Foundation Medicine, Inc. Form S-1/A August 16, 2013 Table of Contents

As filed with the Securities and Exchange Commission on August 16, 2013.

Registration No. 333-190226

# **UNITED STATES**

# SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Amendment No. 2

to

# FORM S-1

# **REGISTRATION STATEMENT**

Under

The Securities Act of 1933

# FOUNDATION MEDICINE, INC.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of 8071 (Primary Standard Industrial 27-1316416 (I.R.S. Employer

incorporation or organization)

Classification Code Number) One Kendall Square, Suite B3501

Identification Number)

Cambridge MA, 02139

(617) 418-2200

(Address, including zip code, and telephone number, including area code, of registrant s principal executive offices)

Michael J. Pellini, M.D.

President and Chief Executive Officer

**One Kendall Square, Suite B3501** 

Cambridge, MA 02139

(617) 418-2200

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

Kingsley A. Taft, Esq.	Robert W. Hesslein, Esq.	Patrick O Brien, Esq.			
Arthur R. McGivern, Esq.	Senior Vice President and General Counsel	Ropes & Gray LLP			
Goodwin Procter LLP	Foundation Medicine, Inc.	Prudential Tower			
Exchange Place	One Kendall Square, Suite B3501	800 Boylston Street			
53 State Street	Cambridge, MA 02139	Boston, Massachusetts 02199-3600 (617) 951-7000			
Boston, MA 02109	(617) 418-2200				
(617) 570-1000					

Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this registration statement.

### Edgar Filing: Foundation Medicine, Inc. - Form S-1/A

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, as amended, check the following box."

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering."

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act.

Large accelerated filer

Accelerated filer

Smaller reporting company

(Do not check if a smaller reporting company) x

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until this registration statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

The information in this preliminary prospectus is not complete and may be changed. We may sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell nor does it seek an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

Subject to completion. Dated August 16, 2013.

Prospectus

Shares

# Foundation Medicine, Inc.

## **Common Stock**

This is an initial public offering of shares of common stock of Foundation Medicine, Inc.

We are offering shares to be sold in this offering.

Prior to this offering, there has been no public market for our common stock. It is currently estimated that the initial public offering price per share will be between \$ and \$ . We have applied to list our common stock on The NASDAQ Global Market under the symbol FMI.

We are an emerging growth company under applicable Securities and Exchange Commission rules and will be subject to reduced public company reporting requirements.

Investing in our common stock involves a high degree of risk. See <u>Risk Factors</u> on page 9 to read about factors you should consider before buying shares of the common stock.

Neither the Securities and Exchange Commission nor any other regulatory body has approved or disapproved of these securities or passed upon the accuracy or adequacy of this prospectus. Any representation to the contrary is a criminal offense.

### Edgar Filing: Foundation Medicine, Inc. - Form S-1/A

	Per Share	Total
Initial public offering price	\$	\$
Underwriting discounts and commissions <sup>(1)</sup>	\$	\$
Proceeds to us, before expenses	\$	\$

(1) We refer you to Underwriting beginning on page 144 for additional information regarding total underwriting compensation. We have granted the underwriters an option to purchase up to an additional shares of common stock from us at the initial price to public less the underwriting discount.

The underwriters expect to deliver the shares against payment in New York, New York on , 2013.

# Goldman, Sachs & Co. Leerink Swann

. . .

J.P. Morgan Sanford C. Bernstein

Prospectus dated

, 2013

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Through and including , 2013 (the 25th day after the date of this prospectus), all dealers effecting transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This delivery requirement is in addition to a dealer s obligation to deliver a prospectus when acting as an underwriter and with respect to an unsold allotment or subscription.

We have not authorized anyone to provide you with any information or to make any representation, other than those contained in this prospectus or any free writing prospectus we have prepared. We take no responsibility for, and provide no assurance as to the reliability of, any other information that others may give you. This prospectus is an offer to sell only the shares offered hereby, but only in circumstances and in jurisdictions where it is lawful to so do. The information contained in this prospectus is accurate only as of its date, regardless of the time of delivery of this prospectus or of any sale of our common stock.

Neither we nor any of the underwriters have done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than the United States. You are required to inform yourself about, and to observe any restrictions relating to, this offering and the distribution of this prospectus.

#### PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus and does not contain all of the information that you should consider in making your investment decision. Before investing in our common stock, you should carefully read this entire prospectus, including our financial statements and the related notes included elsewhere in this prospectus. You should also consider, among other things, the matters described under Risk Factors and Management s Discussion and Analysis of Financial Condition and Results of Operations, in each case appearing elsewhere in this prospectus. Unless otherwise stated, all references to us, our, Foundation, we, the Company and similar designations refer to Foundation Medicine, Inc.

#### Overview

We are a commercial-stage company focused on fundamentally changing the way patients with cancer are treated. Our proprietary molecular information platform generates actionable genomic information about a patient s individual cancer, enabling physicians to optimize treatments in clinical practice and enabling biopharmaceutical companies to develop targeted oncology therapies more effectively. We believe we have a significant first mover advantage in providing comprehensive molecular information products on a commercial scale.

FoundationOne, our first clinical product, is, to our knowledge, the only commercially available comprehensive molecular information product designed for use in the routine care of patients with cancer. We commenced our formal commercial launch of FoundationOne for solid tumors in June 2012 and expect to commence our commercial launch of FoundationOne for blood-based cancers, or hematologic malignancies, by early 2014. We believe the annual U.S. market opportunity for a comprehensive molecular diagnostic product like FoundationOne is approximately \$4.0 billion today and will grow to exceed \$7.5 billion over the next several years as medical practice further incorporates the growing understanding of molecular information and the use of targeted oncology therapies.

We have experienced rapid adoption of FoundationOne. More than 1,500 physicians from large academic centers and community-based practices across more than 25 countries have ordered FoundationOne since its formal commercial launch in June 2012. We believe this rapid adoption of FoundationOne, accomplished with a nascent sales team, demonstrates the demand for and utility of a single, comprehensive product that helps oncologists effectively implement the promise of precision medicine. To further accelerate our growth and extend our competitive advantage, we are expanding our sales force, publishing scientific and medical advances, fostering relationships throughout the oncology community, and developing new products.

Key thought leaders at premier cancer centers have embraced our approach, as evidenced by their routine use of FoundationOne for their patients, as well as by our collaborations on clinical studies, peer-reviewed publications, and presentations at scientific and medical conferences. We believe that this validation of our approach by key thought leaders will also help drive adoption in the community oncology setting, where 85% of the approximately 10,000 oncologists in the United States practice. We believe the increasing use of our products, especially among thought leaders, along with the demonstration of the economic and clinical value of FoundationOne, will also help facilitate favorable reimbursement decisions.

We believe FoundationOne has a sustainable competitive advantage because it:

*Comprehensively identifies clinically actionable information* FoundationOne currently assesses 236 biologically relevant cancer genes for all classes of genomic alterations with high sensitivity and specificity, and has identified actionable alterations in 82% of the 3,936 clinical specimens we received and analyzed with FoundationOne following its formal commercial launch in June 2012 through May 17, 2013. FoundationOne identifies genomic alterations that other diagnostic tests cannot. Based on our quantitative analysis, FoundationOne finds more than three times the combined number of actionable genomic alterations identifiable using a collection of six other commercially available and commonly used diagnostic tests;

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

*Readily integrates into routine clinical practice* Our proprietary sample preparation processes and computational biology algorithms allow us to utilize small amounts of routinely collected tumor tissue from a wide variety of sample types, including tissue with low tumor purity. We detect and report the clinically relevant genomic alterations, generally within 14 to 17 days. 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;

*Provides actionable information that physicians can use* In a concise report, FoundationOne communicates the actionable genomic alterations in a patient s cancer and matches these alterations with targeted therapies and relevant clinical trials. Through our online portal, Interactive Cancer Explorer, physicians can access this report and links to peer-reviewed literature; and

*Promotes physician interaction to create a powerful network effect* We are continually augmenting our cancer knowledgebase, and we are expanding the functionality of our Interactive Cancer Explorer to allow for sharing of genomic and treatment data. Together, we believe these efforts will create a network effect of more users and ultimately more actionable information.

Our molecular information platform is currently used by 18 pharmaceutical partners to enhance the development of targeted oncology therapeutics. We use our core proprietary molecular information 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 analysis and information relevant to precision medicine strategies. In addition to generating revenue, these relationships 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 newest oncology therapeutics and practice.

We are dedicated to ongoing innovation in our molecular information platform and new product pipeline. For example, we are incorporating RNA-based sequencing technology to analyze the additional gene fusions commonly found in hematologic malignancies and expect to commence our commercial launch of FoundationOne for hematologic malignancies incorporating this technology by early 2014. We are also exploring and developing new products that are scientifically advanced and clinically-relevant including, for example, products utilizing circulating tumor cells and cell-free plasma DNA, which is DNA that circulates in blood plasma outside of cells, and products that expand our offerings into additional areas such as epigenetics, which examines changes in gene expression that

occur without changes in the underlying DNA, methylation, which is a chemical signaling mechanism that plays a role in regulation of gene expression, and immune response.

Over time, we will expand our ability to capture, aggregate, analyze, and facilitate the broader exchange of genomic data across the global oncology community. 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.

We recorded total revenue of \$10.6 million and \$11.1 million for the year ended December 31, 2012 and the six months ended June 30, 2013, respectively, and our loss from operations during these periods was \$21.9 million and \$17.1 million, respectively. Our accumulated deficit totaled \$64.2 million as of June 30, 2013. In addition, although we are implementing a comprehensive strategy to pursue favorable reimbursement and coverage decisions for FoundationOne and we have been reasonably successful to date in securing reimbursement for tests performed for patients covered by commercial third-party payors, we have not yet received a coverage decision for FoundationOne from any commercial third-party payor or government payor, including Medicare. As a result, there is uncertainty surrounding the amount we will be paid for FoundationOne tests we perform for patients covered by commercial third-party payors and government payors, which tests currently represent a significant percentage of the total number of FoundationOne tests we perform. Ultimately, we believe that adoption of our products, increased support for our products by oncology thought leaders, the completion of clinical studies, and the publication of clinical data in medical and scientific journals will demonstrate the clinical utility of our products and foster favorable reimbursement decisions.

#### **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 guide 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 and our future clinical products.

Demonstrate the value of our products to patients, physicians, and payors.

Enable biopharmaceutical companies to more effectively develop new cancer therapies.

Invest in product enhancements and new product innovations.

Empower the broader cancer community with molecular information. Risk Factors

Our business is subject to numerous risks and uncertainties, including those highlighted in the section entitled Risk Factors immediately following this prospectus summary. These risks include, but are not limited to, the following:

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

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, our revenue and prospects for profitability would be harmed.

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

If our sole laboratory facility becomes damaged or inoperable or our new laboratory facility fails to be certified under federal and state licensing requirements, our ability to conduct our business may be jeopardized.

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

If we are unable to scale our operations to support increased demand for FoundationOne, our business could suffer.

#### We depend on our information technology systems, and any failure of these systems could harm our business. Company and Other Information

We were incorporated under the laws of the State of Delaware in November 2009. Our principal executive office is located at One Kendall Square, Suite B3501, Cambridge MA 02139, and our telephone number is (617) 418-2200. Our website address is www.foundationmedicine.com. We do not incorporate the information on or accessible through our website into this prospectus, and you should not consider any information on, or that can be accessed through, our website as part of this prospectus.

We own various U.S. federal trademark registrations and applications, and unregistered trademarks and servicemarks, including Foundation Medicine<sup>®</sup>, FoundationOne , and Interactive Cancer Explorer . All other trademarks or trade names referred to in this prospectus are the property of their respective owners. Solely for convenience, the trademarks and trade names in this prospectus are referred to without the <sup>®</sup> and symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto. We do not intend the use or display of other companies trademarks and trade names to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

#### THE OFFERING

Common stock offered by us	shares
Common stock to be outstanding after this offering	shares ( shares if the underwriters exercise their option to purchase additional shares in full)
Underwriters option to purchase additional shares	We have granted a 30-day option to the underwriters to purchase up to an aggregate of additional shares of common stock.
Use of proceeds by us	We estimate that we will receive net proceeds from this offering of approximately \$ million based upon an assumed initial public offering price of \$ per share, the midpoint of the estimated price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. We expect to use the net proceeds from this offering to fund the expansion of our commercial and laboratory operations, ongoing and new clinical trials, continue building our technology infrastructure and capabilities, as well as for working capital and other general corporate purposes, including funding the costs of operating as a public company. See Use of Proceeds for additional information.
Risk factors	You should carefully read Risk Factors in this prospectus for a discussion of factors that you should consider before deciding to invest in our common stock.
Proposed NASDAQ Global Market trading symbol The number of shares of our common stock to be out	FMI standing after this offering is based on 16,612,097 shares of our common stock outstanding

The number of shares of our common stock to be outstanding after this offering is based on 16,612,097 shares of our common stock outstanding as of July 31, 2013, including 3,736,598 shares of common stock potentially subject to repurchase by us, and excludes:

8,666,879 shares of common stock issuable upon the exercise of stock options outstanding as of July 31, 2013 at a weighted-average exercise price of \$0.76 per share;

200,000 shares of common stock issuable upon the exercise of a warrant outstanding at an exercise price of \$1.00 per share, which warrant prior to the closing of this offering is exercisable to purchase preferred stock and will be exercisable for common stock following this offering;

1,993,558 shares available for issuance under the Amended and Restated 2010 Stock Incentive Plan; and

shares of common stock reserved for future issuance under our 2013 Stock Option and Grant Plan, or the 2013 Plan.

Unless otherwise indicated, all information in this prospectus reflects or assumes the following:

the filing and effectiveness of our amended and restated certificate of incorporation and the adoption of our amended and restated bylaws, which will occur immediately prior to the closing of this offering;

a 1-for- reverse split of our common stock effected on

the conversion of all of our outstanding 68,512,134 shares of preferred stock into 68,512,134 shares of common stock upon the closing of this offering;

;

the conversion of the warrant exercisable into 200,000 shares of preferred stock into a warrant exercisable for 200,000 shares of common stock;

the 3,736,598 shares of our common stock subject to potential repurchase by us pursuant to their vesting terms are treated as outstanding shares of our common stock;

no issuance or exercise of stock options or warrants on or after July 31, 2013; and

no exercise by the underwriters of their option to purchase up to an additional

shares of common stock in this offering.

#### SUMMARY FINANCIAL DATA

The following summary financial data for the years ended December 31, 2011 and 2012 are derived from our audited financial statements included elsewhere in this prospectus. The summary financial data as of June 30, 2013 and for the six months ended June 30, 2012 and 2013 have been derived from our unaudited financial statements included elsewhere in this prospectus. These unaudited financial statements have been prepared on a basis consistent with our audited financial statements and, in our opinion, contain all adjustments, consisting only of normal and recurring adjustments, necessary for a fair presentation of such financial data. You should read this data together with our audited financial statements and the information under the captions Selected Financial Data and Management s Discussion and Analysis of Financial Condition and Results of Operations. Our historical results are not necessarily indicative of

Management s Discussion and Analysis of Financial Condition and Results of Operations. Our historical results are not necessarily indicative of our future results, and our operating results for the six-month period ended June 30, 2013 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2013 or any other interim periods or any future year or period.

	Years Ended December 31,		Six Months Ende June 30,					
		2011		2012		2012 (upg	(batibu	2013
	(unaudited) (in thousands, except share and per share data)						,	
Statements of Operations Data:				, <b>,</b>		•		
Revenue	\$	2,057	\$	10,645	\$	2,429	\$	11,120
Costs and expenses								
Cost of revenue		258		5,681		1,830		4,597
Sales and marketing		1,555		3,454		1,347		4,686
General and administrative		6,992		8,644		3,699		7,905
Research and development		9,023		14,777		6,623		11,079
Total costs and expenses		17,828		32,556		13,499		28,267
Loss from operations		(15,771)		(21,911)		(11,070)		(17,147)
Interest expense, net		(421)		(421)		(221)		(141)
Other expense, net		(845)		(61)		(53)		(102)
Net loss	\$	(17,037)	\$	(22,393)	\$	(11,344)	\$	(17,390)
Accretion of redeemable convertible preferred stock		(296)		(286)		(162)		(92)
Net loss applicable to common stockholders	\$	(17,333)	\$	(22,679)	\$	(11,506)	\$	(17,482)
Net loss per common share applicable to common stockholders, basic and diluted <sup>(1)</sup>	\$	(3.52)	\$	(2.62)	\$	(1.54)	\$	(1.48)
Weighted-average common shares outstanding, basic and diluted	2	4,930,634		8,667,326	7	,485,723	1	1,803,985
Pro forma net loss per common share applicable to common stockholders, basic and diluted <sup>(1)</sup>			\$	(0.41)			\$	(0.22)
Pro forma weighted-average common shares outstanding, basic and diluted			5	5,642,878			8	0,516,119
Comprehensive loss	\$	(17,037)	\$	(22,393)	\$	(11,344)	\$	(17,390)
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(1) See Note 2 within the notes to our financial statements appearing elsewhere in this prospectus for a description of the method used to calculate basic and diluted net loss per share of common stock and pro forma basic and diluted net loss per share of common stock.

		As of June 30, 2013				
	Actual	Pro Forma <sup>(1)</sup> (unaudited) (in thousands)		Pro Forma As Adjusted <sup>(2)(3)</sup>		
Balance Sheet Data:						
Cash and cash equivalents	\$ 35,965	\$	35,965	\$		
Working capital	32,226		32,226			
Total assets	52,269		52,269			
Notes payable, excluding current portion	634		634			
Redeemable convertible preferred stock warrant liability	328					
Redeemable convertible preferred stock	98,740					
Accumulated deficit	(64,209)		(64,140)			
Total stockholders (deficit) equity	\$ (58,851)	\$	40,217	\$		

(1) Pro forma to reflect (i) the automatic conversion of all outstanding shares of our preferred stock into shares of our common stock, and the conversion of our outstanding warrant to purchase our Series A preferred stock into a warrant to purchase our common stock, upon the closing of this offering and (ii) the filing and effectiveness of our amended and restated certificate of incorporation, which will occur immediately prior to the closing of this offering.

- (2) Pro forma as adjusted to reflect the pro forma adjustments described in (1) above, and to further reflect the sale of shares of our common stock offered in this offering, assuming an initial public offering price of \$ per share, the midpoint of the price range set forth on the cover page of this prospectus, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.
- (3)A \$1.00 increase (decrease) in the assumed initial public offering price of \$ per share, the midpoint of the price range set forth on the cover of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash and cash equivalents and total stockholders (deficit) equity by approximately \$ million, assuming that the number of shares offered by us, as set forth on the cover of this prospectus, remains the same and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase (decrease) of one million shares offered by us would increase (decrease) the net proceeds to us from this offering by approximately \$ million, assuming the assumed initial public offering price remains the same and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. A increase in the number of shares offered by us together with a concomitant \$1.00 increase in the assumed initial public offering price of per share, the midpoint of the price range set forth on the cover of this prospectus, would increase each of cash and cash \$ equivalents and total stockholders (deficit) equity by approximately \$ million after deducting underwriting discounts and commissions and any estimated offering expenses payable by us. Conversely, a share decrease in the number of shares offered by us together with a concomitant \$1.00 decrease in the assumed initial public offering price of \$ per share, the midpoint of the price range set forth on the cover of this prospectus, would decrease each of cash and cash equivalents and total stockholders (deficit) equity by approximately \$ million after deducting underwriting discounts and commissions and any estimated offering expenses

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payable by us.

#### **RISK FACTORS**

Before you invest in our common stock, you should understand the high degree of risk involved. You should carefully consider the following risks and other information in this prospectus, including our consolidated financial statements and related notes included elsewhere in this prospectus, before you decide to purchase shares of our common stock. The following risks may adversely impact our business, financial condition, and operating results. As a result, the trading price of our common stock could decline and you could lose part or all of your investment.

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

# We may not be able to generate sufficient revenue from FoundationOne 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 product, FoundationOne for solid tumors, to physicians in clinical practice, to launch and commercialize FoundationOne for blood-based cancers, or hematologic malignancies, to continue to expand our current relationships and develop new relationships with biopharmaceutical partners, and to develop and commercialize new molecular information products. The demand for FoundationOne may decrease or may not continue to increase at historical rates for a number of reasons. In addition, FoundationOne does not yet have coverage contracts with or coverage decisions from commercial third-party payors and government payors, including Medicare. We have experienced early revenue growth from the sale of FoundationOne to physicians, principally since its formal commercial launch in June 2012. 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 and FoundationOne.

We are currently not profitable. Even if we succeed in increasing adoption of FoundationOne by physicians, 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 may never achieve significant commercial market acceptance.

FoundationOne 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 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 FoundationOne, it is 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. Publication in leading medical journals is subject to a peer-review process, and peer reviewers may not consider the results of studies involving FoundationOne sufficiently novel or worthy of publication.

The failure to be listed in physician guidelines or 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 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, Inc., or 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, could affect the performance specifications of our laboratory operations or could require that we revalidate FoundationOne. 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 or we are required to vacate our existing facility, and our new laboratory facility has not yet been, or fails to be, certified under federal and state licensing requirements, our ability to conduct our genomic analyses and pursue our research and development efforts may be jeopardized.

We currently derive 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 intend to move our laboratory into a new facility at our new corporate headquarters in Cambridge, Massachusetts in September 2013. This relocation could disrupt laboratory operations, resulting in an inability to meet customer turnaround time expectations, and could be delayed, resulting in slower realization of laboratory efficiencies anticipated from the use of the new facilities. We might also encounter delays in completing the transfer or issuance of new licenses or other approvals necessary to allow our clinical laboratory operations to commence at the new facility. Adverse consequences resulting from a delay in the laboratory relocation or resulting from an interruption of laboratory operations, including as a result of a failure to be certified under the Clinical Laboratory Improvement Amendments of 1988, or CLIA, the College of American Pathologists, or CAP, and state licensing requirements, could harm our relationships with our customers and our reputation, and could affect our ability to generate revenue.

We carry insurance for damage to our property 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 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, such as FoundationOne for hematologic malignancies, 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 now scaling up our RNA sequencing capabilities and we believe we will be the first company to perform RNA sequencing for clinical testing at our clinical scale. 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 commercialize FoundationOne for hematologic malignancies or any other products we may develop on a timely basis, or at all.

FoundationOne for hematologic malignancies, for which we expect to commence our commercial launch by early 2014, will take time to commercialize, and its launch may be delayed or may not be successful. There can be no assurance that FoundationOne for hematologic malignancies will be successful in the evaluation of blood-based cancers for a variety of technical and market reasons. Our other new molecular information products, 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 forms of cancer other than cancers found in solid tumors. 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;

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

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 next generation sequencing, or 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, as well as companies

such as Abbott Laboratories, Qiagen N.V., Roche Molecular Systems, Inc. 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.

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 University of Michigan, Baylor Medical Genetics Laboratories, Washington University in St. Louis and other academic hospitals and research centers.

In addition to developing kits, certain diagnostic companies also provide NGS platforms. Illumina, Life Technologies Corporation, and other companies develop NGS platforms that are being sold directly to research centers, biopharmaceutical 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 will continue to commercialize products focused on the clinical oncology market. We believe diagnostic platform providers will seek to place sequencing machines in laboratories to develop NGS-based laboratory-developed tests, or LDTs. In addition, we believe these companies will also develop their own FDA-approved diagnostic kits, which can be sold to the clients who have purchased their platforms. Also, many private companies are developing information technology-based tools to support the integration of NGS testing into the clinical setting. These companies may also use their patent portfolios, developed in connection with developing their tests, to allege that FoundationOne 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, 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, 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 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 technology 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 yields. Low sequencing yields, or higher than anticipated variability, increases total sequencing costs and reduces the number of samples we can sequence in a given time period, which can cause variability in our operating results and damage our reputation.

# 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 cancer patients, which may limit our revenue growth and ability to achieve profitability.

We have established relationships with leading oncology thought leaders at premier cancer institutions, such as the Memorial Sloan-Kettering Cancer Center, Vanderbilt-Ingram Cancer Center and The US Oncology Network. If these key thought leaders determine that our molecular information platform, FoundationOne or other products that we develop are not clinically effective or 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 and FoundationOne 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, 2011 and 2012 and the six months ended June 30, 2013, 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.

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 the 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, certain 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.

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 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. 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 management 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. We may not be able to market, sell, or distribute FoundationOne or other products we may develop effectively enough to support our planned growth. We sell FoundationOne 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 we may potentially enlist local laboratories, 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.

# 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. Recruiting 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 partners to terminate existing agreements and potential clinical partners to seek other partners, any of which could impact our results of operations.

#### We may acquire other businesses or 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.

We may pursue 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. We may not be able to find suitable partners or acquisition candidates, and we may not be able to complete such transactions on favorable terms, if at all. If we make any acquisitions, we may not be able to integrate these acquisitions successfully into our existing business, and we could assume unknown or contingent liabilities. Any future acquisitions 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. We may experience losses related to investments in other companies, which could have a material negative effect on our results of operations and financial condition. We may not realize the anticipated benefits of any acquisition, technology license, strategic alliance, or joint venture.

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.

# 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 plan to maintain sales representatives and distributor relationships, to conduct physician and patient association outreach activities, to extend laboratory capabilities 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 may currently order FoundationOne and we are 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 reliance on independent distributors to sell FoundationOne 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 one or more of our practices to be in compliance with these laws or 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.

#### 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 Interactive Cancer Explorer 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, 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 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 soon will facilitate the exchange of, sensitive patient data to customers through Interactive Cancer Explorer. 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: loss of 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 legal claims or proceedings, liability under laws that protect the privacy of personal information, such as the Health Insurance Portability and Accountability Act of 1996, or HIPAA, and regulatory penalties. Although we have implemented security measures and a formal, dedicated enterprise security program to prevent unauthorized access to patient data, Interactive Cancer Explorer, which is currently accessible through our online portal and will also soon be accessible through our mobile applications, gives broad access to physicians, at which point we lose ability to control access, and there is no guarantee we can continue to protect our online portal or will be able to protect 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 r

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, 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 the 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. 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.

#### 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.

#### Our term loan contains restrictions that limit our flexibility in operating our business.

In November 2010, we entered into a loan and security agreement with Lighthouse Capital Partners, or Lighthouse, secured by a lien on equipment, fixtures or personal property financed pursuant to any agreements with Lighthouse. This loan contains various covenants that limit our ability to engage in specified types of transactions. These covenants limit our ability to, among other things:

sell, transfer, lease or dispose of certain assets;

encumber or permit liens on certain assets;

make certain restricted payments, including paying dividends on, or repurchasing or making distributions with respect to, our common stock; and

enter into certain transactions with affiliates.

A breach of any of the covenants under the loan and security agreement could result in a default under the loan. Upon the occurrence of an event of default under the loan, the lender could elect to declare all amounts outstanding to be immediately due and payable and terminate all commitments to extend further credit. If we are unable to repay those amounts, the lender could proceed against the collateral granted to them to secure such indebtedness.

#### 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 or future products we develop, if any, our revenue and prospects for profitability would be harmed.

In both domestic and foreign markets, sales of FoundationOne 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, private health insurers, and other organizations. In particular, we believe that obtaining a positive national coverage decision and favorable reimbursement rate from the Centers for Medicare and Medicaid Services, or CMS, for FoundationOne will be a necessary element in achieving material commercial success. Physicians and patients may not order FoundationOne

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 if CMS 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 decision, 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, requested that we not submit claims for services provided to Medicare patients while the contractor assessed the appropriate coverage and payment for FoundationOne as a whole. Pending the response, no claims have been billed to either Medicare or Medicare patients. Accordingly, we do not currently receive any payment for FoundationOne provided to patients covered by Medicare. If CMS does not issue a positive national coverage decision with respect to FoundationOne, or if CMS denies reimbursement of FoundationOne, withdraws its coverage policies after reimbursement is obtained, reviews and adjusts the rate of reimbursement, or stops paying for FoundationOne altogether, our revenue and results of operations would be adversely affected.

We intend, before the end of 2013, to commence submitting claims to CMS for FoundationOne tests provided to Medicare patients. We will inform our Medicare contractor prior to submitting these claims for services provided to Medicare patients. The response of the Medicare contractor to the submission of such a claim is uncertain and the claim 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. Alternatively, CMS may defer processing a claim pending a coverage or payment determination. Even if we do receive payments from CMS, 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, CMS may issue a negative coverage determination for FoundationOne that would apply to future claims. Although we would have the opportunity to submit additional materials to CMS in support of a positive coverage determination for FoundationOne, there is no guarantee that CMS would provide us with a positive coverage decision or reverse a negative 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 may reduce, suspend, revoke, or discontinue payments or coverage at any time.

As a result, there is significant uncertainty surrounding whether the use of products that incorporate new technology, such as FoundationOne, 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. 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 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.

As a result, our efforts to receive reimbursement on behalf of patients will take a substantial amount of time, and commercial third-party payors and government payors may never cover or provide adequate payment for FoundationOne 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, engaging 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 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-contracting provider by commercial third-party payors because we have not entered into specific contracts to provide FoundationOne 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 contracting provider in the future, the amount of overall reimbursement we receive may decrease if we were to be reimbursed less money per product 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 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 delay or additional expense in offering our products and products that we may develop in the future.

While the FDA currently exercises its enforcement discretion for LDTs by not enforcing its regulations, the FDA has stated that it has a mandate to regulate in this field and that it may address LDT regulation using a risk-based, phased-in approach similar to the existing *in vitro* diagnostic framework. In particular, as recently as June 2013, the Commissioner of the FDA has stated that the FDA is working to make sure that the accuracy and clinical validity of high-risks tests are established before they come to market. Thus, the FDA may seek to more actively regulate, including requiring clearance or approval of, our molecular information products in the future. Moreover, the FDA could disagree with our assessment that FoundationOne is a LDT, including FoundationOne for hematologic malignancies that we are developing with Memorial Sloan-Kettering Cancer Center, and could require us to seek clearance or approval to offer FoundationOne for clinical use. If the FDA requires us to seek clearance or approval to offer FoundationOne 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. Failure to comply with applicable regulatory requirements can result in enforcement action by the FDA, which may include any of the following sanctions: warning letters; fines; injunctions; civil or criminal penalties; recall or seizure of current or future products; operating restrictions; partial suspension or total shutdown of production;

denial of applications; or challenges to clearances or approvals. In July 2010, the FDA s Office of In-Vitro Diagnostic Device Evaluation and Safety held a public meeting to discuss oversight of LDTs. The FDA highlighted the lack of standardized clinical validation at the test level under current CLIA regulatory guidelines and noted that CLIA does not require post-market surveillance or monitoring of LDTs. The comment period for providing the FDA with written comments expired on August 15, 2010, but the FDA has not yet published additional guidance on the oversight of LDTs. We cannot provide any assurance that FDA regulation, including premarket review, will not be required for our molecular information products. 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.

In addition, in June 2011, the FDA issued draft guidance regarding the sale and use of products labeled for research use only. Among other things, the draft guidance advises manufacturers to cease the sale of research use only products to customers that the manufacturer knows use the product for clinical diagnostic purposes. Certain of the reagents and other products we use in FoundationOne are labeled as research use only products. If the FDA were to enforce this June 2011 draft guidance, certain 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, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively referred to as the Affordable Care Act, was enacted in the United States, which made a number of substantial changes in the way health care is financed by both governmental and private insurers. Among other things, the Affordable Care Act:

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 may apply to FoundationOne and some or all of our products which are in development.

