

Foundation Medicine, Inc.  
Form 10-K  
March 13, 2015  
[Table of Contents](#)

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**  
**Washington, D.C. 20549**

**Form 10-K**

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

**For the fiscal year ended December 31, 2014**

**or**

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

**For the transition period from \_\_\_\_\_ to \_\_\_\_\_.**

**Commission File Number 001-36086**

**FOUNDATION MEDICINE, INC.**

**(Exact name of registrant as specified in its charter)**

# Edgar Filing: Foundation Medicine, Inc. - Form 10-K

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**27-1316416**  
(IRS Employer  
Identification No.)

**150 Second Street**

**Cambridge MA, 02141**

(Address of principal executive offices, including zip code)

**Registrant's Telephone Number, Including Area Code:**

**(617) 418-2200**

**Securities registered pursuant to Section 12(b) of the Act:**

**Common Stock, \$0.0001 Par Value**  
(Title of each class)

**The NASDAQ Global Select Market**  
(Name of each exchange on which registered)

**Securities registered pursuant to Section 12(g) of the Act: NONE**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically 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 (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). ☒ Yes ☐ No

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. ☒

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 definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in 12b-2 of the Exchange Act.

Large accelerated filer <input type="checkbox"/>	Accelerated filer <input checked="" type="checkbox"/>
Non-accelerated filer <input type="checkbox"/>	Smaller reporting company <input type="checkbox"/>

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

## Edgar Filing: Foundation Medicine, Inc. - Form 10-K

As of June 30, 2014, the last business day of the registrant's most recently completed second fiscal quarter, the aggregate market value of common stock held by non-affiliates of the registrant computed by reference to the last reported sale price of the registrant's common stock on the Nasdaq Global Select Market as of such date was approximately \$516.5 million. As of March 9, 2015 there were 29,132,003 shares of the registrant's common stock, \$0.0001 par value per share, outstanding.

### **DOCUMENTS INCORPORATED BY REFERENCE**

The registrant intends to file a definitive proxy statement pursuant to Regulation 14A within 120 days of the end of the fiscal year ended December 31, 2014. Portions of such definitive proxy statement are incorporated by reference into Part III of this Annual Report on Form 10-K.

**Table of Contents**

**FOUNDATION MEDICINE, INC.**

**ANNUAL REPORT ON FORM 10-K**

**For the Year Ended December 31, 2014**

	<b>PAGE</b>
<b><u>PART I</u></b>	1
<u>Item 1. Business</u>	1
<u>Item 1A. Risk Factors</u>	47
<u>Item 1B. Unresolved Staff Comments</u>	83
<u>Item 2. Properties</u>	83
<u>Item 3. Legal Proceedings</u>	83
<u>Item 4. Mine Safety Disclosures</u>	83
<b><u>PART II</u></b>	83
<u>Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	83
<u>Item 6. Selected Financial Data</u>	86
<u>Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	87
<u>Item 7A. Quantitative and Qualitative Disclosures About Market Risk</u>	103
<u>Item 8. Financial Statements and Supplementary Data</u>	103
<u>Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure</u>	103
<u>Item 9A. Controls and Procedures</u>	104
<u>Item 9B. Other Information</u>	104
<b><u>PART III</u></b>	105
<u>Item 10. Directors, Executive Officers and Corporate Governance</u>	105
<u>Item 11. Executive Compensation</u>	105
<u>Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	105
<u>Item 13. Certain Relationships and Related Transactions, and Director Independence</u>	105
<u>Item 14. Principal Accounting Fees and Services</u>	105
<b><u>PART IV</u></b>	106
<u>Item 15. Exhibits, Financial Statement Schedules</u>	106
<b><u>SIGNATURES</u></b>	110

## **Table of Contents**

### **PART I**

*This Annual Report on Form 10-K, or this Annual Report, contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, and is subject to the safe harbor created by those sections. Any statements about our expectations, beliefs, plans, objectives, assumptions or future events or performance are not historical facts and may be forward-looking. Some of the forward-looking statements can be identified by the use of forward-looking terms such as believes, expects, may, will, should, seek, intends, plans, estimates, projects, anticipates, or other comparable terms. These forward-looking statements involve risk and uncertainties. We cannot guarantee future results, levels of activity, performance or achievements, and you should not place undue reliance on our forward-looking statements. Our actual results may differ significantly from the results discussed in the forward-looking statements. Factors that might cause such a difference include, but are not limited to, those set forth in Item 1A. Risk Factors and elsewhere in this Annual Report. Except as may be required by law, we have no plans to update our forward-looking statements to reflect events or circumstances after the date of this Annual Report. We caution readers not to place undue reliance upon any such forward-looking statements, which speak only as of the date made.*

*Unless the content requires otherwise, references to Foundation, the Company, we, our, and us, in this Annual Report refer to Foundation Medicine, Inc. and its subsidiaries.*

## **ITEM 1. BUSINESS**

### **Overview**

We are a molecular information company focused on fundamentally changing the way in which patients with cancer are evaluated and treated. We believe an information-based approach to making clinical treatment decisions based on comprehensive genomic profiling will become a standard of care for patients with cancer. We derive revenue from selling products that are enabled by our molecular information platform to physicians and biopharmaceutical companies. Our platform includes proprietary methods and algorithms for analyzing specimens across all types of cancer, and for incorporating that information into clinical care in a concise and user-friendly fashion. Our products provide genomic information about each patient's individual cancer, enabling physicians to optimize treatments in clinical practice and biopharmaceutical companies to develop targeted oncology therapies more effectively. We believe we have a significant first mover advantage in providing comprehensive genomic profiling and molecular information products on a commercial scale.

Our first clinical products, FoundationOne® for solid tumors, and FoundationOne Heme for blood-based cancers, or hematologic malignancies, including leukemia, lymphoma, myeloma, and many sarcomas and pediatric cancers, are, to our knowledge, the only widely available comprehensive genomic profiles designed for use in the routine care of patients with cancer. To accelerate our commercial growth and enhance our competitive advantage, we are continuing to expand our sales force, grow our molecular information knowledgebase, called FoundationCORE, publish scientific and medical advances, foster relationships throughout the oncology community, and develop new clinical and technology products.

The cancer treatment paradigm is evolving rapidly, and we believe there is now widespread recognition that cancer is a disease of the genome, rather than a disease defined solely by its specific anatomical location in the body. Today, physicians increasingly use precision medicines to target cancers based on the specific genomic alterations driving their growth. We believe physicians need molecular information about their patients' unique cancers to determine the optimal course of treatment. However, most currently available molecular diagnostic tests capture only a limited number of the most common and known genomic alterations. We believe this narrow approach often fails to identify relevant targeted treatment options.

We believe the oncology community needs comprehensive molecular information products that can assess the known biologically relevant genomic alterations from a patient's tumor and distill complex molecular

## **Table of Contents**

information into a concise and actionable format, and we designed FoundationOne and FoundationOne Heme to be such products. We believe a new, comprehensive approach to providing molecular information for use in clinical settings addresses an area of significant unmet medical need for patients suffering from advanced, or active metastatic, cancers. We estimate that there are approximately 1.1 million patients per year in the United States with newly-diagnosed or recurrent active metastatic cancers who fall into challenging treatment categories, including patients who have rare or aggressive diseases, patients whose disease has progressed after standard treatments, and patients who have tested negative under, or been ineligible for, traditional molecular diagnostic tests. We are initially focusing on these patients because we believe this patient population will benefit most from comprehensive molecular information products.

As the number of available targeted therapies expands and as physicians gain further experience using comprehensive molecular information in their routine treatment decisions, we believe that the potentially addressable market for comprehensive molecular information products will expand over the next five years to include most patients who have metastatic disease and even some patients with earlier stage disease, not limited to the challenging treatment categories noted above. We estimate that this potential market expansion could include an additional 800,000 total patients for FoundationOne and an additional 80,000 total patients for FoundationOne Heme on an annual basis.

We believe we have built the only commercially available molecular information platform that comprehensively assesses cancer simultaneously for all four classes of genomic alterations (i.e., base pair substitutions, copy number alterations, short insertions and deletions, and gene rearrangements and fusions) across all cancer-related genes with the sensitivity and specificity required for routine medical practice. We published our analytic validation for FoundationOne in *Nature Biotechnology* in October 2013, and are in the process of preparing a similar validation publication for FoundationOne Heme. FoundationOne and FoundationOne Heme deliver this complex molecular information in a concise report that matches detected molecular alterations with potentially relevant treatment options and clinical trials.

We believe the genomic alterations identified for each patient should be accompanied by the most current and relevant scientific and medical literature related to those alterations, and that this information should be presented in a clear and concise manner. Our molecular information knowledgebase, FoundationCORE, stores this genomic alteration data and currently includes more than 35,000 genomic profiles. Test reports are now available to physicians using ICE 2, the newest version of our online Interactive Cancer Explorer®, launched in December 2014. We believe ICE 2 will help physicians to more efficiently use our clinical products and will enhance the utility of comprehensive genomic profiling. An important new component of ICE 2 is PatientMatch, a technology tool that leverages FoundationCORE to increase the utility of FoundationOne and FoundationOne Heme results. Using PatientMatch, physicians within the ICE 2 network are able to connect with other physicians treating patients with similar genomic profiles and share treatment and outcome information in a manner compliant with the Health Insurance Portability and Accountability Act, or HIPAA. We believe ICE 2 and PatientMatch may be very important technology tools to support and accelerate the broad adoption of our products, and to create an important network effect among users.

Our clinical products have been rapidly adopted in the marketplace, and several thousand physicians from large academic centers and community-based practices have ordered FoundationOne or FoundationOne Heme. We believe this rapid adoption, which has been accomplished in the early stages of our commercial growth, demonstrates the demand for and utility of a single, comprehensive solution that helps oncologists effectively implement the promise of precision medicine.

We believe our molecular information products have a sustainable competitive advantage because they:

***Comprehensively identify clinically relevant information*** FoundationOne currently assesses 315 biologically relevant cancer genes for all classes of genomic alterations with high sensitivity and

## **Table of Contents**

specificity, and has identified a genomic alteration associated with an FDA-approved targeted therapy or with a clinical trial in 85% of the approximately 13,000 clinical specimens we received and analyzed with FoundationOne following its formal commercial launch in June 2012 through March 2014. We believe FoundationOne identifies genomic alterations that other commercially available diagnostic tests cannot. FoundationOne Heme employs RNA sequencing of 265 genes in addition to DNA sequencing of 405 genes to detect all classes of genomic alterations across genes known to be altered other than through inherited genetic characteristics, which are also known as somatic alterations, in hematologic malignancies, pediatric cancers, and sarcomas, which we believe also will lead to the identification of clinically relevant information;

***Promote physician interaction to create a powerful network effect*** We are continually augmenting FoundationCORE and expanding the functionality of our Interactive Cancer Explorer to allow for sharing of genomic and treatment data through PatientMatch in a HIPAA-compliant fashion. We believe these efforts will create a network effect of more users and ultimately more actionable information;

***Incorporate the latest scientific and medical advances*** We have extensive relationships across the scientific and medical oncology communities, including with key thought leaders and leading biopharmaceutical companies. These relationships help us incorporate new cancer genes, the latest scientific findings, newly available targeted therapeutics, and relevant clinical trials into FoundationOne and FoundationOne Heme test results;

***Readily integrate into routine clinical practice*** Our proprietary sample preparation processes and computational biology algorithms allow us to utilize small amounts of tumor tissue from a wide variety of sample types, including tissue with low tumor purity, so as to allow for routine specimen collection. We detect and report the clinically relevant genomic alterations, generally within 11 to 14 days for FoundationOne and within 15 to 18 days for FoundationOne Heme, in each case from the time the specimen is received. We are dedicated to providing high-quality support to our customers, from order initiation and sample acquisition through report delivery and follow-up with our medical affairs team; and

***Provide clinically relevant information that physicians can use*** In a concise report, our products communicate the relevant genomic alterations in a patient's cancer and based on peer-reviewed literature and clinical and governmental databases, match these alterations with targeted therapies and relevant clinical trials.

Our molecular information platform is currently used by more than 20 biopharmaceutical partners to enhance their development of targeted oncology therapies. We use our core proprietary testing platform, computational biology, and information technology capabilities to analyze patient samples from both retrospective and prospective clinical trials. We provide our biopharmaceutical partners comprehensive genomic profiling, access to data within FoundationCORE, and companion diagnostic development and support to help drive their precision medicine strategies. In addition to generating revenue, these relationships often enable us to identify new cancer genes under investigation that can be incorporated into our platform at an early stage, as well as to participate in the development of the newest oncology therapeutics and practice. We are actively working to expand these relationships.

We are dedicated to ongoing innovation in our molecular information platform and new product pipeline. Our product development investments have already yielded enhancements to FoundationOne and the platform generally, enabling us to analyze more genes, using less tissue, while reducing turn-around time. We also utilize RNA-based sequencing technology to analyze additional gene fusions commonly found in hematologic malignancies, pediatric cancers, and sarcomas, and we launched FoundationOne Heme, which incorporates this technology, in December 2013. In addition, we are exploring and developing new scientifically-advanced and clinically relevant products that include, for example, products to analyze circulating tumor cells (CTCs) and circulating tumor DNA (ctDNA), which is DNA from tumors that circulates in blood plasma outside of cells, and products that expand our offerings into additional areas such as immune response. We believe that our

---

## **Table of Contents**

development of a suite of product offerings will be instrumental in providing patients and physicians with the comprehensive molecular information needed to evaluate a patient's cancer and enable more informed treatment decisions.

The increasing availability and understanding of molecular information within the practice of oncology is driving a revolution in the treatment of cancer. We seek to leverage the vast array of genomic data generated by our molecular information platform together with clinical data to position ourselves at the nucleus of this new treatment paradigm. Our biopharmaceutical partners have already begun using our data to further refine clinical trial design and drug development. In an example of the power of our molecular information platform, after a biopharmaceutical partner's Phase II trial that used a narrowly focused molecular diagnostic test to screen trial subjects failed to meet its primary endpoint, we performed our comprehensive genomic profile on the tissue collected from trial participants. Our analysis helped our biopharmaceutical partner predict a response to the drug, created new hypotheses to test in upcoming Phase III trials, and may have increased the target population who could benefit from this therapeutic approach.

Over time, we intend to expand our ability to capture, aggregate, analyze, and facilitate the broader exchange of genomic data across the global oncology community. We are investing in our technology architecture to allow oncologists to share clinical data. Through ICE 2 and PatientMatch, as well as data partnerships with leading technology and software companies such as Flatiron Health and Clinical Outcomes and Tracking Analysis, or COTA, we are building a data platform that efficiently captures and allows for the analysis of data that we believe will create a network effect leading to more users and, in turn, more relevant genomic and clinical data. If we, in conjunction with oncologists, pathologists, biopharmaceutical companies, and academic researchers, can successfully capture and utilize this data, we believe we will play an even more integral role in transforming care for the millions of patients suffering from cancer.

### ***Proposed Strategic Collaboration with Roche***

On January 12, 2015, we announced a proposed broad, strategic collaboration with Roche Holdings, Inc., or Roche, and certain of its affiliates, in the field of molecular information for oncology. The transaction, which is subject to a number of closing conditions as further explained in our other public filings and in the section below entitled "Proposed Strategic Collaboration with Roche," is a broad multi-part agreement that includes an R&D collaboration, a U.S. educational support collaboration, an ex-U.S. commercial collaboration, a binding term sheet for an *in vitro* diagnostic product development collaboration and an equity investment with certain governance provisions. We believe this proposed strategic collaboration with Roche will accelerate many aspects of our business strategy and further advance our leadership position in molecular information solutions.

Under the terms of the R&D collaboration agreement, Roche may pay potentially more than \$150 million over five years to access our molecular information platform and to fund R&D product development programs. Roche will utilize our molecular information platform to standardize its clinical trial testing to enable comparability of clinical trial results for R&D purposes and to better understand the potential for combination therapies. The initial focus of the R&D product development programs will be to develop genomic profiling tests for continuous blood-based monitoring and cancer immunotherapies, and to develop next generation companion diagnostics. We believe that the Roche collaboration will not adversely impact our ongoing biopharmaceutical client relationships, since we will remain operationally independent from Roche based on the investment transaction governance provisions and because we have a proven track record with our multiple existing biopharmaceutical partners. As our capabilities increase through our collaboration with Roche, we expect to have more offerings available to existing and new clients.

The commercial collaborations are designed to significantly broaden our reach across international clinical and molecular information markets. Specifically, under the ex-U.S. commercial collaboration, Roche will obtain ex-U.S. commercialization rights to our existing products and to future co-developed products. Under the U.S.



## **Table of Contents**

educational support collaboration, while we will remain solely responsible for commercialization of our products within the United States, Roche will engage its medical education team to provide non-branded information to pathologists across the United States specific to comprehensive genomic profiling in cancer.

Under the terms of the proposed investment transaction, Roche has agreed to purchase 5 million shares of newly issued common stock at \$50 per share, resulting in gross proceeds to us of \$250 million. These proceeds will fund our continued operations and development. In addition, Roche commenced a tender offer to acquire a number of outstanding shares of common stock at \$50 per share, which, when combined with Roche's direct investment of \$250 million, will result in Roche owning a minimum of 52.4% and a maximum of 56.3% of our outstanding common stock on a fully diluted basis. The completion of Roche's direct investment and the successful outcome of the tender offer, as well as the effectiveness of the collaboration agreements are all cross-conditional and subject to approval of our stockholders and other customary closing conditions.

### **Our Strategy**

Our objective is to transform the care of patients with cancer by leading the development and commercialization of proprietary molecular information products that inform the diagnosis and treatment of cancer, and that enhance the development of cancer therapies. To achieve this objective, our strategy is to:

***Drive awareness and adoption of FoundationOne, FoundationOne Heme, and future products we may develop*** We have built an experienced, oncology-focused sales force, continue to collaborate with thought leaders to validate our platform and influence utilization of our products, promote physician interaction, engage with patient advocacy and other key oncology stakeholders, and continue to pursue payment and reimbursement for our products.

***Empower the broader cancer community with molecular information*** We are investing in technologies to allow oncologists to collaborate and share treatment and other clinical information. We have launched ICE 2 and PatientMatch to further this goal. Over time, we intend to expand our capacity to capture, aggregate, analyze and facilitate the broader exchange of genomic and clinical data across the global oncology community—a strategy that we believe eventually will create a network effect encouraging physician participation and the development of substantial amounts of data that, in turn, will positively impact the treatment of cancer.

***Demonstrate the value of our products to patients, physicians, and payors*** To illustrate the value of our products, we are educating physicians and payors about the patients most likely to benefit from our products, conducting clinical trials and health economic studies, and communicating our data through peer-reviewed journals and conference presentations.

***Enable biopharmaceutical companies to more effectively develop new cancer therapies*** We are continuing to expand our commercial relationships with biopharmaceutical partners to enable us to discover and interrogate new cancer genes, to assist in the development of novel targeted therapeutics and companion diagnostic tests, to improve clinical trial efficiency and outcomes, and to continue our involvement at the cutting edge of cancer treatment.

***Invest in product enhancements and new product innovations*** We are developing new molecular information products and conducting research and development into potential products to evaluate and monitor disease progression utilizing circulating tumor cells and circulating tumor DNA and to better understand markers of response to targeted therapies and immunotherapies. We believe these investments will enable our companion diagnostics development and our FDA-regulated products strategy.

## **Table of Contents**

### **Our Industry**

Despite enormous investment in research and the introduction of new treatments, cancer remains a critical area of unmet medical need. According to a 2014 American Cancer Society report, *Cancer Treatment and Survivorship Facts & Figures 2014-2015*, in 2014 in the United States, more than 14 million people were suffering from cancer and more than 1.6 million people were newly diagnosed with the disease. Hematologic malignancies, most commonly leukemias, lymphomas, and myelomas, are cancers that affect the body's blood, lymphatic system, or bone marrow. Taken together, hematologic malignancies account for approximately 10% of new cancer diagnoses in the United States.

The global cancer burden is growing. The World Health Organization predicts in its *Global Action Against Cancer* publication that in 2020 there will be 16 million new cancer cases and 10 million cancer deaths globally. A recent report by the American Cancer Society, *The Global Economic Cost of Cancer*, estimates that the total annual economic impact of premature death and disability from cancer worldwide is approximately \$900 billion.

According to the American Society of Clinical Oncology, there are more than 10,000 practicing oncologists treating patients with cancer in the United States. Whereas a small portion of oncologists practice in major academic-based cancer centers, the National Cancer Institute estimates that approximately 85% of the oncologists in the United States practice in community-based settings where the vast majority of patients with cancer are treated.

The diagnosis of cancer is complex and multidimensional. Practicing oncologists order multiple tests, including currently available molecular diagnostic tests, to better understand the genomic alterations that are driving their patients' cancer growth.

### ***Cancer Treatment is Evolving to a Molecular-Based Paradigm***

Cancer is not a single disease. The term "cancer" describes a class of diseases characterized by uncontrolled cell growth. Cells can experience uncontrolled growth if there are alterations to DNA, such as damage or mutations, and, therefore, disruption to the genes and proteins regulating cell division.

Surgery is often the first line of therapy for cancer where possible, and, according to the American Cancer Society, most patients with cancer will have some type of surgery. Surgery often presents the greatest chance for a cure, especially if the cancer has been detected early in its development and has not spread to other parts of the body. Many patients, however, require therapeutic intervention beyond surgery alone.

Physicians have used radiation as a cancer therapy since the early 20th century, and modern radiation techniques deliver therapy with significant precision. Nevertheless, even today, radiation's use and efficacy is limited because the high doses necessary to kill cancer cells often cause damage to healthy cells in the treatment area and fail to kill all cancer cells, particularly if the cancer has spread to other parts of the body.

Physicians began using chemotherapy in the 1940s as a drug therapy approach that acts by killing cells that divide rapidly, one of the main properties of most cancer cells. These cytotoxic therapies are often prescribed by a trial and error approach—both because certain chemotherapies have limited efficacy with some patients and the treatment effect might be inconsistent, and because the therapies' indiscriminate destruction of healthy cells involved in critical biological functions can cause severe toxic side effects in some patients.

More recently, oncologists are integrating a precision medicine approach by utilizing therapeutics that target cancers based on the specific genomic alterations driving their growth. We believe the oncology community is generally beginning to change clinical practice so that oncologists treat each individual's cancer according to its unique genomic alterations that impact the underlying biological pathways within the patient's cancer, rather than treating a patient's cancer based solely on its initial anatomical location in the body, such as the breast,

## **Table of Contents**

colon or lung. In addition, as a result of advancements in cancer biology and genomic technology that enable the identification of new cancer genes, biopharmaceutical companies are directing more research and development resources towards targeted therapies. There are currently more than 40 approved targeted oncology therapies on the market and approximately 950 unique clinical trials testing more than 470 targeted oncology therapies. In 2013, according to IMS Health, global sales of targeted oncology therapies totaled approximately \$41.9 billion, compared to less than \$4.4 billion in 2003.

The rapid increase in molecular information related to cancer, as well as the increasing array of targeted oncology therapeutics, are making it more difficult for physicians to make treatment decisions. The National Comprehensive Cancer Network estimates that 50% to 75% of cancer therapies in the United States are used off label, meaning that physicians prescribe therapies for clinical indications in manners different from those approved by FDA. Off-label usage of traditional cytotoxic therapies is often driven by physicians struggling to treat a patient's disease after it fails to respond to initial treatment regimens. Targeted therapies are used off label by oncologists who have expertise in genomics or access to diagnostic tools that allow them to make informed decisions about off-label use of targeted therapies.

In order to maximize the utility of diverse cancer-related molecular information to better guide the use of targeted therapies, we believe a new approach is needed. Specifically, the oncology community needs comprehensive genomic information products that can assess the known and biologically relevant genomic alterations, and distill complex molecular information into a concise and actionable format.

### ***Current Challenges of Evaluating Cancer on a Molecular Level***

Today, physicians are faced with numerous challenges when making decisions on how to best utilize currently available molecular diagnostics for cancer, including:

- the inherent limitations of molecular diagnostic tests that are typically capable of identifying only single-marker or test panels that capture a limited number of genomic markers and address only a subset of the four classes of genomic alterations found in cancers, which are also known as hotspot panel tests;

- in the case of solid tumors, insufficient and/or poor quality tumor biopsy tissue relative to the amount and quality needed to perform all desired or required tests; and

- difficulty of integrating existing molecular diagnostic tests into clinical practice, including the decisions about which tests to order and how to effectively match the genomic information provided by tests with current targeted therapies or clinical trials.

#### ***Single-Marker or Hotspot Panel Tests May Miss Relevant Information***

Most currently available molecular diagnostic tests are single-marker or hotspot panel tests that capture only one or a limited number of the most common, well-known gene alterations that these tests are designed to target. There are four classes of genomic alterations that are clinically relevant to the treatment of cancer: base pair substitutions; copy number alterations; short insertions and deletions; and gene rearrangements and fusions. Hotspot panel tests generally are only able to identify base pair substitutions and specific gene rearrangements, do not routinely detect copy number alterations, and often lack the sensitivity to identify short insertions and deletions. In addition, hotspot panel tests are typically incapable of detecting gene fusions, a type of alteration that is a common driver of hematologic malignancies, sarcomas and pediatric cancers.

The following table summarizes the uses and inherent limitations of the current testing methods utilized in commercially available single-marker and hotspot panel tests for cancer, including the most commonly ordered according to results of a 2008 survey of oncologists and hematologists published in the *Journal of Clinical Pathology* article, "Molecular testing for somatic cancer mutations: a survey of current and future testing in UK

## **Table of Contents**

laboratories. Although oncologists may order these tests to look for one or a limited number of specific gene alterations, we believe the inherent limitations of tests using these methods are understood by pathologists and genomicists who perform the tests and the oncologists who order them.

<b>Name</b>	<b>Uses</b>	<b>Limitations</b>
<i>Polymerase chain reaction</i> , or PCR-based tests, a technology used for amplifying DNA sequences	Enable the detection of short fragment DNA or RNA sequences.	Single-gene tests for specific and limited number of mutations.
<i>Immunohistochemical</i> , or IHC, stains, a process used to diagnose abnormal cells	Utilize antibody proteins to identify certain antigens that are unique to various types of cancer.	Only identify known and select base substitutions and short insertions or deletions, such as BRAF V600E.  Only identify the expressed presence of a known and select protein or specific protein marker, such as HER2, related to a particular genomic alteration.
<i>FISH-based DNA</i> probes, a mechanism for detecting DNA sequences through the use of fluorescent technology	Reveal specific genomic abnormalities, including insertion/deletions and rearrangements.	Only detect select gene rearrangements, such as EML4-ALK.
<i>Flow Cytometry</i>	Detection of tumor cell DNA aneuploidy, the analysis of tumor cell proliferation and the immunophenotyping of leukemias.	Difficult to test for multiple markers.  Only looks at a limited number of cells, and does not detect broader range of genomic alterations.
<i>Cytogenetics</i>	Determination of which chromosomal translocations and fusion genes are present in malignant cells.	Cannot detect other types of genomic abnormalities.

Since current hotspot panel tests typically cannot detect many genomic alterations present in cancer, physicians who use these tests may fail to identify relevant information about their patients' cancers that could inform a preferable treatment approach. We believe the limitations of this narrowly-focused approach of looking for a limited number of pre-selected genomic alterations will be further compounded as more actionable genomic alterations are identified and additional targeted therapies are developed.

### *Limited Tissue Availability and Poor Tissue Quality Restrict Testing Options*

Many clinical tumor samples are provided from standard biopsies, needle biopsies or fine needle aspirates that yield very small tissue amounts. Small amounts of tissue samples limit the number of diagnostic tests a physician can order, and ordering one or a limited number of tests that look for one or a limited number of genomic alterations necessarily increases the likelihood that a physician may fail to identify other genomic alterations and ultimately therapeutic options.

Clinical tumor specimens also often have low tumor purity, meaning that the relevant genomic alterations occur in low frequencies within the sample and are difficult to detect. Moreover, the vast majority of clinical samples are stored as formalin-fixed and paraffin-embedded, or FFPE, specimens. FFPE preservation can damage DNA and RNA. Low tumor purity or damage to DNA or RNA may limit the availability of hotspot tests to identify certain genomic alterations.

## **Table of Contents**

### *A Growing Number of Molecular Diagnostics are Often Difficult to Integrate into Clinical Practice*

Physicians today face an increasingly difficult decision about which single-marker or hotspot tests to order. There are a growing number of tests, each specific to a different cancer type and each having limited ability to detect multiple genomic alterations. Typically, in the case of solid tumors, only a small amount of tumor biopsy is available, forcing the physician to order only a subset of desired diagnostic tests, often one test at a time in a serial manner. Furthermore, tests are usually selected based on the traditional treatment paradigm of the cancer's location in the body or by simple trial and error. Integration of molecular diagnostics into clinical practice is particularly challenging with hematologic cancers in which lack of tissue distinctions within the cancers often lead to misdiagnosis, lack of prognostic information and, thus, mistreatment.

Running multiple, disjointed tests also poses logistical challenges associated with routing samples to several different laboratories and high costs associated with conducting multiple tests. Moreover, limited tissue availability may prevent relevant tests from being ordered, tests conducted may miss genomic alterations, and the results may not be delivered soon enough to be used during the typical treatment cycle for a patient. Even if a physician has enough cancer specimen to order a sufficient number of hotspot and individual molecular tests to identify relevant genomic alterations and receives the results of all of these tests in a timely fashion, the physician would commonly receive a series of uncoordinated individual reports from different laboratories that are difficult for non-specialized pathologists or other physicians to interpret and synthesize. Compounding these challenges, especially in the community oncology setting, is how to effectively match the genomic information provided by tests with current targeted therapies or clinical trials for a particular patient. As a result of one or a combination of these current limitations, physicians may fail to identify or to prescribe a potentially appropriate targeted oncology therapy or to direct a patient to a potentially appropriate clinical trial.

### *The Opportunity for a Single, Comprehensive Molecular Information Solution*

In order to harness the potential of understanding the genomic drivers of a patient's cancer and new therapies targeted at specific genomic alterations, we believe the oncology community needs a new approach: a single molecular information platform that can assess a solid tumor or hematologic malignancy for the presence of biologically relevant genomic alterations. This solution would also provide assistance to physicians in matching the genomic alterations identified in their patients' cancers with relevant available therapeutic alternatives and clinical trials.

Our molecular information platform, which includes proprietary technology, methods and computational algorithms, is the product of years of research and development and significant capital investment. Through this platform we deliver comprehensive genomic profiling to support physicians in the improvement of clinical

## **Table of Contents**

patient care and to support biopharmaceutical companies in the development of novel cancer therapeutics. The first molecular information products enabled by our platform are FoundationOne, which is optimized for use with solid tumors, and FoundationOne Heme, which is optimized for hematologic cancers, including leukemia, lymphoma and myeloma, as well as pediatric cancers and many sarcomas. FoundationOne, our initial clinical product launched in June 2012, is a comprehensive genomic profile that identifies the individual molecular alterations present in a patient's cancer tumor and matches them with relevant targeted therapies and clinical trials. FoundationOne Heme, our second commercially available product, which we developed in collaboration with Memorial Sloan-Kettering Cancer Center, or MSKCC, and launched in December 2013, is a comprehensive genomic profile that identifies the individual molecular alterations present in a patient's blood-based cancer and matches them with relevant targeted therapies and clinical trials.

### ***FoundationOne and FoundationOne Heme Integrate Complex Molecular Information into Routine Clinical Care***

FoundationOne and FoundationOne Heme are, to our knowledge, the first commercially available comprehensive genomic profiles used in the analysis of routine cancer specimens in a clinical setting. We believe these products are the only molecular information products that can comprehensively assess cancer tissue simultaneously for all four classes of genomic alterations with sufficient sensitivity and specificity for routine medical practice. Moreover, FoundationOne and FoundationOne Heme deliver this complex molecular information in a contextualized report that matches detected molecular alterations with potentially relevant treatment options and clinical trials. We perform our clinical tests in our laboratory located in Cambridge, Massachusetts, which is certified under the Clinical Laboratory Improvement Amendments, or CLIA, accredited by the College of American Pathologists, or CAP, and licensed by New York, Massachusetts and other states. Optimization and automation enable workflows to deliver medical reports to ordering physicians generally within 11 to 14 days for FoundationOne and within 15 to 18 days for FoundationOne Heme, in each case from the time the specimen is received.

---

## **Table of Contents**

### *A Comprehensive Clinical Assessment of Relevant Alterations in Cancer Genes*

FoundationOne interrogates the genes known to be somatically altered in human solid tumors that are validated targets for therapy or are unambiguous drivers of cancer. We have selected this set of genes based upon the advice of an international group of key opinion leaders in oncology and cancer biology, input offered by our biopharmaceutical partners and our extensive review of the relevant literature. The current version of FoundationOne interrogates the entire coding sequence of 315 cancer-related genes across all four classes of genomic alterations, as well as certain intronic regions, which are DNA sequences that do not encode for proteins, of 28 genes commonly involved in rearrangements. FoundationOne Heme interrogates genes somatically altered in hematologic malignancies, sarcomas, and pediatric cancers that are validated targets for therapy or unambiguous drivers of cancer based on current scientific knowledge. The current version of FoundationOne Heme interrogates 265 cancer-related genes through RNA sequencing and 405 cancer-related genes through DNA sequencing across all classes of genomic alterations, as well as certain intronic regions of 31 commonly rearranged genes. FoundationOne Heme has been specifically validated to detect gene fusions, a type of alteration that is a common driver in hematologic malignancies, sarcomas, and pediatric cancers, with high accuracy. Both tests include those genes implicated in cancers for which a targeted therapy is FDA-approved and for which targeted therapies are in current or near-term clinical development. We update our tests periodically to reflect new scientific and medical knowledge about cancer biology, including newly relevant cancer genes along with those genes for which there are newly available targeted therapeutics and clinical trials.

Based on our actual experience with patient cases since its launch, we believe FoundationOne's ability to identify clinically relevant genomic alterations exceeds that of other commercially available molecular diagnostic tests. We define a clinically relevant alteration as an identified genomic alteration in an analyzed cancer cell associated with an FDA-approved targeted therapy indicated for use in the tumor type, an FDA-approved targeted therapy indicated for use in another tumor type, or an open clinical trial for which the alteration confers eligibility. Our comparative quantitative analysis demonstrated that running four commercially available tests that also utilize next-generation sequencing, or NGS, plus two relevant and commonly-used hotspot tests together would collectively identify only a maximum of 31% of the actionable genomic alterations that can be identified by FoundationOne. We presented this comparative quantitative analysis at the American Society of Clinical Oncology, or ASCO, in June 2013 and published its results in *Nature Biotechnology* in October 2013.

FoundationOne's and FoundationOne Heme's ability to identify genomic alterations is greater than other commercially available molecular tests, in part, because we believe our products:

examine the entire coding region of each gene analyzed, enabling much broader interrogation of potential alterations for each gene;

are the only molecular diagnostic products that can comprehensively assess cancer tissue simultaneously for all classes of genomic alterations;

assess samples with high sensitivity and specificity across all four classes of genomic alterations for a wide array of cancer-related genes; and

interrogate more cancer-related genes than many other molecular diagnostic tests.

FoundationOne identified at least one genomic alteration that is associated with an FDA-approved targeted therapy or with a clinical trial in 85% of approximately 13,000 clinical specimens we received and analyzed with FoundationOne following its formal commercial launch in June 2012 through March 2014.

### *A Validated and Highly Precise Process of Testing*

Our proprietary methods and workflow make FoundationOne and FoundationOne Heme suitable for clinical use at a commercial scale. Standard biopsies and needle biopsies obtained in a clinical setting often yield very small tissue amounts that have a low concentration of tumor cells and are preserved in a FFPE format. We have





## **Table of Contents**

developed proprietary techniques for optimizing pre-sequencing sample preparation and have built post-sequencing computational algorithms that enable our products to be sufficiently sensitive to perform comprehensive genomic profiling on routine clinical tumor samples. We have optimized our processes to maximize throughput, efficiency, and quality. These laboratory processes have allowed us to successfully deliver results for FoundationOne since launch in greater than 95% of all clinical tumor samples we have analyzed to date, against a sample failure rate of less than 5%.

FoundationOne has undergone an extensive analytical validation that demonstrates test performance using both reference specimens and hundreds of actual FFPE clinical cancer specimens with results derived from prior standard diagnostic tests. We performed validation studies in which FoundationOne testing was conducted on previously characterized cell lines known to contain various base substitutions and cancer specimens known to contain various insertions, deletions, and copy number alterations to evaluate whether FoundationOne was capable of detecting these pre-defined genomic alterations. FoundationOne was found to be highly sensitive in identifying these genomic alterations even where the percentage of cells in test samples containing the alterations (versus normal cells not containing the alterations) was very low. Specifically, FoundationOne was able to detect 99% of base substitutions contained in test samples in which less than 10% of the cells contained the alterations, 97% of insertions and deletions in samples in which 10% to 20% of the cells contained the alterations, and 99% of copy number alterations of at least 8-fold in which 30% of the cells contained the alterations. In aggregate, FoundationOne detected greater than 99% of the genomic alterations contained in the samples tested in the validation study. We believe these results demonstrate the importance of our proprietary methods, algorithms, and advanced bioinformatics, and will help to set the industry standards for validation of comprehensive genomic profiling. The analytic validation results of our studies on FoundationOne were published in *Nature Biotechnology* in October 2013.

FoundationOne Heme has undergone an extensive analytical validation for both the DNA and RNA sequencing components of the test. Test performance of the DNA component matched the high accuracy achieved by FoundationOne for all classes of genomic alterations. Test performance of the RNA component demonstrated a sensitivity to detect greater than 99% of known gene fusions at 20% tumor content and 97% of known gene fusions at 10% tumor content. The analytic validation results of our studies on FoundationOne Heme were presented at the annual meeting of the American Society of Hematology, or ASH, in December 2013, and we are in the process of submitting this validation work for publication.

### *A Report Physicians Can Readily Understand and Use to Guide Patient Care*

We designed the FoundationOne and FoundationOne Heme reports, in collaboration with leading oncologists, to deliver clinically relevant information in a manner that seamlessly integrates into their practices. We present the results from our tests in a medically relevant and, we believe, practice-friendly manner that empowers physicians to make informed treatment decisions. During a period of active treatment, patients typically visit their physician every three to four weeks. We report the clinically relevant genomic alterations to a physician for use, generally within 11 to 14 days for FoundationOne and within 15 to 18 days for FoundationOne Heme, in each case from the time the specimen is received.

The first page of the report clearly illustrates the test's key findings. Specifically, it lists the analyzed cancer's relevant genomic alterations and matches them with either FDA-approved therapies or open clinical trials for therapies targeting these alterations. The report also identifies noteworthy absences of genomic alterations typically associated with anatomical tumors of the same type. In addition, the report includes summaries of and references to supporting data from peer-reviewed publications and clinical trial information. All of the information on the report can also be accessed by ordering physicians through the newest version of our online Interactive Cancer Explorer, ICE 2.

## Table of Contents

### An Example of Page One Findings from a FoundationOne Report

<b>PATIENT RESULTS</b>	<b>TUMOR TYPE: BLADDER UROTHELIAL (TRANSITIONAL CELL) CARCINOMA</b>
4 genomic alterations	<b>Genomic Alterations Identified</b>
4 therapies associated with potential clinical benefit	NF2 Y153fs*1
0 therapies associated with lack of response	ATM V2119fs*8
8 clinical trials	ATR splice site 7349+2T>C
	TP53 R280K
	For a complete list of the genes assayed, please refer to the Appendix
	*See Appendix for details

### THERAPEUTIC IMPLICATIONS

	FDA Approved Therapies (in patient's tumor type)	FDA Approved Therapies (in another tumor type)	Potential Clinical Trials
<b>Genomic Alterations Detected</b>			
<b>NF2</b>	None	Everolimus	Yes, see clinical trials section
Y153fs*1		Lapatinib	
		Temsirolimus	
<b>ATM</b>	None	Trametinib	Yes, see clinical trials section
V2119fs*8		None	
<b>ATR</b>	None	None	Yes, see clinical trials section
splice site 7349+2T>C			
<b>TP53</b>	None	None	Yes, see clinical trials section
R280K			

Note: Genomic alterations detected may be associated with activity of certain FDA-approved drugs; however, the agents listed in this report may have varied clinical evidence in the patient's tumor type. Neither the therapeutic agents nor the trials identified are ranked in order of potential or predicted efficacy for this patient, nor are they ranked in order of level of evidence for this patient's tumor type.

We deliver the FoundationOne and FoundationOne Heme reports along with easy access to current information about the reported genomic alterations, associated therapies, and clinical trials. We intend to continue updating our Interactive Cancer Explorer with new important features and tools, such as our recently implemented PatientMatch tool, as we gather feedback from our ordering clients over time.

*Strong Evidence of Clinically Relevant Findings with FoundationOne*

## Edgar Filing: Foundation Medicine, Inc. - Form 10-K

We designed FoundationOne and FoundationOne Heme to address challenges associated with the everyday clinical management of patients diagnosed with cancer. We have experienced rapid adoption of our clinical products, and several thousand physicians from large academic centers and community-based practices have ordered FoundationOne or FoundationOne Heme.

We believe that the following case studies illustrate the power of FoundationOne to impact treatment regimens for patients in a clinical setting.

## **Table of Contents**

### *Case Study 1: FoundationOne Identifies a Clinically Relevant Genomic Rearrangement in Rare Tumor Pediatric Patient Receives Matched Targeted Therapy.*

We received and analyzed a tumor specimen from a six year old boy having a history of cough and fatigue and who had been diagnosed with an Inflammatory Myofibroblastic Tumor (IMT) in his chest. IMTs are known to be frequently associated with ALK fusions, an actionable alteration. However, traditional diagnostic analyses on the boy's tumor specimen, including standard clinical immunohistochemistry and a customary FISH-based test failed to reveal any ALK fusion. The patient received anti-inflammatory agents and chemotherapy over a two year period, with minimal improvement of his anemia, no tumor shrinkage, and persistent tumor-related symptoms. FoundationOne was then performed and detected a clinically relevant genomic alteration, a *TFG-ROS1* fusion, which was not identified in initial testing. Based on this information, the patient was then treated with XALKORI® (crizotinib), a targeted therapy that inhibits the activity of the ROS1 fusion protein.

The treatment shrank the tumor and led to improvements in the boy's symptoms, including decreased cough and significantly increased energy. As of March 2015, the young boy has been on XALKORI (crizotinib) for 10 months and is continuing to do well with an improved quality of life, and a decreased tumor burden. These results were published in the *Cancer Discovery* in August 2014.

### *Case Study 2: FoundationOne Identifies Clinically Relevant Mutation in Muscle-Invasive Bladder Cancer and Patient Receives a Personalized Combination of Targeted Therapy and Chemotherapy.*

We received and analyzed a tumor specimen from a 60 year old female who had been diagnosed with muscle-invasive bladder cancer. The patient received multiple cycles of platinum-based chemotherapy. Her bladder was surgically removed, but shortly thereafter she developed metastatic disease. FoundationOne analysis of the patient's tumor specimen detected several genomic alterations, among them an *NF2* point mutation leading to an inactive truncated NF2 protein. Preclinical work suggests that loss of *NF2* activity may be associated with sensitivity to analogs of rapamycin, an mTOR inhibitor. On the basis of these findings, the patient was treated with a targeted therapy, everolimus (a rapamycin analog), in combination with a chemotherapeutic agent, paclitaxel, using a dosing regimen currently being examined in a Phase II study in bladder cancer. This treatment shrank the tumor by 65% and improved cancer-related symptoms.

Following tumor progression after using platinum-based therapy in the first-line setting, no standard of care exists for second line treatment of metastatic bladder cancer, and tumor regression rates in these cases range from 0-25%. In contrast, this patient had a profound durable response to a targeted therapy with a chemotherapy backbone that is ongoing after 13 months. The results of this case study were published in *European Urology* in January 2015.

### ***Our Platform for Biopharmaceutical Research and Development***

For many of the same reasons our products provide information that is well suited for the clinical setting, our molecular information platform enhances the ability of our biopharmaceutical partners to develop targeted oncology therapies. We deploy our molecular information platform to analyze tissue samples provided by biopharmaceutical partners from their clinical trials, and we provide our partners access to our FoundationCORE knowledgebase to provide insight into molecular information derived from our analysis. We use our core proprietary platform testing, computational biology, and information technology capabilities to provide our biopharmaceutical partners with comprehensive genomic profiling and information relevant to precision medicine strategies for both retrospective and prospective clinical studies and other drug development activities. Our platform capabilities enable our biopharmaceutical partners to:

accelerate clinical development timelines and increase the likelihood of patient response by prospectively analyzing tumor specimens to identify patients with certain genomic alterations for enrollment in clinical trials for targeted cancer therapeutics;

---

## **Table of Contents**

understand complex combinations of genomic alterations to facilitate development of companion diagnostic tests that may be necessary to bring a targeted cancer therapeutic to market;

guide usage and inform future development opportunities for experimental and marketed therapies by retrospectively analyzing clinical trial patients to stratify them as responders or non-responders based on the presence or absence of certain genomic alterations;

create opportunities for drug combination studies or new target discovery by identifying mechanisms of primary and acquired resistance; and

inform improvements to clinical trial design by contributing to the understanding of why some clinical studies have not met their primary endpoints.

We currently have ongoing relationships with more than 20 biopharmaceutical partners, many of which are leaders in developing targeted cancer therapies, and those relationships have expanded over time. Our publicly announced biopharmaceutical customers include Agios Pharmaceuticals, Inc., ARIAD Pharmaceuticals, Inc., Array BioPharma Inc., AstraZeneca UK Limited, Celgene Corporation, Clovis Oncology, Inc., Eisai Co., Ltd., Johnson & Johnson, Novartis, and Sanofi.

In addition to customary clinical settings in which physicians prescribe an FDA-approved therapy, approximately 3% of patients with cancer in the United States are currently enrolled in clinical trials of new experimental therapies sponsored by biopharmaceutical companies. By broadening our relationships with our biopharmaceutical partners, we expect to deploy our molecular information platform for an increasing portion of patients with cancer enrolled in clinical trials both in and outside the United States. We recently announced a collaboration with WuXi PharmaTech Inc., or WuXi, who will perform the laboratory component of our tests in its laboratories in Shanghai. Our partnership with WuXi will allow us to offer our comprehensive genomic profiles to biopharmaceutical companies conducting clinical trials in China. We expect our biopharmaceutical partner relationships will continue to expand and will provide more opportunities to sell our molecular information products for companion diagnostic development, research and development projects, and new target discovery and validation. In addition, we believe our proposed strategic collaboration with Roche represents a significant opportunity to further standardize clinical trial testing across many cancer therapeutics development programs, develop additional companion diagnostic products, and grant access to our molecular information knowledgebase, FoundationCORE.

In addition to generating near and longer term revenue, we believe our relationships with our biopharmaceutical partners provide us with important strategic opportunities, including enabling us to identify new genes under investigation that can be incorporated early into our molecular information platform and our products, and more broadly allowing us to actively participate in the newest oncology therapeutics and practice. For example, we are providing comprehensive genomic profiling for the Novartis Signature program, which rapidly matches patients to treatments that target their tumor's molecular alterations and brings the trial to the patient rather than the patient traveling to a trial site. We are also participating in the Lung Cancer Master Protocol (LUNG-MAP) trial, a genomically-driven clinical trial sponsored by a unique collaboration of various public and private entities. We believe our activities with leading drug development companies that are focused on cancer therapeutics further our relationships with the broader oncology community, including thought leaders who are important to the adoption of our commercial products.

