months pos-diagnosis which demonstrated the durability of a GEC benign result to change patient care.
		GEC results significantly altered care outcomes with 11 out of 174 (6%) GEC benign patients that underwent surgery as compared to 121 out of 148 (82%) GEC suspicious patients that underwent surgery.
The Impact of Benign Gene Expression Classifier Test Results on the Endocrinologist-Patient Decision to Operate on Patients with Thyroid Nodules with Indeterminate Fine-Needle Aspiration Cytopathology(1)(3)	*Thyroid* (October 2012)	Large multicenter study of endocrinologists' practices
		Approximately one surgery was avoided for every two GEC tests run on thyroid FNAs with indeterminate cytology
Clinical Practice Impact of a Novel mRNA-based Gene Expression Classifier in Thyroid Nodules with Indeterminate Fine Needle Aspiration Cytopathology(1)(3)	*American Thyroid Association* (*Abstract Poster Presentation*) (October 2011)	Assessed clinical utility by surveying physicians' treatment decisions

		Applying the survey results to 540 patients with indeterminate cytopathology, physicians recommended watchful waiting and sonographic follow up in lieu of surgery in 89% (234 of 263) of patients with a benign GEC result
Health Economics		
Cost-Effectiveness of a Novel Molecular Test for Cytologically Indeterminate Thyroid Nodules ©*The Endocrine Society*(3)(4)	*Journal of Clinical Endocrinology and Metabolism* (November 2011)	Use of Afirma can potentially avoid almost three-fourths of currently performed surgeries in patients with benign nodules
Analytical Validity		
Analytical Performance Verification of a Molecular Diagnostic for Cytology-Indeterminate Thyroid Nodules(1)	*Journal of Clinical Endocrinology and Metabolism* (October 2012)	Analytical sensitivity, analytical specificity, robustness, and quality control of the GEC were successfully verified, indicating its suitability for clinical use
Other Studies		
A Large Multicenter Correlation Study of Thyroid Nodule Cytopathology and Histopathology(1)(3)	*Thyroid* (March 2011)	Prospective multicenter study and meta-review of 11 recently published U.S. based pathology series
		Two-thirds of cytologically indeterminate nodules were found to be benign post-operatively
		Operated cytology benign nodules were found to have an 11% risk of malignancy in the prospective study and 6% risk of malignancy in the meta-review (range 2%-18%)

(1) Sponsored by Veracyte and/or co-authored by a Veracyte employee(s).

(2) An institution of a co-author received institutional grant support as part of this study.

(3) Indeterminate results were defined to include any cytological results suspicious for malignancy in addition to AUS/FLUS and SFN/SHN.

(4) A co-author of this study is a consultant and/or member of our clinical advisory board, and owns shares of our common stock.

Table of Contents

The table below summarizes review articles related to Afirma that have been published to date:

Title	Publication	Summary
Use of the Afirma Gene Expression Classifier for Preoperative Identification of Benign Thyroid Nodules with Indeterminate Fine Needle Aspiration Cytopathology(1)	*PLoS Currents: Evidence on Genomic Tests* (February 2013)	Studies reviewed regarding clinical validity, analytic validity, and clinical utility support recommendation for offering patients the alternative of using the GEC in lieu of thyroid resection in the specific case of thyroid FNAs with indeterminate cytopathology
Minimizing Unnecessary Surgery for Thyroid Nodules	*The New England Journal of Medicine* (August 2012)	Clinical algorithm recommending monitoring in lieu of diagnostic surgery in patients with indeterminate FNA cytopathology results
Diagnostic Use of Molecular Markers in the Evaluation of Thyroid Nodules(2)	*Endocrine Practice* (September/October 2012)	Genomic tests exhibit variable performance characteristics and require clinical validation in prospective, multicenter, blinded studies before widespread adoption
Molecular Biomarkers in Thyroid FNA Samples	*Journal of Clinical Endocrinology and Metabolism* (December 2012)	Prospective, large-scale validation of Afirma provides the broadest available data among any of the thyroid nodule diagnostic tests Clinical implementation of genomic tests requires robust demonstration of analytic validity, as reported for Afirma in Walsh et al *JCEM* 2012 As many as 30-40% of thyroid carcinomas do not display known somatic oncogene mutations and may harbor novel genetic alterations
Diagnosis and Management of Differentiated Thyroid Cancer using Molecular Biology(3)(4)	*Laryngoscope* (April 2013)	The mutation assessment test may serve best as a diagnostic algorithm to identify suspected malignancy with an NPV of up to 95%, Afirma may serve to exclude malignancy Molecular markers can be classified broadly into those with high positive predictive value (BRAF, RET/PTC, PAX8/PPARc) and those with potentially high negative predictive value (gene expression microarrays)

		Gene expression microarrays may eliminate the need for unnecessary diagnostic lobectomy in 60% to 90% of cases
Molecular markers in the diagnosis of thyroid nodules(1)	*Brazilian Archives of Endocrinology and Metabolism* (March 2013)	
		The Afirma GEC raises specificity on indeterminate cytology thyroid nodules from 0% to 52%, effectively reducing the need to operate by one-half
Progress in Molecular-based Management of Differentiated Thyroid Cancer	*The Lancet* (March 2013)	
		The GEC performed best on the atypia of undetermined significance (AUS) or follicular lesion of undetermined significance (FLUS) and follicular neoplasm or suspicious for follicular neoplasm lesions (SFN/SHN) (sensitivity 90%, NPV 94-95%), whereas the NPV was lower for the suspicious for malignancy lesions (85%), which have a higher prevalence of malignancy

(1) Sponsored by Veracyte and/or co-authored by a Veracyte employee.

(2) A co-author is a Veracyte consultant and/or member of our clinical advisory board, and owns shares of our common stock.

(3) Indeterminate results were defined to include any cytological results suspicious for malignancy in addition to UAS/FLUS and SFN/SHN.

(4) A co-author of this study is a consultant and/or member of our clinical advisory board.

Table of Contents

Practice Guidelines

We believe inclusion of new products in practice guidelines is essential to drive their broad adoption and reimbursement. In order to change patient care, tests must carry a high level of published evidence demonstrating clinical validity, analytic validity, clinical utility and cost effectiveness. When studies with such evidence are published in peer-reviewed journals, the authors of practice guidelines may assess the level of evidence and determine whether modifying existing guidelines to include new technology is warranted. In January 2013, the NCCN modified its thyroid cancer guidelines to recommend that physicians consider molecular testing for those patients with cytopathology indeterminate thyroid nodules who have a low risk of cancer. The 2013 NCCN Guidelines further suggest that if a molecular diagnostic test predicts a risk of malignancy comparable to the risk of malignancy of a benign cytopathology result, observation in lieu of a diagnostic surgery is recommended. Based on published evidence, the GEC meets these criteria. Additionally, UpToDate, a leading evidence-based clinical decision support resource for physicians, recommended the GEC in its February 2013 review. We believe our published evidence provides a basis for the American Thyroid Association and the American Association of Clinical Endocrinologists to consider inclusion of the GEC in their treatment guidelines.

Marketing and Sales

Marketing

Our marketing strategy focuses on the comprehensive nature of the Afirma Thyroid FNA Analysis which includes as its centerpiece our proprietary GEC. Our comprehensive solution reduces the number of unnecessary diagnostic surgeries for patients with thyroid nodules. We believe our solution-based approach differentiates us in the marketplace because we serve as a one-stop provider Afirma integrates disparate diagnostic procedures into one comprehensive offering, simplifying and improving the diagnostic process for physicians. Our approach can deliver a number of benefits to physicians, payers, and patients, including:

- reduction of unnecessary thyroid surgeries;
- lower healthcare costs; and
- actionable information from a single patient visit.

We employ diverse marketing programs to inform key stakeholders of the value of our 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 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. We market to patient advocacy organizations and managed care organizations directly through meetings, phone calls and direct educational efforts. Finally, our website serves as a portal for educational material for healthcare professionals, payers and patients.

Sales

Pursuant to our co-promotion agreement with Genzyme, we engage in joint marketing and sales efforts with sales professionals from Genzyme. Our primary target market for Afirma is the approximately 3,500 endocrinologists in the United States whom we believe perform the majority of FNAs in community-based practice settings. We also serve other specialists, including radiologists and ENT physicians who also perform FNAs. To address this concentrated market, we deploy a team of our internal sales professionals and professionals from Genzyme that specialize in endocrinology sales. Our sales team is organized into three regions with 16 territories anticipated by the end of 2014, of which 14 are currently filled. Each

Table of Contents

territory will have a Veracyte sales person complemented by Genzyme sales professionals. We have designed sales goals and financial incentives to align the interests of all sales representatives, regardless of company affiliation, to drive Afirma adoption and growth. Our combined sales team has significant experience selling sophisticated diagnostic services to physicians and deep expertise working with endocrinologists who diagnose and treat patients with thyroid disease and cancer.

We have experienced a high level of customer retention. Of the more than 500 physicians who ordered the Afirma solution in 2011 and 2012 for a minimum of 15 FNAs, nearly 85% continued to order through the end of 2013.

We, together with Genzyme, are in the early stages of commercializing Afirma internationally. We intend to enter select markets in 2014.

Third-party Relationships

Genzyme

In January 2012, we entered into a co-promotion agreement with Genzyme Corporation, a subsidiary of Sanofi, whereby we granted Genzyme the co-exclusive right to market Afirma in the United States and in 40 countries pursuant to which we received a $10.0 million up-front fee from Genzyme. Genzyme is an established leader in endocrinology globally, developing and commercializing Thyrogen® (thyrotropin alfa for injection) in 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. Afirma offers the Genzyme endocrinology sales force a diagnostic solution that can be promoted as part of a comprehensive solution aimed at improving the quality of care for patients with suspected or confirmed thyroid cancer. We began joint marketing under the agreement in June 2012. We manage the relationship through a steering committee that oversees tactical and strategic planning activities.

Under the agreement, we are required to pay Genzyme a co-promotion fee that is equal to a percentage of our cash receipts from Afirma. As of January 2013, the percentage was 40%, but it decreased to 32% on March 1, 2014 and will remain at that level thereafter. We may receive up to an additional $3.0 million from Genzyme consisting of $0.6 million for each country outside of the United States in which we obtain regulatory authorization to market Afirma and achieve a specified level of reimbursement, for up to five countries. Genzyme has also agreed to spend $0.5 million to support clinical development expenses required for entry into the international markets covered by our agreement. This obligation expires in July 2014. 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.

Our agreement with Genzyme expires in January 2027 and either party may terminate the agreement at any time without cause and with six months prior notice. If we terminate the agreement without cause between January 2014 and January 2015, we will be required to repay 40% of the $10.0 million up-front fee, with such percentage being reduced to 30% of such fee if we were to terminate between January 2015 and January 2016. After January 2016, we are not required to return any portion of the fee if we terminate the agreement without cause. In addition, either party may terminate the agreement upon the occurrence of certain events or cause. We have also granted Genzyme a right of first offer to co-promote any future thyroid cancer product that we commercialize.

TCP

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. We originally entered into the pathology services agreement in November 2010 with Brazos Valley Pathology, P.A. D/B/A Reitpath,

Table of Contents

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 is effective until December 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 Afirma 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.

Payer Landscape for Afirma

Reimbursement for Afirma is comprised of two separate components: routine cytopathology and, when cytopathology yields an indeterminate result, reimbursement for the GEC. Substantially all patient samples are assessed with cytopathology for which we bill both the technical and professional component using established CPT codes. We bill payers directly for the GEC using either a unique code or a miscellaneous code. Payers generally assign the GEC its own specific code once a contracting decision is made by the payer.

Effective January 2012, Palmetto GBA, a Medicare administrative contractor, or MAC, with jurisdiction at that time over reimbursement coverage determinations for our products, completed and published an independent technology assessment of Afirma GEC. The review determined that Afirma met 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 Afirma. In mid-September 2013, Noridian Administrative Services succeeded Palmetto as the MAC for our region. Noridian continues 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. Operational changes in contractors processing claims have affected providers in the past, in some cases delaying payment for covered services while claims payment systems are brought on line and fully operational. Changes in the administrative contractor processing Medicare claims for our tests could impact the coverage or payment rates for our current test, could impact our ability to obtain Medicare coverage for products for which we do not yet have coverage or any products we may launch in the future, and may delay payments for our tests.

Collectively, we have more than 120 million lives covered for Afirma, and hundreds of payers have reimbursed one or more GEC tests as of December 2013. We have obtained positive coverage decisions from commercial payers, including UnitedHealthcare in March 2013, Aetna in June 2013, Humana in July 2013 and Cigna in December 2013, as well as several regional payers.