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.

establishes an Independent Payment Advisory Board to reduce the per capita rate of growth in Medicare spending. The Independent Payment Advisory Board has broad discretion to propose policies, which may have a negative impact on payment rates for our products beginning in 2016.

The Medicare Physician Fee Schedule rates for diagnostic tests are updated annually under the current statutory formula. For the past several years, the application of the statutory formula would have resulted in substantial payment reductions if Congress failed to intervene. In the past, Congress passed interim legislation to prevent the decreases. On November 1, 2012, CMS issued its 2013 Physician Fee Schedule Final Rule, or the Final Rule. In the Final Rule, CMS called for a reduction of approximately 26.5% in the 2013 conversion factor that is used to calculate physician reimbursement. However, the American Taxpayer Relief Act of 2012, which was signed into law on January 2, 2013, prevented this proposed cut and keeps the current reimbursement rate in effect until December 31, 2013. If similar proposed reductions are not offset in future years, the resulting decrease in payment could adversely impact our revenue and results of operations.

In addition, many of the Current Procedure Terminology, or CPT, procedure codes that we use to bill our products were recently revised by the American Medical Association, effective January 1, 2013.

In the Final Rule, CMS announced that it has decided to keep the new molecular codes on the Clinical Laboratory Fee Schedule, rather than move them to the Physician Fee Schedule as some stakeholders had urged. CMS has also announced that for 2013 it will price the new codes using a gapfilling process by which it will refer the codes to the Medicare contractors to allow them to determine an appropriate price. In addition, it has also stated that it will not recognize certain of the new codes for Multi-analyte Assays with Algorithmic Analyses, or MAAAs, because it does not believe they qualify as clinical laboratory tests. Our reimbursement could be adversely affected by CMS action in this area. If it reduces reimbursement for the new test codes or does not pay for our new MAAA codes, then our revenue will be adversely affected. There can be no guarantees that Medicare and other payors will establish positive or adequate coverage policies or reimbursement 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 our product and future products or our medical procedure volumes 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 20% coinsurance on patients for clinical laboratory tests reimbursed under the clinical laboratory fee schedule, which would require us to bill patients for these amounts. Because of the relatively low reimbursement for many clinical laboratory tests, in the event that Congress were to ever enact such legislation, the cost of billing and collecting for these tests would often exceed the amount actually received from the patient and effectively increase our costs of billing and collecting.

# 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 random inspections of our clinical reference laboratory.

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 reference laboratory, including the training and skills required of personnel and quality control. We also maintain a license to conduct testing in California, Pennsylvania, Maryland, Florida, and Rhode Island. In addition, our clinical reference laboratory is required to be licensed on a product-specific basis by New York State. New York law also mandates proficiency testing for laboratories licensed under New York state law, regardless of whether or not such laboratories are located in New York. Our application for such a license from New York State is currently pending and we operate based on a waiver by New York State of the obligations to have the license. If we are unable to obtain the necessary approvals or if New York State does not extend our waiver, our business could suffer. Moreover, several other states require that we hold licenses to test specimens from patients in those states. Other states may have similar requirements or may adopt similar requirements in the future. Finally, we may be subject to regulation in foreign jurisdictions as we seek to expand international distribution of our products, which may require review of our products in order to offer our services or may have other limitations such as prohibitions on the export of tissue necessary for us to perform our tests that may limit our ability to distribute outside of the United States.

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.

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, Interactive Cancer Explorer;

amendments to HIPAA under the Health Information Technology for Economic and Clinical Health 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

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 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 delivers to physicians a report that describes a tumor 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 tumor type 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 report 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 shareholder 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 reports we are practicing medicine without a license.

Our FoundationOne 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 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 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 and FoundationOne, 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 FoundationOne in its current or an updated form, 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 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 July 3, 2012, the USPTO issued a memorandum to patent examiners providing interim guidelines for examining process claims for patent eligibility in view of the Supreme Court decision in

*Prometheus.* The guidance indicates that claims directed to a law of nature, a natural phenomenon, or an abstract idea that do not meet the eligibility requirements should be rejected as non-statutory subject matter. We cannot assure you that our efforts to seek patent protection for our technology and products will not be negatively impacted by 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 and Myriad may have on the ability of biopharmaceutical companies or other entities to obtain or enforce patents relating to genes or genomic discoveries in the future. Despite the USPTO memorandum described above, the Prometheus decision is new and the contours of when certain method claims allegedly directed to laws of nature or natural phenomenon meet the patent eligibility requirements are not clear and may take many years to develop via interpretation in the courts. There are many patents claiming diagnostic methods based on similar or related correlations that issued before Prometheus, and although some of these patents may be invalid under the standard set forth in Prometheus, 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 Prometheus, we could have to defend ourselves against claims of patent infringement, or choose to license rights, if available, under patents claiming such methods. Moreover, 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 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. Our patent applications are in the early stages of prosecution and none have yet issued as patents. 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 forgo 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 on our patents, or used them without authorization, 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.

### 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, 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 was 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 capitalize on the market potential of these inventions. In addition, we may face claims by third parties 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 \$22.4 million in 2012. From our inception in 2009 through June 30, 2013, we had an accumulated deficit of \$64.2 million. We expect our losses to continue as a result of ongoing research and development expenses and increased sales 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.

Based on our current business plan, we believe the net proceeds from this offering, together with our current cash and cash equivalents and anticipated cash flow from operations, will be sufficient to meet our anticipated cash requirements over at least the next 12 months and for the foreseeable future. If our available cash balances, net proceeds from this offering, 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 prospectus, 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 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;

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;

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 not be available on reasonable terms, if at all. In addition, our current loan and security agreement with Lighthouse restricts our ability to raise funds through additional debt or other financing options. If we cannot secure additional funding when needed, we may have to

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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 will incur significant costs as a result of operating as a public company and our management expects to devote substantial time to public company compliance programs.

As a public company, we will 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 will 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 Securities Exchange Act of 1934, or 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 that we may be required to include in our periodic reports we will file with the SEC under Section 404 of the Sarbanes-Oxley Act, harm our operating results, cause us to fail to meet our reporting obligations, or result in a restatement of our prior period 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 NASDAQ.

We are not currently required to comply with the SEC rules that implement Section 404 of the Sarbanes-Oxley Act, and are therefore not yet required to make a formal assessment of the effectiveness of our internal control over financial reporting for that purpose. Upon becoming a public company, we will be required to comply with certain of these rules, which will require 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 our second annual report. This assessment will need 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 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 may not be required to formally attest to the effectiveness of our internal control over financial reporting until the later of our second annual report or 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 this offering and some of which are outside of our control, 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.

Prior to this offering, you could not buy or sell our common stock publicly. Although we anticipate our common stock being approved for listing on NASDAQ, an active trading market for our shares may never develop or be sustained following this offering. We will negotiate and determine the initial public offering price with the underwriters based on several factors. This price may vary from the market price of our common stock after this offering. You may be unable to sell your shares of common stock at or above the initial offering price. 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;

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 principal stockholders will exercise significant control over our company.

Assuming they do not purchase shares in this offering, investment funds affiliated with Third Rock Ventures and Kleiner Perkins Caufield & Byers, and Google Ventures 2011, L.P., our current largest stockholders, will beneficially own, in the aggregate, shares representing approximately % of our outstanding capital stock immediately after this offering. Although we are not aware of any voting arrangements that will be in place among these stockholders following this offering, if these stockholders were to choose to act together, as a result of their stock ownership, they may be able to 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.

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

If our existing stockholders sell, or indicate an intent to sell, substantial amounts of our common stock in the public market after the 180-day contractual lock-up and other legal restrictions on resale discussed in this prospectus lapse, the trading price of our common stock could decline significantly and could decline below the initial public offering price. Based on shares outstanding as of July 31, 2013, upon the completion of this offering, we will have outstanding shares of common stock, assuming no exercise of outstanding options. Of these shares, assuming no shares are purchased in this offering by our existing stockholders, shares of common stock, plus any shares sold pursuant to the underwriters option to purchase additional shares, will be immediately freely tradable, without restriction, in the public market.

After the lock-up agreements pertaining to this offering expire and based on shares outstanding as of July 31, 2013, an additional

shares will be eligible for sale in the public market. In addition, the shares subject to outstanding options under our stock option plans and the shares reserved for future issuance under our stock option plans will become eligible for sale in the public market in the future, subject to certain legal and contractual limitations. Moreover, 180 days after the completion of this offering, holders of approximately of our common stock will have the right to require us to register these shares under the Securities Act of 1933, as amended, or the Securities Act, pursuant to an investors rights agreement. If our existing stockholders sell substantial amounts of our common stock in the public market, or if the public perceives that such sales could occur, this could have an adverse impact on the market price of our common stock, even if there is no relationship between such sales and the performance of our business.

# We will have broad discretion in how we use the net proceeds of this offering. We may not use these proceeds effectively, which could affect our results of operations and cause our stock price to decline.

We will have considerable discretion in the application of the net proceeds of this offering, including for any of the purposes described in the section entitled Use of Proceeds. We intend to use the net proceeds from this offering for expansion of our commercial and laboratory operations, ongoing and new clinical trials, supporting our molecular information platform, and for working capital and other general corporate purposes. As a result, investors will be relying upon management s judgment with only limited information about our specific intentions for the use of the balance of the net proceeds of this offering. We may use the net proceeds for purposes that do not yield a significant return or any return at all for our stockholders. In addition, pending their use, we may invest the net proceeds from this offering in a manner that does not produce income or that loses value.

# 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-Oxlev 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 shareholder 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, as amended, or the Securities Act, for complying with new or revised 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 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 these exemptions. 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 this 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 our future earnings, if any, to fund the development and growth of our business. In addition, the terms of our indebtedness with Lighthouse prohibit us from paying dividends. 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.

### Investors in this offering will pay a higher price than the book value of our common stock.

If you purchase common stock in this offering, you will pay more for your shares than the amounts paid by existing stockholders for their shares. You will incur immediate and substantial dilution of \$ per share, representing the difference between our pro forma net tangible book value per share after giving effect to this offering and an assumed initial public offering price of \$ per share, the midpoint of the price range set forth on the cover of this prospectus. In the past, we issued restricted stock, options and a warrant to acquire capital stock at prices significantly below the assumed initial public offering price. To the extent any outstanding options or warrants are ultimately exercised, you will sustain further dilution.

# 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 will rely 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 or will 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 or will 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

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

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.

### SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus, including the sections entitled Prospectus Summary, Risk Factors, Management s Discussion and Analysis of Financial Condition and Results of Operations and Business, contains forward-looking statements that are based on our management s belief and assumptions and on information currently available to our management. Although we believe that the expectations reflected in these forward-looking statements are reasonable, these statements relate to future events or our future financial performance, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements in this prospectus include, but are not limited to, statements about:

the evolving treatment paradigm for cancer, including physicians use of molecular information and targeted oncology therapeutics and the market size for molecular information products;

physicians need for molecular information products and any perceived advantage of our products over those of our competitors, including the ability of our molecular information platform to help physicians treat their patients cancers, our first mover advantage in providing comprehensive molecular diagnostic information products on a commercial scale or the sustainability of our competitive advantages;

our ability to generate revenue from sales of products enabled by our molecular information platform to physicians in clinical practice and our biopharmaceutical partners, including our ability to increase adoption of FoundationOne and expand existing or develop new relationships with biopharmaceutical partners;

our ability to increase the commercial success of FoundationOne;

our plans or ability to obtain reimbursement for FoundationOne, including expectations as to our ability or the amount of time it will take to achieve successful reimbursement from third-party payors, such as commercial insurance companies and health maintenance organizations, and government insurance programs, such as Medicare and Medicaid;

the outcome or success of our clinical trials;

the ability of our molecular information platform to enhance our biopharmaceutical partners ability to develop targeted oncology therapies;

our ability to comprehensively assess cancer tissue simultaneously for all known genomic alterations across all known cancer-related genes, including our ability to update our molecular information platform to interrogate new cancer genes and incorporate new targeted oncology therapies and clinical trials;

our ability to scale our molecular information platform, including the capacity to process additional tests at high specificity and sensitivity as our volume increases;

our ability to capture, aggregate, analyze, or otherwise utilize genomic data in new ways;

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the acceptance of our publications in peer-reviewed journals or of our presentations at scientific and medical conference presentations;

our relationships with our suppliers from whom we obtain laboratory reagents, equipment, or other materials which we use in our molecular information platform, some of which are sole source arrangements;

our plans and ability to develop and commercialize new products, including to commence our commercial launch of FoundationOne for hematologic malignancies by early 2014;

the expansion of the capabilities of our Interactive Cancer Explorer portal and the development and launch of its associated applications in 2014;

the impact of the relocation our laboratory into a new facility in 2013;

federal, state, and foreign regulatory requirements, including potential FDA regulation of FoundationOne and the other tests performed using our molecular information platform;

our ability to protect and enforce our intellectual property rights, including our trade secret protected proprietary rights in our molecular information platform;

our anticipated cash needs and our estimates regarding our capital requirements and our needs for additional financing; and

anticipated trends and challenges in our business and the markets in which we operate.

In some cases, you can identify forward-looking statements by terminology such as may, will, should, expects, intends, plans, anticipate potential. continue or the negative of these terms or other comparable terminology. These statements are only believes. estimates. predicts. predictions. You should not place undue reliance on forward-looking statements because they involve known and unknown risks, uncertainties and other factors, which are, in some cases, beyond our control and which could materially affect results. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under Risk factors and elsewhere in this prospectus. If one or more of these risks or uncertainties occur, or if our underlying assumptions prove to be incorrect, actual events or results may vary significantly from those implied or projected by the forward-looking statements. No forward-looking statement is a guarantee of future performance. You should read this prospectus and the documents that we reference in this prospectus and have filed with the Securities and Exchange Commission as exhibits to the registration statement, of which this prospectus is a part, completely and with the understanding that our actual future results may be materially different from any future results expressed or implied by these forward-looking statements.

The forward-looking statements in this prospectus represent our views as of the date of this prospectus. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so except to the extent required by applicable law. You should therefore not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this prospectus.

### **USE OF PROCEEDS**

We estimate that the net proceeds to us from the sale of based upon an assumed initial public offering price of \$ shares of common stock in this offering will be approximately \$ million per share, the midpoint of the price range set forth on the cover of this prospectus, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. If the underwriters exercise their option to purchase additional shares in full, we estimate that our net proceeds will be approximately \$ million, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

A \$1.00 increase (decrease) in the assumed initial public offering price of \$ per share would increase (decrease) the net proceeds to us from this offering by approximately \$ million, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase (decrease) of one million shares offered by us would increase (decrease) the net proceeds to us from this offering by million, assuming the assumed initial public offering price remains the same and after deducting underwriting discounts approximately \$ and commissions and estimated offering expenses payable by us. A share increase in the number of shares offered by us together with a concomitant \$1.00 increase in the assumed initial public offering price of \$ per share, the midpoint of the price range set forth on the cover of this prospectus, would increase the net proceeds to us from this offering by approximately \$ million after deducting underwriting discounts and commissions and any estimated offering expenses payable by us. Conversely, a share decrease in the number of shares offered by us together with a concomitant \$1.00 decrease in the assumed initial public offering price of \$ per share, the midpoint of the price range set forth on the cover of this prospectus, would decrease the net proceeds to us from this offering by approximately million after deducting underwriting discounts and commissions and any estimated offering expenses payable by us. \$

The principal purposes of this offering are to increase our financial flexibility, create a public market for our common stock, and to facilitate our access to the public equity markets. We currently expect to use the net proceeds from this offering as follows:

approximately \$ million for the expansion of our commercial operations, including the growth of our sales force within the United States and internationally;

approximately \$ million for the expansion of our laboratory operations to support future growth;

approximately \$ million to fund ongoing and new clinical trials to demonstrate the utility of our products and support our reimbursement efforts; and

approximately \$ million to continue the expansion of our technology infrastructure and capabilities for our molecular information platform.

We expect expenditures in connection with these above-described items will utilize the substantial majority of the expected net proceeds from the offering. We expect to use the remainder of any net proceeds from this offering for new product development, including costs related to the development of products in areas such as epigenetics, methylation, and immune response, capital expenditures, including costs related to required expansion in connection with increased demand, and working capital and other general corporate purposes, including the costs of operating as a public company. Although we currently anticipate that we will use the net proceeds from this offering as described above, there may be circumstances where a reallocation of funds is necessary. The amounts and timing of our actual expenditures will depend upon numerous factors, including our commercialization efforts, demand for our products, rates of reimbursement, the costs of equipment,

the progress of our research and development efforts, our operating costs and the other factors described under Risk Factors in this prospectus. Accordingly, our management will have flexibility in applying the net proceeds from this offering. An investor will not have the opportunity to evaluate the economic, financial or other information on which we base our decisions on how to use the proceeds.

The costs and timing of our commercialization efforts are highly uncertain, are subject to substantial risks and can often change. Accordingly, we may change the allocation of use of these proceeds among the uses described above as a result of contingencies such as the demand for our products, rates of reimbursement, the costs of equipment, the progress of our research and development efforts and operating costs and expenditures. Although we may use a portion of the net proceeds of this offering for the acquisition or licensing, as the case may be, of additional technologies, other assets or businesses, or for other strategic investments or opportunities, we have no current understandings, agreements or commitments to do so.

Pending these uses, we intend to invest the net proceeds in high quality, investment grade instruments, certificates of deposit or direct or guaranteed obligations of the U.S. government, or hold as cash.

### **DIVIDEND POLICY**

We have never declared or paid any dividends on our capital stock. We currently intend to retain all available funds and any future earnings, if any, to fund the development and expansion of our business and we do not anticipate paying any cash dividends in the foreseeable future. Any future determination to pay dividends will be made at the discretion of our board of directors. In addition, the terms of our outstanding indebtedness restrict our ability to pay dividends, and any future indebtedness that we may incur could preclude us from paying dividends. Investors should not purchase our common stock with the expectation of receiving cash dividends.

# CAPITALIZATION

The following table sets forth our cash, cash equivalents and capitalization as of June 30, 2013:

on an actual basis;

on a pro forma basis to give effect to (i) the conversion of all outstanding shares of our preferred stock into an aggregate of 68,512,134 shares of common stock upon the closing of this offering, (ii) the conversion of our outstanding warrant to purchase 200,000 shares of our Series A preferred stock into a warrant to purchase 200,000 shares of our common stock upon closing of this offering, and (iii) the filing and effectiveness of our amended and restated certificate of incorporation, which will occur immediately prior to the closing of this offering; and

on a pro forma as adjusted basis to give further effect to our sale in this offering of shares of common stock at an assumed initial public offering price of \$ per share (the midpoint of the range set forth on the cover page of this prospectus), after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

You should read the following table together with Management s Discussion and Analysis of Financial Condition and Results of Operations, Description of Capital Stock, and the financial statements and related notes appearing elsewhere in this prospectus.

	Actual	As of June 30, 2013 Pro Forma (unaudited) sands, except share share data)	Pro Forma As Adjusted
Cash and cash equivalents	\$ 35,965	\$ 35,965	\$
Notes payable Warrant to purchase preferred stock	\$ 2,346 328	\$ 2,346	\$
Series A redeemable convertible preferred stock, \$0.0001 par value; 43,950,000 shares authorized; 43,750,000 issued and outstanding (actual); no shares authorized, issued and outstanding (pro forma and pro forma as adjusted)	43,045		
Series B redeemable convertible preferred stock, \$0.0001 par value; 24,762,134 shares authorized; issued and outstanding (actual); no shares authorized, issued and outstanding (pro forma and pro forma as adjusted)	55,695		
Stockholders (deficit) equity: Undesignated preferred stock, par value \$0.0001; no shares authorized, issued or outstanding (actual); shares authorized, no shares issued or outstanding (pro			
forma and pro forma adjusted) Common stock, \$0.0001 par value; 96,000,000 shares authorized, 12,761,284 shares issued and outstanding (actual), 96,000,000 shares authorized, 81,273,418 issued and outstanding (pro forma); shares authorized, shares issued and			
outstanding (pro forma as adjusted)	1	8	
Additional paid-in capital Accumulated deficit	5,357 (64,209)	104,349 (64,140)	
Total stockholders (deficit) equity	(58,851)	40,217	
Total capitalization	\$ 42,563	\$ 42,563	\$

The information above is illustrative only and our capitalization following the completion of this offering will be adjusted based on the actual initial public offering price and other terms of this offering determined at pricing.

A \$1.00 increase (decrease) in the assumed initial public offering price of \$ per share, the midpoint of the estimated price range shown on the cover page of this prospectus, would increase (decrease) the amount of cash and cash equivalents, additional paid-in capital, total stockholders equity (deficit) and total capitalization on a pro forma as adjusted basis by approximately \$ million, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase (decrease) of one million shares offered by us would increase (decrease) cash and cash equivalents, total stockholders equity (deficit) and total capitalization on a pro forma as adjusted basis by approximately \$ million, assuming the assumed initial public offering price remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. A share increase in the number of shares offered by us together with a concomitant \$1.00 increase in the assumed initial public offering price of \$ per share, the midpoint of the price range set forth on the cover of this prospectus, would increase each of cash and cash equivalents and total stockholders (deficit) equity by approximately \$ million after deducting underwriting discounts and commissions and any estimated offering expenses payable by us. Conversely, a share decrease in the number of shares offered by us together with a concomitant \$1.00 decrease in the assumed initial per share, the midpoint of the price range set forth on the cover of this prospectus, would decrease each of cash public offering price of \$ and cash equivalents and total stockholders (deficit) equity by approximately \$ million after deducting underwriting discounts and commissions and any estimated offering expenses payable by us. The pro forma as adjusted information discussed above is illustrative only and will be adjusted based on the actual public offering price and other terms of this offering determined at pricing.

The actual, pro forma and pro forma as adjusted information set forth in the table excludes (i) 8,691,566 shares of common stock issuable upon the exercise of stock options outstanding as of June 30, 2013 with a weighted-average exercise price of \$0.76 per share, (ii) 3,850,813 shares of common stock that are outstanding but potentially subject to repurchase by us, (iii) 200,000 shares of common stock issuable upon the exercise of a warrant outstanding as of June 30, 2013 at an exercise price of \$1.00 per share, which warrant prior to the closing of this offering is exercisable for shares of preferred stock and (iv) shares of common stock reserved for future issuance under our 2013 Stock Option and Grant Plan.

### DILUTION

If you invest in our common stock in this offering, your interest will be diluted to the extent of the difference between the public offering price per share of our common stock and the pro forma net tangible book value per share of our common stock immediately after this offering.

The net tangible book value of our common stock as of June 30, 2013 was \$ million, or \$ per share of common stock. Net tangible book value per share represents our total tangible assets less our total tangible liabilities, divided by the number of shares of common stock before giving effect to the conversion of all outstanding shares of preferred stock into shares of common stock, upon the completion of this offering. The pro forma net tangible book value of our common stock as of June 30, 2013 was \$ million, or approximately \$ per share of common stock. Pro forma net tangible book value gives effect to the conversion of all outstanding shares of preferred stock into shares of common stock and the conversion of the outstanding warrant to purchase Series A preferred stock into a warrant to purchase shares of common stock upon the closing of this offering.

Net tangible book value dilution per share to new investors represents the difference between the amount per share paid by purchasers of common stock in this offering and the pro forma net tangible book value per share of our common stock immediately after the completion of this offering. After giving effect to (i) the automatic conversion of all outstanding shares of preferred stock into shares of common stock immediately prior to completion of this offering and (ii) our sale of shares in this offering at an assumed initial public offering price of \$ per share, which is the midpoint of the estimated price range set forth on the cover page of this prospectus, and after deducting estimated underwriting discounts and commissions and estimated offering expenses, our pro forma as adjusted net tangible book value as of June 30, 2013 would have been \$ per share. This represents an immediate increase in net tangible book value of \$ per share to existing stockholders and an immediate dilution in net tangible book value of \$ per share to purchasers of common stock in this offering, as illustrated in the following table:

Assumed initial public offering price per share		\$
Pro forma net tangible book value per share as of June 30, 2013	\$	
Increase in net tangible book value per share attributable to new investors		
Pro forma as adjusted net tangible book value per share at June 30, 2013 after gi	ving effect to the offering	\$
Dilution per share to new investors		\$
A \$1.00 increase (decrease) in the assumed initial public offering price of \$	per share would increase (decrease) the pro forma as	adjusted

A \$1.00 increase (decrease) in the assumed initial public offering price of \$ per share would increase (decrease) the pro forma as adjusted per share and the dilution to new investors by \$ per share, assuming the number of shares offered by net tangible book value, by \$ us, as set forth on the cover page of this prospectus, remains the same, and after deducting underwriting discounts and commissions and estimated expenses payable by us. Similarly, each increase (decrease) of one million shares offered by us would increase (decrease) the pro forma as adjusted net tangible book value by \$ per share and the dilution to new investors by \$ per share, assuming the assumed initial public offering price remains the same and after deducting underwriting discounts and commissions and estimated expenses payable by us. A share increase in the number of shares offered by us together with a concomitant \$1.00 increase in the assumed initial public per share, the midpoint of the price range set forth on the cover of this prospectus, would increase the pro forma as offering price of \$ adjusted net tangible book value by approximately \$ million after deducting underwriting discounts and commissions and any estimated offering expenses payable by us. Conversely, a share decrease in the number of shares offered by us together with a concomitant \$1.00 decrease in the assumed initial public offering price of \$ per

share, the midpoint of the price range set forth on the cover of this prospectus, would decrease the pro forma as adjusted net tangible book value by approximately \$ million after deducting underwriting discounts and commissions and any estimated offering expenses payable by us. If the underwriters exercise their over-allotment option in full, the pro forma as adjusted net tangible book value would be \$ per share, and the dilution in pro forma net tangible book value per share to investors in this offering would be \$ per share.

The following table summarizes, on a pro forma as adjusted basis as of June 30, 2013, the differences between the number of shares of common stock purchased from us, the total consideration and the average price per share paid by existing stockholders (giving effect to the conversion of all of our preferred stock into 68,512,134 shares of common stock prior to the completion of this offering) and by investors participating in this offering, after deducting estimated underwriting discounts and commissions and estimated offering expenses, at an assumed initial public offering price of \$ per share, the midpoint of the price range set forth on the cover of this prospectus.

	Shares P	urchased	Total Con	Avg price /	
	Number	Percent	Amount	Percent	share
Existing stockholders		%	\$	%	\$
New investors					
Total		100%	\$	100%	\$

The above discussion and tables are based on 16,612,097 shares of common stock issued and outstanding as of June 30, 2013 and also reflects the conversion of all outstanding shares of preferred stock into an aggregate of 68,512,134 shares of common stock immediately prior to the completion of this offering, and excludes:

8,691,566 shares of common stock issuable upon the exercise of stock options outstanding as of June 30, 2013 at a weighted-average exercise price of \$0.76 per share;

200,000 shares of common stock issuable upon the exercise of a warrant outstanding as of June 30, 2013 at an exercise price of \$1.00 per share, which warrant prior to the closing of this offering is exercisable to purchase Series A preferred stock;

1,968,871 shares available for issuance under the Amended and Restated 2010 Stock Incentive Plan; and

shares of common stock reserved for future issuance under our 2013 Stock Option and Grant Plan, or the 2013 Plan. A \$1.00 increase (decrease) in the assumed initial public offering price of \$ per share, the midpoint of the price range set forth on the cover of this prospectus, would increase (decrease) the total consideration paid by new investors by approximately \$ million, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

If the underwriters exercise their option to purchase additional shares in full, pro forma as adjusted net tangible book value as of , 2013 will increase to \$ million, or \$ per share, representing an increase to existing stockholders of \$ per share, and there will be per share to new investors.

To the extent that outstanding options and warrants are exercised, you will experience further dilution. In addition, we may choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of these securities may result in further dilution to our stockholders.

### SELECTED FINANCIAL DATA

You should read the following selected historical consolidated financial data below together with Capitalization, Management s Discussion and Analysis of Financial Condition and Results of Operations and the financial statements, related notes and other financial information included elsewhere in this prospectus. The selected financial data in this section are not intended to replace the financial statements and are qualified in their entirety by the financial statements and related notes included elsewhere in this prospectus.

The following selected statements of operations data for the years ended December 31, 2011 and 2012 and the balance sheet data as of December 31, 2011 and 2012 are derived from our audited financial statements appearing elsewhere in this prospectus. The selected statements of operations data for the six months ended June 30, 2012 and 2013 and the balance sheet data as of June 30, 2013 have been derived from our unaudited financial statements included elsewhere in this prospectus. In our opinion, these unaudited financial statements have been prepared on a basis consistent with our audited financial statements and contain all adjustments, consisting only of normal and recurring adjustments, necessary for a fair presentation of such financial data. You should read this data together with our audited financial statements and related notes appearing elsewhere in this prospectus and the information under the captions. Selected Financial Data and Management s Discussion and Analysis of Financial Condition and Results of Operations. Our historical results are not necessarily indicative of our future results, and our operating results for the six-month period ended June 30, 2013 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2013 or any other interim periods or any future year or period.

	Years Ended December 31,				Six Months Ended June 30,				
		2011		2012		2012	udited)	2013	
		(i	n thousa	nds, except sl	unaud) t share and per share dat			,	
Statements of Operations Data:				· •		•			
Revenue	\$	2,057	\$	10,645	\$	2,429	\$	11,120	
Costs and expenses									
Cost of revenue		258		5,681		1,830		4,597	
Sales and marketing		1,555		3,454		1,347		4,686	
General and administrative		6,992		8,644		3,699		7,905	
Research and development		9,023		14,777		6,623		11,079	
Total costs and expenses		17,828		32,556		13,499		28,267	
Loss from operations		(15,771)		(21,911)		(11,070)		(17,147)	
Interest expense, net		(421)		(421)		(11,070) (221)		(141)	
Other expense, net		(845)		(61)		(53)		(141)	
Net loss	\$	(17,037)	\$	(22,393)	\$	(11,344)	\$	(17,390)	
Accretion of redeemable convertible preferred stock		(296)		(286)		(162)		(92)	
Net loss applicable to common stockholders	\$	(17,333)	\$	(22,679)	\$	(11,506)	\$	(17,482)	
Net loss per common share applicable to common stockholders, basic and diluted <sup>(1)</sup>	\$	(3.52)	\$	(2.62)	\$	(1.54)	\$	(1.48)	
Weighted-average common shares outstanding, basic and diluted	2	4,930,634	8	8,667,326	,	7,485,723	1	1,803,985	
Pro forma net loss per common share applicable to common stockholders, basic and diluted <sup><math>(1)</math></sup>			\$	(0.41)			\$	(0.22)	
Pro forma weighted-average common shares outstanding, basic and diluted			55	5,642,878			8	0,516,119	

Comprehensive loss	\$ (17,037)	\$ (22,393)	\$ (11,344)	\$ (17,390)

(1) See Note 2 within the notes to our financial statements appearing elsewhere in this prospectus for a description of the method used to calculate basic and diluted net loss per share of common stock and pro forma basic and diluted net loss per share of common stock.