### *Biopharmaceutical Services Agreement*

In November 2011, we entered into a laboratory master services agreement with Novartis pursuant to which we agreed to provide molecular information and genomic profiling analysis in support of Novartis' clinical oncology programs. Pursuant to the agreement, we were paid based on the number of tests we performed. The

## **Table of Contents**

original term of the agreement commenced in November 2011 and was set to expire in November 2014. In May 2012, we amended this agreement to extend the term through May 1, 2015 and to include certain guaranteed quarterly minimum payments by Novartis to us in return for our providing sufficient laboratory capacity to perform up to a maximum number of tests. We executed a second amendment to the agreement extending the term through at least September 2016. We will continue to provide sufficient laboratory capacity to perform our molecular diagnostic tests on patients from Novartis' clinical oncology trials in exchange for fixed quarterly minimum payments. We will also provide molecular information owned by us upon Novartis' request for an additional minimum quarterly payment. Novartis also has an option to extend the agreement for an additional two-year period. We may bill Novartis for any extra services performed if during each contract year Novartis provides excess samples such that the value of our services ultimately exceeds the payments already received under the quarterly schedule. The agreement also establishes a joint steering committee responsible for facilitating communication between the parties, overseeing collaboration, and periodically reviewing and setting overall goals and strategy for provision of our services to Novartis. Except for termination due to material breach of the agreement, Novartis is responsible for payments on services rendered through the termination date. The agreement also contains customary representations and warranties, indemnification, assignment, data privacy security measures and other provisions.

### **Market Opportunities for FoundationOne and FoundationOne Heme**

We believe that the ability of FoundationOne to comprehensively evaluate all solid tumors and FoundationOne Heme to comprehensively evaluate many hematologic malignancies, and the ability of our information platform to comprehensively match genomic alterations to relevant treatment options, will continue to serve as a valuable tool for a greater number of physicians. Aggregating and delivering complex molecular, medical and scientific information in a single report that can be understood and acted upon has become increasingly important, especially as a growing percentage of our test volume is driven by physicians in community-based practices rather than academic medical centers. Physicians in the community setting often see patients across a wide spectrum of cancer types, which can be particularly challenging as new data emerges that is specific to each cancer type. In 2013, approximately 30% of our test volume was driven by physicians in community practices, and in 2014, approximately 60% of our test volume was driven by community physicians. Approximately 80% of patients with cancer in the United States today are treated in community practice settings.

As we deploy our commercialization strategy, we continue to work with our growing network of oncology thought leaders to identify the subsets of patients with metastatic cancer for whom FoundationOne and FoundationOne Heme are most likely to positively inform treatment decisions. We are focused on driving awareness of the potential utility of our tests in these subsets of patients, defined as:

patients who had tested negative under the traditional hotspot tests for their tumor type, such as negative for alterations in the genes EGFR, ALK, and KRAS in non-small cell lung cancer;

patients for whom there was not enough available tissue to perform multiple hotspot molecular tests, such as patients with non-small cell lung cancer with very little tumor tissue left in archive;

patients for whom standard treatments had been tried and failed, such as patients with breast cancer who continue to progress despite multiple chemotherapy regimens;

patients with rare or uncommon tumors, such as certain sarcomas or non-colon/small-bowel gastrointestinal tumors, for whom no standard treatment approach exists; and

patients who had an aggressive disease, such as pancreatic cancer, or were late in the progression of their disease.

## **Table of Contents**

While these groups are not mutually exclusive, we estimate that annually in the United States there are approximately one million patients who suffer from the above-described or similar cancers and who would most benefit from FoundationOne testing, and another approximately one hundred thousand patients who would most benefit from FoundationOne Heme. These estimates are based upon a combination of feedback from our network of oncology thought leaders, data published by the National Cancer Institute in the *Cancer Statistics Review*, and focused market research that we commissioned.

As the number of available targeted therapies expands and as physicians gain further experience using comprehensive genomic profiling in their routine treatment decisions, we believe that the potential addressable market for comprehensive genomic profiling will expand over the next five years to include most patients who have metastatic disease, not only those patients limited to the challenging treatment categories noted above. These patients may include, for example, those who are earlier in the treatment cycle, those who suffer from a broader set of disease conditions or those patients diagnosed with rare and uncommon cancers regardless of stage. We estimate that this potential market expansion could include an additional 800,000 total patients for FoundationOne and a similar 80% percent increase in total patients for FoundationOne Heme annually based upon the same combination of sources of information we used to estimate the size of the patient population we are initially targeting. Although we expect existing and future diagnostic testing providers to also target these patient populations, we believe FoundationOne and FoundationOne Heme are currently the only commercially available comprehensive genomic profiles that comprehensively assesses cancer tissue simultaneously for all four classes of genomic alterations across all cancer-related genes with the sensitivity and specificity required for routine medical practice.

### **Commercialization Strategy**

We continue to drive awareness and adoption of our comprehensive molecular information products through our commercialization strategy to:

build an experienced, oncology-focused sales force in the United States;

build international distribution channels;

collaborate with oncology thought leaders, leading academic institutions, and community-based oncology networks on FoundationOne and FoundationOne Heme clinical cases, clinical research, publications, and product development;

drive broader adoption and increased ordering per physician by offering ongoing product innovation, new technology tools and features, easier access to clinically relevant information, and active medical affairs and client services teams to build new and ongoing client relationships;

publish important medical and scientific data in peer-reviewed journals and present at major industry conferences, and conduct clinical trials;

work with patient advocacy groups and medical societies to drive awareness of FoundationOne and FoundationOne Heme and the importance of incorporating molecular diagnostics into cancer treatment; and

facilitate broader access to care through our partnership with EmergingMed, FoundationOne Careline and our technology tools.

## **Table of Contents**

Through these efforts, we are driving awareness of the unique capabilities of our comprehensive genomic profiling products throughout the oncology community from patients suffering from cancer, to the physicians treating them, to the third-party payors for these treatments and to biopharmaceutical companies developing new treatments all with the goal of facilitating better-informed treatment decisions for the greatest number of patients with cancer. We believe that by driving physician and patient demand for FoundationOne and FoundationOne Heme, and by being part of improving patient outcomes, we will continue to increase utilization of our products and obtain favorable reimbursement decisions by third-party payors.

### ***Building an Experienced, Oncology-Focused Sales Force***

#### *United States*

Our sales force in the United States works with oncologists and pathologists at hospitals and cancer centers in both the community and academic settings. We launched FoundationOne in June 2012 with a sales force of only two people that has now grown to 48 professionals as of December 31, 2014. These sales professionals have an average of 10 years of experience in clinical oncology and pathology sales working at leading biopharmaceutical or specialty reference laboratory companies. We will continue to grow this specialized, oncology-focused sales force and support it with medical specialists who bring extensive knowledge in the design and use of molecular information products.

Our current sales efforts focus on building relationships with thought leaders at leading academic research institutions, pathologists and physicians in community practice settings, and leading physician networks to demonstrate the clinical usefulness of FoundationOne and FoundationOne Heme. We continue to optimize our partnership with ION Solutions, a diversified physician services organization whose membership represents more than half of the private practice oncologists in the United States. In 2014, we were selected as ION's preferred partner for comprehensive genomic profiling services, and over the past twelve months we have experienced significant volume growth within the various ION practices. Other oncology networks, such as Cancer Treatment Centers of America, have chosen to use FoundationOne and FoundationOne Heme. In addition, we are also focusing on developing relationships with pathologists so that we can better serve the pathology community by providing value-added molecular information products and technology and integration services. As we continue to grow our sales force and streamline ordering, data collection, and clinical trial enrollment, we will increasingly have the capacity to target community hospitals and community-based cancer centers that we believe require a reliable and collaborative partner for molecular information solutions.

We believe that our proposed U.S. Education Collaboration Agreement (as described in detail in our other public filings and below in the section entitled "Proposed Strategic Collaboration with Roche, " ) with Genentech, Inc., a wholly owned subsidiary of Roche, or Genentech, will drive awareness of comprehensive genomic profiling and thereby supplement the education provided today by our field sales team. Genentech will develop unbranded education materials related to next generation sequencing, or NGS, and comprehensive genomic profiling, and provide materials and related education to clinicians and hospitals. We believe this effort will have a meaningful impact on awareness and adoption of comprehensive genomic profiling, especially among pathologists and in community-based practices.

#### *International*

Our international sales strategy has been focused on partnering with leading distributors, including distributors in Israel, Spain, Portugal and Hong Kong, and building our direct selling efforts in countries such as Brazil. We anticipate pursuing additional markets based upon the demand from those markets, the ability to access those markets, and the regulatory and reimbursement environment of those markets.



## **Table of Contents**

We believe that our proposed Ex-U.S. Commercial Agreement with Roche will accelerate our access to global markets. Roche will have the right to commercialize FoundationOne and FoundationOne Heme, as well as other products that are jointly developed with us, in all countries outside of the United States. Roche has significant experience, expertise, and local market knowledge across many regions around the world, and we believe they are uniquely positioned to understand local market dynamics, payor systems, and regulatory systems. Upon consummation of the agreement, there will be a one year planning period during which we will work together with Roche to identify an initial set of countries in which to work. Important additional details about this agreement are described below in the section entitled **Proposed Strategic Collaboration with Roche** and in our other public filings.

### ***Collaborating with Thought Leaders to Shape the New Cancer Treatment Paradigm***

We believe physicians look to peers and key thought leaders in the medical community when evaluating a new technology. Oncology thought leaders have historically been early adopters of new technologies because they have greater access to new therapies, clinical trials, and diagnostic tools than many community oncologists. Since our inception, our founders, medical affairs group, senior management, and now sales personnel and reimbursement teams have leveraged existing and built new relationships with these early adopters.

Key opinion leaders, or KOLs, and leading cancer researchers have embraced our comprehensive molecular information approach, including oncologists at premier cancer institutions such as MSKCC, Vanderbilt-Ingram Cancer Center, and the Taussig Cancer Institute at the Cleveland Clinic. In addition to routinely using FoundationOne for clinical cases, these individuals and institutions collaborate with us on clinical studies, peer-reviewed publications, and medical and scientific conference presentations. We believe our relationships with KOLs help validate our platform, drive adoption of our clinical products in community oncology settings and international markets, establish our leadership position in the field of molecular information about cancer and thereby further our ultimate goal to facilitate better-informed treatment decisions for the greatest number of patients with cancer.

Our relationships with KOLs in oncology have been instrumental in driving the early adoption of FoundationOne and FoundationOne Heme. We believe initial awareness of FoundationOne within the community oncology setting was largely driven by our publications and presentations with KOLs and the resulting peer-to-peer interaction they generated. We will continue to nurture these relationships with thought leaders as we drive adoption of FoundationOne and FoundationOne Heme, and as we develop new products.

### ***Promoting Physician Interaction and Creating a Network Effect***

We believe that if we can continue to integrate the results of our products into the everyday clinical practice of oncologists, we will become an even more important partner in their efforts to treat patients with cancer. Our goal is for physicians to use the latest version of our Interactive Cancer Explorer, ICE 2, in the context of their busy clinical practices, to shape each patient's treatment plan. Through ICE 2, we deliver the key genomic information identified by FoundationOne and FoundationOne Heme in an organized fashion along with access to current information about the reported genomic alterations, associated therapies, and clinical trials. ICE 2 presents complex genomic information in what was designed as a practice-friendly interface that links directly into publicly available databases, such as PubMed and clinicaltrials.gov. The portal also provides direct links or references to journal articles and clinical trials information relevant to a patient's identified genomic alterations. Over time, we intend for ICE 2 to link to additional public and private data sources as we continue to rationalize, correlate, and incorporate disparate sources of information into our products. By making this information more readily accessible to physicians, we aim to make it easier for them to bring new, relevant information to each patient's treatment plan.

## **Table of Contents**

An important new component of ICE 2 is PatientMatch, a technology tool that leverages the experience of more than 35,000 genomic profiles already in FoundationCORE to increase the utility of FoundationOne and FoundationOne Heme results. Using PatientMatch, physicians within the ICE 2 network are able to connect with other physicians treating patients with similar disease profiles (tumor type and genomic alteration(s)) and share treatment and outcome information in a HIPAA-compliant manner. ICE 2 also has a number of important efficiency-improving features to help physicians care for their patients, including the ability to track samples through our pipeline before we have reported the results and in-application notifications. Another new feature in ICE 2 is advanced search, which allows physicians to search across all of their patients by gene, alteration, and tumor type. Practice administrators and researchers can use this same capability to query patients across their entire institution. We believe ICE 2 and PatientMatch will be important tools to support and accelerate the broad adoption of our products, build client relationships, and create an important network effect among users. We believe the better we can integrate our solutions into a physician's routine clinical practice, the more likely a physician is to order our products.

### ***Supporting Adoption through Publications and Clinical Trials***

We believe the successful completion of multiple clinical trials, our publication of scientific and medical results in peer-reviewed journals, and presentations at leading conferences are critical to the broad adoption of products enabled by our proprietary platform. Our publications and presentations to date have helped communicate our capabilities and the clinical results that early adopters of our platform have achieved. We will continue to use these channels to drive commercial adoption of FoundationOne and FoundationOne Heme and obtain favorable reimbursement decisions.

Since the beginning of 2012, we have had:

59 peer-reviewed articles published or accepted for publication, including by *Nature Medicine*, *Nature Biotechnology*, *Clinical Cancer Research*, *Cancer Discovery*, *Cancer Research*, *Clinical Breast Cancer*, *Hematology & Oncology*, *American Journal of Surgical Pathology*, *Journal of Clinical Oncology*, *Journal of Thoracic Oncology*, *Blood*, and *Genome Medicine*;

over 100 poster presentations based on clinical and research data that have been accepted and presented at major scientific conferences on themes that include the identification of multiple novel actionable drug targets, known drug targets in novel tumor types, novel resistance mechanisms to targeted therapies, new insights into models of metastasis, and novel hypotheses on the molecular basis of response or resistance to certain targeted therapies; and

more than 50 speaking presentations at scientific meetings such as ASCO, American Association of Cancer Research (AACR), San Antonio Breast Cancer Symposium, US and Canadian Association of Pathology (USCAP), Advances in Genome Biology and Technology (AGBT), and ASH, among others.

We have a number of Company-sponsored clinical trials and clinical trials sponsored by individual physicians, or investigator-initiated clinical trials, underway or completed, such as:

***The US Oncology Decision Impact Study.*** This study was designed to assess the impact of FoundationOne on physician decision-making in a real world setting. FoundationOne will be performed on solid tumors from 300 patients during their second or later line of therapy. When the patient progresses, the impact of FoundationOne in switching a physician's recommended next course of treatment will be evaluated. Other endpoints may be evaluated as well. Interim data from the study, which was presented at ASCO's annual meeting in June 2014, demonstrated that FoundationOne testing resulted in an altered therapeutic choice in 28 percent of advanced solid tumor patients.

***The FoundationOne Registry.*** The objective of this study is to better understand the impact of FoundationOne on a clinical population including, importantly, how physicians act on the results and how the results impact care and outcomes. The study was designed to recruit up to 3,000 patients over



## **Table of Contents**

three years, with the initial 500 patients drawn from all patients for whom the FoundationOne test is ordered. A wide array of clinical variables will be assessed, including subsequent treatments and responses to those treatments. These patients may be followed for one year. The later cohorts of patients will be adaptive, with entry criteria to be determined based on initial outcomes of the study. Enrollment of the initial 500 patient study was completed in July 2014. We have submitted data from the predefined interim analysis of baseline observations from this study for potential presentation at ASCO's annual meeting in June 2015.

***The MD Anderson Prospective Study.*** This study aims to compare the clinical outcomes of patients who are treated with targeted therapy after testing with FoundationOne compared to historical outcomes for patients treated with chemotherapy. The study was designed to enroll a group of 300 patients with advanced solid tumors who were to be screened at enrollment with FoundationOne. These patients may then be treated with a targeted therapy selected on the basis of the FoundationOne report. The clinical outcomes for these patients will be compared to recent historical results for patients who received treatment with conventional chemotherapy for the same tumor types and stage. We have submitted an abstract describing the initial findings from this study for potential presentation at ASCO's annual meeting in June 2015.

***The MD Anderson Randomized Phase III Trial.*** This study aims to compare the progression free survival of individuals who receive a targeted matched therapy based on FoundationOne testing versus those who receive an empiric therapy without knowledge of the FoundationOne results.

***Our Study with MSKCC on FoundationOne Heme.*** In this study, MSKCC and our researchers used FoundationOne Heme to analyze routine cancer specimens from 746 patients with a range of hematologic malignancies, including leukemia, lymphoma and myeloma. The data from the study, which was presented at ASH's annual meeting in December 2014, demonstrated the feasibility of comprehensive genomic profiling in patients with hematologic malignancies. FoundationOne Heme was shown to enable the identification of genomic alterations that are molecular drivers of the observed patients' cancers which may help to expand and inform treatment options for individual patients, advance the development of new therapies against these targets, and ultimately improve patient outcomes. In addition, robust analytic validity was demonstrated.

### ***Engaging With Patient Advocacy Groups and Other Important Stakeholders to Drive Awareness***

We have established relationships with many patient advocacy groups to drive awareness of our test and to educate the advocacy community and other key stakeholders, including major medical societies and networks, about the shifting oncology paradigm towards precision medicine.

Patient advocates are important stakeholders in the cancer community because they have influence within the patient community and with health care providers, KOLs, and policy makers. We established our advocacy relations program with the following goals:

- develop awareness around genomic testing;

- position us as a patient-centered company within the patient community by creating goodwill and becoming a trustworthy corporate partner;

- effectively shape the dialogue around cancer genomics with key constituents; and

- work with advocates to help increase genomics conversation and drive the use of molecular information testing.

To date, we have been successful in establishing key relationships to help educate advocates about us and our capabilities in oncology. Some of the organizations we engage with include Friends of Cancer Research, Patient Advocate Foundation, Clearity Foundation, American Cancer Society Cancer Action Network, Lung



## **Table of Contents**

Cancer Foundation of America, Bonnie J. Addario Lung Cancer Foundation, Uniting Against Lung Cancer, Pancreatic Cancer Action Network, and many others. In 2014, we continued to engage representatives from several patient advocacy organizations, establishing our commitment to understanding patients' needs and positioning us as a neutral facilitator of oncology stakeholders, with important insight and relationships across industry, advocacy, and regulatory bodies. Through these activities to date, we have developed the basis for a meaningful advocacy relations program, with opportunities to more strategically engage advocates moving forward. During 2014, we worked with 16 lung cancer advocacy groups in a campaign called "Don't Guess. Test." to raise awareness about comprehensive genomic profiling for patients with lung cancer. We expect to continue similar efforts in 2015 and beyond.

Our relationships with other influential organizations that shape the delivery of care are also critical as we work to develop and educate the market. We currently work with and aim to work with many organizations, including the National Comprehensive Cancer Network, ASCO, USCAP, CAP and others regarding the role of NGS and broader molecular profiling in the evaluation of patients and their tumors. We are working with these organizations both on potential educational initiatives as well as the evolution of guidelines, which today are very much tumor-type specific, to recognize the growing importance of the molecular characterization of the collection of diseases known as cancer.

### ***Enabling Broader Access to Care***

Adoption of comprehensive genomic profiling by academic and community-based oncologists supports the clinical utility required to improve health outcomes and quality of life for select groups of patients that can benefit from targeted therapy treatment. However, it can sometimes be difficult for patients and their physicians to gain access to these potentially life-saving treatments. We are focusing on three primary areas to increase this access, which we believe will also facilitate the actionability of FoundationOne and FoundationOne Heme.

The first is our partnership with EmergingMed, where we are offering personalized clinical trial navigation services to help health care providers and their patients who have received our tests to identify and access appropriate clinical trials based on their specific genomic profiles and clinical characteristics. We believe these services will increase physicians' ability to act on comprehensive genomic profiling results and more frequently consider clinical trial enrollment while making treatment decisions. Likewise, through FoundationOne Careline, our partnership with Patient Advocate Foundation (PAF), we are providing personalized case management services to patients who are uninsured, underinsured or insured, but who are facing obstacles obtaining prescribed targeted therapies that are approved in an indication other than their tumor type. We help these patients navigate appropriate channels to secure treatments by leveraging peer-reviewed literature supporting their use, as well as the reimbursement system to help cover treatment costs and the costs associated with our tests. We believe this will increase physicians' ability to act on our test results. Finally, through our ICE 2 and PatientMatch tools, we are helping to facilitate treatment decisions by connecting physicians with their peers who have seen patients with similar genomic profiles in order to learn about their peers' treatment decisions and related outcomes. All three of these areas of focus provide tangible steps our clinical partners can take to enhance the actionability of FoundationOne and FoundationOne Heme results.

### ***Payment and Reimbursement for Our Molecular Information Products***

The principal groups that currently pay us, or that we expect to pay us in the future, for our molecular information products include:

our biopharmaceutical customers, with whom we have individual agreements;

certain hospitals, cancer centers, and other institutions that pay us directly at negotiated rates for their physicians' test orders;

international patients and distributors who pay us directly at agreed-upon prices;

---

## **Table of Contents**

commercial third-party payors who currently pay us based on Current Procedural Terminology, or CPT®, codes;

government payors, including Medicare, to whom we have been submitting claims, and state Medicaid plans; and

patients who make self-payments, or co-payment, co-insurance or deductible payments and other amounts that we have been unable to collect from their third-party payors.

We believe that our products present unique solutions for commercial third-party payors and government payors who are faced with an increasingly complex and dynamic cancer diagnostic and treatment environment. These complexities include a growing number of single-marker and hotspot panel tests, the increasing number and cost burden of targeted oncology therapies, and an underlying shift in physicians' treatment of cancer that is based on molecular pathways rather than tumor location. In addition, this shifting treatment paradigm comes at a time when commercial third-party payors and government payors are increasingly making significant efforts to contain healthcare costs. We believe the use of FoundationOne and FoundationOne Heme aligns with payors' goals to improve the safety, efficacy, and affordability of cancer diagnosis and treatment.

Adequate reimbursement is an important factor in achieving broad clinical adoption of FoundationOne and FoundationOne Heme. At the same time, we believe broad clinical adoption will help drive favorable reimbursement decisions. To achieve broad reimbursement coverage with commercial third-party and government payors, including Medicare and Medicaid, we are focused on demonstrating the economic and clinical value of FoundationOne and FoundationOne Heme to payors by:

**Setting a High Bar for Validation and Performance.** Our products provide clinically relevant results that are highly reproducible and sensitive, and we believe that a majority of our relevant findings would not be detected by many other commercial tests on the market today. Patients may benefit from our detection of otherwise unknown genomic alterations that can lead to their physicians choosing alternate therapies. We have presented data on the reproducibility, sensitivity, specificity, and comprehensive scope of FoundationOne and FoundationOne Heme at numerous conferences and in peer-reviewed journals. In October 2013, the analytic validation results of our studies on FoundationOne were published in *Nature Biotechnology*. In 2014, we received approval from the New York State Department of Health for FoundationOne and FoundationOne Heme, which represents a high standard for quality in large-scale, multi-gene sequencing-based testing in cancer. Also in 2014, Palmetto GBA, or Palmetto, an influential Medicare Administrative Contractor, or MAC, published validation guidelines for NGS tests. In early 2015, Palmetto then published a draft local coverage determination, or LCD, that outlines the rigorous validation requirements for coverage and reimbursement of comprehensive genomic profiles in certain forms of cancer, and we believe our products meet those validation criteria.

**Increasing Physician Demand.** Several thousand physicians from large academic centers and community-based practices have ordered FoundationOne or FoundationOne Heme since their respective formal commercial launches in June 2012 and December 2013. The expansion of our sales force is driving accelerated volume growth by expanding and strengthening customer relationships with academic and community-based oncologists. We believe that this adoption, including significant repeat usage, demonstrates growing physician demand for a single, comprehensive solution to help in the treatment of their patients. In addition, we believe that increasing adoption and consistent utilization of our products and their impact on improving outcomes for patients with cancer will lead to favorable reimbursement decisions.

**Engaging Key Members of the Oncology Community.** We will continue to work with oncology thought leaders, professional societies, patient advocacy groups, and cancer networks. We believe these relationships help validate our platform, drive adoption of our products in the broad community oncology setting and establish our leadership position in the field of molecular information about

## Table of Contents

cancer. In addition, we believe adoption of our products by key members of the oncology community will help to influence the inclusion of FoundationOne and FoundationOne Heme in practice guidelines as well as coverage decisions by commercial third-party payors and government payors.

**Publishing in Peer-Reviewed Publications.** We seek to publish in scientific and medical journals such as *Nature Medicine*, *Nature Biotechnology*, *Journal of Thoracic Oncology*, *Cancer Discovery*, *Clinical Cancer Research*, *Blood*, *Hematology & Oncology*, and others. Our publications have covered novel scientific findings, clinical utility of test results, individual patient outcomes, and common traits of genomic alterations in primary and metastatic tumors, among many others. We believe that our approach, which we have designed to be rigorous and data-driven, is important in establishing requisite evidence of our analytical validity, clinical validity, and clinical utility with payors.

**Demonstrating Clinical Utility.** To demonstrate the impact of FoundationOne and FoundationOne Heme on physician treatment decisions and patient outcomes, we have conducted and will continue to conduct a number of clinical studies with organizations such as US Oncology, MD Anderson Cancer Center, MSKCC, and other leading academic and community-based medical centers. We are also enrolling patients into a registry through which we will track changes in physician treatment patterns as well as longitudinal patient outcome data.

**Improving Health Economics.** We have built economic models to measure the financial benefits of using our products in guiding patient treatment by selecting targeted therapies for each patient and for minimizing the use of drugs that will not likely have a positive impact. Additionally, we intend to launch several health economics studies in real-world clinical settings in 2015. We plan to use the data we gather through the use of these models and studies as we meet with commercial third-party payors and government payors.

We are initially focused on obtaining reimbursement coverage from third-party payors for patients in six specific clinical indications, including (1) patients with newly-diagnosed stage IV non-small cell lung cancer, (2) patients with newly-diagnosed cancer of unknown origin or unknown primary anatomic site, (3) patients with newly-diagnosed stage IV rare or uncommon solid tumors for whom very limited or no systemic treatment options exist in clinical care guidelines or pathways, (4) patients with newly-diagnosed stage IV solid tumors who have received limited to no benefit from standard chemotherapy and whose tumors typically include a high prevalence of clinically relevant genomic alterations, (5) patients with solid tumors whose available biopsy sample proves insufficient for traditional molecular diagnostic testing, and (6) patients with stage IV solid tumors who have exhausted the established guideline driven systemic therapy or therapies but who maintain adequate functional status as deemed by their treating physician. After obtaining reimbursement coverage for one or more of these six initial clinical indications, we may seek broader coverage for additional indications.

In October 2014, we announced a formal agreement with Priority Health, a regional commercial third-party payor in Michigan, for broad coverage of FoundationOne and FoundationOne Heme. We believe this was an important initial coverage agreement given that it includes both of our products and covers five of the six initial clinical indications noted above for FoundationOne.

In January 2015, a draft LCD was published by Palmetto and includes proposed reimbursement for comprehensive genomic profiles for highly validated testing in an initial subset of patients diagnosed with non-small cell lung cancer. We believe this is an important first step towards broader coverage, and we believe Palmetto is considered a key thought leader among the other MACs. We will continue to work with our regional MAC, National Government Services, to pursue similar progress within our own Medicare jurisdiction. The Priority Health agreement and the Palmetto LCD are important initial milestones that we believe can lay the groundwork for broader commercial third-party and government payor coverage of FoundationOne and FoundationOne Heme.



---

## **Table of Contents**

We believe there was no direct precedent for reimbursement of our tests by commercial third-party payors and government payors prior to coverage by Priority Health. In addition, the reimbursement environment is evolving as regulators and payors try to establish new rules and frameworks for the reimbursement of molecular diagnostic tests. Our continued ability to participate in the development and implementation of those rules and frameworks is important in order to differentiate between our products and others in the marketplace.

The current list price for the FoundationOne test is \$5,800, and the current list price for the FoundationOne Heme test is \$7,200. Payment for the tests is not certain and may come from various sources. Actual payment will often be less than the list prices. Sources of current or potential payment include: (1) commercial third-party payors, such as health insurance or managed care plans; (2) government health benefit programs such as Medicare and Medicaid; (3) other healthcare providers, such as hospitals, accountable care organizations, or ACOs, cancer centers and other institutions; (4) international distributors; and (5) individual patients.

Currently we are not a participating provider with any commercial third-party payor other than Priority Health, and, therefore do not have specific coverage decisions for FoundationOne or FoundationOne Heme with established payment rates for all other commercial third-party payor claims. Currently, commercial third-party payors reimburse our claims based upon stacked CPT codes, the predominant methodology, or based on other methods such as percentages of charges or other formulas that are not made known to us. In addition, a small portion of payors outsource our claims to preferred provider organizations or third-party administrators, who process our claims and pay us directly at negotiated rates. Coverage and payment is determined by the third-party payor on a case-by-case basis.

We are not currently a participating provider in any state Medicaid program and therefore do not have coverage decisions under which our tests are covered by these Medicaid programs. We are a participating provider in the Medicare program, but, as described below, currently no specific Medicare national or finalized local coverage determinations for FoundationOne or FoundationOne Heme with established payment rates have been issued.

We do have agreements in place with various healthcare providers and with international distributors pursuant to which we process FoundationOne and FoundationOne Heme tests on specimens submitted, and the providers or distributors pay us for the test results based on negotiated rates. Those rates vary but are less than our list prices. We may also negotiate rates with individual patients, if the patient is responsible for payment.

We submit claims for FoundationOne and FoundationOne Heme to commercial third-party payors using CPT codes for molecular testing services. We receive payments on some, but not all, of our claims submitted. In 2014, new CPT codes were approved by the American Medical Association, or AMA, that are intended to classify with greater specificity those molecular tests that rely on NGS and evaluate multiple genes at once. These new CPT Codes became effective on January 1, 2015. We do not believe that these new CPT codes describe our tests since they do not appropriately differentiate our comprehensive genomic profiles from other hotspot multi-gene molecular tests. Therefore, unless payors specifically request use of these new CPT codes, we intend to continue submitting claims for our tests utilizing methodologies that we believe are more effective under the circumstances, including stacked CPT codes, McKesson Z-Codes (as described below) and other potential approaches.

Since we are not currently a participating provider with commercial third-party payors, with the exception of Priority Health, and we have not received a coverage decision from any other commercial third-party payor, payment for our test remains largely uncertain. We request that physicians discuss with their patients the potential responsibility of the patient for the cost of our products should the patient's insurance policy not cover those costs. We undertake the primary responsibility for obtaining third-party reimbursement on behalf of patients, including appeals for any initial denials, prior to billing a patient. With this practice established, we believe that most patients receiving our tests know that they may be responsible for some portion of the cost of the test should their third-party payor deny or limit coverage. We also offer a comprehensive patient assistance

## **Table of Contents**

program to support patients whose incomes are below certain thresholds and to allow for extended payment terms, as necessary, given the patient's economic situation.

We are enrolled in the Medicare program in order to bill Medicare for FoundationOne and FoundationOne Heme tests performed for the benefit of Medicare patients. There is currently no national coverage determination in effect or under consideration to our knowledge that provides for or contemplates a consideration for coverage of our tests by Medicare. In the absence of national coverage determinations for our tests, MACs have some discretion in determining coverage, and, therefore, payment for our tests using an LCD process. When FoundationOne was launched in 2012, our then-current MAC requested that we not submit claims for services provided to Medicare patients to allow our MAC time to assess the appropriate coding, coverage and payment for FoundationOne. To accommodate this request, we deferred the submission of claims until November 2013, when we initiated the process of submitting claims to National Government Services, for FoundationOne for Medicare patients with dates of service on or after November 1, 2013. We began submitting claims to National Government Services for FoundationOne Heme in December 2013 immediately upon launch of the product.

The claims submitted to National Government Services use a miscellaneous CPT code. When submitting claims for services or procedures that do not have specific CPT codes, providers may submit those claims using a code, referred to as the miscellaneous code, to provide the means of reporting and tracking services and procedures until a more specific code is established. We have not yet received any payments from Medicare for the claims that have been submitted with that miscellaneous code. The claims submitted to National Government Services may be denied or paid, in whole or in part. If a claim is denied or paid in part, we may decide to appeal the denied claim or any denied portion of the claim. National Government Services may also issue a non-coverage determination for one or both of FoundationOne or FoundationOne Heme that would apply to future claims, or National Government Services may defer processing or paying a claim pending the issuance of a coverage determination for one or both of FoundationOne and FoundationOne Heme. Once a coverage determination is made, we will have the opportunity to submit additional materials to National Government Services in support of an adjustment to such determination, if needed.

Given the multiple potential outcomes that could result from the submission of our claims to National Government Services, we may determine to provide appropriate advance notices to patients covered by Medicare to enable us to bill a Medicare patient for all or part of a claim that is denied coverage by National Government Services. Based on the response of National Government Services to our submitted claims, we will also assess our ability to submit claims to Medicare, or bill Medicare patients, for previously reported tests. If we submit claims for these tests, and if Medicare denies coverage for these previously reported tests, our ability to bill Medicare patients for such tests will be limited.

To assist payors in making reimbursement and coverage decisions, the McKesson Diagnostics Exchange, or McKesson DEX, has been created. Tests that are registered with McKesson DEX are assigned, based on the uniqueness of each test, a five-digit alphanumeric McKesson Z-Code identifier, or Z-Code. These identifiers are intended to enable the consistent identification of tests across systems by laboratories, providers, and payors. Because we believe the current CPT codes associated with our tests do not adequately address the comprehensive and precise characteristics of FoundationOne and FoundationOne Heme, we have established unique Z-Codes for FoundationOne and FoundationOne Heme.

Palmetto, which currently plays a leading role in discussions about coverage determinations for complex molecular tests, has established the Molecular Diagnostic Services program, or MolDX, which is currently used to help determine coverage and payment for Medicare in 17 states. Z-Codes have been adopted by Palmetto as part of MolDX. While Massachusetts is not one of the 17 states, MolDX is expected by many to be adopted broadly by other MACs and commercial payors, including potentially National Government Services.

The AMA is responsible for establishing CPT codes. In 2013 the AMA began working with McKesson DEX to map Z-Codes to CPT code sets in a project known as CPT CodeBridge. We expect the map between

## **Table of Contents**

CPT code sets and Z-Codes to facilitate coverage and payment decisions by payors, but the CPT CodeBridge project is still in process, and it is unclear how this project will impact payors or the reimbursement of our tests.

### **Investing in Ongoing and New Product Innovations**

We were founded as a scientifically and medically driven company and are dedicated to ongoing innovation in our molecular information platform and commercial product pipeline. We have invested, and will continue to invest, significant time and resources into the improvement of our platform and the development and introduction of new products. We are focused on new clinical products and on new technologies and features that will increase the actionability, connectivity and utilization of our clinical products.

We believe we have a first mover advantage in offering comprehensive genomic profiling products that interrogate with precision the genes known to be altered in human cancer. Since our formal commercial launch of FoundationOne in June 2012, we have continued to invest in its improvement, including periodic updates to increase the number of relevant cancer-related genes, decrease tissue size requirements, increase sensitivity and improve turn-around time. We have also incorporated RNA-based sequencing technology into FoundationOne Heme to identify additional gene fusions commonly found in hematologic malignancies and sarcomas.

We endeavor to stay at the cutting edge of molecular information and genomic testing and to maintain our advantages by continuously exploring and developing new clinically relevant approaches to improving cancer care. Our ongoing research and technology development efforts to advance our product pipeline and expand the impact of molecular information for improving cancer care include:

developing new products to evaluate and monitor cancer progression over time, including products that enable validated testing of circulating tumor cells and circulating tumor DNA;

building and validating our quality system regulation (QSR) laboratory to pursue our companion diagnostics and FDA-regulated products strategy;

enhancing our understanding of markers of response to targeted therapies and immunotherapies, and researching immuno-diagnostic assays;

enhancing our Interactive Cancer Explorer and developing networking tools such as PatientMatch; and

creating advanced search capabilities within FoundationCORE and across the public domain to enhance the utility and value of our aggregated datasets.

#### ***Interactive Cancer Explorer and Patient Match***

Our online Interactive Cancer Explorer, the latest release of which is ICE 2, allows physicians to access the key genomic information identified by FoundationOne and FoundationOne Heme along with current information about the reported genomic alterations, associated therapies, and clinical trials. Interactive Cancer Explorer presents complex genomic information in what was designed as a practice-friendly interface that links directly into publicly available databases, such as PubMed and clinicaltrials.gov, to provide additional information relevant to a patient's identified genomic alterations.

ICE 2, launched in December 2014, includes a new feature called PatientMatch, which is a tool that leverages more than 35,000 genomic profiles already stored in the FoundationCORE knowledgebase. Using PatientMatch, physicians within our network are able to connect with other physicians treating patients with similar genomic profiles to share treatment and outcome information in a HIPAA-compliant manner. We believe ICE 2 and PatientMatch are important tools to support and accelerate the broad adoption of our products, and to create an important network effect among users. We anticipate building additional features in ICE 2 to continue to improve efficiency of patient care and the actionability of our tests, including smart clinical trials matching,



## **Table of Contents**

online ordering, genomic dashboards, and integration with FoundationOne Careline and our clinical trial matching service collaboration with EmergingMed.

### ***FoundationCORE***

The increasing availability and understanding of molecular information about cancer is driving a revolution in treating the entire class of diseases. FoundationCORE is our knowledgebase that includes genomic data, medical and scientific literature, clinical trial information, and a small but growing amount of clinical outcome information. We believe that FoundationCORE, which is driven by our molecular information platform, positions us at the nucleus of this new treatment paradigm in cancer care.

Some of our biopharmaceutical partners currently utilize FoundationCORE to further refine their clinical trial design and drug discovery and development activities. For example, they use this data to better understand the prevalence of certain genomic alterations, or combinations thereof, across various cancer types or patient profiles. FoundationCORE will now power ICE 2 and PatientMatch, so that oncologists in clinical practice can utilize this aggregated data set to collaborate and share treatment choices, response rates and other clinical information in a HIPAA-compliant manner. Over time, we plan to expand our capacity to capture, aggregate, analyze, and facilitate the broader exchange of genomic data across the global oncology community. Examples of such initiatives include our collaborations with Flatiron Health and COTA, each of which is anticipated to yield broader clinical datasets that will reside in FoundationCORE. We believe ICE 2 will eventually create a network effect as more data is shared among physicians, thereby driving further utilization and ultimately leading to a larger and more impactful dataset.

We believe that our molecular information platform will continue to add to the collective knowledgebase of cancer biology and clinical practice and potentially contribute to advancements in the treatment of cancer by:

creating additional utility for our physician customers by delivering new potentially actionable information through Interactive Cancer Explorer;

informing data driven patient care decisions;

providing molecular epidemiology for novel and known targets for target validation;

identifying known drug targets in novel tumor types;

identifying novel resistance mechanisms to targeted therapy;

discovering new insights into models of metastasis;

illuminating new cancer targets, including determining the role of genomic variants of previously unknown significance;

enabling combination therapy; and

enhancing clinical trial design.

We expect the importance of our molecular information strategy will increase with the number of our patient cases and as we augment FoundationCORE with clinical data. If we, in conjunction with our partners, oncologists, pathologists, biopharmaceutical companies, and

## Edgar Filing: Foundation Medicine, Inc. - Form 10-K

academic researchers, can successfully capture and utilize this data, we believe we can continue to play an even more integral role in transforming care for the millions of patients suffering from cancer.

## **Table of Contents**

### **Operations**

#### ***Composition of FoundationOne and FoundationOne Heme Analyses***

We currently perform all of our tests in our diagnostic laboratory located in Cambridge, Massachusetts. When a physician orders FoundationOne or FoundationOne Heme, he or she does not need to alter the standard surgical technique or tissue handling processes. The physician's staff typically completes an order form (either by hand, electronically, or via electronic medical records technology), packages the specimen in a kit we provide and then ships the kit via overnight carrier. Once we receive the specimen at our laboratory and enter all pertinent information about the specimen into our clinical laboratory information management system, we prepare the specimen for testing. Each FoundationOne and FoundationOne Heme analysis consists of three parts: specimen preparation, sequencing, and data analysis.

#### ***Specimen Preparation***

For FoundationOne, where samples are submitted as FFPE blocks or slides, our first step is pathology review, in which we assess the quality of the tissue sample to determine if it is suitable for testing using FoundationOne. We are able to process samples for testing using a very small amount of DNA. In general, the sample must be at least 40 microns in thickness and consist of at least 20% tumor cells. Almost all samples meeting our tissue requirements will allow extraction of enough high-quality DNA (50 nanograms) for FoundationOne for solid tumor analysis.

For FoundationOne Heme samples submitted as FFPE blocks or slides, the process and requirements are exactly as outlined for FoundationOne above except that we extract both RNA and DNA. For FoundationOne Heme samples received in this manner, we require 500 nanograms of RNA in addition to the 50 nanograms of DNA. For FoundationOne Heme samples submitted as liquids, such as blood or bone marrow aspirates, it may not be possible to measure the percentage of tumor content and thus samples proceed directly to extraction where we require 300 nanograms of RNA as well as the 50 nanograms of DNA because the quality of the extracted RNA is higher than from FFPE tissue.

Following FoundationOne test ordering, pathology review and DNA extraction, the extracted DNA is broken down into small fragments which we then manipulate using standard and molecular biology techniques, some of which represent our trade secrets and know-how, to create a complex mixture of DNA molecules. We then separate DNA fragments from the relevant cancer genes through our proprietary hybrid capture process. After hybrid capture, we are ready to interrogate the DNA content to determine where the critical genomic alterations exist.

The DNA component of the FoundationOne Heme test is identical to FoundationOne described above, but the RNA component has an additional step where the RNA must first be converted into cDNA. Once in this state, the RNA component of the FoundationOne Heme test progresses side by side with the DNA component.

#### ***Sequencing***

The content of each DNA or cDNA molecule is determined using a process called sequencing in which sequences of DNA molecules, or nucleotides, are identified in every position of every molecule. NGS involves the massively parallel sequencing of DNA or RNA isolated from human cells that, in the context of cancer, can be applied to genes throughout the entire cancer genome. FoundationOne and FoundationOne Heme are able to detect genomic alterations that may be present in as low as 1% of all cells being tested. We have made substantial modifications to our process in order to maximize throughput, efficiency and quality based upon the NGS technology we currently use that is supplied by Illumina, Inc., or Illumina.

## **Table of Contents**

### *Data Analysis*

At the end of the sequencing process, we have identified the sequence of every DNA molecule in the mix, and that data is entered into a sophisticated series of our proprietary computational algorithms designed to detect and identify all genomic alterations present in the cancer sample.

The first analysis looks at the quality of every sequence and discards anything below a certain quality threshold. The next step involves a careful alignment of every DNA sequence with a known reference sequence. We have validated our algorithms that perform this alignment by running tens of thousands of samples through the process. Once all DNA sequences are aligned against the reference, specific algorithms search for differences between the sequenced DNA and the reference. These differences represent potential genomic alterations.

Not all of the genomic alterations that are detected are responsible for driving the cancer; therefore, we further distill the alterations to a point where we have a list of only those alterations that are cancer drivers and where there is a therapy, FDA-approved drug, or available clinical trial for which the patient is eligible based on the genomic characteristics of his or her sample. A qualified computational biologist further scrutinizes identified alterations to ensure accuracy.

The last part of our process involves synthesizing the data into clinically relevant information. This is a multi-faceted procedure performed by a team of trained scientists that culminates in the production and review of a patient result report. This document contains information about the alterations detected and what therapeutic options may be available based on the genomic findings. This report is reviewed and signed by our medical staff and is returned to the ordering physician who can use the data in conjunction with a clinical assessment to inform his or her treatment decisions.

A report is typically delivered to the physician generally within 11 to 14 days for FoundationOne and within 15 to 18 days for FoundationOne Heme, in each case from the time the specimen is received.

### *Quality Assurance*

We are committed to providing reliable and accurate molecular information to our customers. Accurate specimen identification, timely communication of results, and prompt correction of errors is critical. We monitor our quality through a variety of methods, including performance improvement indicators, proficiency testing, internal and external audits, and satisfaction surveys. Any quality concerns and incidents are subject to risk assessment, root cause analysis and a corrective action plan that is reviewed monthly with department management to ensure that we are providing the best products possible to our customers. Protection of patient results from misuse and improper access is important and thus patient confidential information is limited to necessary personnel.

We have established a comprehensive quality assurance program for our laboratory designed to produce accurate and timely test results and to ensure the consistent high quality of our tests. Our quality assurance program includes policies and procedures covering personnel qualifications and training requirements, process and test validation, quality control of reagents and test processes, proficiency testing, routine monitoring, and internal audit. Quality control metrics are assessed at various points in the testing process and final disposition of patient results requires adherence to quality control metrics that meet and exceed recommendations by professional organizations and regulatory authorities. Additionally, the long-term trends in quality control metrics are reviewed monthly by management. Our quarterly internal quality assurance audits cover pre-analytic, analytic and post-analytic functions, assess improvement indicators, and set new metrics for the following quarter. We also have an extensive, internally administered program of specimen proficiency testing to ensure that test performance is reproducible and functioning optimally.



## **Table of Contents**

Policies and procedures have been developed to satisfy all applicable requirements necessary for federal and state licensures and accreditation for clinical diagnostic laboratories. We follow the policies and procedures for patient and employee safety, hazardous waste disposal, and fire codes stated in the general laboratory procedure manuals. We believe that all pertinent regulations of CLIA, Occupational Safety and Health Administration, Environmental Protection Agency, and FDA are satisfied by following the established guidelines and procedures of our quality assurance program.

### ***Reproducibility***

Our ability to reproduce high quality results is critical to ensuring that we deliver better-informed treatment options to the greatest number of patients with cancer. We have worked to ensure the results of FoundationOne and FoundationOne Heme are commensurate by conducting an extensive analytical validation that robustly demonstrates test performance using both reference specimens and hundreds of routine FFPE clinical cancer specimens with results derived from prior standard diagnostic tests. For example, in validation studies on actual clinical cancer specimens, including samples where as few as 20% of the nuclei in the specimen were derived from tumor cells, high accuracy for FoundationOne was observed across all classes of genomic alterations, including sensitivity greater than 99% for detection of base substitutions, greater than 98% for detection of insertions and deletions, and greater than 95% for detection of copy number alterations. Our specificity was greater than 99% across all classes of alterations.

### ***Supply Agreement***

In July 2013, we entered into a five-year supply, service and support agreement with Illumina, or the supply agreement, for Illumina to provide products and services that support and can be used for the gene sequencing component of our molecular testing activities. During the term of the supply agreement, Illumina will supply us with sequencers, reagents and other consumables for use with the Illumina sequencers, and service contracts for the maintenance and repair of the sequencers.

During the term of the supply agreement, we are required to make a rolling forecast of our expected needs for reagents and other consumables, and we may place purchase orders for reagents and other consumables that conform to such forecast. Illumina may not unreasonably reject conforming purchase orders and will, in its reasonable discretion, accept additional purchase orders for quantities of reagents and other consumables beyond our forecast requirements. During each six-month period we have a binding obligation to purchase an amount of reagents and other consumables equal to the greater of a percentage of our six-month forecast and a fixed minimum amount. Subject to discounts that vary depending on the volume of hardware and reagents and other consumables ordered, the price for sequencers and for service contracts is based on Illumina list prices, and the price for reagents and other consumables is based on contract prices that are fixed for a set period of time and may increase thereafter subject to limitations. The supply agreement does not require us to order minimum amounts of hardware, or to use exclusively the Illumina platform for conducting our sequencing.