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 32%, 34% and 38% of our revenue for the years ended December 31, 2013, 2012, and 2011, respectively. UnitedHealthcare accounted for 18%, 12% and 13% of our revenue for the years ended December 31, 2013, 2012 and 2011,

Table of Contents

respectively. Aetna accounted for 9%, 13% and 14% of our revenue for the years ended December 31, 2013, 2012 and 2011, 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 Afirma:

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. The data published on the GEC to date is consistent with the requirements of the widely-recognized NCCN clinical practice guidelines. We believe that our data provides compelling evidence for inclusion in the American Thyroid Association and the American Association of Clinical Endocrinologists guidelines as well.

Execute an internal managed care policy 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 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.

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.

Our Product Pipeline

We are continuously evaluating substantial unmet clinical needs in 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 are routinely collected from numerous organs such as breast, cervix, endometrium and others. Similar to thyroid, these often generate ambiguous results that lead to invasive procedures including surgery.

Afirma Malignancy Classifiers

Our product development pipeline includes additional molecular cytology tests to complement Afirma that can serve our current customer physician base. We believe we can add value to physicians, payers, and patients by characterizing thyroid nodule FNAs classified as suspicious or malignant by cytopathology with genomic information that determines subclass or suspected malignant diagnosis that could influence the choice of surgery. Several clinical manifestations that may present as a malignant thyroid nodule, such as a recurrent metastatic cancer from another organ or parathyroid conditions, would not be treated by removing the thyroid. Additionally, medullary thyroid cancer, a rare and aggressive form of thyroid cancer, requires a full central neck and lymph node surgery for treatment. Today, many of these remain undiagnosed until thyroid surgery is performed, requiring a second and more invasive surgery. We believe

Table of Contents

the only way to positively affect patient care and costs is to diagnose these conditions from the FNA. Our Afirma Malignancy Classifiers are being developed to inform on surgical strategy using the FNA and to help direct the patient to the right surgery the first time. We intend to introduce this product in the second quarter of 2014, which will expand the number of patients for which we can perform testing using the Afirma solution.

Idiopathic Pulmonary Fibrosis and Nodules Suspicious for Lung Cancer

We believe the lung disease market provides several opportunities to expand our molecular cytology platform to improve patient care and reduce costs. We have chosen ILDs as our entry into the lung vertical, as it is a large and often overlooked disease area in need of diagnostics that would meaningfully improve the standard of care. We estimate that over 200,000 patients present each year with an ILD for whom accurate diagnosis is crucial in order to develop optimal treatment plans and accurately communicate prognosis. According to a joint industry statement published in the *American Journal of Respiratory and Critical Care Medicine* in 2011, bronchoscopy, a minimally invasive procedure often used to diagnose lung cancer, is typically inadequate for definitive diagnosis of ILDs. As a result, tens of thousands of patients undergo expensive and invasive surgeries in an effort to obtain a diagnosis. In addition, we estimate over 100,000 patients each year, many of whom would benefit from surgical pathology diagnosis but are not good surgical candidates, are left with ambiguity in their diagnosis, resulting in suboptimal and often harmful treatment. The risks and comorbitities of thoracic surgery to obtain a sample for diagnosis limits the number of patients taken through this diagnostic pathway. However, high resolution CAT scans and clinical history are often not sufficient in order to make a diagnosis. We believe a molecular cytology solution performed on minimally invasive bronchoscopy samples has the potential to inform clinical diagnosis without surgery and to improve the outcomes and lower the cost of care for a significant number of the 200,000 patients suspected of having an ILD, including IPF.

We are in late stage biomarker discovery for IPF, one of the more challenging ILDs to diagnose. Based on promising early results in surgical tissue samples, we have increased the number of clinical sites to 14, including one site in Europe, and we anticipate further site expansion. These sites will accrue clinical bronchoscopy samples to enable the optimization of our classifier based on these samples and will serve as core sites for a prospective, multi-center clinical validation study required prior to targeted commercialization in 2016. We also have early biomarker discovery efforts underway to help resolve the diagnosis of nodules found on imaging modalities that are suspicious for lung cancer.

Table of Contents

Developing new products is a lengthy and complex process, and is subject to numerous risks and uncertainties. We may not be able to commercialize on a timely basis, or at all, products we are developing. If we are not able to do so, our business and our ability to generate revenue could be harmed.

Research and Development

Our technology platform offers a number of key attributes:

Core expertise in whole genome 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 make sense of 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 FNAs, 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 the GEC. 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 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

23

Table of Contents

biomarker discovery using a range of technologies, including gene expression and DNA methylation, as well as DNA and RNA sequencing.

Our research and development expenses for the years ended December 31, 2013, 2012 and 2011were $7.8 million, $6.6 million and $6.7 million, respectively.

Laboratory Operations

Our laboratory operations are headquartered at our CLIA-certified laboratory in South San Francisco, California, where we perform all GEC testing. Beginning in May 2013, our customers began shipping samples 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 an FNA sample is diagnosed as indeterminate following cytopathology, the sample is transferred to South San Francisco where we perform GEC testing. Our South San Francisco facility is responsible for quality assurance oversight, licensing and regulation compliance and maintenance for both of our laboratories to ensure data integrity and consistent, validated processes.

We believe we have sufficient laboratory capacity to process Afirma tests, including our planned Afirma Malignancy Classifiers.

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 our target market include:

quality and strength of clinical and analytical validation data;

confidence in diagnostic results;

the extent of reimbursement;

inclusion in practice guidelines;

cost-effectiveness; and

ease of use.

We believe we compete favorably on the factors described above.

Our principal competition for Afirma comes from traditional methods used by physicians to diagnose thyroid cancer. 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, as well as in many international markets, for many years, and we will need to educate physicians about the benefits of our test in order to change clinical practice.

Table of Contents

We also face competition from commercial laboratories, such as Laboratory Corporation of America Holdings and Quest Diagnostics Incorporated, 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 announced their intention to enter the clinical diagnostics market. Other potential competitors include companies that develop diagnostic tests such as Roche Diagnostics, a division of Roche Holding Ltd, Siemens AG and Qiagen N.V. We also face competition from Asuragen Inc. and other companies that measure mutational markers such as BRAF and KRAS to identify nodules that are malignant instead of benign. In the future, we may also face competition from companies developing new products or technologies.

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.

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 our stock price to decline.

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 seven pending United States nonprovisional patent applications and two patents which expire between 2030 and 2031 related to methods that are used in the Afirma diagnostic and one pending United States provisional patent application relating to our lung disease product under development. Many of these patent applications have also been filed in one or more foreign countries.

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

We hold registered trademarks in the United States for "Veracyte" and "Afirma," and 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

Table of Contents

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, that 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 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).

Table of Contents

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 container we provide for collection and transport of FNA samples from a physician to our clinical reference laboratory is listed with the FDA as a Class I medical device and is subject to regulation by the FDA. If the FDA were to determine that our sample collection container is a Class II medical device, we would be required to obtain FDA clearance to use the container.

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 Afirma are regulated under CLIA, as administered by the Centers for Medicare & Medicaid Services, or 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 is an LDT. As a result, we believe our diagnostic services should not be subject to regulation under established FDA policies. Beginning in 1992, the FDA began expressing its view that all LDTs were subject to FDA regulation as devices; however, it stated that it would generally exercise enforcement discretion and not apply the regulatory requirements for medical devices to LDTs. In June 2010, the FDA announced that it was revisiting its policy of exercising enforcement discretion with respect to LDTs. The FDA held a public meeting in July 2010, and FDA officials subsequently indicated that the FDA is interested in developing a risk-based application of oversight for LDTs and that it plans to issue draft guidance on the regulation of LDTs that would more stringently regulate LDTs that met criteria that would be established by the FDA. In June 2013, FDA Commissioner Margaret A. Hamburg reiterated calls made by other Agency officials for increased FDA oversight of LDTs. Two days later, a laboratory association petitioned the FDA to refrain from issuing any such LDT guidance. Meanwhile, the Food and Drug Administration Safety and Innovation Act requires the FDA to notify Congress at least 60 days prior to issuing a draft or final guidance on the regulation of LDTs. The notice must include anticipated details of the action. Draft guidance has not yet been issued with respect to this proposed oversight of LDTs.

Some 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

Table of Contents

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.

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 United States Department of Commerce, the European Commission and the Swiss Federal Data Protection and Information Commissioner have agreed

Table of Contents

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.

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.

Table of Contents

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.

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

Table of Contents

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 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

Table of Contents

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

Because we receive specimens from New York State, our clinical reference laboratories are required to be licensed by New York, under New York laws and regulations, which establish standards for:

- day-to-day operation of a clinical laboratory, including training and skill levels required of laboratory personnel;
- physical requirements of a facility;
- equipment; and
- validation and quality control.

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 DOH, may suspend, limit, revoke or annul the laboratory's New York license, censure the holder of the license or assess civil money penalties. Statutory or regulatory noncompliance may result in a laboratory's operator being found guilty of a misdemeanor under New York law. DOH also must approve the LDT before the test is offered in New York. Should we be found out of compliance with New York laboratory requirements, we could be subject to such sanctions, which could harm our business. We maintain a current license in good standing with DOH for our South San Francisco and Austin laboratories. We cannot provide assurance that the DOH 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

Table of Contents

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 is effective until December 2015 and automatically renews on an annual basis unless either party provides notice of intent not to renew.

Employees

At December 31, 2013, we had 115 employees, of which 21 work in laboratory operations, 21 in research and development and clinical development, 18 in selling and marketing, 55 in general and administrative including 30 in billing and client services, eight in information technology, four in human resources, and two in quality and regulatory affairs. None of our employees are the subject of collective bargaining arrangements, and our management considers its relationships with employees to be good.

Environmental Matters

Our operations require the use of hazardous materials (including biological materials) which subject us to a variety of federal, state and local environmental and safety laws and regulations. Some of these regulations provide for strict liability, holding a party potentially liable without regard to fault or negligence. We could be held liable for damages and fines as a result of our, or others', business operations should contamination of the environment or individual exposure to hazardous substances occur. We cannot predict how changes in laws or new regulations will affect our business, operations or the cost of compliance.

Raw Materials and Suppliers

We procure reagents, equipment, chips and other materials we use to perform the GEC from sole suppliers such as NuGEN Technologies, Inc. and Affymetrix, Inc. We also purchase components used in our Afirma 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

Table of Contents

need them. If these suppliers can no longer provide us with the materials we need to perform the GEC and for our collection kits, if the materials do not meet our quality specifications, or if we cannot obtain acceptable substitute materials, our business would be negatively affected.

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 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 7000 Shoreline Court, Suite 250, 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*.

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 years ended December 31, 2013, 2012 and 2011, we had a net loss of $25.6 million, $18.6 million and $14.4 million, respectively, and we expect to incur additional losses in the future. As of December 31, 2013, we had an accumulated deficit of $85.6 million. To date, we have generated only limited revenue, and 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 and to develop future diagnostic solutions. 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 historical revenue has 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 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 of Afirma, expand reimbursement for Afirma, or successfully 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.

Table of Contents

We depend on Medicare, Aetna and UnitedHealthcare for a significant portion of our revenue and if one or more significant payers stop providing reimbursement or decrease the amount of reimbursement for our tests, our revenue could decline.

Reimbursement on behalf of patients covered by Medicare accounted for 32%, 34% and 38% of our revenue for the years ended December 31, 2013, 2012 and 2011, respectively. UnitedHealthcare accounted for 18%, 12% and 13% of our revenue for the years ended December 31, 2013, 2012 and 2011, respectively. Aetna accounted for 13% and 14% of our revenue for the years ended December 31, 2012 and 2011, respectively. 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 on the GEC. On a five-year rotational basis, Medicare requests bids for its regional MAC services. In mid-September 2013, Noridian Administrative Services succeeded Palmetto as the MAC for our region. We believe the transition is complete with claims being processed by Noridian using the Z code established by Palmetto at the prior negotiated pricing level. This change, or any future changes, in the MAC processing Medicare claims for the GEC could result in a change in the coverage or reimbursement rates for the GEC, or the loss of coverage. In addition, the transition to Noridian has resulted in some delays in payments made to us on behalf of Medicare patients and a slower payment cycle in general.

We do not have a contracted rate of reimbursement with Aetna, Cigna, Humana or UnitedHealthcare. 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 or delay payments for our tests, or if we are unable to successfully negotiate 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 the GEC. Reimbursement by a payer may depend on a number of factors, including a payer's determination that tests such as the GEC are:

not experimental or investigational;

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 policy or enter into a contract to reimburse our test, seeking these approvals is a time-consuming and costly process.