	Decem	June 30,		
	2011 2012		2013 (unaudited)	
		(in thousands)	(unauuteu)	
Balance Sheet Data:				
Cash and cash equivalents	\$ 10,852	\$ 54,838	\$ 35,965	
Working capital	7,521	49,856	32,226	
Total assets	18,065	66,039	52,269	
Notes payable, excluding current portion	3,041	1,441	634	
Redeemable convertible preferred stock warrant liability	94	225	328	
Redeemable convertible preferred stock	32,455	98,658	98,740	
Accumulated deficit	(24,426)	(46,819)	(64,209)	
Total stockholders deficit	\$ (22,303)	\$ (43,397)	\$ (58,851)	

### 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 financial statements, related notes, and other financial information included elsewhere in this prospectus. 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 commercial-stage company focused on fundamentally changing the way patients with cancer are treated. Our proprietary molecular information platform generates actionable genomic information about a patient s individual cancer, enabling physicians to optimize treatments in clinical practice and enabling biopharmaceutical companies to develop targeted oncology therapies more effectively.

FoundationOne, our first clinical product, is, to our knowledge, the only commercially available comprehensive molecular information product designed for use in the routine care of patients with cancer. In November 2011, we first offered for sale FoundationOne for clinical use to a limited network of key oncology thought leaders and their colleagues and leading academic centers. We then commenced our formal commercial launch of FoundationOne for solid tumors in June 2012 and expect to commercial sales of FoundationOne for clinical use, we generated revenue from our molecular information platform under relationships with biopharmaceutical partners, starting in December 2010. Our molecular information platform is currently used by 18 biopharmaceutical partners to enhance the development of targeted oncology therapies. To accelerate our growth and enhance our competitive advantage, we are extending our sales force, publishing scientific and medical advances, fostering relationships throughout the oncology community, and developing new products.

We have experienced rapid adoption of FoundationOne. More than 1,500 physicians from large academic centers and community-based practices have ordered FoundationOne since its formal commercial launch in June 2012. We believe this rapid adoption of FoundationOne, accomplished with a nascent sales team, demonstrates the demand for and utility of a single comprehensive product that helps oncologists effectively implement the promise of precision medicine.

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 for solid tumors, and the development of new products such as FoundationOne for hematologic malignancies. We have incurred significant losses since our inception, and as of June 30, 2013, our accumulated deficit was \$64.2 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.

### **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 for our clinical customers and is not branded for our biopharmaceutical customers. For the years ended

December 31, 2011 and 2012, and the six months ended June 30, 2013, revenue totaled \$2.1 million, \$10.6 million, and \$11.1 million, respectively.

The principal focus of our commercial operations currently is to continue to drive adoption of products enabled by our molecular information platform. In particular, we seek to increase sales volume of FoundationOne for solid tumors in the clinical setting. For the year ended December 31, 2012, which included only seven months of sales of FoundationOne subsequent to its formal commercial launch in June 2012, and for the six months ended June 30, 2013, we performed approximately 1,750 and 2,766 FoundationOne tests for ordering physicians, respectively. Similarly, we seek to increase the volume of tests enabled by our molecular information platform that we perform for our biopharmaceutical customers. For the year ended December 31, 2012, and for the six months ended June 30, 2013, we performed approximately 1,350,479, and 1,218 tests for our biopharmaceutical customers, respectively.

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. Currently we are not a participating provider with any commercial third-party payors and therefore do not have specific coverage decisions for the FoundationOne test with established payment rates. Currently, 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 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 test is covered by these Medicaid programs. We are a participating provider in the Medicare program but we do not have a coverage decision and have not yet submitted claims for our test 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. 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 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 collectibility is not reasonably assured, including due to the fact that we do not have coverage decisions in place and have a limited history of collecting claims. We expect to use judgment in assessing whether the fee is fixed or determinable and whether collectibility 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 tests are recognized in advance of any associated revenues. Because of the increasing period-to-period FoundationOne 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.

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 decision, 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, requested that we not submit claims for services provided to Medicare patients while the

contractor assessed the appropriate coverage and payment for FoundationOne as a whole. Pending the response, no claims have been billed to either Medicare or Medicare patients and we have not generated any revenue from these FoundationOne tests. As a result, while we incur costs to perform these FoundationOne tests, we are not currently generating revenue from the sale of FoundationOne for patients covered by Medicare. Our net loss is therefore higher than if we were recognizing revenue from the sale of FoundationOne for patients covered by Medicare. FoundationOne tests for patients covered by Medicare represented approximately 28% and 29% of total FoundationOne tests ordered by physicians in the United States during 2012 and the six months ended June 30, 2013, respectively.

We intend to seek a national coverage determination from our Medicare contractor, which, if obtained, will establish a standard for the reimbursement for our Medicare claims. If we do not receive definitive direction from our Medicare contractor regarding our submission of claims for services provided to Medicare patients, we intend, before the end of 2013, to commence submitting claims to Medicare for FoundationOne tests provided to Medicare patients. The response of the Medicare contractor to the submission of such a claim is uncertain and the claim 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. Our Medicare contractor may also issue a negative coverage determination for FoundationOne 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 FoundationOne 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 test volumes increase period-to-period. Following our achievement of a coverage decision from a commercial third-party payor or government payor or once we have a sufficient history of claims collections with any such payor that we conclude the fee for FoundationOne 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 June 30, 2013, we had cash and cash equivalents of approximately \$36.0 million. We do not believe that the adverse impacts on our liquidity related to the absence of coverage decisions from commercial third-party payors and government payors will materially adversely affect our business or prospects over at least the next 12 months and likely not for the foreseeable future. If we are not able to obtain coverage decisions from commercial third-party payors and our available cash balances, net proceeds from this offering, 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 do bill patients for amounts that we have been unable to collect from their third-party payors. While we are not currently seeking reimbursement from Medicare or billing Medicare patients, we may 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 situation.

Revenue from our biopharmaceutical customers are based on a negotiated price per test or on the basis of agreements to provide certain testing volumes 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 are provided, as appropriate.

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 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 cancer patients 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 salary, 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. During the year ended December 31, 2012 and the six months ended June 30, 2013, our cost of revenue represented approximately 53% and 41%, respectively, of our total revenue. Our cost of revenue during the year ended December 31, 2011 was primarily attributable to a pilot agreement with a biopharmaceutical customer.

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.

### Sales and Marketing Expenses

Our sales 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 sales and marketing costs as incurred.

During the years ended December 31, 2011 and 2012, and the six months ended June 30, 2013, our sales and marketing expenses represented approximately 76%, 32%, and 42%, respectively, of our total revenue. We expect our sales and marketing costs to continue to increase in absolute dollars as we expand our sales force, increase our presence within and outside of the United States, and increase our marketing activities to drive further awareness and adoption of FoundationOne and our future products.

### 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 and legal 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 increase after this offering, primarily due to the costs of operating as a public company, such as additional legal, accounting, corporate governance, and investor relations expenses, and higher directors and officers insurance premiums.

#### 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, the development of our knowledgebase for genomic 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 unless they meet the criteria to be capitalized as internal-use software costs. These 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, 2011 and 2012, and the six months ended June 30, 2013, interest income was not material, although we expect our interest income to increase as we invest the net proceeds from this offering.

Other Expense, Net

Other expense, net consists of changes in the fair value of our investor rights obligation, which was the right to purchase additional shares of our Series A convertible preferred stock at a fixed price per share upon the achievement of certain pre-defined milestones that was settled in 2011, and changes in the fair value of our preferred stock warrant liability. These other expenses are offset, in part, by other income from grants received by us, including a grant from the Internal Revenue Service s Qualifying Therapeutic Discovery Program.

### **Results of Operations**

Comparison of Years Ended December 31, 2011 and 2012

		Years Ended December 31,		ge
	2011	2012	\$	%
	(i	(in thousands, except percentages)		
Statements of Operations Data:				
Revenue	\$ 2,057	\$ 10,645	\$ 8,588	418%
Costs and expenses				
Cost of revenue	258	5,681	5,423	2,102
Sales and marketing	1,555	3,454	1,899	122
General and administrative	6,992	8,644	1,652	24
Research and development	9,023	14,777	5,754	64
Total costs and expenses	17,828	32,556	14,728	83
Loss from operations	(15,771)	(21,911)	(6,140)	39
Interest expense, net	(421)	(421)		
Other expense, net	(845)	(61)	784	93
Net loss	\$ (17,037)	\$ (22,393)	\$ (5,356)	31%

Revenue

Total revenue for the year ended December 31, 2012 was \$10.6 million and consisted of \$8.0 million in revenue from our biopharmaceutical customers and \$2.6 million in revenue from FoundationOne tests ordered by clinical physicians. During 2012, we performed approximately 1,350 tests for our biopharmaceutical customers and approximately 1,750 FoundationOne tests for ordering physicians.

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

In 2012, the average revenue per FoundationOne test for clinical use that met our revenue recognition criteria during 2012 was approximately \$3,800. This average revenue per FoundationOne test does not account for 641 FoundationOne tests that were billed to commercial third-party payors during 2012 and were not paid during 2012, or for the 398 FoundationOne tests that we performed during 2012 for patients covered by Medicare but for which claims were not submitted during 2012.

We billed commercial third-party payors for these 641 FoundationOne tests performed during 2012 (but for which we had not recognized revenue as of December 31, 2012) at \$5,800 per test, the current list price for FoundationOne, which represents a maximum potential revenue to us of \$3.7 million, if collected in full. We will continue to make requests for payment and/or appeal payment decisions made by commercial third-party payors. Because we are in an early stage of commercialization, we have limited payment experience, and it is therefore difficult to predict future revenue from the previously performed FoundationOne tests.

Pending receipt of definitive direction from our Medicare contractor, we have not submitted claims to Medicare for the 398 FoundationOne tests performed during 2012 for patients covered by Medicare nor have we billed Medicare patients for these tests. Based upon the current \$5,800 per test list price

for FoundationOne, the 398 tests we performed for Medicare patients in 2012 represent a maximum potential revenue to us of \$2.3 million, if collected in full. We currently expect to submit claims to Medicare for FoundationOne tests previously performed by us for patients covered by Medicare; however, we will continue to assess our ability to bill Medicare or Medicare patients for these tests, pending receipt of definitive direction from our Medicare contractor. Notwithstanding our current intentions to seek payment for these tests, our Medicare contractor may deny our claim, in whole or in part, we may never receive any revenue from any of the 398 FoundationOne tests that we performed during 2012 for patients covered by Medicare and even if we do receive revenue from these tests, we do not expect to receive the full \$5,800 list price per test.

The cumulative amount of FoundationOne tests that have been billed to commercial third-party payors and completed for patients covered by Medicare for which we have not recognized revenue was 641 and 401 (3 of which were conducted during 2011), respectively, as of December 31, 2012. 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 performed FoundationOne tests will favorably impact our liquidity and results of operations in future periods.

Our revenue during 2011 was primarily attributable to a pilot agreement with a biopharmaceutical customer.

None of our revenue recognized in the year ended December 31, 2011 was associated with customers outside of the United States. The majority of our revenue from customers outside of the United States in the year ended December 31, 2012 was generated from two customers from whom we recognized revenue of \$0.8 million.

#### Cost of Revenue

Cost of revenue increased to \$5.7 million for the year ended December 31, 2012 from \$0.3 million for the year ended December 31, 2011. This increase was caused primarily by our performance of tests for our ordering physicians and for our 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. Our cost of revenue during the year ended December 31, 2011 was primarily attributable to a pilot agreement with a biopharmaceutical customer.

#### Sales and Marketing Expenses

Sales and marketing expenses increased by 122% to \$3.5 million for the year ended December 31, 2012 from \$1.6 million for the year ended December 31, 2011. The increase was primarily due to an increase of \$1.3 million in personnel-related costs as the result of hiring 10 employees over the course of the year in our sales, marketing, client service, and reimbursement departments, and an increase of \$0.6 million in marketing costs related to our commercial launch of FoundationOne.

### General and Administrative Expenses

General and administrative expenses increased by 24% to \$8.6 million for the year ended December 31, 2012 from \$7.0 million for the year ended December 31, 2011. The increase was primarily due to a \$2.4 million increase in employee-related expenses, including a \$1.4 million increase in stock-based compensation, to support and expand our legal, finance, and human resources infrastructure. This increase was offset by a \$0.8 million decrease in legal fees driven by establishing an in-house legal team.

### Research and Development Expenses

Research and development expenses increased by 64% to \$14.8 million for the year ended December 31, 2012 from \$9.0 million for the year ended December 31, 2011. The increase was primarily due to a \$2.1 million increase in employee and contractor-related expenses, including stock-based compensation, to support our molecular information platform and product development, a \$1.9 million increase in expenses related to clinical trials to evaluate the clinical utility of FoundationOne, a \$1.5 million increase in technology expenses related to data management, FoundationOne report design and functionality, and customer interface development, and a \$0.3 million increase in lab supplies to support product development.

#### Interest Expense, Net

Interest expense, net was \$0.4 million for the years ended December 31, 2012 and 2011.

#### Other Expense, Net

Other expense, net decreased to \$0.1 million for the year ended December 31, 2012 from \$0.8 million for the year ended December 31, 2011. Other expense, net for the year ended December 31, 2011 included a \$1.1 million fair value adjustment for our investor rights obligation and an insignificant fair value adjustment for our warrant liability, offset by \$0.2 million in grant income from the Internal Revenue Service s Qualifying Therapeutic Discovery Program. The investor rights obligation was settled and reclassified to additional paid-in capital in 2011. We recorded \$0.1 million associated with the change in fair value of our warrant liability in the year ended December 31, 2012. Upon completion of this offering, the preferred stock warrant will automatically convert into a warrant to purchase common stock, and is expected to be reclassified into additional paid-in capital at that time unless exercised earlier.

#### Comparison of Six Months Ended June 30, 2012 and 2013

	Six Montl June	Change		
	2012	2013 (unaudite	\$ ed)	%
	(in	thousands, excep	/	
Statement of Operations Data:				
Revenue	\$ 2,429	\$ 11,120	\$ 8,691	358%
Costs and expenses				
Cost of revenue	1,830	4,597	2,767	151
Sales and marketing	1,347	4,686	3,339	248
General and administrative	3,699	7,905	4,206	114
Research and development	6,623	11,079	4,456	67
Total costs and expenses	13,499	28,267	14,768	109
	,	,	,	
Loss from operations	(11,070)	(17,147)	(6,077)	55
Interest expense, net	(221)	(141)	80	36
Other expense, net	(53)	(102)	(49)	(92)
Net loss	\$ (11,344)	\$ (17,390)	\$ (6,046)	53%

### Revenue

Total revenue for the six months ended June 30, 2013 was \$11.1 million and consisted of \$6.0 million in revenue from our biopharmaceutical customers and \$5.1 million in revenue from FoundationOne tests ordered by clinical physicians. During the six months ended June 30, 2013, we performed 1,218 tests for our biopharmaceutical customers and 2,766 FoundationOne tests for our ordering clinical physicians.

For our biopharmaceutical customer revenue that was based on a negotiated price per test, the average revenue per test in the first six months of 2013 was approximately \$3,800. We expect this average revenue per test for biopharmaceutical customers to remain fairly consistent over time. Approximately \$4.0 million of our biopharmaceutical revenue in the six months ended June 30, 2013 represented minimum guaranteed payments under contracts with multiple element arrangements that were not negotiated on a price per test basis.

In the first six months of 2013, we recognized revenue from 404 FoundationOne tests performed for clinical use during 2012 that were paid during the first six months of 2013.

During the six months ended June 30, 2013 the average revenue per FoundationOne test for clinical use that met our revenue recognition criteria during this period was approximately \$3,700. This average revenue per FoundationOne test does not account for 1,117 FoundationOne tests that were billed to commercial third-party payors during the six months ended June 30, 2013 and were not paid during the six months ended June 30, 2013 or for the 611 FoundationOne tests that we performed during the six months ended June 30, 2013 for patients covered by Medicare but for which claims were not submitted during the six months ended June 30, 2013. We do not have comparable data from the first six months of 2012 because we had not yet formally launched FoundationOne.

We billed commercial third-party payors for these 1,117 FoundationOne tests performed during the six months ended June 30, 2013 (but for which we had not recognized revenue as of June 30, 2013) at \$5,800 per test, the current list price for FoundationOne, which represents a maximum potential revenue to us of \$6.5 million, if collected in full. We will continue to make requests for payment and/or appeal payment decisions made by commercial third-party payors. Because we are in an early stage of commercialization, we have limited payment experience, and it is therefore difficult to predict future revenue from the previously performed FoundationOne tests.

Pending receipt of definitive direction from our Medicare contractor, we have not submitted claims to Medicare for the 611 FoundationOne tests performed during the six months ended June 30, 2013 for patients covered by Medicare nor have we billed Medicare patients for these tests. Based upon the current \$5,800 per test list price for FoundationOne, the 611 tests we performed for Medicare patients during the six months ended June 30, 2013 represent a maximum potential revenue to us of approximately \$3.5 million, if collected in full. We currently expect to submit claims to Medicare for FoundationOne tests previously performed by us for patients covered by Medicare; however, we will continue to assess our ability to bill Medicare or Medicare patients for these tests, pending receipt of definitive direction from our Medicare contractor. Notwithstanding our current intentions to seek payment for these tests, our Medicare contractor may deny our claim, in whole or in part, we may never receive any revenue from any of the 611 FoundationOne tests that we performed during the six months ended June 30, 2013 for patients covered by Medicare and even if we do receive revenue from these tests, we do not expect to receive the full \$5,800 list price per test.

The cumulative amount of FoundationOne tests that have been billed to commercial third-party payors and completed for patients covered by Medicare for which we have not recognized revenue was 1,354 and 1,012, respectively, as of June 30, 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.

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Any revenue that we receive in respect of these previously performed FoundationOne tests will favorably impact our liquidity and results of operations in future periods.

Our revenue during the six months ended June 30, 2012 consisted primarily of revenue from our biopharmaceutical customers. For biopharmaceutical customer revenue that was based on a negotiated price per test, the average revenue per test was approximately \$3,500 in the first six months of 2012 over approximately 300 tests.

Revenue from our international customers did not represent a significant driver of the increased revenue from the first six months of 2012 to the first six months of 2013.

#### Cost of Revenue

Cost of revenue increased to \$4.6 million for the six months ended June 30, 2013 from \$1.8 million for the six months ended June 30, 2012. The increase was due to sales of FoundationOne for clinical use to ordering physicians and to increased testing volume with our biopharmaceutical customers, which drove higher reagent and consumable costs, additional laboratory personnel-related costs, and higher depreciation expenses related to equipment purchases. We expect our cost of revenue to increase as we expand our sales force and drive higher test volume from both our biopharmaceutical customers and our ordering physicians.

#### Sales and Marketing Expenses

Sales and marketing expenses increased by 248% to \$4.7 million for the six months ended June 30, 2013 from \$1.3 million for the six months ended June 30, 2012. The increase primarily resulted from a \$2.1 million increase in personnel-related costs related to the expansion of our sales force, a \$0.5 million increase in facilities expenses, an increase of \$0.4 million in marketing expenses and an increase of \$0.3 million in travel-related expenses.

#### General and Administrative Expenses

General and administrative expenses increased by 114% to \$7.9 million for the six months ended June 30, 2013 from \$3.7 million for the six months ended June 30, 2012. The increase was primarily driven by a \$2.2 million increase in personnel-related costs, including a \$1.4 million increase in stock-based compensation, a \$1.5 million increase in facilities expenses and billing fees and a \$0.4 million increase in legal fees.

### Research and Development Expenses

Research and development expenses increased by 67% to \$11.1 million for the six months ended June 30, 2013 from \$6.6 million for the six months ended June 30, 2012. The increase was mainly related to a \$1.7 million increase in personnel-related costs associated with new hires, including a \$0.1 million increase in stock-based compensation, a \$0.9 million increase in technology infrastructure spending, a \$0.6 million increase in facilities expenses and a \$1.3 million increase in clinical trial spending.

### Interest Expense, Net

Interest expense, net was \$0.2 million and \$0.1 million for the six months ended June 30, 2012 and 2013, respectively.

Other Expense, Net

Other expense, net was insignificant for the six months ended June 30, 2012 and 2013.

### Liquidity and Capital Resources

We have incurred losses and negative cash flows from operations since our inception in November 2009, and as of June 30, 2013, we had an accumulated deficit of \$64.2 million. We expect that our sales and marketing, research and development, and general and administrative expenses will continue to increase. We expect these increased costs to be funded by our product revenue, subject to the rate of reimbursement we receive from commercial third-party payors and government payors, our existing cash and cash equivalents, and the net proceeds of this offering. We may also seek additional capital to fund our operations through equity offerings, debt financings, other third-party funding, or a combination thereof.

We have funded our operations principally from the sale of preferred stock, product revenue and the incurrence of indebtedness. Since we have not received a coverage decision for FoundationOne from any commercial third-party payor and have a limited history of collecting claims, we currently recognize revenue on a cash basis from 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, we currently expect to submit claims to Medicare for FoundationOne tests previously performed by us for patients covered by Medicare and we may receive payment for a portion of these FoundationOne tests, although our requests for payments could be denied in whole. 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 performed FoundationOne tests will favorably impact our liquidity in future periods.

In November 2010, we entered into a loan and security agreement, or the loan and security agreement, with Lighthouse Capital Partners, or Lighthouse, for \$5.0 million, which was fully drawn by June 21, 2011. As of June 30, 2013, \$2.3 million of principal and deferred interest payments were outstanding under the loan and security agreement. Under the terms of the loan and security agreement, we are precluded from entering into certain financing, restructuring and other transactions, including disposing of certain assets, and are subject to various non-financial covenants, including requirements that we maintain standard levels of insurance, maintain our assets in good condition, and file all required tax returns. The loan and security agreement also restricts our ability to pay dividends without the prior written consent of Lighthouse. We believe we were in compliance with all covenants under the loan and security agreement as of June 30, 2013.

As of June 30, 2013, we had cash and cash equivalents of approximately \$36.0 million. Cash in excess of immediate requirements is invested in accordance with our investment policy, primarily with a view to liquidity and capital preservation. Currently, our 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:

		Years Ended December 31,		hs Ended e 30,
	2011	2011 2012		2013
			(unau	dited)
		(In tho	isands)	
Net cash provided by (used in):				
Operating activities	\$ (14,133)	\$ (17,249)	\$ (11,002)	\$ (13,710)
Investing activities	(5,410)	(3,183)	(1,678)	(3,023)
Financing activities	28,986	64,418	9,455	(2,140)
Net increase (decrease) in cash and cash equivalents	\$ 9,443	\$ 43,986	\$ (3,225)	\$ (18,873)

*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 \$14.1 million for the year ended December 31, 2011, and consisted primarily of a net loss of \$17.0 million adjusted for non-cash items including depreciation of \$1.5 million, the change in fair value of the investor rights obligation of \$1.1 million, non-cash interest expense of \$0.1 million, stock-based compensation of \$0.1 million, and a net decrease in operating assets and liabilities of \$0.1 million. The significant items in the change in operating assets and liabilities include decreases in accounts payable of \$0.3 million and deferred revenue of \$1.1 million and an increase in inventory of \$0.3 million, offset, in part, by a decrease in accounts receivable of \$1.0 million, an increase in accrued expenses of \$0.6 million and an increase in deferred rent of \$0.4 million.

The net cash used in operating activities was \$17.2 million for the year ended December 31, 2012, and consisted primarily of a net loss of \$22.4 million adjusted for non-cash items including depreciation of \$2.9 million, stock-based compensation expense of \$1.5 million, and a net increase in operating assets and liabilities of \$0.5 million. The significant items in the change in operating assets and liabilities include increases in accrued expenses of \$1.4 million, accounts payable of \$0.1 million, and deferred revenue of \$1.6 million, partially offset by increases in accounts receivable of \$1.9 million, prepaid expenses and other current assets of \$0.2 million, and inventory of \$0.5 million.

The net cash used in operating activities was \$11.0 million for the six months ended June 30, 2012, and consisted primarily of a net loss of \$11.3 million adjusted for non-cash items including depreciation of \$1.3 million and stock-based compensation expense of \$0.5 million and a net increase in operating assets and liabilities of \$1.5 million. The significant items in the change in operating assets and liabilities include increases in accounts receivable of \$1.9 million, prepaid expenses and other current assets of \$0.3 million and inventory of \$0.3 million and a decrease in accounts payable of \$0.2 million, partially offset by increases in accrued expenses of \$0.6 million and deferred revenue of \$0.5 million.

The net cash used in operating activities was \$13.7 million for the six months ended June 30, 2013, and consisted primarily of a net loss of \$17.4 million adjusted for non-cash items including depreciation of \$2.1 million, stock-based compensation expense of \$2.0 million, and a net increase in operating assets and liabilities of \$0.5 million. The significant items in the change in operating assets and liabilities include increases in accounts receivable of \$1.9 million, and an increase in prepaid expenses and other current assets of \$0.5 million, partially offset by an increase in accounts payable of \$0.4 million, an increase in deferred rent of \$0.8 million and an increase in deferred revenue of \$0.5 million.

*Investing Activities*. Net cash used in investing activities consisted of purchases of fixed assets and an increase in restricted cash related to a security deposit. Net cash used in investing activities for the years ended December 31, 2011 and 2012 was \$5.4 million and \$3.2 million, respectively, and consisted of purchases of property and equipment. Net cash used in investing activities for the six months ended June 30, 2012 was \$1.7 million and consisted of purchases of property and equipment. Net cash used in investing activities for the six months ended June 30, 2013 was \$3.0 million and consisted of an increase in restricted cash of \$1.7 million related to our new laboratory and office facilities, and purchases of property and equipment.

*Financing Activities*. Net cash provided by financing activities for the year ended December 31, 2011 of \$29.0 million included \$26.3 million of net proceeds from the sale of Series A preferred stock and \$3.0 million in net proceeds from our loan facility, offset, in part, by \$0.4 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 Series A preferred stock for net proceeds of \$10.2 million and the sale of Series B preferred stock for net proceeds of \$55.7 million, offset, in part, by \$1.6 million in loan principal payments. Net cash provided by financing activities for the six months ended June 30, 2012 was \$9.5 million and reflects the sale of Series A preferred stock for net proceeds of \$10.2 million and reflects the sale of Series B preferred stock for the six months ended June 30, 2012 was \$9.5 million and reflects the sale of Series A preferred stock for net proceeds of \$10.2 million and reflects the sale of Series A preferred stock for net proceeds of \$10.2 million and reflects the sale of Series A preferred stock for net proceeds of \$10.2 million and reflects the sale of Series A preferred stock for net proceeds of \$10.2 million and reflects the sale of Series A preferred stock for net proceeds of \$10.2 million and reflects the sale of Series A preferred stock for net proceeds of \$10.2 million and reflects the sale of Series A preferred stock for net proceeds of \$10.2 million and consisted of loan principal payments. Net cash used in financing activities for the six months ended June 30, 2013 was \$2.1 million and consisted of loan principal repayments and issuance costs related to our planned initial public offering.

### **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 for solid tumors, launch FoundationOne for hematologic malignancies, invest in clinical trials, innovate our molecular information platform, and develop new product offerings. Our liquidity requirements have and will continue to consist of sales and marketing expenses, research and development expenses, capital expenditures, working capital, debt service, and general corporate expenses. As demand for FoundationOne 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 we will use a portion of the net proceeds of this offering, in combination with our existing cash and cash equivalents, for these purposes and for the increased costs associated with being a public company. The amount by which we increase our sales and marketing expenses and research and development expenses will be dependent upon the net proceeds of this offering and cannot currently be estimated. We expect that our planned expenditures will be funded from our ongoing operations, as well as from the net proceeds of this offering.

Based on our current business plan, we believe the net proceeds from this offering, together with our current cash and cash equivalents and anticipated cash flow from operations, will be sufficient to meet our anticipated cash requirements over at least the next 12 months and for the foreseeable future. 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 sales and marketing activities and continue to invest in new product offerings. As sales of FoundationOne grow, we expect our accounts receivable balance to increase. Any increase in accounts payable and accrued expenses may not be completely offset by increases in accounts receivable, which could result in greater working capital requirements.

If our available cash balances, net proceeds from this offering, 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 prospectus, 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. 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.

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 the section Risk Factors of this prospectus. 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 contractual obligations at December 31, 2012.

	Total	2013	2014-2015 (in thousands)	2016-2018	Thereafter
Operating lease <sup>(1)</sup>	\$ 2,900	\$ 1,007	\$ 1,893	\$	\$
Notes payable <sup>(2)</sup>	3,424	1,874	1,550		
Total	\$ 6,324	\$ 2,881	\$ 3,443	\$	\$

(1) We lease 22,506 square feet for office and laboratory space in Cambridge, Massachusetts under an operating lease that expires in July 2015.

(2) We entered into a loan agreement with Lighthouse to borrow up to \$5,000,000 at a fixed interest rate of 8.25% on November 2010. The final payment will be made on December 31, 2014. Our notes payable balance includes interest payments.

The following table summarizes our contractual obligations at June 30, 2013.

	Total	2013	2014-2015 (in thousands)	2016-2018	Thereafter
Operating leases <sup>(1)</sup>	\$ 29,536	\$ 580	\$ 6,862	\$ 11,423	\$ 10,671
Notes payable <sup>(2)</sup>	2,487	937	1,550		
Total	\$ 32,023	\$ 1,517	\$ 8,412	\$ 11,423	\$ 10,671

(1) Our operating leases include the following:

22,506 square feet of office and laboratory space in Cambridge, Massachusetts under a lease that expires in July 2015;

approximately 10,000 square feet of office space in Cambridge, Massachusetts under a lease that expires in March 2014; and

61,591 square feet of office and laboratory space in Cambridge, Massachusetts under a lease that expires in February 2021.

(2) We entered into a loan agreement with Lighthouse to borrow up to \$5,000,000 at a fixed interest rate of 8.25% on November 2010. The final payment is due on December 31, 2014. Our notes payable balance includes interest payments.

In July 2013, we entered into a Supply, Service and Support Agreement with Illumina, Inc., pursuant to which we agreed to purchase a minimum quantity of reagents and other consumables and access to services and capital equipment over a five-year term. Our minimum purchase commitment over the term of the agreement is approximately \$6.1 million as of the effective date of the agreement.

### Net Operating Loss Carryforwards

We have deferred tax assets of approximately \$18.0 million as of December 31, 2012, which 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, 2012, we had federal NOL carryforwards of approximately \$39.9 million and state NOL carryforwards of \$39.1 million available to reduce future taxable income, if any. These federal NOL carryforwards expire at various times through 2029 and the state NOL carryforwards begin to expire in 2014. 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, 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. If we experience a Section 382 ownership change in connection with this offering or as a result of future changes in our stock ownership, some of which changes are outside our control, the tax benefits related to the NOL carryforwards may be limited or lost.

#### **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 Securities and Exchange Commission.

#### Quantitative and Qualitative Disclosures about Market Risk

We are exposed to market risk related to changes in interest rates. As of December 31, 2012, we had cash and cash equivalents of \$54.8 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.

### **Application of Critical Accounting Policies**

We have prepared our financial statements in accordance with U.S. generally accepted accounting principles. Our preparation of these 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 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 financial statements included later in this prospectus, we believe the following accounting policies to be critical to the judgments and estimates used in the preparation of our 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.