We may use equipment, reagents and other materials supplied by third parties in the operation of our business. The agreement contains customary use limitations, representations and warranties, indemnification, limitations of liability, and other provisions.

### **Intellectual Property**

Our business relies upon proprietary technologies, methods and processes, product designs and branding that we have invented, developed, or licensed. Our policy is to seek patent protection and trademark registration for commercially valuable assets we develop, as appropriate, and maintain as trade secrets other aspects of our proprietary platform, processes, and know-how.

---

## **Table of Contents**

### ***Patents***

Our patent portfolio includes a single issued U.S. patent, pending U.S. provisional and utility applications, and strategically focused corresponding international applications filed via the Patent Cooperation Treaty, or PCT, and foreign national and regional counterpart applications. We believe our portfolio of patents and patent applications serve to protect our business in the United States and in foreign jurisdictions in which we elect to pursue and are successful in obtaining patent rights. These applications fall into three broad categories:

applications relating to our genomic analysis methodologies and procedures, including claims directed to process innovations and advances in solution hybridization, bait selection and capture, variant calling, and somatic versus germline alteration differentiation;

applications relating to genomic discoveries, including claims relating to novel genomic alterations correlated to various cancers and associated methods of treatment of patients harboring such genomic alterations; and

applications relating to genomic information and correlated treatment and outcome information management, matching, and delivery, including claims directed to web-mediated systems for capturing, managing, tracking and reporting genomic information and associated clinical outcome data, as well as other applications relating to annotation and curation of genomic results for medical reporting.

A number of our patent applications that pertain to genomic alterations and associated methods of treatment provide us with potential royalty-bearing licensing opportunities. These opportunities arise primarily with companies developing or selling therapeutic products for cancer treatment. These companies may determine that the products or tests they are developing or selling require a license to the methods claimed in our patents and patent applications.

### ***Trade Secrets and Trademarks***

In addition to patents, we rely on trade secrets and know-how to develop and maintain our competitive position. For example, significant elements of FoundationOne and FoundationOne Heme, including aspects of sample preparation, computational-biological algorithms, and related processes and software, are based on unpatented trade secrets and know-how that are not publicly disclosed. We protect trade secrets and know-how by establishing confidentiality agreements and invention assignment agreements with our employees, consultants, scientific advisors, contractors, and commercial partners. These agreements generally provide that all confidential information developed or made known during the course of an individual or entity's relationship with us must be kept confidential during and after the relationship and that all inventions or developments resulting from work performed for us or relating to our business and conceived or completed during the period of employment or assignment, as applicable, shall be our exclusive property. In addition, we take other appropriate precautions, such as physical and technological security measures, to guard against misappropriation of our proprietary technology by third parties. We have also adopted policies and conduct training that provides guidance on our expectations, and our advice for best practices, in protecting our trade secrets.

We also seek trademark protection in the United States and in foreign jurisdictions where available and when appropriate. Foundation Medicine®, FoundationOne®, Interactive Cancer Explorer®, Once. And for All®, and The Molecular Information Company® are all registered trademarks of Foundation in the United States, and several of these marks are at various stages of the registration process in other countries. ICE 2, FoundationCORE and PatientMatch are also trademarks of Foundation. Other trademarks or service marks that may appear in this Annual Report are the property of their respective holders. For convenience, we do not use the ® and ™ symbols in each instance in which one of our trademarks appears throughout this Annual Report, but this should not be construed as any indication that we will not assert, to the fullest extent under applicable law, our rights thereto.

## **Table of Contents**

### **Competition**

We believe FoundationOne and FoundationOne Heme are currently the only commercially available comprehensive molecular information products that provide a fully informative genomic profile in a concise and actionable format designed for use in the clinical setting. Our principal competition comes from existing large and small commercial diagnostic companies, as well as certain medical institutions that offer single-marker or hotspot panel tests that can capture only the most common and known gene alterations and a limited set of gene rearrangements. Although these tests assess only a limited number of genes and are unable to detect copy number alterations and often miss short insertions and deletions, in many circumstances, these are the diagnostic methods that physicians use and have used for many years. It may be difficult to change the methods or behavior of the referring physicians to incorporate our products into their practices. In addition, academic research centers and NGS platform developers are offering or developing NGS-based testing intended to be comprehensive for known cancer genes that may seek to compete with FoundationOne or FoundationOne Heme on the number of genes they interrogate. However, we are not aware of any of these tests having sufficient sensitivity and specificity, operational scale, or reporting elements to fit the realities of current clinical practice, including volume and quality limits of tumor samples, demands on turnaround time, and ease of use.

#### ***Single-Marker and Hotspot Panel Tests***

We may face competition from companies that offer products or have conducted research to profile genes and gene expression in various cancers. Personalized genetic diagnostics is a new area of science, and we cannot predict what tests others will develop that may compete with or provide results comparable or superior to the results we are able to achieve. Our competitors include laboratory companies such as Bio-Reference Laboratories, Inc., Laboratory Corporation of America Holdings, Quest Diagnostics Incorporated, Molecular Health, Caris Life Sciences, Guardant Health, Paradigm, NeoGenomics Laboratories, as well as companies that manufacture or may manufacture diagnostic testing kits such as Abbott Laboratories, Qiagen N.V. and Sequenom, Inc. These kits, which companies often include with capital equipment and reagents to local pathology laboratories, can be used directly by the physician, which can facilitate adoption. In addition, companies such as Genomic Health, Inc. and Myriad Genetics, Inc. have well-established commercial organizations that sell molecular diagnostic tests to physicians and may develop tests which compete with FoundationOne and FoundationOne Heme on price.

#### ***Academic Research Centers and NGS Platforms***

Many hospitals and academic centers may look to internalize the type of comprehensive molecular testing we perform. Our competition may include entities such as the MD Anderson Cancer Center, MSKCC, University of Michigan, Baylor Medical Genetics Laboratories, Washington University in St. Louis, University of Washington, and other academic hospitals and research centers. Although these academic centers could have greater access to, and ability to drive adoption with, certain key thought leaders than we do, we expect that the competition from these academic centers will, for the most part, be restricted to their local markets.

In addition to developing kits, certain life sciences and diagnostic companies also provide NGS platforms. Illumina, Thermo Fisher Scientific, Inc., and other companies develop NGS platforms that are being sold directly to research centers, pharmaceutical companies, and clinical laboratories. While many of the applications for these platforms are focused on the research and development markets and others are focused on testing for non-cancer conditions, each of these companies has launched and may continue to commercialize products used in the clinical oncology market. We believe diagnostic platform providers will seek to place sequencing machines in laboratories to develop sequencing-based laboratory based testing services. In addition, Illumina has received FDA-approval for a diagnostic kit for clinical use outside of oncology, which is sold to clients who have purchased its platforms. We believe Illumina and other diagnostic platform providers may develop additional FDA-approved diagnostic kits for clinical use by clients who have purchased their platforms, potentially including for these clients to identify genomic alternations in samples of solid tumors or blood-based cancers. Many private companies are developing information technology-based tools to support the integration of NGS

## **Table of Contents**

testing into the clinical setting. These companies could have substantially greater financial, technical, and other resources than we do and may be more successful than we may be in achieving widespread market acceptance. Any tests they develop may be more effective, or more effectively marketed and sold, than FoundationOne or FoundationOne Heme.

### ***Our Competitive Strengths***

Our molecular information platform enables us to offer comprehensive molecular information products that interrogate with precision the genes known to be altered in human cancer. Our products are uniquely differentiated from other oncology diagnostic products because, to our knowledge, they are the first and only products to comprehensively address all solid tumors and hematologic malignancies, and to deliver a clear, concise report detailing clinically relevant treatment alternatives. We believe our products have a sustainable competitive advantage on the basis of:

our ability, with FoundationOne, to assess 315 cancer-related genes for all classes of genomic alterations with high sensitivity and specificity, as described in our October 2013 *Nature Biotechnology* publication, unlike currently available single gene and hotspot molecular diagnostic tests, which focus only on a limited numbers of genes and a subset of genomic alteration types;

our ability, with FoundationOne Heme, to detect all classes of genomic alterations, including base pair substitutions, insertions and deletions, copy number alterations and select gene rearrangements in 405 cancer-related genes, in addition to utilizing RNA sequencing across 265 genes to capture a broad range of gene fusions, a type of alteration that is a common driver of hematologic cancers and sarcomas;

our proprietary optimizations allow us to utilize a wide variety of sample types, including small biopsies and fine needle aspirates, and samples with low tumor purity;

our ability to leverage our founders' expertise and our relationships with oncology thought leaders to keep pace with scientific and medical advances to, among other things, incorporate newly relevant cancer genes along with newly available targeted therapeutics and clinical trials;

our ability to deliver, in a concise report, actionable information regarding the relevant genomic alterations in a patient's cancer and to match these alterations with targeted therapies based on peer-reviewed literature in a medically relevant time frame;

our ability to deliver complex information through the convenience and utility of our Interactive Cancer Explorer;

our ability, through PatientMatch, to connect physicians with peers who have seen patients with similar genomic profiles and learn about their treatment decisions and outcomes to facilitate their own decision making;

our efforts to capture, aggregate, analyze, and facilitate the broader exchange of genomic data across the global oncology community to create a network effect as more data is gathered which will lead to more users and ultimately more comprehensive datasets;

our ability to leverage the vast array of genomic data generated by our molecular information platform, included in FoundationCore, together with clinical data to position ourselves at the nucleus of this new treatment paradigm;

## Edgar Filing: Foundation Medicine, Inc. - Form 10-K

our ability to actively participate in the development of the newest oncology therapeutics and practice through our relationships with our biopharmaceutical partners; and

our ability to provide value-added services to help our physician customers and patients act on the results of their comprehensive genomic profiling test results, including FoundationOne Careline to help patients access prescribed therapies and our collaboration with EmergingMed to provide a clinical trial matching service for patients.

## **Table of Contents**

### **Proposed Strategic Collaboration with Roche**

On January 12, 2015, we announced a proposed broad, strategic collaboration with Roche and certain of its affiliates in the field of molecular information for oncology. The transaction, which is subject to a number of closing conditions, includes an R&D collaboration, a U.S. educational support collaboration, an ex-U.S. commercial collaboration, a binding term sheet for an *in vitro* diagnostic product development collaboration and an equity investment with certain governance provisions.

#### ***Transaction Agreement***

Under the terms of the Transaction Agreement, dated January 11, 2015, by and between us and Roche, or the Transaction Agreement, Roche has agreed to (1) make a primary investment of \$250 million in cash to purchase 5 million newly issued shares of our common stock, or the Issuance Shares, at a purchase price of \$50.00 per share, or the Issuance, and (2) commence a tender offer, or the Offer, to acquire approximately 15.6 million outstanding shares of our common stock at a price of \$50.00 per share so that, when combined with Issuance Shares and existing shares of our common stock held by Roche Holding Ltd and its subsidiaries, Roche and its affiliates will own a minimum of 52.4% and a maximum of 56.3% of our outstanding shares, on a fully diluted basis, at the closing of the transactions contemplated by the Transaction Agreement, or the Closing. Roche's obligation to consummate the Offer is subject to certain conditions, including, among other things, (a) the condition that there shall have been validly tendered and not validly withdrawn prior to the time at which shares of our common stock are first accepted for payment under the Offer, or the Acceptance Time, that number of shares which, when combined with the Issuance Shares and existing shares of our common stock held by Roche Holding Ltd and its subsidiaries, represents at least 52.4% of our outstanding shares on a fully diluted basis, (b) our stockholders' approval, or the Company Stockholder Approval, of (i) the Transaction Agreement and the transactions contemplated thereby (ii) Roche's anti-dilution protection rights under the Investor Rights Agreement dated January 11, 2015, by and among us, Roche, the Company and certain of our existing stockholders, or the Investor Rights Agreement, and (iii) certain amendments to our certificate of incorporation to provide for the declassification of our board of directors and the waiver of the corporate opportunity doctrine with respect to Roche and its affiliates, (c) each of the Collaboration Agreements described below and the Investor Rights Agreement continuing to be in full force and effect, (d) the approval of the Issuance Shares for listing on the NASDAQ Global Select Market, and (e) other customary closing conditions. The Transaction Agreement includes termination rights for both us and Roche and provides that, prior to the Acceptance Time, we have the right to terminate the Transaction Agreement in connection with entering into a definitive agreement with respect to a superior proposal with a third party, subject to certain conditions, including our compliance with certain procedures set forth in the Transaction Agreement and payment of a termination fee of \$30 million to Roche. Neither the Issuance nor the Offer is subject to a financing condition. If the Closing occurs, the Transaction Agreement also provides for us to indemnify Roche for breaches of the Transaction Agreement by us subject to negotiated limitations. We can provide no assurance that the transactions contemplated by the Transaction Agreement will be completed. On February 2, 2015, Roche commenced the Offer and filed a Tender Offer Statement on Schedule TO, and we filed a Solicitation/Recommendation Statement on Schedule 14D-9 relating to the Issuance and the Offer. On April 2, 2015, we will hold a special meeting of stockholders in which we will seek to obtain the Company Stockholder Approval.

#### ***Collaboration***

In connection with the Issuance and the Offer and simultaneously with the execution of the Transaction Agreement, we entered into a strategic collaboration with certain affiliates of Roche to develop and commercialize comprehensive molecular information and genomic analysis products for the treatment of cancer patients, or the Collaboration, pursuant to (a) a Collaboration Agreement, or the R&D Collaboration Agreement, by and among us, F. Hoffmann-La Roche Ltd, or Roche Basel, and Hoffmann-La Roche Inc., or Roche U.S., (b) a US Education Collaboration Agreement, or the U.S. Education Collaboration Agreement, by and between us and Genentech, (c) an Ex-US Commercialization Agreement, or the Ex-U.S. Commercialization Agreement, by and between us and Roche Basel and (d) a Binding Term Sheet for an In Vitro Diagnostics (IVD) Agreement,

## **Table of Contents**

or the IVD Term Sheet, by and between us and Roche Basel, each of which will become effective at the Acceptance Time. We refer to the R&D Collaboration Agreement, the U.S. Education Collaboration Agreement, the Ex-U.S. Commercialization Agreement and the IVD Term Sheet collectively as the Collaboration Agreements.

Pursuant to the R&D Collaboration Agreement, we will collaborate with Roche on multiple programs related to the use and development of products and services for use in molecular information, immunotherapy, circulating tumor DNA and companion diagnostics. These programs will be conducted pursuant to agreed-upon work plans and be subject to the oversight of a joint research and development committee. Under the molecular information platform program, Roche will pay us \$85 million over five years for the molecular genomic profiling of a minimum number of cancer samples and to access our molecular information database. We could also receive up to approximately \$74 million for the currently contemplated scope of activities related to the immunotherapy testing platform program, the circulating tumor DNA platform program and the companion diagnostics platform program. Separate and apart from the R&D Collaboration Agreement, we are carrying out limited work, which would continue and be paid for separately regardless of whether the Issuance closes and the R&D Collaboration Agreement becomes effective. The initial term of the R&D Collaboration Agreement is five years. However, certain provisions of the R&D Collaboration Agreement may remain in effect after such initial five-year term so long as Roche and its affiliates own at least a majority of the outstanding shares of our common stock. We or Roche may terminate the R&D Collaboration Agreement in the event of a breach of the agreement by the other party.

Pursuant to the U.S. Education Collaboration Agreement, we and Genentech, a wholly owned subsidiary of Roche, will conduct an education support program for healthcare professionals and laboratories in the United States regarding the use of next-generation sequencing and comprehensive genomic profiling technology. Genentech will develop education materials based upon information related to comprehensive genomic profiling provided by us, and we and Genentech will share the costs related to the education support program activities. In addition, in the event we seek to promote any companion diagnostic product for use with a Genentech therapeutic in the United States, Genentech will have a right of first negotiation, subject to certain conditions, with respect to the co-promotion of such companion diagnostic product. The U.S. Education Collaboration Agreement will remain in effect for five years, and either party may terminate the agreement without cause upon six months' written notice during the first year of the term and upon three months' written notice thereafter, and either party may terminate in the event of a breach by the other party.

Pursuant to the Ex-U.S. Commercialization Agreement, Roche will have the right to commercialize our existing clinical diagnostic testing products, including FoundationOne and FoundationOne Heme, any clinical diagnostic products developed under the R&D Collaboration Agreement and any other products upon mutual agreement. Beginning one year after the effective date of the Ex-U.S. Commercialization Agreement, Roche will have the exclusive right to commercialize such products worldwide, excluding the United States and any countries Roche elects to exclude during the first year of the term. Roche also holds a right of first negotiation with respect to the commercialization of our future clinical diagnostic products, excluding *in vitro* diagnostic tests, companion diagnostic products developed by us for third parties and any standalone data or molecular information products. Roche may pay us an agreed amount for the right to extend the launch timeline for FoundationOne and FoundationOne Heme by specified periods in specified countries. Roche will also pay agreed upon royalties and commercial milestones. Further, if Roche fails to meet certain minimum revenue requirements for FoundationOne or FoundationOne Heme tests for three consecutive years in a specified country, we have the right to terminate Roche's exclusive commercialization rights in the applicable country. The Ex-U.S. Commercialization Agreement will remain in effect for five years and may be extended by Roche for additional two-year periods. Roche shall have the right to terminate the agreement without cause upon six months' written notice after the initial five year term, and either party may terminate the agreement in the event of breach by the other party.

Pursuant to the IVD Term Sheet, we have agreed with Roche to use commercially reasonable efforts to negotiate and enter into a definitive agreement within one year after the Closing (unless such period is extended by mutual agreement of the parties) regarding a non-exclusive collaboration to develop and commercialize *in*

## **Table of Contents**

*vitro* diagnostic versions of certain of our existing products, including FoundationOne and FoundationOne Heme, and our future products, including those developed under the R&D Collaboration Agreement, or the IVD Kits. The IVD Term Sheet provides that we may not develop IVD Kits that use a sequencing platform owned or controlled by Roche for internal purposes or with third parties without the prior written consent of Roche. The IVD Term Sheet contemplates that Roche will bear all development costs related to the development of the Roche sequencing platform. The IVD Term Sheet will control this relationship between the parties until the parties enter into a definitive agreement or mutually agree to terminate their relationship.

### ***Investor Rights Agreement***

In connection with the Issuance and simultaneously with the execution of the Transaction Agreement, we entered into the Investor Rights Agreement, which will become effective at the Acceptance Time with Roche and Third Rock Ventures, L.P., affiliates of KPCB Holdings, Inc. and Google Ventures 2011, L.P., or the Existing VC Investors.

Under the terms of the Investor Rights Agreement, immediately following the Closing, our board of directors will consist of nine directors, consisting of (a) three directors designated by Roche, who initially shall include Daniel O. Day, (b) two of the current independent directors affiliated with the Existing VC Investors, (c) three additional independent directors, or the Independent Directors, who shall initially be current directors Evan Jones and David Schenkein and a third director to be agreed upon by us and Roche prior to the Closing, and (d) Michael Pellini, our President and Chief Executive Officer.

Pursuant to the Investor Rights Agreement, following the Closing: (a) so long as Roche beneficially owns at least 10% of the outstanding shares of our common stock, it will be entitled to the lesser of (i) the number of seats representing 33.34% of our board of directors and (ii) proportionate representation on our board of directors and (b) so long as Roche is entitled to appoint at least one director to our board of directors, it will be entitled to proportionate representation on each committee of our board of directors, subject to compliance with the applicable rules of the SEC and the NASDAQ Stock Market.

Until such time as Roche and its affiliates beneficially owns less than a majority of the outstanding shares of our common stock (subject to a cure period), we may not take certain actions without Roche's prior written consent, including any of the following: (a) appoint a new Chief Executive Officer; (b) incur any indebtedness (as defined in the Investor Rights Agreement) that would result in the outstanding aggregate principal amount of the indebtedness of the Company and its subsidiaries exceeding the lesser of (A) \$200 million and (B) 20% of the Company's aggregate market capitalization at the time of such incurrence; (c) issue or sell any equity securities (including any securities convertible or exercisable into such equity securities), other than (X) common stock issued upon the exercise or settlement of equity awards granted as of the date of the Investor Rights Agreement in accordance with their terms, (Y) equity awards granted after the date of the Investor Rights Agreement pursuant to our 2013 Stock Option and Incentive Plan or any permitted new equity incentive plan or equity incentive plan amendment and (Z) in connection with permitted acquisitions, certain shares of our common stock issued as stock consideration as long as such issuance does not result in Roche beneficially owning less than 50.5% of the outstanding shares of common stock on a fully diluted basis; (d) establish or amend any of our equity incentive plans, except for certain permitted equity incentive plans and permitted equity incentive plan amendments; (e) acquire any entity, business or assets if the aggregate consideration payable by us exceeds the lesser of (X) \$200 million and (Y) 20% of our aggregate market capitalization at the time of such transaction, unless Roche is separately contemplating acquiring the same entity, business or assets; (f) dispose of any entity, business or assets if the aggregate consideration payable to us exceeds \$50 million; (g) change the scope and nature of our business; (h) amend our organizational documents; (i) take any action that would impair in any material respect our ability to perform our obligations under the Investor Rights Agreement or Roche's rights thereunder; or (j) voluntarily dissolve or liquidate or make any voluntary bankruptcy filings.

***Voting Obligations.*** As long as Roche is entitled to appoint at least one director to our board of directors, Roche will be required to (a) cause all of its shares of our common stock to be present for quorum purposes at



---

**Table of Contents**

any meeting of our stockholders, (b) vote all of its shares of our common stock to approve any matter requiring approval by Roche described in the preceding paragraph that Roche has approved within the previous six months and (c) vote all of its shares of our common stock in connection with the election of directors or the adoption of certain equity incentive plans either (i) in accordance with the recommendation of our board of directors or (ii) in the same proportion as the votes cast by all of our stockholders other than Roche and its affiliates.

*Standstill Provisions.* Under the terms of the Investor Rights Agreement, during the period following the Closing and ending on the date three years following the Closing, or the Restricted Period, Roche will be restricted from acquiring additional shares of our common stock, except in order to offset dilution and maintain its aggregate percentage ownership in the Company. During the Restricted Period and for as long as Roche has the right to designate a director, Roche shall not make any proxy solicitations in connection with the election or removal of directors, or knowingly encourage or facilitate a third party to engage in any such solicitation, subject to certain limited exceptions.

Following the Restricted Period, Roche will be permitted to make an offer to purchase all remaining shares of our common stock held by our stockholders, or a Roche Buyout Offer. Prior to the fifth anniversary of the Closing, any Roche Buyout Offer shall be made on a confidential basis, subject to the review, evaluation and approval of a special committee of independent directors who are unaffiliated with Roche and are not officers or employees of the Company, or the Disinterested Directors, and subject to a non-waivable condition that a majority of the shares of our common stock held by stockholders not affiliated with Roche approve the Roche Buyout Offer. From and after the fifth anniversary of the Closing, any Roche Buyout Offer may be made directly to our stockholders without the review, evaluation or approval of our board of directors or the Disinterested Directors, as long as it is subject to the non-waivable condition that a majority of the shares of our common stock held by stockholders not affiliated with Roche approve the Roche Buyout Offer. If, from and after the fifth anniversary of the Closing, Roche makes a Roche Buyout Offer, then at any subsequent annual meeting of our stockholders (or special meeting called for the purpose of electing directors), Roche will be entitled to nominate any individuals who qualify as independent directors under the terms of the Investor Rights Agreement.

The standstill restrictions on Roche will automatically terminate if Roche ceases to own at least 20% of our outstanding common stock or we enter into a definitive agreement with respect to, or our board of directors recommends to our stockholders, a transaction pursuant to which any person or group would acquire, directly or indirectly, voting securities representing more than 20% of the aggregate voting power of all of our then-outstanding voting securities.

*Anti-dilution Protections.* We have agreed to establish and maintain a stock repurchase program at all times following the Closing and to repurchase shares of our common stock in order to maintain Roche's aggregate percentage ownership following the Issuance at no less than 50.5% of the outstanding shares of our common stock on a fully diluted basis, less any shares transferred by Roche. Our obligation to maintain such stock repurchase program will terminate upon the earlier of (a) any transfer by Roche of shares of our common stock, following which Roche beneficially owns less than 40% of the outstanding shares of our common stock on a fully diluted basis and (b) Roche beneficially owning less than 30% of the outstanding shares of our common stock.

Following the Closing and until the date on which Roche beneficially owns less than 30% of the outstanding shares of our common stock, Roche also will hold a continuing option to purchase shares of common stock directly from us or in the open market, at prevailing market prices, in order to maintain its aggregate percentage ownership at no less than 50.5% of the outstanding shares of our common stock on a fully diluted basis, less any shares transferred by Roche, or the Share Percentage Cap. If we fail to or are unable to satisfy our repurchase obligations under the stock repurchase program described above, and Roche purchases shares of common stock from us or in the open market, the Share Percentage Cap will be increased by the percentage of the outstanding shares of common stock, on a fully diluted basis, represented by the shares of common stock that Roche was required to purchase at its cost in order to maintain its aggregate percentage ownership.

## **Table of Contents**

In the event that we issue any securities and, as a result thereof, Roche beneficially owns less than 50.1% of the outstanding shares of our common stock on a fully diluted basis, the restrictions on Roche under the Investor Rights Agreement (including with respect to the agreement to vote Roche's shares of common stock, the standstill restrictions and the transfer restrictions), but not the rights of Roche under the Investor Rights Agreement, will immediately terminate, and Roche will thereafter have the ability to exercise in full its rights as a stockholder.

*Restrictions on Transfer of Shares.* Roche may not transfer any shares of our common stock during the Restricted Period. Thereafter, subject to certain exceptions, Roche may not transfer any shares of our common stock to any person or group, if such person or group would beneficially own in excess of 10% of the outstanding shares of our common stock following such transfer, without the prior consent of a special committee of Disinterested Directors. Following the fifth anniversary of the Closing, Roche will be permitted to transfer all (but not less than all) of its shares of our common stock to a third party that has made an offer to us or our stockholders (including pursuant to a tender offer) to purchase all of the outstanding shares of our common stock if the price, form of consideration and other terms and conditions of the transfer offered to Roche are the same (or no more favorable) than the price, form of consideration and other terms and conditions offered to all of our other stockholders, other than (a) fair market consideration payable in exchange for entering into restrictive covenants and (b) commercial agreements (including with respect to transition services) on arms-length terms, in each case that the purchaser requires as a condition to the transaction.

*Registration Rights.* Following the end of the Restricted Period, Roche will be entitled to customary demand and piggyback registration rights, subject to customary underwriter cutbacks.

*Matters Reserved for Approval of the Disinterested Directors.* For as long as there is at least one director designated by Roche on our board of directors, the following actions will require approval of a majority of the Disinterested Directors (or a special committee of Disinterested Directors): (a) any transaction between Roche or any of its affiliates, on the one hand, and us, on the other hand; (b) any enforcement or waiver of our rights under any agreement between us, on the one hand, and Roche or any of its affiliates, on the other hand; and (c) any purchase of shares of our common stock by Roche or any of its affiliates, except as otherwise expressly set forth in the Investor Rights Agreement.

*Freedom to Pursue Opportunities.* As a general matter, neither we nor Roche will be required to offer a corporate opportunity to the other, and except as agreed in connection with the Collaboration or as part of the Investor Rights Agreement, there will be no restrictions on our or Roche's ability to engage in similar activities or lines of business.

*Termination.* The Investor Rights Agreement will automatically terminate on the later of the date Roche beneficially owns less than 10% of the outstanding shares of our common stock or the date that Roche owns no Registrable Securities (as defined in the Investor Rights Agreement).

### ***Tender and Support Agreements***

Simultaneously with the execution of the Transaction Agreement, the Existing VC Investors also entered into separate Tender and Support Agreements with Roche, or the Tender and Support Agreements, pursuant to which the Existing VC Investors agreed, among other things, (a) to vote their respective shares of our common stock in favor of the Company Stockholder Approval, (b) to tender at least 50% of their respective shares of our common stock into the Offer and (c) if it would result in a higher participation in the Offer, to tender their respective shares of our common stock in proportion to the other stockholders of the Company who are not parties to the Tender and Support Agreements. As of the date of the Tender and Support Agreements, the Existing VC Investors beneficially owned approximately 31% of the outstanding shares of our common stock.

Pursuant to the Tender and Support Agreements, if the shares of our common stock tendered into the Offer, when combined with the Issuance Shares and existing shares of our common stock owned by Roche, are not

## **Table of Contents**

sufficient to result in Roche owning at least 52.4% of the outstanding shares of our common stock on a fully diluted basis immediately following the Closing, certain of the Existing VC Investors have agreed to tender up to 100% of their shares of our common stock in order that tendered shares of our common stock meet such threshold. The participation by the Existing VC Investors in the Offer is otherwise on the same terms and conditions as the other stockholders of the Company.

### ***Board Approval***

The Offer, the Issuance, the Collaboration and other transactions contemplated by the Transaction Agreement have been unanimously approved by our board of directors.

The foregoing summary descriptions of the Transaction Agreement, the Issuance, the Offer, the Collaboration and the Investor Rights Agreement do not purport to be complete and are qualified in their entirety by reference to the applicable agreements, copies of which are filed with this Annual Report. Additional descriptions on the transactions contemplated by the Transaction Agreement have been included in our Current Report on Form 8-K, filed with the Securities and Exchange Commission, or the SEC, on January 12, 2015, our Current Report on Form 8-K/A filed with the SEC on February 2, 2015, our Solicitation/Recommendation Statement on Schedule 14D-9 relating to the Issuance and Offer filed with the SEC on February 2, 2015 (including any amendments thereto on Schedule 14D-9/A), and our definitive Proxy Statement on Schedule 14A relating to the Issuance and Offer filed with the SEC on February 19, 2015 (including any amendments thereto).

## **Governmental Regulations**

### ***Clinical Laboratory Improvement Amendments of 1988 and State Regulation***

As a clinical laboratory, we are required to hold certain federal and state licenses, certifications, and permits to conduct our business. As to federal certifications, in 1988, Congress passed the Clinical Laboratory Improvement Amendments, or CLIA, establishing quality standards for all laboratory testing to ensure the accuracy, reliability, and timeliness of patient test results regardless of where the test was performed. Our laboratory is CLIA certified and accredited by the College of American Pathologists, or CAP, a CLIA approved accrediting organization. In addition, we are required to meet certain laboratory licensing requirements for states with regulations beyond CLIA. For more information on state licensing requirements, see below in the section entitled *Governmental Regulations State Laboratory Testing*.

Under CLIA, a laboratory is any facility which performs laboratory testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention or treatment of disease, or the impairment of, or assessment of health. CLIA also requires that we hold a certificate applicable to the type of work we perform and comply with certain standards. CLIA further regulates virtually all clinical laboratories by requiring they be certified by the federal government and comply with various operational, personnel, facilities administration, quality, and proficiency requirements intended to ensure that their clinical laboratory testing services are accurate, reliable, and timely. Laboratories must register and list their tests with The Centers for Medicare & Medicaid Services, or CMS, the agency that oversees CLIA. CLIA compliance and certification is also a prerequisite to be eligible to bill for services provided to governmental payor program beneficiaries and for many private payors. CLIA is user-fee funded. Therefore, all costs of administering the program must be covered by the regulated facilities, including certification and survey costs.

We are subject to survey and inspection every two years to assess compliance with program standards, and may be subject to additional unannounced inspections. Laboratories performing high complexity testing are required to meet more stringent requirements than laboratories performing less complex tests. In addition, a laboratory like ours that is certified as high complexity under CLIA may develop, manufacture, validate, and use proprietary tests referred to as laboratory developed tests, or LDTs. To date, the FDA has taken the position that LDTs currently do not require FDA approval; however, CLIA requires full validation, including accuracy, precision, specificity, sensitivity, and establishment of a reference range for any LDT used in clinical testing.

---

## **Table of Contents**

In addition to CLIA requirements, we elect to participate in the accreditation program of CAP. CMS has deemed CAP standards to be equally or more stringent than CLIA regulations and has approved CAP as a recognized accrediting organization. Inspection by CAP is performed in lieu of CMS for accredited laboratories. Because we are accredited by the CAP Laboratory Accreditation Program, we are deemed to also comply with CLIA.

CLIA provides that a state may adopt laboratory regulations that are more stringent than those under federal law, and a number of states have implemented their own more stringent laboratory regulatory requirements. State laws may require that laboratory personnel meet certain qualifications, specify certain quality control procedures, facility requirements, or prescribe record maintenance requirements.

### ***State Laboratory Testing***

Several states require the licensure of out-of-state laboratories that accept specimens from those states. For example, New York requires a laboratory to hold a permit which is issued after an on-site inspection and approval of testing methodology, and has various requirements over and above CLIA and CAP, including those for personnel qualifications, proficiency testing, physical facility, equipment, and quality control standards. Our laboratory holds the required licenses for these states, which include Massachusetts, Maryland, Rhode Island, Pennsylvania, Florida, California, and New York.

From time to time, other states may require out of state laboratories to obtain licensure in order to accept specimens from the state. 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 follow instructions from the state regulators as to how we should comply with such requirements.

### ***FDA***

The FDA regulates the sale and distribution in interstate commerce of medical devices under the Federal Food, Drug, and Cosmetic Act, or the FDCA, including *in vitro* diagnostic devices, reagents, and instruments used to perform diagnostic testing. Devices must undergo premarket review by FDA prior to commercialization unless the device is of a type exempted from such review by statute, regulation, or pursuant to FDA's exercise of enforcement discretion. FDA, to date, has generally not exercised its authority to actively regulate the development and use of LDTs, which are tests that are designed, manufactured, validated, and used within a single laboratory, and therefore we do not believe that our LDTs currently requires pre-market clearance or approval. It is likely that FDA will more actively regulate LDTs, which could lead to premarket and post-market obligations. Indeed, in July 2010, FDA held a two-day public meeting on the oversight of LDTs in which the agency stated it decided to exercise authority over LDTs, but had not decided how it would exercise that authority. In October 2014, following a required 60-day Congressional notification period, FDA issued draft guidance documents stating that FDA intends to change its policy and describing an approach to regulating LDTs using a risk-based, phased-in approach. If finalized, the guidance documents would impose premarket review and other medical device requirements under the FDCA on LDTs classified as high and moderate risk. Enforcement of premarket review and Quality System Regulation, or QSR, requirements would be phased-in based on the risk of the LDT over a period of several years, but Medical Device Reporting requirements and compliance with either a new notification procedure in which the laboratory must provide FDA with certain basic information about each LDT offered by their laboratory or FDA's device registration and listing requirements would be required within six months of finalization of the guidance documents (with limited exceptions). There is no time frame in which FDA must finalize the draft guidance documents. In the meantime, we maintain our CLIA certification, which permits the use of LDTs for diagnostic purposes.

FDA regulations pertaining to medical devices govern, among other things, the research, design, development, pre-clinical and clinical testing, manufacture, safety, effectiveness, clearance or approval, record-keeping, packaging, labeling, storage, adverse event reporting, advertising, promotion, marketing, sales, distribution, and import and export of medical devices. Pursuant to the FDCA, medical devices are subject to

---

## **Table of Contents**

varying degrees of regulatory control and are classified in one of three classes depending on the controls FDA determines necessary to reasonably ensure their safety and effectiveness.

Class I devices are those for which reasonable assurance of safety and effectiveness can be provided by adherence to FDA's general controls for medical devices, which include applicable portions of FDA's QSR, facility registration and product listing, reporting of adverse medical events, and appropriate, truthful, and non-misleading labeling, advertising and promotional materials. Many Class I devices are exempt from premarket regulation; however, some Class I devices require premarket clearance by FDA through the 510(k) premarket notification process described below.

Class II devices are subject to FDA's general controls, and any other special controls, such as performance standards, postmarket surveillance, and FDA guidelines, deemed necessary by FDA to provide reasonable assurance of the device's safety and effectiveness. Premarket review and clearance by FDA for Class II devices are accomplished through the 510(k) premarket notification procedure, although some Class II devices are exempt from the 510(k) requirements. Premarket notifications are subject to user fees, unless a specific exemption applies. To obtain 510(k) clearance, a manufacturer must submit a premarket notification demonstrating that the proposed device is substantially equivalent to a predicate device, which is a previously cleared 510(k) device or a preamendment device that was in commercial distribution before May 28, 1976, for which FDA has not yet called for the submission of a premarket approval, or PMA, application. In determining substantial equivalence, FDA assesses whether the proposed device has the same intended use and technical characteristic as the predicate device, or whether the proposed device has different technological characteristics, but the information submitted in the premarket notification demonstrates the device is as safe and effective as a legally marketed device and does not raise different questions of safety and effectiveness than the predicate device. FDA may request additional information, including clinical data. Under the FDCA, a manufacturer submits a premarket notification 90 days before introducing a device into interstate commerce, but FDA's review of the premarket notification can take significantly longer. If FDA determines that the device is substantially equivalent to the predicate device(s), the subject device may be marketed. However, if FDA determines that a device is not substantially equivalent to the predicate device(s), then the device would be regulated as a Class III device, discussed below. If a manufacturer obtains a 510(k) clearance for its device and then makes a modification that could significantly affect the device's safety or effectiveness, a new premarket notification must be submitted to FDA.

Class III devices are those deemed by FDA to pose the greatest risk, such as those for which reasonable assurance of the device's safety and effectiveness cannot be assured solely by the general controls and special controls described above and that are life-sustaining or life-supporting. Some preamendment Class III devices for which FDA has not yet required a PMA require FDA's clearance of a premarket notification in order to be marketed. However, most Class III devices are required to undergo the PMA process in which the manufacturer must demonstrate reasonable assurance of the safety and effectiveness of the device to FDA's satisfaction. A PMA application must provide valid scientific evidence, typically extensive preclinical and clinical trial data, and information about the device and its components regarding, among other things, device design, manufacturing, and labeling. PMA applications (and supplemental PMA applications) are subject to significantly higher user fees than are 510(k) premarket notifications. Some PMA applications are exempt from a user fee, for example a small business's first PMA.

After a PMA application is submitted and found to be sufficiently complete, FDA begins an in-depth review of the submitted information. During this review period, FDA may request additional information or clarification of information already provided. FDA also may convene an advisory panel of outside experts to review and evaluate the application and provide recommendations to FDA as to the approvability of the device. In addition, FDA generally will conduct a pre-approval inspection of the manufacturing facility to ensure compliance with the QSR. FDA can delay, limit, or deny approval of a PMA application for many reasons.

If the FDA's evaluations of both the PMA application and the manufacturing facilities are favorable, FDA will either issue an approval letter authorizing commercial marketing or an approvable letter that usually contains

---

## **Table of Contents**

a number of conditions that must be met in order to secure final approval. If the FDA's evaluations are not favorable, FDA will deny approval of the PMA or issue a not approvable letter. The agency may determine that additional clinical trials are necessary, in which case the PMA approval may be delayed while the trials are conducted and the data acquired and submitted in an amendment to the PMA. Even with additional trials, FDA may not approve the PMA application. The PMA process, including the gathering of clinical and nonclinical data, and the submission to FDA for review, can take several years, and the process can be expensive and uncertain.

Even if FDA approves a PMA, the agency can impose post approval conditions that it believes necessary to ensure the safety and effectiveness of the device, including, among other things, restrictions on labeling, promotion, sale, and distribution. After approval of a PMA, a new PMA or PMA supplement may be required for a modification to the device, its labeling, or its manufacturing process.

A clinical trial may be required in support of a 510(k) submission and generally is required for a PMA application. These trials generally require an Investigational Device Exemption, or IDE, approved by FDA for a specified number of patients, unless the product is exempt from IDE requirements or deemed a non-significant risk device eligible for more abbreviated IDE requirements. The IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. Clinical trials may begin 30 days after the submission of the IDE application unless FDA disapproves the IDE or places the trial on clinical hold. Additionally, clinical trials may not begin until their protocol and informed consent receive approval from the appropriate institutional review boards at the clinical trial sites. All clinical trials must be conducted in accordance with the FDA's IDE regulations.

Even if regulatory approval or clearance of a device is granted, FDA may impose limitations on the uses and indications for which the device may be labeled and promoted, and the device remains subject to significant regulatory requirements. Medical devices may be marketed only for the uses and indications for which they are cleared or approved. Device manufacturers must register their facilities and list their devices with FDA. A device manufacturer's manufacturing processes and those of some of its suppliers are required to comply with the applicable portions of the QSR, which covers quality management, design, production and process controls, quality assurance, labeling, packaging, shipping, and complaint handling. Device manufacturers must submit to the FDA medical device reports for deaths, serious injuries, and certain malfunctions and report certain field corrections and product recalls or removals. Some manufacturers also may be subject to post-market surveillance regulations. Facility records and manufacturing processes are subject to periodic unscheduled inspections by FDA.

Failure to comply with applicable regulatory requirements can result in enforcement action by FDA, which may include any of the following sanctions: public warning letters, fines, injunctions, civil or criminal penalties, recall or seizure of products, operating restrictions, partial suspension or total shutdown of production, delays in or denial of 510(k) clearance or PMA applications for new products, challenges to existing 510(k) clearances or PMA applications, and a recommendation by FDA to disallow a device manufacturer from entering into government contracts. FDA also has the authority to request repair, replacement, or refund of the cost of any device manufactured or distributed. In the event that a supplier fails to maintain compliance with a device manufacturer's quality requirements, the manufacturer may have to qualify a new supplier and could experience manufacturing delays as a result.

We believe that our LDTs would likely be regulated as either a Class II or Class III device. Accordingly, some level of premarket review—either a 510(k) or a PMA—would likely be required for our test if FDA no longer applies its enforcement discretion to LDTs. While the data requirements are typically greater for Class III devices, the data required for Class II devices has increased, and it is possible that some amount of clinical data (retrospective or prospective or both) would be required for either type of submission. Currently, FDA is undertaking a review of the adequacy of the 510(k) process. It is difficult to predict what changes may result, but it should be assumed that any changes will increase, not decrease, the regulatory requirements. We believe that

## **Table of Contents**

products we may develop in the future for use as companion diagnostic tests may be regulated as Class II devices requiring 510(k) clearance or Class III devices requiring PMA approval. We cannot assure you that our current products and other future products will not require 510(k) clearance or PMA approval in the future, or, in such an event, that such approval or clearance would be forthcoming.

### ***HIPAA and HITECH***

Under the administrative simplification provisions of HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or the HITECH Act, the United States Department of Health and Human Services issued regulations that establish uniform standards governing the conduct of certain electronic health care transactions and protecting the privacy and security of protected health information used or disclosed by health care providers and other covered entities. Three principal regulations with which we are required to comply have been issued in final form under HIPAA: privacy regulations, security regulations, and standards for electronic transactions, which establish standards for common health care transactions. The privacy and security regulations were extensively amended in 2013 to incorporate requirements from the HITECH Act.

The privacy regulations cover the use and disclosure of protected health information by health care providers and other covered entities. They also set forth certain rights that an individual has with respect to his or her protected health information maintained by a health care provider, including the right to access or amend certain records containing protected health information, or to request restrictions on the use or disclosure of protected health information. The security regulations establish requirements for safeguarding the confidentiality, integrity, and availability of protected health information that is electronically transmitted or electronically stored. The HITECH Act, among other things, established certain protected health information security breach notification requirements. A covered entity must notify affected individual(s) and the United States Department of Health and Human Services when there is a breach of unsecured protected health information. The HIPAA privacy and security regulations establish a uniform federal floor that health care providers must meet and do not supersede state laws that are more stringent or provide individuals with greater rights with respect to the privacy or security of, and access to, their records containing protected health information. Massachusetts, for example, has a state law that protects the privacy and security of personal information of Massachusetts residents that is more prescriptive than HIPAA.

These laws contain significant fines and other penalties for wrongful use or disclosure of protected health information. Additionally, to the extent that we submit electronic health care claims and payment transactions that do not comply with the electronic data transmission standards established under HIPAA and the HITECH Act, payments to us may be delayed or denied.

### ***Federal, State and Foreign Fraud and Abuse Laws***

In the United States, there are various fraud and abuse laws with which we must comply and we are potentially subject to regulation by various federal, state and local authorities, including CMS, other divisions of the U.S. Department of Health and Human Services (e.g., the Office of Inspector General), the U.S. Department of Justice, and individual U.S. Attorney offices within the Department of Justice, and state and local governments. We also may be subject to foreign fraud and abuse laws.

In the United States, the federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce or in return for patient referrals for, or purchasing, leasing, ordering or arranging for the purchase, lease or order of, any health care item or service reimbursable under a governmental payor program. Courts have stated that a financial arrangement may violate the Anti-Kickback Statute if any one purpose of the arrangement is to encourage patient referrals or other federal health care program business, regardless of whether there are other legitimate purposes for the arrangement. The definition of remuneration has been broadly interpreted to include anything of value, including gifts, discounts, credit arrangements, payments of cash, consulting fees, waivers of co-payments, ownership interests, and providing anything at less than its fair market value. Recognizing that the Anti-Kickback Statute is broad and

## **Table of Contents**

may technically prohibit many innocuous or beneficial arrangements within the health care industry, the U.S. Department of Health and Human Services issued a series of regulatory safe harbors. These safe harbor regulations set forth certain provisions, which, if met, will assure health care providers and other parties that they will not be prosecuted under the federal Anti-Kickback Statute. Although full compliance with these provisions ensures against prosecution under the federal Anti-Kickback Statute, the failure of a transaction or arrangement to fit within a specific safe harbor does not necessarily mean that the transaction or arrangement is illegal or that prosecution under the federal Anti-Kickback Statute will be pursued. Penalties for federal anti-kickback violations are severe, and include imprisonment, criminal fines, civil money penalties, and exclusion from participation in federal health care programs. Many states also have anti-kickback statutes, some of which may apply to items or services reimbursed by any third-party payor, including commercial insurers.

Legislation defining two new federal crimes related to health care were recently enacted: health care fraud and false statements relating to health care matters. The health care fraud statute prohibits knowingly and willfully executing a scheme to defraud any health care benefit program, including private payors. A violation of this statute is a felony and may result in fines, imprisonment, or exclusion from governmental payor programs such as the Medicare and Medicaid programs. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact, or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for health care benefits, items, or services. A violation of this statute is a felony and may result in fines, imprisonment, or exclusion from governmental payor programs.

Finally, another development affecting the health care industry is the increased enforcement of the federal False Claims Act and, in particular, actions brought pursuant to the False Claims Act's whistleblower or qui tam provisions. The False Claims Act imposes liability on any person or entity that, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment by a federal governmental payor program. The qui tam provisions of the False Claims Act allow a private individual to bring actions on behalf of the federal government alleging that the defendant has defrauded the federal government by submitting a false claim to the federal government and permit such individuals to share in any amounts paid by the entity to the government in fines or settlement. When an entity is determined to have violated the False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties ranging from \$5,500 to \$11,000 for each false claim.

In addition, various states have enacted false claim laws analogous to the federal False Claims Act, although many of these state laws apply where a claim is submitted to any third-party payor and not merely a governmental payor program.

In Europe various countries have adopted anti-bribery laws providing for severe consequences, in the form of criminal penalties and/or significant fines, for individuals and/or companies committing a bribery offence. Violations of these anti-bribery laws, or allegations of such violations, could have a negative impact on our business, results of operations and reputation. For instance, in the United Kingdom, under the Bribery Act 2010, which went into effect in July 2011, a bribery occurs when a person offers, gives or promises to give a financial or other advantage to induce or reward another individual to improperly perform certain functions or activities, including any function of a public nature. Bribery of foreign public officials also falls within the scope of the Bribery Act 2010. Under the new regime, an individual found in violation of the Bribery Act 2010, faces imprisonment of up to 10 years. In addition, the individual can be subject to an unlimited fine, as can commercial organizations for failure to prevent bribery.