We do not have a contracted rate of reimbursement with most payers. 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.

We expect to continue to focus substantial resources on increasing adoption of and coverage and reimbursement for Afirma. We believe it may 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 test. In addition, the planned launch

Table of Contents

of our Afirma Malignancy Classifiers and any other new products we may develop in the future may require that we expend substantial time and resources in order to obtain reimbursement. If we fail to establish broad adoption of and reimbursement for our products, or if we are unable to maintain existing reimbursement from payers, our ability to generate revenue could be harmed and our future prospects and our business could suffer.

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

If we are unable to create or maintain demand for Afirma 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 Afirma through published papers, presentations at scientific conferences 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.

Several existing guidelines and historical practices in the United States regarding indeterminate thyroid nodule 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 several current guidelines and historical practice have typically led to such procedures. Moreover, our diagnostic services are performed at our 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 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.

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 co-promotion agreement with Genzyme Corporation. We are also working with Genzyme to begin selling Afirma in certain countries outside of the United States. Under the agreement, we are required to pay Genzyme a co-promotion fee that is equal to a percentage of our cash receipts from Afirma. The percentage was 40% and decreased to 32% on March 1, 2014 and will remain at this level thereafter. Our agreement with Genzyme expires in 2027 and either party may terminate the agreement at any time without cause and with six months prior notice. If we were to terminate the agreement without cause prior to January 2015, we would be required to repay 40% of the $10.0 million fee we received from Genzyme. Such percentage would be reduced to 30% of such fee if we were to terminate the agreement between January 2015 and January 2016. We have also granted Genzyme a right of first offer to co-promote any future thyroid cancer product that we commercialize. If Genzyme does not commit the necessary resources to market and sell Afirma 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. If our agreement with Genzyme were terminated, we would have to hire additional sales personnel to support the growth of Afirma and any other thyroid product we agree to co-promote with Genzyme. Any such termination may also delay our entry into international markets.

Because we do not recognize a significant portion of our revenue on an accrual basis, our quarterly operating results are likely to fluctuate.

We currently recognize the majority 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. These factors will likely result in fluctuations in our quarterly revenue. As a result, comparing our

Table of Contents

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 in Afirma, and we may not be able to find replacements or transition to alternative suppliers.

We rely on sole suppliers, such as NuGEN Technologies, Inc. and Affymetrix, Inc., for critical supply of reagents, equipment, chips and other materials that we use to perform the GEC. We also purchase components used in our Afirma 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 GEC and for our collection kits, if the materials do not meet our quality specifications, or if we cannot obtain acceptable substitute materials, an interruption in test processing could occur and we may not be able to deliver patient reports. Any such interruption may significantly affect our future revenue, cause us to incur higher costs, and harm our customer relations and reputation. In addition, in order to mitigate these risks, we may need to maintain inventories of these supplies at higher levels than would be the case if multiple sources of supply were available.

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 until December 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.

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 are unable to agree on commercial terms and our relationship with TCP were to terminate, our business would be harmed until we are 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 tests until a replacement was fully integrated with our test processing operations.

If we are unable to support demand for Afirma or any of our future products or solutions, our business could suffer.

As demand for Afirma or any of our future products or solutions 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 or inability to meet demand. There can be no assurance that we will be able to perform our

Table of Contents

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.

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 Afirma are regulated under the Clinical Laboratory Improvement Amendments of 1988, or CLIA, as well as by applicable state laws. Most laboratory developed tests, or LDTs, 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. Although the FDA has never defined what qualifies as an LDT, we believe that Afirma is an LDT. As a result, we believe Afirma should not be subject to regulation in accordance with the FDA's current policy of exercising enforcement discretion regarding LDTs.

From time to time, the FDA has indicated that it was revisiting its current policy of enforcement discretion and planned to issue guidance that, when finalized, would adopt a risk-based framework that would increase FDA oversight of LDTs. In July 2010, the FDA convened a public meeting to discuss such a risk-based framework. Legislative proposals addressing oversight of LDTs were introduced in the previous two Congresses and we expect that new legislative proposals will be introduced from time to time. We cannot provide any assurance that FDA regulation, including premarket review, will not be required in the future for our tests, whether through additional guidance or regulations issued by the FDA, new enforcement policies adopted by the FDA or new legislation enacted by Congress. It is possible that legislation will be enacted into law, regulations could be promulgated or guidance could be issued by the FDA which may result in increased regulatory burdens for us to continue to offer our tests or to develop and introduce new tests. We cannot predict the timing or content of future legislation enacted, regulations promulgated or guidance issued regarding LDTs, or how it will affect our business.

If FDA premarket review, including approval, is required for Afirma or any of our future tests we may develop, or we decide to voluntarily pursue FDA approval, we may be forced to stop selling our tests or we may be allowed to keep selling our tests while we work to obtain FDA approval. Our business would be negatively affected until such review is completed and clearance to market or approval is obtained. The regulatory process may involve, among other things, successfully completing additional clinical studies and submitting premarket notification or filing a premarket approval application with the FDA. If premarket review is required by the FDA or if we decide to voluntarily pursue FDA premarket review of our tests, there can be no assurance that Afirma or any tests we may develop in the future will be cleared or approved on a timely basis, if at all, nor can there be assurance that labeling claims will be consistent with our current claims or adequate to support continued adoption of and reimbursement for our tests. If our tests are allowed to remain on the market but there is uncertainty in the marketplace about our tests, if we are required by the FDA to label them investigational, or if labeling claims the FDA allows us to make are limited, orders may decline and reimbursement may be adversely affected. Ongoing compliance with FDA regulations would increase the cost of conducting our business, and subject us to heightened regulation by the FDA and penalties for failure to comply with these requirements.

Some of the materials we use for Afirma are labeled for research use only. In June 2011, the FDA issued draft guidance regarding "Commercially Distributed In Vitro Diagnostic Products Labeled for Research Use Only or Investigational Use Only." To date, the FDA has not issued final research-use only guidance. We cannot predict the ultimate timing or form of any such guidance or regulation and or the potential effect on Afirma, our tests in development or the materials used to perform our tests. While we qualify all materials used in our tests according to CLIA regulations, we cannot be certain that the FDA would not promulgate rules or issue guidance documents that could affect our ability to purchase materials necessary for the performance of our tests. Should any of the reagents, instruments, software or components obtained by us from suppliers and used in conducting our tests be affected by future

Table of Contents

regulatory actions, our business could be adversely affected by those actions, including increasing the cost of testing or delaying, limiting or prohibiting the purchase of reagents, instruments, software or components necessary to perform testing.

In addition, our sample collection container is classified as a Class I medical device and is listed with the FDA. If the FDA was to determine that it is a Class II medical device, we would be required to file a 510(k) application and obtain FDA clearance to use the container, which could be time consuming and expensive.

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 will impose significant added responsibilities on management, including the need to identify, recruit, train and integrate additional employees. In addition, rapid and significant growth may place strain on our administrative and operational infrastructure. Our ability to manage our business and growth will require us to continue to improve our operational, financial and management controls, reporting systems and procedures. We have only recently installed a new, internally developed data warehouse, which is critical to our ability to track our diagnostic services and patient reports delivered to physicians, as well as to support our financial reporting systems. The time and resources required to optimize these systems is uncertain, and failure to complete optimization in a timely and efficient manner could adversely affect our operations. If we are unable to manage our growth effectively, it may be difficult for us to execute our business strategy and our business could be harmed.

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

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 solution 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 Afirma and the reimbursement rates of payers;
- compliance with complex federal and state regulations related to billing Medicare;
- disputes among payers as to which party is responsible for payment;
- differences in coverage among payers and the effect of patient co-payments or co-insurance;
- differences in information and billing requirements among payers;
- incorrect or missing billing information; and
- the resources required to manage the billing and claims appeals process.

As we introduce new tests, such as the Afirma Malignancy Classifiers, 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.

Table of Contents

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. These billing complexities, and the related uncertainty in obtaining payment for our diagnostic solution, 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. If claims for Afirma are not submitted to payers on a timely basis, 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.

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, primarily through our co-promotion agreement with Genzyme, 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, its books and records provisions or its anti-bribery provisions.

Table of Contents

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

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

Our principal competition for Afirma comes from traditional methods used by physicians to diagnose thyroid cancer. 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 educate physicians about the benefits of Afirma to change clinical practice.

We also face competition from commercial laboratories, such as Laboratory Corporation of America Holdings and Quest Diagnostics Incorporated, 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 announced their intention to enter 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. We also face competition from Asuragen Inc. and other companies that measure mutational markers such as BRAF and KRAS to identify nodules that are malignant instead of benign. In the future, we may also face competition from companies developing new products or technologies.

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.

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.

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 have enhancements to our current Afirma offering and other diagnostic solutions under development that will require 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 are in the process of developing Afirma Malignancy Classifiers and a product for interstitial lung disease. These products may not be fully developed and introduced as planned in the second quarter of 2014 and in 2016, respectively. In the longer term, we may face challenges obtaining sufficient numbers of samples to validate a genomic signature for a molecular diagnostic product. In order to develop and commercialize diagnostic products, we need to:

- expend significant funds to conduct substantial research and development;

Table of Contents

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.

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.

As part of our business strategy, we may pursue acquisitions of complementary businesses or assets, as well as technology licensing arrangements. 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 not acquired other companies and have limited experience with respect to the formation of strategic alliances and joint ventures. If we make any acquisitions, we may not be able to integrate these acquisitions successfully into our existing business, and we could assume unknown or contingent liabilities. Any future acquisitions 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 an acquired company or business 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.

Table of Contents

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 standards in the areas of personnel qualifications, administration, and participation in proficiency testing, patient test management and quality assurance. 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, for Afirma. 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.

We are also required to maintain state licenses to conduct testing in our laboratories. California law requires that we maintain a license and establishes standards for the day-to-day operation of our clinical reference laboratory in South San Francisco, including the training and skills required of personnel and quality control matters. In addition, both of our clinical reference laboratories are required to be licensed on a test-specific basis by New York State. 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.

Finally, we may be subject to regulation in foreign jurisdictions as we pursue offering Afirma 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 or the import of tissue into the United States, may limit our ability to offer Afirma internationally in the future.

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 PPACA, enacted in March 2010, makes changes that are expected to significantly affect the pharmaceutical and medical device industries and clinical laboratories. Beginning in 2013, each medical device manufacturer must pay a sales tax in an amount equal to 2.3% of the price for which such manufacturer sells its medical devices that are listed with the FDA. The FDA has asserted that clinical laboratory tests such as Afirma are medical devices. However, consistent with the

Table of Contents

FDA's policy of exercising enforcement discretion for LDTs, Afirma is not currently listed as a medical device with the FDA. We cannot assure you that the tax will not be extended to services such as ours in the future if Afirma were to be regulated as a device. The PPACA also mandates a reduction in payments for clinical laboratory services paid under the Medicare Clinical Laboratory Fee Schedule, or CLFS, of 1.75% for the years 2011 through 2015 and a productivity adjustment to the CLFS which would affect our cytopathology billings.

Other significant measures contained in the PPACA 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 PPACA 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 PPACA 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 PPACA 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 PPACA, 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 lab payment rates on the Medicare CLFS by 2% in 2013. In addition, a further reduction of 2% is anticipated from implementation of the automatic expense reductions (sequester) under the Budget Control Act of 2011, which is legislated to be in effect for dates of service on or after April 1, 2013 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. Recent changes to reimbursement methodologies have not changed the payment rate for Afirma; however, 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 will 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. In particular, recommendations by the Simpson-Bowles Commission called for the combination of Medicare Part A (hospital insurance) and Part B (physician and ancillary service insurance) into a single co-insurance and co-payment structure. Currently, clinical laboratory services are excluded from the Medicare Part B co-insurance and co-payment as preventative services. Combining Parts A and B may require clinical laboratories to collect co-payments from patients which may increase our costs and reduce the amount ultimately collected.

Table of Contents

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.

We are subject to other regulation by both the federal government and the states in which we conduct our business, including:

Medicare billing and payment regulations applicable to clinical laboratories;

the Federal anti-kickback law and state anti-kickback prohibitions;

the Federal physician self-referral prohibition, commonly known as the Stark Law, and state equivalents;

the Federal Health Insurance Portability and Accountability Act of 1996;

the Medicare civil money penalty and exclusion requirements;

the Federal False Claims Act civil and criminal penalties and state equivalents; and

the Foreign Corrupt Practices Act of 1977, which applies 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. The risk of our being found in violation of these or other laws and regulations is further increased by the fact that many have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Any action brought against us for violation of these or other laws or regulations, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. If our operations are found to be in violation of any of these laws and regulations, we may be subject to any applicable penalty associated with the violation, including civil and criminal penalties, damages and fines, we could be required to refund payments received by us, and we could be required to curtail or cease our operations. Any of the foregoing consequences could seriously harm our business and our financial results.