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, and in assessing whether each deliverable is a separate unit of accounting. 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 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 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 prepaid 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.

#### Stock-based Compensation

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:

		ars Ended ember 31,	En	Aonths Ided Ie 30,
	2011	2012	2012 (una)	2013 udited)
		(in the	ousands)	)
Cost of revenue	\$ 1	\$ 22	\$ 5	\$ 17
Sales and marketing		31	5	45
General and administrative	69	1,388	465	1,816
Research and development	3	94	33	117
Total	\$ 73	\$ 1,535	\$ 508	\$ 1,995

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 and restricted stock. The fair value method 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. As a private company, 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 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. For the years ended December 31, 2011 and 2012, and the six months ended June 30, 2012 and 2013, we estimated the fair value of stock options at their respective grant dates using the following assumptions:

	Years Ended December 31,		Six Months Ended June 30,	
	2011	2012	2012	2013
Expected volatility	68.6%	68.0%	69.0%	67.1%
Risk-free interest rate	2.56%	1.29%	1.35%	1.35%
Expected stock option term (in years)	6.25	6.25	6.25	6.25

#### Expected dividend yield

There is a high degree of subjectivity involved when using option-pricing models to estimate stock-based compensation. There is currently no market-based mechanism or other practical application to verify the reliability and accuracy of the estimates stemming from these valuation models, nor is there a means to compare and adjust the estimates to actual values. Although the fair value of stock-based awards is determined using an option-pricing model, that value may not be indicative of the fair value that would be observed in a market transaction between a willing buyer and willing seller. If factors change and we employ different assumptions when valuing our stock options, the compensation expense that we record in the future may differ significantly from what we have historically reported.

#### Determination of the Fair Value of Common Stock on Grant Dates

We are a privately held company with no active public market for our common stock. Therefore, our board of directors, with the assistance and upon the recommendation of management and based upon independent third party valuations, has for financial reporting purposes periodically determined the estimated per share fair value of our common stock at various dates using contemporaneous valuations consistent with the American Institute of Certified Public Accountants Practice Aid, *Valuation of Privately-Held Company Equity Securities Issued as Compensation*, also known as the Practice Aid. We performed these contemporaneous valuations as of August 31, 2011, November 5, 2012, February 15, 2013, and May 10, 2013. In conducting these contemporaneous valuations, our board of directors considered all objective and subjective factors that it believed to be relevant in each valuation conducted, including management s best estimate of our business condition, prospects, and operating performance at each valuation date. Within the contemporaneous valuations performed by our board of directors, a range of factors, assumptions, and methodologies were used. The significant factors included:

the fact that we are a privately held company with illiquid securities;

our stage of commercialization;

the likelihood of achieving a liquidity event for shares of our common stock, such as an initial public offering, given prevailing market conditions;

our historical operating results;

valuations of comparable public companies;

our discounted future cash flows, based on our projected operating results; and

our capital structure, including the rights and preferences of our various classes of equity.

The dates of our contemporaneous valuations have not always coincided with the dates of our stock-based compensation grants. In such instances, our board of directors estimates have been based on the most recent contemporaneous valuation of our shares of common stock and its assessment of additional objective and subjective factors it believed were relevant and which may have changed from the date of the most recent contemporaneous valuation through the date of the grant.

There are significant judgments and estimates inherent in these valuations. These judgments and estimates include assumptions regarding our future operating performance, stage of commercial growth, reimbursement from commercial third-party payors and government payors, the timing of a potential initial public offering or other liquidity event, and the determination of the appropriate valuation method at each valuation date. If we had made different assumptions, our stock-based compensation expense, net loss applicable to common stockholders, and net loss per share applicable to common stockholders could have been significantly different.

The following table summarizes by grant date the number of shares of common stock subject to stock options granted from January 1, 2012 through the date of this prospectus, as well as the associated per share exercise price and the per share estimated fair value of the underlying common stock.

			Common	Stock Fair
Type of Award	Number of Shares	Exercise Price Per Share		Per Share ant Date
Option	1,769,634	\$ 0.21	\$	0.21
Option	842,495	0.21		0.21
Option	492,000	0.21		0.45
Option	571,500	0.21		0.45
Option	430,500	0.21		0.45
Option	778,500	0.99		0.99
Option	2,541,700	1.04		1.04
Option	1,019,800	1.78		1.78
Option	320,000	1.78		1.78
	Award Option Option Option Option Option Option Option Option	Award         Shares           Option         1,769,634           Option         842,495           Option         492,000           Option         571,500           Option         430,500           Option         778,500           Option         2,541,700           Option         1,019,800	Award         Shares         Per Share           Option         1,769,634         \$ 0.21           Option         842,495         0.21           Option         492,000         0.21           Option         571,500         0.21           Option         778,500         0.99           Option         2,541,700         1.04           Option         1,019,800         1.78	Type of Award         Number of Shares         Exercise Price Per Share         Value I on Gr           Option         1,769,634         \$ 0.21         \$           Option         842,495         0.21         \$           Option         492,000         0.21         \$           Option         571,500         0.21         \$           Option         778,500         0.99         \$           Option         2,541,700         1.04         \$           Option         1,019,800         1.78         \$

Common Stock Valuation Methodologies

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.

As provided in the Practice Aid, there are several approaches for allocating enterprise value of a privately held company among the securities held in a complex capital structure. The possible

methodologies include the probability-weighted expected return method, or PWERM, the option-pricing method, or OPM, the current-value method, or a hybrid of the PWERM and the OPM, which we refer to as the hybrid method. Under the PWERM, shares are valued based upon the probability-weighted present value of expected future returns, considering various future outcomes available to us, as well as the rights of each share class. The OPM treats common stock and preferred stock as call options on the enterprise s value. The exercise prices associated with these call options vary according to the liquidation preference of the preferred stock, the preferred stock conversion price, the exercise prices of common stock options, and other features of a company s equity capital structure. The current-value method, which is generally only used for early stage companies, is based on first determining enterprise value using a market, income or asset-based approach, and then allocating that value to the preferred stock based on its liquidation preference or conversion value, whichever would be greater.

#### August 31, 2011 Valuation

We, with the assistance of a third-party valuation specialist, performed a contemporaneous valuation of our common stock as of August 31, 2011, and determined the fair value to be \$0.21 per share as of that date. We used the back-solve method of the OPM, which derives the implied equity value for one type of equity security from a contemporaneous transaction involving another type of equity security. We applied the OPM back-solve method to solve for the equity value and corresponding value of common stock based on the \$1.00 per share price paid for our Series A preferred stock. In August 2011, two unrelated investors, who had not previously invested in Foundation, purchased shares of our Series A preferred stock at a price of \$1.00 per share. Given the proximity to the Series A preferred stock financing, we believed the per share issuance price of the Series A preferred stock provided an indication of the fair value of our equity as of August 31, 2011.

The OPM treats common stock and preferred stock as call options on the total equity value of a company, with exercise prices based on the value thresholds at which the allocation among the various holders of a company s securities changes. Under this method, the common stock has value only if the funds available for distribution to stockholders exceeds the value of the liquidation preference at the time of a liquidity event, such as a strategic sale or merger. The common stock is modeled as a call option on the underlying equity value at a predetermined exercise price. In the model, the exercise price is based on a comparison with the total equity value rather than, as in the case of a regular call option, a comparison with a per share stock price. The OPM uses the Black-Scholes option-pricing model to price the call options. This model defines the securities fair values as functions of the current fair value of a company and uses assumptions, such as the anticipated timing of a potential liquidity event and the estimated volatility of the equity securities.

We estimated the time to liquidity as 2.27 years based on then-current plans and estimates of our board of directors and management regarding a liquidity event. The risk-free rate was estimated as the interpolated 2.3 year yield on government bonds. We estimated annual volatility of 58% based on the observed historical volatility of publicly-traded shares issued by companies which are comparable to ours.

We applied a discount for lack of marketability to the value indicated for our common stock. We believed that a discount was appropriate because our common stock was unregistered, and because the holder of a minority interest in the common stock might not be able to influence the timing of a liquidity event. Our estimate of the appropriate discount for lack of marketability was based on quantitative methods, including the Protective Put Method (Chaffe) and the Asian Protective Put Method, consistent with the Practice Aid. We applied an estimated discount for lack of marketability of 25% to the value indicated for our common stock.

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The following table summarizes the significant assumptions used to determine the fair value of our common stock of \$0.21 as of August 31, 2011:

Years to liquidity	2.27
Annual volatility	58%
Risk-free interest rate	0.21%
Discount for lack of marketability (DLOM)	25%
As a result of the fact that there were no material changes to our business from August 31, 2011 to March 27, 2012, we utilized th	e August 31.

As a result of the fact that there were no material changes to our business from August 31, 2011 to March 27, 2012, we utilized the August 31, 2011 valuation to determine the exercise price of option grants in January and March 2012.

#### November 5, 2012 Valuation

We, with the assistance of a third-party valuation specialist, performed a contemporaneous valuation of our common stock as of November 5, 2012, and determined the fair value to be \$0.99 per share as of that date. We applied the OPM back-solve method to solve for our equity value and corresponding value of common stock based on the \$2.26 per share price paid for our Series B preferred stock. In September 2012, several unrelated investors, who had not previously invested in Foundation, purchased shares of our Series B preferred stock at a price of \$2.26 per share. Given the proximity to the Series B preferred stock financing and the arms-length nature of the transaction, we believed the per share issuance price of the Series B preferred stock provided an indication of the fair value of our equity as of November 5, 2012.

We estimated the time to liquidity as 2.50 years based on then-current plans and estimates of our board of directors and management regarding a liquidity event. The risk free rate was estimated as the interpolated 2.5 year yield on government bonds. We estimated annual volatility based on the observed historical volatility of publicly-traded shares issued by companies which are comparable to ours.

We applied a discount for lack of marketability to the value indicated for our common stock. Our estimate of the appropriate discount for lack of marketability took into consideration put option methodologies consistent with the Practice Aid. We applied an estimated discount for lack of marketability of 25% to the value indicated for our common stock.

The following table summarizes the significant assumptions used to determine the fair value of our common stock of \$0.99 as of November 5, 2012:

Years to liquidity	2.50
Annual volatility	49
Risk-free interest rate	0.38
Discount for lack of marketability (DLOM)	25

In preparing our December 31, 2012 financial statements, we concluded that the fair value of the common stock underlying the stock options granted between May 24, 2012 and July 24, 2012 with an exercise price of \$0.21 per share was \$0.45 per share for financial statement and reporting purposes. Our estimate of \$0.45 per share was based on an analysis of the contemporaneous valuations of our common stock on August 31, 2011 and November 5, 2012, and an evaluation of the key business milestones which increased the fair value of our common stock during that period. The increase in the fair value of our common stock from \$0.21 to \$0.45 was primarily attributable to the formal commercial launch of FoundationOne in early June 2012. We utilized the \$0.45 per share fair value in determining stock-based compensation expense for the above-mentioned grants for the year ended December 31, 2012 and the six months ended June 30, 2013.

The primary factors that supported the increase in the fair value of our common stock from \$0.21 per share to \$0.99 per share on November 5, 2012 were:

we commenced our formal commercial launch of FoundationOne for solid tumors in June 2012;

we secured \$42.5 million in additional financing in September 2012;

in connection with the September financing, the participation and dividend rights of the previously outstanding preferred stock were modified, and those modifications were beneficial to holders of common stock; and

we continued to sign additional agreements with biopharmaceutical customers, which we believe demonstrated early demand for our product.

We utilized the November 5, 2012 valuation to determine the exercise price of options granted on December 18, 2012.

#### February 15, 2013 Valuation

We, with the assistance of a third-party valuation specialist, performed a contemporaneous valuation of our common stock as of February 15, 2013 and determined the fair value to be \$1.04 per share as of that date. During the first quarter of 2013, management and our board of directors believed that a future initial public offering, or IPO, would be possible to the extent we continued to experience strong market adoption for FoundationOne, and received reasonable rates of reimbursement from commercial third-party payors. Without significant market penetration or reimbursement from commercial third-party and government payors, we believed that an IPO in 2013 would be unlikely.

To estimate our enterprise value, we used the hybrid method. The hybrid method is a PWERM where the equity value in one of the scenarios is calculated using an OPM. The hybrid method considers one IPO scenario and one OPM scenario. For the OPM scenario, the type of liquidity event or outcome is undefined. In order to estimate the investment return for the IPO scenario, we considered the price per share of our Series B preferred stock, the expected timing of an IPO, and an estimated rate of return on the Series B investment. In December 2012, three new investors, that had not previously invested in Foundation, purchased shares of our Series B preferred stock at a price of \$2.26 per share. We assumed an IPO would occur 1.50 years after the investment, priced at a level to provide the Series B investors with an annual rate of return of 20%.

As a corroborative calculation, we considered the guideline public company, or GPC, method under the market approach. We considered various GPC s for the February 15, 2013 valuation and concluded that the value we assumed for our IPO was consistent as a multiple of projected revenue with the multiples indicated by the GPC method.

In the OPM scenario, we applied the back-solve method to solve for the equity value and corresponding value of common stock based on the \$2.26 per share price for the additional sale of Series B preferred stock to three new investors in December 2012. Given the proximity to the Series B preferred stock financing in December 2012, and the fact that this financing included and was led by unrelated investors, we believed the per share issuance price of the Series B preferred stock provided an indication of the fair value of our equity as of February 15, 2013. The values indicated for the shares of our preferred stock and common stock by the IPO scenario and the OPM scenario were probability weighted to estimate the fair value of our common stock as of the February 15, 2013 valuation date.

As a corroborative calculation to the OPM, we also considered the discounted cash flow method under the income approach. We converted our projected future cash flows to present value by applying a discount rate of 25%, which we selected based on studies of the rates of return expected by venture

capitalists for companies in the bridge and IPO stage of development. The discounted cash flow method yielded an enterprise value which was consistent with the enterprise value indicated by the OPM back-solve method.

For the February 15, 2013 valuation, we estimated the fair value of our common stock by assigning a 90% weighting to the estimated fair value using the OPM back-solve method and a 10% weighting to the estimated fair value under the IPO scenario. We believed that the 90% weighting on the OPM back-solve method was appropriate due to the proximity of an additional issuance of our Series B preferred stock in December 2012 to the valuation date, and the fact that this December financing included and was led by unrelated investors. The weighting for the IPO scenario was deemed appropriate because at the time of the valuation, we believed that there was a possibility of following a successful Series B financing with an IPO, but given the following risks the probability of an IPO was assessed at only 10%:

there remained uncertainty as to the rate of adoption of FoundationOne given that we only had two quarters of commercial experience, and we believed that our ability to demonstrate a significant and sustained rate of market penetration was necessary to position us for a successful IPO;

on January 1, 2013, new Centers for Medicare and Medicaid Services, or CMS, reimbursement codes, which are used by commercial third-party payors and CMS, for molecular testing services took effect. There was significant uncertainty as to whether, and to what extent, we would get reimbursed for FoundationOne by commercial third-party payors and government payors. Because these codes had just taken effect, we did not then have sufficient experience with reimbursement under these new codes necessary to proceed with an IPO; and

we had not commenced a process to pursue an IPO of our common stock, our board of directors had not authorized any such process, and planning for an IPO can take a significant amount of time.

After weighting the two scenarios, we applied a discount for lack of marketability of 25%, which yielded an estimated value attributable to common stockholders of \$1.04 per share. The discount for lack of marketability of 25% was based on quantitative methods, including the Protective Put Method (Chaffe) and the Asian Protective Put Method, consistent with the Practice Aid.

The following table summarizes the significant assumptions used in the hybrid method to determine the fair value of our common stock as of February 15, 2013:

	IP	O OPM
Probability weighting		10% 90%
Years to liquidity	1.	.37 2.22
Annual volatility	Ν	NA 48%
Risk-free rate	١	NA 0.26%
Discount for lack of marketability (DLOM)		25% 25%
		010 0 01 01

The primary factors that supported an increase in the fair value of our common stock from \$0.99 per share at December 18, 2012 to \$1.04 per share at February 15, 2013 were:

we hired 17 new employees, including a Chief Business Officer and three additional members of our sales force; and

we made progress in scaling our laboratory and information technology capabilities to support our growth expectations.

#### May 10, 2013 Valuation

As a result of favorable capital market conditions, the strong initial adoption of FoundationOne, and the observed reimbursement trends from commercial third-party payors for FoundationOne under the new CMS reimbursement codes that took effect on January 1, 2013, an IPO became more probable in the near-term. During the second quarter of 2013, we began preparations for an IPO, including the selection of underwriters and outside legal counsel. We, our external advisors, the proposed underwriters and their advisors held an organizational meeting in May 2013 to formally begin the IPO process and the underwriter due diligence process.

As a result of these changes in facts and circumstances, we, with the assistance of a third-party valuation specialist, completed another contemporaneous valuation analysis as of May 10, 2013. To estimate our enterprise value, we used the hybrid method. For the IPO scenario, we used the GPC method under the market approach to estimate our enterprise value in an IPO. We estimated our value in an IPO based on GPC multiples of projected revenue.

As a corroborative calculation, we considered the annual rate of return for our Series B preferred stock investors based on our estimated value in an IPO. This calculation supported the value determined under the GPC method.

In the OPM scenario, we estimated our equity value using the discounted cash flow method under the income approach. We converted our projected future cash flows to present value by applying a discount rate of 25%, which we selected based on studies of the rates of return expected by venture capitalists for companies in the bridge and IPO stage of development.

We assigned a 60% probability of the IPO scenario and a 40% probability to the OPM scenario. The primary factors that supported these probabilities, and the primary reasons for the increase in the fair value of our common stock from \$1.04 per share to \$1.78 per share at May 21, 2013, were:

FoundationOne test volume and our customer base increased significantly during March, April, and the first week of May 2013;

reimbursement received from commercial third-party payors under the new CMS reimbursement codes that took effect on January 1, 2013;

we entered into a collaboration with Memorial Sloan-Kettering Cancer Center for the development of FoundationOne for hematologic malignancies;

we entered into agreements with new and existing biopharmaceutical partners;

several of our scientific discoveries were accepted for publication and we were selected for several high profile presentations, including at the American Society of Clinical Oncology, or ASCO;

our decision to accelerate our field sales hiring plan based on observed adoption of FoundationOne; and

as a result of favorable capital market conditions and the factors noted above, we began the process of preparing for an IPO. After weighting the two scenarios, we applied a discount for lack of marketability of 15%, which yielded an estimated value attributable to common stockholders of \$1.78 per share. This discount for lack of marketability was based on quantitative methods, including the Protective Put Method (Chaffe) and the Asian Protective Put Method, consistent with the Practice Aid.

The following table summarizes the significant assumptions used in the hybrid method to determine the fair value of our common stock as of May 10, 2013:

	IPO	OPM
Probability weighting	60%	40%
Years to liquidity	0.39	1.99
Annual volatility	NA	47%
Risk-free rate	NA	0.26%
Discount for lack of marketability (DLOM)	15%	15%
JOBS Act		

In April 2012, the Jumpstart Our Business Startups Act, or the JOBS Act, was enacted in the United States. Section 107 of the JOBS Act 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, as amended, for complying with new or revised accounting standards. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this extended transition period and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth companies.

### BUSINESS

#### Overview

We are a commercial-stage company focused on fundamentally changing the way patients with cancer are treated. Our proprietary molecular information platform generates actionable genomic information about a patient s individual cancer, enabling physicians to optimize treatments in clinical practice and enabling biopharmaceutical companies to develop targeted oncology therapies more effectively. We believe we have a significant first mover advantage in providing comprehensive molecular information products on a commercial scale.

Our first clinical product, FoundationOne, is, to our knowledge, the only commercially available comprehensive molecular information product designed for use in the routine care of patients with cancer. We commenced our formal commercial launch of FoundationOne for solid tumors in June 2012 and expect to commence our commercial launch of FoundationOne for blood-based cancers, or hematologic malignancies, by early 2014. To accelerate our growth and enhance our competitive advantage, we are extending our sales force, publishing scientific and medical advances, fostering relationships throughout the oncology community, and developing new products.

The cancer treatment paradigm is evolving rapidly. Today, physicians increasingly use precision medicines to target cancers based on the specific genomic alterations driving their growth. 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 a single product that can assess the known biologically relevant genomic alterations and distill complex molecular information into a concise and actionable format and we designed FoundationOne to be that product. We believe the annual U.S. market opportunity for a comprehensive molecular diagnostic product like FoundationOne is approximately \$4.0 billion today and will grow to exceed \$7.5 billion over the next several years as medical practice further incorporates the growing understanding of molecular information and use of targeted oncology therapies.

We believe we have built the only molecular information platform 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. FoundationOne has identified at least one genomic alteration that is actionable, meaning the alteration is associated with an FDA-approved targeted therapy or with a clinical trial, in 82% of the 3,936 clinical specimens we received and analyzed with FoundationOne following its formal commercial launch in June 2012 through May 17, 2013. FoundationOne delivers this complex molecular information in a concise report that matches detected molecular alterations with potentially relevant treatment options and clinical trials. The FoundationOne report is also available to physicians through an online portal and soon through interactive mobile applications.

We have experienced rapid adoption of FoundationOne. More than 1,500 physicians from large academic centers and community-based practices across more than 25 countries have ordered FoundationOne since its formal commercial launch in June 2012. We believe this rapid adoption of FoundationOne, which has been accomplished with a nascent sales team, demonstrates the demand for and utility of a single, comprehensive product that helps oncologists effectively implement the promise of precision medicine.



We believe FoundationOne has a sustainable competitive advantage because it:

*Comprehensively identifies clinically actionable information* FoundationOne currently assesses 236 biologically relevant cancer genes for all classes of genomic alterations with high sensitivity and specificity, and has identified actionable alterations in 82% of the 3,936 clinical specimens we received and analyzed with FoundationOne following its formal commercial launch in June 2012 through May 17, 2013. FoundationOne identifies genomic alterations that other diagnostic tests cannot. Based on our quantitative analysis, FoundationOne finds more than three times the combined number of actionable genomic alterations identifiable using a collection of six commercially available and commonly used diagnostic tests;

*Incorporates 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;

*Readily integrates into routine clinical practice* Our proprietary sample preparation processes and computational biology algorithms allow us to utilize small amounts of routinely collected tumor tissue from a wide variety of sample types, including tissue with low tumor purity. We detect and report the clinically relevant genomic alterations, generally within 14 to 17 days. 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;

*Provides actionable information that physicians can use* In a concise report, FoundationOne communicates the actionable genomic alterations in a patient s cancer and matches these alterations with targeted therapies and relevant clinical trials. Through our online portal, Interactive Cancer Explorer, physicians can access this report and links to topical peer-reviewed literature; and

*Promotes physician interaction to create a powerful network effect* We are continually augmenting our cancer knowledgebase, and we are expanding the functionality of our Interactive Cancer Explorer to allow for sharing of genomic and treatment data. Together, we believe these efforts will create a network effect of more users and ultimately more actionable information.

Key opinion leaders and leading cancer researchers, including oncologists at premier cancer institutions, such as Memorial Sloan-Kettering Cancer Center, Vanderbilt-Ingram Cancer Center, and The US Oncology Network, have embraced our approach and products. We believe that our relationships with thought leaders help validate our platform, drive adoption of our products in community oncology settings, and establish our leadership position in the field of molecular information related to cancer. We believe that the increasing use of our products, particularly among thought leaders, and the demonstration of the economic and clinical value of FoundationOne will help facilitate favorable reimbursement decisions. In addition to routinely using FoundationOne for clinical cases, many thought leaders collaborate with us on clinical studies, peer-reviewed publications, and medical and scientific conference presentations. Our effort in building these relationships furthers our ultimate goal to facilitate better-informed treatment decisions for patients with cancer.

Our molecular information platform also is currently used by 18 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 analysis and information relevant to precision medicine strategies. In addition to generating revenue, these relationships 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 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 improvements to FoundationOne and the platform generally, enabling us to analyze more genes using less tissue while reducing turn-around time. Already more than 40% of FoundationOne customers use Interactive Cancer Explorer, the online portal we developed in consultation with Google Ventures, one of our investors, and launched in December 2012. We are also incorporating RNA-based sequencing technology to analyze the additional gene fusions commonly found in hematologic malignancies and expect to commence our commercial launch of FoundationOne for hematologic malignancies incorporating this technology by early 2014. In addition, we are exploring and developing new scientifically-advanced and clinically-relevant products that include, for example, products utilizing circulating tumor cells and, or cell-free plasma DNA, which is DNA that circulates in blood plasma outside of cells, and products that expand our offerings into additional areas such as epigenetics, which examines changes in gene expression that occur without changes in the underlying DNA, methylation, which is a chemical signaling mechanism that plays a role in regulation of gene expression, and immune response.

The increasing availability and understanding of molecular information about cancer 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 a recent example of the power of our molecular information platform, after a biopharmaceutical partner s Phase 2 trial that used a narrowly focused test to screen trial subjects failed to meet its primary endpoint, we performed our comprehensive genomic analysis on trial subjects. Our analysis helped our biopharmaceutical partner predict a response to the drug, created new hypotheses to test in upcoming Phase 3 trials, and may have increased the target population who could benefit from this therapeutic approach.

Over time, we will 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 Interactive Cancer Explorer, which is currently accessible through an online web portal and will also soon be accessible through mobile applications, we are building a data platform that efficiently captures and allows for the analysis of data that will create a network effect leading to more users and ultimately more useful 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.

#### **Our Strategy**

Our objective is to transform the care of patients with cancer by leading the development and commercialization of proprietary genomic information products that guide 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 and our future clinical products* We are building an experienced, oncology-focused sales force, collaborating with thought leaders to validate our platform and influence utilization of our products, promoting physician interaction, engaging with patient advocacy and other key oncology stakeholders, and pursuing payment and reimbursement for our products.

*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 expanding 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, 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, such as FoundationOne for hematologic malignancies, conducting research and development into potential products to monitor disease progression utilizing circulating tumor cells and cell-free plasma DNA, and introducing powerful tools, such as our Interactive Cancer Explorer portal, to access and disseminate our molecular information.

*Empower the broader cancer community with molecular information* We are investing in technology to allow oncologists to collaborate and share response rates and other clinical information. We have launched Interactive Cancer Explorer, and intend to make this information accessible through additional applications in 2014. Over time, we will expand our capacity to capture, aggregate, analyze and facilitate the broader exchange of genomic data across the global oncology community a strategy that we believe eventually will create a network effect stimulating physician participation and the development of substantial amounts of data that, in turn, will positively impact the treatment of cancer.

#### **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 2012 American Cancer Society report, Cancer Treatment and Survivorship Facts & Figures 2012-2013, in 2012 in the United States, more than 13 million people were suffering from cancer and 1.6 million people were newly diagnosed with the disease. 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. According to a Genomeweb web posting, Clinical MDx Testing Growing Twice as Fast as Routine Dx; \$58B by 2026?, the global market for molecular diagnostic tests characterizing cancer was estimated to be \$7.0 billion in 2011 and is projected to grow by more than 15% annually.

#### 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 tumors, rather treating a patient s tumors based on their initial anatomical location in the body, such as the breast, 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 2011, global spending on the targeted oncology therapies totaled \$21.7 billion as compared to just \$2.0 billion in 2002.

The rapid increase in molecular information about cancer and 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 a single product that can assess the known and biologically relevant genomic alterations, and distill complex molecular information into a concise and actionable format.

### Current Challenges of Diagnosing 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;

insufficient and/or poor quality tumor biopsy tissue relative to the amount and quality needed to perform all desired or required tests; and

the 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 Actionable 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, cannot detect copy number alterations, and sometimes lack the sensitivity to identify short insertions and deletions.

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 that are 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 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.

Name Polymerase chain reaction, or PCR-based tests, a technology used for amplifying DNA sequences Uses Enable the detection of short fragment DNA or RNA sequences. Limitations Single-gene tests for specific and limited number of mutations.

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

*Immunohistochemical*, 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.

to a particular genomic alteration.

*FISH-based DNA* 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.

Difficult to test for multiple markers.

Since current hotspot panel tests typically cannot detect many genomic alterations present in cancer, physicians who use these tests may fail to identify actionable 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.

#### Molecular Diagnostics are 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, 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.

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 tumor sample 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 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 actionable assistance to physicians in matching the genomic alterations identified in their patients cancers with relevant available therapeutic alternatives and clinical trials.

### Our Solution A Single Molecular Information Platform to Improve Patient Care

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 insights into cancer to support physicians in the improvement of clinical patient care, to support biopharmaceutical companies in the development of novel cancer therapeutics, and to drive further research and development to advance our understanding of oncology. The first molecular information product enabled by our platform is branded as FoundationOne for our clinical customers.

#### FoundationOne Integrates Complex Molecular Information into Routine Clinical Care

FoundationOne is, to our knowledge, the first commercially available comprehensive molecular information product for analysis of routine cancer specimens in a clinical setting. We believe FoundationOne is the only molecular information product 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 delivers this complex molecular information in a concise report that matches detected molecular alterations with potentially relevant treatment options and clinical trials. We perform FoundationOne 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 Massachusetts and other states.

Optimization and Automation Enables FoundationOne Workflow to Deliver Report in 14-17 days.

#### A Comprehensive Clinical Assessment of Actionable Alterations in Cancer Genes

FoundationOne reports on the genes known to be 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 236 genes (representing 3,734 exons, which are sequences of DNA molecules, or nucleotides, involved in DNA replication that encode for proteins) across all four classes of genomic alterations, as well as 47 introns, which are sequences of nucleotides involved in DNA replication that do not encode for proteins, of 19 genes commonly involved in rearrangements. The test includes 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 FoundationOne periodically to reflect new scientific and medical knowledge about cancer biology, including newly relevant cancer genes along with newly available targeted therapeutics and clinical trials.

We believe FoundationOne s ability to identify actionable genomic alterations far exceeds that of other commercially available molecular diagnostic tests. We define an actionable alteration as an identified genomic alteration in an analyzed cancer cell associated with an FDA-approved targeted therapy in the tumor type, an FDA-approved targeted therapy 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 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 2013 and have included it in a manuscript that has been accepted for publication in a high-profile scientific journal.

FoundationOne s ability to identify actionable alterations is greater than other commercially available molecular tests, in part, because we believe FoundationOne:

interrogates many more cancer-related genes than other molecular diagnostic tests;

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

is the only molecular diagnostic product that can comprehensively assess cancer tissue simultaneously for all classes of genomic alterations; and

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

FoundationOne has identified at least one actionable genomic alteration in 82% of the 3,936 clinical specimens we received and analyzed with FoundationOne following its formal commercial launch in June 2012 through May 17, 2013 because of its high sensitivity and specificity of interrogation of cancer-related genes for all classes of genomic alterations. We had previously applied this same methodology in an analysis of our first 2,221 clinical cases and determined that FoundationOne identified at least one actionable genomic alteration in 76% of reported clinical cases. We presented the results of this earlier analysis at ASCO s annual meeting in June 2013. While we do not regularly analyze the percentage of our performed tests that identify actionable genomic alterations, we have not observed any patterns that we believe would substantially alter the typical frequency with which FoundationOne identifies actionable genomic alterations.