### ***Physician Referral Prohibitions***

Under a federal law directed at self-referral, commonly known as the Stark Law, there are prohibitions, with certain exceptions, on referrals for certain designated health services, including laboratory services, that are covered by the Medicare and Medicaid programs by physicians who personally, or through a family member, have an investment or ownership interest in, or a compensation arrangement with, an entity performing the tests. The prohibition also extends to payment for any testing referred in violation of the Stark Law. A person who



## **Table of Contents**

engages in a scheme to circumvent the Stark Law's referral prohibition may be fined up to \$100,000 for each such arrangement or scheme. In addition, any person who presents or causes to be presented a claim to the Medicare or Medicaid programs in violation of the Stark Law is subject to civil monetary penalties of up to \$15,000 per bill submission, an assessment of up to three times the amount claimed and possible exclusion from participation in federal governmental payor programs. Bills submitted in violation of the Stark Law may not be paid by Medicare or Medicaid, and any person collecting any amounts with respect to any such prohibited bill is obligated to refund such amounts. Many states have comparable laws that are not limited to Medicare and Medicaid referrals.

### ***Corporate Practice of Medicine***

Numerous states have enacted laws prohibiting business corporations, such as us, from practicing medicine and employing or engaging physicians to practice medicine, generally referred to as the prohibition against the corporate practice of medicine. These laws are designed to prevent interference in the medical decision-making process by anyone who is not a licensed physician. For example, California's Medical Board has indicated that determining what diagnostic tests are appropriate for a particular condition and taking responsibility for the ultimate overall care of the patient, including providing treatment options available to the patient, would constitute the unlicensed practice of medicine if performed by an unlicensed person. Violation of these corporate practice of medicine laws may result in civil or criminal fines, as well as sanctions imposed against us and/or the professional through licensure proceedings. Typically such laws are only applicable to entities that have a physical presence in the state.

### ***Other Regulatory Requirements***

Our laboratory is subject to federal, state and local regulations relating to the handling and disposal of regulated medical waste, hazardous waste and biohazardous waste, including chemical, biological agents and compounds, blood and bone marrow samples, and other human tissue. Typically, we use outside vendors who are contractually obligated to comply with applicable laws and regulations to dispose of such waste. These vendors are licensed or otherwise qualified to handle and dispose of such waste.

The U.S. Occupational Safety and Health Administration has established extensive requirements relating to workplace safety for health care employers, including requirements to develop and implement programs to protect workers from exposure to blood-borne pathogens by preventing or minimizing any exposure through needle stick or similar penetrating injuries.

## **Segment, Revenue and Geographical Information**

We operate in one reportable business segment and derive revenue from multiple countries, with 85.8%, 83.5%, and 89.1% of our total revenue coming from the United States in fiscal years 2014, 2013 and 2012, respectively. In 2014, we generated total revenue of \$61.1 million from the sale of our products, compared to \$29.0 million in 2013 and \$10.6 million in 2012.

In January 2011, we announced a pilot alliance with Novartis as our first biopharmaceutical relationship. This alliance has continued to expand and Novartis has accounted for more than 10% of our revenues in each of the years ended December 31, 2014, 2013, and 2012.

## **Employees**

As of January 31, 2015, we had 293 full-time employees, with 254 in technology, research and development, business development and laboratory and commercial operations, and 39 in general and administrative functions. We had 232 full-time employees in our Cambridge, Massachusetts facility, and 61 of

---

## **Table of Contents**

our full-time employees work remotely. None of our employees is represented by a labor union with respect to his or her employment with us.

### **Research and Development Expenses**

Research and development expenses increased to \$30.6 million for the year ended December 31, 2014 from \$24.9 million for the year ended December 31, 2013. The increase was primarily due to a \$4.5 million increase in employee and contractor-related expenses, a \$1.4 million increase in technology-related support and maintenance, a \$0.2 million increase in facilities, partially offset by a \$0.3 million decrease in clinical trials expense and a \$0.1 million decrease in research-related lab supplies and materials.

Research and development expenses increased to \$24.9 million for the year ended December 31, 2013 from \$14.8 million for the year ended December 31, 2012. The increase was primarily due to a \$4.7 million increase in employee and contractor-related expenses, including a \$0.7 million increase in stock-based compensation, a \$2.2 million increase in technology investments related to data management, FoundationOne report design and functionality, and customer interface development, a \$0.8 million increase in facilities, a \$1.2 million increase in clinical trial expenses, and a \$0.5 million increase in overhead allocations and other expenses.

### **Where You Can Find More Information**

Our website address is [www.foundationmedicine.com](http://www.foundationmedicine.com). Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, including exhibits, proxy and information statements and amendments to those reports filed or furnished pursuant to Sections 13(a), 14, and 15(d) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, are available through the Investors portion of our website free of charge as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. Information on our website is not part of this Annual Report on Form 10-K or any of our other securities filings unless specifically incorporated herein by reference. The public may read and copy these materials at the SEC's Public Reference Room at 100 F Street, NE, Washington, DC 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. In addition, our filings with the SEC may be accessed through the SEC's Interactive Data Electronic Applications system at <http://www.sec.gov>. All statements made in any of our securities filings, including all forward-looking statements or information, are made as of the date of the document in which the statement is included, and we do not assume or undertake any obligation to update any of those statements or documents unless we are required to do so by law.

## **ITEM 1A. RISK FACTORS**

*The following risks and uncertainties, together with all other information in this Annual Report, including our consolidated financial statements and related notes, should be considered carefully. Any of the risk factors we describe below could adversely affect our business, financial condition or results of operations, and could cause the market price of our common stock to fluctuate or decline.*

### **Risks Relating to Our Business and Strategy**

*We may not be able to generate sufficient revenue from FoundationOne, FoundationOne Heme, or our relationships with our biopharmaceutical partners to achieve and maintain profitability.*

We believe our commercial success is dependent upon our ability to successfully market and sell our first molecular information products, FoundationOne for solid tumors and FoundationOne Heme for blood-based cancers, or hematologic malignancies, to physicians in clinical practice, to continue to expand our current relationships and develop new relationships with biopharmaceutical partners, and to develop and commercialize

## **Table of Contents**

new molecular information products. The demand for FoundationOne and FoundationOne Heme may decrease or may not continue to increase at historical rates for a number of reasons. In addition, FoundationOne and FoundationOne Heme only have one coverage decision from a commercial third-party payor and do not yet have coverage contracts with or coverage decisions from other commercial third-party payors or government payors, including Medicare. Certain other commercial third-party payors have declined to reimburse FoundationOne or FoundationOne Heme because they have designated our products as experimental and investigational. The experimental and investigational designation is customarily assigned to a product or service by a third-party payor pending the development of clinical information deemed sufficient by a third-party-payor to support a positive coverage decision. During this assessment period our products do not have the benefit of a positive coverage decision or a coverage contract from these third-party payors, resulting, in the aggregate, in a material loss of revenue to us. We have experienced early revenue growth from the sale of each of FoundationOne and FoundationOne Heme to physicians, principally since their formal commercial launches in June 2012 and December 2013, respectively. We may not be able to continue revenue growth or maintain existing revenue levels.

Our biopharmaceutical partners may decide to decrease or discontinue their use of our molecular information platform due to changes in research and product development plans, failures in their clinical trials, financial constraints, or utilization of internal molecular testing resources or molecular tests performed by other parties, which are circumstances outside of our control. In addition to reducing our revenue, this may reduce our exposure to early stage research that facilitates the incorporation of newly developed information about cancer into our molecular information platform, FoundationOne and FoundationOne Heme.

We are currently not profitable. Even if we succeed in increasing adoption of FoundationOne and FoundationOne Heme by physicians, obtaining additional coverage decisions from commercial third-party and government payors, maintaining and creating relationships with our existing and new biopharmaceutical partners and developing and commercializing additional molecular information products, we may not be able to generate sufficient revenue to achieve profitability.

### ***FoundationOne and FoundationOne Heme may never achieve significant commercial market acceptance.***

FoundationOne and FoundationOne Heme may never gain significant acceptance in the marketplace and, therefore, may never generate substantial revenue or profits for us. Our ability to achieve commercial market acceptance for FoundationOne and FoundationOne Heme will depend on several factors, including:

our ability to convince the medical community of the clinical utility of our products and their potential advantages over existing molecular tests;

the willingness of physicians and patients to utilize our products; and

the agreement by commercial third-party payors and government payors to reimburse our products, the scope and amount of which will affect patients' willingness or ability to pay for our products and likely heavily influence physicians' decisions to recommend our products.

In addition, physicians may rely on guidelines issued by industry groups, such as the National Comprehensive Cancer Network, medical societies, such as the College of American Pathologists, or other key oncology-related organizations before utilizing any diagnostic test. Although we have a number of company-sponsored clinical trials and clinical trials sponsored by individual physicians, or investigator-initiated clinical trials, underway to demonstrate the clinical utility of each of FoundationOne and FoundationOne Heme, they are not yet, and may never be, listed in any such guidelines.

We believe that the successful completion of clinical trials, publication of scientific and medical results in peer-reviewed journals, and presentations at leading conferences are critical to the broad adoption of FoundationOne and FoundationOne Heme. Publication in leading medical journals is subject to a peer-review process, and peer reviewers may not consider the results of studies involving FoundationOne and FoundationOne Heme sufficiently novel or worthy of publication.

## **Table of Contents**

The failure to be listed in physician guidelines or the failure of our trials to produce favorable results or to be published in peer-reviewed journals could limit the adoption of our products. Failure to achieve widespread market acceptance of FoundationOne or FoundationOne Heme would materially harm our business, financial condition, and results of operations.

***We rely on a limited number of suppliers or, in some cases, sole suppliers, for some of our laboratory instruments and materials and may not be able to find replacements or immediately transition to alternative suppliers.***

We rely on several sole suppliers, including Illumina, for certain laboratory substances used in the chemical reactions incorporated into our processes, or reagents, sequencers, equipment, and other materials which we use in our laboratory operations. An interruption in our laboratory operations could occur if we encounter delays or difficulties in securing these reagents, sequencers, or other laboratory materials, and if we cannot then obtain an acceptable substitute. Any such interruption could significantly affect our business, financial condition, results of operations, and reputation. We rely on Illumina as the sole supplier of the sequencers and various associated reagents, and as the sole provider of maintenance and repair services for these sequencers. Any disruption in Illumina's operations could impact our supply chain and laboratory operations of our molecular information platform and our ability to conduct our business and generate revenue.

We believe that there are only a few other equipment manufacturers that are currently capable of supplying and servicing the equipment necessary for our laboratory operations, including sequencers and various associated reagents. The use of equipment or materials furnished by these replacement suppliers would require us to alter our laboratory operations. Transitioning to a new supplier would be time consuming and expensive, may result in interruptions in our laboratory operations, would likely affect the performance specifications of our laboratory operations, and would require that we revalidate FoundationOne and FoundationOne Heme. There can be no assurance that we will be able to secure alternative equipment, reagents, and other materials, and bring such equipment, reagents, and materials on line and revalidate them without experiencing interruptions in our workflow. In the case of an alternative supplier for Illumina, there can be no assurance that replacement sequencers and various associated reagents will be available or will meet our quality control and performance requirements for our laboratory operations. If we should encounter delays or difficulties in securing, reconfiguring, or revalidating the equipment and reagents we require for our products, our business, financial condition, results of operations and reputation could be adversely affected.

***If our sole laboratory facility becomes damaged or inoperable, if we are required to vacate our laboratory facility, or if our construction of additional laboratory space in our headquarters is delayed or never completed, our ability to conduct our genomic analyses and pursue our research and development efforts or our companion diagnostics partnerships may be jeopardized.***

We derive substantially all of our revenue from tests conducted at a single laboratory facility located in Cambridge, Massachusetts. Our facility and equipment could be harmed or rendered inoperable by natural or man-made disasters, including war, fire, earthquake, power loss, communications failure, or terrorism, which may render it difficult or impossible for us to operate our molecular information platform for some period of time. The inability to perform our molecular tests or to reduce the backlog of analyses that could develop if our facility is inoperable, for even a short period of time, may result in the loss of customers or harm to our reputation, and we may be unable to regain those customers or repair our reputation in the future. Furthermore, our facility and the equipment we use to perform our research and development work could be unavailable or costly and time-consuming to repair or replace. It would be difficult, time-consuming, and expensive to rebuild our facility or license or transfer our proprietary technology to a third-party, particularly in light of the licensure and accreditation requirements for a commercial laboratory like ours. Even in the unlikely event we are able to find a third party with such qualifications to enable us to conduct our molecular tests, we may be unable to negotiate commercially reasonable terms.

We are building additional laboratory space at our corporate headquarters to support our development of companion diagnostic tests and new product development, including the development of a circulating tumor

## **Table of Contents**

DNA assay. If we are delayed in building the new laboratory for companion diagnostic tests, or if we never complete construction and validation, this delay could result in our inability to meet agreed upon timelines with certain of our biopharmaceutical partners, which could cause us to breach our agreement or result in harm to our business and reputation. In addition, if we are delayed in building additional laboratory space for new product development, or if we never complete construction and validation, this delay could impact our ability to develop and launch new products such as a circulating tumor DNA assay, which could adversely affect our business, financial condition and results of operations.

We carry insurance for damage to our property and laboratory and the disruption of our business, but this insurance may not cover all of the risks associated with damage or disruption to our business, may not provide coverage in amounts sufficient to cover our potential losses, and may not continue to be available to us on acceptable terms, if at all.

***If we are unable to support demand for FoundationOne, FoundationOne Heme and our future products, including ensuring that we have adequate capacity to meet increased demand, or we are unable to successfully manage the evolution of our molecular information platform, our business could suffer.***

As our volume grows, we will need to continue to increase our workflow capacity for sample intake, customer service, billing and general process improvements, expand our internal quality assurance program, and extend our platform to support comprehensive genomic analyses at a larger scale within expected turnaround times. We will need additional certified laboratory scientists and other scientific and technical personnel to process higher volumes of our molecular information products. Portions of our process are not automated and will require additional personnel to scale. We will also need to purchase additional equipment, some of which can take several months or more to procure, setup, and validate, and increase our software and computing capacity to meet increased demand. There is no assurance that any of these increases in scale, expansion of personnel, equipment, software and computing capacities, or process enhancements will be successfully implemented, or that we will have adequate space in our laboratory facility to accommodate such required expansion.

As additional products are commercialized, we will need to incorporate new equipment, implement new technology systems and laboratory processes, and hire new personnel with different qualifications. For example, we are building additional laboratory space to allow us to further develop our circulating tumor DNA assay product. Failure to manage this growth or transition could result in turnaround time delays, higher product costs, declining product quality, deteriorating customer service, and slower responses to competitive challenges. A failure in any one of these areas could make it difficult for us to meet market expectations for our products, and could damage our reputation and the prospects for our business.

***New product development involves a lengthy and complex process, and we may be unable to successfully commercialize FoundationOne Heme or any other products we may develop on a timely basis, or at all.***

FoundationOne Heme, which we launched in December 2013 for hematologic cancers, including leukemia, lymphoma and myeloma, as well as pediatric cancers and many sarcomas, will take time to successfully commercialize. There can be no assurance that FoundationOne Heme will be successful in the evaluation of blood-based cancers for a variety of technical and market reasons. Our other new molecular information products, including a circulating tumor DNA assay, which are in various stages of early development, will take time to develop and commercialize, if we are able to commercialize them at all. There can be no assurance that our new products will be capable of reliably identifying relevant genomic alterations in various forms of cancer. Before we can commercialize any new products, we will need to expend significant funds in order to:

conduct substantial research and development, including validation studies and potentially clinical trials;

build additional laboratory space for new products, including a circulating tumor DNA assay;

further develop and scale our laboratory processes to accommodate different products; and

## **Table of Contents**

further develop and scale our infrastructure to be able to analyze increasingly large amounts of data.

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

failure of the product to perform as expected at the research or development stage;

lack of validation data; or

failure to demonstrate the clinical utility of the product.

As we develop products, we will have to make significant investments in product development, marketing, and selling resources. In addition, competitors may develop and commercialize competing products faster than we are able to do so.

***If we cannot compete successfully with our competitors, we may be unable to increase or sustain our revenue or achieve and sustain profitability.***

Personalized genomic diagnostics is a new area of science, and we face competition from companies that offer products or have conducted research to profile genes and gene expression in various cancers. Our principal competition comes from diagnostic companies that offer molecular diagnostic tests that capture only a single-marker or test panels that capture a limited number of the most well-known gene alterations, which are also known as hotspot panel tests. In addition, academic research centers, diagnostic companies and NGS platform developers are offering or developing NGS-based testing.

Our competitors include laboratory companies such as Bio-Reference Laboratories, Inc., Laboratory Corporation of America Holdings, Quest Diagnostics Incorporated, Molecular Health, Caris Life Sciences, Guardant Health, Paradigm, NeoGenomics Laboratories, as well as companies such as Abbott Laboratories, Qiagen N.V., and Sequenom, Inc. that manufacture or may manufacture diagnostic testing kits. In addition, companies such as Genomic Health, Inc. and Myriad Genetics, Inc. have well-established commercial organizations that sell molecular diagnostic tests for cancer to physicians and may develop tests which compete with FoundationOne or FoundationOne Heme.

Many hospitals and academic medical centers may also seek to perform the type of molecular testing we perform at their own facilities. As such, our competition may include entities such as the MD Anderson Cancer Center, MSKCC, University of Michigan, Baylor Medical Genetics Laboratories, Washington University in St. Louis, University of Washington, and other academic hospitals and research centers.

In addition, Illumina, Thermo Fisher, and other companies market NGS platforms that are being sold directly to research centers, biopharmaceutical companies, and clinical laboratories. While these platforms have been largely utilized in research and development settings or testing for non-cancer conditions, each of these companies has launched and will likely continue to commercialize products for focused application in the clinical oncology market. We believe diagnostic platform providers will seek to place sequencing machines in laboratories and to develop NGS-based laboratory-developed tests, or LDTs, for use in clinical oncology, including by seeking to decrease the cost, size, and complexity of their platforms. In addition, Illumina has received FDA-approval for a diagnostic kit for clinical use outside of oncology which is sold to clients who have purchased its platforms. We believe Illumina and other diagnostic platform providers may develop additional FDA-approved diagnostic kits for clinical use by clients who have purchased their platforms, potentially including for these clients to identify genetic alternations in samples of solid tumors or blood-based cancers. Also, many private companies are developing information technology-based tools to support the integration of NGS testing into the clinical setting. The successful development and marketing of these products by diagnostic platform providers could enable some of our potential customers to perform clinical-grade, comprehensive genomic analysis, which could have a material adverse effect on our business and financial condition. These companies may also use their patent portfolios, developed in connection with developing their tests, to allege that

## **Table of Contents**

FoundationOne or FoundationOne Heme infringes their patents, and we could face litigation with respect to such allegations and the validity of such patents.

In addition, because our proprietary molecular information platform consists largely of trade-secret protected technology and know-how and has only limited patent protection, new and existing companies could seek to develop molecular tests that compete with ours. These competitors could have technological, financial, and market access advantages that are not currently available to us.

***The molecular diagnostic industry is subject to rapidly changing technology which could make our molecular information platform, FoundationOne, FoundationOne Heme, and other products we develop obsolete.***

Our industry is characterized by rapid technological changes, frequent new product introductions and enhancements, and evolving industry standards, all of which could make our molecular information platform, FoundationOne, FoundationOne Heme, and the other molecular information products we are developing obsolete. Our future success will depend on our ability to keep pace with the evolving needs of our customers on a timely and cost-effective basis and to pursue new market opportunities that develop as a result of technological and scientific advances. In recent years, there have been numerous advances in technologies relating to the diagnosis and treatment of cancer. There have also been advances in methods used to analyze very large amounts of genomic information. We must continuously enhance our molecular information platform and develop new products to keep pace with evolving standards of care. If we do not update our molecular information platform to reflect new scientific knowledge about cancer biology, information about new cancer therapies, or relevant clinical trials, our molecular information platform could become obsolete and sales of FoundationOne, FoundationOne Heme, and any new products could decline, which would have a material adverse effect on our business, financial condition, and results of operations.

***If our products do not perform as expected, our operating results, reputation, and business will suffer.***

Our success depends on the market's confidence that we can provide reliable, high-quality molecular information products. There is no guarantee that the accuracy and reproducibility we have demonstrated to date will continue, particularly for clinical samples, as our test volume increases. We believe that our customers are likely to be particularly sensitive to product defects and errors, including if our products fail to detect genomic alterations with high accuracy from clinical specimens or if we fail to list, or inaccurately include, certain treatment options and available clinical trials in our test report. As a result, the failure of our products to perform as expected would significantly impair our operating results and our reputation. We may be subject to legal claims arising from any defects or errors.

We refer to the efficiency of our sequencing process as its yield. The sequencing process yields that we achieve depend on the design and operation of our sequencing process, which uses a number of complex and sophisticated biochemical, informatics, optical, and mechanical processes, many of which are highly sensitive to external factors. An operational or technological failure in one of these complex processes or fluctuations in external variables may result in sequencing processing yields that are lower than we anticipate or that vary between sequencing runs. In addition, we are regularly evaluating and refining our sequencing process. These refinements may initially result in unanticipated issues that further reduce our sequencing process yields or increase the variability of our sequencing process yields. Low sequencing process yields, or higher than anticipated variability, referring to yields of variability, increase total sequencing costs and reduce the number of samples we can sequence in a given time period, which can cause variability in our operating results and damage our reputation.

In addition, our FoundationOne and FoundationOne Heme reports match identified genomic alterations with FDA-approved targeted therapies or relevant clinical trials of targeted therapies. If a patient or clinical physician who orders FoundationOne or FoundationOne Heme is unable to obtain, or be reimbursed for the use of, targeted therapies because they are not indicated in the FDA-approved product label for treatment of a patient's cancer,

## **Table of Contents**

the patient is unable to enroll in an identified clinical trial due to the enrollment criteria of the trial, or some other reason, the patient or ordering clinical physician may conclude the FoundationOne or FoundationOne Heme report does not contain actionable information. If physicians do not believe FoundationOne or FoundationOne Heme consistently generates actionable information about their patients' cancers, they may be less likely to order our products in the future, our reputation could be harmed, and our business and results of operations could suffer.

***If we lose the support of key thought leaders, it may be difficult to establish products enabled by our molecular information platform as a standard of care for patients with cancer, which may limit our revenue growth and ability to achieve profitability.***

We have established relationships with leading oncology thought leaders at premier cancer institutions and oncology networks such as the MSKCC, the Vanderbilt-Ingram Cancer Center, and the Taussig Cancer Institute at the Cleveland Clinic. If these key thought leaders determine that our molecular information platform, FoundationOne, FoundationOne Heme, or other products that we develop are not clinically effective, that alternative technologies are more effective, or if they elect to use internally developed products, we would encounter significant difficulty validating our testing platform, driving adoption, or establishing our molecular information platform, FoundationOne, and FoundationOne Heme as a standard of care, which would limit our revenue growth and our ability to achieve profitability.

***If we cannot maintain our current relationships, or enter into new relationships, with biopharmaceutical companies, our product development could be delayed.***

We deploy our molecular information platform to analyze tissue samples provided by biopharmaceutical partners from their clinical trials. We have entered into agreements with biopharmaceutical companies in the cancer field including, for example, Agios Pharmaceuticals, Inc., ARIAD Pharmaceuticals, Inc., Array BioPharma Inc., AstraZeneca UK Limited, Celgene Corporation, Clovis Oncology, Inc., Eisai Co., Ltd., Johnson & Johnson, Novartis, and Sanofi, among others. In each of the years ended December 31, 2014, 2013, and 2012, our alliance with Novartis accounted for more than 10% of our revenue. The revenue attributable to Novartis may also fluctuate in the future, which could have an adverse effect on our financial condition and results of operations. In addition, the termination of this relationship could result in a temporary or permanent loss of revenue to us.

Our success in the future depends in part on our ability to maintain these relationships and to enter into new relationships. This can be difficult due to several factors, including internal and external constraints placed on these organizations, including Novartis, that can limit the number and type of relationships with companies like us that can be considered and consummated; the agreements governing our relationships are generally terminable at will by our biopharmaceutical customers; our biopharmaceutical customers, including Novartis, may be dissatisfied with our products; and continued usage of our products among particular biopharmaceutical customers, including Novartis, may depend on whether the partner obtains positive data in its clinical trials or other administrative factors that are outside our control. Additionally, some of our biopharmaceutical partners have contracted with us to provide testing for large numbers of samples, which could strain our testing capacity and restrict our ability to perform additional tests for other customers. If we fail to maintain these relationships, or enter into new ones, our business could suffer.

In addition, certain biopharmaceutical companies, including those with which we currently have agreements, may choose not to do business with us if our proposed transactions with Roche are consummated, particularly if they are competitors with Roche. If we are unable to continue to grow our business with biopharmaceutical companies, our business and results of operations would be adversely affected.

From time to time, we expect to engage in discussions with biopharmaceutical companies regarding commercial opportunities. There is no assurance that any of these discussions will result in a commercial



---

## **Table of Contents**

agreement, or if an agreement is reached, that the resulting engagement will be successful or that clinical studies conducted as part of the engagement will produce successful outcomes. Speculation in the industry about our existing or potential engagements with biopharmaceutical companies can be a catalyst for adverse speculation about us, our products, and our technology, which can result in harm to our reputation and our business.

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

We anticipate growth in our business operations, including the addition of laboratory space. This future growth could create strain on our organizational, administrative, and operational infrastructure, including laboratory operations, quality control, customer service, and sales force management. We may not be able to maintain the quality or expected turnaround times of our products or satisfy customer demand as it grows. Our ability to manage our growth properly will require us to continue to improve our operational, financial, and managerial controls, as well as our reporting systems and procedures. We plan to implement new enterprise software systems in a number of areas affecting a broad range of business processes and functional areas. The time and resources required to implement these new systems is uncertain, and failure to complete this in a timely and efficient manner could adversely affect our operations.

***We have limited experience in marketing and selling our products, and if we are unable to expand our direct sales and marketing force to adequately address our customers' needs, our business may be adversely affected.***

We have limited experience in marketing and selling FoundationOne, which had its formal commercial launch in June 2012, and FoundationOne Heme, which launched in December 2013. We may not be able to market, sell, or distribute FoundationOne, FoundationOne Heme, or other products we may develop effectively enough to support our planned growth. We sell our products in the United States through our own sales force and outside the United States with the assistance of distribution partners.

Our future sales in the United States will depend in large part on our ability to develop, and substantially expand, our sales force and to increase the scope of our marketing efforts. Our target market of physicians is a large and diverse market. As a result, we believe it is necessary to develop a sales force that includes sales representatives with specific technical backgrounds. We will also need to attract and develop marketing personnel with industry expertise. Competition for such employees is intense. We may not be able to attract and retain personnel or be able to build an efficient and effective sales and marketing force, which could negatively impact sales and market acceptance of our products and limit our revenue growth and potential profitability.

Our expected future growth will impose significant added responsibilities on members of management, including the need to identify, recruit, maintain, and integrate additional employees. Our future financial performance and our ability to commercialize our products and to compete effectively will depend in part on our ability to manage this potential future growth effectively, without compromising quality.

Outside the United States, we enlist distribution partners and in one instance, a local laboratory, to assist with sales, distribution, and customer support. Locating, qualifying, and engaging distribution partners and local laboratories with local industry experience and knowledge will be necessary to effectively market and sell our products outside the United States. We may not be successful in finding, attracting, and retaining distribution partners or laboratories, or we may not be able to enter into such arrangements on favorable terms. Sales practices utilized by our distribution parties that are locally acceptable may not comply with sales practices standards required under United States laws that apply to us, which could create additional compliance risk. If our sales and marketing efforts are not successful outside the United States, we may not achieve significant market acceptance for our products outside the United States, which would materially and adversely impact our business operations.

## **Table of Contents**

***The loss of any member of our senior management team or our inability to attract and retain highly skilled scientists, clinicians, and salespeople could adversely affect our business.***

Our success depends on the skills, experience and performance of key members of our senior management team, including Michael J. Pellini, M.D., our President and Chief Executive Officer. The individual and collective efforts of these employees will be important as we continue to develop our molecular information platform and additional products, and as we expand our commercial activities. The loss or incapacity of existing members of our executive management team could adversely affect our operations if we experience difficulties in hiring qualified successors. Our executive officers have employment agreements; however, the existence of an employment agreement does not guarantee the retention of the executive officer for any period of time. We do not maintain key person insurance on any of our employees.

Our research and development programs and laboratory operations depend on our ability to attract and retain highly skilled scientists and technicians. We may not be able to attract or retain qualified scientists and technicians in the future due to the competition for qualified personnel among life science businesses, particularly in Cambridge, Massachusetts. We also face competition from universities and public and private research institutions in recruiting and retaining highly qualified scientific personnel. We may have difficulties locating, recruiting, or retaining qualified sales people. Recruitment and retention difficulties can limit our ability to support our research and development and sales programs. All of our employees are at will, which means that either we or the employee may terminate their employment at any time.

***If we were sued for product liability or professional liability, we could face substantial liabilities that exceed our resources.***

The marketing, sale, and use of our products could lead to the filing of product liability claims were someone to allege that our products identified inaccurate or incomplete information regarding the genomic alterations of the tumor or malignancy analyzed, reported inaccurate or incomplete information concerning the available therapies for a certain type of cancer, or otherwise failed to perform as designed. We may also be subject to liability for errors in, a misunderstanding of, or inappropriate reliance upon the information we provide in the ordinary course of our business activities. A product liability or professional liability claim could result in substantial damages and be costly and time-consuming for us to defend.

We maintain product and professional liability insurance, but this insurance may not fully protect us from the financial impact of defending against product liability or professional liability claims. Any product liability or professional 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 damage our reputation or cause current clinical or biopharmaceutical partners to terminate existing agreements and potential clinical or biopharmaceutical partners to seek other partners, any of which could impact our results of operations.

***We depend on our information technology systems, and any failure of these systems could harm our business.***

We depend on information technology and telecommunications systems for significant elements of our operations, including our laboratory information management system, our computational biology system, our knowledge management system, our customer reporting, and our ICE 2 portal. We have installed, and expect to expand, a number of enterprise software systems that affect a broad range of business processes and functional areas, including, for example, systems handling human resources, financial controls and reporting, contract management, regulatory compliance, and other infrastructure operations. In addition to the aforementioned business systems, we intend to extend the capabilities of both our preventative and detective security controls by augmenting the monitoring and alerting functions, the network design, and the automatic countermeasure operations of our technical systems. These information technology and telecommunications systems support a variety of functions, including laboratory operations, test validation, sample tracking, quality control, customer service support, billing and reimbursement, research and development activities, scientific and medical curation,

## **Table of Contents**

and general administrative activities. In addition, our third-party billing and collections provider depends upon technology and telecommunications systems provided by outside vendors. Information technology and telecommunications systems are vulnerable to damage from a variety of sources, including telecommunications or network failures, malicious human acts, and natural disasters. Moreover, despite network security and back-up measures, some of our servers are potentially vulnerable to physical or electronic break-ins, computer viruses, and similar disruptive problems. Despite the precautionary measures we have taken to prevent unanticipated problems that could affect our information technology and telecommunications systems, failures or significant downtime of our information technology or telecommunications systems, or those used by our third-party service providers, could prevent us from conducting our comprehensive genomic analyses, preparing and providing reports and data to pathologists and oncologists, billing payors, processing reimbursement appeals, handling patient or physician inquiries, conducting research and development activities, and managing the administrative aspects of our business. Any disruption or loss of information technology or telecommunications systems on which critical aspects of our operations depend could have an adverse effect on our business.

***Security breaches, loss of data, and other disruptions 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 billing and collections provider collect and store sensitive data, including legally protected health information, personally identifiable information, intellectual property, and proprietary business information owned or controlled by ourselves or our customers, payors, and biopharmaceutical partners. 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 also communicate, and facilitate the exchange of, sensitive patient data to customers through our ICE 2 portal. These applications and data encompass a wide variety of business-critical information including research and development information, commercial information, and business and financial information. We face four primary risks relative to protecting this critical information, including: unauthorized access risk; inappropriate disclosure risk; inappropriate modification risk; and the risk of our being unable to adequately monitor our controls over the first three risks.

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, and that of our third-party billing and collections provider, may be vulnerable to attacks by hackers or viruses or breached due to employee error, malfeasance, or other disruptions. Any such breach or interruption could compromise our networks, and the information stored there could be accessed by unauthorized parties, publicly disclosed, lost, or stolen. Any such access, disclosure, or other loss of information could result in governmental investigations, class action legal claims or proceedings, liability under laws that protect the privacy of personal information, such as HIPAA, and regulatory penalties. Although we have implemented security measures and a formal, dedicated enterprise security program to prevent unauthorized access to patient data, the ICE 2 portal, which is currently accessible through our online portal and will, in the future, be accessible through dedicated mobile applications, gives broad access to physicians, at which point we lose ability to control access, and there is no guarantee we absolutely protect our online portal or our mobile applications, from breach. Unauthorized access, loss, or dissemination could also disrupt our operations, including our ability to conduct our analyses, provide test results, bill payors 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 products 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.

The U.S. Office of Civil Rights may impose penalties on a covered entity for a failure to comply with a requirement of HIPAA. Penalties will vary significantly depending on factors such as the date of the violation,

## **Table of Contents**

whether the covered entity knew or should have known of the failure to comply, or whether the covered entity's failure to comply was due to willful neglect. These penalties include civil monetary penalties of \$100 to \$50,000 per violation, up to an annual cap of \$1,500,000. A person who knowingly obtains or discloses individually identifiable health information in violation of HIPAA may face a criminal penalty of up to \$50,000 and up to one year imprisonment. The criminal penalties increase to \$100,000 and up to five years imprisonment if the wrongful conduct involves false pretenses, and to \$250,000 and up to 10 years imprisonment if the wrongful conduct involves the intent to sell, transfer, or use identifiable health information for commercial advantage, personal gain, or malicious harm. The U.S. Department of Justice is responsible for criminal prosecutions under HIPAA. Furthermore, in the event of a breach as defined by HIPAA, the covered entity has specific reporting requirements under HIPAA regulations. In the event of a significant breach, the reporting requirements could include notification to the general public.

In addition, the interpretation and application of consumer, health-related, and data protection laws in the United States, Europe, and elsewhere are often uncertain, contradictory, and in flux. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices. If so, this could result in government-imposed fines or orders requiring that we change our practices, which could adversely affect our business. In addition, these privacy regulations may differ from country to country, and may vary based on whether testing is performed in the United States or in the local country. Our operations or business practices may not comply with these regulations in each country, or complying with these various laws could cause us to incur substantial costs or require us to change our business practices and compliance procedures in a manner adverse to our business.

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

Our business strategy may, from time to time, include pursuing acquisitions of businesses and assets. We also may pursue strategic alliances and joint ventures that leverage our proprietary molecular information platform and industry experience to expand our offerings or distribution. We have no experience with acquiring other companies and limited experience with forming strategic partnerships. Negotiating these transactions can be time consuming, difficult and expensive, and our ability to close these transactions may be subject to third-party approvals, such as governmental authorities, which are beyond our control. Consequently, we may not be able to complete such transactions on favorable terms and we can make no assurance that these transactions, once undertaken and announced, will close.

An acquisition or investment may result in unforeseen operating difficulties and expenditures. In particular, we may not be able to integrate the businesses, products, personnel, or operations of the acquired companies, particularly if key personnel of the acquired business choose not to work for us, we could assume unknown or contingent liabilities and we may have difficulty retaining the customers of any acquired business. Acquisitions also could result in the incurrence of debt, contingent liabilities, or future write-offs of intangible assets or goodwill, any of which could have a material adverse effect on our financial condition, results of operations, and cash flows. Integration of an acquired company also may disrupt ongoing operations and require management resources that we would otherwise focus on developing our existing business. As a result, we cannot be assured that the anticipated benefits of any acquisition, technology license, strategic alliance, or joint venture would be realized or that we would not be exposed to unknown liabilities. These challenges related to acquisitions or investments could adversely affect our business, results of operations, and financial condition.

To finance any acquisitions or joint ventures, we may choose to issue shares of our common stock as consideration, which would dilute the ownership of our stockholders. Additional funds may not be available on terms that are favorable to us, or at all. If the price of our common stock is low or volatile, we may not be able to acquire other companies or fund a joint venture project using our stock as consideration.

## **Table of Contents**

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

We currently have limited international operations, but our business strategy incorporates potentially significant international expansion. We currently rely on distributor relationships to conduct physician and patient association outreach activities and to expand payor relationships outside of the United States. Doing business internationally involves a number of risks, including:

multiple, conflicting, and changing laws and regulations such as privacy regulations, tax laws, export and import restrictions, employment laws, regulatory requirements, and other governmental approvals, permits, and licenses;

failure by us or our distributors to obtain regulatory approvals for the use of our products in various countries;

additional, potentially relevant third-party patent rights;

complexities and difficulties in obtaining protection and enforcing our intellectual property;

difficulties in staffing and managing foreign operations;

complexities associated with managing multiple payor reimbursement regimes, government payors, or patient self-pay systems;

logistics and regulations associated with shipping tissue samples, including infrastructure conditions and transportation delays;

limits in our ability to penetrate international markets if we are not able to conduct our molecular tests locally;

financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our products, 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 sales and distributors' activities that may fall within the purview of the U.S. Foreign Corrupt Practices Act, or FCPA, its books and records provisions, or its anti-bribery provisions.

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

### ***We could be adversely affected by violations of the FCPA and other worldwide anti-bribery laws.***

International customers have ordered, or may, in the future, order FoundationOne or FoundationOne Heme, and we are, therefore, subject to the FCPA, which prohibits companies and their intermediaries from making payments in violation of law to non-U.S. government officials for the purpose of obtaining or retaining business or securing any other improper advantage. Our current reliance on third-party distributors to sell

## Edgar Filing: Foundation Medicine, Inc. - Form 10-K

FoundationOne and FoundationOne Heme internationally demands a high degree of vigilance in maintaining our policy against participation in corrupt activity, because these distributors could be deemed to be our agents, and we could be held responsible for their actions. Other U.S. companies in the medical device and pharmaceutical field have faced criminal penalties under the FCPA for allowing their agents to deviate from appropriate practices in doing business with these individuals. We are also subject to similar anti-bribery laws in the jurisdictions in which we operate, including the United Kingdom's Bribery Act of 2010, which went into effect in the third quarter of 2011, which also prohibits commercial bribery and makes it a crime for companies to fail to prevent bribery. These laws are complex and far-reaching in nature, and, as a result, we cannot assure you that we would not be required in the future to alter

## **Table of Contents**

one or more of our practices to be in compliance with these laws, any changes in these laws, or the interpretation thereof. Any violations of these laws, or allegations of such violations, could disrupt our operations, involve significant management distraction, involve significant costs and expenses, including legal fees, and could result in a material adverse effect on our business, prospects, financial condition, or results of operations. We could also suffer severe penalties, including criminal and civil penalties, disgorgement, and other remedial measures.

***Our employees, principal investigators, consultants, and commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements, and insider trading.***

We are exposed to the risk of fraud or other misconduct by our employees, principal investigators, consultants, and commercial partners. Misconduct by these parties could include intentional failures to comply with the regulations of the FDA and non-U.S. regulators, comply with healthcare fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately, or disclose unauthorized activities to us. In particular, sales, marketing, and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing, and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs, and other business arrangements. Such misconduct could also involve the improper use of information obtained in the course of clinical studies, which could result in regulatory sanctions and cause serious harm to our reputation. We currently have a code of conduct applicable to all of our employees, but it is not always possible to identify and deter employee misconduct, and our code of conduct and the other precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses, or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of significant fines or other sanctions, which could have a significant impact on our business. Whether or not we are successful in defending against such actions or investigations, we could incur substantial costs, including legal fees, and divert the attention of management in defending ourselves against any of these claims or investigations.

***Economic or business instability may have a negative impact on our business.***

Continuing concerns over United States health care reform legislation, geopolitical issues, the availability and cost of credit, and government stimulus programs in the United States and other countries have contributed to volatility for the global economy. If the economic climate does not improve, our business, including our access to patient samples and the addressable market for molecular information products that we may successfully develop, as well as the financial condition of our suppliers and our commercial third-party payors, could be adversely affected, resulting in a negative impact on our business, financial condition, and results of operations. Additionally, the instability has resulted in diminished liquidity and credit availability in the market, which could impair our ability to access capital if required or adversely affect our operations. In the event of further economic slowdown, investment in biopharmaceutical research and development may also experience a corresponding slowdown.

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

Our activities currently require the use of hazardous chemicals. 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, and any liability could exceed our resources or any applicable insurance coverage we may have. Additionally, we are subject on an ongoing basis to federal, state, and local laws and regulations governing the use, storage, handling, and disposal of these materials and specified waste products. The cost of compliance with these laws and regulations may become significant, and could negatively affect our operating results.

## **Table of Contents**

***Our income tax provision and other tax liabilities may be insufficient if taxing authorities are successful in asserting tax positions that are contrary to our position.***

Significant judgment is required by us to determine our provision for income taxes and our liabilities for taxes. From time to time, we are reviewed or audited by various federal, state, local and foreign authorities regarding income tax matters. Although we believe our judgment in determining the appropriate tax treatment is supportable and in accordance with relevant guidance, it is possible that the final tax authority may take a tax position that is different than that which is reflected in our income tax provision or different than the taxes we previously paid. Such differences could have a material adverse effect on our income tax provision or benefit or otherwise require the payment of additional taxes and, consequently, have a material adverse effect on our results of operations, financial position, and/or cash flows for such period.

## **Reimbursement and Regulatory Risks Relating to Our Business**

***If commercial third-party payors or government payors fail to provide coverage or adequate reimbursement, or if there is a decrease in the amount of reimbursement for FoundationOne, FoundationOne Heme or future products we develop, if any, our revenue and prospects for profitability would be harmed.***

In both domestic and many international markets, sales of FoundationOne, FoundationOne Heme or any future molecular information products we develop will depend, in large part, upon the availability of reimbursement from third-party payors. These third-party payors include government healthcare programs such as Medicare, managed care providers, ACOs, private health insurers, and other organizations. In particular, we believe that obtaining a positive national coverage decision and favorable reimbursement rate from CMS, for FoundationOne and FoundationOne Heme will be a necessary element in achieving material commercial success. Physicians and patients may not order FoundationOne and FoundationOne Heme unless commercial third-party payors and government payors pay for all, or a substantial portion, of the list price, and certain commercial third-party payors may not agree to reimburse FoundationOne and FoundationOne Heme if CMS or our local MAC does not issue a positive coverage decision.

There is currently no national coverage decision that determines whether and how our test is covered by Medicare. In the absence of a national coverage determination, local MACs, that administer the Medicare program in various regions have some discretion in determining coverage and, therefore, payment for tests. At the time FoundationOne was launched in 2012, our local MAC initially requested that we not submit claims for services provided to Medicare patients while the MAC assessed the appropriate coding, coverage, and payment for FoundationOne as a whole. To accommodate this request, we deferred the submission of claims until November 2013, when we commenced the process of submitting claims to National Government Services, our current MAC, for FoundationOne and FoundationOne Heme tests for Medicare patients with dates of service on or after November 1, 2013.

We are submitting claims to National Government Services using a miscellaneous CPT code. When submitting claims for services or procedures that do not have specific CPT codes, providers may submit those claims using a CPT code, referred to as the miscellaneous CPT code, to provide the means of reporting and tracking services and procedures until a more specific CPT code is established. We are not submitting claims using stacked CPT codes in the manner currently used in submitting claims to non-governmental, commercial third-party payors. The use of a miscellaneous CPT code may decrease the likelihood of reimbursement given that a miscellaneous CPT code is a single CPT code that does not represent an identified service or procedure. We have not received any payments for FoundationOne or FoundationOne Heme provided to patients covered by Medicare to date. If CMS does not issue a positive national coverage determination, or National Government Services does not issue a local coverage determination, with respect to FoundationOne and/or FoundationOne Heme, or if National Government Services denies reimbursement of FoundationOne and/or FoundationOne Heme, withdraws its coverage policies after reimbursement is obtained, reviews and adjusts the rate of reimbursement, or stops paying for FoundationOne and/or FoundationOne Heme altogether, our revenue and results of operations would be adversely affected.



## **Table of Contents**

We have not received payments from Medicare for the claims submitted. The response to date of National Government Services to the submission of our claims has been to deny payment, and we have decided to appeal those claims. The response to those appeals is uncertain. National Government Services may deny paying a claim pending a coverage or payment determination. Even if we do receive payments from National Government Services on these appeals, the reimbursement rate may be lower than we expect, and if such rate is then adopted by commercial third-party payors, it would have an adverse effect on our revenues and results of operations. In addition, National Government Services may issue a non-coverage determination for FoundationOne and/or FoundationOne Heme that would apply to future claims. Although we would have the opportunity to submit additional materials to National Government Services in support of a positive coverage determination for FoundationOne and/or FoundationOne Heme, there is no guarantee that National Government Services would provide us with a positive coverage decision or reverse a non-coverage decision that it already issued.

Commercial third-party payors and government payors are increasingly attempting to contain healthcare costs by demanding price discounts or rebates and limiting both coverage on which diagnostic products they will pay for and the amounts that they will pay for new molecular diagnostic products. Because of the cost-containment trends, commercial third-party payors and government payors that currently provide reimbursement for, or in the future cover, FoundationOne and/or FoundationOne Heme may reduce, suspend, revoke, or discontinue payments or coverage at any time, including those payors that designate FoundationOne and/or FoundationOne Heme as experimental and investigational. The percentage of submitted claims that are ultimately paid, the length of time to receive payment on claims, and the average reimbursement of those paid claims, is likely to vary from period to period.

As a result, there is significant uncertainty surrounding whether the use of products that incorporate new technology, such as FoundationOne and FoundationOne Heme, will be eligible for coverage by commercial third-party payors and government payors or, if eligible for coverage, what the reimbursement rates will be for those products. The fact that a diagnostic product has been approved for reimbursement in the past, for any particular indication or in any particular jurisdiction, does not guarantee that such a diagnostic product will remain approved for reimbursement or that similar or additional diagnostic products will be approved in the future. We have had claims for reimbursement denied by certain commercial third-party payors, in some cases because they have designated FoundationOne and FoundationOne Heme as experimental and investigational. Reimbursement of NGS-based cancer products by commercial third-party payors and government payors may depend on a number of factors, including a payor's determination that FoundationOne, FoundationOne Heme, or products enabled by our molecular information platform are:

not experimental or investigational;

medically necessary;

appropriate for the specific patient;

cost effective;

supported by peer-reviewed publications;

included in clinical practice guidelines; and

supported by clinical utility studies demonstrating improved outcomes.

As a result, our efforts to receive reimbursement on behalf of patients will take a substantial amount of time, and various commercial third-party payors and government payors may never cover or provide adequate payment for FoundationOne, FoundationOne Heme, or future molecular information products we develop. Our strategy to achieve broad reimbursement coverage is focused on demonstrating the clinical utility and economic benefits of FoundationOne and FoundationOne Heme, including engagement with key members of the oncology community and increasing physician demand, but there is no assurance that we will succeed in any of these areas or that, even if we do succeed, we will receive favorable reimbursement decisions. If adequate third-party reimbursement is unavailable, we may not be able to maintain price levels sufficient

to realize an appropriate return on

## **Table of Contents**

investment in product development. Furthermore, if a commercial third-party payor or government payor denies coverage, it may be difficult for us to collect from the patient, and we may not be successful.