If we 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 Afirma could lead to product liability claims if someone were to allege that the GEC failed to perform as it was 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 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 products 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

Table of Contents

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.

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, including licensed clinical laboratory scientists and biostatisticians. 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. Because it is expected that there will be a shortage of clinical laboratory scientists in coming years, it may become more difficult to hire sufficient numbers of qualified personnel. We also face competition from universities and public and private research institutions in recruiting and retaining highly qualified scientific personnel. Additionally, our success depends on our ability to attract and retain qualified salespeople, and in 2014 we plan to significantly expand our sales force. We may have difficulties locating, recruiting or retaining qualified salespeople, which could cause a delay or decline in the rate of adoption of our solution. 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 and sales 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.

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 GEC 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 GEC processing. The equipment we use to perform the GEC would be costly to replace and could require substantial lead time to replace and qualify for use. 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 GEC testing or the backlog of GEC tests that could develop if our California facility is inoperable 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

Table of Contents

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 a diagnostic solution such as Afirma, and our inability to control when and if results are published may delay or limit our ability to derive sufficient revenue from any solution.

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.

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 have not experienced 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 the Health Insurance Portability and Accountability Act of 1996, 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 solution 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

Table of Contents

adversely affect our business. 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 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 seven pending United States nonprovisional patent applications and two patents which expire between 2030 and 2031 related to methods that are used in the Afirma diagnostic and one pending United States provisional patent application relating to our lung disease product under development. It is possible that none of our pending patent applications will result in issued patents in a timely fashion or at all, and even if patents are granted, they may not provide a basis for intellectual property protection of commercially viable products, may not provide us with any competitive advantages, or may be challenged and invalidated by third parties. It is possible that others will design around our current or future patented technologies. We may not be successful in defending any challenges made against our patents or patent applications. Any successful third-party challenge to our patents could result in the unenforceability or invalidity of such patents and increased competition to our business. The outcome of patent litigation can be uncertain and any attempt by us to enforce our patent rights against others may not be successful, or, if successful, may take substantial time and result in substantial cost, and may divert our efforts and attention from other aspects of our business.

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

In particular, the patent positions of companies engaged in the development and commercialization of genomic diagnostic tests, like Afirma, are particularly uncertain. Various courts, including the U.S. Supreme Court, have recently 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

Table of Contents

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 genetic diagnostics tests would be considered natural laws. Accordingly, the evolving case law in the United States may adversely affect our ability to obtain patents and may facilitate third-party challenges to any owned and licensed patents. The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States, and we may encounter difficulties protecting and defending such rights in foreign jurisdictions. The legal systems of many other countries do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biotechnology, which could make it difficult for us to stop the infringement of our patents in such countries. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business.

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

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

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

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

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

We have not registered certain of our trademarks, including Afirma, 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

Table of Contents

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 United States Patent and Trademark Office that could result in substantial cost to us. No assurance can be given that other patent applications will not have priority over our patent applications. In addition, recent changes to the patent laws of the United States allow for various post-grant opposition proceedings that have not been extensively tested, and their outcome is therefore uncertain. Furthermore, if third parties bring these proceedings against our patents, we could experience significant costs and management distraction.

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

As we move into new markets and applications for our products, incumbent participants in such markets may assert their patents and other proprietary rights against us as a means of slowing our entry into such markets or as a means to extract substantial license and royalty payments from us. Our competitors and others may now and, in the future, have significantly larger and more mature patent portfolios than we currently have. In addition, future litigation may involve patent holding companies or other adverse patent owners who have no relevant product revenue and against whom our own patents may provide little or no deterrence or protection. Therefore, our commercial success may depend in part on our non-infringement of the patents or proprietary rights of third parties. Numerous significant intellectual property issues have been litigated, and will likely continue to be litigated, between existing and new participants in our existing and targeted markets and competitors may assert that our products infringe their intellectual property rights as part of a business strategy to impede our successful entry into or growth in those markets. Third parties may assert that we are employing their proprietary technology without authorization. In addition, our competitors and others may have patents or may in the future obtain patents and claim that making, having made, using, selling, offering to sell or importing our

Table of Contents

products infringes these patents. We could incur substantial costs and divert the attention of our management and technical personnel in defending against any of these claims. Parties making claims against us may be able to obtain injunctive or other relief, which could block our ability to develop, commercialize and sell products, and could result in the award of substantial damages against us. In the event of a successful claim of infringement against us, we may be required to pay damages and ongoing royalties, and obtain one or more licenses from third parties, or be prohibited from selling certain products. We may not be able to obtain these licenses on acceptable terms, if at all. We could incur substantial costs related to royalty payments for licenses obtained from third parties, which could negatively affect our financial results. In addition, we could encounter delays in product introductions while we attempt to develop alternative methods or products to avoid infringing third-party patents or proprietary rights. Defense of any lawsuit or failure to obtain any of these licenses could prevent us from commercializing products, and the prohibition of sale of any of our products could materially affect our business and our ability to gain market acceptance for our products.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, during the course of this kind of litigation, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

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

Our 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 capital expenditures and operating expenses to increase 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 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

Table of Contents

marketing initiatives. In addition, we may have to work with a partner on one or more of our products or market development programs, which could lower the economic value of those programs to our company.

We may experience limits on our revenue if patients decide not to use our test.

Some patients may decide not to use Afirma due to its 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. In addition, the current economic environment in the United States has and may continue to result in the loss of healthcare coverage. Implementation of provisions of the PPACA has also resulted in the loss of health insurance, and 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 test, which could have an adverse effect on our revenue.

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 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 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 will be 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 our annual report for the year ending December 31, 2014, provide a management report on the internal control over financial reporting. If we have a material weakness 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 are in the process of compiling the system and processing documentation necessary to perform the evaluation needed to comply with Section 404 of the Sarbanes-Oxley Act. We may not be able to complete our evaluation, testing and any required remediation in a timely fashion. During the evaluation and testing process, if we identify one or more material weaknesses in our internal control over financial reporting, 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.

Table of Contents

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. Internal control deficiencies could also result in a restatement of our financial results in the future.

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 for up to five years, 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. We cannot predict whether investors will find our common stock less attractive if we choose to rely on any of these exemptions. If some investors find our common stock less attractive as a result of any choices to reduce 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 has been 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 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;
- periodic 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;

53

Table of Contents

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 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 in the trading market for our stock shortly following our initial public offering. 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 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.

Future sales of shares by existing stockholders could cause our stock price to decline.

If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after the lock-up and other legal restrictions on resale resulting from our recent initial public offering, the trading price of our common stock could decline. On March 1, 2014, 21,143,313 shares of common stock were outstanding. Of these shares, 5,100,351 are freely tradable, without restriction, in the public market. Each of our directors and officers and substantially all of our other stockholders has entered into a lock-up agreement with the underwriters of our initial public offering that restricts their ability to sell or transfer their shares. The lock-up agreements will expire in April 2014. The underwriters, however, may, in their sole discretion, waive the contractual lock-up prior to the expiration of the lock-up agreements. After the lock-up agreements expire, based on shares outstanding as of March 1, 2014, up to an additional 16,042,962 shares of common stock will be eligible for sale in the public market, of which 14,825,544 shares are held by directors, executive officers and other affiliates and will be subject to volume limitations under Rule 144 under the Securities Act, and various vesting agreements. In addition, 3,027,419 shares of common stock that are subject to outstanding options as of March 1, 2014 will become eligible for sale in the public market to the extent permitted by the provisions of various vesting agreements, the lock-up agreements and Rules 144 and 701 under the Securities Act. We have filed a registration statement on Form S-8 under the Securities Act covering all of the shares of common stock subject to options outstanding and reserved for issuance under our stock plans. This registration statement became effective immediately upon filing, and shares covered by this registration statement are eligible for sale in the public markets, subject to Rule 144 limitations applicable to affiliates and any lock-up agreements described above. If these additional shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

Table of Contents

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

As of March 1, 2014, directors and executive officers and their affiliates beneficially owned, in the aggregate, 71.5% 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 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

We lease 24,000 square feet of office and laboratory space at our headquarters in South San Francisco, California, under a lease that expires in 2016, with an option for us to extend the lease for an additional three years. We also lease approximately 10,400 square feet of office and laboratory space in Austin, Texas, under a lease that expires in 2018, with an option for us to extend the lease for an additional five years. We believe that our existing facilities are adequate to meet our business requirements for at least the next 12 months. However, given that laboratory space is specialized and in limited supply in the San Francisco Bay Area, we regularly review our facilities needs and local available space. We believe that additional space will be available on commercially reasonable terms, if required.

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 1, 2014, are as set forth below:

Name	Age	Position
Bonnie H. Anderson	55	President, Chief Executive Officer and Director
Shelly D. Guyer	53	Chief Financial Officer and Secretary
Christopher M. Hall	45	Chief Commercial 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 Beckmam Coulter, Inc., a manufacturer of biomedical testing instrument systems, tests and supplies, from September 2000 to March 2006. She currently serves as a member of the Board of Trustees of the Keck Graduate Institute of Applied Life Sciences. Ms. Anderson holds a B.S. in Medical Technology from Indiana University of Pennsylvania. Our board of directors has concluded that Ms. Anderson should serve on our board of directors due to her extensive industry experience, strategic perspective of our development, historic knowledge of our company and key leadership position as our President and Chief Executive Officer.

Shelly D. Guyer has served as our Chief Financial Officer and Secretary since April 2013. 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 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 a A.B. in Politics from Princeton University and an M.B.A. from the Haas School of Business at the University of California, Berkeley.

Table of Contents

Christopher M. Hall has served as our Chief Commercial Officer since March 2010. 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 University.

PART II

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

Market Information

Our common stock is traded on The NASDAQ Global Market under the symbol "VCYT." As of March 1, 2014, there were approximately 59 holders of record of our common stock. The high and low sales prices for our common stock on The NASDAQ Global Market for the period from October 30, 2013 (the date our common stock began trading following our initial public offering) to December 31, 2013 were $14.80 and $10.88, respectively.

Table of Contents

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 on the date specified in each of our Common Stock, the NASDAQ Market Index, and the NASDAQ Biotechnology Index for the period commencing on October 30, 2013 (the date our common stock began trading following our initial public offering) and ending on December 31, 2013. The comparison is required by the Securities and Exchange Commission and is not intended to forecast or be indicative of future performance of our common stock.

		Total Return	
Trade Date	**Veracyte, Inc.**	**NASDAQ Market Index**	**NASDAQ Biotech**
10/30/2013	$100.00	$100.00	$100.00
11/29/2013	$ 98.00	$104.00	$109.00
12/31/2013	$109.00	$107.00	$111.00

Dividend Policy

We have never declared or paid any cash dividend on our capital stock. We currently intend to retain any future earnings and do not expect to pay any dividends in the foreseeable future. Our loan and security agreement restricts our ability to pay cash dividends on our common stock, and we may also enter into

58

Table of Contents

credit agreements or other borrowing arrangements in the future that will further 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.

Use of Proceeds

On November 4, 2013, we completed an initial public offering ("IPO") of our common stock. In connection with our IPO, we issued and sold 5,100,351 shares of common stock at a price to the public of $13.00 per share. As a result of the IPO, we received approximately $59.2 million in net proceeds, after deducting underwriting discounts and commissions of $4.6 million and offering expenses of $2.5 million payable by us. The offering was completed in November 2013 at which time an additional 649,649 registered shares were unsold.

We registered the shares under the Securities Act on a Registration Statement on Form S-1 (Registration No. 333-191282), which was filed on September 20, 2013 and declared effective on October 29, 2013, and on a Registration Statement on Form S-1 (Registration No. 333-1919782), which was filed on October 30, 2013 and was immediately effective.

From the date of the initial closing of the IPO through March 1, 2014, we have used a portion of the net proceeds from the sale of these securities to fund our operations, to make capital expenditures, for working capital and for other general corporate purposes.

Sales of Unregistered Securities

From January 1, 2013 through November 4, 2013, we granted stock options under our 2008 Stock Plan to purchase 695,029 shares of our common stock at exercise prices ranging from $4.00 to $12.12 per share, and issued an aggregate of 185,445 shares of common stock pursuant to the exercise of stock options with aggregate proceeds of approximately $0.6 million. These issuances were undertaken in reliance upon an exemption from registration under Rule 701 of the Securities Act of 1933.