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

Our proprietary methods and workflow make FoundationOne 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 developed proprietary techniques for optimizing pre-sequencing sample preparation and have built post-sequencing computational algorithms that enable FoundationOne to be sufficiently sensitive to perform comprehensive genomic analysis on routine clinical tumor samples. We have optimized our NGS processes to maximize throughput, efficiency and quality. These laboratory processes designed to support FoundationOne have allowed us to successfully deliver results in 97% of all clinical tumor samples we have analyzed to date, against a sample failure rate of 3%.

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 predefined 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 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 NGS-based clinical diagnostics. The analytic validation results of our studies on FoundationOne have been accepted for publication in a peer-reviewed scientific journal.

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

We designed the FoundationOne report, in collaboration with leading oncologists, to deliver actionable information in a manner that seamlessly integrates into their practices. We present the results from FoundationOne 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. FoundationOne delivers actionable information to a physician for use typically within 14 to 17 days from the time the sample is received.

The first page of the FoundationOne report clearly illustrates the test s key findings. Specifically, it lists the analyzed tumor s actionable 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.

An Example of Page One of a FoundationOne Report.

Diagnosis

Patient Name Report Date **Breast carcinoma** (NOS) Date of Birth Not Given **Specimen Received** Not Given Client Cancer Center Gender Female **Ordering Physician** Doctor, Paul **Specimen Site** Lung FMI Case # SRF000009 **Additional Recipient** Not Given **Date of Collection** Not Given Medical Record # FMI Client # -1 Specimen Type Slide Specimen ID Pathologist Not Given Not Given ABOUT THE TEST:

FoundationOne is a next-generation sequencing (NGS) based assay which identifies genomic alterations within hundreds of cancer-related genes.

PATIENT RESULTS	TUMOR TYPE: BREAST CARCINOMA (NOS)
6 genomic alterations	Genomic Alterations Identified
6 therapies associated with potential clinical benefit	
0 therapies associated with lack of response	
	ERBB2 amplification
	PIK3CA H1047L
6 clinical trials	AURKA amplification
o chincar thais	TP53 R342P
	CREBBP P858S
	ZNF217 amplification
	For a complete list of the genes assayed, please refer to the Appendix

THERAPEUTIC IMPLICATIONS

Genomic Alterations Detected	FDA Approved Therapies (in patient s tumor type)	FDA Approved Therapies (in another tumor type)	Potential Clinical Trials
ERBB2	Ado-trastuzumab	None	Yes, see clinical trials section
amplification	emtansine		
	Lapatinib		
	Pertuzumab		
РІКЗСА	Trastuzumab None	Temsirolimus	Yes, see clinical trials section
H1047L AURKA	None	Everolimus None	Yes, see clinical trials section
amplification <b>TP53</b>	None	None	None
R342P CREBBP	None	None	None
P858S ZNF217	None	None	None
amplification			

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.

Ordering physicians can also access their FoundationOne report through our Interactive Cancer Explorer, which we developed in consultation with Google Ventures, one of our investors. We deliver the FoundationOne report along with easy access to current information about the reported genomic alterations, associated therapies, and clinical trials. We are also developing additional applications for Interactive Cancer Explorer that we expect to launch in 2014, through which physicians will be able to access their FoundationOne reports on tablet computers and other mobile devices.

#### Expanding FoundationOne to Hematologic Malignancies

We expect to commence our commercial launch of FoundationOne for hematologic malignancies, our second commercial product, by early 2014. 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. Although some physicians today use molecular diagnostic testing to identify certain known genomic alterations to help diagnose hematologic malignancies, we believe there is a large unmet need for a comprehensive hematologic molecular information solution.

Similar to FoundationOne for solid tumors, we are designing FoundationOne for hematologic malignancies to be a single molecular information product to fit the realities of routine medical practice, including volume and quality limits of cancer specimens, demands on turnaround time and the need for a synthesized report that matches detected molecular alterations with potentially relevant targeted therapies and clinical trials. This new product will use RNA sequencing in addition to DNA sequencing to better enable identification of the unique genes and classes of genomic alterations that are characteristic of hematologic malignancies. We believe FoundationOne for hematologic malignancies will be the first commercially available comprehensive molecular information product for analysis of hematologic malignancies specimens in a clinical setting.

We are developing FoundationOne for hematologic malignancies in collaboration with Memorial Sloan-Kettering Cancer Center, or MSKCC, a leading academic cancer center. Leveraging the clinical and genomic expertise in hematologic malignancies of MSKCC s clinicians, we believe FoundationOne for hematologic malignancies will be a best-in-class molecular information product that furthers our collective goal of making it possible for all patients to be treated with the therapies that are matched with their particular cancers.

#### Strong Evidence of Actionability in Clinical Experience for FoundationOne

We designed FoundationOne to address challenges associated with the everyday clinical management of patients diagnosed with cancer. We have experienced rapid adoption of FoundationOne. More than 1,500 physicians from large academic centers and community-based practices across more than 25 countries have ordered FoundationOne since its formal commercial launch in June 2012.

We have already served a growing number of patients for whom we identified actionable alterations that we believe would not have otherwise been detected and who have responded to therapies that we believe would not have otherwise been utilized. FoundationOne has identified at least one actionable alteration in 82% of the 3,936 clinical specimens we received and analyzed with FoundationOne following its formal commercial launch in June 2012 through May 17, 2013.

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



Case Study 1: FoundationOne Identifies Actionable Alteration Missed by Hotspot Tests Patient Receives Matched Targeted Therapy.

Page One of FoundationOne Report for Case Study 1.

				Diagnosis
		Patient Name	Report Date	
				Lung Adenocarcinoma
	Date of Birth	Client	Specimen Received	
	Gender	Physician	Specimen Site	
	FMI Case #	Additional		
		Recipient	Specimen Date	
	Medical Record #	FMI Client #	Specimen Type	
	Block ID	Pathologist		
About th	e Test:			

FoundationOne is a next-generation sequencing (NGS) based assay which identifies genomic alterations within hundreds of cancer-related genes.

PATIENT RESULTS	TUMOR TYPE: LUNG ADENOCARCINOMA
1 genomic alteration	Genomic Alterations Identified
0 therapies associated with potential clinical benefit	ALK rearrangement, intron 19
0 therapies associated with lack of response	1
0 clinical trials	Select Genes with No Actionable Alterations Detected EGFR KRAS BRAF
THERAPEUTIC IMPLICATIONS	
Genomic Alterations Detected (in patient s tumor type)	FDA Approved Therapies Potential Clinical Trials (in another tumor type)

None

None

ALK

Rearrangement,

Crizotinib

intron 19

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 received and analyzed a tumor specimen from a 43 year-old man diagnosed with metastatic adenocarcinoma of the lung involving his bones and pleura. Previous traditional diagnostic tests on the specimen, including a customary FISH-based test, revealed no actionable alterations. The patient received chemotherapy, which was of transient benefit and which he tolerated poorly. FoundationOne detected an actionable alteration, an ALK fusion, which was not identified in the initial testing. The patient was then treated with XALKORI<sup>®</sup> (crizotinib), a targeted therapy that inhibits the activity of the ALK fusion protein. This treatment shrank the tumor and led to improvements in the patient s symptoms. The patient experienced near complete resolution of disease for 16 months. The patient recently experienced one site of disease progression and, as of May 2013, is continuing on XALKORI (crizotinib). Without FoundationOne, this patient likely would have proceeded through various chemotherapies and likely would not have received XALKORI (crizotinib) because the ALK fusion alteration. These results were published in the *Journal of Thoracic Oncology* in September 2012.

Case Study 2: FoundationOne Identifies Actionable Mutation that is Not Otherwise Tested for In Breast Cancer Patient Receives Matched Targeted Therapy.

Page One of FoundationOne Report for Case Study 2.

Diagnosis Patient Name Report Date **Breast Carcinoma** Date of Birth Specimen Client Received Gender Physician Specimen Site FMI Case # Additional Recipient **Specimen Date** FMI Client # Medical Record # Specimen Type Pathologist Block ID

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ABOUT THE TEST:
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FoundationOne is a next-generation sequencing (NGS) based assay which identifies genomic alterations within hundreds of cancer-related genes.

PATIENT RESULTS	TUMOR TYPE: BREAST CARCINOMA
4 genomic alterations	Genomic Alterations Identified
6 therapies associated with potential clinical benefit 0 therapies associated with lack of response	ERBB2 amplification
o therapies associated with fack of response	PIK3CA F1047R
50+ clinical trials	EGFR L858R
	TP53 K132N

THERAPEUTIC IMPLICATIONS			
Genomic Alterations Detected	FDA Approved Therapies (in patient s tumor type)	FDA Approved Therapies (in another tumor type)	Potential Clinical Trials
ERBB2	Lapatinib	None	Yes
amplification <b>PIK3CA</b>	Trastuzumab None	Temsirolimus	Yes
F1047R EFGR	None	Everolimus Erlotinib	Yes
L858R		Gefitinib	

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TP53	None	None	Yes

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 received and analyzed a tumor specimen from a middle-aged woman diagnosed with metastatic inflammatory breast cancer (IBC). She had initially received combination chemotherapy and targeted therapy including Herceptin<sup>®</sup> (trastuzumab), a commonly prescribed targeted therapy for breast cancer, but her disease progressed within 12 months. Few treatment options remained. FoundationOne identified several genomic alterations, among them an EGFR point mutation. This type of alteration is associated with unprecedented sensitivity to tyrosine kinase inhibitors targeting EGFR such as Iressa<sup>®</sup> (gefitinib) and Tarceva<sup>®</sup> (erlotinib) and are present in 20% of lung adenocarcinomas. However, this alteration is not reported with reproducible frequency in other tumor types, and, it would have been unlikely to have been included in a testing panel for breast cancer. On the basis of this finding, the patient commenced Tarceva (erlotinib) therapy as part of a combination regimen. Because therapies have traditionally been indicated based on the tumor s anatomical location in the body, in this case, the breast, and because Tarceva (erlotinib) therapy is associated with a mutation commonly associated with lung (but not breast) cancer, it is likely that, without FoundationOne, this EGFR point mutation would not have been identified and Tarceva (erlotinib) therapy would not have been

commenced. While on Tarceva (erlotinib) therapy, the patient experienced durable symptomatic and radiographic benefit that lasted eight months. The results of this case study, which have not yet been published, are expected to be submitted to a peer-reviewed journal in the near future.

#### Our Platform for Biopharmaceutical Research and Development

For many of the same reasons FoundationOne provides information that is well suited for the clinical setting, our molecular information platform enhances the ability of our biopharmaceutical partner to develop targeted oncology therapies. We deploy our molecular information platform to analyze tissue samples provided by biopharmaceutical partners from their clinical trials. 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 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;

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 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.

As of June 2013, we have ongoing relationships with 18 biopharmaceutical partners, many of which are the leaders in developing targeted cancer therapies. Our relationships with our biopharmaceutical partners 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 expect these relationships will continue to expand and may provide us with opportunities to sell our molecular information products for companion diagnostics development, research and development projects, and new target discovery and validation.

In addition to generating revenue, our relationships with our biopharmaceutical partners enable us to identify new genes under investigation that can be incorporated early into our molecular information platform and our products, and more broadly allow us to actively participate in the newest oncology therapeutics and practice. Also, 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. We believe our biopharmaceutical customers provide us with near and longer term revenue and important strategic opportunities.

# Biopharmaceutical Services Agreement

In November 2011, we entered into a laboratory master services agreement with Novartis pursuant to which we agreed to perform our molecular diagnostic tests on samples provided by Novartis. Pursuant to the agreement, we were paid based on the number of tests we performed. The 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, 2014 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 may bill Novartis for any extra services performed if during the first and second contract years together or the third contract year alone 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

We believe that the ability of FoundationOne to comprehensively address all solid tumors, and soon hematologic malignancies, and to deliver a clear, concise report detailing actionable genomic alterations and corresponding treatment options will continue to drive its adoption by physicians. During the pre-launch phase of FoundationOne, we worked with our network of oncology thought leaders to identify the initial subsets of patients with cancer for whom FoundationOne was most likely to positively inform treatment decisions. Our initial marketing and selling efforts have focused on driving awareness of the potential utility of FoundationOne 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 non-small cell lung cancer patients 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. While these groups are not mutually exclusive, we estimate that there are approximately one million patients annually in the United States who suffer from the above-described or similar cancers. We believe the current U.S. market opportunity for comprehensive molecular diagnostic products for patients suffering from these cancers is approximately \$4.0 billion, based upon modest assumptions for expected prices and rates of reimbursement.

We believe that as physicians increasingly order FoundationOne and experience the positive impact that our analysis can have on their treatment decisions, they will increasingly broaden its usage to other patients who may benefit from the molecular information delivered by FoundationOne. 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. Our marketing and sales activities will then expand to driving awareness of the potential utility of FoundationOne in this broader set of patients. As a result, we believe the potential market for FoundationOne could increase to nearly two million patients annually in the United States. We believe the U.S. market opportunity over the next several years for comprehensive molecular diagnostic products for this broader patient population is approximately \$7.5 billion, based upon modest assumptions for expected prices and rates of reimbursement.

## **Commercialization Strategy for FoundationOne**

We aim 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 and international distribution channels that are supported by dedicated company personnel;

collaborate with oncology thought leaders and leading institutions on FoundationOne clinical cases, clinical research, publications, and product development;

foster adoption and promote physician engagement through our medical affairs and client services efforts, and by developing and deploying practice-friendly technology resources to physicians;

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

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

Through these efforts, we seek to drive awareness of FoundationOne s unique capabilities 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 by being part of improving patient outcomes, we will drive sales 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 targets oncologists and pathologists at hospitals and cancer centers. We launched FoundationOne for solid tumors in June 2012 with a sales force of only two people that has already grown to 15 sales professionals with backgrounds in oncology, pathology, therapeutics, and/or laboratory services. Our sales professionals have an average of 11 years of experience in clinical oncology 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 to demonstrate the clinical usefulness of FoundationOne. We also are building relationships in community oncology practice settings through leading physician networks. For example, The US Oncology Network, whose members include approximately 10% of all U.S. oncologists, selected us as one of its preferred molecular information partners. Other oncology

networks, such as Cancer Treatment Centers of America, which has five centers nationally, have chosen to use FoundationOne across all of their centers. These networks expect to use FoundationOne to streamline ordering and data collection, to provide access to and guidance about use of the most advanced cancer testing and treatments, and to support their clinical trials.

As part of our early launch strategy to drive adoption, our sales force initially targeted key opinion leaders and leading cancer researchers. As we grow our sales force, we will increasingly have the capacity to target community hospitals and community-based cancer centers that need a reliable and collaborative partner for comprehensive molecular information testing.

#### International

Our international sales strategy is currently focused on partnering with leading distributors and selling directly to academic and medical centers. We have targeted various markets outside of the United States, principally based upon the demand from those markets and our own market assessments. As a result of these factors, we have and are responding to opportunities in Central and South America, Western Europe, portions of the Middle East, and Asia, and anticipate exploring opportunities in other geographic areas as well. We are expanding our internal capacity to serve high demand markets by adding dedicated regional managers located outside the United States to oversee our relationships at the local level.

#### 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 diagnostic approach, including oncologists at premier cancer institutions such as Memorial Sloan-Kettering Cancer Center, Vanderbilt-Ingram Cancer Center, and The US Oncology Network. 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 adoption of FoundationOne for solid tumors. 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 believe our effective engagement with KOLs largely explains why the majority of physician customers for FoundationOne placed their original orders even before being visited by our nascent sales team. We will continue to nurture these relationships with thought leaders as we drive adoption of FoundationOne for solid tumors and as we develop FoundationOne for hematologic malignancies in collaboration with MSKCC.

## 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 Interactive Cancer Explorer, our online portal, which we developed in consultation with Google Ventures, one of our investors, in the context of their busy clinical practices, to shape each patient s treatment plan. Through Interactive Cancer Explorer, we deliver the key genomic information identified by FoundationOne in an organized fashion along with access to current information about the reported genomic alterations, associated therapies and clinical trials. Launched in December 2012, already more than 40% of our FoundationOne customers use Interactive Cancer Explorer.

Interactive Cancer Explorer presents complex genomic information in a we believe 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. In the future, we intend for Interactive Cancer Explorer to link to additional public and private data sources like The Cancer Genome Atlas, the Cancer Genome Project, and others, 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 make it easier for them to bring new, relevant information to each patient s treatment plan. We are also developing additional applications for Interactive Cancer Explorer that we expect to launch in 2014.

The better we can integrate our solutions into a physician s routine clinical practice, the more likely a physician is to order FoundationOne. Therefore, we have engineered our client support capabilities, such as online ordering and assistance with tissue sample procurement, to make it easier for physicians to use FoundationOne in their clinical practices.

Additionally, we are investing in our technology architecture to allow physicians to collaborate and share response rates and other clinical information with each other, regardless of location, in compliance with applicable privacy regulations. Over time, we will expand our capacity to capture, aggregate, analyze and facilitate the broader exchange of genomic data across the global oncology community. We are developing a data platform that efficiently captures and allows for the analysis of data that we believe will eventually create a network effect as more data is gathered, which we expect will lead to more users, more comprehensive datasets, and ultimately more business opportunities.

#### 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 FoundationOne s 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 obtain favorable reimbursement decisions.

From the beginning of 2012 through June 2013, we had:

12 peer-reviewed articles published or accepted for publication, including by *Nature Medicine*, *Cancer Discovery*, *Journal of Clinical Oncology*, *Journal of Thoracic Oncology*, *Blood*, and *Genome Medicine*;

10 additional manuscripts under consideration for publication by major journals, including *Nature*, *Nature Medicine*, *Nature Genetics*, *Nature Biotechnology*, *Journal of Clinical Oncology*, and *Cancer Discovery*;

over 35 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

delivered more than 20 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), and Advances in Genome Biology and Technology (AGBT), among others.

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

*The US Oncology Decision Impact Study.* This study is 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.

*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 is designed to recruit 3,000 patients over 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 will 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.

*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 is designed to enroll a group of 300 patients with advanced solid tumors who are screened at enrollment with FoundationOne. These patients will then be treated with a targeted therapy selected on the basis of the FoundationOne test. 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.

#### 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, key opinion leaders, and policy makers. We established our advocacy relations program early in 2011 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 Cancer Foundation of America, Bonnie J. Addario Lung Cancer Foundation, Uniting Against Lung Cancer, Pancreatic Cancer Action Network, and Education Network to Advance Cancer Clinical Trials. In late 2012, we hosted our first advocate roundtable with representatives from 10 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.

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 aim to work with many organizations, including the National Comprehensive Cancer Network, ASCO, 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.

#### 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;

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

government payors, including Medicare, with whom we have agreed to defer billing, and state Medicaid plans, to which we are currently applying; and

patients who make co-payments and pay deductibles and other amounts that we have been unable to collect from their third-party payors.

We believe that FoundationOne presents a unique solution 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 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. At the same time, we believe broad clinical adoption will help drive favorable reimbursement decisions. To achieve broad reimbursement coverage with commercial third-party

payors and government payors, including Medicare and Medicaid, we are focused on demonstrating the economic and clinical value of FoundationOne to payors by:

*Setting a High Bar for Validation and Performance.* FoundationOne provides actionable results that are highly reproducible and sensitive, and we believe that a majority of our actionable results would not be detected by any 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 at numerous conferences and in peer-reviewed journals. Moreover, our approach to the analytic validation of our test has recently been submitted to a peer-reviewed journal.

*Increasing Physician Demand.* More than 1,500 physicians from both large academic centers and community-based practices across more than 25 countries have ordered FoundationOne since its formal commercial launch in June 2012. Many of the initial orders for FoundationOne occurred as we were only starting to build our sales force. We believe that this adoption, including significant repeat usage, demonstrates physician demand for a single, comprehensive solution to help in the treatment of their patients. In addition, we believe that increasing 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, 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 cancer. In addition, we believe adoption of our products by key members of the oncology community will help to influence FoundationOne s listing 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, Journal of Thoracic Oncology, Cancer Discovery, Clinical Cancer Research, Blood*, and others. Our publications have covered novel scientific findings, clinical actionability 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 evidence of our analytical validity and clinical utility with payors.

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

*Improving Economics*. We have built economic models to measure the financial benefits of using FoundationOne 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. We plan to use the data we gather through the use of these models as we meet with commercial third-party payors and government payors.

Since, to our knowledge, FoundationOne is the only commercially available comprehensive molecular information product designed to assess all types of solid tumors and soon hematologic malignancies, we believe there is no direct precedent for reimbursement of our test by commercial third-party payors and government payors. In addition, the reimbursement environment is evolving as regulators and payors try to establish new rules and frameworks for paying for molecular diagnostic tests.

The current list price for the FoundationOne test is \$5,800. Payment for the test is not certain and may come from various sources. Actual payment will often be less than the list price. 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, cancer centers and other institutions; (4) international distributors; and (5) individual patients. Currently we are not a participating provider with any commercial third-party payors and therefore do not have specific coverage decisions for the FoundationOne test with established payment rates. Currently, 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 payors outsource our claims to preferred provider organizations or 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 test is coverage decision and have not yet submitted claims for our test to Medicare. We do have in place agreements with various healthcare providers and with international distributors pursuant to which we process 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 price. We may also negotiate rates with individual patients, if the patient is responsible for payment.

In 2012, we submitted claims to commercial third-party payors using CPT codes that were procedural-based, and we have been reimbursed for a significant majority of these claims following the completion of the claims process. On January 1, 2013, new Centers for Medicare & Medicaid Services, or CMS, reimbursement codes for molecular testing services took effect. We elected to submit claims to commercial third-party payors using these new CPT codes and have received payments based on these claims. We do not expect CPT codes specific to next generation sequencing to be available until 2015 at the earliest, and we expect to continue our current approach until those new codes exist or until we have coverage decisions from payors.

Since we are not currently a participating provider with commercial third-party payors, and we have not received a coverage decision from any commercial third-party payor, payment for our test is uncertain. We request that physicians discuss the patient s responsibility should their policy not cover FoundationOne. 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 the FoundationOne test 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 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 enrolled in the Medicare program in order to bill Medicare for FoundationOne. 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 decision, 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, requested that we not submit claims for services provided to Medicare patients while the contractor assessed the appropriate coverage and payment for FoundationOne as a whole. Pending the response, no claims have been billed to either Medicare or Medicare patients.

Currently, we have not yet received definitive direction from our Medicare contractor. If we do not receive definitive direction, we intend, before the end of 2013, to commence submitting claims to

Medicare for FoundationOne tests provided to Medicare patients. The response of the Medicare contractor to the submission of such a claim is uncertain and the claim 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. Our Medicare contractor may also issue a negative coverage determination for FoundationOne that would apply to future claims or may defer processing a claim pending a coverage or payment determination. Given the uncertain response, we may determine to provide appropriate 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 our Medicare contractor. We will also assess our ability to submit claims to Medicare, or bill Medicare patients, for the tests for which claims are currently being held. In the event of a Medicare denial for tests currently held, our ability to bill Medicare patients for such tests will be limited.

We are also in the process of registering to participate in state Medicaid plans. The number of patients covered by Medicaid plans is expected to increase significantly over the next several years in connection with the Affordable Care Act that was signed into law on March 23, 2010.

Amidst a rapidly evolving reimbursement environment, we have implemented a comprehensive strategy to receive payment for the sale of our products. Ultimately, we believe that our focus on the rapid adoption of our products will both enable better-informed treatment options to the greatest number of patients with cancer and drive favorable reimbursement decisions.

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

We were founded as a scientifically and medically driven company and are dedicated to ongoing innovation both in our molecular information platform and our commercial product pipeline. We have invested, and continue to invest, significant time and resources toward the improvement of our platform and products and toward the introduction of new products.

We believe we have a first mover advantage in offering comprehensive molecular information products that interrogate with precision the genes known to be altered in human cancer. Since commencing our formal commercial launch of FoundationOne in June 2012, we have continued to invest in its improvement, including by updating the product in December 2012 from 180 genes to include the entire coding sequence of 236 genes, enhancing methods to utilize less tissue, lower tumor purity requirements and achieve higher sensitivity, and creating processing improvements to drive down turn-around time.

We have also incorporated RNA-based sequencing technology to analyze the additional gene fusions commonly found in hematologic malignancies and in the future we may incorporate RNA-based sequencing into FoundationOne. We expect to commence our commercial launch of FoundationOne for hematologic malignancies by early 2014. Key milestones that we need to complete prior to this launch include continuing validation activities, increasing laboratory production capacity to meet commercial demand and preparing the marketing strategy for the product.

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

further refinement to the hybrid capture strategy by which we isolate cancer genes of interest from tumor samples so that we can more rapidly incorporate novel cancer genes as they are discovered into FoundationOne;

potential development and introduction of new products for monitoring patients tumor burden over time, utilizing new technologies that enable processing of circulating tumor cells and cell-free plasma DNA; and

enhancing molecular profiling ability through RNA sequencing and developing plans to expand into epigenetics, methylation, immune response, and other areas.

In addition, Interactive Cancer Explorer, our online portal, allows physicians to access the key genomic information identified by FoundationOne along with current information about the reported genomic alterations, associated therapies and clinical trials. Google Ventures, one of our equity investors, provided us with advice and consultation on the design of the Interactive Cancer Explorer portal without charge. Google Ventures provides this type of free support to its portfolio companies from time to time. Interactive Cancer Explorer presents complex genomic information in a we believe 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. In the future, we intend for Interactive Cancer Explorer to link to additional public and private data sources like The Cancer Genome Atlas, The Cancer Genome Project, and others, 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 make it easier for them to bring new, relevant information to each patient s treatment plan. We are also developing additional applications for Interactive Cancer Explorer that we expect to launch in 2014.

#### Building a Cancer Knowledgebase to Improve Patient Care

The increasing availability and understanding of molecular information about cancer is driving a revolution in treating the entire class of diseases. We will 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. For example, at the annual meeting of ASCO in 2013, one of our biopharmaceutical partners presented both clinical and genomic data regarding a Phase 2 trial of their therapy in patients with advanced ovarian cancer that failed to meet its endpoint. Before our involvement, a minority of patients had been tested for a limited set of genomic alterations using traditional hotspot panel tests. We were subsequently engaged by the biopharmaceutical company to conduct comprehensive genomic profiling on the clinical trial patient samples. Our analysis identified a significant number of additional genomic variants that predicted response to the drug, created new hypotheses to test in upcoming Phase 3 trials, and may have increased the target population who could benefit from this therapeutic approach.

We are investing in our technology infrastructure to allow oncologists to collaborate and share response rates and other clinical information in a manner compliant with privacy laws. We have launched our Interactive Cancer Explorer portal, which we developed in consultation with Google Ventures, one of our investors, and through which we report test results and link to relevant scientific and medical literature and clinical trial information. We also intend to make Interactive Cancer Explorer accessible through mobile applications in 2014. Over time, we will expand our capacity to capture, aggregate, analyze and facilitate the broader exchange of genomic data across the global oncology community. We are developing a data platform that efficiently captures and allows for the analysis of data that we believe will eventually create a network effect as more data is gathered which will lead to more users and ultimately more comprehensive datasets.



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 our Interactive Cancer Explorer portal;

informing 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.

Though we are in the early stages of data aggregation, we expect the importance of our molecular information strategy will increase with the number of our patient cases and as we augment the database with clinical data. If we, in conjunction with oncologists, pathologists, biopharmaceutical companies and academic researchers, can successfully capture and utilize this data, we believe we can continue to play an even more integral part in transforming care for the millions of patients suffering from cancer.

#### Operations

#### Composition of a FoundationOne Analysis

We perform all FoundationOne tests in our diagnostic laboratory located in Cambridge, Massachusetts. When a physician orders FoundationOne, he or she does not need to alter the standard surgical technique or tissue handling processes. The physician s staff typically completes a FoundationOne 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 analysis consists of three parts: specimen preparation, sequencing, and data analysis.

#### Specimen Preparation

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. Approximately 95% of all specimens we receive meet these requirements. Almost all samples meeting our tissue requirements will allow extraction of enough high-quality DNA (50 nanograms) for FoundationOne analysis.

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Following 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.

## Sequencing

The content of each DNA 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 is 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.

#### 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, and we are continually improving our ability to perform this analysis. Once all DNA sequences are aligned against the reference, specific algorithms look 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 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 information regarding the identified alterations into actionable 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. It is this result report that 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 FoundationOne report is typically delivered to the physician within 14 to 17 days from our receipt of the sample.

## 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 is reviewed monthly by management. Our quarterly internal quality assurance audits cover pre-analytic, analytic and post-analytic functions, assess improvement indicators, and sets 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.

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 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. 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 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 is greater than 99% across all classes of alterations.

## Supply Agreement

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 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.

#### Patents

Our patent portfolio includes pending U.S. provisional and utility applications, and strategically focused corresponding international applications filed via the Patent Cooperation Treaty, or PCT. We will be filing foreign national or regional counterpart applications, as we deem appropriate and of commercial value, with the first such filing beginning in late June 2013. We believe our portfolio of patent applications includes applications that will 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 testing procedures, including claims directed to process advances in solution hybridization, bait selection and capture, mutation calling algorithms, somatic versus germline alteration differentiation and reduction of off-target hybridization;

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 delivery, including claims directed to web-mediated systems for capturing, managing, tracking and reporting genomic information and associated clinical outcome data.

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 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, 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 is a registered mark in the United States and other countries, and FoundationOne is a registered mark in several countries with registration pending in the United States.

#### Competition

We believe there is no other commercially available comprehensive molecular information product that provides a fully informative genomic profile with characteristics similar to FoundationOne for use in the clinical setting. Our principal competition comes from existing mainstream diagnostic companies 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 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 FoundationOne 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 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, as well as companies that manufacture or may manufacture diagnostic testing kits such as Abbott Laboratories, Qiagen N.V., Roche Molecular Systems, Inc. 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 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 University of Michigan, Baylor Medical Genetics Laboratories, Washington University in St. Louis 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, Life Technologies Corporation, 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 LDT sequencing-based services. In addition, we believe these companies may also develop their own FDA-approved diagnostic kits, which could be sold to clients who have purchased their platforms. Many private companies are developing information technology-based tools to support the integration of NGS 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.

#### **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. FoundationOne is uniquely differentiated from other oncology diagnostic products because, to our knowledge, it is the first and only product to comprehensively address all solid tumors, and soon hematologic malignancies, and to deliver a clear, concise report detailing actionable treatment alternatives. We believe FoundationOne has a sustainable competitive advantage on the basis of:

our ability to assess 236 biologically relevant cancer genes and all classes of genomic alterations with high sensitivity and specificity, 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 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 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 together with clinical data to position ourselves at the nucleus of this new treatment paradigm; and

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

## **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 the section entitled Government Regulations *States 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 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.

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. Therefore, 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, and equipment and quality control standards. Our laboratory holds the required licenses for these states which include Massachusetts, Maryland, Rhode Island, Pennsylvania, Florida and California. Our laboratory is currently in the process of seeking New York State licensing, and currently operates legally under the NY non-permitted laboratory test request program.

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 United States Food and Drug Administration, or 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 LDT currently requires pre-market clearance or approval. It is possible, perhaps 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. Since then FDA has stated its intention to address LDT regulation using a risk-based, phased-in approach stating as recently as June 2013 that it is working to make sure that the accuracy and clinical validity of high-risks tests are established before they come to market. FDA now is required to notify Congress at least 60 days prior to issuing a draft or final guidance regulating LDTs and provide the anticipated details of the action under section 1143 of the Food and Drug Administration Safety and Innovation Act of 2012. In the meantime, we maintain our CLIA accreditation, 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 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 Quality System Regulation, or 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 devices safety and effectiveness. Premarket review and clearance by FDA for Class II devices are accomplished through the 510(k) premarket notification

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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 as the predicate device, and the same technological characteristics as the predicate device or 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 is 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 makes a not substantially equivalent determination, 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 could significantly affect the device is safety or effectiveness, a new premarket notification must be submitted to FDA.