In addition, we are currently considered a non-contracted provider by all but one commercial third-party payor because we have not entered into specific contracts to provide FoundationOne and/or FoundationOne Heme to their covered patients, and as a result we take on primary responsibility for obtaining reimbursement on behalf of patients. If we were to become a contracted provider with additional commercial third-party payors in the future, the amount of overall reimbursement we receive may decrease if we were to be reimbursed less money per test performed at a contracted rate than at a non-contracted rate, which could have a negative impact on our revenue. Further, we may be unable to collect payments from patients beyond that which is paid by their coverage, and will experience lost revenue as a result.

The United States and foreign governments continue to propose and pass legislation designed to reduce the cost of healthcare. For example, in some foreign markets, the government controls the pricing of many healthcare products. We expect that there will continue to be federal and state proposals to implement governmental controls or impose healthcare requirements. In addition, the Medicare program and increasing emphasis on managed or accountable care in the United States will continue to put pressure on product pricing. Cost control initiatives could decrease the price that we would receive for any products in the future, which would limit our revenue and profitability.

***Changes in the way that the FDA regulates products developed, manufactured, validated, and performed by laboratories like ours could result in additional expense in offering our products and products that we may develop in the future or even possible delay or suspension of such products.***

While the FDA currently exercises its enforcement discretion for laboratory developed tests, or LDTs, by not requiring compliance with its regulations, on July 31, 2014, the FDA announced that it intends to change this policy. The FDA previously announced in June 2010 that it intended to no longer exercise enforcement discretion for LDTs and subsequently stated that it would publish guidance documents describing an approach to regulating LDTs. Pursuant to the Food and Drug Administration Safety and Innovation Act of 2012, the FDA was required to notify Congress at least sixty days prior to publishing any guidance documents implementing a new regulatory policy for LDTs. On July 31, 2014, the FDA provided the required notification, including draft guidance documents, to Congress and in October 2014, FDA formally published the draft guidance documents. In the draft guidance documents, the FDA stated that it had serious concerns regarding the lack of independent review of the evidence of clinical validity of LDTs and asserted that the requirements under CLIA do not address the clinical validity of any LDT. If published and finalized in the same form, the guidance documents would impose a risk-based, phased-in approach for LDTs similar to the existing *in vitro* diagnostic devices framework.

Under the risk-based approach described in the draft guidance documents, the FDA would rely upon its existing medical device classification system to evaluate the risk of LDTs. The FDA would require that laboratories providing LDTs, subject to certain limited exemptions, within six months after the guidance documents are finalized comply with (i) either a new notification procedure in which the laboratory must provide the FDA with certain basic information about each LDT offered by their laboratory or the FDA's device registration and listing requirements, and (ii) the medical device reporting requirements for LDTs offered by that laboratory. The FDA's premarket review requirements would begin twelve months after finalization of the guidance documents for the highest risk tests, including LDTs with the same intended use as a companion diagnostic or LDTs with the same intended use as an FDA-approved Class III medical device. Premarket review would begin immediately for newly developed LDTs in this highest-risk group. Premarket review for other LDTs classified as high-risk by the FDA would be phased in over the next four years and the FDA expects to announce the priority list for premarket review for the remaining Class III LDTs within 24 months from finalization of this guidance. The FDA identified certain tests as higher risk, including LDTs that act like companion diagnostics, LDTs that screen for serious diseases or conditions for use in asymptomatic patients with no other available confirmatory diagnostic product or procedure, and LDTs for certain infectious diseases with high-risk intended uses. Such higher risk LDTs would likely receive higher priority during the phased-in enforcement period.

## **Table of Contents**

Premarket review of moderate-risk (Class II) LDTs would be phased-in over a period of four years following completion of the premarket review period for LDTs classified as high-risk. If classified as Class III medical devices, our tests would likely be required to be approved by the FDA under a premarket approval application or PMA, which must be supported by valid scientific evidence to demonstrate the safety and effectiveness of the subject product, typically including the results of human clinical trials. Until premarket review is required for a test, the LDT could remain on the market while the FDA reviews the applications or premarket notifications for such tests. In addition, once a premarket application is submitted to FDA or FDA issues a 510(k) clearance order, the laboratory must also comply with FDA's quality system regulation.

The FDA's draft guidance documents for LDTs were published on October 3, 2014, and the FDA is currently accepting comments from the public for a period of time before deciding whether to issue final guidance documents implementing the same or modified versions of the draft guidance documents. There is no time frame in which the FDA must issue final guidance documents.

If the FDA requires us to seek clearance or approval to offer FoundationOne, FoundationOne Heme, or any of our future products for clinical use, we may not be able to obtain such approvals on a timely basis, or at all. If premarket review is required, our business could be negatively impacted if we are required to stop selling molecular information products pending their clearance or approval or the launch of any new products that we develop could be delayed by new requirements. The cost of conducting clinical trials and otherwise developing data and information to support premarket applications may be significant. In addition, future regulation by the FDA could subject our business to further regulatory risks and costs. Failure to comply with applicable regulatory requirements of the FDA could result in enforcement action, including receiving untitled or warning letters, fines, injunctions, or civil or criminal penalties. In addition, we could be subject to a recall or seizure of current or future products, operating restrictions, partial suspension or total shutdown of production. Any such enforcement action would have a material adverse effect on our business, financial condition and operations.

In addition, in November 2013, the FDA finalized guidance regarding the sale and use of products labeled for research or investigational use only. Among other things, the guidance advises that the FDA continues to be concerned about distribution of research-investigational-use only products intended for clinical diagnostic use and that the manufacturer's objective intent for the product's intended use will be determined by examining the totality of circumstances, including advertising, instructions for clinical interpretation, presentations that describe clinical use, and specialized technical support such as assistance performance clinical validation, surrounding the distribution of the product in question. The FDA has advised that if evidence demonstrates that a product is inappropriately labeled for research or investigational use only, the device would be misbranded and adulterated within the meaning of the Federal Food, Drug and Cosmetic Act. Some of the reagents and other products we use in FoundationOne are currently labeled as research-use only products. If the FDA were to undertake enforcement actions, some of our suppliers may cease selling research-use only products to us, and any failure to obtain an acceptable substitute could significantly and adversely affect our business, financial condition and results of operations.

***Healthcare policy changes, including recently enacted legislation reforming the U.S. health care system, may have a material adverse effect on our financial condition, results of operations, and cash flows.***

In March 2010, legislation collectively referred to as the Affordable Care Act, or ACA, was enacted in the United States. The ACA made a number of substantial changes in the way healthcare is financed by both governmental and private insurers. Among other things, the ACA:

requires each medical device manufacturer to pay a sales tax equal to 2.3% of the price for which such manufacturer sells its medical devices, beginning in 2013. This tax could apply to FoundationOne, FoundationOne Heme and some or all of our products which are in development; and

mandates a reduction in payments for clinical laboratory services paid under the Medicare Clinical Laboratory Fee Schedule of 1.75% for the years 2011 through 2015. In addition, a productivity adjustment is made to the fee schedule payment amount.

## **Table of Contents**

On April 1, 2013, cuts to the federal budget were implemented, requiring a 2% cut in Medicare payments for all services, including clinical laboratory testing. In December 2013, Congress extended this 2% cut for an additional two years until 2023.

Many CPT procedure codes that we use to bill our products were revised by the American Medical Association, effective January 1, 2013. These new CPT codes were developed and implemented for individual genes, or the components of a multi-gene panel. In the Final Rule for 2013, CMS announced that it decided to keep the new molecular codes on the CLFS, rather than move them to the PFS. CMS then announced that for 2013, it would price the new codes using a gap filling process. Under this approach, CMS referred the CPT codes to the MACs to allow them to determine an appropriate price. CMS then calculated the median of the pricing provided by the MACs to establish and publish a National Limit Amount, or NLA, by CPT code for 2014.

In 2014, new codes for sequencing-based panel tests were approved and implemented by the American Medical Association, effective January 1, 2015. In the fall of 2014, CMS announced that for 2015, it would price the new codes using a gap filling process. Under this approach, CMS referred the CPT codes to the MACs to allow them to determine an appropriate price if they deem the codes to be covered services. CMS will then calculate the median of the pricing provided by the MACs to establish and publish a National Limit Amount, or NLA, by CPT code for 2016. However, for 2015, if CMS reduces reimbursement for the new CPT codes for individual genes or fails to price the new multi-gene panel codes, or if commercial payors who often base pricing on Medicare fee schedules reduce non-contracted payment rates below the new NLA amount for CPT codes corresponding to individual genes, mandate use of the new sequencing-based panel CPT codes, or decide to stop payment on specific CPT codes altogether, our revenue could be adversely affected.

Additionally, in April 2014 the Protecting Access to Medicare Act of 2014, or the Act, was enacted into law which reforms the Medicare payment system for clinical laboratory tests paid through the Clinical Laboratory Fee Schedule, or CLFS. The Act rescinds CMS statutory authority to make adjustments to future payments for tests based on technological changes, which CMS had intended to apply to certain test codes on the CLFS beginning in calendar year 2015. Beginning in January 2017, Medicare payment for clinical diagnostic laboratory tests will be established by a market-based payment system. Under this new methodology CMS will establish Medicare payment for each test based on the weighted median of the payment rates for private payors for the test. The Act creates a new class of Advanced Diagnostic Laboratory Tests defined as sole source multi-analyte tests with a unique algorithm yielding a single result or a test that is cleared or approved by FDA or other such criteria developed by the Secretary of Health and Human Services. For Medicare payment prior to 2017, the Act creates a transitional period for both new and existing tests. Our average commercial payor reimbursement starting in 2017 could be adversely affected depending upon if and how payors adopt this new CMS pricing methodology and resulting rates.

We cannot predict whether future health care initiatives will be implemented at the federal or state level, or how any future legislation or regulation may affect us. The taxes imposed by the new federal legislation and the expansion of government's role in the U.S. health care industry, as well as changes to the reimbursement amounts paid by payors for FoundationOne, FoundationOne Heme, and future products may reduce our profits, and have a materially adverse effect on our business, financial condition, results of operations, and cash flows. Moreover, Congress has proposed, on several occasions, to impose a significant reduction in payment rates and/or 20% coinsurance on patients for clinical laboratory tests reimbursed under the CLFS. These adjustments would require us to bill patients for these amounts, which could have a material adverse effect on our business, financial condition, results of operations, and cash flows.

## **Table of Contents**

*If we fail to comply with the complex federal, state, local and foreign laws and regulations that apply to our business, we could suffer severe consequences that could materially and adversely affect our operating results and financial condition.*

We are subject to the 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, quality control, quality assurance, and inspections. We have a current certificate of accreditation under CLIA to conduct our genomic analyses through our accreditation by CAP. To renew this certificate, we are subject to survey and inspection every two years. Moreover, CLIA inspectors may make unannounced inspections of our clinical reference laboratory at any time.

We are also required to maintain a license to conduct testing in Massachusetts. Massachusetts laws establish standards for day-to-day operation of our clinical laboratory, including the training and skills required of personnel and quality control over and above that required by CLIA. We are also licensed to conduct testing by the states of California, Pennsylvania, Maryland, Florida, Rhode Island, and in New York, where we have received a permit from the New York State Department of Health to conduct FoundationOne and FoundationOne Heme testing and deliver the related test report for specimens originating from New York. If we do not maintain these licenses or if our approval is revoked, our business would suffer. Moreover, other states may adopt similar requirements in the future. We may be subject to regulation in foreign jurisdictions as we seek to expand international distribution of our products and consider establishing clinical laboratory operations outside the United States. International regulation may require prior review or approval of our products or services, may impose limits on the export of tissue necessary for us to perform our tests, and, should we establish laboratory operations outside the United States, may require us to obtain licenses and other operating permits. This additional regulation may affect our ability to provide our products and services and to conduct laboratory operations outside of the United States. If we are unable to comply with existing laws and regulations or changes to the laws and regulations, our business could be materially and adversely affected.

Any sanction imposed under CLIA, its implementing regulations, or state or foreign laws or regulations governing licensure, or our failure to renew a CLIA certificate, a state or foreign license, or accreditation, could have a material adverse effect on our business. Most CLIA deficiencies are not classified as condition-level deficiencies, and there are no adverse effects upon the laboratory operations as long as the deficiencies are corrected. Remediation of these deficiencies are routine matters, with corrections occurring within several hours or weeks. More serious CLIA deficiencies could rise to the level of condition-level deficiencies, and CMS has the authority to impose a wide range of sanctions, including revocation of the CLIA certification along with a bar on the ownership or operation of a CLIA certified laboratory by any owners or operators of the deficient laboratory. There is an administrative hearing procedure that can be pursued by the laboratory in the event of imposition of such sanctions, during which the sanctions are stayed, but the process can take a number of years to complete. If we were to lose our CLIA certification or CAP accreditation, we would not be able to operate our clinical reference laboratory and conduct our molecular tests, which would result in material harm to our business and results of operations.

We furnish to biopharmaceutical partners and academic researchers genomic information that has been de-identified in accordance with HIPAA and relevant international health information privacy regulations. The laws of certain states may require specific consent either to retain or utilize certain genetic information even if such information has been de-identified. A finding that we have failed to comply with any such laws and any remedial activities required to ensure compliance with such laws could cause us to incur substantial costs, to change our business practices, or to limit the retention or use of genetic information in a manner that, individually or collectively, could be adverse to our business.

## **Table of Contents**

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

HIPAA, which established comprehensive federal standards with respect to the privacy and security of protected health information and requirements for the use of certain standardized electronic transactions, particularly with respect to our online portal, the Interactive Cancer Explorer;

amendments to HIPAA under the HITECH Act, which strengthen and expand HIPAA privacy and security compliance requirements, increase penalties for violators, extend enforcement authority to state attorneys general, and impose requirements for breach notification;

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

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

the federal False Claims Act, which imposes liability on any person or entity that, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment to the federal government;

the federal Civil Monetary Penalties Law, which prohibits, among other things, the offering or transfer of remuneration to a Medicare or state health care program beneficiary if the person knows or should know it is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of services reimbursable by Medicare or a state health care program, unless an exception applies;

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

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

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

state laws that prohibit other specified practices, such as billing physicians for testing that they order; waiving coinsurance, copayments, deductibles, and other amounts owed by patients; billing a state Medicaid program at a price that is higher than what is charged to one or more other payors; and

## Edgar Filing: Foundation Medicine, Inc. - Form 10-K

similar foreign laws and regulations that apply to us in the countries in which we operate.

Our failure to comply could lead to civil or criminal penalties, exclusion from participation in government health care programs, or prohibitions or restrictions on our laboratory's ability to conduct commercial activities. We believe that we are in material compliance with all statutory and regulatory requirements, but there is a risk that one or more government agencies could take a contrary position. These laws and regulations are complex and are subject to interpretation by the courts and by government agencies. If one or more such agencies alleges that we may be in violation of any of these requirements, regardless of the outcome, it could damage our



## **Table of Contents**

reputation and adversely affect important business relationships with third parties, including managed care organizations and other commercial third-party payors.

***The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products. If we are found to have improperly promoted off-label uses, we may become subject to significant fines and other liability.***

FoundationOne and FoundationOne Heme deliver to physicians a report that describes a tumor's or hematologic cancer's genomic alterations and matches them with FDA-approved therapies or open clinical trials for therapies targeting cancers driven by those alterations. In some cases, the therapies identified in our report are not approved for the patient's cancer or disease state. The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription drug and device products. In particular, a product may not be promoted for uses or indications beyond those contained in such product's approved labeling. The U.S. government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If the FDA determines that we have engaged in off-label promotion in our FoundationOne or FoundationOne Heme reports by providing information regarding approved therapies, we may be subject to civil or criminal fines.

In addition, incentives exist under applicable laws that encourage competitors, employees, and physicians to report violations of rules governing promotional activities for pharmaceutical products. These incentives could lead to so-called whistleblower lawsuits as part of which such persons seek to collect a portion of monies allegedly overbilled to government agencies due to, for example, promotion of pharmaceutical products beyond labeled claims. These incentives could also lead to suits that we have mischaracterized a competitor's product in the marketplace and, as a result, we could be sued for alleged damages to our competitors. Such lawsuits, whether with or without merit, are typically time-consuming and costly to defend. Such suits may also result in related stockholder lawsuits, which are also costly to defend.

***We may be subject to fines, penalties, licensure requirements, or legal liability, if it is determined that through our FoundationOne or FoundationOne Heme reports we are practicing medicine without a license.***

Our FoundationOne and FoundationOne Heme reports delivered to physicians provide information regarding FDA-approved therapies and clinical trials that oncologists may use in making treatment decisions for their patients. We make members of our organization available to discuss the information provided in the report. State laws prohibit the practice of medicine without a license. Our customer service representatives provide support to our customers, including assistance in interpreting the FoundationOne and FoundationOne Heme report results. A governmental authority or individual actor could allege that the identification of available therapies and clinical trials in our reports and the related customer service we provide constitute the practice of medicine. A state may seek to have us discontinue the inclusion of certain aspects of our reports or the related services we provide or subject us to fine, penalties, or licensure requirements. Any determination that we are practicing medicine without a license may result in significant liability to us.

***If the validity of an informed consent from a patient enrolled in a clinical trial with one of our biopharmaceutical partners was challenged, we could be forced to stop using some of our resources, which would hinder our molecular information product development efforts.***

We have implemented measures to ensure that all clinical data and genetic and other biological samples that we receive from our biopharmaceutical partners have been collected from subjects who have provided appropriate informed consent for purposes which extend to our product development activities. We seek to ensure these data and samples are provided to us on a subject de-identified manner. We also have measures in place to ensure that the subjects from whom the data and samples are collected do not retain or have conferred on them any proprietary or commercial rights to the data or any discoveries derived from them. Our

---

## **Table of Contents**

biopharmaceutical partners conduct clinical trials in a number of different countries, and, to a large extent, we rely upon them to comply with the subject's informed consent and with local law and international regulation. The collection of data and samples in many different countries results in complex legal questions regarding the adequacy of informed consent and the status of genetic material under a large number of different legal systems. The subject's informed consent obtained in any particular country could be challenged in the future, and those informed consents could prove invalid, unlawful, or otherwise inadequate for our purposes. Any findings against us, or our biopharmaceutical partners, could deny us access to or force us to stop using some of our clinical samples, which would hinder our molecular information product development efforts. We could become involved in legal challenges, which could consume our management and financial resources.

### ***Ethical, legal, and social concerns related to the use of genomic information could reduce demand for our molecular information products.***

Genomic testing, like that conducted using our molecular information platform, FoundationOne and FoundationOne Heme, has raised ethical, legal, and social issues regarding privacy and the appropriate uses of the resulting information. Governmental authorities could, for social or other purposes, limit or regulate the use of genomic information or genomic testing or prohibit testing for genetic predisposition to certain conditions, particularly for those that have no known cure. Similarly, these concerns may lead patients to refuse to use genomic tests even if permissible.

Ethical and social concerns may also influence U.S. and foreign patent offices and courts with regard to patent protection for technology relevant to our business. These and other ethical, legal, and social concerns may limit market acceptance of our products or reduce the potential markets for products enabled by our molecular information platform, either of which could have an adverse effect on our business, financial condition, or results of operations.

## **Intellectual Property Risks Related to Our Business**

### ***Litigation or other proceedings or third-party claims of intellectual property infringement could require us to spend significant time and money and could prevent us from selling our products or impact our stock price.***

Third parties have asserted and may in the future assert that we are employing their proprietary technology without authorization. As we continue to commercialize each of FoundationOne and FoundationOne Heme in their current or updated forms, launch new products, and enter new markets, we expect that competitors will claim that our products infringe their intellectual property rights as part of business strategies designed to impede our successful commercialization and entry into new markets. We occasionally receive letters from third parties inviting us to take licenses under, or alleging that we infringe, their patents. Third parties may have obtained, and may in the future obtain, patents under which such third parties may claim that the use of our technologies constitutes patent infringement.

We could incur substantial costs and divert the attention of our management and technical personnel in defending ourselves against any of these claims. Any adverse ruling or perception of an adverse ruling in defending ourselves against these claims could have a material adverse impact on our cash position and stock price. Furthermore, 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 or misappropriation against us, we may be required to pay damages and obtain one or more licenses from third parties, or be prohibited from selling certain products, all of which could have a material adverse impact on our cash position and business and financial condition.

In addition, we may be unable to obtain these licenses at a reasonable cost, if at all. We could, therefore, incur substantial costs related to royalty payments for licenses obtained from third parties, which could negatively affect our gross margins. Moreover, we could encounter delays in product introductions while we

## **Table of Contents**

attempt to develop alternative methods or products. Defense of any lawsuit or failure to obtain any of these licenses on favorable terms could prevent us from commercializing products, and the prohibition of sale of any of our products would materially affect our ability to grow and maintain profitability and have a material adverse impact on our business.

### ***Developments in patent law could have a negative impact on our business.***

From time to time, the United States Supreme Court, or the Supreme Court, other federal courts, the United States Congress, or the United States Patent and Trademark Office, or the USPTO, may change the standards of patentability and any such changes could have a negative impact on our business.

Two cases involving diagnostic method claims and gene patents have recently been decided by the Supreme Court. On March 20, 2012, the Supreme Court issued a decision in *Mayo Collaborative v. Prometheus Laboratories*, or *Prometheus*, a case involving patent claims directed to optimizing the amount of drug administered to a specific patient. According to that decision, *Prometheus* claims failed to incorporate sufficient inventive content above and beyond mere underlying natural correlations to allow the claimed processes to qualify as patent-eligible processes that apply natural laws. On June 13, 2013, the Supreme Court subsequently decided *Association for Molecular Pathology v. Myriad Genetics*, or *Myriad*, a case brought by multiple plaintiffs challenging the validity of patent claims held by Myriad Genetics, Inc. relating to the breast cancer susceptibility genes BRCA1 and BRCA2, holding that isolated genomic DNA that exists in nature, such as the DNA constituting the BRCA1 and BRCA2 genes, is not patentable subject matter, but that cDNA, which is an artificial construct created from RNA transcripts of genes, may be patent eligible.

On December 16, 2014, the USPTO issued interim guidance, entitled 2014 Interim Guidance on Patent Subject Matter Eligibility, which is for use by USPTO personnel in examining patent claims reciting judicially recognized exceptions to patentable subject matter, including laws of nature, natural phenomena, or abstract ideas, for patent eligibility in view of the Supreme Court decisions in *Prometheus*, *Myriad*, and *Alice Corporation Pty. Ltd. v. CLS Bank International*, or *Alice Corp.* The guidance indicates that claims reciting a judicial exception to patent-eligible subject matter must amount to significantly more than the judicial exception itself in order to be patent-eligible subject matter. We cannot assure you that our efforts to seek patent protection for our technology and products will not be negatively impacted by this interim guidance issued by the USPTO, the decisions described above, rulings in other cases, or changes in guidance or procedures issued by the USPTO.

We cannot fully predict what impact the Supreme Court's decisions in *Prometheus*, *Myriad*, and *Alice Corp.* may have on the ability of biopharmaceutical companies or other entities to obtain or enforce patents relating to DNA, genes, or genomic-related discoveries in the future. Despite the USPTO interim guidance described above, the contours of when claims reciting laws of nature, natural phenomena, or abstract ideas may meet the patent eligibility requirements are not clear and may take years to develop via interpretation at the USPTO and in the courts. There are many previously issued patents claiming nucleic acids and diagnostic methods based on natural correlations that issued before the recent Supreme Court decisions discussed, and although many of these patents may be invalid under the standards set forth in the Supreme Court's recent decisions, until successfully challenged, these patents are presumed valid and enforceable, and certain third parties could allege that we infringe, or request that we obtain a license to, these patents. Whether based on patents issued prior to or after these Supreme Court decisions, we could have to defend ourselves against claims of patent infringement, or choose to license rights, if available, under patents claiming such methods. In particular, although the Supreme Court has held in *Myriad* that isolated genomic DNA is not patent-eligible subject matter, certain third parties could allege that activities that we may undertake infringe other classes of gene-related patent claims, and we could have to defend ourselves against these claims by asserting non-infringement and/or invalidity positions, or pay to obtain a license to these claims. In any of the foregoing or in other situations involving third-party intellectual property rights, if we are unsuccessful in defending against claims of patent infringement, we could be forced to pay damages or be subjected to an injunction that would prevent us from utilizing the patented subject matter in question if we are unable to obtain a license on reasonable terms. Such outcomes could

## **Table of Contents**

materially affect our ability to offer our products and have a material adverse impact on our business. Even if we are able to obtain a license or successfully defend against claims of patent infringement, the cost and distraction associated with the defense or settlement of these claims could have a material adverse impact on our business.

In addition, the Leahy-Smith America Invents Act, or the America Invents Act, which was signed into law in 2011, includes a number of significant changes to U.S. patent law. These changes include a transition from a first-to-invent system to a first-to-file system, changes to the way issued patents are challenged, and changes to the way patent applications are disputed during the examination process. These changes may favor larger and more established companies that have greater resources to devote to patent application filing and prosecution. The USPTO has developed new and untested regulations and procedures to govern the full implementation of the America Invents Act, and many of the substantive changes to patent law associated with the America Invents Act, and, in particular, the first-to-file provisions, became effective on March 16, 2013. Substantive changes to patent law associated with the America Invents Act may affect our ability to obtain patents, and, if obtained, to enforce or defend them. Accordingly, it is not clear what, if any, impact the America Invents Act will ultimately have on the cost of prosecuting our patent applications, our ability to obtain patents based on our discoveries and our ability to enforce or defend any patents that may issue from our patent applications, all of which could have a material adverse effect on our business.

### ***We may be unable to protect or enforce our intellectual property effectively, which could harm our competitive position.***

Obtaining and maintaining a strong patent position is important to our business. Many of our patent applications are in the early stages of prosecution. Patent law relating to the scope of claims in the technology fields in which we operate is complex and uncertain, so we cannot be assured that we will be able to obtain or maintain patent rights, or that the patent rights we may obtain will be valuable, provide an effective barrier to competitors or otherwise provide competitive advantages. Others have filed, and in the future are likely to file, patent applications that are similar or identical to ours or those of our licensors. To determine the priority of inventions, or demonstrate that we did not derive our invention from another, we may have to participate in interference or derivation proceedings in the USPTO or in court that could result in substantial costs in legal fees and could substantially affect the scope of our patent protection. We cannot be assured our patent applications will prevail over those filed by others. Also, our intellectual property rights may be subject to other challenges by third parties. Patents we obtain could be challenged in litigation or in administrative proceedings such as *ex parte* reexam, *inter partes* review, or post-grant review in the United States or opposition proceedings in Europe or other jurisdictions.

Obtaining and maintaining a patent portfolio entails significant expense and resources. Part of the expense includes periodic maintenance fees, renewal fees, annuity fees, various other governmental fees on patents and/or applications due in several stages over the lifetime of patents and/or applications, as well as the cost associated with complying with numerous procedural provisions during the patent application process. We may or may not choose to pursue or maintain protection for particular inventions. In addition, there are situations in which failure to make certain payments or noncompliance with certain requirements in the patent process can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If we choose to forego patent protection or allow a patent application or patent to lapse purposefully or inadvertently, our competitive position could suffer.

Legal actions to enforce our patent rights can be expensive and may involve the diversion of significant management time. In addition, these legal actions could be unsuccessful and could also result in the invalidation of our patents or a finding that they are unenforceable. We may or may not choose to pursue litigation or interferences against those that have infringed our patents, due to the associated expense and time commitment of monitoring these activities. If we fail to protect or to enforce our intellectual property rights successfully, our competitive position could suffer, which could harm our results of operations.

## **Table of Contents**

### ***If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.***

In addition to patent protection, we also rely upon copyright and trade secret protection, as well as non-disclosure agreements and invention assignment agreements with our employees, consultants and third parties, to protect our confidential and proprietary information. For example, significant elements of FoundationOne and FoundationOne Heme, including aspects of sample preparation, computational-biological algorithms, and related processes and software, are based on unpatented trade secrets and know-how that are not publicly disclosed. In addition to contractual measures, we try to protect the confidential nature of our proprietary information using physical and technological security measures. Such measures may not, for example, in the case of misappropriation of a trade secret by an employee or third party with authorized access, provide adequate protection for our proprietary information. Our security measures may not prevent an employee or consultant from misappropriating our trade secrets and providing them to a competitor, and recourse we take against such misconduct may not provide an adequate remedy to protect our interests fully. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive, and time-consuming, and the outcome is unpredictable. In addition, trade secrets may be independently developed by others in a manner that could prevent legal recourse by us. If any of our confidential or proprietary information, such as our trade secrets, were to be disclosed or misappropriated, or if any such information were independently developed by a competitor, our competitive position could be harmed.

### ***We may not be able to enforce our intellectual property rights throughout the world.***

The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection, especially those relating to biotechnology. This could make it difficult for us to stop the infringement of our patents, if obtained, or the misappropriation of our other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, many countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit. Patent protection must ultimately be sought on a country-by-country basis, which is an expensive and time-consuming process with uncertain outcomes. Accordingly, we may choose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries.

Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate. In addition, changes in the law and legal decisions by courts in the United States and foreign countries may affect our ability to obtain adequate protection for our technology and the enforcement of intellectual property.

### ***Third parties may assert ownership or commercial rights to inventions we develop.***

Third parties may in the future make claims challenging the inventorship or ownership of our intellectual property. For example, we rely on certain third parties to provide us with tissue samples and biological materials that we use to conduct our genomic analyses. We have written agreements with collaborators that provide for the ownership of intellectual property arising from our collaborations. These agreements provide that we must negotiate certain commercial rights with collaborators with respect to joint inventions or inventions made by our collaborators that arise from the results of the collaboration. In some instances, there may not be adequate written provisions to address clearly the resolution of intellectual property rights that may arise from a collaboration. If we cannot successfully negotiate sufficient ownership and commercial rights to the inventions that result from our use of a third-party collaborator's materials where required, or if disputes otherwise arise with respect to the intellectual property developed with the use of a collaborator's samples, we may be limited in our ability to

## **Table of Contents**

capitalize on the market potential of these inventions. In addition, we may face claims that our agreements with employees, contractors, or consultants obligating them to assign intellectual property to us are ineffective, or in conflict with prior or competing contractual obligations of assignment, which could result in ownership disputes regarding intellectual property we have developed or will develop and interfere with our ability to capture the commercial value of such inventions. Litigation may be necessary to resolve an ownership dispute, and if we are not successful, we may be precluded from using certain intellectual property, or may lose our exclusive rights in that intellectual property. Either outcome could have an adverse impact on our business.

***Third parties may assert that our employees or consultants have wrongfully used or disclosed confidential information or misappropriated trade secrets.***

We employ individuals who were previously employed at universities or other diagnostic or biopharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees and consultants do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of a former employer or other third parties. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

### **Risks Relating to Our Financial Condition and Capital Requirements**

***We are an early, commercial-stage company and have a limited operating history, which may make it difficult to evaluate our current business and predict our future performance.***

We are an early, commercial-stage company and have a limited operating history. We were incorporated in Delaware and began operations in November 2009. Our limited operating history, particularly in light of our business model based upon sales of novel products enabled by our molecular information platform and the rapidly evolving genomic analysis industry, may make it difficult to evaluate our current business and predict our future performance. Any assessment of our profitability or prediction about our future success or viability is subject to significant uncertainty. We have encountered and will continue to encounter risks and difficulties frequently experienced by early-, commercial-stage companies in rapidly evolving industries. If we do not address these risks successfully, our business will suffer.

***We have a history of net losses. We expect to incur net losses in the future and we may never achieve sustained profitability.***

We have historically incurred substantial net losses, including a net loss of \$52.2 million in 2014. From our inception in 2009 through December 31, 2014, we had an accumulated deficit of \$142.0 million. We expect our losses to continue as a result of ongoing research and development expenses and increased selling and marketing costs. These losses have had, and will continue to have, an adverse effect on our working capital, total assets, and stockholders' equity. Because of the numerous risks and uncertainties associated with our research, development, and commercialization efforts, we are unable to predict when we will become profitable, and we may never become profitable. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our inability to achieve and then maintain profitability would negatively affect our business, financial condition, results of operations, and cash flows.

***We may need to raise additional capital to fund our existing operations, develop our molecular information platform, commercialize new products and expand our operations.***

If our available cash balances, net proceeds from our initial public offering, and anticipated cash flow from operations are insufficient to satisfy our liquidity requirements including because of lower demand for our

## **Table of Contents**

products as a result of lower than currently expected rates of reimbursement from commercial third-party payors and government payors or other risks described in this Annual Report, we may seek to sell common or preferred equity or convertible debt securities, enter into an additional credit facility or another form of third-party funding, or seek other debt financing.

We may consider raising additional capital in the future to expand our business, to pursue strategic investments, to take advantage of financing opportunities, or for other reasons, including to:

increase our sales and marketing efforts to drive market adoption of FoundationOne and FoundationOne Heme and address competitive developments;

fund development and marketing efforts of any future products;

further expand our clinical laboratory operations;

expand our technologies into other types of cancers;

acquire, license or invest in technologies, including information technologies;

acquire or invest in complementary businesses or assets; and

finance capital expenditures and general and administrative expenses.

Our present and future funding requirements will depend on many factors, including:

our ability to achieve revenue growth;

our rate of progress in establishing reimbursement arrangements with domestic and international commercial third-party payors and government payors;

the cost of expanding our laboratory operations and offerings, including our sales and marketing efforts;

our rate of progress in, and cost of the sales and marketing activities associated with, establishing adoption of and reimbursement for FoundationOne and FoundationOne Heme;

our rate of progress in, and cost of research and development activities associated with, products in research and early development;

the effect of competing technological and market developments;

costs related to international expansion; and

the potential cost of and delays in product development as a result of any regulatory oversight applicable to our products. The various ways we could raise additional capital carry potential risks. If we raise funds by issuing equity securities, dilution to our stockholders could result. Any equity securities issued also could provide for rights, preferences, or privileges senior to those of holders of our common stock. If we raise funds by issuing debt securities, those debt securities would have rights, preferences, and privileges senior to those of holders of our common stock. The terms of debt securities issued or borrowings pursuant to a credit agreement 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 platform technologies or products, or grant licenses on terms that are not favorable to us.

The credit markets and the financial services industry have experienced a period of unprecedented turmoil and upheaval characterized by the bankruptcy, failure, collapse, or sale of various financial institutions and an unprecedented level of intervention from the United States federal government. These events have generally made equity and debt financing more difficult to obtain. Accordingly, additional equity or debt financing might



## **Table of Contents**

not be available on reasonable terms, if at all. If we cannot secure additional funding when needed, we may have to delay, reduce the scope of, or eliminate one or more research and development programs or sales and marketing initiatives. In addition, we may have to work with a partner on one or more of our development programs, which could lower the economic value of those programs to us.

### ***We incur significant costs as a result of operating as a public company and our management devotes substantial time to public company compliance programs.***

As a public company, we incur significant legal, accounting, and other expenses due to our compliance with regulations and disclosure obligations applicable to us, including compliance with the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, as well as rules implemented by the SEC, and the NASDAQ Stock Market, or NASDAQ. The SEC and other regulators have continued to adopt new rules and regulations and make additional changes to existing regulations that require our compliance. In July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that have required the SEC to adopt additional rules and regulations in these areas. Stockholder activism, the current political environment, and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact, in ways we cannot currently anticipate, the manner in which we operate our business. Our management and other personnel devote a substantial amount of time to these compliance programs and monitoring of public company reporting obligations, and as a result of the new corporate governance and executive compensation related rules, regulations, and guidelines prompted by the Dodd-Frank Act, and further regulations and disclosure obligations expected in the future, we will likely need to devote additional time and costs to comply with such compliance programs and rules. These rules and regulations will cause us to incur significant legal and financial compliance costs and will make some activities more time-consuming and costly.

To comply with the requirements of being a public company, we may need to undertake various actions, including implementing new internal controls and procedures and hiring new accounting or internal audit staff. The Sarbanes-Oxley Act requires that we maintain effective disclosure controls and procedures and internal control over financial reporting. We are continuing to develop and refine our disclosure controls and other procedures that are designed to ensure that information required to be disclosed by us in the reports that we file with the SEC is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms, and that information required to be disclosed in reports under the Exchange Act is accumulated and communicated to our principal executive and financial officers. Our current controls and any new controls that we develop may become inadequate, and weaknesses in our internal control over financial reporting may be discovered in the future. Any failure to develop or maintain effective controls could adversely affect the results of periodic management evaluations and annual independent registered public accounting firm attestation reports regarding the effectiveness of our internal control over financial reporting, which we may be required to include in our periodic reports we will file with the SEC under Section 404 of the Sarbanes-Oxley Act, and could harm our operating results, cause us to fail to meet our reporting obligations, or result in a restatement of our prior period financial statements. In the event that we are not able to demonstrate compliance with the Sarbanes-Oxley Act, that our internal control over financial reporting is perceived as inadequate, or that we are unable to produce timely or accurate financial statements, investors may lose confidence in our operating results, and the price of our ordinary shares could decline. In addition, if we are unable to continue to meet these requirements, we may not be able to remain listed on the NASDAQ Global Select Market.

We are required to comply with certain of the SEC rules that implement Section 404 of the Sarbanes-Oxley Act, which requires management to certify financial and other information in our quarterly and annual reports and provide an annual management report on the effectiveness of our internal control over financial reporting commencing with this Annual Report. This assessment needs to include the disclosure of any material weaknesses in our internal control over financial reporting identified by our management or our independent registered public accounting firm. We are just beginning the costly and challenging process of compiling the

---

## **Table of Contents**

system and processing documentation needed to comply with such requirements. 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, we will be unable to assert that our internal control over financial reporting is effective.

Our independent registered public accounting firm will not be required to formally attest to the effectiveness of our internal control over financial reporting until the first annual report required to be filed with the SEC following the date we are no longer an emerging growth company as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, depending on whether we choose to rely on certain exemptions set forth in the JOBS Act. We cannot assure you that there will not be material weaknesses or significant deficiencies in our internal controls in the future. If we are unable to assert that our internal control over financial reporting is effective, or if our independent registered public accounting firm is unable to express an opinion on the effectiveness of our internal control over financial reporting, we could lose investor confidence in the accuracy and completeness of our financial reports, which could have a material adverse effect on the price of our ordinary shares.

### ***Our ability to use our net operating loss carryforwards to offset future taxable income may be subject to certain limitations.***

In general, under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an ownership change is subject to annual limitations on its ability to use its pre-change net operating loss carryforwards or other tax attributes, or NOLs, to offset future taxable income or reduce taxes. Our past issuances of stock and other changes in our stock ownership may have resulted in ownership changes within the meaning of Section 382 of the Code; accordingly, our pre-change NOLs may be subject to limitation under Section 382. If we determine that we have not undergone an ownership change, the Internal Revenue Service could challenge our analysis, and our ability to use our NOLs to offset taxable income could be limited by Section 382 of the Code. Future changes in our stock ownership, including in connection with the consummation of the proposed transactions with Roche, could result in ownership changes under Section 382 of the Code further limiting our ability to utilize our NOLs. Furthermore, our ability to use NOLs of companies that we may acquire in the future may be subject to limitations. For these reasons, we may not be able to use a material portion of the NOLs, even if we attain profitability.

## **Risks Related to Our Common Stock**

### ***We expect that our stock price may fluctuate significantly.***

There has been a public market for our common stock for only a short period of time. Although our common stock is listed on the NASDAQ Global Select Market, an active public market for our common stock may not be sustained.

In addition, the market price of shares of our common stock could be subject to wide fluctuations in response to many risk factors listed in this section, and others beyond our control, including:

actual or anticipated fluctuations in our financial condition and operating results;

actual or anticipated changes in our growth rate relative to our competitors;

competition from existing products or new products that may emerge;

announcements by us, our biopharmaceutical partners, or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations, or capital commitments;

failure to meet or exceed financial estimates and projections of the investment community or that we provide to the public;

## **Table of Contents**

issuance of new or updated research or reports by securities analysts;

fluctuations in the valuation of companies perceived by investors to be comparable to us;

share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;

additions or departures of key management or scientific personnel;

disputes or other developments related to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our technologies;

changes to reimbursement levels by commercial third-party payors and government payors, including Medicare, and any announcements relating to reimbursement levels;

announcement or expectation of additional debt or equity financing efforts;

sales of our common stock by us, our insiders, or our other stockholders; and

general economic and market conditions.

These and other market and industry factors may cause the market price and demand for our common stock to fluctuate substantially, regardless of our actual operating performance, which may limit or prevent investors from readily selling their shares of common stock and may otherwise negatively affect the liquidity of our common stock. In addition, the stock market in general, and NASDAQ and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. In the past, when the market price of a stock has been volatile, holders of that stock have instituted securities class action litigation against the company that issued the stock. If any of our stockholders brought a lawsuit against us, we could incur substantial costs defending the lawsuit. Such a lawsuit could also divert the time and attention of our management.

### ***Our executive officers, directors, and principal stockholders exercise significant control over our company.***

Investment funds affiliated with Third Rock Ventures, L.P. and Kleiner Perkins Caufield & Byers, and Google Ventures 2011, L.P., along with our executive officers and directors, beneficially own, in the aggregate, shares representing approximately 31% of our outstanding capital stock as of December 31, 2014. If these stockholders were to choose to act together, as a result of their stock ownership, they could influence our management and affairs and control all matters submitted to our stockholders for approval, including the election of directors and approval of any merger, consolidation, or sale of all or substantially all of our assets. This concentration of ownership may have the effect of delaying or preventing a change in control of our company and might affect the market price of our common stock.

### ***We are an emerging growth company and will be able to avail ourselves of reduced disclosure requirements applicable to emerging growth companies, which could make our common stock less attractive to investors.***

We are an emerging growth company, as defined in the Jumpstart our Business Startups Act of 2012, or the JOBS Act, and we intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. In addition, Section 107 of the JOBS Act also provides that an emerging growth company can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act of 1933, or the Securities Act, for complying with new or revised

## Edgar Filing: Foundation Medicine, Inc. - Form 10-K

accounting standards. In other words, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. However, we are electing not to take advantage of such extended transition period, and as a result we will comply with new or

## **Table of Contents**

revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth companies. Section 107 of the JOBS Act provides that our decision to not take advantage of the extended transition period for complying with new or revised accounting standards is irrevocable.

We cannot predict if investors will find our common stock less attractive because we may rely on any of the exemptions available under the JOBS Act. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We may take advantage of these reporting exemptions until we are no longer an emerging growth company. We will remain an emerging growth company until the earliest of (i) the last day of the fiscal year in which we have total annual gross revenue of \$1.0 billion or more; (ii) the last day of our fiscal year following the fifth anniversary of the date of the completion of our initial public offering; (iii) the date on which we have issued more than \$1.0 billion in nonconvertible debt during the previous three years; and (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC.

***We have never paid dividends on our capital stock, and we do not anticipate paying any dividends in the foreseeable future. Consequently, any gains from an investment in our common stock will likely depend on whether the price of our common stock increases.***

We have not paid dividends on any of our classes of capital stock to date, and we currently intend to retain all of our future earnings, if any, to fund the development and growth of our business. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future. Consequently, in the foreseeable future, you will likely only experience a gain from your investment in our common stock if the price of our common stock increases.

***If equity research analysts do not publish research or reports about our business or if they issue unfavorable commentary or downgrade our common stock, the price of our common stock could decline.***

The trading market for our common stock relies in part on the research and reports that equity research analysts publish about us and our business. We do not control these analysts. The price of our common stock could decline if one or more equity analysts downgrade our common stock or if analysts issue other unfavorable commentary or cease publishing reports about us or our business.

***Anti-takeover provisions contained in our certificate of incorporation and bylaws, as well as provisions of Delaware law, could impair a takeover attempt.***

Our certificate of incorporation, bylaws, and Delaware law contain provisions which could have the effect of rendering more difficult, delaying or preventing an acquisition deemed undesirable by our board of directors. Our corporate governance documents include provisions:

creating a classified board of directors whose members serve staggered three-year terms;

authorizing blank check preferred stock, which could be issued by our board of directors without stockholder approval and may contain voting, liquidation, dividend, and other rights superior to our common stock;

limiting the liability of, and providing indemnification to, our directors and officers;

limiting the ability of our stockholders to call and bring business before special meetings;

requiring advance notice of stockholder proposals for business to be conducted at meetings of our stockholders and for nominations of candidates for election to our board of directors;

controlling the procedures for the conduct and scheduling of board of directors and stockholder meetings; and

## Edgar Filing: Foundation Medicine, Inc. - Form 10-K

providing our board of directors with the express power to postpone previously scheduled annual meetings and to cancel previously scheduled special meetings.

---

## **Table of Contents**

These provisions, alone or together, could delay or prevent hostile takeovers and changes in control or changes in our management.

As a Delaware corporation, we are also subject to provisions of Delaware law, including Section 203 of the Delaware General Corporation law, which prevents some stockholders holding more than 15% of our outstanding common stock from engaging in certain business combinations without approval of the holders of substantially all of our outstanding common stock.

Any provision of our certificate of incorporation, bylaws or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock, and could also affect the price that some investors are willing to pay for our common stock.

In the event our proposed transactions with Roche are consummated, effective upon the Closing, our certificate of incorporation will be amended to, among other things, provide for the declassification of our board of directors, and all of our directors would be elected annually and serve one-year terms.

***Our certificate of incorporation designates the Court of Chancery of the State of Delaware as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or other employees.***

Our certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware shall be the sole and exclusive forum for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers, or other employees to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, our certificate of incorporation or our bylaws, or (iv) any action asserting a claim against us governed by the internal affairs doctrine. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and consented to the provisions of our certificate of incorporation described above. This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers, and other employees. Alternatively, if a court were to find these provisions of our certificate of incorporation inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect our business, financial condition or results of operations.

### **Risks Related to the Proposed Strategic Collaboration with Roche**

As disclosed above under Item 1. Business Proposed Strategic Collaboration with Roche, we and Roche entered into a Transaction Agreement pursuant to which Roche has agreed, subject to the terms and conditions thereof, to acquire at least 52.4% and up to approximately 56.3% of our outstanding shares of common stock on a fully-diluted basis at the closing of the transactions contemplated by the Transaction Agreement, or the Transactions. In addition, we entered into four separate agreements, each of which will become effective upon the Closing, with certain affiliates of Roche to develop and commercialize comprehensive molecular information and genomic analysis products for the treatment of cancer patients. If approved and the conditions to closing are satisfied, the Transactions are expected to close during the second quarter of 2015.

The following discussion highlights some of the potential risks that may arise in connection with the proposed transactions with Roche.

## **Table of Contents**

***Roche's obligation to consummate the Transactions is subject to certain conditions, which if not satisfied may prevent, delay or jeopardize the consummation of the Transactions, result in additional expenditures of money and resources, and/or reduce the anticipated benefits of the Transactions.***

Roche's obligation to consummate the Transactions is subject to customary closing conditions. These closing conditions include, among others, (a) that there shall have been validly tendered and not validly withdrawn prior to the Acceptance Time that number of shares which, when combined with the Issuance Shares and existing shares of our common stock held by Roche Holding Ltd and its subsidiaries, represents at least 52.4% of our outstanding shares on a fully diluted basis, or the Minimum Condition, (b) receipt of the Company Stockholder Approval, (c) each of the Collaboration Agreements and the Investor Rights Agreement continuing in full force and effect, (d) the approval of the Issuance Shares for listing on the NASDAQ Global Select Market, (e) the continued accuracy of our representations and warranties, subject to specified materiality standards, and (f) the performance by us of our covenants and agreements.