In June 2013, we issued 6,904,761 shares of our Series C convertible preferred stock with aggregate proceeds of $13.0 million. Also in June 2013, we issued a warrant to purchase 99,206 shares of our Series C preferred stock, which became exercisable for 24,801 shares of our common stock upon completion of our IPO. These issuances were undertaken in reliance upon an exemption from registration under Section 4(2) of the Securities Act of 1933 or Regulation D promulgated thereunder.

None of the above transactions involved any underwriters, underwriting discounts or commissions.

Table of Contents

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 financial statements and related notes included elsewhere in this annual report. The selected consolidated balance sheet data at December 31, 2013 and 2012 and the selected consolidated statements of operations data for each of the years ended December 31, 2013, 2012 and 2011 have been derived from our audited consolidated financial statements that are included elsewhere in this report. The financial data included in this report are historical and are not necessarily indicative of results to be expected in any future period.

	Year Ended December 31,		
	2013	2012	2011
	(In thousands except share and per share data)		
Statements of Operations Data:			
Revenue	$ 21,884	$ 11,628	$ 2,645
Operating expenses:			
Cost of revenue(1)	12,607	7,584	2,925
Research and development(1)	7,810	6,608	6,680
Selling and marketing(1)	12,540	8,447	2,934
General and administrative(1)	12,100	7,918	5,372
Total operating expenses(1)	45,057	30,557	17,911
Loss from operations	(23,173)	(18,929)	(15,266)
Interest income	5	2	2
Interest expense	(233)		
Other income (expense), net	(2,179)	278	819
Net loss	$ (25,580)	$ (18,649)	$ (14,445)
Net loss per common share, basic and diluted	$ (6.15)	$ (28.68)	$ (24.90)
Shares used in computing net loss per common share, basic and diluted	4,158,664	650,333	580,061
Other Operating Data:			
FNAs received	49,670	25,890	6,402

(1)

Includes employee stock-based compensation as follows:

	Year Ended December 31,		
	2013	2012	2011
	(In thousands)		
Cost of revenue	$ 34	$ 26	$ 32
Research and development	250	131	130
Selling and marketing	169	111	77
General and administrative	794	407	227
Total stock-based compensation	$ 1,247	$ 675	$ 466

Table of Contents

Balance Sheets Data:

	As of December 31,		
	2013	2012	2011
	(In thousands)		
Cash and cash equivalents	$ 71,220	$ 14,002	$ 7,566
Working capital	61,019	7,390	6,707
Total assets	79,630	19,067	10,451
Convertible preferred stock		63,372	49,296
Accumulated deficit	(85,649)	(60,069)	(41,420)
Total stockholders' equity (deficit)	56,443	(58,471)	(40,766)

Table of Contents

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

The following discussion of our financial condition and results of operations should be read in conjunction with our financial statements and related notes included elsewhere in this report. This discussion contains certain forward-looking statements that involve risk and uncertainties. Our actual results may differ materially from those discussed below. Factors that could cause or contribute to such differences include, but are not limited to, those identified below and those set forth under the Section entitled "Risk Factors" in Item 1A, and other documents we file with the Securities and Exchange Commission. Historical results are not necessarily indicative of future results.

Overview

We are a diagnostics company pioneering the field of molecular cytology to improve patient outcomes and lower healthcare costs. We specifically target diseases that often require invasive procedures for an accurate diagnosis diseases where many healthy patients undergo costly interventions that ultimately prove unnecessary. We improve the accuracy of diagnosis at an earlier stage of patient care by deriving clinically actionable genomic information from cytology samples collected in an outpatient setting. We developed our first commercial solution, the Afirma Thyroid FNA Analysis, or Afirma, to address a significant unmet need in thyroid nodule diagnosis. In the United States alone, physicians perform over 525,000 fine needle aspiration, or FNA, biopsies annually on thyroid nodules suspicious for cancer, which in approximately 15% to 30% of patients, FNAs analyzed using cytopathology testing alone yield inconclusive, or indeterminate, results. Prior to Afirma, the standard of care for patients with indeterminate cytopathology results was to surgically remove a portion or all of the thyroid. The Afirma solution includes as its centerpiece our Gene Expression Classifier, which we refer to as the GEC. The GEC helps physicians reduce the number of unnecessary surgeries by approximately 50% by employing a proprietary 142-gene signature to preoperatively determine whether thyroid nodules previously classified by cytopathology as indeterminate can be reclassified as benign. We have demonstrated the clinical utility and cost effectiveness of the GEC in studies published in peer-reviewed journals and established the clinical validity of the GEC in a study published in *The New England Journal of Medicine* in 2012. Since we commercially launched Afirma in January 2011, we have received over 80,000 FNA samples for evaluation using Afirma and performed approximately 16,000 GECs to resolve indeterminate cytopathology results. We estimate the global, addressable market opportunity for Afirma to be approximately $800 million, with the U.S. market comprising $500 million of the total.

We market and sell Afirma with a sales force consisting of our own sales professionals and members of the Genzyme endocrinology sales team. In January 2012, we entered into a co-promotion agreement with Genzyme for the co-exclusive right to promote and market Afirma in the United States and in 40 countries pursuant to which we received a $10.0 million fee from Genzyme. Under the agreement, we are required to pay Genzyme a co-promotion fee that is equal to a percentage of our cash receipts from Afirma.

We increased the list price for the GEC from $4,275 to $4,875 per test in January 2014, while the list price for routine cytopathology remained at $490 per test. We obtained Medicare coverage for the GEC effective in January 2012 which provides reimbursement at an agreed upon rate. In addition, we received positive coverage decisions for the GEC from UnitedHealthcare in March 2013, Aetna in June 2013, Humana in July 2013, and Cigna in December 2013, and have also received positive coverage decisions from a number of other regional payers. Collectively, these payers represent more than 120 million covered lives. Reimbursement rates vary by payer.

Our revenue increased $10.4 million, or 89%, from $11.6 million for the year ended December 31, 2012 to $21.9 million for the year ended December 31, 2013, and $9.0 million, or 340%, from $2.6 million for the year ended December 31, 2011 to $11.6 million for the year ended December 31, 2012. We incurred

Table of Contents

a net loss of $25.6 million, $18.7 million and $14.4 million for the years ended December 31, 2013, 2012 and 2011, respectively. As of December 31, 2013, we had an accumulated deficit of $85.6 million.

Factors Affecting Our Performance

The Number of FNAs We Receive and Test

The growth in our business is tied to the number of FNAs we receive. Approximately 95% of FNAs we receive are for the Afirma solution, which consists of cytopathology, and if the cytopathology finding is indeterminate, the GEC. The remaining approximate 5% of FNAs are received from centers performing cytopathology in their institution where the cytopathology result is indeterminate and we perform the GEC only. Generally 5%-10% of the FNA samples we receive for cytopathology have insufficient cellular material from which to render a cytopathology diagnosis. We only bill the technical component, including slide preparation, for these tests. For results that are benign or suspicious/malignant, we bill for the cytopathology test. If the sample is indeterminate, defined as atypia/follicular lesions of undetermined significance (AUS/FLUS) or suspicious for FN/HCN, we perform the GEC. Historically, approximately 14%-17% of samples we have received for the Afirma solution have yielded indeterminate results by cytopathology. Of the FNA samples sent for GEC testing, approximately 5%-10% have insufficient RNA from which to render a finding. We issue a patient report classifying the sample as GEC Benign, GEC Suspicious or GEC No Result. We bill for the GEC Benign and GEC Suspicious results only. After the GEC is completed, we issue the cytopathology report for the indeterminate samples, and bill for the cytopathology portion of the test at this time. We incur costs of collecting and shipping the FNAs and a portion of the costs of performing tests where we cannot ultimately issue a patient report. Because we cannot bill for all samples received, the number of FNAs received does not directly correlate to the total number of patient reports issued and the amount billed.

Continued Adoption of and Reimbursement for Afirma

We increased our list price for the GEC from $4,275 to $4,875 per test in January 2014, while our list price for routine cytopathology remained at $490 per test. To date only a portion of payers have reimbursed us at full list price. Revenue growth depends on our ability to achieve broader reimbursement at increased levels from third-party payers and to expand our base of prescribing physicians. To drive increased adoption of Afirma, we plan to increase our marketing efforts and to selectively increase our internal sales force in high-volume geographies domestically and to leverage our relationship with Genzyme to accelerate Afirma growth both in the United States and internationally. Because many payers consider the GEC experimental and investigational, we may not receive payment on many tests and payments may not be at acceptable levels compared to what we have billed. We expect our revenue growth will increase as more payers make a positive coverage decision, which should enhance our collections. If we are unable to expand the base of prescribing physicians at an acceptable rate, or if we are not able to execute our strategy for increasing reimbursement, we may not be able to effectively increase our revenue.

How We Recognize Revenue

A significant portion of our revenue is recognized when cash is received. Medicare and three small commercial payers are the only payers with agreed upon reimbursement rates or expected payments and a predictable history of collections, which allows us to recognize the related revenue on an accrual basis. Until we achieve a predictable pattern of collections and a consistent payment amount from a larger number of payers, we will recognize a large portion of our revenue upon the earlier of notification of payment or when cash is received. Additionally, as we commercialize new products, we will need to achieve a predictable pattern of collections and a consistent payment amount for each payer for each new product offering prior to being able to recognize the related revenue on an accrual basis. Because the timing and amount of cash payments received from payers is difficult to predict, we expect that our revenue will fluctuate significantly in any given quarter. In addition, even if we begin to accrue larger amounts of

Table of Contents

revenue related to Afirma, when we introduce new products we do not expect we will be able to recognize revenue from new products on an accrual basis for some period of time. This may result in continued fluctuations in our revenue.

As of December 31, 2012, amounts billed for tests processed which were not recognized as revenue upon delivery of a patient report because our accrual revenue recognition criteria were not met and for which we have not recognized either notification of payment or collected cash, totaled $17.0 million. Of this amount, we recognized revenue of $2.6 million in the year ended December 31, 2013.

As of December 31, 2013, amounts billed for tests processed which were not recognized as revenue upon delivery of a patient report because our accrual revenue recognition criteria were not met and for which we have not received either notification of payment or collected cash totaled $40.9 million.

These amounts are cumulative as of the date referenced and include all amounts billed in prior periods that have not yet been paid or written off as uncollectible. It is difficult to predict future revenue from tests performed but where we have not been paid. Accordingly, we cannot provide any assurance as to when, if ever, or to what extent any of these amounts will be collected. Because we are in the early stages of commercialization of Afirma, we have had limited payment and collection history. Notwithstanding our efforts to obtain payment for these tests, payers may deny our claims, in whole or in part, and we may never receive revenue from any previously performed but unpaid tests. Revenue from these tests, if any, may not be equal to the billed amount due to a number of factors, including differences in reimbursement rates, the amounts of patient co-payments, the existence of secondary payers and claims denials.

We incur expense for tests in the period in which the test is conducted and recognize revenue for tests in the period in which our revenue recognition criteria are met. Accordingly, any revenue that we recognize as a result of cash collection in respect of previously performed but unpaid Afirma tests will favorably impact our liquidity and results of operations in future periods.

Impact of Genzyme Co-promotion Agreement

The $10.0 million fee we received from Genzyme under our co-promotion agreement is being amortized over a four-year period beginning in 2012, and is recorded as a reduction of selling and marketing expenses. Under the agreement, we pay a portion of our cash receipts to Genzyme for co-promoting Afirma, and such amounts are recorded in selling and marketing expense. We incurred $8.6 million and $5.5 million in co-promotion fees in the years ended December 31, 2013 and 2012, respectively. The co-promotion agreement requires that we pay a certain percentage of our cash receipts to Genzyme, which percentage decreases over time. In January 2013, the percentage is 40%, but it will decrease to 32% on March 1, 2014 and remain at that level thereafter. As our cash collections grow, both from volume growth as well as from increased reimbursement rates and collections for Afirma, the total amount we pay to Genzyme will increase in absolute dollars although the percentage of revenue we are required to pay Genzyme decreases over time. We believe our relationship with Genzyme will accelerate sales of Afirma. As a result, our selling and marketing expense may be higher than what we would have incurred if we alone were marketing and promoting Afirma.

We also may receive up to an additional $3.0 million from Genzyme, consisting of $0.6 million for each of up to five countries outside of the United States in which we obtain regulatory authorization to market Afirma and achieve a specified level of reimbursement. Genzyme has also agreed to spend $0.5 million to support clinical development expenses required for entry into the international markets covered by our agreement. This obligation expires in July 2014.