Class III devices are 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 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 are 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 and review by FDA, 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, or IRBs, 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 LDT 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 likely 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 cannot assure you that our product and 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 the Health Insurance Portability and Accountability Act, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, 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 regulations cover the use and disclosure of protected health information by health care providers. 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 health information security breach notification requirements. A covered entity must notify any individual whose protected health information is breached. The HIPAA privacy and security regulations establish a uniform federal floor 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 of personal information of Massachusetts residents.

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 HITECH, 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 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 new 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 of 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 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 and Geographical Information

We operate in one reportable business segment and derive revenue from multiple countries, with 100%, 89.1%, and 86.2% coming from the United States in fiscal years 2011 and 2012, and during the six months ended June 30, 2013, respectively.

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, 2011 and 2012 and the six months ended June 30, 2013.

#### Employees

As of July 31, 2013, we had 132 full-time employees, with 110 in technology, research and development, business development and laboratory and commercial operations, and 22 in general and administrative functions. We had 114 full-time employees in our Cambridge, Massachusetts facilities, and 18 of 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.

#### Facilities

In March 2010, we entered into a lease effective through October 2015 for approximately 22,500 square feet of space in Cambridge, Massachusetts. Our CLIA laboratory is currently located at this facility. In March 2013, we entered into a new lease effective through 2021 for approximately 61,591 square feet of space in a new facility in Cambridge, Massachusetts. We expect to transition our principal executive office, all of our employees, and CLIA laboratory to this new facility in September and October of 2013. We believe these facilities are sufficient to meet our current needs.

## **Research and Development Expenses**

Research and development expenses were \$14.8 million for the year ended December 31, 2012 and \$9.0 million for the year ended December 31, 2011. The 64% increase was primarily due to a \$2.1 million increase in employee and contractor-related expenses, including stock-based compensation, to support our molecular information platform and product development, a \$1.9 million increase in expenses related to clinical trials to evaluate the clinical utility of FoundationOne, a \$1.5 million increase in technology expenses related to data management, FoundationOne report design and functionality, and customer interface development, and a \$0.3 million increase in lab supplies to support product development.

#### Legal Proceedings

From time to time, we may be subject to legal proceedings and claims in the ordinary course of business. We have received, and may in the future continue to receive, letters from third parties inviting us to take licenses under, or alleging that we infringe, their patents. While to date no such notice has ever led to a lawsuit, or a license, future litigation may be necessary to defend ourselves, our partners and our customers by determining the scope, enforceability, and validity of third-party proprietary rights or to establish our proprietary rights. The results of any current or future litigation cannot be predicted with certainty, and regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources, and other factors.

### MANAGEMENT

### **Directors and Executive Officers**

Our executive officers and directors and their respective ages and positions as of July 29, 2013:

Name	Age	Position
Executive officers:		
Michael J. Pellini, M.D.	47	President, Chief Executive Officer and Director
Steven J. Kafka, Ph.D.	43	Chief Operating Officer
Kevin Krenitsky, M.D.	46	Chief Commercial Officer and Senior Vice President
Vincent A. Miller, M.D.	51	Chief Medical Officer
Robert W. Hesslein, J.D.	60	Senior Vice President and General Counsel
Jason Ryan	39	Vice President, Finance
Non-management directors:		
Alexis Borisy(1)(2)	41	Chairman of the Board of Directors
Brook Byers(1)(3)	67	Director
Evan Jones(2)	56	Director
Mark Levin(3)	63	Director
David Schenkein, M.D.(2)(3)	56	Director
Krishna Yeshwant, M.D.(1)(2)	35	Director

(1) Member of the Compensation Committee.

(2) Member of the Audit Committee.

(3) Member of the Nominating and Corporate Governance Committee.

Executive Officers

*Michael J. Pellini, M.D.*, has served as our President and Chief Executive Officer and as a member of our board of directors since May 2011. Dr. Pellini joined us from Clarient, Inc., or Clarient, a General Electric Healthcare Company, where he held the position of president and chief operating officer from April 2008 to April 2011 and served on its board of directors from May 2007 to April 2009. Dr. Pellini served as vice president, life sciences at Safeguard Scientifics, Inc. (NYSE: SFE), a private equity and venture capital firm specializing in expansion financings, growth capital, management buyouts, recapitalizations, industry consolidations, corporate spinouts, growth stage, and early stage financings, from March 2007 to April 2008 and, as part of this role, was detailed to Clarient beginning in July 2007. Dr. Pellini received a B.A. from Boston College, an M.B.A. from Drexel University and an M.D. from Jefferson Medical College of Thomas Jefferson University. Dr. Pellini s qualifications to sit on our board of directors include his extensive leadership, executive, managerial, business, and diagnostic company experience, along with his years of industry experience in the development and commercialization of pharmaceutical products.

*Steven J. Kafka, Ph.D.*, joined us in January 2013 and serves as our Chief Operating Officer. Dr. Kafka was previously chief operating officer and chief financial officer at Aileron Therapeutics Inc., or Aileron, a biopharmaceutical company based in Cambridge, Massachusetts from September 2009 to October 2012. Before Aileron, from September 2006 to September 2009, Dr. Kafka was vice president of finance at Infinity Pharmaceuticals, Inc. (NASDAQ: INFI), a drug discovery and development company. Dr. Kafka earned his B.A. with Distinction and Honors from Stanford University and his Ph.D. from Harvard University.

*Kevin Krenitsky, M.D.*, joined us in June 2011 and serves as our Chief Commercial Officer and Senior Vice President, International Strategy. Prior to joining Foundation, he served as president of

Enzo Clinical Labs, Inc., or Enzo, a full service clinical reference laboratory, from March 2009 to June 2011. Before his employment at Enzo, he was the chief executive officer of BioServe Biotechnologies, Ltd., a global biotechnology company specializing in processing genetic diagnostic tests from 2007 to February 2009. From 2006 to 2007, he was the interim chief executive officer of Parkway Clinical Laboratories Inc., a clinical diagnostic lab providing comprehensive routine and esoteric testing. Dr. Krenitsky received a B.S. in business management from the University of Scranton and an M.D. from Jefferson Medical College.

*Vincent A. Miller, M.D.*, was appointed to serve as our Chief Medical Officer on July 31, 2013. He joined us in October 2011 and served as our Senior Vice President, Clinical Development between then and July 2013. Dr. Miller served between July 1991 and October 2011 as an attending physician, and Dr. Miller has served since November 2011 to the present as a consulting physician, at Memorial Sloan-Kettering Cancer Center. Dr. Miller earned his B.A. from the University of Pennsylvania and his M.D. from the University of Medicine and Dentistry of New Jersey in Newark.

*Robert W. Hesslein, J.D.*, has served as our Senior Vice President and General Counsel since May 2012. Mr. Hesslein was previously senior vice president and deputy general counsel at Genzyme Corporation, or Genzyme, a biotechnology company based in Cambridge, Massachusetts, which is now a wholly-owned subsidiary of Sanofi (NYSE: SNY), from 1996 to 2012. Before Genzyme, from 1990 to 1996, Mr. Hesslein was a second vice president and counsel at The New England, a mutual life insurance corporation. From 1978 to 1990, Mr. Hesslein was an associate and subsequently a partner at Csaplar & Bok, a Boston law firm. Mr. Hesslein earned his B.A. with Honors from Yale University and his J.D. from The Cornell Law School.

*Jason Ryan* has served as our Vice President, Finance since March 2012. He previously served as our Senior Director, Finance from May 2011 to March 2012. Prior to joining us, Mr. Ryan led the finance and strategic planning functions of Taligen Therapeutics, Inc., which was acquired by Alexion Pharmaceuticals, Inc. (NASDAQ: ALXN), from May 2009 to April 2011, Codon Devices Inc. from May 2007 to May 2009, and Genomics Collaborative, Inc., which was acquired by SeraCare Life Sciences, Inc. (NASDAQ: SRLS), from September 1998 to September 2004. He began his career at Deloitte & Touche. Mr. Ryan holds a B.S. in economics from Bates College and an M.B.A. from Babson College, and earned a C.P.A. in Massachusetts.

### Non-Management Directors

*Alexis Borisy* has served as a member of our board of directors since 2009 and Chairman since 2011. He co-founded Foundation in 2009 and served as our interim Chief Executive Officer through May 2011. Since 2009, Mr. Borisy has been a partner at Third Rock Ventures, a life sciences venture capital firm focused on the formation, development and strategy of new companies. In addition, since earlier this year, Mr. Borisy has served as chairman of Warp Drive Bio, LLC, a life sciences company focusing on genomics where he served as chief executive officer from 2011 to 2013. From 2007 through 2012, Mr. Borisy served as chairman a FORMA Therapeutics, Inc., a life science company focused on targeting cancers for treatment. In 2000, Mr. Borisy founded CombinatoRx, Inc. (now Zalicus Inc. (NASDAQ: ZLCS)), a drug development company, and served as its chief executive officer and on its board of directors from 2000 to 2009. Mr. Borisy holds an A.B. in chemistry from the University of Chicago, and an A.M. from Harvard University. We believe Mr. Borisy s detailed knowledge of our company and long tenure with us, having served as one of our founders, along with his experience working with and serving on the boards of directors of life sciences companies and his experience working in the venture capital industry qualifies him to serve on our board of directors.

*Brook Byers* has served as a member of our board of directors since 2011. Mr. Byers has been a venture capital investor since 1972 and is a managing partner of Kleiner Perkins Caufield & Byers. He has been closely involved with more than 50 new technology-based ventures, many of which have

already become public companies. He formed the first life sciences practice group in the venture capital profession at Kleiner Perkins Caufield & Byers in 1984. Mr. Byers served on the board of directors of Genomic Health, Inc. (NASDAQ: GHDX) from 2001 to 2011 and serves on the board of directors of Pacific Biosciences of California, Inc. (NASDAQ: PACB). Mr. Byers holds a B.S. in electrical engineering from the Georgia Institute of Technology and an M.B.A. from Stanford University. We believe that Mr. Byers possesses specific attributes that qualify him to serve as a member of our Board of Directors, including his experience with growing multiple companies in the life sciences industry and his leadership in personalized medicine initiatives.

*Evan Jones* has served as a member of our board of directors since 2013. Since 2007, Mr. Jones has served as managing member of jVen Capital, LLC, a life sciences investment company. He also serves as executive chairman of OpGen, Inc., a privately held genetic analysis company. Previously, he co-founded Digene Corporation, or Digene, a publicly traded biotechnology company focused on women s health and molecular diagnostic testing that was sold to Qiagen N.V. (NASDAQ: QGEN) in 2007. He served as chairman of Digene s board of directors from 1995 to 2007, as Digene s chief executive officer from 1990 to 2006, and as Digene s president from 1990 to 1999. Mr. Jones has served as a member of the board of directors of CAS Medical Systems, Inc. (NASDAQ: CASM), a developer of patient vital signs monitoring products and technologies, since June 2008, and Fluidigm Corporation (NASDAQ: FLDM), a technology company that develops, manufactures and markets microfluidic systems in the life science and agricultural biotechnology industries, since March 2011. Mr. Jones received a B.A. from the University of Colorado and an M.B.A. from The Wharton School at the University of Pennsylvania. We believe that Mr. Jones qualifications to serve on our board of directors include his extensive experience in the molecular diagnostic testing industry, including as chief executive officer of a public company focused on molecular diagnostic testing, as well as his service as a board member with other public and private companies.

*Mark Levin* has served as a member of our board of directors since 2010. Mr. Levin currently serves as a partner at Third Rock Ventures, a life sciences venture capital firm focused on the formation, development and strategy of new companies, which he co-founded in 2007. Mr. Levin served as founding chief executive officer of Millennium Pharmaceuticals, Inc. from 1993 to 2005. Mr. Levin was co-founder of the life sciences effort of the Mayfield Fund, a global venture capital firm, where he was also the founding chief executive officer of Cell Genesys, Inc. from 1989 to 1991, Tularik Inc. from 1991 to 1992, Focal, Inc. from 1992 to 1993, and StemCells, Inc. (NASDAQ: STEM) from 1990 to 1992. Mr. Levin started his career as a process engineer and project leader at Eli Lilly and Company (NASDAQ: LLY) and Genentech, Inc. Mr. Levin holds both a B.S. and M.S. in chemical and biomedical engineering from Washington University. We believe Mr. Levin s experience working with and serving on the boards of directors of life sciences companies and his experience working in the venture capital industry qualifies him to serve on our board of directors.

*David Schenkein, M.D.*, has served as a member of our board of directors since 2010. Dr. Schenkein currently serves as the chief executive officer of Agios Pharmaceuticals, Inc., or Agios, a biopharmaceutical company, a position he has held since August 2009. Prior to joining Agios, Dr. Schenkein was the senior vice president, clinical hematology/oncology at Genentech, Inc., or Genentech, where he was responsible for leading the medical and scientific strategies for their bio-oncology portfolio. Prior to joining Genentech, Dr. Schenkein spent 17 years in academic and clinical medicine as an attending physician in hematology/oncology at the Tufts-New England Medical Center, where he was an associate professor and held the position of director of the cancer center. Dr. Schenkein holds a B.A. in chemistry from Wesleyan University and an M.D. from the State University of New York Upstate Medical School. We believe Dr. Schenkein s medical experience as an oncologist and extensive background in the biotechnology industry, including his roles at Agios and Genentech, provide a critical contribution to our board of directors.

*Krishna Yeshwant, M.D.*, has served as a member of our board of directors since 2011. Dr. Yeshwant currently serves as a partner at Google Ventures, a venture-capital fund. Dr. Yeshwant has been working with Google Ventures since June 2008. Before joining Google Ventures, in 1996 he founded Stanford Students Consulting, an electronic data interchange company that was acquired by Hewlett-Packard Company (NYSE: HPQ) in 2000. In 2000, he founded Recourse Technologies, Inc., a network security company that was acquired by Symantec Corporation (NASDAQ: SYMC) in 2002. Since 2009, Dr. Yeshwant has also been employed by Partners Healthcare, a not-for-profit health care system, as an Internal Medicine physician at Brigham and Women s Hospital. Dr. Yeshwant has a B.S. in Computer Science from Stanford University, an M.D. from Harvard Medical School and an M.B.A. from Harvard Business School. We believe Dr. Yeshwant s medical experience as a physician and experience working with and serving on the boards of directors of life sciences companies and his experience working in the venture capital industry qualifies him to serve on our board of directors.

### Founding Advisors

We leverage the expertise of our founding advisors to help us build and guide the deployment of our molecular information platform. Our founding advisors are world leaders in the fields of cancer genomics, cancer biology, clinical oncology, and information sciences, and consist of: Eric Lander, Ph.D., who serves as the Founding Director of the Broad Institute, Professor of Biology at Massachusetts Institute of Technology, and Professor of Systems Biology at Harvard Medical School and was a key leader of the Human Genome Project; Todd Golub, M.D., who is a founding member of the Broad Institute, serving as Director of its Cancer Program and Chief Scientific Officer, as well as the Charles A. Dana Investigator in Human Cancer Genetics at the Dana-Farber Cancer Institute, an investigator at Howard Hughes Medical Institute and Professor of Pediatrics at Harvard Medical School; Levi Garraway, M.D., Ph.D., who is an Associate Professor of Dana-Farber s Center for Cancer Genome Discovery and a Senior Associate Member of the Broad Institute; and Matthew Meyerson, M.D., Ph.D., who serves as Professor of Pathology at Dana-Farber Cancer Institute and Harvard Medical School, Director of the Center for Cancer Genome Discovery at Dana-Farber Cancer Institute, and Matthew Meyerson, M.D., Ph.D., who serves as Professor of Pathology at Dana-Farber Cancer Institute, and Broad Institute. We intend to continue to leverage the expertise of our founding advisors by seeking their counsel on important topics across a range of key disciplines relevant to our medical and scientific expertise, our molecular information platform and our business strategy.

### **Composition of Our Board of Directors**

Our board of directors currently consists of seven members, all of whom were elected pursuant to the board composition provisions of our stockholders voting agreement. These board composition provisions will terminate immediately prior to the closing of this offering, upon which there will be no further contractual obligations regarding the election of our directors. Our nominating and governance committee and board of directors may thereafter consider a broad range of factors relating to the qualifications and background of nominees, which may include but is not limited to diversity considerations such as race, gender, or national origin. We have no formal policy regarding board diversity. Our nominating and governance committee s and board of directors priority in selecting board members is identification of persons who will further the interests of our stockholders through their established record of professional accomplishment, knowledge of our business, understanding of the competitive landscape, professional and personal experiences and expertise relevant to our growth strategy, and the ability to contribute positively to the collaborative culture among board members. Our directors hold office until their successors have been elected and qualified or until the earlier of their resignation or removal.

Our amended and restated certificate of incorporation and amended and restated bylaws, which will become effective immediately prior to the closing of this offering, also provide that our directors

may be removed only for cause by the affirmative vote of the holders of at least 75% of the shares entitled to vote in an annual election of directors, and that any vacancy on our board of directors, including a vacancy resulting from an enlargement of our board of directors, may be filled only by vote of a majority of our directors then in office.

*Director Independence.* Our board of directors has determined that all members of the board of directors, except Dr. Pellini and Mr. Borisy, are independent, as determined in accordance with the rules of the NASDAQ Stock Market. In making such independence determination, the board of directors considered the relationships that each such non-employee director has with us and all other facts and circumstances that the board of directors deemed relevant in determining their independence, including the beneficial ownership of our capital stock by each non-employee director. In considering the independence of the directors listed above, our board of directors considered the association of our directors with the holders of more than 5% of our common stock. Upon the closing of this offering, we expect that the composition and functioning of our board of directors and each of its committees will comply with all applicable requirements of the NASDAQ Stock Market and the rules and regulations of the SEC. There are no family relationships among any of our directors or executive officers.

*Staggered Board.* In accordance with the terms of our amended and restated certificate of incorporation and amended and restated bylaws that will become effective upon the completion of this offering, our board of directors will be divided into three classes, class I, class II and class III, with each class serving staggered three-year terms. Upon the expiration of the term of a class of directors, directors in that class will be eligible to be elected for a new three-year term at the annual meeting of stockholders in the year in which their term expires.

Our Class I directors will be Mark Levin, Brook Byers and Michael Pellini;

Our Class II directors will be David Schenkein and Krishna Yeshwant; and

Our Class III directors will be Evan Jones and Alexis Borisy.

Our amended and restated certificate of incorporation and amended and restated bylaws that will become effective immediately prior to the closing of this offering provide that the authorized number of directors may be changed only by resolution of the board of directors. Any additional directorships resulting from an increase in the number of directors will be distributed among the three classes so that, as nearly as possible, each class shall consist of one third of the board of directors.

The division of our board of directors into three classes with staggered three-year terms may delay or prevent stockholder efforts to effect a change of our management or a change in control.

### Board Leadership Structure and Board s Role in Risk Oversight

The positions of our Chairman of the board and Chief Executive Officer are presently separated. Separating these positions allows our Chief Executive Officer to focus on our day-to-day business, while allowing the Chairman of the board to lead the board of directors in its fundamental role of providing advice to and independent oversight of management. Our board of directors recognizes the time, effort and energy that the Chief Executive Officer must devote to his position in the current business environment, as well as the commitment required to serve as our Chairman, particularly as the board of directors oversight responsibilities continue to grow. Our board of directors also believes that this structure ensures a greater role for the non-management directors in the oversight of our company and active participation of the independent directors in setting agendas and establishing priorities and procedures for the work of our board of directors. Our board of directors believes its administration of its risk oversight function has not affected its leadership structure. Although our amended and restated bylaws that will be in effect upon the completion of this offering will not require

our Chairman and Chief Executive Officer positions to be separate, our board of directors believes that having separate positions is the appropriate leadership structure for us at this time.

Our board of directors oversees the management of risks inherent in the operation of our business and the implementation of our business strategies. Our board of directors performs this oversight role by using several different levels of review. In connection with its reviews of the operations and corporate functions of our company, our board of directors addresses the primary risks associated with those operations and corporate functions. In addition, our board of directors reviews the risks associated with our company s business strategies periodically throughout the year as part of its consideration of undertaking any such business strategies.

Each of our board committees also oversees the management of our risk that falls within the committee s areas of responsibility. In performing this function, each committee has full access to management, as well as the ability to engage advisors. Our Vice President, Finance reports to the audit committee and is responsible for identifying, evaluating and implementing risk management controls and methodologies to address any identified risks. In connection with its risk management role, our audit committee meets privately with representatives from our independent registered public accounting firm, and privately with our Vice President, Finance. The audit committee oversees the operation of our risk management program, including the identification of the primary risks associated with our business and periodic updates to such risks, and reports to our board of directors regarding these activities.

### **Board Committees**

Our board of directors has established an audit committee, a compensation committee and a nominating and corporate governance committee, each of which operates pursuant to a separate charter adopted by our board of directors. The composition and functioning of all of our committees will comply with all applicable requirements of the Sarbanes-Oxley Act of 2002, the NASDAQ Stock Market and the Securities and Exchange Commission, or SEC, rules and regulations.

#### Audit Committee

Evan Jones, David Schenkein and Krishna Yeshwant currently serve on the audit committee, which is chaired by Evan Jones. Our board of directors has determined that each member of the audit committee is independent for audit committee purposes as that term is defined in the rules of the SEC and the applicable NASDAQ Stock Market rules. Our board of directors has designated Evan Jones as an audit committee financial expert, as defined under the applicable rules of the SEC. The audit committee s responsibilities include:

appointing, approving the compensation of, and assessing the independence of our independent registered public accounting firm;

approving auditing and permissible non-audit services, and the terms of such services, to be provided by our independent registered public accounting firm;

reviewing the internal audit plan with the independent registered public accounting firm and members of management responsible for preparing our financial statements;

reviewing and discussing with management and the independent registered public accounting firm our annual and quarterly financial statements and related disclosures as well as critical accounting policies and practices used by us;

reviewing the adequacy of our internal control over financial reporting;

establishing policies and procedures for the receipt and retention of accounting-related complaints and concerns;

recommending, based upon the audit committee s review and discussions with management and the independent registered public accounting firm, whether our audited financial statements shall be included in our Annual Report on Form 10-K;

monitoring the integrity of our financial statements and our compliance with legal and regulatory requirements as they relate to our financial statements and accounting matters;

preparing the audit committee report required by SEC rules to be included in our annual proxy statement;

overseeing our compliance with applicable legal and regulatory requirements;

reviewing all related party transactions for potential conflict of interest situations and approving all such transactions; and

reviewing quarterly earnings releases. *Compensation Committee* 

Alexis Borisy, Brook Byers and Krishna Yeshwant currently serve on the compensation committee, which is chaired by Alexis Borisy. Under NASDAQ Stock Market rules, we are permitted to phase in our compliance with the independent compensation committee requirements set forth in NASDAQ Marketplace Rule 5605(d). Our board of directors has determined that each of Brook Byers and Krishna Yeshwant is independent as that term is defined in the applicable NASDAQ Stock Market rules. Within one year of our listing on The NASDAQ Global Market, we expect that Mr. Borisy will be independent under NASDAQ Stock Market rules, as his service as our chief executive officer ended in May 2011. The compensation committee s responsibilities include:

annually reviewing and recommending to our board of directors corporate goals and objectives, and determination of the achievement thereof, relevant to the compensation of our Chief Executive Officer and other executive officers;

evaluating the performance of our Chief Executive Officer in light of such corporate goals and objectives and recommending to our board of directors the compensation of our Chief Executive Officer;

reviewing and approving the compensation of our other executive officers;

reviewing and establishing our overall management compensation philosophy and policy;

overseeing and administering our compensation and similar plans;

evaluating and assessing potential current compensation advisors in accordance with the independence standards identified in the applicable NASDAQ Stock Market rules;

retaining and approving the compensation of any compensation advisors;

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reviewing and approving our policies and procedures for the grant of equity-based awards;

determining or reviewing and making recommendations to our board of directors with respect to director compensation;

preparing the compensation committee report required by SEC rules to be included in our annual proxy statement;

reviewing and discussing with management the compensation discussion and analysis to be included in our annual proxy statement or Annual Report on Form 10-K; and

reviewing and discussing with our board of directors corporate succession plans for the Chief Executive Officer and other key officers.

### Nominating and Corporate Governance Committee

David Schenkein, Brook Byers and Mark Levin currently serve on the nominating and corporate governance committee, which is chaired by David Schenkein. Our board of directors has determined that each member of the nominating and corporate governance committee is independent as that term is defined in the applicable NASDAQ Stock Market rules. The nominating and corporate governance committee s responsibilities include:

developing and recommending to our board of directors criteria for board and committee membership;

establishing procedures for identifying and evaluating board of director candidates, including nominees recommended by stockholders;

identifying individuals qualified to become members of the board of directors;

recommending to our board of directors the persons to be nominated for election as directors and to each of the board s committees;

developing and recommending to our board of directors a set of corporate governance guidelines; and

overseeing the evaluation of our board of directors and management. Our board of directors may establish other committees from time to time.

#### **Compensation Committee Interlocks and Insider Participation**

None of the members of our compensation committee has at any time during the prior three years been one of our officers or employees. None of our executive officers currently serves, or in the past fiscal year has served, as a member of the board of directors or compensation committee of any entity that has one or more executive officers serving on our board of directors or compensation committee.

#### **Corporate Governance**

Prior to the completion of this offering, we will adopt a written code of business conduct and ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. Following the completion of this offering, a current copy of the code will be posted on the Corporate Governance section of our website, which is located at www.foundationmedicine.com. If we make any substantive amendments to, or grant any waivers from, the code of business conduct and ethics for any officer, we will disclose the nature of such amendment or waiver on our website or in a current report on Form 8-K.

#### Limitation of Liability

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers, or controlling persons, we have been informed that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

### **EXECUTIVE COMPENSATION**

#### **Executive Compensation Overview**

Historically, our executive compensation program has reflected our growth and corporate goals. To date, the compensation of Michael J. Pellini, M.D., our President and Chief Executive Officer, and the other executive officers identified below in the summary compensation table, who we refer to as the named executive officers, has consisted of a combination of base salary, bonuses and long-term incentive compensation in the form of restricted common stock and stock options. Our executive officers and all salaried employees are also eligible to receive health and welfare benefits.

As we transition from a private company to a publicly-traded company, we will evaluate our compensation values and philosophy and compensation plans and arrangements as circumstances require. At a minimum, we expect to review executive compensation annually with input from a compensation consultant if and when determined by the compensation committee. As part of this review process, we expect the board of directors and the compensation committee to apply our compensation philosophy when considering the compensation levels needed to ensure our executive compensation program remains competitive. We will also review whether we are meeting our retention objectives and the potential cost of replacing a key employee.

#### **Compensation Tables**

#### Summary Compensation Table 2012

The following table presents information regarding the total compensation awarded to, earned by, and paid to our chief executive officer and the two most highly-compensated executive officers (other than the chief executive officer) who were serving as executive officers at the end of the last completed fiscal year for services rendered in all capacities to us for the year ended December 31, 2012. These individuals are our named executive officers for 2012.

Name and principal position Michael J. Pellini, M.D.,	Year 2012	Salary (\$) 395,000	<b>Option</b> <b>awards</b> (\$)(1) 130,157	Non-equity incentive plan compensation (\$) 158,000	All other compensation (\$) 60.713 <sup>(2)</sup>	<b>Total</b> (\$) 743.870
President and Chief Executive Officer	2012	393,000	150,157	158,000	00,715	745,870
Kevin Krenitsky, M.D., Chief Commercial Officer & Senior Vice President, International Strategy	2012	330,000	13,232	102,800		446,032
Vincent A. Miller, M.D., Chief Medical Officer	2012	334,995	42,000	117,250	80,953 <sup>(3)</sup>	575,198

- (1) Amounts reflect the grant date fair value of option awards granted in 2012 in accordance with Accounting Standards Codifcation Topic 718. For information regarding assumptions underlying the valuation of equity awards, see note 2 to our financial statements and the discussion under Management s Discussion and Analysis of Financial Condition and Results of Operations Application of Critical Accounting Policies Stock-Based Compensation included elsewhere in this prospectus. These amounts do not correspond to the actual value that will be recognized by the named executive officers.
- (2) Pursuant to the terms of his employment agreement, Dr. Pellini is entitled to living expense assistance in connection with his commuting to our principal executive offices in Cambridge, Massachusetts. This amount represents (i) an aggregate of \$43,273 for reimbursed expenses for

airline travel between Dr. Pellini s principal residence and Boston, and reimbursed expenses for parking, transportation and related travel incidentals, and (ii) for one-third of the aggregate costs related to a corporate apartment in Cambridge, Massachusetts utilized by Dr. Pellini and two other executives.

(3) Pursuant to the terms of his employment agreement, Dr. Miller is entitled to living expense assistance in connection with his commuting to our principal executive offices in Cambridge, Massachusetts. This amount represents (i) an aggregate of \$13,513 for reimbursed expenses for airline travel, parking, transportation and related travel incidentals, and (ii) for one-third of the aggregate costs related to a corporate apartment in Cambridge, Massachusetts utilized by Dr. Miller and two other executives. Dr. Miller was also paid a bonus of \$50,000 in 2012, representing a portion of his signing bonus.

#### **Employment Agreements with Our Named Executive Officers**

We have entered into an employment agreement with each of the named executive officers. These employment agreements provide for at will employment.

Michael J. Pellini, M.D. On March 14, 2011, we entered into an employment agreement with Dr. Pellini for the position of President and Chief Executive Officer. Dr. Pellini currently receives a base salary of \$406,850, which is subject to review and adjustment in accordance with our corporate policy. Dr. Pellini is also eligible for an annual discretionary bonus with a target amount of up to 40% of his base salary, payable at the discretion of the compensation committee. The amount of such bonus will be determined annually based upon individual and/or our achievement of certain measurable goals established by the compensation committee after discussion with Dr. Pellini. Dr. Pellini is eligible to participate in employee benefit plans generally available to our executive employees, subject to the terms of those plans. Dr. Pellini is entitled to living expense assistance in connection with his commuting to our principal executive offices in Cambridge, Massachusetts. All living expense assistance amounts are grossed up for applicable state and federal taxes. Under the agreement, we agreed to make an equity award to Dr. Pellini in the form of an option to purchase 2,200,000 shares of our common stock. This amount represented 5.5% of our shares on a fully-diluted basis. We agreed to grant Dr. Pellini an option to purchase additional shares to maintain his 5.5% ownership if we increased the size of our Series A financing on or prior to March 14, 2012. Following the closing of the second tranche of our Series A financing, we granted Dr. Pellini an additional option to purchase 592,634 shares of our common stock. Pursuant to the agreement, both the initial and subsequent option grants are subject to the following terms: 25% of the two stock options will immediately vest upon the closing of this offering and, upon any later change of control, 100% of the then unvested portion of the two stock options will immediately vest. For purposes of payments made, benefits provided or equity awards accelerated that would constitute an excess parachute payment within the meaning of Section 280G of the Internal Revenue of Code of 1986, as amended, or the Code, Dr. Pellini s agreement provides that we will make a gross-up payment in an amount equal to 100% of the applicable excise tax with regard to such payments.