We cannot predict whether and when these conditions will be satisfied, and no assurance can be given that the required Company Stockholder Approval will be obtained or that the other required closing conditions will be satisfied. In the event that the Transactions are not consummated, we will have spent considerable time and resources, and incurred substantial costs, including costs related to the Transactions, many of which must be paid even if the Transactions are not completed. If the Transactions are not consummated, our reputation in our industry and in the investment community could be damaged and, as a result, the market price of our common stock could decline.

***The Transaction Agreement may be terminated in accordance with its terms.***

The Transaction Agreement contains certain termination rights for both us and Roche, including, among other things, for (a) the failure of the Acceptance Time to occur by October 11, 2015, (b) the enactment, adoption, enforcement, promulgation or application of any final and non-appealable applicable law, order, injunction or judgment that makes the consummation of the Transactions illegal or otherwise prohibited or permanently enjoins either us or Roche from consummating the Transactions, (c) the failure to receive the Company Stockholder Approval, and (d) breaches of representations, warranties or covenants by a party that, in the case of us, result in the failure of certain conditions to closing being satisfied, or, in the case of Roche, would reasonably be expected to prevent Roche from consummating the Transactions. Furthermore, the parties can mutually decide to terminate the Transaction Agreement at any time prior to the consummation of the Transactions.

***The Transaction Agreement contains provisions that restrict our ability to pursue alternatives to the Transactions and, in specified circumstances, could require us to pay Roche a termination fee of \$30 million.***

Pursuant to the Transaction Agreement, we are restricted, subject to certain exceptions, from soliciting, initiating or taking any action to knowingly assist, facilitate or encourage the submission of, or furnishing information with regard to a competing acquisition proposal from any person or entity. In the event that we receive an acquisition proposal from another person, we have agreed to notify Roche of such proposal and negotiate in good faith with Roche prior to terminating the Transaction Agreement or effecting a change in the recommendation of our board of directors to our stockholders with respect to the proposed Transactions. Prior to the Acceptance Time, we may terminate the Transaction Agreement in connection with entering into a definitive agreement with respect to a superior proposal with a third party, subject to certain conditions, including our compliance with certain procedures set forth in the Transaction Agreement and payment of a termination fee of \$30 million to Roche. These provisions could discourage a third party that may have an interest in acquiring all or a significant part of our business from considering or proposing that acquisition, even if such third party were prepared to enter into a transaction that would be more favorable to us and our stockholders than the Transactions. These provisions also might result in a potential third-party acquiror proposing to pay a lower price to our stockholders than it might otherwise have proposed to pay because of the added expense of the \$30 million termination fee that may become payable in certain circumstances.



## **Table of Contents**

If the Transaction Agreement is terminated and we determine to seek another business combination, we may not be able to negotiate a transaction with another party on terms comparable to, or better than, the terms of the proposed Transactions.

***Failure to complete the Transactions within the expected time frame, or at all, could adversely affect our stock price, financial results and our future business and operations.***

In the event that the Transactions are not completed or delayed our business may be harmed because:

matters related to the proposed Transactions may require substantial commitments of time and resources thereby diverting management's and our employees' attention from our day-to-day business, including servicing existing customers, attracting new customers and developing new products and strategies;

our relationships with customers, distributors, collaborative partners, suppliers and patients may be harmed as a result of the proposed Transactions and result in uncertainties with respect to our products, employees and business;

our financial performance may be negatively impacted by disruptions in our sales and marketing, research and development, value improvement initiatives, and other business activities;

we may fail to retain key employees who have sought and obtained different employment in anticipation of the Transactions being completed;

we have agreed to restrict certain of our activities pending the consummation of the Transactions that may negatively affect our ability to execute on our business strategies and attain our financial goals; and

certain significant costs related to the proposed Transactions, such as legal, advisor and accounting fees and other expenses, are payable by us whether or not the proposed Transactions are completed, including a termination fee under certain circumstances.

If the Transactions are not consummated, the market price of our common stock may decline to the extent that the current market price of our common stock reflects a positive market assumption that the Transactions will be completed. Our stock price may also fluctuate significantly based on announcements by Roche and other third parties or us regarding the Transactions, or based on market perceptions of the likelihood of us obtaining the Company Stockholder Approval. Such announcements may lead to perceptions in the market that the Transactions may not be completed, which could cause our stock price to fluctuate or decline. In addition, if the Transaction Agreement is terminated our stock price could decline significantly.

Any of these events could harm our results of operations and financial condition and could cause a decline in the price of our common stock, particularly if the Transactions are not completed.

***While the Transactions are pending, we will be subject to business uncertainties that could adversely affect our business.***

Uncertainty about the effect of the Transactions on employees, customers and suppliers may have an adverse effect on our business. These uncertainties may impair our ability to attract, retain and motivate key personnel until the Transactions are consummated and for a period of time thereafter, and could cause customers, suppliers and others who deal with us to seek to change their existing business relationships with us. In addition, the Transaction Agreement restricts us from taking specified actions until the Transactions occur without the consent of Roche. These restrictions may prevent us from pursuing attractive business opportunities that may arise prior to the completion of the Transactions. In addition, the Transactions could expose us or members of our board of directors to litigation. Any such legal proceedings could delay or prevent the Transactions from becoming effective within the agreed upon timeframe or at all. If closing of the Transactions is delayed or does not occur, it could have a material adverse effect on our business.



---

**Table of Contents**

**Risks Related to the Business of the Company after Consummation of the Transactions and the Collaboration**

*We may not fully realize the anticipated benefits of the Transactions or in the expected time frame.*

The Transactions may result in material unanticipated problems, expenses, liabilities, competitive responses, loss of customer relationships, and diversion of management's attention, including, among others:

difficulties in achieving anticipated business opportunities and growth prospects;

difficulties in managing the expanded operations of a more complex company;

challenges resulting from increased complexities in accounting and tax matters, which could be heightened by potential required or desired changes in our third party accounting or tax service providers or in satisfying accounting practices and procedures required by Roche;

challenges in keeping existing customers and obtaining new customers, including any biopharmaceutical customers that are actual or potential competitors with Roche;

challenges in our relationships with collaboration partners, suppliers, distributors, and patients; and

challenges in attracting and retaining key personnel that may arise from working in a more complex company or due to changes in our equity incentive program that may be adopted to maintain Roche's percentage ownership interest.

Many of these factors will be outside of our control and any one of them could result in increased costs, decreases in the amount of expected revenues and diversion of management's time and energy, which could materially impact our business, financial condition and results of operations. In addition, even if the full benefits of the Transactions are realized, including the sales and growth opportunities that are expected, these benefits may not be achieved within the anticipated time frame and additional unanticipated costs may be incurred in connection with the Transactions. All of these factors could negatively impact the price of our common stock. As a result, we cannot assure you that the Transactions will result in the realization of the anticipated benefits.

***As long as Roche owns greater than a majority of our outstanding shares of common stock, other holders of our common stock will have limited ability to influence matters requiring stockholder approval and Roche's interest may conflict with ours and other stockholders.***

If the Transactions with Roche are consummated, Roche will beneficially own up to approximately 63% of our outstanding common stock as of the Closing. As a result, until such time as Roche and its affiliates hold shares representing less than a majority of the votes entitled to be cast by the holders of our outstanding common stock at a stockholder meeting, Roche generally will have the ability to control the outcome of any matter submitted for the vote of our stockholders, except in certain circumstances set forth in our certificate of incorporation, bylaws and the Investor Rights Agreement.

The interests of Roche may not coincide with the interests of our other stockholders. Roche's ability, subject to the limitations in our certificate of incorporation, bylaws and the Investor Rights Agreement, to control all matters submitted to our stockholders for approval limits the ability of other stockholders to influence corporate matters and, as a result, we may take actions that our stockholders do not view as beneficial. As a result, the market price of our common stock could be adversely affected. In addition, the existence of a controlling stockholder may have the effect of making it more difficult for a third party to acquire, or discouraging a third party from seeking to acquire, our business. A third party would be required to negotiate any such transaction with Roche, and the interests of Roche with respect to such transaction may be different from the interests of our other stockholders. In addition, the performance of Roche or speculation about the possibility of future actions Roche may take in connection with us may adversely affect our share price.



## **Table of Contents**

***We have entered into contractual provisions that may significantly limit our ability to conduct certain operations, raise capital or require us to make material expenditures.***

Pursuant to the Investor Rights Agreement, until such time as Roche and its affiliates beneficially owns less than a majority of the outstanding shares of our common stock (subject to a cure period), we may not take certain actions without Roche's prior written consent, including any of the following: (a) appoint a new Chief Executive Officer; (b) incur any indebtedness (as defined in the Investor Rights Agreement) that would result in the outstanding aggregate principal amount of the indebtedness of the Company and its subsidiaries exceeding the lesser of (A) \$200 million and (B) 20% of the Company's aggregate market capitalization at the time of such incurrence; (c) issue or sell any equity securities (including any securities convertible or exercisable into such equity securities), other than (X) common stock issued upon the exercise or settlement of equity awards granted as of the date of the Investor Rights Agreement in accordance with their terms, (Y) equity awards granted after the date of the Investor Rights Agreement pursuant to our 2013 Stock Option and Incentive Plan or any permitted new equity incentive plan or equity incentive plan amendment and (Z) in connection with permitted acquisitions, certain shares of our common stock issued as stock consideration as long as such issuance does not result in Roche beneficially owning less than 50.5% of the outstanding shares of our common stock on a fully diluted basis; (d) establish or amend any of our equity incentive plans, except for certain permitted equity incentive plans and permitted equity incentive plan amendments; (e) acquire any entity, business or assets if the aggregate consideration payable by us exceeds the lesser of (X) \$200 million and (Y) 20% of our aggregate market capitalization at the time of such transaction, unless Roche is separately contemplating acquiring the same entity, business or assets; (f) dispose of any entity, business or assets if the aggregate consideration payable to us exceeds \$50 million; (g) change the scope and nature of our business; (h) amend our organizational documents; (i) take any action that would impair in any material respect our ability to perform our obligations under the Investor Rights Agreement or Roche's rights thereunder; or (j) voluntarily dissolve or liquidate or make any voluntary bankruptcy filings. If we are unable to complete any of these actions because Roche does not provide its consent, it could adversely impact and our business and results of operations.

The Investor Rights Agreement also requires us to establish and maintain a stock repurchase program at all times following the Closing and to repurchase shares of our common stock in order to maintain Roche's aggregate percentage ownership following the Issuance at no less than 50.5% of the outstanding shares of our common stock on a fully diluted basis, less any shares transferred by Roche. Our obligation to maintain such stock repurchase program may involve material expenditures of cash by us. If we fail to or are unable to satisfy our repurchase obligations under the stock repurchase program and we issue any securities and, as a result thereof, Roche beneficially owns less than 50.1% of the outstanding shares of our common stock on a fully diluted basis, the restrictions on Roche under the Investor Rights Agreement (including with respect to the agreement to vote Roche's shares of common stock, the standstill restrictions and the transfer restrictions), but not the rights of Roche under the Investor Rights Agreement, will immediately terminate, and Roche will thereafter have the ability to exercise in full its rights as a stockholder.

In addition, the Transaction Agreement provides for us to indemnify Roche for breaches of the Transaction Agreement by us subject to negotiated limitations. If we are required to indemnify Roche for any such breaches, it could have a material adverse impact on our results of operations.

***The Transactions with Roche will modify our investor composition and could have a material negative impact on the liquidity of our common stock.***

Following the Transactions, Roche will own a minimum of 52.4% and a maximum of 56.3% of our Company on a fully diluted basis, or up to approximately 63% of our outstanding shares of common stock. In addition, the Investor Rights Agreement contains provisions that enable Roche to maintain its percentage ownership interest in our common stock and require us to establish a stock repurchase program designed to maintain Roche's percentage ownership interest in our common stock. This ownership and these provisions will result in changes in the ownership levels of our most significant shareholders and will likely result in a less liquid

**Table of Contents**

trading market for our shares. This lack of liquidity may make it more difficult for investors to transact in our shares and the price of our stock may suffer as a result.

**ITEM 1B. UNRESOLVED STAFF COMMENTS**

Not applicable.

**ITEM 2. PROPERTIES**

We have leased approximately 62,000 square feet of laboratory and office space at 150 Second Street, Cambridge, Massachusetts through February 2021 and approximately 38,411 square feet of office space at Ten Canal Park in Cambridge, Massachusetts through approximately September 2020. We believe that our existing facilities are adequate for our current needs. When each of our leases expire, we may renew the applicable existing lease or look for additional or alternate space for our operations. We believe that any additional space we may require will be available on commercially reasonable terms.

**ITEM 3. LEGAL PROCEEDINGS**

The Company, from time to time, is party to litigation arising in the ordinary course of its business. Management does not believe that the outcome of these claims will have a material adverse effect on the financial position, results of operations, or cash flows of the Company based on the status of proceedings at this time.

**ITEM 4. MINE SAFETY DISCLOSURES**

Not applicable.

**PART II****ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES****Market Information**

Our common stock commenced trading under the symbol "FMI" on the NASDAQ Global Select Market on September 25, 2013. Prior to that time, there was no public market for our common stock.

The following table sets forth on a per share basis, for the periods indicated, the low and high close prices of our common stock as reported by the NASDAQ Global Select Market.

	<b>High</b>	<b>Low</b>
<b>Year ended December 31, 2014</b>		
First Quarter	\$ 43.62	\$ 22.87
Second Quarter	\$ 31.52	\$ 20.30
Third Quarter	\$ 29.30	\$ 18.96
Fourth Quarter	\$ 27.62	\$ 18.67

	<b>High</b>	<b>Low</b>
<b>Year ended December 31, 2013</b>		
Third Quarter (from September 25, 2013)	\$ 39.64	\$ 35.35
Fourth Quarter	\$ 36.85	\$ 20.42



## **Table of Contents**

On March 9, 2015, the last reported sales price of our common stock on the Nasdaq Global Select Market was \$47.74 and as of March 9, 2015, there were approximately 25 holders of record of our common stock. However, because many of our outstanding shares are held in accounts with brokers and other institutions, we believe we have more beneficial owners.

### **Dividend Policy**

We have never declared or paid dividends on our common stock and do not expect to pay dividends on our common stock for the foreseeable future. Instead, we anticipate that all of our earnings in the foreseeable future will be used for the operation and growth of our business. Any future determination to declare dividends will be subject to the discretion of our board of directors and will depend on various factors, including applicable laws, our results of operations, financial condition, future prospects, and any other factors deemed relevant by our board of directors. In addition, any future indebtedness that we may incur could preclude us from paying dividends.

### **Stock Performance Graph**

This graph is not soliciting material, is not deemed filed with the SEC and is not to be incorporated by reference into any of our filings under the Securities Act or the Exchange Act, whether made before or after the date hereof and irrespective of any general incorporation language in any such filing.

The following graph shows the total stockholder return of an investment of \$100 in cash on September 25, 2013 (the first day of trading of our common stock), through December 31, 2014 for (i) our common stock, (ii) the NASDAQ Composite Index (U.S.), and (iii) the NASDAQ Biotechnology Index. Pursuant to applicable SEC rules, all values assume reinvestment of the full amount of all dividends, however no dividends have been declared on our common stock to date. The stockholder return shown on the graph below is not necessarily indicative of future performance, and we do not make or endorse any predictions as to future stockholder returns.

### **Equity Compensation Plan Information**

For information regarding securities authorized for issuance under equity compensation plans, see Part III Item 12 Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.



## **Table of Contents**

### **Sales of Unregistered Securities**

None.

### **Use of Proceeds**

On September 30, 2013, we closed the sale of 6,772,221 shares of common stock to the public (inclusive of 883,333 shares of common stock sold by us pursuant to the full exercise of an overallotment option granted to the underwriters) at a price of \$18.00 per share, before underwriting discounts. The offer and sale of the shares in our initial public offering was registered under the Securities Act pursuant to registration statements on Form S-1 (File No. 333-190226), which was filed with the SEC on July 29, 2013 and amended subsequently and declared effective by the SEC on September 24, 2013, and Form S-1MEF (File No. 333-191333), which was filed with the SEC on September 24, 2013 and automatically effective upon filing. Following the sale of the shares in connection with the closing of our initial public offering, the offering terminated. The offering did not terminate before all the securities registered in the registration statements were sold. Goldman, Sachs & Co. and J.P. Morgan Securities LLC acted as joint book-running managers of the offering, and Leerink Swann LLC and Sanford C. Bernstein & Co., LLC acted as co-managers of the offering.

We raised approximately \$110.4 million in net proceeds after deducting underwriting discounts and commissions of approximately \$8.5 million and other offering expenses of approximately \$3.0 million. None of these expenses consisted of direct or indirect payments made by us to directors, officers or persons owning 10% or more of our common stock or to their associates, or to our affiliates. There has been no material change in our use of the proceeds from our initial public offering as described in our final prospectus filed with the SEC on September 25, 2013, and as of February 26, 2015, we have used approximately \$65.8 million of the net proceeds. We have invested the remaining amount of the net proceeds in cash equivalents and other short-term investments in accordance with our investment policy.

### **Issuer Purchases of Equity Securities by the Issuer and Affiliated Purchasers**

None.

**Table of Contents****ITEM 6. SELECTED FINANCIAL DATA**

The selected financial data set forth below as of December 31, 2014, 2013 and for each of the years ended December 31, 2014, 2013, and 2012 have been derived from the audited consolidated financial statements of the Company, which are included elsewhere in this Annual Report on Form 10-K. We derived the consolidated financial data for the year ended December 31, 2011 and as of December 31, 2012 and 2011 from our audited consolidated financial statements that are not included elsewhere in this Annual Report on Form 10-K.

The information set forth below should be read in conjunction with Management's Discussion and Analysis of Financial Condition and Results of Operations and the audited consolidated financial statements, and the notes thereto, and other financial information included herein. Our historical results are not necessarily indicative of our future results.

	2014	Year Ended December 31,		2011
		2013	2012	
	(in thousands, except share and per share data)			
Statement of Operations Data:				
Revenue	\$ 61,079	\$ 28,990	\$ 10,645	\$ 2,057
Costs and expenses				
Cost of revenue	27,434	11,659	5,681	258
Selling and marketing	28,997	12,326	3,454	1,555
General and administrative	27,302	21,865	8,644	6,992
Research and development	30,629	24,901	14,777	9,023
Total costs and expenses	114,362	70,751	32,556	17,828
Loss from operations	(53,283)	(41,761)	(21,911)	(15,771)
Interest expense, net	(42)	(235)	(421)	(421)
Other income (expense), net	1,103	(948)	(61)	(845)
Net loss	(52,222)	(42,944)	(22,393)	(17,037)
Accretion of convertible preferred stock		(139)	(286)	(296)
Net loss applicable to common stockholders	\$ (52,222)	\$ (43,083)	\$ (22,679)	\$ (17,333)
Net loss per common share applicable to common stockholders, basic and diluted	\$ (1.87)	\$ (4.64)	\$ (10.47)	\$ (14.06)
Weighted average common shares outstanding, basic and diluted	27,954,773	9,294,730	2,166,832	1,232,658
	2014	December 31,		2011
		2013	2012	
	(in thousands)			
Balance Sheet Data:				
Cash and cash equivalents	\$ 72,080	\$ 124,293	\$ 54,838	\$ 10,852
Working capital	73,202	117,551	49,856	7,521
Total assets	111,938	157,268	66,039	18,065
Notes payable, excluding current portion			1,441	3,041
Redeemable convertible preferred stock warrant liability			225	94
Redeemable convertible preferred stock			98,658	32,455
Accumulated deficit	(141,985)	(89,763)	(46,819)	(24,426)
Total stockholders' equity (deficit)	\$ 111,938	\$ 131,711	\$ (43,397)	\$ (22,303)



## **Table of Contents**

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

*The following discussion and analysis of our financial condition and results of operations should be read together with our Selected Financial Data and our consolidated financial statements, related notes, and other financial information included elsewhere in this Annual Report on Form 10-K. This discussion contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those described in, or implied by, the forward-looking statements. Factors that could cause or contribute to those differences include, but are not limited to, those identified below and those discussed above in the section entitled Risk Factors.*

#### **Overview**

We are a molecular information company focused on fundamentally changing the way in which patients with cancer are evaluated and treated. We believe an information-based approach to making clinical treatment decisions based on comprehensive genomic profiling will become a standard of care for patients with cancer. We derive revenue from selling products that are enabled by our molecular information platform to physicians and biopharmaceutical companies. Our platform includes proprietary methods and algorithms for analyzing specimens across all types of cancer, and for incorporating that information into clinical care in a concise and user-friendly fashion. Our products provide genomic information about each patient's individual cancer, enabling physicians to optimize treatments in clinical practice and biopharmaceutical companies to develop targeted oncology therapies more effectively. We believe we have a significant first mover advantage in providing comprehensive genomic profiling and molecular information products on a commercial scale.

Our first clinical products, FoundationOne for solid tumors, and FoundationOne Heme for blood-based cancers, or hematologic malignancies, including leukemia, lymphoma, myeloma, and many sarcomas and pediatric cancers, are, to our knowledge, the only widely available comprehensive genomic profiles designed for use in the routine care of patients with cancer. To accelerate our commercial growth and enhance our competitive advantage, we are continuing to expand our sales force, grow our molecular information knowledgebase, called FoundationCORE, publish scientific and medical advances, foster relationships throughout the oncology community, and develop new clinical and technology products.

The cancer treatment paradigm is evolving rapidly, and we believe there is now widespread recognition that cancer is a disease of the genome, rather than a disease defined solely by its specific anatomical location in the body. Today, physicians increasingly use precision medicines to target cancers based on the specific genomic alterations driving their growth. We believe physicians need molecular information about their patients' unique cancers to determine the optimal course of treatment. However, most currently available molecular diagnostic tests capture only a limited number of the most common and known genomic alterations. We believe this narrow approach often fails to identify relevant targeted treatment options.

Since our inception in 2009, we have devoted substantially all of our resources to the development of our molecular information platform, the commercialization of FoundationOne, and the development of new products such as FoundationOne Heme. We have incurred significant losses since our inception, and as of December 31, 2014 our accumulated deficit was \$142.0 million. We expect to continue to incur operating losses over the near term as we expand our commercial operations, conduct clinical trials, and invest in our molecular information platform and additional product offerings.

#### **Recent Developments**

On January 12, 2015, we announced a potential broad, strategic collaboration with Roche Holdings, Inc., or Roche, and certain of its affiliates, in the field of molecular information for oncology. The proposed transaction,

## **Table of Contents**

which is subject to a number of closing conditions as further explained in our public filings and in the section above under Item 1. Business Proposed Strategic Collaboration with Roche, is a broad multi-part agreement that includes an R&D collaboration, a U.S. educational support collaboration, an ex-U.S. commercial collaboration, a binding term sheet for an *in vitro* diagnostic product development collaboration and an equity investment with certain governance provisions. We believe this proposed strategic collaboration with Roche will accelerate many aspects of our business strategy and further advance our leadership position in molecular information solutions.

## **Financial Operations Overview**

### ***Revenue***

We derive our revenue from selling products that are enabled by our molecular information platform. The information provided in our test results is branded as FoundationOne and FoundationOne Heme for our clinical customers and is not branded for our biopharmaceutical customers. The principal focus of our commercial operations is to continue to drive adoption of products enabled by our molecular information platform. In particular, we seek to increase sales volume of FoundationOne and FoundationOne Heme in the clinical setting and increase the volume of tests and data access enabled by our molecular information platform that we perform for our biopharmaceutical customers.

For many physician orders within the United States, the payment we ultimately receive depends upon the rate of reimbursement from commercial third-party payors and government payors. In October 2014, we announced a formal agreement with Priority Health, a regional commercial third-party payor in Michigan, for broad coverage of FoundationOne and FoundationOne Heme. We are not currently a participating provider with any other commercial third-party payors and, therefore, do not have specific coverage decisions from those third-party payors for our products with established payment rates. Currently, most commercial third-party payors reimburse our claims based upon the stacked CPT codes, the predominant methodology, or based on other methods such as percentages of charges or other formulas that are not made known to us. In addition, a small portion of commercial third-party payors outsource our claims to preferred provider organizations or third-party administrators, who process our claims and pay us directly at negotiated rates. Coverage and payment is determined by each third-party payor on a case-by-case basis. We are not currently a participating provider in any state Medicaid program and therefore do not have coverage decisions under which our tests are covered by these Medicaid programs. We are a participating provider in the Medicare program but we do not have a coverage decision. At the end of 2013, we began the process of submitting claims for our tests to Medicare. We may also negotiate rates with patients, if the patient is responsible for payment. Our efforts in obtaining reimbursement based on individual claims, including pursuing appeals or reconsiderations of claim denials, take a substantial amount of time, and bills may not be paid for many months or at all. Furthermore, if a third-party payor denies coverage after final appeal, payment may not be received at all.

We currently recognize revenue on a cash basis from most commercial third-party payors and from patients who make co-payments, pay deductibles, or pay other amounts that we have been unable to collect from their third-party payors because the payment is not fixed or determinable and collectability is not reasonably assured as a result of the fact that we do not have coverage decisions in place. We expect to use judgment in assessing whether the fee is fixed or determinable and whether collectability is reasonably assured as we continue to gain payment experience with third-party payors and patients. Costs associated with performing tests are recorded as tests are processed. These costs are recorded regardless of when or whether revenue is recognized with respect to those tests. Because we currently recognize revenue on a cash basis from commercial third-party payors, the costs of those FoundationOne and FoundationOne Heme tests are recognized in advance of any associated revenues. Due to the increasing period-to-period test volumes that we have observed to date, our revenue from these payors is lower and our net loss is higher than if we were recognizing revenue from these payors on an accrual basis in the period during which the work was performed and costs were incurred.

## **Table of Contents**

There are currently no local or national coverage decisions that determine whether and how our tests are covered by Medicare. In the absence of national coverage decisions, local Medicare contractors that administer the Medicare program in various regions have some discretion in determining coverage and therefore payment for tests. Our local Medicare contractor, who would process our claims on behalf of Medicare, initially requested that we not submit claims for FoundationOne tests provided to Medicare patients while the contractor assessed the appropriate coverage and payment for FoundationOne as a whole. Based on the volume of our Medicare claims, we began the process of submitting claims to Medicare in November 2013, but we have not generated any revenue from Medicare for our FoundationOne or FoundationOne Heme tests to date. As a result, while we incur costs to perform these tests, we are not currently generating revenue from the sale of our products for patients covered by Medicare. Our net loss is therefore higher than if we were recognizing revenue from the sale of our products for patients covered by Medicare. FoundationOne and FoundationOne Heme tests for patients covered by Medicare represented approximately 31%, 30%, and 29% of total tests reported to physicians in the United States during the years ended December 31, 2014, 2013, and 2012, respectively.

We are seeking a positive coverage determination from our Medicare contractor, which, if obtained, will establish a standard for the reimbursement for our Medicare claims. At the end of 2013, we commenced the process of submitting claims to Medicare for FoundationOne tests provided to Medicare patients. As of December 31, 2014, we have not been reimbursed by our Medicare contractor for the claims that we have submitted, and we are in the process of appealing these unpaid claims. In the future, our Medicare contractor may issue a non-coverage decision for FoundationOne and/or FoundationOne Heme that would apply to future claims or may defer processing a claim pending a coverage or payment determination. If a claim is paid by our Medicare contractor, either upon acceptance of the claim or following a successful appeal of a denied claim, we will generate revenue from Medicare for our testing.

We expect that the current lack of coverage decisions and the uncertainty of reimbursement on a case-by-case basis may continue to negatively impact our revenue and earnings, particularly as FoundationOne and FoundationOne Heme test volumes increase period-to-period. Following our achievement of a coverage decision from a commercial third-party payor or a government payor or once we have a sufficient history of claims collections with any such payor that we conclude the fee for FoundationOne and FoundationOne Heme tests for individuals insured by such payor is sufficiently fixed or determinable and collectability is reasonably assured, we will begin to recognize revenue from such payor on an accrual basis. As of December 31, 2014, we had cash and cash equivalents of approximately \$72.1 million. If we are not able to obtain coverage decisions from additional commercial third-party payors and government payors in the future, and our available cash balances and cash flow from claims for reimbursement on behalf of each patient on a case-by-case basis and other operations are insufficient to satisfy our liquidity requirements, we may require additional capital beyond our currently anticipated amounts. Additional capital may not be available on reasonable terms, or at all.

We recognize revenue from the sale of our products to certain hospitals, cancer centers, other institutions, and patients at the time results are reported to physicians if all revenue recognition criteria have been met.

We also receive a small portion of revenue from patients who make co-payments and pay deductibles. In addition, while we take on the primary responsibility for obtaining third-party reimbursement on behalf of patients, including appeals for any initial denials, we ultimately bill patients for amounts that we have been unable to collect from their third-party payors. We are seeking reimbursement from Medicare, and we may also decide to provide appropriate notices to patients covered by Medicare to enable us to bill a patient for all or part of a claim that is denied coverage by our Medicare contractor. We offer a comprehensive patient assistance program to support patients whose incomes are below certain thresholds and to allow for extended payment terms, as necessary, given the patient's economic situation.

Revenue from our biopharmaceutical customers is based on a negotiated price per test or on the basis of agreements to provide certain testing volumes, access to our data, or other deliverables over defined periods. We recognize revenue upon delivery of the test results, or over the period that testing volume or other deliverables

## **Table of Contents**

are provided, as appropriate, assuming all other revenue recognition criteria have been met. Certain of our arrangements include multiple deliverables. We evaluate these deliverables pursuant to ASC 605-25 *Revenue Recognition: Multiple-Element Arrangements* to determine if they represent separate units of accounting. We then allocate the non-contingent consideration to the units of accounting using the relative selling price model, and recognize revenue as appropriate based upon the nature of the deliverable.

We expect our revenue to increase over time as we expand our commercial efforts within and outside of the United States. Positive reimbursement decisions from additional commercial third-party payors and government payors, such as Medicare and Medicaid, would eliminate much of the uncertainty around payment, should allow us to recognize revenue earlier, and increase our overall revenue growth from ordering physicians within the United States. We also expect to grow our biopharmaceutical customer base. Over time, we expect that our revenue from ordering physicians within and outside of the United States will significantly exceed revenue from our biopharmaceutical customers, given the higher percentage of patients with cancer who are treated outside of clinical trial settings.

### ***Cost of Revenue and Operating Expenses***

We allocate certain overhead expenses, such as rent, utilities, and depreciation to cost of revenue and operating expense categories based on headcount and facility usage. As a result, an overhead expense allocation is reflected in cost of revenue and each operating expense category.

#### ***Cost of Revenue***

Cost of revenue consists of personnel expenses, including salaries, bonuses, employee benefits and stock-based compensation expenses, cost of laboratory supplies, depreciation of laboratory equipment and amortization of leasehold improvements, shipping costs, and certain allocated overhead expenses. We expect these costs will increase in absolute dollars as we increase our sales volume, but will decrease as a percentage of revenue over time as our sales increase and we gain operating efficiencies.

Costs associated with performing tests are recorded as tests are processed. These costs are recorded regardless of whether revenue is recognized with respect to those tests. Because we currently recognize revenue on a cash basis from commercial third-party payors and patients who make co-payments, pay deductibles or pay other amounts that we have been unable to collect from their insurers, the costs of those tests are often recognized in advance of any associated revenues.

#### ***Selling and Marketing Expenses***

Our selling and marketing expenses include costs associated with our sales organization, including our direct sales force and sales management, client services, marketing, reimbursement, and business development personnel who are focused on our biopharmaceutical customers. These expenses consist principally of salaries, commissions, bonuses, employee benefits, travel, and stock-based compensation, as well as marketing and educational activities, and allocated overhead expenses. We expense all selling and marketing costs as incurred.

During the years ended December 31, 2014, 2013, and 2012, our selling and marketing expenses represented approximately 47%, 43%, and 32%, respectively, of our total revenue. We expect our selling and marketing costs to continue to increase in absolute dollars as we expand our sales force, increase our presence in the marketplace, and increase our marketing activities to drive further awareness and adoption of FoundationOne, FoundationOne Heme, and any future products we may develop. In the short-term, our selling and marketing expenses may also increase as a percentage of total revenues as we make these investments.

---

## **Table of Contents**

### *General and Administrative Expenses*

Our general and administrative expenses include costs for our executive, accounting and finance, legal, and human resources functions. These expenses consist principally of salaries, bonuses, employee benefits, travel, and stock-based compensation, as well as professional services fees such as consulting, audit, tax, legal and billing fees, and general corporate costs and allocated overhead expenses. We expense all general and administrative expenses as incurred.

We expect that our general and administrative expenses will continue to increase, primarily due to increasing costs to support the growth of the Company and an increase in billing costs related to our anticipated increase in revenues. We also expect to incur significant legal fees in connection with the proposed transaction with Roche.

### *Research and Development Expenses*

Our research and development expenses consist primarily of costs incurred for new product research and development, significant product improvements, clinical trials to evaluate the clinical utility of FoundationOne and FoundationOne Heme, the development of our FoundationCORE knowledgebase for genomic, medical and clinical data, and the development of our online tools, such as our online portal and mobile applications for Interactive Cancer Explorer. Costs to develop our online tools are recorded as research and development expenses unless they meet the criteria to be capitalized as internal-use software costs. Our research and development activities include the following costs:

personnel-related expenses such as salaries, bonuses, employee benefits, and stock-based compensation;

fees for contractual and consulting services;

costs to manage and synthesize our medical data and to expand our knowledgebase;

clinical trials;

laboratory supplies; and

allocated overhead expenses.

We expect that our overall research and development expenses will continue to increase in absolute dollars as we continue to innovate our molecular information platform, develop additional products, expand our genomic and medical data management resources, and conduct our ongoing and new clinical trials.

### *Interest Expense, Net*

Interest expense, net consists primarily of interest expense on our loan balance and the amortization of debt discounts. Interest income consists of interest earned on our cash and cash equivalents. During the years ended December 31, 2014, 2013, and 2012, interest income was not material. Our loan balance was paid in full during the year ended December 31, 2014.

### *Other Income (Expense), Net*

Other income (expense), net for the year ended December 31, 2014 resulted from a tax incentive award from the Massachusetts Life Sciences Center. Other income (expense), net for the year ended December 31, 2013 resulted from changes in the fair value of our preferred stock warrant liability, which was exercised in October 2013, partially offset by a tax incentive award from the Massachusetts Life Sciences Center.





**Table of Contents****Results of Operations****Comparison of Years Ended December 31, 2014 and 2013**

	Year Ended December 31, 2014	Year Ended December 31, 2013	Change \$	%
<i>(in thousands, except percentages)</i>				
<b>Statement of Operations Data:</b>				
Revenue	\$ 61,079	\$ 28,990	\$ 32,089	111%
Costs and expenses				
Cost of revenue	27,434	11,659	15,775	135%
Selling and marketing	28,997	12,326	16,671	135%
General and administrative	27,302	21,865	5,437	25%
Research and development	30,629	24,901	5,728	23%
Total costs and expenses	114,362	70,751	43,611	62%
Loss from operations	(53,283)	(41,761)	(11,522)	(28%)
Interest expense, net	(42)	(235)	193	(82%)
Other income (expense), net	1,103	(948)	2,051	216%
Net loss	\$ (52,222)	\$ (42,944)	\$ (9,278)	(22%)

**Revenue**

Total revenue increased to \$61.1 million for the year ended December 31, 2014 from \$29.0 million during the year ended December 31, 2013. Revenue from tests reported for our ordering physicians increased to \$36.6 million for the year ended December 31, 2014 from \$14.8 million for the year ended December 31, 2013. The increase was driven by our growing test volumes and expanding commercialization efforts. The increase in revenue from our biopharmaceutical customers to \$24.4 million from \$14.2 million for the years ended December 31, 2014 and 2013, respectively, resulted from increased activity among our new and existing biopharmaceutical customers.

During the year ended December 31, 2014, we reported 24,271 clinical tests to ordering physicians, including 3,716 FoundationOne Heme tests, as compared to 9,095 FoundationOne tests and no FoundationOne Heme tests reported during the year ended December 31, 2013. We also reported 5,586 and 3,776 tests to our biopharmaceutical customers during the years ended December 31, 2014 and 2013, respectively.

The average revenue per test for clinical use that met our revenue recognition criteria during the year ended December 31, 2014 was approximately \$3,600. This average revenue per test does not include 6,363 FoundationOne and FoundationOne Heme tests reported during the period for patients covered by Medicare and for which claims were not yet submitted or paid, 348 tests that were reported and not billed, and 8,830 tests that were reported and billed to commercial third-party payors during the period but were not paid during the period. This average revenue includes 1,559 tests reported in prior years for which revenue was recognized during the year ended December 31, 2014.

The average revenue per test for clinical use that met our revenue recognition criteria during the year ended December 31, 2013 was approximately \$3,500. This average revenue per test does not include 2,080 FoundationOne tests reported during the period for patients covered by Medicare and for which claims were not yet submitted or paid, 198 tests that were reported and not billed, and 2,963 tests that were reported and billed to commercial third-party payors during the period but were not paid during the period. This average revenue includes 435 tests reported in prior years for which revenue was recognized during the year ended December 31, 2013.

## **Table of Contents**

Our average revenue per test excludes tests for which we have not yet recognized revenue. Because we recognize revenue on a cash basis from most commercial third-party payors and from patients who make co-payments, and our efforts to obtain payment for individual claims can take a substantial amount of time, there is typically a significant lag between the time the test is reported and the time we actually recognize the revenue from such test. As a result, if we were to include tests for which we have not recognized revenue in our average revenue per test calculation for a particular period, it would imply that we will not receive any revenue for such tests. Despite our lack of coverage decisions, we have been reasonably successful in securing reimbursement from many commercial third-party payors for tests reported in prior periods. With respect to tests reported for patients covered by Medicare, we commenced the process of submitting claims to Medicare for these tests in November 2013 and have not yet been reimbursed for these claims. We also expect to record revenue from patients who make co-payments, pay deductibles, or pay other amounts that we have been unable to collect from third-party payors. While receipt of payment from third-party payors and patients in respect of these claims is not currently fixed or determinable and collectability is not reasonably assured, we do expect to record revenue in the future for some of the tests reported in this period. However, it is difficult to predict future revenue from the previously reported FoundationOne and FoundationOne Heme tests because we are in an early stage of commercialization and do not yet have broad coverage decisions. As a result, we cannot be certain that the revenue per test we recognize in the future will equal or exceed the average revenue per test reported above.

The cumulative amount of both FoundationOne and FoundationOne Heme tests that have been billed to commercial third-party payors and reported for patients covered by Medicare but for which we have not recognized revenue was 10,471 and 8,844, respectively, as of December 31, 2014. If commercial third-party payors or government payors agree to pay us for any of these tests in the future, we will recognize revenue for any such tests in the period in which our revenue recognition criteria are met. Any revenue that we receive in respect of these previously reported tests will favorably impact our liquidity and results of operations in future periods.

For our biopharmaceutical customer revenue that was based on a negotiated price per test, the average revenue per test was approximately \$3,300 and \$3,700 for the years ended December 31, 2014 and 2013, respectively. This decrease in average revenue per test was due in part to several large projects that included certain volume-based discounts. We expect our average revenue per test for biopharmaceutical customers to remain fairly consistent going forward. Approximately \$11.6 million and \$8.9 million of our biopharmaceutical revenue for the years ended December 31, 2014 and 2013, respectively, represented payments under contracts with multiple element arrangements that were not negotiated on a price per test basis.

### *Cost of Revenue*

Cost of revenue increased to \$27.4 million for the year ended December 31, 2014 from \$11.7 million for the year ended December 31, 2013. This increase was driven by increasing test volumes from our ordering physicians and biopharmaceutical customers. The average cost per test does not differ materially by customer. Additional volume led to higher reagent and consumable costs, additional laboratory personnel-related costs, and higher depreciation expense related to new equipment purchases. During the years ended December 31, 2014 and 2013, our cost of revenue represented approximately 44.9% and 40.2%, respectively, of our total revenue. We expect to make additional investments in personnel, infrastructure, and systems to scale our laboratory operations to meet future anticipated demand.

### *Selling and Marketing Expenses*

Selling and marketing expenses increased to \$29.0 million for the year ended December 31, 2014 from \$12.3 million for the year ended December 31, 2013. The increase was primarily due to an increase of \$13.5 million in personnel related to an increase in headcount in our sales, marketing, client service, and reimbursement departments, a \$2.2 million increase in marketing expenditures on market development and product marketing activities to support our growing commercial and clinical business, a \$0.7 million increase in consulting, and a \$0.3 million increase in various other expenses.

## Table of Contents

### General and Administrative Expenses

General and administrative expenses increased to \$27.3 million for the year ended December 31, 2014 from \$21.9 million for the year ended December 31, 2013. The increase was primarily due to a \$3.7 million increase in legal, consulting, audit, and billing fees, a \$3.6 million increase in personnel and related costs to support and expand our legal, finance, and human resources infrastructure, and a \$1.8 million increase in rent and other facilities costs, partially offset by a \$3.7 million decrease in stock-based compensation primarily as a result of restricted stock that fully vested during 2013.

### Research and Development Expenses

Research and development expenses increased to \$30.6 million for the year ended December 31, 2014 from \$24.9 million for the year ended December 31, 2013. The increase was primarily due to a \$4.5 million increase in employee and contractor-related expenses, a \$1.4 million increase in technology-related support and maintenance, and a \$0.2 million increase in facilities, partially offset by a \$0.4 million decrease in clinical trials expense and research-related lab supplies and materials.

### Interest Expense, Net

Interest expense, net was \$42,000 and \$235,000 for the years ended December 31, 2014 and 2013, respectively. The decrease was due to the reduction in our outstanding loan balance, as the amount was paid in full in December 2014.

### Other Income (Expense), Net

Other income (expense), net was \$1.1 million for the year ended December 31, 2014 resulting from a tax incentive award granted by the Massachusetts Life Sciences Center. Other income (expense), net was \$(0.9) million for the year ended December 31, 2013 resulting from \$1.4 million of other expense associated with the change in the fair value of our warrant liability immediately before it converted into a warrant to purchase common stock and was reclassified into additional paid-in capital, partially offset by \$0.4 million of other income resulting from a tax incentive award granted by the Massachusetts Life Sciences Center.

### Comparison of Years Ended December 31, 2013 and 2012

	Year Ended December 31,		Change	
	2013	2012	\$	%
	(in thousands, except percentages)			
<b>Statement of Operations Data:</b>				
Revenue	\$ 28,990	\$ 10,645	\$ 18,345	172%
Costs and expenses				
Cost of revenue	11,659	5,681	5,978	105%
Selling and marketing	12,326	3,454	8,872	257%
General and administrative	21,865	8,644	13,221	153%
Research and development	24,901	14,777	10,124	69%
Total costs and expenses	70,751	32,556	38,195	117%
Loss from operations	(41,761)	(21,911)	(19,850)	(91%)
Interest expense, net	(235)	(421)	(186)	(44%)
Other expense, net	(948)	(61)	887	1,454%
Net loss	\$ (42,944)	\$ (22,393)	\$ (20,551)	(92%)

## **Table of Contents**

### *Revenue*

Total revenue increased to \$29.0 million for the year ended December 31, 2013 from \$10.6 million during the year ended December 31, 2012. Revenue from tests reported for our ordering physicians increased to \$14.8 million for the year ended December 31, 2013 from \$2.6 million for the year ended December 31, 2012 following the formal commercial launch of FoundationOne in June 2012. The increase was driven by our growing test volumes and expanding commercialization efforts. The increase in revenue from our biopharmaceutical customers to \$14.2 million from \$8.0 million for the years ended December 31, 2013 and 2012, respectively, resulted from increased business development activity among our new and existing biopharmaceutical customers.

During the years ended December 31, 2013 and 2012, we reported 9,095 and 1,750 FoundationOne tests, respectively, for ordering physicians, and 3,776 and 1,350 tests, respectively, for our biopharmaceutical customers.

The average revenue per FoundationOne test for clinical use that met our revenue recognition criteria during the year ended December 31, 2013 was approximately \$3,500. This average revenue per test does not include 2,080 FoundationOne tests reported during the period for patients covered by Medicare and for which claims were not yet submitted or paid, 198 tests that were reported and not billed, and 2,963 tests that were reported and billed to commercial third-party payors during the period but were not paid during the period. This average revenue includes 435 tests reported in prior years for which revenue was recognized during the year ended December 31, 2013.

The average revenue per FoundationOne test for clinical use that met our revenue recognition criteria during the year ended December 31, 2012 was approximately \$3,800. This average revenue per test does not include 398 FoundationOne tests reported during the year for patients covered by Medicare and for which claims were not submitted, 28 tests that were reported and not billed, and 641 tests that were reported and billed to commercial third-party payors during the year but were not paid during the year.

Our average revenue per FoundationOne test excludes tests for which we have not yet recognized revenue. Because we recognize revenue on a cash basis from commercial third-party payors and from patients who make co-payments, and our efforts to obtain payment for individual claims can take a substantial amount of time, there is typically a significant lag between the time the FoundationOne test is reported and the time we actually recognize the revenue from such test. As a result, if we were to include tests for which we have not recognized revenue in our average revenue per test calculation for a particular period, it would imply that we will not receive any revenue for such tests. Despite our lack of coverage decisions, we have been reasonably successful in securing reimbursement from commercial third-party payors for tests reported in prior periods. Similarly, with respect to tests reported for patients covered by Medicare, though we have not yet received payment, we commenced the process of submitting claims to Medicare for these tests in November 2013. We also expect to record revenue from patients who make co-payments, pay deductibles, or pay other amounts that we have been unable to collect from third-party payors. While receipt of payment from third-party payors and patients in respect of these claims is not currently fixed and determinable and collectability is not reasonably assured, we do expect to record revenue in the future for tests reported in this period. However, it is difficult to predict future revenue from the previously reported FoundationOne tests because the test is in an early stage of commercialization and we have limited payment history. As a result, we cannot be certain that the revenue per test we recognize in the future will equal or exceed the average revenue per test reported above.

The cumulative amount of FoundationOne tests that have been billed to commercial third-party payors and reported for patients covered by Medicare but for which we have not recognized revenue was 3,200 and 2,481, respectively, as of December 31, 2013. If commercial third-party payors or government payors agree to pay us for these FoundationOne tests in the future, we will recognize revenue for such FoundationOne tests in the period in which our revenue recognition criteria are met. Any revenue that we receive in respect of these previously reported FoundationOne tests will favorably impact our liquidity and results of operations in future periods.

## **Table of Contents**

For our biopharmaceutical customer revenue that was based on a negotiated price per test, the average revenue per test was approximately \$3,700 for each of the years ended December 31, 2013 and 2012. We expect this average revenue per test for biopharmaceutical customers to remain fairly consistent over time. Approximately \$8.9 million and \$4.4 million of our biopharmaceutical revenue for the years ended December 31, 2013 and 2012, respectively, represented payments under contracts with multiple element arrangements that were not negotiated on a price per test basis.

### *Cost of Revenue*

Cost of revenue increased to \$11.7 million for the year ended December 31, 2013 from \$5.7 million for the year ended December 31, 2012. This increase was driven by increasing test volumes from our ordering physicians and biopharmaceutical customers. The average cost per test does not differ materially by customer. Additional volume led to higher reagent and consumable costs, additional laboratory personnel-related costs, and higher depreciation expense related to new equipment purchases. During the years ended December 31, 2013 and 2012, our cost of revenue represented approximately 40.2% and 53.4%, respectively, of our total revenue. We expect to make additional investments in personnel, infrastructure, and systems to scale our laboratory operations to meet future anticipated demand. As a result, our cost of revenue as a percentage of total revenue could increase in the short-term.