Our agreement with Genzyme expires in 2027 and either party may terminate the agreement at any time without cause and with six months' prior notice. If we terminate the agreement without cause between January 2014 and January 2015, we will be required to repay 40% of the $10.0 million fee we received. The percentage decreases to 30% of such fee if we were to terminate the agreement between January 2015 and

Table of Contents

January 2016. Subsequent to January 2016, we are not required to repay any portion of the fee in the event we terminate the agreement without cause.

Development of Additional Products

We rely on sales of Afirma to generate all of our revenue. Our product development pipeline includes Afirma Malignancy Classifiers, which we believe will serve our current base of prescribing physicians. We also plan to pursue development of products for additional diseases to increase and diversify our revenue. For example, we are pursuing a solution for interstitial lung disease, or ILD, that will offer an alternative to surgery by developing a genomic signature to classify samples collected through less invasive bronchoscopy techniques. Accordingly, we expect to continue to invest heavily in research and development in order to expand the capabilities of our solution and to develop additional products. Our success in developing new products will be important in our efforts to grow our business by expanding the potential market for our products and diversifying our sources of revenue.

Timing of Our Research and Development Expenses

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

Historical Seasonal Fluctuations in FNA Volume and Collections

Our business is subject to fluctuations in FNA volume throughout the year as a result of physician practices being closed for holidays or endocrinology and thyroid-related industry meetings which are widely attended by our prescribing physicians. Like other companies in our field, vacations by physicians and patients tend to negatively affect our volumes more during the summer months and during the end of year holidays compared to other times of the year. Additionally, we may receive fewer FNAs in the winter months due to severe weather if patients are not able to visit their doctor's office. Our reimbursed rates and cash collections are also subject to seasonality. Medicare normally makes downward adjustments in its fee schedules at the beginning of the year which may negatively affect our reimbursement. Additionally, patient deductibles generally reset at the beginning of each year which means that patients early in the year are responsible for a greater portion of the cost of our tests, and we have lower collection rates from individuals than from third-party payers. Later in the year, particularly in the fourth quarter, we experience better payment results as third-party payers tend to clear pending claims toward year end. This trend historically has increased our cash collections in the fourth quarter and decreased cash collections for the subsequent first quarter of the succeeding year. The effects of these seasonal fluctuations in prior periods may have been obscured by the growth of our business.

Table of Contents

Financial Overview

Revenue

We generate revenue from the sale of our Afirma solution. We generally invoice third-party payers upon delivery of a patient report to the prescribing physician. As such, we take the assignment of benefits and the risk of collection from the third-party payer and individual patients.

For tests performed where an agreed upon reimbursement rate and/or a predictable history of collections exists, such as in the case of Medicare, we recognize 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 collect. We determine the amount we expect to collect based on a per payer, per contract or agreement basis, after analyzing payment history. The expected amount is typically lower than the agreed upon reimbursement amount due to several factors, such as the amount of patient co-payments, the existence of secondary payers and claim denials. In all other situations, as we do not have sufficient history of collection and are not able to determine a predictable pattern of payment, we recognize revenue upon the earlier of receipt of third-party payer notification of payment or when cash is received. Upon ultimate collection, the amount received from Medicare and commercial payers with a predictable pattern of payment is compared to previous estimates and the contractual allowance is adjusted accordingly. Our ability to increase our revenue will depend on our ability to penetrate the market, obtain contracted reimbursement from additional third-party payers and increase our collection rate for tests performed.

Cost of Revenue

The components of our cost of revenue are materials and service costs, including cytopathology testing services, stock-based compensation expense, direct labor costs, equipment and infrastructure expenses associated with testing samples, shipping charges to transport samples, and allocated overhead including rent, information technology, equipment depreciation and utilities. Costs associated with performing tests are recorded as the test is processed regardless of whether and when revenue is recognized with respect to that test. As a result, our cost of revenue as a percentage of revenue may vary significantly from period to period because we do not recognize all revenue in the period in which the associated costs are incurred. We expect cost of revenue in absolute dollars to increase as the number of tests we perform increases. However, we expect that the cost per test will decrease over time due to the efficiencies we may gain as test volume increases and from automation, process efficiencies and other cost reductions.

Research and Development

Research and development expenses include costs incurred to develop our technology, collect clinical samples and conduct clinical studies to develop and support our products. These costs consist of personnel costs, including stock-based compensation expense, prototype materials, laboratory supplies, consulting costs, costs associated with setting up and conducting clinical studies at domestic and international sites, and allocated overhead including rent, information technology, equipment depreciation and utilities. We expense all research and development costs in the periods in which they are incurred. We expect our research and development expenses will increase in absolute dollars in future periods as we continue to invest in research and development activities related to developing additional products and evaluating various platforms. We expect that in the next 12 months the increase in research and development expenses will be for the continued development and support of Afirma and other new products and programs under development, including Afirma Malignancy Classifiers and our lung program. Specifically, we plan to increase the body of clinical and pharmacoeconomic evidence to support inclusion in additional clinical practice guidelines in order to expand our base of prescribing physicians and achieve broader

Table of Contents

reimbursement for Afirma. In our lung program, we expect to incur expenses related to the collection of prospective samples and advancing the program into product development.

Selling and Marketing

Selling and marketing expenses consist of personnel costs, including stock-based compensation expense, direct marketing expenses, consulting costs, and allocated overhead including rent, information technology, equipment depreciation and utilities. In addition, up-front co-promotion fees paid to Genzyme, net of amortization, are included in selling and marketing expenses. We expect our selling and marketing expenses to increase over the next 12 months primarily driven by the co-promotion fees to Genzyme, which fees increase as cash receipts from Afirma increase (test volume is increasing at a greater rate than the contractual rate reduction), the costs of hiring additional internal sales and marketing personnel associated with further penetrating the domestic market and selectively launching in international markets, and marketing and education expenses to drive market penetration and reimbursement.

General and Administrative

General and administrative expenses include executive, finance and accounting, human resources, billing and client services, and quality and regulatory functions. These expenses include personnel costs, including stock-based compensation expense, audit and legal expenses, consulting costs, and allocated overhead including rent, information technology, equipment depreciation and utilities. We expect to incur additional expenses over the next 12 months as a result of operating as a public company, including expenses related to compliance with the rules and regulations of the Securities and Exchange Commission and The NASDAQ Stock Market, additional insurance expenses, investor relations activities and other administrative and professional services. We also expect our general and administration expenses will increase in absolute dollars over the next 12 months as we expand our billing group to support anticipated increased demand for our tests and begin to incur expenses related to the documentation of our internal controls in connection with Section 404 of the Sarbanes-Oxley Act.

Interest Income

Interest income is from interest on our cash equivalents.

Interest Expense

Interest expense is attributable to our borrowings under the loan agreement entered into in June 2013.

Other Income (Expense), Net

Other income (expense), net is related primarily to the change in value of the preferred stock liability associated with our obligation to issue additional shares of Series C convertible preferred stock. In November 2012, we entered into a tranched Series C convertible preferred stock purchase agreement. In connection with the initial closing, we agreed to issue to the purchasers, and the purchasers agreed to purchase, additional shares of the Series C convertible preferred stock within a specified timeframe. We determined that the liability to issue additional Series C convertible preferred stock at a future date was a freestanding instrument that should be accounted for as a liability. Accordingly, we recorded a liability related to this instrument at the time of the initial close in November 2012, and we remeasured the liability at each reporting period with the corresponding gain or loss from the adjustment recorded as other income (expense), net through the issuance of the final Series C tranche in June 2013.

In addition, other income (expense), net includes changes in value of the preferred stock warrant liability. In June 2013, in conjunction with the execution of our loan and security agreement with a

Table of Contents

financial institution, we issued to the lender a warrant to purchase up to 49,602 shares of Series C convertible preferred stock with an exercise price of $7.56 per share. Upon the draw-down in June 2013 of a $5.0 million term loan, the warrant became exercisable for 24,801 shares. Accordingly, we recorded a liability related to this warrant at the time of the initial close in June 2013 and re-measured the liability at each reporting period with the corresponding gain or loss from the adjustment recorded as other income (expense), net through the conversion of the warrant into a warrant to purchase common stock effective upon the completion of our IPO.

Critical Accounting Polices and Estimates

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

Revenue Recognition

Our revenue is generated from the provision of diagnostic services using the Afirma solution. Our service is completed upon the delivery of test results to the prescribing physician which triggers the billing for the service. We recognize revenue related to billings for Medicare and commercial payers on an accrual basis, net of contractual adjustments, when there is a predictable pattern of collectability. These contractual adjustments represent the difference between the list price (the billing rate) and the reimbursement rate set by Medicare and commercial payers. Upon ultimate collection, the amount received from Medicare and commercial payers with a predictable pattern of payment is compared to previous estimates and the contractual allowance is adjusted accordingly. Until a contract has been negotiated with a commercial carrier or governmental program, the Afirma solution may or may not be covered by these entities' existing reimbursement policies. In addition, patients do not enter into direct agreements with us that commit them to pay any portion of the cost of the tests in the event that their insurance declines to reimburse us. In the absence of an agreement or other clearly enforceable legal right to demand payment, when test services are provided to patients with non-contracted insurance carriers or no insurance, the related revenue is only recognized upon the earlier of payment notification, if applicable, or cash receipt.

For all services performed, we consider whether or not the following revenue recognition criteria are met: persuasive evidence of an arrangement exists; delivery has occurred or services have been rendered; the fee is fixed or determinable; and collectability is reasonably assured.

Persuasive evidence of an arrangement exists and delivery is deemed to have occurred upon delivery of a patient report to the prescribing physician. The assessment of the fixed or determinable nature of the fees charged for testing performed and the collectability of those fees require significant judgment by management. Management believes that these two criteria have been met when there is a contracted reimbursement rate and/or a predictable pattern of collectability with individual third-party payers and accordingly, we recognize revenue upon delivery of the patient report. Some patients have out-of-pocket costs for amounts not covered by their insurance carrier, and we may bill the patient directly for these amounts in the form of co-payments and co-insurance in accordance with their insurance carrier and

Table of Contents

health plans. Some payers may not cover the GEC as ordered by the prescribing physician under their reimbursement policies. We pursue reimbursement from such patients on a case-by-case basis. In the absence of contracted reimbursement coverage or a predictable pattern and history of collectability, we believe that the fee is fixed or determinable and collectability is reasonably assured only upon receipt of third-party payer notification of payment or when cash is received and accordingly, recognize revenue at that time.

We use judgment in our assessment of whether the fee is fixed or determinable and whether collectability is reasonably assured in determining when to recognize revenue in the future as we continue to gain payment experience with third-party payers and patients.

Allowance for Doubtful Accounts

We estimate an allowance for doubtful accounts against our individual accounts receivable based on estimates of expected payment consistent with historical payment experience. Our allowance for doubtful accounts is evaluated on a regular basis and adjusted when trends or significant events indicate that a change in estimate is appropriate. Historically, the amounts of uncollectible individual accounts receivable that have been written off have been consistent with management's expectations. Accounts receivable are written off against the allowance when the appeals process is exhausted or when there is other substantive evidence that the account will not be paid. If the financial conditions of our customers were to deteriorate resulting in an impairment of their ability to make payments, additional allowances may be required.

If the financial conditions of our customers were to deteriorate, resulting in an impairment of their ability to make payments, additional allowances may be required.

Derivative Liability

We account for derivative financial instruments as either equity or liabilities based upon the characteristics and provisions of each instrument. We recorded the preferred stock liability incurred in connection with our Series C convertible preferred stock and the preferred stock warrant liability related to the issuance of a warrant for Series C convertible preferred stock, each as a derivative financial instrument liability at their fair value on the date of issuance, and we remeasure them on each subsequent balance sheet date. The changes in fair value are recognized as a gain or loss from the adjustment to other income (expense), net in the statements of operations and comprehensive loss. We estimate the fair value of this liability using option-pricing models that include assumptions for future financings, expected volatility, expected life, yield and risk-free interest rate. The preferred stock liability was extinguished in 2013 and the warrant to purchase Series C convertible preferred stock was converted into a warrant to purchase our common stock as of the close of the IPO.

Deferred Tax Assets

We file U.S. federal income tax returns and tax returns in California, Texas and other states. To date, we have not been audited by the Internal Revenue Service or any state income tax authority.

As of December 31, 2013, our gross deferred tax assets were $32.8 million. The deferred tax assets were primarily comprised of federal and state tax net operating loss and tax credit carryforwards. Utilization of the net operating loss and tax credit carryforwards may be subject to annual limitation due to historical or future ownership percentage change rules provided by the Internal Revenue Code of 1986, and similar state provisions. The annual limitation may result in the expiration of certain net operating loss and tax credit carryforwards before their utilization.