*Kevin Krenitsky*, *M.D.* On March 7, 2013, we entered into an employment agreement with Dr. Krenitsky for the position of Chief Commercial Officer & Senior Vice President, International Strategy. Dr. Krenitsky currently receives a base salary of \$338,350, which is subject to review and adjustment at the discretion of the compensation committee. Dr. Krenitsky is also eligible for an annual discretionary bonus with a target amount of up to 35% of his base salary, payable at the discretion of the compensation committee. Dr. Krenitsky is eligible to participate in employee benefit plans generally available to our full-time employees, subject to the terms of those plans.

*Vincent A. Miller, M.D.* On August 1, 2011, we entered into an employment agreement with Dr. Miller for the position of Senior Vice President, Clinical Development. In July 2013, Dr. Miller was promoted to the position of our Chief Medical Officer. Dr. Miller currently receives a base salary of \$335,000, which is subject to review and adjustment at the discretion of the compensation committee. Dr. Miller is also eligible for an annual discretionary bonus with a target amount of up to 35% of his base salary, payable at the discretion of the compensation committee. Dr. Miller is entitled to living expense assistance in connection with his commuting to our principal executive offices in Cambridge, Massachusetts. All living expense assistance amounts are grossed up for applicable state and federal taxes. Dr. Miller is eligible to participate in employee benefit plans generally available to our full-time employees, subject to the terms of those plans.

The employment agreements with Drs. Pellini, Miller and Krenitsky provide for certain payments and benefits in the event of an involuntary termination of employment. In addition, each of Drs. Pellini, Miller and Krenitsky are entitled to accelerated vesting of certain outstanding and unvested equity awards held by them in certain circumstances. The information below describes certain compensation and equity acceleration that may become payable as a result of certain events. These payments and benefits are in addition to benefits available generally to salaried employees, including distributions under our 401(k) plan, accrued benefits under our health and welfare plans and arrangements, and accrued vacation pay. Outstanding equity awards for the named executive officers as of December 31, 2012 are set forth under Outstanding Equity Awards at Fiscal Year End Table 2012.

#### Involuntary Termination of Employment and Change of Control

Pursuant to his employment agreement, Dr. Pellini is eligible to receive certain payments and benefits in the event his employment is terminated by us without cause (as defined in his employment agreement) or he terminates his employment with good reason (as defined in his employment agreement). Pursuant to his employment agreement, each of Dr. Krenitsky and Dr. Miller is eligible to receive certain payments and benefits in the event his employment is terminated by us without cause (as defined in the pertinent employment agreement) or in the event that, following a deemed liquidation event or a change of control resulting in the payment of proceeds to our stockholders (a change of control ), he terminates his employment with good reason (as defined in the employment agreements).

Each of Dr. Pellini and Dr. Miller is eligible to receive 12 months of base salary continuation, pro-rated target bonus and 12 months of COBRA continuation medical benefits paid by us in the event of a termination by us without cause or by Dr. Pellini or Dr. Miller for good reason, provided that he executes and does not revoke a release agreement. In addition, the options and restricted stock held by Dr. Pellini and Dr. Miller that would have become vested in the 12-month period following termination of employment would become vested. Dr. Krenitsky is eligible to receive nine months of base salary continuation (but subject to offset by compensation earned during the severance period) and up to nine months of COBRA continuation medical benefits subsidized by us in the event of a termination by us without cause or, following a change of control, by the officer for good reason, provided that he executes, not revokes and fully complies with a separation agreement that includes a general release of us and our affiliates.

In addition to the previously described severance provisions, pursuant to the terms of his employment agreement and the option award agreements with Dr. Pellini, in the event of a change in control, 100% of the unvested portion of his options would immediately become vested. Pursuant to the employment agreements with Dr. Krenitsky and Dr. Miller, in the event of a termination by us without cause, or by the officer for good reason, in each case following a change in control, 100% of the unvested portion of each of their options would immediately become vested.

#### Definitions

For purposes of the employment agreements with each of Dr. Pellini and Dr. Miller cause means:

conviction of a felony;

willful failure to substantially perform (other than by reason of disability) the officer s duties and responsibilities as set forth in, or determined in accordance with, the employment agreement that results in material harm to us, which failure continues, or which harm remains unremedied, after 10 days notice setting forth in reasonable detail the nature of such failure;

material breach of the officer s employment agreement that results in material harm to us, which breach continues or remains uncured after 10 days notice setting forth in reasonable detail the nature of such breach; or

material fraudulent conduct by the officer s with respect to us. For purposes of the employment agreements with each of Dr. Pellini and Dr. Miller, good reason means:

a material diminution in the officer s responsibilities, authority or duties;

a material diminution in the officer s base salary, except for across-the-board salary reductions based on our financial performance similarly affecting all or substantially all of our senior management employees; or

a material breach by us of the officer s employment agreement or any of the agreements he has with us relating to his options or other types of our equity.

For purposes of the employment agreement with Dr. Krenitsky, cause means:

conviction of, or the entry of a pleading of guilty or nolo contendere to, any crime involving (A) fraud or embezzlement, or (B) any felony;

willful failure to perform (other than by reason of disability), or gross negligence in the performance of, the officer s duties and responsibilities as set forth in his job description;

material breach by the officer of any provision of his employment agreement or any of the other agreements he has with us, which breach continues or remains uncured after 30 days notice setting forth in reasonable detail the nature of such breach; or

material fraudulent conduct by the officer with respect to us. For purposes of the employment agreement with Dr. Krenitsky, good reason means:

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a change in title, responsibility and authority to a position less than his title, responsibility and authority as of the effective date of the change in control (by reference to his title, responsibility and authority within his business unit following a change in control, and not necessarily us as a whole);

the officer s work location is located more than 50 miles from the office location at which the officer was working as of the effective date of the change in control; or

a material breach by us of his employment agreement, his option agreements or any of the agreements he has with us relating to his employment, which breach continues or remains uncured after 30 days notice from the officer setting forth in reasonable detail the nature of such breach.

### Outstanding Equity Awards at Fiscal Year-End Table 2012

The following table summarizes, for each of the named executive officers, the number of shares of common stock underlying outstanding stock options held as of December 31, 2012.

		Option Awards			Stock Awards		
	Number of securities underlying unexercised options	Number of securities underlying unexercised	<b>Option</b> exercise	Option	Number of Shares That Have	Market Value of Shares or Units of Stock That Have Not	
Name	(#) exercisable	options (#) unexercisable	price (\$)	expiration date	Not Vested (#)	Vested(1) (\$)	
Michael J. Pellini, M.D.			,		1,375,000(2)		
	222,238	370,396(3)	0.21	1/10/2022			
		390,995(4)	0.21	3/27/2022			
Kevin Krenitsky, M.D.					343,750(5)		
	18,750	81,250(6)	0.21	3/27/2022			
Vincent A. Miller, M.D.					309,375(7)		
	18,750	81,250(8)	0.21	1/10/2022			
		100,000(9)	0.21	1/10/2022			

- (1) There was no public market for our common stock at December 31, 2012. We have estimated the market value of the unvested stock awards based on an assumed initial public offering price of \$ per share, the midpoint of the range listed on the cover of this prospectus.
- (2) On May 9, 2011, Dr. Pellini was granted an option for 2,200,000 shares of our common stock, 25% of such option to vest on May 9, 2012, and the remaining unvested shares to vest in equal quarterly installments through May 9, 2015. Pursuant to the terms of his option agreement, Dr. Pellini early exercised his option on May 12, 2011. Pursuant to the terms of Dr. Pellini s corresponding restricted stock agreement, the remaining unvested shares will vest in equal quarterly installments through May 9, 2015. Vesting of 25% of the restricted shares subject to the agreement accelerates in connection with an IPO and the remaining shares accelerate in connection with an acquisition event.
- (3) Represents options to purchase shares of our common stock granted on January 11, 2012. The shares underlying these options vest as follows: 25% vest on May 9, 2012, with the remainder of the shares vesting in equal quarterly installments over the following three years through May 9, 2015. Vesting of 25% of the options subject to the stock option agreement, to the extent unvested, accelerate in connection with an IPO and the remaining then unvested options will accelerate in connection with an acquisition event.
- (4) Represents options to purchase shares of our common stock granted on March 27, 2012. The shares underlying these options vest as follows: 25% vest on March 27, 2013, with the remainder of the shares vesting in equal quarterly installments over the following three years through March 27, 2016.
- (5) On June 15, 2011, Dr. Krenitsky was granted an option for 550,000 shares of our common stock, 25% of such option to vest on May 31, 2012, and the remaining unvested shares to vest in equal quarterly installments through May 31, 2015. Pursuant to the terms of his option agreement, Dr. Krenitsky early exercised his option on August 4, 2011. Under the terms of Dr. Krenitsky s corresponding restricted stock agreement, the remaining unvested shares will vest in equal quarterly installments through May 31, 2015.
- (6) Represents options to purchase shares of our common stock granted on March 27, 2012. The shares underlying these options vest in equal quarterly installments over four years through March 27, 2016.
- (7) Pursuant to the terms of Dr. Miller s restricted stock agreement, the remaining unvested shares will vest in equal quarterly installments through October 15, 2015.

- (8) Represents options to purchase shares of our common stock granted on January 11, 2012. The shares underlying these options vest in equal quarterly installments over four years through October 17, 2015.
- (9) Represents options to purchase shares of our common stock granted on January 11, 2012. The shares underlying these options will commence vesting on December 31, 2013 and thereafter vest in quarterly installments through October 17, 2015. Director Compensation

The following table presents the total compensation for each person who served as a member of our board of directors during 2012, other than Dr. Pellini. Other than as set forth in the table and described more fully below, we did not pay any compensation, make any equity awards or non-equity awards to, or pay any other compensation to any of the non-employee members of our board of directors in 2012. Dr. Pellini, who is also our Chief Executive Officer, receives no compensation for his service as a director, and, consequently, is not included in this table. The compensation received by Dr. Pellini as our Chief Executive Officer during 2012 is presented in Summary Compensation Table 2012. Mr. Jones, a current member of the Board, was elected in 2013 and is not included in the following table.

In 2012, we did not maintain any standard fee arrangements for the non-employee members of our board of directors for their service as a director. We intend to put in place a formal director compensation policy for all of our non-employee directors prior to the completion of this offering.

### Director Compensation Table 2012

Director name	Fees earned or paid in cash (\$)	Option awards (\$)	All other compensation (\$)	Total (\$)
Alexis Borisy				
Brook Byers				
Mark Levin				
David Schenkein, M.D.	\$ 35,000 <sup>(1)</sup>			\$ 35,000 <sup>(1)</sup>
Krishna Yeshwant, M.D.				

(1) Dr. Schenkein received payments for service as a director pursuant to a board service agreement.

1	2	9

Our board of directors has adopted a non-employee director compensation policy, effective as of the closing of this offering, that is designed to provide a total compensation package that enables us to attract and retain, on a long-term basis, high caliber non-employee directors. Under the policy, all non-employee directors will be paid cash compensation from and after the completion of this offering, as set forth below:

	Annua	l Retainer
Board of Directors:		
All non-employee members	\$	35,000
Additional retainer for Board Chairperson	\$	50,000
Audit Committee:		
Chairperson	\$	15,000
Non-Chairperson members	\$	7,500
Compensation Committee:		
Chairperson	\$	10,000
Non-Chairperson members	\$	5,000
Nominating and Corporate Governance Committee:		
Chairperson	\$	10,000
Non-Chairperson members	\$	5,000
Under the new ampleuse director companyation policy, each person who is initially appoint	ated or elected to the board of directors will	he aligible

Under the non-employee director compensation policy, each person who is initially appointed or elected to the board of directors will be eligible for an option grant to purchase up to shares of our common stock under our 2013 Plan on the date he or she first becomes a non-employee director, which will vest in two equal annual installments during the two years following the grant date, subject to the director s continued service on the board of directors. In addition, on the date of the annual meeting of stockholders, each continuing non-employee director will be eligible to receive an annual option grant to purchase up to earlier of the first anniversary of the date of grant or the date of the following annual meeting of stockholders. All of the foregoing options will be granted at fair market value on the date of grant.

#### **Compensation Risk Assessment**

We believe that although a portion of the compensation provided to our executive officers and other employees is performance-based, our executive compensation program does not encourage excessive or unnecessary risk taking. This is primarily due to the fact that our compensation programs are designed to encourage our executive officers and other employees to recognize and support both short-term and long-term strategic goals, in particular in connection with our pay-for-performance compensation philosophy. As a result, we do not believe that our compensation programs are reasonably likely to have a material adverse effect on us.

#### **Employee Share Plans**

#### Share Options

The two equity incentive plans described in this section are the Foundation Medicine, Inc. Amended and Restated 2010 Stock Incentive Plan, or the 2010 Plan, and the Foundation Medicine, Inc. 2013 Stock Option and Grant Plan, or the 2013 Plan. Prior to this offering, we granted awards to eligible participants under the 2010 Plan. Following the closing of this offering, we expect to grant awards to eligible participants only under the 2013 Plan. In addition, our Senior Executive Cash

Incentive Bonus Plan, or the Bonus Plan, which will be used following completion of this offering, is described below.

### 2010 Plan

The 2010 Plan was approved by our board of directors and our stockholders on March 29, 2010 and was most recently amended on March 7, 2013. Under the 2010 Plan, 16,930,000 shares of common stock have been reserved for issuance in the form of stock options, restricted stock, restricted stock units and other stock-based awards.

The shares issuable pursuant to awards granted under the 2010 Plan are authorized but unissued shares. The shares underlying any awards that are forfeited, repurchased terminated, surrendered or cancelled without having been exercised are available for issuance under the 2010 Plan. Shares tendered by a participant to exercise options are also added to the number of shares available for issuance under the 2010 Plan.

The 2010 Plan is administered by our board of directors, which has full power to select the employees, prospective employees, directors and service providers to whom awards will be granted and to determine the specific terms and conditions of each award, subject to the provisions of the 2010 Plan.

The option exercise price of each option granted under the 2010 Plan is determined by our board of directors and may not to be less than the fair market value of a share of common stock on the date of grant. The term of each option is fixed by the board of directors. The board of directors determines at what time or times each option may be exercised when granting the option.

The board of directors may grant awards under the 2010 Plan entitling the participants to acquire shares of common stock subject to the right of repurchase (or forfeiture if issued at no cost) in the event the conditions specified by the board of directors in connection with the awards are not met. The board of directors may also grant awards of restricted stock units under the 2010 Plan entitling the participants to receive shares of common stock or cash at the time the awards vest.

The board of directors may also grant other stock-based awards under the 2010 Plan such as stock appreciation rights and other types of awards which entitle the participants to receive shares of common stock or cash in the future.

The 2010 Plan provides that, upon a reorganization event, which includes a merger or a sale of substantially all of our common stock, the board of directors may take any one or a combination of the following actions with respect to outstanding awards other than restricted stock and restricted stock units: (i) require that awards be substituted with new awards of the successor entity on substantially identical terms; (ii) provide for a cash payment equal to the in-the-money value of the awards; (iii) provide for full vesting of the awards; or (iv) provide that all awards not exercised within a specified period will terminate upon the closing of the transaction. In the case of restricted stock awards and restricted stock units, unless the board of directors determines otherwise in connection with a reorganization event, the repurchase and other rights of ours with respect to restricted stock and restricted stock units shall inure to the benefit of our successors and shall apply to the cash, securities or other property paid with respect to the common stock in connection with the reorganization.

Our board of directors may amend the 2010 Plan but no such action may adversely affect the rights of an award holder without such holder s consent. Approval by our stockholders of amendments to the 2010 Plan must be obtained if required by law.

As of July 31, 2013, options to purchase 8,666,879 shares of common stock and 2,641,807 shares of restricted stock were outstanding under the 2010 Plan. Our board of directors has

determined not to make any further awards under the 2010 Plan following the closing of this offering. Shares of common stock originally reserved for issuance under our 2010 Plan but which were not issued or subject to awards under the 2010 Plan on the effective date of our 2013 Plan, and shares subject to outstanding options or forfeiture restrictions under our 2010 Plan on the effective date of our 2013 Plan that are subsequently forfeited or terminated for any reason before being exercised, will become available for awards under our 2013 Plan.

### 2013 Plan

On 2013, our board of directors adopted and our stockholders approved our 2013 Plan to replace the 2010 Plan. Our 2013 Plan provides us flexibility to use various equity-based incentive and other awards as compensation tools to motivate our workforce. These tools include stock options, stock appreciation rights, restricted stock, restricted stock units, unrestricted stock, performance share awards and cash-based awards. The 2013 Plan will become effective immediately prior to the closing of this offering.

We have initially reserved shares of common stock for the issuance of awards under the 2013 Plan, which includes shares of common stock that were not previously exercised or currently outstanding under the 2010 Plan. The 2013 Plan provides that the number of shares reserved and available for issuance will automatically increase each January 1, beginning on January 1, 2014, by 4% of the outstanding number of shares of our common stock on the immediately preceding December 31 or such lesser number as determined by our compensation committee. This number is subject to adjustment in the event of a stock split, stock dividend or other change in our capitalization. In addition, shares not needed to fulfill any obligations under the 2010 Plan will also be available for issuance under the 2013 Plan.

The shares issuable pursuant to awards granted under the 2013 Plan will be authorized but unissued shares or shares that we reacquire. The shares of common stock underlying any awards from the 2013 Plan and the 2010 Plan that are forfeited, cancelled, held back upon exercise or settlement of an award to satisfy the exercise price or tax withholding, reacquired by us prior to vesting, satisfied without any issuance of common stock, expire or are otherwise terminated (other than by exercise) under the 2010 Plan will be added back to the shares available for issuance under the 2013 Plan.

Under the 2013 Plan, stock options or stock appreciation rights with respect to no more than shares may be granted to any one individual in any one calendar year. No more than the initial number of shares reserved and available for issuance under the 2013 Plan may be issued in the form of incentive stock options, such number to be cumulatively increased on January 1, 2014 and on each January 1 thereafter by the lesser of 4% of the outstanding number of shares of our common stock on the immediately preceding December 31 and shares of our common stock.

The 2013 Plan is administered by the compensation committee. The compensation committee has full power to select, from among the individuals eligible for awards, the individuals to whom awards will be granted, to make any combination of awards to participants, and to determine the specific terms and conditions of each award, subject to the provisions of the 2013 Plan. Employees, non-employee directors and other key persons (including consultants) are eligible to receive awards under the 2013 Plan.

The 2013 Plan permits the granting of both options to purchase common stock intended to qualify as incentive stock options under Section 422 of the Code and options that do not so qualify. The exercise price of each stock option will be determined by the compensation committee but may not be less than 100% of the fair market value of our common stock on the date of grant or, in the case of an incentive stock option will be fixed to a 10% owner, less than 110% of the fair market value of our common stock on the date of grant. The term of each stock option will be fixed by the compensation committee and may not exceed 10 years from the date of grant (or five years in the case of an incentive stock

option granted to a 10% owner). The compensation committee will determine at what time or times each option may be exercised.

The compensation committee may award stock appreciation rights subject to such conditions and restrictions as it may determine. Stock appreciation rights entitle the recipient to shares of common stock, or cash, equal to the value of the appreciation in our stock price over the exercise price. The exercise price of each stock appreciation right may not be less than 100% of fair market value of the common stock on the date of grant.

The compensation committee may award restricted stock or restricted stock units to participants subject to such conditions and restrictions as it may determine. These conditions and restrictions may include the achievement of certain performance goals and/or continued employment or service with us through a specified vesting period. The compensation committee may also grant cash-based awards to participants subject to such conditions and restrictions as it may determine. The compensation committee may also grant shares of common stock that are free from any restrictions under the 2013 Plan. Unrestricted stock may be granted to participants in recognition of past services or for other valid consideration and may be issued in lieu of cash compensation due to such participant.

The compensation committee may grant performance share awards to participants that entitle the recipient to receive share awards of common stock upon the achievement of certain performance goals and such other conditions as our compensation committee shall determine.

The compensation committee may grant cash bonuses under the 2013 Plan to participants, subject to the achievement of certain performance goals.

The compensation committee may grant performance-based awards to participants in the form of restricted stock, restricted stock units, performance shares or cash-based awards upon the achievement of certain performance goals and such other conditions as the compensation committee shall determine. The compensation committee may grant such performance-based awards under the 2013 Plan that are intended to qualify as performance-based compensation under Section 162(m) of the Code. Those awards would only vest or become payable upon the attainment of performance goals that are established by our compensation committee and related to one or more performance criteria. The performance criteria that could be used with respect to any such awards include: revenue, expense levels, cash flow, business development and financing milestones and developments, earnings before interest, taxes, depreciation and amortization, net income (loss) (either before or after interest, taxes, depreciation and/or amortization), changes in the market price of our common stock, economic value-added, funds from operations or similar measure, sales or revenue, acquisitions or strategic transactions, operating income (loss), cash flow (including, but not limited to, operating cash flow and free cash flow), return on capital, assets, equity, or investment, stockholder returns, return on sales, gross or net profit levels, productivity, expense, margins, operating efficiency, customer satisfaction, working capital, earnings (loss) per share, sales or market shares and number of clients, any of which may be measured either in absolute terms or as compared to any incremental increase or as compared to results of a peer group. From and after the time that we become subject to Section 162(m) of the Code, the maximum award that is intended to qualify as performance-based compensation under Section 162(m) of the Code that may be made to any one employee during any one calendar year period is 1,100,000 shares with respect to a stock-based award and \$2,000,

The 2013 Plan provides that, upon the effectiveness of a sale event, as defined in the 2013 Plan, in the event that all awards are not assumed or continued or substituted by the successor entity, all awards granted under the 2013 Plan shall terminate. In addition, in connection with the termination of the 2013 Plan upon a sale event, we may make or provide for a cash payment to participants holding options and stock appreciation rights, equal to the difference between the per share cash consideration payable to stockholders in the sale event and the exercise price of the options or stock appreciation rights.

Our board of directors may amend or discontinue the 2013 Plan and our compensation committee may amend or cancel outstanding awards for purposes of satisfying changes in law or any other lawful purpose, including option repricing, but no such action may adversely affect rights under an award without the holder s consent. Certain amendments to the 2013 Plan may require the approval of our stockholders.

No awards may be granted under the 2013 Plan after the date that is ten years from the date of stockholder approval of the 2013 Plan. Our board of directors has approved the issuance under the 2013 Plan of stock options to acquire an aggregate of 265,750 shares of common stock on the effective date of the registration statement of which this prospectus is a part. These stock options will have an exercise price equal to the public offering price. No other awards under the 2013 Plan have been made prior to the date hereof.

### 2013 Employee Stock Purchase Plan

Our 2013 Employee Stock Purchase Plan was adopted by our board of directors and approved by our stockholders in . Our 2013 Employee Stock Purchase Plan authorizes the initial issuance of up to a total of shares of our common stock to participating employees.

All employees who have been employed by us or our designated subsidiaries for at least six weeks and whose customary employment is for more than 20 hours a week are eligible to participate in our 2013 Employee Stock Purchase Plan. Any employee who owns, or would own upon such purchase under our 2013 Employee Stock Purchase Plan, 5% or more of the voting power or value of our stock is not eligible to purchase shares under our 2013 Employee Stock Purchase Plan.

We may make one or more offerings to our employees to purchase stock under our 2013 Employee Stock Purchase Plan. If the 2013 Employee Stock Purchase Plan is implemented and unless otherwise determined by the administrator of our 2013 Employee Stock Purchase Plan, the first offering will begin on either January 1st or July 1st of the year designated by the administrator, and will end on the following June 30th or December 31st, respectively. Unless otherwise determined by the administrator, subsequent offerings will begin on the first business day occurring on or after each January 1st and July 1st and will end on the last business day occurring on or before the following June 30th and December 31st, respectively, each referred to as offering periods. The administrator may designate different offering periods in its discretion, but no offering shall exceed six months in duration or overlap with another offering.

Each employee who is a participant in our 2013 Employee Stock Purchase Plan may purchase shares by authorizing payroll deductions of up to 10% of his or her eligible compensation during an offering period. 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, provided that no more than shares of common stock or such other maximum number established by the compensation committee may be purchased by any one employee during each offering period. Under applicable tax rules, an employee may purchase no more than \$25,000 worth of common stock, valued at the start of the purchase period, under our 2013 Employee Stock Purchase Plan in any calendar year.

An employee s rights under our 2013 Employee Stock Purchase Plan terminate upon voluntary withdrawal from the plan or when the employee ceases employment for any reason and any accumulated payroll deductions of such employee will be refunded.

Our 2013 Employee Stock Purchase Plan may be terminated or amended by our board of directors at any time. Amendments that increase the number of shares of our common stock authorized under our 2013 Employee Stock Purchase Plan and certain other amendments require the approval of our stockholders.

### **Bonus Plan**

In July 2013, our board of directors adopted the Bonus Plan. The Bonus Plan provides for cash bonus payments based upon the attainment of performance targets established by the compensation committee. The payment targets will be related to financial and operational measures or objectives with respect to us, or Corporate Performance Goals, as well as individual performance objectives.

Our compensation committee may select Corporate Performance Goals from among the following: revenue; expense levels; cash flow (including, but not limited to, operating cash flow and free cash flow); business development and financing milestones; earnings before interest, taxes, depreciation and amortization; net income (loss) (either before or after interest, taxes, depreciation and/or amortization); changes in the market price of our common stock; economic value-added; sales; acquisitions or strategic transactions; operating income (loss); return on capital, assets, equity, or investment; stockholder returns; return on sales; gross or net profit levels; productivity; expense; margins; operating efficiency; customer satisfaction; clinical trial results; publications; reimbursement decisions; working capital; earnings (loss) per share of our common stock; sales or market shares and number of clients or units of products sold; bookings; and Adjusted EBIDTA, any of which may be measured in absolute terms, as compared to any incremental increase, in terms of growth, or as compared to results of a peer group.

Each executive officer who is selected to participate in the Bonus Plan will have a target bonus opportunity set for each performance period. The bonus formulas will be adopted in each performance period by the compensation committee and communicated to each executive. The Corporate Performance Goals will be measured at the end of each performance period after our financial reports have been published or such other appropriate time as the compensation committee determines. If the Corporate Performance Goals and individual performance objectives are met, payments will be made as soon as practicable following the end of each performance period. Subject to the rights contained in any agreement between the executive officer and us, an executive officer must be employed by us on the bonus payment date to be eligible to receive a bonus payment. The Bonus Plan also permits the compensation committee to approve additional bonuses to executive officers in its sole discretion.

### 401(k) Plan

We maintain a tax-qualified retirement plan that provides eligible employees in the United States with an opportunity to save for retirement on a tax-advantaged basis. All participants interests in their contributions are 100% vested when contributed. Pre-tax contributions are allocated to each participant s individual account and are then invested in selected investment alternatives according to the participants directions. The retirement plan is intended to qualify under Sections 401(a) and 501(a) of the Code.

## CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

Other than compensation arrangements, we describe below the transactions and series of similar transactions, during our last three fiscal years, to which we were a party or will be a party, in which:

the amounts involved exceeded or will exceed \$120,000; and

any of our directors, executive officers or holders of more than 5% of our capital stock, or any member of the immediate family of the foregoing persons, had or will have a direct or indirect material interest.

Compensation arrangements for our directors and named executive officers are described elsewhere in this prospectus.

#### **Sales and Purchases of Securities**

### Series A Financing

On March 30, 2010, we entered into a securities purchase agreement pursuant to which we issued an aggregate of 13,000,000 shares of our Series A Preferred Stock at a price of \$1.00 per share in three tranches to certain investors. On August 8, 2011, we entered into an additional securities purchase agreement pursuant to which we issued an aggregate of 20,500,000 shares of our Series A Preferred Stock at a price of \$1.00 per share in two tranches to certain investors. On April 18, 2012, we entered into a securities purchase agreement pursuant to which we issued an aggregate of 10,250,000 shares of our Series A Preferred Stock at a price of \$1.00 per share to certain investors.

The following table summarizes the participation in the Series A Preferred Stock financing by any of our directors, executive officers, holders of more than 5% of our voting securities, or any member of the immediate family of the foregoing persons.

Name	Shares of Series A Preferred Stock	Aggregate Purchase Price Paid
Third Rock Ventures, L.P.(1)	23,772,388	\$ 23,772,388
KPCB Holdings, Inc.(2)	12,985,075	\$ 12,985,075
Google Ventures 2011, L.P.(3)	6,742,537	\$ 6,742,537
David Schenkein, M.D.(4)	250,000	\$ 250,000

(1) Alexis Borisy and Mark Levin, partners at Third Rock Ventures, of which Third Rock Ventures, L.P. is an affiliated fund, are members of our board of directors.

(2) Brook Byers, a partner at Kleiner Perkins Caufield & Byers, of which KPCB Holdings, Inc. is an affiliated fund, is a member of our board of directors.

(3) Google Ventures 2011, L.P. is a holder of more than 5% of our voting securities. Dr. Krishna Yeshwant, an affiliate of Google Ventures 2011, L.P., is a member of our board of directors.

(4) David Schenkein is a member of our board of directors.

Series B Financing

On September 10, 2012, we entered into a securities purchase agreement pursuant to which we issued an aggregate of 18,805,304 shares of our Series B Preferred Stock at a price of \$2.26 per share to certain investors. The securities purchase agreement was subsequently amended in December 2012 to provide for the issuance of additional shares of our Series B Preferred Stock in one additional tranche, pursuant to which 5,956,830 shares of our Series B Preferred Stock were issued to certain investors.

The following table summarizes the participation in the Series B Preferred Stock financing by any of our directors, executive officers, holders of more than 5% of our voting securities, or any member of the immediate family of the foregoing persons.

	Shares of Series B	Aggregate Purchase
Name	Preferred Stock	Price Paid
Third Rock Ventures, L.P.(1)	1,106,194	\$ 2,499,998
Google Ventures 2011, L.P.(2)	3,036,075	\$ 6,861,530
KPCB Holdings, Inc.(3)	1,106,194	\$ 2,499,998
jVen Capital, LLC(4)	221,238	\$ 499,998
Laboratory Corporation of America Holdings	4,424,778	\$ 9,999,998
Gates Ventures, LLC	4,424,778	\$ 9,999,998
Wellington Management Company, LLP(5)	4,368,143	\$ 9,872,003

(1) Alexis Borisy and Mark Levin, partners at Third Rock Ventures, of which Third Rock Ventures, L.P. is an affiliated fund, are members of our board of directors.

(2) Google Ventures 2011, L.P. is a holder of more than 5% of our voting securities. Dr. Krishna Yeshwant, an affiliate of Google Ventures 2011, L.P., is a member of our board of directors.

(3) Brook Byers, a partner at Kleiner Perkins Caufield & Byers, of which KPCB Holdings, Inc. is an affiliated fund, is a member of our board of directors.

(4) Evan Jones, the managing member of jVen Capital, LLC, is a member of our board of directors.

(5) Wellington Management Company, LLP, or Wellington Management, is an investment adviser registered under the Investment Advisers Act of 1940, as amended. Wellington Management, in such capacity, may be deemed to share beneficial ownership (within the meaning of Rule 13d-3 promulgated under the Exchange Act) of the shares held by its client accounts.