### *Selling and Marketing Expenses*

Selling and marketing expenses increased to \$12.3 million for the year ended December 31, 2013 from \$3.5 million for the year ended December 31, 2012. The increase was primarily due to an increase of \$6.5 million in personnel-related costs related to 19 new employees in our sales, marketing, client service, and reimbursement departments, a \$1.7 million increase in consulting, and a \$0.6 million increase in various other expenses.

### *General and Administrative Expenses*

General and administrative expenses increased to \$21.9 million for the year ended December 31, 2013 from \$8.6 million for the year ended December 31, 2012. The increase was primarily due to a \$5.0 million increase in stock-based compensation, a \$2.6 million increase in rent and other facilities costs, a \$2.6 million increase in personnel costs to support and expand our legal, finance, and human resources infrastructure, a \$1.4 million increase in insurance and other office expenses, a \$1.7 million increase in legal, consulting, audit, and billing fees.

### *Research and Development Expenses*

Research and development expenses increased to \$24.9 million for the year ended December 31, 2013 from \$14.8 million for the year ended December 31, 2012. The increase was primarily due to a \$4.7 million increase in employee and contractor-related expenses, including a \$0.7 million increase in stock-based compensation, a \$2.2 million increase in technology investments related to data management, FoundationOne report design and functionality, and customer interface development, a \$0.8 million increase in facilities, a \$1.2 million increase in clinical trial expenses, and a \$0.5 million increase in overhead allocations and other expenses.

### *Interest Expense, Net*

Interest expense, net was \$0.2 and \$0.4 million for the years ended December 31, 2013 and 2012, respectively.

### *Other Expense, Net*

Other expense, net increased to \$0.9 million for the year ended December 31, 2013 from \$0.1 million for the year ended December 31, 2012. We recorded \$1.4 million of other expense associated with the change in the fair

## Table of Contents

value of our warrant liability immediately before it converted into a warrant to purchase common stock and was reclassified into additional paid-in capital.

### Liquidity and Capital Resources

We have incurred losses and negative cash flows from operations since our inception in November 2009, and as of December 31, 2014, we had an accumulated deficit of \$142.0 million.

We have funded our operations principally from the sale of common stock, preferred stock and revenue from clinical testing and our biopharmaceutical partners. Since we have received only one coverage decision for FoundationOne or FoundationOne Heme from a commercial third-party payor in October 2014 and have a limited history of collecting claims, we currently recognize revenue on a cash basis from most commercial third-party payors. We will continue to make requests for payment and/or appeal payment decisions made by commercial third-party payors. In addition, FoundationOne and FoundationOne Heme are not currently covered by Medicare, and we have not received payment on the claims we have submitted to Medicare. If commercial third-party payors or government payors agree to pay us for any of these tests in the future, we would recognize revenue for any such tests in the period in which our revenue recognition criteria are met.

On September 30, 2013, we completed our initial public offering, or IPO, which resulted in the sale of 6,772,221 shares of our common stock at a public offering price of \$18.00 per share, before underwriting discounts, including 883,333 shares of common stock issued upon the exercise in full by the underwriters of their option to purchase additional shares at the public offering price to cover over-allotments. We received net proceeds from the IPO of approximately \$110.4 million after deducting underwriting discounts, commissions, and expenses payable by us.

As of December 31, 2014, we had cash and cash equivalents of approximately \$72.1 million. Cash in excess of immediate requirements is invested in accordance with our investment policy, primarily with a view to liquidity and capital preservation. These excess funds are held in money market mutual funds consisting of U.S. government-backed securities.

We have occasionally received letters from third parties inviting us to take licenses under, or alleging that we infringe, their patents. While any potential infringement claims could pose an uncertainty for our business, no notice of alleged infringement that we have received to date has led to a lawsuit or a license, and, as a result, no such claim has had an impact on our results of operations.

### Cash Flows

The following table sets forth the primary sources and uses of cash for each of the periods set forth below:

	Year Ended December 31,		
	2014	2013	2012
	(in thousands)		
Net cash provided by (used in):			
Operating activities	\$ (42,736)	\$ (30,766)	\$ (17,249)
Investing activities	(8,827)	(8,494)	(3,183)
Financing activities	(650)	108,715	64,418
Net (decrease) increase in cash and cash equivalents	\$ (52,213)	\$ 69,455	\$ 43,986

## **Table of Contents**

### ***Operating Activities***

Net cash used in operating activities in all periods resulted primarily from our net losses adjusted for non-cash charges and changes in components of working capital. The net cash used in operating activities was \$42.7 million for the year ended December 31, 2014 compared to \$30.8 million for the year ended December 31, 2013. The increase in cash used in operating activities was driven primarily by an increase in net loss of \$9.3 million and a \$2.7 million increase in cash used to support working capital requirements during the year ended December 31, 2014 as compared to the year ended December 31, 2013.

The net cash used in operating activities was \$30.8 million for the year ended December 31, 2013 compared to \$17.2 million for the year ended December 31, 2012. The increase in cash used in operating activities was driven primarily by an increase in net loss of \$20.6 million and changes in working capital of \$2.5 million for the year ended December 31, 2013 as compared to the year ended December 31, 2012, offset by increases in stock-based compensation expense of \$5.8 million and depreciation expense of \$2.1 million, an increase in the fair value adjustment of the warrant liability of \$1.2 million, and an increase in fixed asset impairment charge of \$0.4 million between the respective periods.

### ***Investing Activities***

Net cash used in investing activities for the year ended December 31, 2014 was \$8.8 million and consisted of purchases of property and equipment of \$9.7 million, partially offset by a decrease in restricted cash of \$0.9 million due to the release of a portion of the restricted cash balance related to our laboratory and office facilities. Net cash used in investing activities for the year ended December 31, 2013 was \$8.5 million and consisted of an increase in restricted cash of \$1.6 million related to our new laboratory and office facilities, and purchases of property and equipment of \$6.9 million. Net cash used in investing activities for the year ended December 31, 2012 was \$3.2 million and consisted solely of purchases of property and equipment.

### ***Financing Activities***

Net cash used in financing activities for the year ended December 31, 2014 was \$0.7 million and consisted primarily of \$1.3 million of loan principal payments, partially offset by \$0.6 million of proceeds from the exercise of stock options. Net cash provided by financing activities for the year ended December 31, 2013 was \$108.7 million and reflects the net proceeds from our IPO of \$110.4 million, offset in part by \$1.7 million in loan principal repayments. Net cash provided by financing activities for the year ended December 31, 2012 was \$64.4 million and reflects the sale of our Series A preferred stock for net proceeds of \$10.2 million and the sale of our Series B preferred stock for net proceeds of \$55.7 million, offset in part by \$1.6 million in loan principal repayments.

### ***Operating Capital Requirements***

We expect to incur additional operating losses in the near future and our operating expenses will increase as we continue to expand our sales force, increase our marketing efforts to drive market adoption of FoundationOne and FoundationOne Heme, invest in clinical trials, innovate our molecular information platform, and develop new product offerings. Our liquidity requirements have and will continue to consist of selling and marketing expenses, research and development expenses, capital expenditures, working capital and general corporate expenses. As demand for our products continues to increase from physicians and biopharmaceutical companies, we anticipate that our capital expenditure requirements will also increase in order to build additional capacity. We expect that our planned expenditures will be funded from our ongoing operations and from our existing cash and cash equivalents.

Based on our current business plan, we believe our current cash and cash equivalents and anticipated cash flow from operations will be sufficient to meet our anticipated cash requirements over the next 12 months. If the



**Table of Contents**

proposed transaction with Roche is consummated, we will raise \$250 million in gross proceeds from the sale of 5 million shares of common stock to Roche at a price of \$50 per share. We believe this incremental capital would be sufficient to meet our anticipated cash requirements for the foreseeable future, and we may consider raising additional capital to pursue strategic investments. In the absence of the Roche transaction, we may consider raising additional capital to expand our business, to pursue strategic investments, to take advantage of financing opportunities, or for other reasons. In the future, we expect our operating and capital expenditures to increase as we increase our headcount, expand our selling and marketing activities and continue to invest in new product offerings. As sales of our products grow, we expect our accounts receivable balance to increase. Any increase in accounts payable and accrued expenses may not completely offset increases in accounts receivable, which could result in greater working capital requirements.

If our available cash balances and anticipated cash flow from operations are insufficient to satisfy our liquidity requirements, including because of lower demand for our products as a result of lower than currently expected rates of reimbursement from commercial third-party payors and government payors or other risks described in this Annual Report on Form 10-K, we may seek to sell common or preferred equity or convertible debt securities, enter into a credit facility or another form of third-party funding, or seek other debt financing. The sale of equity and convertible debt securities may result in dilution to our stockholders and those securities may have rights senior to those of our common shares. If we raise additional funds through the issuance of preferred stock, convertible debt securities or other debt financing, these securities or other debt could contain covenants that would restrict our operations. Any other third-party funding arrangement could require us to relinquish valuable rights. We may require additional capital beyond our currently anticipated amounts. Additional capital may not be available on reasonable terms, or at all. If the proposed transaction with Roche is consummated, Roche will obtain certain anti-dilution protections that will relate to future financings.

These estimates are forward-looking statements and involve risks and uncertainties and actual results could vary materially and negatively as a result of a number of factors, including the factors discussed in Part I, Item 1A. Risk Factors of this Annual Report on Form 10-K. We have based our estimates on assumptions that may prove to be wrong and we could utilize our available capital resources sooner than we currently expect. If we cannot expand our operations or otherwise capitalize on our business opportunities because we lack sufficient capital, our business, financial condition, and results of operations could be materially adversely affected.

**Contractual Obligations and Commitments**

The following table summarizes our principal contractual obligations at December 31, 2014.

	<b>Total</b>	<b>2015</b>	<b>2016-2017</b> <i>(in thousands)</i>	<b>2018-2019</b>	<b>Thereafter</b>
Operating lease obligations <sup>(1) (2) (3)</sup>	\$ 27,254	\$ 4,251	\$ 8,600	\$ 9,049	\$ 5,354
Purchase obligations <sup>(4)</sup>	7,350	4,850	2,000	500	
<b>Total</b>	<b>\$ 34,604</b>	<b>\$ 9,101</b>	<b>\$ 10,600</b>	<b>\$ 9,549</b>	<b>\$ 5,354</b>

<sup>(1)</sup> In 2013, we leased 61,591 square feet for office and laboratory space in Cambridge, Massachusetts under an operating lease that expires in February 2021. On June 30, 2014 we signed an amendment to the lease adding 8,164 square feet of additional office and laboratory space under an operating lease which also expires in February 2021.

<sup>(2)</sup> In April 2014, we leased 1,975 square feet for office space in Palo Alto, California under an operating lease that expires in May 2016.

<sup>(3)</sup> In September 2014, we extended the lease of a corporate apartment in Cambridge, Massachusetts under an operating lease that expires in September 2015.

<sup>(4)</sup> In July 2013, we entered into a five-year supply, service and support agreement, or the supply agreement, with Illumina for Illumina to provide products and services that support and can be used for the gene sequencing component of our molecular testing activities. During the remaining term of this supply

## **Table of Contents**

agreement, the actual amount of the purchase obligation shall be determined during each period set forth in the table but will not be lower than the amounts set forth in the table. The actual amount of the purchase obligation shall be based upon a percentage of the forecasts we submit for Illumina product and services.

### **Net Operating Loss Carryforwards**

We have deferred tax assets of approximately \$63.3 million and deferred tax liabilities of \$8.4 million as of December 31, 2014. The deferred tax assets have been fully offset by a valuation allowance due to uncertainties surrounding our ability to realize these tax benefits. The deferred tax assets are primarily composed of federal and state tax net operating loss, or NOL, carryforwards and research and development tax credit carryforwards. As of December 31, 2014, we had federal NOL carryforwards of approximately \$96.1 million and state NOL carryforwards of \$86.7 million available to reduce future taxable income, if any. These federal NOL carryforwards expire at various times through 2034 and the state NOL carryforwards begin to expire in 2024. In general, if we experience a greater than 50 percent aggregate change in ownership of certain significant stockholders over a three-year period, or a Section 382 ownership change, including in connection with the consummation of the proposed transactions with Roche, utilization of our pre-change NOL carryforwards are subject to an annual limitation under Section 382 of the Internal Revenue Code of 1986, as amended, and similar state laws. Such limitations may result in expiration of a portion of the NOL carryforwards before utilization and may be substantial. We have not, as of yet, conducted a study to determine if any such changes have occurred that could limit our ability to use the NOLs and tax credit carryforwards.

### **Off-Balance Sheet Arrangements**

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

### **Application of Critical Accounting Policies**

We have prepared our consolidated financial statements in accordance with accounting principles generally accepted in the United States. The preparation of these consolidated financial statements requires us to make estimates, assumptions, and judgments that affect the reported amounts of assets, liabilities, expenses, and related disclosures at the date of the consolidated financial statements, as well as revenue and expenses recorded during the reporting periods. We evaluate our estimates and judgments on an ongoing basis. We base our estimates on 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 could therefore differ materially from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in Note 2 to our consolidated financial statements included later in this Annual Report on Form 10-K, we believe the following accounting policies to be critical to the judgments and estimates used in the preparation of our consolidated financial statements.

#### ***Revenue Recognition***

We currently derive revenue from selling products that are enabled by our molecular information platform. We recognize revenue when all of the following criteria are present: persuasive evidence of an arrangement exists; delivery has occurred; the fee is fixed or determinable; and collectability is reasonably assured. We receive payments from: commercial third-party payors; certain hospitals and cancer centers with which we have direct bill relationships; individual patients; and our biopharmaceutical customers.

## **Table of Contents**

We currently recognize revenue on a cash basis for sales of our products for which we receive payments from commercial third-party payors and patients who make co-payments, pay deductibles or other amounts that we have been unable to collect from their third-party payors since the fee is not fixed or determinable and collectability is not reasonably assured. Our products are delivered electronically and, as such, there are no shipping and handling fees incurred by us or billed to our customers. We believe our products are exempt from state sales taxation due to the nature of our products. As a result, we do not charge our customers state sales tax. Because we have limited payment experience with third-party payors and patients, we have not concluded that the fee is fixed or determinable or that collectability is reasonably assured, and therefore, we recognize revenue on a cash basis. We expect to 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 payors and patients.

We recognize revenue from the sale of our products to certain hospitals, cancer centers, other institutions, and patients at the time results of our tests are reported to physicians, assuming all revenue recognition criteria have been met.

Our arrangements with biopharmaceutical customers are based on a negotiated price per test or an agreement to provide certain testing volume over a defined period. We recognize revenue from sales of our products to biopharmaceutical customers upon delivery of the test results or over the period the testing volume is provided, as appropriate.

For revenue arrangements with multiple deliverables, each deliverable is evaluated to determine whether it qualifies as a separate unit of accounting. This determination is based on whether the deliverable has stand-alone value to the customer and whether a general right of return exists. The consideration that is fixed or determinable is then allocated to each separate unit of accounting based on the relative selling price of each deliverable. The consideration allocated to each unit of accounting is recognized as the related goods or services are delivered, limited to the consideration that is not contingent upon future deliverables. We use judgment in identifying the deliverables in our arrangements, assessing whether each deliverable is a separate unit of accounting, and in determining the best estimate of selling price for certain of the deliverables. We also use judgment in determining the period over which the deliverables are recognized in certain of our arrangements.

### ***Accrued Expenses***

As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued expenses. This process involves reviewing quotations and contracts, identifying services that have been performed on our behalf, and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost. The majority of our service providers invoice us monthly in arrears for services. We make estimates of our accrued expenses as of each balance sheet date in our consolidated financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of our estimates with the service providers and make adjustments if necessary. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or prepayment accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and could result in us reporting amounts that are too high or too low in any particular period. To date, there have been no material differences from our estimates to the amounts actually incurred.

**Table of Contents*****Stock-based Compensation***

Prior to becoming a public company, we utilized significant estimates and assumptions in determining the fair value of our common stock. We granted stock options at exercise prices not less than the fair value of our common stock as determined by our board of directors, with input from management. The board of directors determined the estimated fair value of our common stock based on a number of objective and subjective factors, including external market conditions affecting the biotechnology industry sector and the prices at which we sold shares of redeemable convertible preferred stock, the superior rights and preferences of securities senior to our common stock at the time, our stage of commercialization, our historical operating results and the likelihood of achieving a liquidity event, such as an initial public offering or sale of our company.

We utilized various valuation methodologies in accordance with the framework of the 2004 American Institute of Certified Public Accountants Technical Practice Aid, or Practice Aid, Valuation of Privately-Held Company Equity Securities Issued as Compensation, to estimate the fair value of our common stock. Our board of directors estimated our enterprise value as of the various valuation dates using a market approach and an income approach, which are acceptable valuation methods in accordance with the Practice Aid. Under the market approach, enterprise value can be estimated by evaluating recent arm's length transactions involving the sale of our preferred stock to investors and by comparisons to similar publicly traded companies. Under the income approach, enterprise value can be estimated using the discounted cash flow method. Additionally, each valuation reflects a marketability discount, resulting from the illiquidity of our common stock. We performed these contemporaneous valuations as of August 31, 2011, November 5, 2012, February 15, 2013, and May 10, 2013.

We have included stock-based compensation as part of our cost of revenue and our operating expenses in our statements of operations and comprehensive loss as follows:

	Year Ended December 31,		
	2014	2013	2012
Cost of revenue	\$ 466	\$ 67	\$ 22
Selling and marketing	1,130	142	31
General and administrative	2,635	6,346	1,388
Research and development	1,758	761	94
<b>Total</b>	<b>\$ 5,989</b>	<b>\$ 7,316</b>	<b>\$ 1,535</b>

We account for stock-based compensation arrangements with our employees, consultants, and non-employee directors using a fair value method, which requires us to recognize compensation expense for costs related to all share-based payments. To date, our stock-based awards have included grants of stock options, restricted stock units, or RSUs, and restricted stock.

The fair value method for stock option awards requires us to estimate the fair value of stock-based awards to employees and non-employees on the date of grant using the Black-Scholes option-pricing method. The fair value is then recognized, net of estimated forfeitures, as stock-based compensation expense over the requisite service period, which is typically the vesting period, of the award. Stock-based awards granted to non-employees are subject to periodic revaluation over their vesting term.

The Black-Scholes option-pricing model requires the input of subjective assumptions, including expected stock price volatility and the expected life of stock options. We do not have sufficient history to estimate the volatility of our common stock price or the expected term of our stock options. We calculate expected volatility based on historical volatility data of a representative group of companies that are publicly traded. We selected representative companies with comparable characteristics to us, including risk profiles, position within the industry, and with historical stock price information sufficient to meet the expected term of the stock-based awards. We compute the historical volatility of this selected group using the daily closing prices for the selected

## **Table of Contents**

companies' shares during the equivalent period of the calculated expected term of our stock-based awards. We will continue to use the representative group volatility information until the historical volatility of our common stock is relevant to measure expected volatility for future stock option grants.

We determine the expected term of stock options according to the simplified method. Under this method, the expected term is calculated as the average of the time-to-vesting and the contractual life of the stock option. The assumed dividend yield is based on our expectation that we will not pay dividends in the foreseeable future, which is consistent with our history of not paying dividends. We determine the risk-free interest rate by using the equivalent to the expected term based on the U.S. Treasury yield curve in effect as of the date of grant. We estimate forfeitures at the time of grant and revise our estimates, as appropriate, but actual future forfeiture rates may differ. If actual results differ significantly from these estimates, stock-based compensation expense and our statements of operations and comprehensive loss could be materially impacted.

We have also granted performance-based stock options with terms that allow the recipients to vest in a specific number of shares based upon the achievement of performance-based milestones as specified in the grants. Stock-based compensation expense associated with these performance-based stock options is recognized if the performance condition is considered probable of achievement using management's best estimates of the time to vesting for the achievement of the performance-based milestones. If the actual achievement of the performance-based milestones varies from our estimates, stock-based compensation expense could be materially different than what is recorded in the period. The cumulative effect on current and prior periods of a change in the estimated time to vesting for performance-based stock options will be recognized as compensation cost in the period of the revision, and recorded as a change in estimate.

The fair values of our restricted stock and RSUs are based on the market value of our stock on the date of grant. Compensation expense for restricted stock and RSUs is recognized on a straight-line basis over the applicable service period.

While the assumptions used to calculate and account for share-based compensation awards represents management's best estimates, these estimates involve inherent uncertainties and the application of management's judgment. As a result, if revisions are made to our underlying assumptions and estimates, our share-based compensation expense could vary significantly from period to period.

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

We are exposed to market risk related to changes in interest rates. As of December 31, 2014, we had cash and cash equivalents of \$72.1 million held primarily in money market mutual funds consisting of U.S. government-backed securities. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our investments are in short-term securities. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, an immediate one percent change in interest rates would not have a material effect on the fair market value of our portfolio.

## **ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

Our consolidated financial statements, together with the report of independent registered public accounting firm, appear at pages F-1 through F-25 of this Annual Report on Form 10-K for the year ended December 31, 2014.

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

None.

## **Table of Contents**

### **ITEM 9A. CONTROLS AND PROCEDURES**

#### ***Evaluation of Disclosure Controls and Procedures***

Disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) are designed only to provide reasonable assurance that they will meet their objectives. Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness, as of December 31, 2014, of the design and operation of our disclosure controls and procedures, as such term is defined in Exchange Act Rules 13a-15(e) and 15d-15(e). Based on this evaluation, our principal executive officer and principal financial officer have concluded that, as of such date, our disclosure controls and procedures are effective to ensure that information required to be disclosed by us in our Exchange Act reports is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

#### ***Management's Annual Report on Internal Control Over Financial Reporting***

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as such term is defined in Exchange Act Rule 13a-15(f) or 15d-15(d). Our internal control system was designed to provide reasonable assurance to our management and our board of directors regarding the preparation and fair presentation of published financial statements. All internal control systems, no matter how well designed have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2014. In making this assessment, our management used the criteria set forth in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission in 2013, or the COSO criteria. Based on this assessment, management concluded that our internal control over financial reporting was effective as of December 31, 2014. This Annual Report on Form 10-K does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of the Company's independent registered public accounting firm due to a transition period established by rules of the Securities and Exchange Commission for newly public companies.

#### ***Changes in Internal Control Over Financial Reporting***

There were no changes in our internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) or 15d-15(d)) during the quarter ended December 31, 2014 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

### **ITEM 9B. OTHER INFORMATION**

None.

**Table of Contents**

**PART III**

**ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE**

The information required under this item is incorporated herein by reference to the Company's definitive proxy statement to be filed in connection with its annual stockholder meeting pursuant to Regulation 14A, which proxy statement will be filed with the SEC not later than 120 days after the close of the Company's fiscal year ended December 31, 2014.

**ITEM 11. EXECUTIVE COMPENSATION**

The information required under this item is incorporated herein by reference to the Company's definitive proxy statement to be filed in connection with its annual stockholder meeting pursuant to Regulation 14A, which proxy statement will be filed with the SEC not later than 120 days after the close of the Company's fiscal year ended December 31, 2014.

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

The information required under this item is incorporated herein by reference to the Company's definitive proxy statement to be filed in connection with its annual stockholder meeting pursuant to Regulation 14A, which proxy statement will be filed with the SEC not later than 120 days after the close of the Company's fiscal year ended December 31, 2014.

**ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE**

The information required under this item is incorporated herein by reference to the Company's definitive proxy statement to be filed in connection with its annual stockholder meeting pursuant to Regulation 14A, which proxy statement will be filed with the SEC not later than 120 days after the close of the Company's fiscal year ended December 31, 2014.

**ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES**

The information required under this item is incorporated herein by reference to the Company's definitive proxy statement to be filed in connection with its annual stockholder meeting pursuant to Regulation 14A, which proxy statement will be filed with the SEC not later than 120 days after the close of the Company's fiscal year ended December 31, 2014.

**Table of Contents**

**PART IV**

**ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES**

**(a) 1. Consolidated Financial Statements.**

For a list of the consolidated financial statements included herein, see Index on page F-1 of this report.

**2. Financial Statement Schedules.**

All required information is included in the financial statements or notes thereto.

**3. List of Exhibits.**

See the Exhibit Index in Item 15(b) below.

**(b) Exhibit Index.**

<b>Exhibit No.</b>	<b>Exhibit Index</b>
2.1	Transaction Agreement, by and between the Company and Roche Holdings, Inc., dated January 11, 2015 (incorporated by reference to Exhibit 2.1 of the Company's Form 8-K filed on January 12, 2015)
3.1	Sixth Amended and Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1 of the Company's Form 8-K filed on October 2, 2013)
3.2	Amended and Restated Bylaws of the Company (incorporated by reference to Exhibit 3.2 of the Company's Form 8-K filed on October 2, 2013)
4.1	Form of Common Stock certificate of the Company (incorporated by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-1/A (File No. 333-190226) filed on September 12, 2013)
4.2	Warrant to Purchase Preferred Stock of the Company, dated as of November 1, 2010, issued to Lighthouse Capital Partners VI, L.P. (incorporated by reference to Exhibit 4.2 to the Company's Registration Statement on Form S-1 (File No. 333-190226) filed on July 29, 2013)
4.3	Second Amended and Restated Investors' Rights Agreement, by and between the Company and the Investors named therein, dated as of June 20, 2013 (incorporated by reference to Exhibit 4.3 to the Company's Registration Statement on Form S-1 (File No. 333-190226) filed on July 29, 2013)
4.4	Investor Rights Agreement, by and between the Company and Roche Holdings, Inc., dated January 11, 2015 (incorporated by reference to Exhibit 4.1 of the Company's Form 8-K filed on January 12, 2015)
4.5	Amendment to Second Amended and Restated Investors' Rights Agreement, by and between the Company and the Investors named therein, dated January 11, 2015 (incorporated by reference to Exhibit 4.2 of the Company's Form 8-K filed on January 12, 2015)
10.1	Amended and Restated 2010 Stock Incentive Plan and forms of agreements thereunder (incorporated by reference to Exhibit 10.1 to the Company's Registration Statement on Form S-1 (File No. 333-190226) filed on July 29, 2013)
10.2	2013 Stock Option and Incentive Plan and forms of agreements thereunder (incorporated by reference to Exhibit 10.2 to the Company's Registration Statement on Form S-1/A (File No. 333-190226) filed on September 12, 2013)





## **Table of Contents**

<b>Exhibit No.</b>	<b>Exhibit Index</b>
10.3	Executive Employee Offer Letter issued by the Company to Michael J. Pellini, dated as of September 9, 2013 (incorporated by reference to Exhibit 10.3 to the Company's Registration Statement on Form S-1/A (File No. 333-190226) filed on September 12, 2013)
10.4	Executive Employee Offer Letter issued by the Company to Kevin Krenitsky, dated as of March 7, 2013 (incorporated by reference to Exhibit 10.4 to the Company's Registration Statement on Form S-1 (File No. 333-190226) filed on July 29, 2013)
10.5	Executive Employee Offer Letter issued by the Company to Robert W. Hesslein, dated as of March 7, 2013 (incorporated by reference to Exhibit 10.5 to the Company's Registration Statement on Form S-1 (File No. 333-190226) filed on July 29, 2013)
10.6	Executive Employee Offer Letter issued by the Company to Jason Ryan, dated as of March 7, 2013 (incorporated by reference to Exhibit 10.6 to the Company's Registration Statement on Form S-1 (File No. 333-190226) filed on July 29, 2013)
10.7	Executive Employee Offer Letter issued by the Company to Steven J. Kafka, dated as of May 21, 2013, as amended (incorporated by reference to Exhibit 10.7 to the Company's Registration Statement on Form S-1/A (File No. 333-190226) filed on September 12, 2013)
10.8	Form of Indemnification Agreement, to be entered into between the Company and its directors and officers (incorporated by reference to Exhibit 10.8 to the Company's Registration Statement on Form S-1/A (File No. 333-190226) filed on August 16, 2013)
10.9	Lease, by and between the Company and 150 Second Street, LLC, dated as of February 4, 2013 (incorporated by reference to Exhibit 10.10 to the Company's Registration Statement on Form S-1 (File No. 333-190226) filed on July 29, 2013)
10.10	Lease, by and between the Company and 150 Second Street, LLC, dated as of March 27, 2013 (incorporated by reference to Exhibit 10.11 to the Company's Registration Statement on Form S-1 (File No. 333-190226) filed on July 29, 2013)
10.11	Loan and Security Agreement, by and between the Company and Lighthouse Capital Partners VI, L.P., dated as of November 1, 2010, as amended (incorporated by reference to Exhibit 10.12 to the Company's Registration Statement on Form S-1 (File No. 333-190226) filed on July 29, 2013)
10.12#	Supply and Support Agreement, by and between the Company and Illumina, Inc., effective as of July 25, 2013 (incorporated by reference to Exhibit 10.13 to the Company's Registration Statement on Form S-1/A (File No. 333-190226) filed on August 2, 2013)
10.13#	Laboratory Master Services Agreement, by and between the Company and Novartis Pharmaceuticals Corporation, dated as of November 21, 2011, as amended (incorporated by reference to Exhibit 10.14 to the Company's Registration Statement on Form S-1/A (File No. 333-190226) filed on August 2, 2013)
10.14	Executive Employee Offer Letter issued by the Company to Vincent A. Miller, dated as of August 1, 2011, as amended (incorporated by reference to Exhibit 10.15 to the Company's Registration Statement on Form S-1/A (File No. 333-190226) filed on September 12, 2013)
10.15	2013 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.16 to the Company's Registration Statement on Form S-1/A (File No. 333-190226) filed on September 12, 2013)
10.16	First Amendment to Lease, by and between the Company and 150 Second Street, LLC, dated November 27, 2013 (incorporated by reference to Exhibit 10.1 of the Company's Form 8-K filed on December 4, 2013)

## **Table of Contents**

<b>Exhibit No.</b>	<b>Exhibit Index</b>
10.17#	Second Amendment to Laboratory Master Services Agreement, by and between the Company and Novartis Pharmaceuticals Corporation, dated January 6, 2014 (incorporated by reference to Exhibit 10.1 of the Company's Form 8-K filed on January 7, 2014)
10.18	Second Amendment to Lease, by and between the Company and ARE-MA REGION NO. 50, LLC, dated June 30, 2014 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on July 2, 2014).
10.19	Tax Sharing Agreement, by and between the Company and Roche Holdings, Inc., dated January 11, 2015 (incorporated by reference to Exhibit 10.1 of the Company's Form 8-K filed on January 12, 2015)
10.20#	Collaboration Agreement, by and among the Company, F. Hoffman-La Roche Ltd and Hoffman-La Roche Inc., dated January 11, 2015 (incorporated by reference to Exhibit 10.2 of the Company's Form 8-K/A filed on February 2, 2015)
10.21#	Ex-US Commercialization Agreement, by and between the Company and F. Hoffmann-La Roche Ltd, dated January 11, 2015 (incorporated by reference to Exhibit 10.3 of the Company's Form 8-K/A filed on February 2, 2015)
10.22#	US Education Collaboration Agreement, by and between the Company and Genentech, Inc., dated January 11, 2015 (incorporated by reference to Exhibit 10.4 of the Company's Form 8-K/A filed on February 2, 2015)
10.23#	Binding Term Sheet for an In Vitro Diagnostics Collaboration, by and between the Company and F. Hoffman-La Roche Ltd, dated January 11, 2015 (incorporated by reference to Exhibit 10.5 of the Company's Form 8-K/A filed on February 2, 2015)
10.24	Executive Employee Offer letter issued by the Company to David J. Daly, dated as of November 20, 2014 (incorporated by reference to Exhibit (e)(26) to the Company's Solicitation/Recommendation Statement on Schedule 14D-9 filed on February 2, 2015)
10.25	Deed of Lease, by and between the Company and BCSP Cambridge Ten Property LLC, dated March 11, 2015 (incorporated by reference to Exhibit 10.1 of the Company's Form 8-K filed on March 12, 2015)
21.1*	Subsidiaries of the Company
23.1*	Consent of Ernst & Young LLP
31.1*	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1**	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101	Interactive Data Files regarding (a) our Consolidated Balance Sheets as of December 31, 2014 and 2013, (b) our Consolidated Statements of Operations and Comprehensive Loss for the Years Ended December 31, 2014, 2013 and 2012, (c) our Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit) for the Years Ended December 31, 2014, 2013 and 2012, (d) our Consolidated Statements of Cash Flows for the Years Ended December 31, 2014, 2013 and 2012, and (e) the Notes to such Consolidated Financial Statements

**Table of Contents**

- \* Filed herewith.
- \*\* Furnished herewith.
- Indicates a management contract or any compensatory plan, contract or arrangement.
- # Confidential treatment has been requested or granted for certain information contained in this exhibit. Such information has been omitted and filed separately with the Securities and Exchange Commission.

**Table of Contents****SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

FOUNDATION MEDICINE, INC.

Date: March 13, 2015

By: /s/ Michael J. Pellini, M.D.  
Michael J. Pellini, M.D.  
President and Chief Executive Officer

*(Principal Executive Officer)*

Date: March 13, 2015

By: /s/ Jason Ryan  
Jason Ryan  
Senior Vice President, Finance

*(Principal Financial and Accounting Officer)*

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Name	Title	Date
/s/ Michael J. Pellini, M.D.	President, Chief Executive Officer and Director	March 13, 2015
Michael J. Pellini, M.D.	<i>(Principal Executive Officer)</i>	
/s/ Jason Ryan	Senior Vice President, Finance	March 13, 2015
Jason Ryan	<i>(Principal Financial and Accounting Officer)</i>	
/s/ Alexis Borisy	Director	March 13, 2015
Alexis Borisy		
/s/ Brook Byers	Director	March 13, 2015
Brook Byers		
/s/ Evan Jones	Director	March 13, 2015
Evan Jones		
/s/ David Schenkein, M.D.	Director	March 13, 2015
David Schenkein, M.D.		
/s/ Krishna Yeshwant, M.D.	Director	March 13, 2015

Krishna Yeshwant, M.D.

**Table of Contents**

**Index to Consolidated Financial Statements**

	<b>PAGE</b>
<u>Report of Independent Registered Public Accounting Firm</u>	F-2
<u>Consolidated Balance Sheets as of December 31, 2014 and 2013</u>	F-3
<u>Consolidated Statements of Operations and Comprehensive Loss for the Years Ended December 31, 2014, 2013 and 2012</u>	F-4
<u>Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit) for the Years Ended December 31, 2014, 2013 and 2012</u>	F-5
<u>Consolidated Statements of Cash Flows for the Years Ended December 31, 2014, 2013 and 2012</u>	F-6
<u>Notes to Consolidated Financial Statements</u>	F-7

**Table of Contents**

**Report of Independent Registered Public Accounting Firm**

The Board of Directors and Stockholders of

Foundation Medicine, Inc.

We have audited the accompanying consolidated balance sheets of Foundation Medicine, Inc. (the Company) as of December 31, 2014 and 2013, and the related consolidated statements of operations and comprehensive loss, redeemable convertible preferred stock and stockholders' equity (deficit) and cash flows for each of the three years in the period ended December 31, 2014. 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 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. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also 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.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Foundation Medicine, Inc. at December 31, 2014 and 2013, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2014, in conformity with U.S. generally accepted accounting principles.

/s/ Ernst & Young LLP

Boston, Massachusetts

March 13, 2015



**Table of Contents****FOUNDATION MEDICINE, INC.****Consolidated Balance Sheets***(In thousands, except share and per share data)*

	<b>December 31,</b>	
	<b>2014</b>	<b>2013</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 72,080	\$ 124,293
Accounts receivable	9,894	6,262
Inventory	4,809	1,763
Prepaid expenses and other current assets	2,865	992
Total current assets	89,648	133,310
Property and equipment, net	21,015	22,104
Restricted cash	864	1,725
Other assets	411	129
Total assets	\$ 111,938	\$ 157,268
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 7,263	\$ 7,007
Accrued expenses and other current liabilities	7,414	5,168
Deferred revenue	340	918
Current portion of deferred rent	1,429	1,167
Current portion of notes payable		1,499
Total current liabilities	16,446	15,759
Deferred rent, net of current portion	9,315	9,710
Restricted stock liability	8	88
Commitments and contingencies (Note 11 )		
Stockholders' equity:		
Preferred stock, \$0.0001 par value, 5,000,000 authorized; no shares issued and outstanding at December 31, 2014 and 2013		
Common stock, \$0.0001 par value, 150,000,000 shares authorized; 28,223,958 and 27,630,781 shares issued and outstanding at December 31, 2014 and 2013, respectively	3	3
Additional paid-in capital	228,151	221,471
Accumulated deficit	(141,985)	(89,763)
Total stockholders' equity	86,169	131,711
Total liabilities and stockholders' equity	\$ 111,938	\$ 157,268

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

F-3

**Table of Contents****FOUNDATION MEDICINE, INC.****Consolidated Statements of Operations and Comprehensive Loss***(In thousands, except share and per share data)*

	<b>Year Ended December 31,</b>		
	<b>2014</b>	<b>2013</b>	<b>2012</b>
Revenue	\$ 61,079	\$ 28,990	\$ 10,645
Costs and expenses:			
Cost of revenue	27,434	11,659	5,681
Selling and marketing	28,997	12,326	3,454
General and administrative	27,302	21,865	8,644
Research and development	30,629	24,901	14,777
Total costs and expenses	114,362	70,751	32,556
Loss from operations	(53,283)	(41,761)	(21,911)
Other income (expense):			
Interest expense, net	(42)	(235)	(421)
Other income (expense), net	1,103	(948)	(61)
Total other income (expense), net	1,061	(1,183)	(482)
Net loss	(52,222)	(42,944)	(22,393)
Accretion of redeemable convertible preferred stock		(139)	(286)
Net loss applicable to common stockholders	\$ (52,222)	\$ (43,083)	\$ (22,679)
Net loss per common share applicable to common stockholders, basic and diluted	\$ (1.87)	\$ (4.64)	\$ (10.47)
Weighted average common shares outstanding, basic and diluted	27,954,327	9,294,730	2,166,832
Comprehensive loss	\$ (52,222)	\$ (42,944)	\$ (22,393)

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

**Table of Contents****FOUNDATION MEDICINE, INC.****Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders Equity (Deficit)***(In thousands, except share and per share data)*

	<b>Series A</b>		<b>Series B</b>		<b>Common Stock</b>		<b>Additional</b>	<b>Accumulated</b>	<b>Total</b>
	<b>Redeemable Convertible</b>	<b>Preferred Stock</b>	<b>Redeemable Convertible</b>	<b>Preferred Stock</b>	<b>Shares</b>	<b>Amount</b>	<b>Paid-In</b>	<b>Deficit</b>	<b>Stockholders</b>
	<b>Shares</b>	<b>Amount</b>	<b>Shares</b>	<b>Amount</b>	<b>Shares</b>	<b>Amount</b>	<b>Capital</b>	<b>Deficit</b>	<b>(Deficit)</b>
									<b>Equity</b>
Balance at December 31, 2011	33,500,000	\$ 32,455		\$	1,651,625	\$	\$ 2,123	\$ (24,426)	\$ (22,303)
Issuance of Series A redeemable convertible preferred stock net of issuance costs of \$21,618	10,250,000	10,228							
Issuance of Series B redeemable convertible preferred stock net of issuance costs of \$273,022			24,762,134	55,689					
Accretion of redeemable convertible preferred stock to redemption value		279		7			(286)		(286)
Vesting of restricted stock					1,075,818		50		50
Stock-based compensation expense							1,535		1,535
Net loss								(22,393)	(22,393)
Balance at December 31, 2012	43,750,000	42,962	24,762,134	55,696	2,727,443		3,422	(46,819)	(43,397)
				(10)					

Issuance costs related to Series B preferred stock offering									
Accretion of redeemable convertible preferred stock to redemption value		125		14			(139)		(139)
Conversion of redeemable convertible preferred stock into common stock	(43,750,000)	(43,087)	(24,762,134)	(55,700)	17,128,024	2	98,785		98,787
Reclassification of warrant to purchase redeemable convertible preferred stock into warrant to purchase common stock							1,605		1,605
Issuance of common stock from initial public offering, net of underwriters discounts and issuance costs					6,772,221	1	110,380		110,381
Issuance of common stock in exchange for services					633		4		4
Exercise of warrant for common stock					44,566				
Exercise of stock options					48,863		49		49
Vesting of restricted stock					909,031		49		49
Stock-based compensation expense							7,316		7,316
Net loss								(42,944)	(42,944)
					27,630,781	3	221,471	(89,763)	131,711

Balance at December 31, 2013							
Exercise of stock options		212,822		637			637
Vesting of restricted stock		380,355		54			54
Stock-based compensation expense				5,989			5,989
Net loss					(52,222)		(52,222)
Balance at December 31, 2014	\$	\$	28,223,958	\$ 3	\$ 228,151	\$ (141,985)	\$ 86,169

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

F-5

**Table of Contents****FOUNDATION MEDICINE, INC.****Consolidated Statements of Cash Flows***(In thousands)*

	<b>Year Ended December 31,</b>		
	<b>2014</b>	<b>2013</b>	<b>2012</b>
<b>Operating activities</b>			
Net loss	\$ (52,222)	\$ (42,944)	\$ (22,393)
Adjustments to reconcile net loss to cash used in operating activities:			
Depreciation and amortization expense	8,195	5,006	2,894
Stock-based compensation	5,989	7,316	1,535
Impairment of fixed assets		439	
Change in fair value of warrant liability		1,380	131
Common stock issued in exchange for professional services		4	
Non-cash interest expense	3	58	104
Changes in operating assets and liabilities:			
Accounts receivable	(3,632)	(4,067)	(1,917)
Inventory	(3,046)	(960)	(485)
Prepaid expenses and other current assets	(1,873)	(442)	(237)
Other assets	(282)	(102)	10
Accounts payable	3,119	1,672	147
Accrued expenses	1,724	1,515	1,447
Deferred rent	(133)	1,219	(109)
Deferred revenue	(578)	(860)	1,624
Net cash used in operating activities	(42,736)	(30,766)	(17,249)
<b>Investing activities</b>			
Purchases of property and equipment	(9,688)	(6,930)	(3,183)
Decrease (increase) in restricted cash	861	(1,564)	
Net cash used in investing activities	(8,827)	(8,494)	(3,183)
<b>Financing activities</b>			
Proceeds from issuance of restricted stock and stock option exercises	637	49	70
Payments of notes payable	(1,287)	(1,705)	(1,569)
Proceeds from issuance of common stock, net of issuance costs		110,381	
Proceeds from issuance of Series A Preferred Stock and related investor rights, net of issuance costs			10,228
Proceeds from issuance of Series B Preferred Stock, net of issuance costs		(10)	55,689
Net cash (used in) provided by financing activities	(650)	108,715	64,418
Net (decrease) increase in cash and cash equivalents	(52,213)	69,455	43,986
Cash and cash equivalents at beginning of period	124,293	54,838	10,852
Cash and cash equivalents at end of period	\$ 72,080	\$ 124,293	\$ 54,838

**Supplemental disclosure of cash flow information**

Cash paid for interest	\$	263	\$	171	\$	305
------------------------	----	-----	----	-----	----	-----

**Supplemental disclosure of non-cash investing and financing activities**

Conversion of convertible preferred stock into common stock	\$		\$	98,787	\$	
---	----	--	----	--------	----	--

Acquisition of property and equipment included in accounts payable and accrued expenses	\$	1,334	\$	3,916	\$	1,070
---	----	-------	----	-------	----	-------

Reclassification of warrant liability to additional paid-in capital	\$		\$	1,605	\$	
---	----	--	----	-------	----	--

Accretion of convertible preferred stock to redemption value	\$		\$	139	\$	286
--	----	--	----	-----	----	-----

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

F-6



---

**Table of Contents**

**FOUNDATION MEDICINE, INC.**

**Notes to Consolidated Financial Statements**

**1. Nature of Business**

Foundation Medicine, Inc. (including its subsidiary, and collectively, the Company) is a molecular information company focused on fundamentally changing the way in which patients with cancer are evaluated and treated. We believe an information-based approach to making clinical treatment decisions based on comprehensive genomic profiling will become a standard of care for patients with cancer. We derive revenue from selling products that are enabled by our molecular information platform to physicians and biopharmaceutical companies.

Our first clinical products, FoundationOne® for solid tumors, and FoundationOne Heme for blood-based cancers, or hematologic malignancies, including leukemia, lymphoma, myeloma, and many sarcomas and pediatric cancers, are, to our knowledge, the only widely available comprehensive genomic profiles designed for use in the routine care of patients with cancer. To accelerate our commercial growth and enhance our competitive advantage, we are continuing to expand our sales force, grow our molecular information knowledgebase, called FoundationCORE, publish scientific and medical advances, foster relationships throughout the oncology community, and develop new clinical and technology products.

The Company, originally named Foundation Genomics, Inc., is a Delaware company founded in November 2009 and has a principal place of business in Cambridge, Massachusetts.

The Company believes that its existing cash and cash equivalents at December 31, 2014 will be sufficient to allow the Company to fund its current operating plan through at least January 1, 2016. As the Company continues to incur losses, its transition to profitability is dependent upon a level of revenues adequate to support the Company's cost structure. If the Company's transition to profitability is not consistent with its current operating plan, the Company may have to seek additional capital.

**2. Summary of Significant Accounting Policies and Basis of Presentation**

**A. Basis of Presentation and Consolidation**

The Company's consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States (GAAP). Any reference in these notes to applicable guidance is meant to refer to the authoritative United States generally accepted accounting principles as found in the Accounting Standards Codification (ASC) and Accounting Standards Update (ASU) of the Financial Accounting Standards Board (FASB). The Company's consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary, Foundation Medicine Securities Corporation. All intercompany balances and transactions have been eliminated.

**B. Use of Estimates**

The preparation of financial statements in conformity with GAAP requires management 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 consolidated financial statements and the reported amounts of revenue and expenses during the reporting period. The Company bases its estimates on historical experience and other market-specific or other relevant assumptions that it believes to be reasonable under the circumstances. This process may result in actual results differing materially from those estimated amounts used in the preparation of the financial statements if these results differ from historical experience, or other assumptions do not turn out to be substantially accurate, even if such assumptions are reasonable when made. Significant estimates relied upon in preparing these consolidated financial statements include revenue recognition, accrued expenses, the determination of the fair value of stock awards issued prior to the initial public offering in September 2013, stock-based compensation expense, and the valuation allowance on the Company's deferred tax asset.

F-7

---

**Table of Contents**

**C. Off-Balance Sheet Risk and Concentrations of Credit Risk**

The Company has no off-balance sheet risk, such as foreign exchange contracts, option contracts, or other foreign hedging arrangements. Financial instruments, which potentially subject the Company to significant concentrations of credit risk, consist primarily of cash and cash equivalents and accounts receivable. The primary objectives for the Company's investment portfolio are the preservation of capital and the maintenance of liquidity. The Company's investment policy includes guidelines on the quality of the institutions and financial instruments and defines allowable investments that the Company believes minimizes the exposure to concentration of credit risk.

The Company routinely assesses the creditworthiness of its customers. The Company has not experienced any material losses related to receivables from individual customers, or groups of customers. The Company does not require collateral. Due to these factors, no additional credit risk beyond amounts provided for collection losses is believed by management to be probable in the Company's accounts receivable.