Table of Contents

We are required to reduce our deferred tax assets by a valuation allowance if it is more likely than not that some or all of our deferred tax assets will not be realized. We must use judgment in assessing the potential need for a valuation allowance, which requires an evaluation of both negative and positive evidence. The weight given to the potential effect of negative and positive evidence should be commensurate with the extent to which it can be objectively verified. In determining the need for and amount of our valuation allowance, if any, we assess the likelihood that we will be able to recover our deferred tax assets using historical levels of income, estimates of future income and tax planning strategies. As a result of historical cumulative losses and, based on all available evidence, we believe it is more likely than not that our recorded net deferred tax assets will not be realized. Accordingly, we recorded a valuation allowance against all of our net deferred tax assets at December 31, 2013. We will continue to maintain a full valuation allowance on our deferred tax assets until there is sufficient evidence to support the reversal of all or some portion of this allowance.

Stock-based Compensation

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

Results of Operations

Comparison of the Years Ended December 31, 2013 and 2012

	Year Ended December 31,		Dollar Change	% Change
	2013	2012		
	(In thousands)			
Revenue	$ 21,884	$ 11,628	$ 10,256	88%
Operating expenses:				
Cost of revenue	12,607	7,584	5,023	66%
Research and development	7,810	6,608	1,202	18%
Selling and marketing	12,540	8,447	4,093	48%
General and administrative	12,100	7,918	4,182	53%
Total operating expenses	45,057	30,557	14,500	47%
Loss from operations	(23,173)	(18,929)	(4,244)	22%
Interest income	5	2	3	150%
Interest expense	(233)		(233)	N/A
Other income (expense), net	(2,179)	278	(2,457)	N/A
Net loss	$ (25,580)	$ (18,649)	$ (6,931)	37%

Table of Contents

Revenue

Revenue increased $10.3 million, or 88%, for the year ended December 31, 2013 compared to the same period in 2012 primarily as a result of a $7.2 million increase in commercial revenue from increased reimbursement and collections and a $3.1 million increase in Medicare revenue as a result of increased Afirma adoption.

Cost of revenue

Cost of revenue increased $5.0 million, or 66%, for the year ended December 31, 2013 compared to the same period in 2012. This increase was primarily due to a $4.7 million, or 77%, increase in variable costs that are directly related to the increase in the number of FNAs received, offset in part by continuing refinements in our testing process and economies of scale related to the increase in FNAs. FNAs received increased 23,780, or 92%, to 49,670 in the year ended December 31, 2013.

Research and development

Research and development expense increased $1.2 million, or 18%, for the year ended December 31, 2013 compared to the same period in 2012. This increase was primarily due to a $0.7 million increase in personnel expenses related to a 24% increase in headcount, and a $0.5 million increase in licensing expenses to secure intellectual property to augment our existing thyroid patent portfolio.

Selling and marketing

Selling and marketing expense increased $4.1 million, or 48%, for the year ended December 31, 2013 compared to the same period in 2012. This increase was primarily due to a $3.0 million increase in net expense recognized under our co-promotion agreement with Genzyme, partially offset by amortization of the deferred fee, a $0.5 million increase in personnel expenses related to a 28% increase in headcount, a $0.5 million increase in marketing and promotional materials, and a $0.1 million increase in consulting expenses.

General and administrative

General and administrative expense increased $4.2 million, or 53%, for the year ended December 31, 2013 compared to the same period in 2012. This increase was primarily due to a $2.0 million increase in personnel expenses related to a 63% increase in headcount, a $1.4 million increase in professional fees primarily due to non-capitalizable IPO related audit and legal services, a $0.4 million increase in stock-based compensation expense primarily related to 2013 option grants, a $0.4 million increase in rent and other facilities expenses primarily due to the opening of the Austin, Texas facility, and a $0.2 million increase in insurance expenses related to higher premiums associated with being a public company.

Interest income

Interest income increased 150% for the year ended December 31, 2013 compared to the same period in 2012 due primarily to the increase in cash in 2013 from the $59.2 million in net proceeds from the IPO, $12.9 million in net proceeds received from the sale of convertible preferred stock and $4.9 million in net borrowings under our loan and security agreement.

Interest expense

Interest expense increased $0.2 million for the year ended December 31, 2013 compared to the same period in 2012. Interest expense of $0.2 million for the year ended December 31, 2013 is interest incurred on the initial June 2013 drawdown of $5.0 million under our loan and security agreement. We did not have any debt in the same period in 2012.

Table of Contents

Other income (expense), net

Other income (expense), net, decreased $2.5 million in the year ended December 31, 2013 compared to the same period in 2012. The decrease was primarily related to a $2.4 million increase in the fair value of the preferred stock liability from a gain of $0.3 million in 2012 to a loss of $2.1 million in 2013, and a $0.1 million increase in the fair value of the preferred stock warrant liability. As the preferred stock liability was extinguished in 2013, and the preferred stock warrant liability was converted into a warrant to purchase our common stock upon the completion of the IPO in 2013, any related expenses will not carry forward to future periods.

Comparison of the Years Ended December 31, 2012 and 2011

	Year Ended December 31,		Dollar Change	% Change
	2012	2011		
	(In thousands)			
Revenue	$ 11,628	$ 2,645	$ 8,983	340%
Operating expenses:				
Cost of revenue	7,584	2,925	4,659	159%
Research and development	6,608	6,680	(72)	1%
Selling and marketing	8,447	2,934	5,513	188%
General and administrative	7,918	5,372	2,546	47%
Total operating expenses	30,557	17,911	12,646	71%
Loss from operations	(18,929)	(15,266)	(3,663)	24%
Interest expense	2	2		
Other income (expense), net	278	819	(541)	66%
Net loss	$ (18,649)	$ (14,445)	$ (4,204)	29%

Revenue

Revenue increased $9.0 million, or 340%, for the year ended December 31, 2012 compared to the same period in 2011 primarily due to a $6.4 million increase in revenue from increased Afirma adoption, resulting in increased collections, and a $2.6 million increase in revenue from Medicare.

Cost of revenue

Cost of revenue increased $4.7 million, or 159%, for the year ended December 31, 2012 compared to the same period in 2011. This increase is primarily due to a $4.3 million, or 237%, increase in variable costs which are directly related to the increase in the number of FNAs received for analysis from 6,402 in 2011 to 25,890 in 2012, offset by continuing refinements in our testing process and economies of scale related to the increase in FNAs. The remaining increase of $0.4 million relates to increases in indirect labor costs, supplies, and depreciation and facility allocations.

Research and development

Research and development expenses were essentially flat in the year ended December 31, 2012 compared to the same period in 2011. Our research and development expenses in 2011 reflect the conclusion of clinical studies and other research and development activities supporting the commercial launch of Afirma. In 2012, our research and development expenses shifted to the development of our product pipeline as well as the continued support of Afirma.

72

Table of Contents

Selling and marketing

Selling and marketing expenses increased $5.5 million, or 188%, in the year ended December 31, 2012 compared to the same period in 2011. This increase was primarily due to $3.1 million in net expense recognized under our co-promotion agreement with Genzyme, partially offset by amortization of the deferred fee. The remaining $2.4 million increase included a $1.4 million increase in personnel expenses as we hired a vice president of sales and additional sales representatives in 2012, a $0.4 million increase in marketing and promotional materials, a $0.3 million increase in allocated information technology, facilities and other costs, and a $0.3 million increase in travel and meetings related expenses.

General and administrative

The $2.5 million, or 47%, increase in general and administrative expenses in the year ended December 31, 2012 compared to the same period in 2011 was due to a $1.8 million increase in personnel expenses primarily from increased headcount, higher bonus payments and higher stock-based compensation expense, a $0.3 million increase in professional fees, and a $0.3 million increase in occupancy and equipment expenses.

Other income (expense), net

Other income (expense), net was $0.8 million for the year ended December 31, 2011, and is primarily comprised of $0.7 million related to the decrease in value of the preferred stock liability associated with our obligation to issue additional shares of Series B convertible preferred stock. In addition, $0.1 million represents a payment made to us by Genzyme in connection with the right to negotiate an exclusive co-promotion arrangement. Other income (expense), net was $0.3 million for the year ended December 31, 2012, which represents the decrease in value of the preferred stock liability associated with our obligation to issue additional shares of Series C convertible preferred stock.

Liquidity and Capital Resources

We have incurred net losses since our inception. For the years ended December 31, 2013, 2012 and 2011, we had a net loss of $25.6 million, $18.6 million and $14.4 million, respectively, and we expect to incur additional losses in the foreseeable future. As of December 31, 2013, we had an accumulated deficit of $85.6 million. To date, we have generated only limited revenue, and we may never achieve revenue sufficient to offset our expenses.

Since inception, we have received $153.4 million in net proceeds from various sources with which to finance our operations, including net proceeds of $78.6 million from sales of our preferred stock, net proceeds of $59.2 million from our IPO, $10.0 million from the Genzyme co-promotion agreement, net borrowings of $4.9 million under our loan and security agreement, and $0.7 million from the exercise of stock options. As of December 31, 2013 and December 31, 2012, we had $71.2 million and $14.0 million of cash and cash equivalents, respectively.

In June 2013, we entered into a loan and security agreement with a financial institution. This agreement provides for term loans of up to an aggregate of $10.0 million. On entering into the agreement, we drew down an initial $5.0 million term loan. We may request a second term loan of up to $5.0 million on or prior to March 31, 2014. Loans drawn under the loan and security agreement will be used for working capital and general corporate purposes.

The initial term loan bears interest at a fixed rate equal to 6.06%. The second term loan, if drawn, will bear interest at a fixed rate equal to the greater of (a) 5.88% or (b) the three-year U.S. Treasury note rate, plus 5.40%. We are required to repay any outstanding principal amounts of each loan in 30 equal monthly installments beginning 18 months after the date of each borrowing. In each case, on the date of our final

Table of Contents

principal payment, we must also pay an end-of-term payment equal to 4.45% of the amount borrowed. We may, at our option, prepay the term loan borrowings by paying the lender a prepayment premium.

Our obligations under the loan and security agreement are secured by a security interest on substantially all of our assets, excluding our intellectual property and certain other assets. The loan and security agreement contains customary conditions to borrowing, events of default, and covenants, including covenants limiting our ability to dispose of assets, undergo a change in control, merge with or acquire other entities, incur debt, incur liens, pay dividends or other distributions to holders of our capital stock, repurchase stock and make investments, in each case subject to certain exceptions. The loan and security agreement does not require that we comply with any financial covenants.

In connection with the draw-down of the initial $5.0 million term loan under the loan and security agreement, we issued the lender a warrant to purchase 99,206 shares of our Series C preferred stock, which became exercisable for 24,801 shares of our common stock upon completion of the IPO. The warrant will expire on the seventh anniversary of the IPO. If we draw-down the second term loan under the loan and security agreement, the warrant will become exercisable for an additional 24,801 shares on identical terms.

Our primary uses of cash are to fund our operations as we continue to grow our business. We expect to continue to incur operating losses in the near term as our operating expenses will be increased to support the growth of our business. We expect that our selling and marketing, research and development, and general and administrative expenses will continue to increase as we expand our marketing efforts and increase our internal sales force to drive increased adoption of and reimbursement for Afirma, prepare to commercialize our Afirma Malignancy Classifiers, continue our research and development efforts with respect to our lung program and further develop our product pipeline, and manage increases in billing and cash collection transactional volumes, and the costs of being a public company. Cash used to fund operating expenses is impacted by the timing of when we pay expenses, as reflected in the change in our outstanding accounts payable and accrued expenses.

We expect that our near- and longer-term liquidity requirements will continue to consist of selling and marketing expenses, research and development expenses, working capital, and general corporate expenses associated with the growth of our business. Based on our current business plan, we believe our existing cash and cash equivalents as of December 31, 2013 and our revenue from the sale of Afirma will be sufficient to meet our anticipated cash requirements for at least the next 12 months. However, we may also use cash to acquire or invest in complementary businesses, technologies, services or products that would change our cash requirements. If we are not able to generate revenue to finance our cash requirements, we will need to finance future cash needs primarily through public or private equity offerings, debt financings, borrowings or strategic collaborations or licensing arrangements. If we raise funds by issuing equity securities, dilution to stockholders may result. Any equity securities issued may also provide for rights, preferences or privileges senior to those of holders of our common stock. If we raise funds by issuing debt securities, these debt securities would have rights, preferences and privileges senior to those of holders of our common stock. The terms of debt securities or borrowings could impose significant restrictions on our operations. If we raise funds through collaborations and licensing arrangements, we might be required to relinquish significant rights to our technologies or products, or grant licenses on terms that are not favorable to us. The credit market and financial services industry have in the past, and may in the future, experience periods of upheaval that could impact the availability and cost of equity and debt financing. If we are not able to secure additional funding when needed, on acceptable terms, 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 product or market development programs, which could lower the economic value of those programs to us.