**D. Segment Information**

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. The Company views its operations and manages its business in one operating segment, which is the business of delivering molecular information about cancer to its customers.

The Company's revenue is generated primarily in the United States. The majority of the Company's revenue from customers located outside the United States, which was generated from four customers, was \$4,450,000, \$3,234,000, and \$788,000 for the years ended December 31, 2014, 2013, and 2012, respectively. All of the Company's long-lived assets are located in the United States.

**E. Cash and Cash Equivalents**

The Company considers all highly liquid investments with original maturity from the date of purchase of three months or less to be cash equivalents. Cash and cash equivalents include bank demand deposits and money market funds that invest primarily in U.S. government treasuries. Cash equivalents are carried at cost, which approximates their fair value.

**F. Accounts Receivable**

The Company's accounts receivable consist primarily of amounts due from biopharmaceutical customers, and from certain hospitals, cancer centers and other institutions with whom it has negotiated price per test (direct bill) relationships for tests performed using its molecular information platform. There are no accounts receivable associated with amounts that are billed to commercial third-party payors or directly to patients, because this revenue is recognized on a cash basis (see Note 2 Section K). At each reporting period, management reviews all outstanding customer balances to determine if the facts and circumstances of each customer relationship indicate the need for a reserve. The Company did not have an allowance for doubtful accounts at December 31, 2014 or 2013.

Four customer account balances consisting of \$1,673,000, \$1,168,000, \$1,128,000 and \$1,073,000 were greater than 10% of the total accounts receivable balance representing 17%, 12%, 11% and 11%, respectively, of accounts receivable at December 31, 2014. Three customer account balances consisting of \$1,418,000, \$1,047,000, and

\$771,000 were greater than 10% of the total accounts receivable balance representing 23%, 17%, and 12%, respectively, of accounts receivable at December 31, 2013.

F-8

**Table of Contents****G. Inventory**

Inventories are stated at the lower of cost or market on a first-in, first-out basis. In order to assess the ultimate realization of inventories, the Company is required to make judgments as to future demand requirements compared to current or committed inventory levels. The Company evaluates its inventories for excess quantities and obsolescence. Inventories that are considered excess or obsolete are expensed.

At December 31, 2014 and 2013, inventory consisted of the following (in thousands):

	<b>December 31,</b>	
	<b>2014</b>	<b>2013</b>
Raw materials	\$ 3,851	\$ 1,479
Work-in-process	958	284
	<b>\$ 4,809</b>	<b>\$ 1,763</b>

**H. Property and Equipment**

Property and equipment are stated at cost, less accumulated depreciation and amortization. Property and equipment are depreciated and amortized using the straight-line method over the estimated useful lives of the assets. Maintenance and repairs are expensed as incurred. The following estimated useful lives are used to depreciate the Company's assets:

	<b>Estimated Useful Life</b>
Computer equipment and software	3 years
Lab equipment	3 years
Furniture and fixtures	5 years
Leasehold improvements	Lesser of initial lease term or useful life

The Company capitalizes certain costs incurred for software developed or obtained for internal use, including external direct material and service costs. Capitalized internal-use software costs, which are included in property and equipment, are generally depreciated over three years.

The Company reviews long-lived assets when events or changes in circumstances indicate the carrying value of the assets may not be recoverable. Recoverability is measured by comparison of the assets' book value to future net undiscounted cash flows that the assets are expected to generate. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the book value of the assets exceeds their fair value, which is measured based on the projected discounted future net cash flows arising from the assets. No impairment losses have been recorded during the years ended December 31, 2014, 2013 and 2012. (See Note 3)

**I. Restricted Cash**

Restricted cash consists of deposits securing collateral letters of credit issued in connection with the Company's operating leases. The Company had restricted cash of \$864,000 and \$1,725,000 as of December 31, 2014 and 2013, respectively.

**J. Fair Value of Financial Instruments**

The Company is required to disclose information on all assets and liabilities reported at fair value that enables an assessment of the inputs used in determining the reported fair values. FASB ASC Topic 820, *Fair Value Measurements and Disclosures* ( ASC 820 ), establishes a hierarchy of inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that

F-9

## **Table of Contents**

the observable inputs be used when available. Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from sources independent of the company. Unobservable inputs are inputs that reflect a company's assumptions about the inputs that market participants would use in pricing the asset or liability, and are developed based on the best information available in the circumstances. The fair value hierarchy applies only to the valuation inputs used in determining the reported fair value of the investments and is not a measure of the investment credit quality. The hierarchy defines three levels of valuation inputs:

- Level 1 inputs    Quoted prices in active markets for identical assets or liabilities
- Level 2 inputs    Inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly
- Level 3 inputs    Unobservable inputs that reflect the company's own assumptions about the assumptions market participants would use in pricing the asset or liability

The fair value hierarchy prioritizes valuation inputs based on the observable nature of those inputs. Assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires management to make judgments and consider factors specific to the asset or liability. (See Note 6)

## **K. Revenue Recognition**

The Company derives revenue from selling products that are enabled by its molecular information platform. The Company currently receives payments from: commercial third-party payors; certain hospitals and cancer centers with which it has direct-bill relationships; individual patients; and its biopharmaceutical customers.

The Company recognizes revenue in accordance with FASB ASC Topic 605, *Revenue Recognition* (ASC 605). Accordingly, the Company recognizes revenue when all of the following criteria are met: (i) persuasive evidence of an arrangement exists; (ii) delivery has occurred; (iii) the fee is fixed or determinable; and (iv) collectability is reasonably assured. Criterion (i) is satisfied when the Company has an arrangement or contract in place. Criterion (ii) is satisfied when the Company delivers a report to the ordering physician or the biopharmaceutical customer. Determination of criteria (iii) and (iv) are based on management's judgments regarding whether the fee is fixed or determinable, and whether the collectability of the fee is reasonably assured.

The Company recognizes revenue on a cash basis when it cannot conclude that criteria (iii) and (iv) have been met. The Company currently recognizes revenue on a cash basis from sales of its products for which the Company receives payments from commercial third-party payors and from patients who make co-payments, pay deductibles or from other amounts that the Company has been unable to collect from third-party payors. The Company uses judgment in its 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 it continues to gain payment experience with third-party payors and patients. Accordingly, the Company expects to recognize revenue on a cash basis for these customers until it has sufficient history to reliably estimate payment patterns. The Company's products are delivered electronically, and as such there are no shipping and handling fees incurred by the Company or billed to customers. The Company's products are exempt from state sales taxation due to the nature of the products. As a result, the Company does not charge customers state sales tax.

The Company recognizes revenue from the sale of its products to certain hospitals, cancer centers, other institutions and patients at the time results of the test are reported to physicians, if criteria (i) through (iv) above are met.

Revenue from sales of the Company's products to biopharmaceutical customers are based on a negotiated price per test or on the basis of an agreement to provide certain testing volume, data access, or other services over

F-10



## **Table of Contents**

a defined period. The Company recognizes revenue upon delivery of the test results, or over the period the testing volume is provided, as appropriate.

Certain of the Company's arrangements with biopharmaceutical customers include multiple deliverables. For revenue arrangements with multiple deliverables, the Company evaluates each deliverable to determine whether it qualifies as a separate unit of accounting. This determination is based on whether the deliverable has stand-alone value to the customer and whether a general right of return exists. The consideration that is fixed or determinable is then allocated to each separate unit of accounting based on the relative selling price of each deliverable. The consideration allocated to each unit of accounting is recognized as the related goods or services are delivered, limited to the consideration that is not contingent upon future deliverables. The Company uses judgment in identifying the deliverables in its arrangements, assessing whether each deliverable is a separate unit of accounting, and in determining the best estimate of selling price for certain deliverables. The Company also uses judgment in determining the period over which the deliverables are recognized in certain of its arrangements. Any amounts received that do not meet the criteria for revenue recognition are recorded as deferred revenue until such criteria are met.

One customer arrangement, consisting of \$7,996,000 of revenue was greater than 10% of total revenue, representing 13% of the Company's total revenue for the year ended December 31, 2014. Two customer arrangements, consisting of \$6,813,000 and \$3,652,000 of revenue were greater than 10% of total revenue, representing 23% and 13%, respectively, of the Company's total revenue for the year ended December 31, 2013. Two customer arrangements, consisting of \$4,233,000 and \$1,339,000 of revenue, were greater than 10% of total revenue, representing 40% and 13%, respectively, of the Company's total revenue for the year ended December 31, 2012.

## **L. Research and Development Expenses**

Research and development costs are expensed as incurred and include salaries and benefits, facilities costs, overhead costs, clinical trial costs, contract services and other related costs.

## **M. Stock-Based Compensation**

The Company accounts for stock-based compensation awards in accordance with FASB ASC Topic 718, *Compensation - Stock Compensation* (ASC 718). ASC 718 requires all stock-based compensation to employees, including grants of employee stock options and restricted stock and modifications to existing stock options, to be recognized in the statement of operations and comprehensive loss based on their fair values.

Compensation expense related to awards to employees is recognized on a straight-line basis, based on the grant date fair value, over the requisite service period of the award, which is generally the vesting term. Awards to non-employees are adjusted through stock-based compensation expense as the awards vest to reflect the current fair value of such awards, and are expensed using the straight-line method.

The Company expenses restricted stock awards based on the fair value of the award on a straight-line basis over the requisite service period of the award. The unvested portion of awards of restricted stock to non-employees is subject to remeasurement over the vesting term.

The Company estimates the fair value of its stock-based awards to employees and directors using the Black-Scholes option pricing model, which requires subjective assumptions, including (a) the expected stock price volatility, (b) the expected term of the award, (c) the risk-free interest rate, and (d) expected dividends. Due to the lack of

Company-specific historical and implied volatility data, the Company has based its estimate of expected volatility on the historical volatility of a representative group of companies that are publicly traded. The Company selected a representative group of companies with comparable characteristics to it, including risk profiles, position within the industry, and with historical share price information sufficient to meet the expected

F-11

**Table of Contents**

term of the stock-based awards. The Company computes the historical volatility of this selected group using the daily closing prices for the selected companies' shares during the equivalent period of the calculated expected term of the stock-based awards. The Company will continue to apply this process until a sufficient amount of historical information regarding the volatility of its own stock price becomes available. The Company estimates the expected life of its employee stock options using the simplified method, whereby, the expected life equals the arithmetic average of the vesting term and the original contractual term of the option due to its lack of sufficient historical data. The risk-free interest rates for periods within the expected term of the option are based on the U.S. Treasury securities with a maturity date commensurate with the expected term of the associated award. The Company has never paid, and does not expect to pay, dividends in the foreseeable future; therefore, the expected dividend yield is assumed to be zero.

Forfeitures are required to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. The term forfeitures is distinct from cancellations and represents only the unvested portion of the surrendered option. Ultimately, the actual expense recognized over the vesting period will only be for those options that vest. (See Note 8)

**N. Income Taxes**

Income taxes are recorded in accordance with FASB ASC Topic 740, *Income Taxes* (ASC 740), which provides for deferred taxes using an asset and liability approach. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases using enacted tax rates in effect for the year in which the differences are expected to affect taxable income. Tax benefits are recognized when it is more likely than not that a tax position will be sustained during an audit. Deferred tax assets are reduced by a valuation allowance if current evidence indicates that it is considered more likely than not that these benefits will not be realized.

**O. Net Loss Per Share**

Basic net loss per share is calculated by dividing net loss applicable to common stockholders by the weighted-average shares outstanding during the period, without consideration for common stock equivalents. Diluted net loss per share is calculated by adjusting the weighted-average shares outstanding for the dilutive effect of common stock equivalents outstanding for the period, determined using the treasury-stock method. For purposes of the diluted net loss per share calculation, Preferred Stock, stock options, restricted stock awards, and warrants are considered to be common stock equivalents but are excluded from the calculation of diluted net loss per share because their effect would be anti-dilutive. Therefore, basic and diluted net loss per share applicable to common stockholders were the same for all periods presented.

**P. Comprehensive Loss**

Comprehensive income (loss) is defined as the change in equity of a business enterprise during a period from transactions, other events, and circumstances from non-owner sources. Comprehensive income (loss) consists of net income (loss) and other comprehensive income (loss), which includes certain changes in equity that are excluded from net income (loss). Comprehensive loss is included in the accompanying statements of operations and comprehensive loss and equals the Company's net loss for all periods presented.

**Q. Application of new or revised accounting standards**

On April 5, 2012, the Jump-Start Our Business Startups Act (the JOBS Act) was signed into law. The JOBS Act contains provisions that, among other things, reduce certain reporting requirements for an emerging growth company. As an emerging growth company, the Company has elected to not take advantage of the extended transition period afforded by the JOBS Act for the implementation of new or revised accounting standards, and as a result, will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth companies.

F-12

**Table of Contents****R. Recent Accounting Pronouncements**

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies and adopted by the Company as of the specified effective date. Unless otherwise discussed, the Company believes that the impact of recently issued standards that are not yet effective will not have a material impact on its financial position or results of operations upon adoption.

In May 2014, the FASB and the International Accounting Standards Board jointly issued ASU No. 2014-09, *Revenue from Contracts with Customers* ( ASU 2014-09 ), which supersedes the revenue recognition requirements in ASC 605 and most industry-specific guidance. The new standard requires that an entity recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. The update also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract.

ASU 2014-09 is effective for public entities for annual and interim periods beginning after December 15, 2016. Early adoption is not permitted under GAAP and retrospective application is permitted but not required. The Company is evaluating the method of adoption and the potential impact this standard may have on its consolidated financial position, results of operations or cash flows.

In August 2014, the FASB issued ASU No. 2014-15, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern* ( ASU 2014-15 ). ASU 2014-15 requires management to evaluate, at each annual or interim reporting period, whether there are conditions or events that exist that raise substantial doubt about an entity's ability to continue as a going concern within one year after the date the financial statements are issued and provide related disclosures. ASU 2014-15 is effective for annual periods ending after December 15, 2016 and earlier application is permitted. The adoption of ASU 2014-15 is not expected to have a material effect on the Company's consolidated financial statements or disclosures.

**S. Subsequent Events**

The Company considers events or transactions that occur after the balance sheet date but prior to the issuance of the consolidated financial statements to provide additional evidence relative to certain estimates or to identify matters that require additional disclosure.

**3. Property and Equipment**

Property and equipment and related accumulated depreciation and amortization are as follows (in thousands):

	<b>December 31,</b>	
	<b>2014</b>	<b>2013</b>
Lab equipment	\$ 14,843	\$ 12,193
Computer equipment	6,673	4,772
Software	2,111	542
Furniture and office equipment	1,974	1,610
Leasehold improvements	12,834	12,213

	38,435	31,330
Less accumulated depreciation and amortization	(17,420)	(9,226)
	\$ 21,015	\$ 22,104

F-13

**Table of Contents**

Depreciation and amortization expense for the years ended December 31, 2014, 2013, and 2012 was \$8,195,000, \$5,006,000, and \$2,894,000, respectively. The Company classifies capitalized internal-use software in lab equipment, computer equipment and software based on its intended use. Depreciation expense related to all capitalized internal-use software for the years ended December 31, 2014, 2013 and 2012 was \$459,000, \$459,000 and \$221,000, respectively. The remaining unamortized capitalized internal-use software costs at December 31, 2014 and 2013 were \$238,000 and \$698,000, respectively.

**4. Accrued Expenses**

Accrued expenses consisted of the following (in thousands):

	<b>December 31,</b>	
	<b>2014</b>	<b>2013</b>
Payroll and employee-related costs	\$ 5,011	\$ 3,258
Professional services	1,123	1,127
Equipment purchases	471	122
Other	809	661
	<b>\$ 7,414</b>	<b>\$ 5,168</b>

**5. Net Loss Per Common Share**

The following potential common stock equivalents were not included in the calculation of diluted net loss per common share because the inclusion thereof would be antidilutive.

	<b>Year Ended December 31,</b>		
	<b>2014</b>	<b>2013</b>	<b>2012</b>
<b>Denominator:</b>			
Series A Preferred Stock			10,937,500
Series B Preferred Stock			6,190,526
Warrant			50,000
Outstanding stock options	2,792,021	2,314,284	1,221,396
Unvested restricted stock	335,933	517,237	1,423,698
<b>Total</b>	<b>3,127,954</b>	<b>2,831,521</b>	<b>19,823,120</b>

**6. Fair Value Measurements**

As referenced in Note 2, accounting principles provide guidance for using fair value to measure assets and liabilities based on a hierarchy of inputs and requires management to make judgments and consider factors specific to the asset or liability.

As of December 31, 2014 and 2013, Company's financial instruments consist of cash and cash equivalents, accounts receivable, accounts payable, accrued liabilities and notes payable. The carrying amount of cash and cash equivalents, accounts receivable, accounts payable, accrued liabilities, and notes payable approximate their fair values because of the short-term nature of the instruments or, in the case of the notes payable, because the interest rates the Company believes it could obtain for similar borrowings are similar to the existing interest rates on the notes payable.

F-14



**Table of Contents**

The following tables present information about the Company's assets and liabilities that are measured at fair value on a recurring basis as of December 31, 2014 and 2013, and indicate the fair value hierarchy of the valuation techniques utilized to determine such fair value (in thousands):

**Fair Value Measurement at December 31, 2014**

	<b>Quoted Prices in Active Markets (Level 1)</b>	<b>Significant Other Observable Inputs (Level 2)</b>	<b>Significant Unobservable Inputs (Level 3)</b>	<b>Total</b>
<b>Assets:</b>				
Cash held in money market funds	\$ 68,016	\$	\$	\$ 68,016
<b>Total</b>	<b>\$ 68,016</b>	<b>\$</b>	<b>\$</b>	<b>\$ 68,016</b>

**Fair Value Measurement at December 31, 2013**

	<b>Quoted Prices in Active Markets (Level 1)</b>	<b>Significant Other Observable Inputs (Level 2)</b>	<b>Significant Unobservable Inputs (Level 3)</b>	<b>Total</b>
<b>Assets:</b>				
Cash held in money market funds	\$ 125,001	\$	\$	\$ 125,001
<b>Total</b>	<b>\$ 125,001</b>	<b>\$</b>	<b>\$</b>	<b>\$ 125,001</b>

The Company measures eligible assets and liabilities at fair value, with changes in value recognized in the statement of operations and comprehensive loss. Fair value treatment may be elected either upon initial recognition of an eligible asset or liability or, for an existing asset or liability, if an event triggers a new basis of accounting. The Company did not elect to remeasure any of its existing financial assets or liabilities, and did not elect the fair value option for any financial assets and liabilities transacted during the years ended December 31, 2014 and 2013.

**7. Notes Payable**

In November 2010, the Company entered into a Loan Agreement with Lighthouse Capital Partners VI, L.P., whereby the Company had access to borrow up to \$5,000,000. The Company borrowed all \$5,000,000 available under the Loan Agreement in increments greater than \$100,000 through January 31, 2012 (the "Commitment Termination Date"). For each advance, the Company paid interest only payments at a fixed rate of 8.25% for six months, followed by 36 months of interest and principal payments and a final payment of 4.5% of the advance. The debt was secured by certain property and equipment. The final payments were amortized over the term of the advances and recorded in interest expense. At December 31, 2014, the loan was paid in full. At December 31, 2013 there was \$1,499,000 outstanding under the Loan Agreement, which included \$215,000 of deferred interest payments. In connection with the Loan Agreement, the Company recorded interest expense in the accompanying consolidated statements of operations and comprehensive loss totaling \$61,000, \$228,000, and \$408,000 during the years ended December 31,

2014, 2013, and 2012, respectively.

In connection with the Loan Agreement, the Company issued a warrant to purchase up to 200,000 shares of the Series A Preferred Stock at a purchase price of \$1.00 per share. As of December 31, 2012, the warrant was exercisable for 200,000 shares of Series A Preferred Stock. In conjunction with the closing of the Company's IPO, the warrant was automatically converted into a warrant exercisable for 50,000 shares of common stock at a purchase price of \$4.00 per share, which resulted in the reclassification of the related convertible preferred stock warrant liability to additional paid-in capital as the warrant met the criteria for equity classification upon conversion to a warrant for the purchase of common stock. In October 2013, Lighthouse Capital Partners completed a cashless exercise of the warrant and received 44,566 shares of the Company's common stock.

F-15

**Table of Contents****8. Stockholders Equity**  
**Common Stock**

On September 30, 2013, the Company closed its initial public offering ( IPO ) whereby the Company sold 6,772,221 shares of common stock (inclusive of 883,333 shares of common stock sold by the Company pursuant to the full exercise of an overallotment option granted to the underwriters in connection with the offering) at a price of \$18.00 per share, for net proceeds of \$110,381,000. The shares began trading on the Nasdaq Global Select Market on September 25, 2013. Upon the closing of the IPO, all outstanding shares of convertible preferred stock converted into 17,128,024 shares of common stock.

Common stockholders are entitled to one vote per share. Holders of common stock are entitled to receive dividends, when and if declared by the Board of Directors. The voting, dividend, and liquidation rights of the holders of the common stock are subject to, and qualified by, the rights of the holders of the preferred stock, of which no shares were outstanding at December 31, 2014.

The Company has reserved for future issuance the following number of shares of common stock:

	<b>December 31,</b>	
	<b>2014</b>	<b>2013</b>
Unvested restricted stock	335,933	517,237
Common stock options outstanding	2,792,021	2,314,284
Shares available for issuance under the 2013 Stock Plan	1,375,555	1,139,244
Shares available for issuance under the 2013 Employee Stock Purchase Plan	788,503	788,503
	<b>5,292,012</b>	<b>4,759,268</b>

In November 2009, the Company issued 2,125,000 shares of common stock to the founders of the Company for consideration equal to the par value per share, the then estimated fair value of the common stock. The founders entered into restricted stock agreements whereby the shares of common stock issued were subject to vesting and became fully vested in November 2013. An additional 112,500 shares of common stock subject to repurchase were issued to employees and consultants at fair value during the year ended December 31, 2010. Shares subject to repurchase by the Company are recorded as a liability at their original purchase price. Shares subject to repurchase that were issued to non-employees are revalued at each vesting date and at the end of the reporting period, with changes in fair value recorded as stock-based compensation expense on a straight-line basis. As the Company's right to repurchase the shares lapses, the liability is reclassified to additional paid-in capital. The following table shows a roll forward of restricted stock activity outside of the 2010 Stock Plan and the 2013 Stock Plan, each as defined and discussed below:

	<b>Number of Shares</b>
Unvested at December 31, 2013	2,606
Granted	
Vested	(2,606)

Unvested at December 31, 2014

Total stock-based compensation expense recognized for restricted stock issued outside of the 2010 Plan was \$5,764,000 and \$1,284,000 for the years ended December 31, 2013 and 2012, respectively. There was no stock-based compensation expense for the year ended December 31, 2014. The total fair value of the restricted stock issued outside of the 2010 Plan that vested during the years ended December 31, 2014, 2013 and 2012 was \$78,000, \$5,943,000 and \$1,113,000, respectively.

F-16

**Table of Contents****2010 and 2013 Stock Incentive Plans**

In 2010, the Company adopted the Foundation Medicine, Inc. 2010 Stock Incentive Plan (the "2010 Stock Plan") under which it may grant restricted stock, incentive stock options ("ISOs") and non-statutory stock options to eligible employees, officers, directors and consultants to purchase up to 1,162,500 shares of common stock. In the year ended December 31, 2013, the Company amended the 2010 Stock Plan to increase the number of shares of common stock available for issuance to 4,232,500.

In 2013, the Company adopted the Foundation Medicine, Inc. 2013 Stock Option and Incentive Plan (the "2013 Stock Plan") under which it may grant restricted and unrestricted stock, restricted stock units, ISOs, non-statutory stock options, stock appreciation rights, cash-based awards, performance share awards and dividend equivalent rights to eligible employees, officers, directors and consultants to purchase up to 1,355,171 shares of common stock. In connection with the establishment of the 2013 Stock Plan, the Company terminated the 2010 Stock Plan and the 512,568 shares available for grant under the 2010 Stock Plan were included in the number of shares authorized under the 2013 Stock Plan. Shares forfeited or repurchased from the 2010 Stock Plan are returned to the 2013 Stock Plan for future issuance. On January 1, 2014, the number of shares reserved and available for issuance under the 2013 Stock Plan increased by 1,125,921 shares of common stock pursuant to a provision in the 2013 Stock Plan that provides that the number of shares reserved and available for issuance will automatically increase on January 1 of each year, beginning on January 1, 2014, by 4% of the number of shares of the Company's common stock issued and outstanding on the immediately preceding December 31 or such lesser number as determined by the compensation committee of the Board of Directors.

The terms of stock award agreements, including vesting requirements, are determined by the Board of Directors, subject to the provisions of the 2010 Stock Plan and the 2013 Stock Plan. Options granted by the Company typically vest over a four-year period. Certain of the options are subject to acceleration of vesting in the event of certain change of control transactions. The options are exercisable from the date of grant for a period of 10 years. For options granted to date, the exercise price equaled the estimated fair value of the common stock as determined by the Board of Directors on the date of grant.

*Restricted Stock*

The 2010 Stock Plan and the 2013 Stock Plan allow for granting of restricted stock awards. For restricted stock awards granted to employees, the intrinsic value on the date of grant is recognized as stock-based compensation expense ratably over the period in which the restrictions lapse. For restricted stock awards granted to non-employees the intrinsic value is remeasured at each vesting date and at the end of the reporting period. The following table shows a roll forward of restricted stock activity pursuant to the 2010 Stock Plan and the 2013 Stock Plan:

	<b>Number of Shares</b>
Unvested at December 31, 2013	72,198
Granted	210,615
Vested	(60,119)
Cancelled	(3,077)
Unvested at December 31, 2014 <sup>(1)</sup>	219,617

(1) Excludes 116,316 shares of unvested restricted stock remaining from the early exercise of stock options. Total stock-based compensation expense recognized for restricted stock awards was \$740,000, \$153,000, and \$36,000 for the years ended December 31, 2014, 2013 and 2012, respectively. The total fair value of the restricted stock awards that vested during the years ended December 31, 2014, 2013 and 2012 approximated the stock-based compensation expense recorded during the respective periods. As of December 31, 2014, \$4,025,000

F-17

**Table of Contents**

of unrecognized compensation expense related to restricted stock is expected to be recognized over a weighted-average period of 3.4 years.

*Stock Options*

A summary of stock option activity under the 2010 Stock Plan and the 2013 Stock Plan is as follows (in thousands, except share and per share amounts):

	Number of Shares	Weighted- Average Exercise Price	Weighted- Average Remaining Contractual Term (In Years)	Aggregate Intrinsic Value <sup>(2)</sup>
Outstanding as of December 31, 2013	2,314,284	\$ 4.78	8.8	\$ 44,236
Granted	797,874	26.30		
Exercised	(212,822)	3.00		
Cancelled	(107,315)	10.23		
Outstanding as of December 31, 2014	2,792,021	\$ 10.82	8.3	\$ 35,390
Exercisable as of December 31, 2014	1,136,238	\$ 4.72	7.7	\$ 20,259
Vested and expected to vest at December 31, 2014 <sup>(1)</sup>	2,652,414	\$ 10.03	8.2	\$ 35,528

(1) This represents the number of vested options plus the number of unvested options expected to vest at the respective dates, based on unvested options adjusted for estimated forfeitures.

(2) The aggregate intrinsic value was calculated based on the positive difference between the estimated fair value of the Company's common stock on December 31, 2014, or the date of exercise, as appropriate, and the exercise price of the underlying options.

Certain stock options contain provisions allowing for the early exercise of such options into shares subject to repurchase by the Company. For the years ended December 31, 2013 and 2012, 8,750 and 119,812 options, respectively, were exercised prior to vesting. At December 31, 2014, 116,316 shares, which were early exercised, remain subject to repurchase.

The weighted-average fair value of options granted for the years ended December 31, 2014, 2013, and 2012 was \$15.88, \$4.89, and \$1.08, respectively. The Company recorded total stock-based compensation expense for stock options granted to employees, directors and non-employees from the 2010 Stock Plan and the 2013 Stock Plan of \$5,249,000, \$1,399,000, and \$215,000 during the years ended December 31, 2014, 2013 and 2012, respectively. The aggregate intrinsic value of stock options exercised during the years ended December 31, 2014, 2013, and 2012 was \$4,799,000, \$791,000, and \$268,000, respectively. As of December 31, 2014, unrecognized compensation cost of \$11,461,000 related to non-vested employee stock-based compensation arrangements is expected to be recognized over a weighted-average period of 3.0 years.

The Company recorded stock-based compensation expense in the consolidated statements of operations and comprehensive loss as follows (in thousands):

	<b>Year Ended December 31,</b>		
	<b>2014</b>	<b>2013</b>	<b>2012</b>
Cost of revenue	\$ 466	\$ 67	\$ 22
Selling and marketing	1,130	142	31
General and administrative	2,635	6,346	1,388
Research and development	1,758	761	94
<b>Total</b>	<b>\$ 5,989</b>	<b>\$ 7,316</b>	<b>\$ 1,535</b>

F-18



**Table of Contents**

The weighted-average assumptions used to estimate the fair value of stock options using the Black-Scholes option pricing model were as follows:

	<b>Year Ended December 31,</b>		
	<b>2014</b>	<b>2013</b>	<b>2012</b>
Expected volatility	64.2%	66.9%	68.8%
Risk-free interest rate	1.99%	1.49%	1.29%
Expected option term (in years)	6.25	6.25	6.25
Expected dividend yield	0.0%	0.0%	0.0%

**2013 Employee Stock Purchase Plan**

In September 2013, the Company adopted the Foundation Medicine, Inc. Employee Stock Purchase Plan (the 2013 Employee Stock Purchase Plan), under which the Company is authorized to issue and sell shares of its common stock to participating employees. A total of 788,503 shares of common stock are available for issuance under the 2013 Employee Stock Purchase Plan.

All employees who have been employed by the Company or its designated subsidiaries for at least six weeks and whose customary employment is for more than 20 hours a week are eligible to participate in the 2013 Employee Stock Purchase Plan. Any employee who owns, or would own upon such purchase under the 2013 Employee Stock Purchase Plan, 5% or more of the voting power or value of the Company's stock is not eligible to purchase shares under the 2013 Employee Stock Purchase Plan.

The Company may make one or more offerings to its employees to purchase stock under the 2013 Employee Stock Purchase Plan. The period of any offering shall not exceed six months in duration or overlap with another offering period. Each employee who is a participant in the 2013 Employee Stock Purchase Plan may purchase shares by authorizing payroll deductions of up to 10% of his or her eligible compensation during any offering. Unless the participating employee has previously withdrawn from the offering, his or her accumulated payroll deductions will be used to purchase common stock on the last business day of the offering period at a price equal to 85% of the fair market value of the common stock on the first business day or the last business day of the offering period, whichever is lower. During any offering period, an employee may not acquire shares constituting 5% or more of the voting power of the Company's stock, or such other maximum number established by the Company. During any calendar year, an employee may not purchase more than \$25,000 worth of common stock, valued at the start of the offering period. An employee's participation under the 2013 Employee Stock Purchase Plan terminates upon voluntary withdrawal or upon termination of employment. Accumulated payroll deductions at the time the employee's participation ends shall be refunded to the employee.

Although authorized, the 2013 Employee Stock Purchase Plan has not been implemented by the Company. As of December 31, 2014, no employees are participating in, and no shares have been purchased under, the 2013 Employee Stock Purchase Plan.

**9. Income Taxes**

The Company accounts for income taxes under ASC 740. Deferred income tax assets and liabilities are determined based upon differences between financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse.

## Edgar Filing: Foundation Medicine, Inc. - Form 10-K

For the years ended December 31, 2014, 2013, and 2012, the Company has not recorded a provision for federal or state income taxes as it has incurred cumulative net operating losses since inception.

As of December 31, 2014, the Company had federal and state net operating loss carryforwards of approximately \$96,100,000 and \$86,700,000, respectively, which were available to reduce future taxable income. The federal and state net operating loss carryforwards exclude approximately \$3,200,000 and \$2,400,000 of

F-19

**Table of Contents**

deductions related to the exercise of stock options, respectively. This amount represents an excess tax benefit and has not been included in the gross deferred tax asset reflected for net operating losses and is credited directly to additional paid-in capital when realized. The net operating loss carryforwards expire at various times beginning in 2029 for federal purposes and 2024 for state purposes.

The Company also had federal and state tax credits of approximately \$3,600,000 and \$3,000,000, respectively, which may be used to offset future tax liabilities. These tax credit carryforwards will expire at various times beginning in 2029 for federal purposes and 2015 for state purposes.

The net operating loss and tax credit carryforwards are subject to review and possible adjustment by the Internal Revenue Service and state tax authorities. Net operating loss and tax credit carryforwards may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant stockholders over a three-year period in excess of 50%, as defined under Sections 382 and 383 of the Internal Revenue Code, respectively, as well as similar state provisions. This could limit the amount of tax attributes that can be utilized annually to offset future taxable income or tax liabilities. The amount of the annual limitation is determined based on the value of the Company immediately prior to the ownership change. Subsequent ownership changes may further affect the limitation in future years. The Company has not, as yet, conducted a study to determine if any such changes have occurred that could limit its ability to use the net operating loss and tax credit carryforwards.

The Company has not recorded any reserves for uncertain tax positions as of December 31, 2014 or 2013. If the Company did record a reserve, it would be a component of income tax expense. The Company has not, as yet, conducted a study of research and development credit carryforwards. This study may result in an adjustment to the Company's research and development credit carryforwards; however, until a study is completed and any adjustment is known, no amounts are being presented as an uncertain tax position. As of December 31, 2014, the Company had no accrued interest or penalties related to uncertain tax positions. Since the Company is in a loss carryforward position, the Company is generally subject to examination by the U.S. federal, state and local income tax authorities for all tax years in which a loss carryforward is available. The Company is not currently under examination by the Internal Revenue Service or any other jurisdictions for any tax years.

The principal components of the Company's deferred tax assets are as follows:

	<b>As of December 31,</b>	
	<b>2014</b>	<b>2013</b>
Deferred tax assets:		
Net operating loss carryforwards	\$ 37,245	\$ 27,585
Deferred revenue	130	359
Accrued bonus	1,162	954
Deferred rent	4,110	4,247
Nonaccrual receivables	13,372	
Other	1,702	878
Research and development credits	5,544	3,009
Gross deferred tax assets	63,265	37,032
Deferred tax liability	(8,429)	(3,455)
Valuation allowance	(54,836)	(33,577)

Edgar Filing: Foundation Medicine, Inc. - Form 10-K

Net deferred tax assets	\$	\$
-------------------------	----	----

ASC 740 requires a valuation allowance to reduce the deferred tax assets reported if, based on the weight of available evidence, it is more likely than not that some portion or all of the deferred tax assets will not be realized. After consideration of all the evidence, both positive and negative, the Company has recorded a valuation allowance against its deferred tax assets at December 31, 2014 and 2013, respectively, because the

F-20

**Table of Contents**

Company's management has determined that it is more likely than not that these assets will not be fully realized. The increase in the valuation allowance of \$21,300,000 in 2014 primarily relates to the net loss incurred by the Company during that period.

A reconciliation of the income tax expense at the federal statutory tax rate to the Company's effective income tax rate follows:

	<b>Year Ended December 31,</b>		
	<b>2014</b>	<b>2013</b>	<b>2012</b>
Statutory tax rate	34.0%	34.0%	34.0%
State taxes, net of federal benefit	3.7%	4.0%	4.8%
Permanent differences	(1.9%)	(6.7%)	(2.5%)
Research and development credit	4.9%	5.0%	1.1%
Other		0.1%	(0.3%)
Change in valuation allowance	(40.7%)	(36.4%)	(37.1%)
Effective tax rate	0.0%	0.0%	0.0%

**10. Significant Agreements***Biopharmaceutical Customer*

In November 2011, the Company entered into a Master Services Agreement (MSA) with a biopharmaceutical customer (Customer) establishing the legal and administrative framework for collaboration. In May 2012, the Company and Customer amended the MSA to include certain guaranteed quarterly minimum payments by Customer in return for the Company providing sufficient laboratory capacity to perform up to a maximum number of tests. The amendment defined an initial two year term beginning on the amendment date, during which Customer agreed to pay the Company \$14,200,000. The Company and Customer executed a second amendment to the MSA, which was effective in October 2013, and extended the term through at least September 2016 during which time the Customer agreed to pay the Company \$17,100,000. The Company concluded that the second amendment represented a material modification to the arrangement pursuant to ASC 605-25 *Revenue Recognition: Multiple-Element Arrangements*. At the date of the modification, there was no deferred revenue balance on the consolidated balance sheet. The Company identified three deliverables under the amended agreement: (1) project management and Joint Steering Committee services, (2) the provision of molecular information developed by the Company upon Customer's request, and (3) the provision of sufficient laboratory capacity to test a minimum number of samples provided by Customer. The Company then determined the project management and Joint Steering Committee services did not have standalone value as a result of the fact these services are not sold separately by any vendor, and a customer could not resell these deliverables on a standalone basis without the provision of the laboratory capacity. The provision of molecular information was determined to have stand-alone value, as the services could be sold separately and the Customer could get the intended benefit from the services without the receipt of the remaining deliverables in the amended MSA. Thus, the Company determined the arrangement includes two units of accounting, and revenue is being recognized on both units of accounting over the three-year term of the amended MSA as there is no evidence to suggest revenue is earned or obligations are fulfilled in a different pattern. Under the amended MSA, the Company recognized revenue of \$7,996,000, \$6,812,000 and \$4,233,000 for the years ended December 31, 2014, 2013, and 2012, respectively.

## **11. Commitments and Contingencies**

### *One Kendall Square*

In May 2010, the Company commenced a facility lease which was due to expire in October 2015. In November 2013, the Company terminated this lease effective October 31, 2013 (the Surrender Date ). The Company paid rent, operating expenses and other charges due under the facility lease through the Surrender

F-21

**Table of Contents**

Date. In exchange for terminating the facility lease, the Company paid the landlord an additional \$338,000 equal to two additional months of rent, operating expenses and all other charges due under the facility lease, plus reimbursement to the landlord for a portion of the brokerage commissions incurred by the landlord in leasing the facility to a new tenant. In connection with the lease termination, the Company recorded an impairment charge of \$439,000 associated with fixed assets left at the facility. The Company also reversed \$290,000 of deferred rent associated with the lease. The Company recorded \$730,000 and \$875,000 of rent expense in the years ended December 31, 2013 and 2012, respectively, associated with this lease.

*150 Second Street*

In 2013, the Company signed two separate facility leases. The first lease commenced in March 2013 and had a one year expected term which was terminated in October 2013. The second lease (the Headquarters Lease ) commenced in September 2013 and initially had an eight year expected term. The Headquarters Lease is subject to fixed rate escalation increases and the landlord waived the Company's rent obligation for the first 10.5 months of the lease, having an initial value of \$3,300,000. The landlord also agreed to fund up to \$9,239,000 in tenant improvements. The Company recorded the tenant improvements as leasehold improvements and deferred rent on the consolidated balance sheet. Deferred rent is amortized as a reduction in rent expense over the term of the Headquarters Lease. The Company recognizes rent expense on a straight-line basis over the expected lease term. In connection with the Company's termination of the lease at One Kendall Square, the rent abatement was reduced to approximately \$1,841,000 and the expected term of the Headquarters Lease was reduced to 7.5 years. The Company began to record rent expense in April 2013 upon gaining access to and control of the space. Upon execution of the Headquarters Lease, the Company paid a security deposit of \$1,725,000 which was reduced to approximately \$864,000 in 2014. The security deposit is included in restricted cash in the accompanying balance sheet as of December 31, 2014 and 2013.

On June 30, 2014, the Company executed a Second Amendment to Lease amending the Headquarters Lease, resulting in 8,164 square feet of additional space commencing in November 2014. The Company began recording rent expense upon gaining access to and control of the space in July 2014. The landlord has also agreed to fund up to \$1,020,500 in normal tenant improvements.

The Company recorded rent expense of \$2,411,000 and \$1,640,000 for the years ended December 31, 2014 and 2013, respectively, associated with the Headquarters lease.

As of December 31, 2014, the minimum future rent payments under the Company's lease agreements are as follows:

2015	\$ 4,251
2016	4,272
2017	4,328
2018	4,458
2019	4,591
Thereafter	5,354
<b>Total minimum lease payments</b>	<b>\$ 27,254</b>

*Supply Agreement*

In July 2013, the Company entered into a five-year supply, service and support agreement (the "Supply Agreement") with Illumina, Inc. ("Illumina") for Illumina to provide products and services that support and can be used for the gene sequencing component of its molecular testing activities. During the term of the Supply Agreement, Illumina will supply the Company with sequencers, reagents and other consumables for use with the Illumina sequencers, and service contracts for the maintenance and repair of the sequencers.

F-22



---

**Table of Contents**

During the term of the Supply Agreement, the Company is required to make a rolling forecast of its expected needs for reagents and other consumables, and it may place purchase orders for reagents and other consumables that conform to such forecast. Illumina may not unreasonably reject conforming purchase orders and will, in its reasonable discretion, accept additional purchase orders for quantities of reagents and other consumables beyond the Company's forecast requirements. During each six-month period the Company has a binding obligation to purchase an amount of reagents and other consumables equal to the greater of a percentage of its six-month forecast and a fixed minimum amount. Subject to discounts that vary depending on the volume of hardware and reagents and other consumables ordered, the price for sequencers and for service contracts is based on Illumina list prices, and the price for reagents and other consumables is based on contract prices that are fixed for a set period of time and may increase thereafter subject to limitations. The Supply Agreement does not require the Company to order minimum amounts of hardware, or to use exclusively the Illumina platform for conducting its sequencing. As of December 31, 2014, the Company's minimum remaining purchase commitment for the remainder of the term of the Supply Agreement was not lower than approximately \$7,350,000.

**Legal Matters**

The Company, from time to time, is party to litigation arising in the ordinary course of its business. Management does not believe that the outcome of these claims will have a material adverse effect on the financial position, results of operations or cash flows of the Company based on the status of proceedings at this time.

**12. Related Party Transactions**

Since inception, the Company has received consulting and management services from an investor. The Company made no payments to this investor for these services during the year ended December 31, 2014 and made payments of approximately \$119,000, and \$362,000 for these services during the years ended December 31, 2013, and 2012, respectively. Of these amounts, \$7,000 and \$92,000 of amounts due to the investor were included in accounts payable and accrued expenses at December 31, 2013 and 2012, respectively.

The Company recognized revenue of \$858,000, \$854,000 and \$287,000 during the years ended December 31, 2014, 2013 and 2012, respectively, from an arrangement with an investor executed in the year ended December 31, 2012. There was no balance in accounts receivable at December 31, 2014 and 2013.

The Company recognized revenue of \$641,000 for the year ended December 31, 2014 and no revenue for the years ended December 31, 2013 from an arrangement with an entity affiliated with a member of the Company's Board of Directors executed in the year ended December 31, 2013. Of these amounts, \$419,000 was included in accounts receivable at December 31, 2014.

**Table of Contents****13. Selected Quarterly Financial Data (Unaudited)**

The following table contains quarterly financial information for fiscal years 2014 and 2013. The Company believes that the following information reflects all normal recurring adjustments necessary for a fair statement of the information for the periods presented.

	<b>First Quarter</b>	<b>Second Quarter</b>	<b>Third Quarter</b>	<b>Fourth Quarter</b>
<b>2014</b>				
Revenue	\$ 11,455	\$ 14,496	\$ 16,448	\$ 18,680
Costs and expenses	\$ 23,596	\$ 28,259	\$ 29,426	\$ 33,081
Net loss applicable to common stockholders	\$ (12,166)	\$ (13,779)	\$ (12,980)	\$ (13,297)
Basic and diluted net loss per share	\$ (0.44)	\$ (0.49)	\$ (0.46)	\$ (0.47)
<b>2013</b>				
Revenue	\$ 5,200	\$ 5,920	\$ 8,208	\$ 9,662
Costs and expenses	\$ 12,321	\$ 15,946	\$ 19,332	\$ 23,152
Net loss applicable to common stockholders	\$ (7,253)	\$ (10,229)	\$ (12,510)	\$ (13,091)
Basic and diluted net loss per share	\$ (2.56)	\$ (3.34)	\$ (3.51)	\$ (0.48)

**14. Subsequent Events****Roche**

On January 12, 2015, the Company announced a broad strategic collaboration with Roche Holdings, Inc. ( Roche ) to further advance its leadership position in molecular information solutions. The proposed transaction, subject to a number of closing conditions, is a broad multi-part agreement that includes an R&D collaboration, commercial collaborations, and an equity investment with certain governance provisions.

Under the terms of the R&D collaboration agreement, Roche may pay potentially more than \$150,000,000 over five years to access the Company's molecular information platform and to fund R&D programs. Roche will utilize the Company's platform to standardize its clinical trial testing, to enable comparability of clinical trial results for R&D purposes, and to better understand the potential for combination therapies. The initial focus of the R&D programs will be on developing genomic profile tests for continuous blood-based monitoring and cancer immunotherapies, and to develop next generation companion diagnostics.

In addition to the R&D collaboration, the Company will enter into commercial collaboration agreements designed to significantly broaden its reach across international clinical and molecular information markets. Specifically, Roche will obtain ex-U.S. commercialization rights to the Company's existing products and to future co-developed products, and the Company will remain solely responsible for commercialization of its products within the U.S. In addition, within the U.S., Roche has agreed to engage its medical education team to provide information to pathologists specific to comprehensive genomic profiling in cancer.

Under the terms of the contemplated transaction, Roche has agreed to (a) make a primary investment of \$250,000,000 in cash to purchase 5,000,000 newly issued shares of the Company's common stock at a purchase price of \$50.00 per share and (b) commence a tender offer to acquire up to 15,604,288 outstanding shares of the Company's common stock at a price of \$50.00 per share so that, when complete, Roche and its affiliates will own a minimum of 52.4% and

a maximum of 56.3% of the Company's outstanding shares on a fully diluted basis. The completion of Roche's direct investment and the successful outcome of the tender offer, as well as the effectiveness of the collaboration agreements are all cross-conditional and subject to approval of our stockholders and other customary closing conditions.

The transaction has been unanimously approved by the Company's Board of Directors. In addition, Third Rock Ventures, Kleiner Perkins Caufield & Byers and Google Ventures, three of the Company's shareholders owning approximately 31% of the Company's outstanding common stock, have entered into a support agreement

## **Table of Contents**

pursuant to which they have each committed to vote in favor of the transaction and to tender at least a majority of their shareholdings in the tender offer. Upon the closing of the transaction, the Company's Board of Directors will be increased to nine directors and will include three designees of Roche. Four existing independent directors and Michael Pellini, M.D. will continue as directors and one new independent director will be added.

### **Ten Canal Park Lease**

The Company signed a facility lease ( Lease ) on March 11, 2015 for approximately 38,411 square feet of office space at Ten Canal Park in Cambridge, Massachusetts ( Premises ). The Lease commences on the later of (a) March 11, 2015 and (b) the date the landlord receives the Letter of Credit (as defined in the Lease), and expires five years after the earlier of the date when the Company first opens for business in the Premises or September 1, 2015. The Company will pay annual rent of \$54.00 per rentable square foot, or \$172,849.50 per month for the first year, increasing annually by \$1.00 per rentable square foot during the term of the Lease and shall receive up to \$1,995,550 from the Landlord for tenant improvements to the Premises. In connection with the Lease, the Company will provide a security deposit in the amount of \$1,037,097, which will be reduced to \$530,548.50 on the date the Company provides evidence to the landlord of a capital contribution to the Company that results in a net increase in cash in the Company's balance sheet of at least \$200 million.