Table of Contents

The following table summarizes our cash flows for the years ended December 31, 2013 and 2012:

	Years Ended December 31,		
	2013	2012	2011
	(in thousands)		
Cash used in operating activities	$ (19,159)	$ (7,167)	$ (13,524)
Cash used in investing activities	(1,282)	(1,462)	(331)
Cash provided by financing activities	77,659	15,065	18,646

Cash Flows from Operating Activities

Cash used in operating activities for the year ended December 31, 2013 was $19.2 million. The net loss of $25.6 million was offset by non-cash charges of $2.1 million for the change in the value of the preferred stock liability, $2.5 million in amortization of the deferred fee received from Genzyme, $1.2 million of stock based compensation, $1.0 million of depreciation and amortization, $0.1 million of bad debt expense, a $0.1 million charge for the change in value of the preferred stock warrant liability, and $0.1 million for non-cash interest on the outstanding debt. The increase in net changes in assets and liabilities of $4.3 million was primarily due to a $7.2 million increase in accounts payable and accrued liabilities due to timing of payments offset by a $2.9 million increase in assets, including a $0.7 million increase in prepaid expenses due primarily to increased public company related prepaid insurance premiums, a $1.5 million increase in supply inventory due to the increase in volume of testing performed, and a $0.7 million increase in accounts receivable due to increased revenues from Medicare.

Cash used in operating activities for the year ended December 31, 2012 was $7.2 million. The net loss of $18.6 million was offset by non-cash charges of $0.9 million of stock- and equity-based compensation, $0.7 million for depreciation and amortization, $0.3 million for the change in value of the preferred stock liability and $0.2 million of bad debt expense. The increase in net operating assets of $12.3 million was primarily due to the $10.0 million deferred payment from Genzyme, of which we amortized $2.4 million as of December 31, 2012. Accounts payable and accrued liabilities increased $3.9 million due to the growth in our operations and the timing of our payments. Accounts receivable increased by $0.6 million due to the increase in accrued revenue in 2012 as we had only begun to sell Afirma in 2011. In addition, there was a $0.8 million increase in supplies inventory related to increased test demand.

Cash used in operating activities for the year ended December 31, 2011 was $13.5 million. The net loss of $14.4 million was offset by non-cash charges of $0.7 million of stock- and equity-based compensation, $0.7 million for the change in value of the preferred stock liability, $0.6 million of depreciation and amortization, $0.2 million of bad debt expense and a $0.2 million loss on the disposal of property and equipment. The decrease in net operating assets of $0.1 million was primarily due to the increase in accounts receivable as 2011 was our first year with revenue, and an increase of $0.1 million in supplies inventory, offset by an increase in accounts payable and accrued liabilities of $0.6 million due to the growth in our operations and the timing of payments.

Cash Flows from Investing Activities

Cash used in investing activities is primarily related to the acquisition of property and equipment of $1.3 million, $1.5 million and $0.3 million for the years ended December 31, 2013, 2012 and 2011, respectively. Purchases of property and equipment were primarily for leasehold improvements and laboratory equipment.

Cash Flows from Financing Activities

Cash provided by financing activities for the year ended December 31, 2013 of $77.7 million was primarily from the receipt of $59.9 million in net proceeds from the issuance of common stock in connection with our IPO and from the exercise of options to purchase our common stock, the receipt of

Table of Contents

$12.9 million in net proceeds from the sale of our convertible preferred stock, and net borrowings of $4.9 million under the loan and security agreement.

Cash provided by financing activities for the years ended December 31, 2012 and 2011 of $15.1 million and $18.6 million, respectively, were primarily due to the net proceeds from the sale of our convertible preferred stock.

Contractual Obligations

The following table summarizes certain contractual obligations as of December 31, 2013 (in thousands):

	Payments Due by Period				
	Less than 1 Year	1 to 3 Years	3 to 5 Years	More than 5 Years	Total
Operating lease obligations	$ 938	$ 1,402	$ 352	$	$ 2,692
Long-term debt obligations		3,938	1,062		5,000
Interest on debt	307	388	242		937
Volume purchase commitment	125	125			250
Total	$ 1,370	$ 5,853	$ 1,656	$	$ 8,879

In February 2010, we entered into a non-cancelable lease agreement for our headquarters and laboratory space in South San Francisco, California. The lease expires in March 2016.

In November 2012, we entered into a non-cancelable lease agreement commencing February 2013 for our laboratory and office space in Austin, Texas. The lease expires in July 2018.

In June 2013, we entered into a $10.0 million loan and security agreement with a financial institution, and drew down an initial term loan of $5.0 million. We are required to pay interest only on this loan for the first 18 months and then will begin paying principal and interest over the subsequent 30-month period.

In February 2013, we entered into a non-cancelable volume purchase agreement with a supplier to purchase a minimum quantity of supplies inventory at a fixed price. The total amount of the arrangement was $0.4 million.

Off-balance Sheet Arrangements

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

JOBS Act Accounting Election

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

Recent Accounting Pronouncements

In July 2013, Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, No. 2013-11, *Presentation of an Unrecognized Tax Benefit when a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists (a consensus of the FASB Emerging Issues Task Force).* The amendments in this ASU provide guidance on the financial statements presentation of an unrecognized tax benefit when a net operating loss carryforward, a similar tax loss, or a tax credit

Table of Contents

carryforward exists. An unrecognized tax benefit should be presented in the financial statements as a reduction to a deferred tax asset for a net operating loss carryforward, a similar tax loss, or a tax credit carryforward with certain exceptions, in which case such an unrecognized tax benefit should be presented in the financial statements as a liability. The amendments in this ASU do not require new recurring disclosures and are effective for fiscal years, and interim periods within those years, beginning after December 15, 2013. We are currently assessing the impact of this ASU on our financial statements.

In February 2013, the FASB issued ASU No. 2013-02, *Reporting of Amounts Reclassified Out of Accumulated Other Comprehensive Income*. This ASU requires reporting and disclosure about changes in accumulated other comprehensive income balances and reclassifications out of accumulated other comprehensive income. We adopted this guidance as of January 1, 2013 on a prospective basis and the adoption did not have a material effect on our financial statements as we do not have comprehensive income (loss).

Table of Contents

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

We are exposed to market risks in the ordinary course of our business. These risks primarily relate to interest rates. We had cash and cash equivalents of $71.2 million and $14.0 million as of December 31, 2013 and December 31, 2012, respectively, which consist of bank deposits and money market funds. Such interest-bearing instruments carry a degree of risk; however, we have not been exposed to, nor do we anticipate being exposed to, material risks due to changes in interest rates. A hypothetical 10% change in interest rates during any of the periods presented would not have had a material impact on our audited financial statements.

Table of Contents

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Veracyte, Inc.
Index to Financial Statements

Table of Contents

Report of Independent Registered Public Accounting Firm

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

In our opinion, the accompanying balance sheets and the related statements of operations and comprehensive loss, of convertible preferred stock and stockholders' deficit, and of cash flows present fairly, in all material respects, the financial position of Veracyte, Inc. at December 31, 2013 and 2012, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2013 in conformity with accounting principles generally accepted in the United States of America. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits of these statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers LLP

San Jose, California
March 20, 2014

Table of Contents

VERACYTE, INC.

Balance Sheets

(In thousands, except share and per share amounts)

	As of December 31,	
	2013	**2012**
Assets		
Current assets:		
Cash and cash equivalents	$ 71,220	$ 14,002
Accounts receivable, net of allowance of $107 and $222 as of December 31, 2013 and 2012	1,143	569
Supplies inventory	2,567	1,050
Prepaid expenses and other current assets	1,477	710
Restricted cash		50
Total current assets	76,407	16,381
Property and equipment, net	2,952	2,446
Restricted cash	118	118
Other assets	153	122
Total assets	$ 79,630	$ 19,067
Liabilities, Convertible Preferred Stock, and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 5,294	$ 1,888
Accrued liabilities	7,594	4,020
Deferred Genzyme co-promotion fee	2,500	2,500
Preferred stock liability		583
Total current liabilities	15,388	8,991
Long-term debt, net of current portion	4,899	
Deferred rent, net of current portion	286	61
Deferred Genzyme co-promotion fee, net of current portion	2,614	5,114
Total liabilities	23,187	14,166
Commitments and contingencies (Note 8)		
Convertible preferred stock, $0.001 par value; 0 and 59,147,999 shares authorized, 0 and 53,084,507 shares issued and outstanding as of December 31, 2013 and December 31, 2012; aggregate liquidation value of $0 and $65,835 as of December 31, 2013 and 2012		63,372
Stockholders' deficit:		
Common stock, $0.001 par value; 125,000,000 and 77,000,000 shares authorized, 21,143,313 and 667,684 shares issued and outstanding as of December 31, 2013 and 2012	21	1
Additional paid-in capital	142,071	1,597

Preferred stock, $0.001 par value; 5,000,000 and 0 shares authorized, 0 shares issued and outstanding as of December 31, 2013 and 2012		
Accumulated deficit	(85,649)	(60,069)
Total stockholders' equity (deficit)	56,443	(58,471)
Total liabilities, convertible preferred stock, and stockholders' equity (deficit)	$ 79,630	$ 19,067

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

Table of Contents

VERACYTE, INC.

Statements of Operations and Comprehensive Loss

(In thousands, except share and per share amounts)

	Year Ended December 31,		
	2013	**2012**	**2011**
Revenue	$ 21,884	$ 11,628	$ 2,645
Operating expenses:			
Cost of revenue	12,607	7,584	2,925
Research and development	7,810	6,608	6,680
Selling and marketing	12,540	8,447	2,934
General and administrative	12,100	7,918	5,372
Total operating expenses	45,057	30,557	17,911
Loss from operations	(23,173)	(18,929)	(15,266)
Interest income	5	2	2
Interest expense	(233)		
Other income (expense), net	(2,179)	278	819
Net loss and comprehensive loss	$ (25,580)	$ (18,649)	$ (14,445)
Net loss per common share, basic and diluted	$ (6.15)	$ (28.68)	$ (24.90)
Shares used to compute net loss per common share, basic and diluted	4,158,664	650,333	580,061

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

Table of Contents

VERACYTE, INC.

Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)

(In thousands, except share and per share amounts)

	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount			
Balance January 1, 2011	30,249,334	$ 30,674	556,844	$ 1	$ 163	$ (26,975)	$ (26,811)
Issuance of Series B convertible preferred stock in February 2011 at $1.25 per share, net of issuance costs of $1	7,449,335	9,311					
Issuance of Series B convertible preferred stock in July 2011 at $1.25 per share, net of issuance costs of $1	7,449,330	9,311					
Common stock issued on exercise of stock options			38,097		24		24
Stock-based compensation expense (employee)					378		378
Stock-based compensation expense (non-employee)					88		88
Net loss and comprehensive loss						(14,445)	(14,445)
Balance December 31, 2011	45,147,999	$ 49,296	594,941	$ 1	$ 653	$ (41,420)	$ (40,766)
Issuance of Series C convertible preferred stock in November and December 2012 at $1.89 per share, net of issuance costs of $63 and $861 preferred stock liability	7,936,508	14,076					
Common stock issued on exercise of stock options			72,743		76		76
Stock-based compensation expense (employee)					590		590
Stock-based compensation expense (non-employee)					85		85
Equity-based compensation					193		193
Net loss and comprehensive loss						(18,649)	(18,649)
Balance December 31, 2012	53,084,507	$ 63,372	667,684	$ 1	$ 1,597	$ (60,069)	$ (58,471)
Issuance of Series C convertible preferred stock in June 2013 at $1.89 per share, net of issuance costs of $53	6,904,761	12,997					
Extinguishment of preferred stock liability		2,653					
Issuance of common stock on exercise of stock options			377,966		552		552
Issuance of common stock in initial public offering, net of discounts and commissions of $4,642 and issuance costs of $2,507			5,100,351	5	59,151		59,156
Conversion of preferred stock into common stock upon initial public offering	(59,989,268)	(79,022)	14,997,312	15	79,007		79,022
Reclassification of preferred stock warrant liability into additional paid-in capital upon initial public offering					261		261
Stock-based compensation expense (employee)					1,041		1,041
Stock-based compensation expense (non-employee)					206		206
Equity-based compensation					259		259
Common stock subject to repurchase					(3)		(3)
Net loss and comprehensive loss						(25,580)	(25,580)
Balance December 31, 2013			21,143,313	$ 21	$ 142,071	$ (85,649)	$ 56,443