#### **Consulting Arrangements**

During the fiscal years ended December 31, 2010, 2011 and 2012, we incurred consulting fees to Third Rock Ventures, LLC in the amount of \$691,000, \$535,000 and \$362,000, respectively. Third Rock Ventures, LLC is a management company that is party to a services agreement with Third Rock Ventures, L.P., the beneficial owner of more than 5% of our voting securities. Alexis Borisy and Mark Levin are members of our board of directors, and Mark Levin is a managing member of TRV GP, LLC, which is the general partner of Third Rock Ventures GP, L.P., the general partner of Third Rock Ventures, L.P. and a managing member of Third Rock Ventures, LLC. These consulting fees were paid to Third Rock Ventures, LLC in amounts mutually agreed upon in advance by us and Third Rock Ventures, LLC in consideration of certain strategic and ordinary course business operations consulting services provided to us on an as-needed basis, from time to time and at our request, by individuals related to Third Rock Ventures, LLC, including Mr. Borisy but not including Mr. Levin. Such fees were payable pursuant to invoices submitted to us by Third Rock Ventures, LLC from time to time. None of these consulting fees were paid directly or indirectly to Messrs. Borisy and Levin. The consulting fees paid to Third Rock Ventures, LLC did not exceed 5% percent of the consolidated gross revenue of Third Rock Ventures, LLC and we do not expect to engage Third Rock Ventures, LLC for consulting services on a going forward basis.

### **Biopharmaceutical Relationship**

In February 2013, we entered into a master services agreement with Agios Pharmaceuticals, Inc., or Agios, in the ordinary course pursuant to which we will perform tests utilizing our molecular information platform when ordered by Agios. To date, we have not performed any tests for Agios, invoiced Agios or otherwise received any payments from Agios under the master services agreement. In the event Agios elects to retain our services for a particular project, Agios would submit a specific work order for the applicable project, with a payment schedule for the particular project included in such work order. In the event we are asked to perform services beyond what is included in the applicable work order, such additional services and the corresponding compensation provided by Agios must be mutually agreed upon by the parties in writing prior to the provision of such services or our obligation to provide such services. Any payments for services will be made pursuant to invoices that we will submit to Agios. The agreement terminates at the later of February 28, 2015 and the completion of all services provided pursuant to outstanding work orders. We may terminate the agreement in the event Agios fails to pay a disputed invoice, following a negotiation between the parties in good faith. The agreement also contains customary confidentiality, indemnification, insurance and assignment provisions. David Schenkein, a member of our board of directors, is the chief executive officer of Agios. These fees will be paid by Agios in consideration of certain sequencing and related consulting services provided by us to Agios. Under the master services agreement, none of these fees will be paid directly or indirectly by Mr. Schenkein.

#### **Indemnification Agreements**

We intend to enter into agreements to indemnify our directors and executive officers to the maximum extent allowed under Delaware law. Subject to the provisions of these agreements, these agreements will, among other things, indemnify these individuals for certain expenses (including attorneys fees), judgments, fines and settlement amounts reasonably incurred by such person in any action or proceeding, including any action by or in our right, on account of any services undertaken by such person on behalf of us or that person s status as a member of our board of directors.

### **Policies for Approval of Related Party Transactions**

Our board of directors reviews and approves transactions with directors, officers and holders of 5% or more of our voting securities and their affiliates, or each, a related party. Prior to this offering, the material facts as to the related party s relationship or interest in the transaction are disclosed to our board of directors prior to their consideration of such transaction, and the transaction is not considered approved by our board of directors unless a majority of the directors who are not interested in the transaction approve the transaction. Further, when stockholders are entitled to vote on a transaction with a related party, the material facts of the related party s relationship or interest in the transaction are disclosed to the stockholders, who must approve the transaction in good faith.

In connection with this offering, we intend to adopt a written related party transactions policy that such transactions must be approved by our audit committee or another independent body of our board of directors.

### PRINCIPAL STOCKHOLDERS

The following table and footnotes set forth certain information known to us regarding beneficial ownership of our capital stock as of July 31, 2013, as adjusted to reflect the sale of common stock offered by us in this offering, for:

each person known by us to be the beneficial owner of more than 5% of our capital stock;

our named executive officers;

each of our directors; and

all executive officers and directors as a group.

Beneficial ownership is determined in accordance with the rules of the Securities and Exchange Commission and generally includes voting or investment power with respect to securities. Except as noted by footnote, and subject to community property laws where applicable, we believe based on the information provided to us that the persons and entities named in the table below have sole voting and investment power with respect to all common stock shown as beneficially owned by them.

The table lists applicable percentage ownership based on 85,124,231 shares of common stock outstanding as of July 31, 2013 and also lists applicable percentage ownership based on shares of common stock assumed to be outstanding after the closing of the offering. These amounts assume the conversion of all outstanding shares of our preferred stock into common stock, which will occur immediately prior to the closing of this offering, and that no shares of our common stock are purchased by our directors or executive officers or by the beneficial owners of more than 5% of our capital stock in the offering. Options to purchase shares of common stock that are exercisable within 60 days of July 31, 2013 are deemed to be beneficially owned by the persons holding these options for the purpose of computing percentage ownership of that person, but are not treated as outstanding for the purpose of computing any other person s ownership percentage.

	Number of Shares Beneficially Owned	Shares Beneficially O Beneficially	
Name and address of beneficial owner(1) 5% Stockholders	Prior to this Offering	Prior to this Offering	After this Offering
Third Rock Ventures, L.P.(2)	26,278,582	30.9%	
KPCB Holdings, Inc.(3)	14,091,269	16.6%	
Google Ventures 2011, L.P.(4)	9,778,612	11.5%	
Laboratory Corporation of America Holdings(5)	4,424,778	5.2%	
Gates Ventures, LLC (6)	4,424,778	5.2%	
Wellington Management Company, LLP(7)	4,368,143	5.1%	
Named executive officers and directors			
Michael J. Pellini, M.D.(8)	2,723,730	3.2%	
Kevin Krenitsky, M.D.(9)	593,750	*	
Vincent A. Miller, M.D.(10)	575,000	*	
Alexis Borisy(11)	1,162,500	1.4%	
Brook Byers(3)			
Evan Jones(12)	229,676	*	
Mark Levin(11)			
David Schenkein, M.D.(13)	377,187	*	
Krishna Yeshwant, M.D.(4)			

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## All directors and named executive officers as a group (9 persons)

6.6%

5,661,843

- \* Represents beneficial ownership of less than one percent.
- (1) Unless otherwise indicated, the address for each beneficial owner is c/o Foundation Medicine, Inc., One Kendall Square, Suite B3501, Cambridge, MA 02139.

- (2) Consists of 23,772,388 shares common stock issuable upon conversion of Series A Preferred Stock, 1,106,194 shares common stock issuable upon conversion of Series B Preferred Stock and 1,400,000 shares of common stock. All shares are held directly by Third Rock Ventures, L.P., or TRV LP. Each of Third Rock Ventures GP, LP, or TRV GP, the general partner of TRV LP, and Third Rock Ventures GP, LLC, or TRV LLC, the general partner of TRV GP, may be deemed to have voting and dispositive power over the shares held by TRV LP. Investment decisions with respect to the shares held by TRV LP are made by an investment committee at TRV GP comprised of Mark Levin, Kevin Starr, Bob Tepper, Neil Exter, Kevin Gillis, Lou Tartaglia, Craig Muir, Cary Pfeffer, Alexis Borisy and Craig Greaves. No stockholder, director, officer, manager, member or employee of TRV GP or TRV LLC has beneficial ownership (within the meaning of Rule 13d-3 promulgated under the Exchange Act) of any shares held by TRV LP. The address of Third Rock Ventures, L.P. is 29 Newbury Street, 3rd Floor, Boston, MA 02116.
- (3) Consists of (i) 11,972,240 shares common stock issuable upon conversion of Series A Preferred Stock and 1,019,910 shares common stock issuable upon conversion of Series B Preferred Stock held by Kleiner Perkins Caufield & Byers XIV, LLC, or KPCB XIV, and (ii) 1,012,835 shares common stock issuable upon conversion of Series A Preferred Stock and 86,284 shares common stock issuable upon conversion of Series B Preferred Stock held by KPCB XIV Founders Fund, LLC, or KPCB XIV Founders. The shares held by KPCB XIV and KPCB XIV Founders are held for convenience in the name of KPCB Holdings, Inc., as nominee. KPCB Holdings, Inc. has no voting, dispositive or pecuniary interest in any such shares. The managing member of KPCB XIV and KPCB XIV Founders is KPCB XIV Associates, LLC, or KPCB XIV Associates. Brook Byers, L. John Doerr, Raymond Lane, Theodore Schlein, William Joy, William B. Gordon, the managing members of KPCB XIV Associates, exercise shared voting and dispositive control over the shares directly held by KPCB XIV and KPCB XIV Founders. Mr. Byers disclaims beneficial ownership of all shares held by KPCB XIV and KPCB XIV and KPCB XIV Founders. Mr. Byers disclaims for all entities and individuals affiliated with Kleiner Perkins Caufield & Byers is 2750 Sand Hill Road, Menlo Park, California 94025.
- (4) Consists of 6,742,537 shares common stock issuable upon conversion of Series A Preferred Stock and 3,036,075 shares common stock issuable upon conversion of Series B Preferred Stock. Google Ventures 2011 GP, L.L.C. is the general partner of Google Ventures 2011, L.P. Voting and dispositive power with respect to shares held by Google Ventures 2011, L.P. reside with the Google Ventures Investment Committee. Dr. Krishna Yeshwant is an affiliate of Google Ventures 2011, L.P., but is not a member of the Google Ventures Investment Committee and does not have voting or dispositive power over the shares held by Google Ventures 2011, L.P. Dr. Yeshwant disclaims beneficial ownership with respect to any such shares, except to the extent of his pecuniary interest therein, if any. The address for all entities and individuals affiliated with Google Ventures 2011, L.P. is 1600 Amphitheatre Parkway, Mountain View, California 94043.
  (5) Consist of 4,424,778 shares common stock issuable upon conversion of Series P. Berferred Stock. The address of a laboratory is a start of series and stock issuable upon conversion of Series and Stock.
- (5) Consists of 4,424,778 shares common stock issuable upon conversion of Series B Preferred Stock. The address of Laboratory Corporation of America Holdings is 531 South Spring Street, Burlington, North Carolina 27215.
- (6) Consists of 4,424,778 shares common stock issuable upon conversion of Series B Preferred Stock. William H. Gates III has voting and dispositive power over the shares held by Gates Ventures, LLC. The address of Gates Ventures, LLC is 2365 Carillon Point, Kirkland, Washington 98033.
- (7) Wellington Management is an investment adviser registered under the Investment Advisers Act of 1940, as amended. Wellington Management, in such capacity, may be deemed to share beneficial ownership (within the meaning of Rule 13d-3 promulgated under the Exchange Act) of the shares held by its client accounts, which consist of (i) 1,223,346 shares common stock issuable upon conversion of Series B Preferred Stock held by Quissett Investors (Bermuda) L.P., or Quissett Investors, (ii) 1,123,894 shares common stock issuable upon conversion of Series B Preferred Stock held by Hawkes Bay Master Investors (Cayman) LP, or Hawkes Bay, (iii) 963,381 shares common stock issuable upon conversion of Series B Preferred Stock held by Quissett Partners, L.P., or Quissett Partners, (iv) 602,257 shares common stock issuable upon conversion of Series B Preferred Stock held by Salthill Partners, L.P., or Salthill Partners, and (v) 455,265 shares common stock issuable upon conversion of Series B Preferred Stock held by Salthill Investors (Bermuda) L.P., or Salthill Investors. Wellington Management Company, LLP is the investment advisor for Quissett Investors, Hawkes Bay, Quissett Partners, Salthill Partners and Salthill Investors. The address for all entities and individuals affiliated with Wellington Management Company, LLP, 280 Congress Street, Boston, MA 02210.
- (8) Includes options to purchase 523,725 shares exercisable within 60 days of July 31, 2013.
- (9) Includes options to purchase 43,750 shares exercisable within 60 days of July 31, 2013.
- (10) Includes options to purchase 31,250 shares exercisable within 60 days of July 31, 2013.
- (11) Represents shares held individually by the director. Investment decisions with respect to the shares held by TRV LP are made by an investment committee at TRV GP comprised of Mark Levin, Kevin Starr, Bob Tepper, Neil Exter, Kevin Gillis, Lou Tartaglia, Craig Muir, Cary Pfeffer, Alexis Borisy and Craig Greaves. No stockholder, director, officer, manager, member or employee of TRV GP or TRV LLC has beneficial ownership (within the meaning of Rule 13d-3 promulgated under the Exchange Act) of any shares held by TRV LP.
- (12) Consists of (i) 221,238 shares common stock issuable upon conversion of Series B Preferred Stock held by jVen Capital, LLC and (ii) options to purchase 8,438 shares exercisable within 60 days of July 31, 2013. Evan Jones is the managing member of jVen Capital, LLC.
- (13) Consists of (i) options to purchase 2,187 shares exercisable within 60 days of July 31, 2013 and (ii) 250,000 shares common stock issuable upon conversion of Series A Preferred Stock held in trusts for the benefit of Dr. Schenkein and certain of his family members. Dr. Schenkein has voting and dispositive power over the shares held by such trusts.

### DESCRIPTION OF CAPITAL STOCK

The following descriptions are summaries of the material terms of our amended and restated certificate of incorporation and amended and restated bylaws, which will be effective upon closing of this offering. The descriptions of the common stock and preferred stock give effect to changes to our capital structure that will occur immediately prior to the closing of this offering. We refer in this section to our amended and restated certificate of incorporation as our certificate of incorporation, and we refer to our amended and restated bylaws as our bylaws.

### General

Upon completion of this offering, our authorized capital stock will consist of 150,000,000 shares of common stock, par value \$0.0001 per share, and 5,000,000 shares of preferred stock, par value \$0.0001 per share, all of which shares of preferred stock will be undesignated.

As of July 31, 2013, 16,612,097 shares of our common stock were outstanding and held by 74 stockholders of record. In addition, as of July 31, 2013, we had outstanding options to purchase 8,666,879 shares of our common stock, at a weighted average exercise price of \$0.76 per share, 1,531,884 of which were exercisable, and an outstanding warrant to purchase 200,000 shares of our Series A preferred stock, at an exercise price of \$1.00 per share. These amounts assume the conversion of all outstanding shares of our preferred stock into common stock, which will occur immediately prior to the closing of this offering.

#### **Common Stock**

The holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of the stockholders. The holders of our common stock do not have any cumulative voting rights. Holders of our common stock are entitled to receive ratably any dividends declared by the board of directors out of funds legally available for that purpose, subject to any preferential dividend rights of any outstanding preferred stock. Our common stock has no preemptive rights, conversion rights or other subscription rights or redemption or sinking fund provisions.

In the event of our liquidation, dissolution or winding up, holders of our common stock will be entitled to share ratably in all assets remaining after payment of all debts and other liabilities and any liquidation preference of any outstanding preferred stock. The shares to be issued by us in this offering will be, when issued and paid for, validly issued, fully paid and non-assessable.

### **Preferred Stock**

Immediately prior to the closing of this offering, all outstanding shares of our preferred stock will be converted into shares of our common stock. Immediately prior to the closing of this offering, our certificate of incorporation will be amended and restated to delete all references to such shares of preferred stock. Upon the closing of this offering, our board of directors will have the authority, without further action by our stockholders, to issue up to 5,000,000 shares of preferred stock in one or more series and to fix the rights, preferences, privileges and restrictions thereof. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences, sinking fund terms and the number of shares constituting, or the designation of, such series, any or all of which may be greater than the rights of common stock. The issuance of our preferred stock could adversely affect the voting power of holders of common stock and the likelihood that such holders will receive dividend payments and payments upon our liquidation. In addition, the issuance of preferred stock could have the effect of delaying, deferring or preventing a

change in control of our company or other corporate action. Immediately after closing of this offering, no shares of preferred stock will be outstanding, and we have no present plans to issue any shares of preferred stock.

### Warrant

In connection with the loan and security agreement, entered into with Lighthouse Capital Partners, or Lighthouse, in November 2010, we issued to Lighthouse a warrant exercisable for up to 200,000 shares of our Series A preferred stock. The warrant may be exercised at the option of the holder either by delivery of the exercise price in cash or by a cashless exercise. The warrant will automatically become a warrant for the purchase of 200,000 shares of our common stock upon the closing of this offering at an exercise price of \$1.00 per share.

### **Registration Rights**

Upon the completion of this offering, the holders of our registrable shares, as described in the Second Amended and Restated Investors Rights Agreement between us and the holders of these shares, or the investors rights agreement, including shares issuable upon the conversion of preferred stock or their permitted transferees, are entitled to rights with respect to the registration of these shares under the Securities Act of 1933, as amended, or the Securities Act. These rights are provided under the terms of the investors rights agreement, and include demand registration rights, short-form registration rights and piggyback registration rights. All fees, costs and expenses of underwritten registrations will be borne by us and all selling expenses, including underwriting discounts and selling commissions, will be borne by the holders of the shares being registered.

### Demand Registration Rights

Upon the completion of this offering, the holders of shares of our common stock, including shares issuable upon the conversion of preferred stock or their permitted transferees, are entitled to demand registration rights. Under the terms of the investors rights agreement, we will be required, upon the written request of holders of at least 25% of the shares issued pursuant to conversion of our preferred stock, to use our commercially reasonable efforts to effect the registration of all or a portion of these shares for public resale. We are required to effect only two registrations pursuant to this provision of the investors rights agreement. A demand for registration may not be made until six months after the completion of this offering.

### Short Form Registration Rights

Upon the completion of this offering, the holders of shares of our common stock issued upon the conversion of preferred stock or their permitted transferees are also entitled to short form registration rights. If we are eligible to file a registration statement on Form S-3, upon the written request of holders of our common stock, issued upon conversion of our preferred stock upon consummation of this offering, to sell registrable securities at an aggregate price of at least \$3,000,000, we will be required to use our best efforts to effect a registration of such shares. We are required to effect only two registrations in any 12 month period pursuant to this provision of the investors rights agreement.

## Piggyback Registration Rights

Upon the completion of this offering, the holders of shares of our common stock issued upon the conversion of preferred stock or their permitted transferees, are entitled to piggyback registration rights. If we register any of our securities either for our own account or for the account of

other security holders, the holders of these shares are entitled to include their shares in the registration. Subject to certain exceptions, we and the underwriters may limit the number of shares included in the underwritten offering if the underwriters believe that including these shares would adversely affect the offering.

### Indemnification

Our investors rights agreement contains customary cross-indemnification provisions, under which we are obligated to indemnify holders of registrable shares in the event of material misstatements or omissions in the registration statement attributable to us, and they are obligated to indemnify us for material misstatements or omissions attributable to them.

### **Expiration of Registration Rights**

The registration rights granted under the investors rights agreement will terminate on the fifth anniversary of the completion of this offering.

### Anti-takeover Effects of Our Certificate of Incorporation, Bylaws and Delaware Law

Our certificate of incorporation and bylaws that will be effective upon consummation of this offering include a number of provisions that may have the effect of delaying, deferring or preventing another party from acquiring control of us and encouraging persons considering unsolicited tender offers or other unilateral takeover proposals to negotiate with our board of directors rather than pursue non-negotiated takeover attempts. These provisions include the items described below.

### **Board Composition and Filling Vacancies**

Our certificate of incorporation provides for the division of our board of directors into three classes serving staggered three-year terms, with one class being elected each year. Our certificate of incorporation also provides that directors may be removed only for cause and then only by the affirmative vote of the holders of 75% or more of the shares then entitled to vote at an election of directors. Furthermore, any vacancy on our board of directors, however occurring, including a vacancy resulting from an increase in the size of our board, may only be filled by the affirmative vote of a majority of our directors then in office even if less than a quorum. The classification of directors, together with the limitations on removal of directors and treatment of vacancies, has the effect of making it more difficult for stockholders to change the composition of our board of directors.

#### No Written Consent of Stockholders

Our certificate of incorporation provides that all stockholder actions are required to be taken by a vote of the stockholders at an annual or special meeting, and that stockholders may not take any action by written consent in lieu of a meeting. This limit may lengthen the amount of time required to take stockholder actions and would prevent the amendment of our bylaws or removal of directors by our stockholders without holding a meeting of stockholders.

#### Meetings of Stockholders

Our certificate of incorporation and bylaws provide that only a majority of the members of our board of directors then in office may call special meetings of stockholders and only those matters set forth in the notice of the special meeting may be considered or acted upon at a special meeting of stockholders. Our bylaws limit the business that may be conducted at an annual meeting of stockholders to those matters properly brought before the meeting.

### Advance Notice Requirements

Our bylaws establish advance notice procedures with regard to stockholder proposals relating to the nomination of candidates for election as directors or new business to be brought before meetings of our stockholders. These procedures provide that notice of stockholder proposals must be timely given in writing to our corporate secretary prior to the meeting at which the action is to be taken. Generally, to be timely, notice must be received at our principal executive offices not less than 90 days nor more than 120 days prior to the first anniversary date of the annual meeting for the preceding year. Our bylaws specify the requirements as to form and content of all stockholders notices. These requirements may preclude stockholders from bringing matters before the stockholders at an annual or special meeting.

### Amendment to Certificate of Incorporation and Bylaws

Any amendment of our certificate of incorporation must first be approved by a majority of our board of directors, and if required by law or our certificate of incorporation, must thereafter be approved by a majority of the outstanding shares entitled to vote on the amendment and a majority of the outstanding shares of each class entitled to vote thereon as a class, except that the amendment of the provisions relating to stockholder action, board composition, limitation of liability and the amendment of our certificate of incorporation must be approved by not less than 75% of the outstanding shares entitled to vote on the amendment, and not less than 75% of the outstanding shares of each class entitled to vote of a majority of the directors then in office, subject to any limitations set forth in the bylaws; and may also be amended by the affirmative vote of at least 75% of the outstanding shares entitled to vote on the amendment, or, if our board of directors recommends that the stockholders approve the amendment, by the affirmative vote of the majority of the outstanding shares entitled to vote on the amendment, in each case voting together as a single class.

### **Undesignated Preferred Stock**

Our certificate of incorporation provides for 5,000,000 authorized shares of preferred stock. The existence of authorized but unissued shares of preferred stock may enable our board of directors to discourage an attempt to obtain control of us by means of a merger, tender offer, proxy contest or otherwise. For example, if in the due exercise of its fiduciary obligations, our board of directors were to determine that a takeover proposal is not in the best interests of our stockholders, our board of directors could cause shares of preferred stock to be issued without stockholder approval in one or more private offerings or other transactions that might dilute the voting or other rights of the proposed acquirer or insurgent stockholder or stockholder group. In this regard, our certificate of incorporation grants our board of directors broad power to establish the rights and preferences of authorized and unissued shares of preferred stock. The issuance of shares of preferred stock could decrease the amount of earnings and assets available for distribution to holders of shares of common stock. The issuance may also adversely affect the rights and powers, including voting rights, of these holders and may have the effect of delaying, deterring or preventing a change in control of us.

### Section 203 of the Delaware General Corporation Law

Upon completion of this offering, we will be subject to the provisions of Section 203 of the Delaware General Corporation Law. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a business combination with an interested stockholder for a three-year period following the time that this stockholder becomes an interested stockholder, unless the business combination is approved in a prescribed manner. Under Section 203, a business combination between a corporation and an interested stockholder is prohibited unless it satisfies one of the following conditions:

before the stockholder became interested, our board of directors approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;

upon consummation of the transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding, shares owned by persons who are directors and also officers, and employee stock plans, in some instances, but not the outstanding voting stock owned by the interested stockholder; or

at or after the time the stockholder became interested, the business combination was approved by our board of directors and authorized at an annual or special meeting of the stockholders by the affirmative vote of at least two-thirds of the outstanding voting stock which is not owned by the interested stockholder.

Section 203 defines a business combination to include:

any merger or consolidation involving the corporation and the interested stockholder;

any sale, transfer, lease, pledge or other disposition involving the interested stockholder of 10% or more of the assets of the corporation;

subject to exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;

subject to exceptions, any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; and

the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an interested stockholder as any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by the entity or person.

### **Exchange Listing**

We have applied to list our common stock on the NASDAQ Global Market under the trading symbol FMI.

#### **Transfer Agent and Registrar**

The transfer agent and registrar for our common stock will be	. The transfer agent and registrar s address is	, and its
telephone number is		

### SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there has been no public market for our shares. Future sales of our common stock in the public market, or the availability of such shares for sale in the public market, could adversely affect market prices prevailing from time to time. As described below, only a limited number of shares will be available for sale shortly after this offering due to contractual and legal restrictions on resale. Nevertheless, sales of our common stock in the public market after such restrictions lapse, or the perception that those sales may occur, could adversely affect the prevailing market price at such time and our ability to raise equity capital in the future.

Based on the number of shares outstanding as of July 31, 2013, upon the completion of this offering, shares of our common stock will be outstanding, assuming no exercise of the underwriters option to purchase additional shares and no exercise of outstanding options. Of the outstanding shares, all of the shares sold in this offering will be freely tradable, except that any shares held by our affiliates, as that term is defined in Rule 144 under the Securities Act, may only be sold in compliance with the limitations described below.

#### Rule 144

In general, a person who has beneficially owned restricted stock for at least six months would be entitled to sell their securities provided that (i) such person is not deemed to have been one of our affiliates at the time of, or at any time during the 90 days preceding, a sale and (ii) we are subject to the Securities Exchange Act of 1934, as amended, or the Exchange Act, periodic reporting requirements for at least 90 days before the sale. Persons who have beneficially owned restricted shares for at least six months but who are our affiliates at the time of, or any time during the 90 days preceding, a sale, would be subject to additional restrictions, by which such person would be entitled to sell within any three-month period only a number of securities that does not exceed the greater of either of the following:

1% of the number of shares then outstanding, which will equal approximately shares immediately after this offering assuming no exercise of the underwriters option to purchase additional shares, based on the number of shares outstanding as of July 31, 2013; or

the average weekly trading volume of our common stock on on Form 144 with respect to the sale. during the four calendar weeks preceding the filing of a notice

Provided, in each case, that we are subject to the Exchange Act periodic reporting requirements for at least 90 days before the sale. Such sales both by affiliates and by non-affiliates must also comply with the manner of sale, current public information and notice provisions of Rule 144.

### Rule 701

Rule 701 under the Securities Act, as in effect on the date of this prospectus, permits resales of shares in reliance upon Rule 144 but without compliance with certain restrictions of Rule 144, including the holding period requirement. Most of our employees, executive officers or directors who purchased shares under a written compensatory plan or contract may be entitled to rely on the resale provisions of Rule 701, but all holders of Rule 701 shares are required to wait until 90 days after the date of this prospectus before selling their shares. However, substantially all Rule 701 shares are subject to lock-up agreements as described below and under Underwriting included elsewhere in this prospectus and will become eligible for sale upon the expiration of the restrictions set forth in those agreements.

## Lock-up Agreements

In connection with this offering, all of our directors and executive officers and certain holders of our shares, who collectively held shares of common stock (assuming conversion of all of our outstanding shares of preferred stock) as of July 31, 2013, and substantially all of our optionholders who are not stockholders, have signed lock-up agreements which prevent them from selling any of our common stock or any securities convertible into or exercisable or exchangeable for common stock for a period of not less than 180 days from the date of the preliminary prospectus prepared for this offering without the prior written consent of each of Goldman Sachs & Co. and J.P. Morgan Securities LLC. The representatives may in their sole discretion and at any time without notice release some or all of the shares subject to lock-up agreements prior to the expiration of the 180-day period. When determining whether or not to release shares from the lock-up agreements, the representatives may consider, among other factors, the stockholder s reasons for requesting the release, the number of shares for which the release is being requested and market conditions at the time. In addition, our optionholders who have not executed lock-up agreements are nevertheless subject to similar restrictions set forth in the option agreements executed in connection with our 2010 Plan.

#### **Registration Rights**

Upon completion of this offering, the holders of shares of common stock or their transferees will be entitled to various rights with respect to registration of these shares under the Securities Act. Registration of these shares under the Securities Act would result in these shares becoming fully tradable without restriction under the Securities Act immediately upon the effectiveness of the registration. See Description of Capital Stock Registration Rights for additional information.

#### **Stock Option Plans**

We intend to file one or more registration statements on Form S-8 under the Securities Act to register our shares issued or reserved for issuance under our stock option plans. The first such registration statement is expected to be filed soon after the date of this prospectus and will automatically become effective upon filing with the SEC. Accordingly, shares registered under such registration statement will be available for sale in the open market, unless such shares are subject to vesting restrictions with us or the lock-up restrictions described above. As of July 31, 2013, we estimate that such registration statement on Form S-8 will cover approximately shares.

## CERTAIN MATERIAL U.S. FEDERAL INCOME TAX CONSIDERATIONS

The following is a summary of certain material U.S. federal income tax considerations relating to the acquisition, ownership and disposition of shares of our common stock issued pursuant to this offering. This summary deals only with shares of our common stock acquired by a stockholder in this offering and that are held as a capital asset within the meaning of Section 1221 of the Internal Revenue Code of 1986, as amended, or the Code. This summary does not address the U.S. federal income tax considerations applicable to a stockholder that is subject to special treatment under U.S. federal income tax laws, including: a dealer in securities or currencies; a financial institution; a regulated investment company; a real estate investment trust; a tax-exempt organization; an insurance company; a person holding our common stock as part of a hedging, integrated, conversion or straddle transaction or a person deemed to sell our common stock under the constructive sale provisions of the Code; a trader in securities that has elected the mark-to-market method of accounting; an entity that is treated as a partnership for U.S. federal income tax purposes; a person that received our common stock in connection with services provided to the company or any of its affiliates; a U.S. person whose functional currency is not the U.S. dollar; a controlled foreign corporation ; a passive foreign investment company ; or a U.S. expatriate.

This summary is based upon provisions of the Code, and applicable Treasury regulations promulgated or proposed thereunder, rulings and judicial decisions, all as in effect as of the date hereof. Those authorities may be changed, perhaps with retroactive effect, or may be subject to differing interpretations, which could result in U.S. federal income tax consequences different from those discussed below. This summary does not address all aspects of U.S. federal income tax, does not address all tax considerations that may be relevant to stockholders in light of their personal circumstances and does not address any state, local, foreign, gift, estate or alternative minimum tax considerations.

For purposes of this discussion, a U.S. holder is a beneficial holder of our common stock that is: an individual citizen or resident of the United States for U.S. federal income tax purposes; a corporation (or any other entity treated as a corporation for U.S. federal income tax purposes) created or organized in or under the laws of the United States, any state thereof or the District of Columbia; an estate the income of which is subject to U.S. federal income taxation regardless of its source; or a trust if it (1) is subject to the primary supervision of a court within the United States and one or more U.S. persons (as defined in the Code) have the authority to control all substantial decisions of the trust or (2) has a valid election in effect under applicable U.S. Treasury regulations to be treated as a U.S. person.

For purposes of this discussion, a non-U.S. holder is a beneficial holder of our common stock that is for U.S. federal income tax purposes an individual, corporation, estate or trust and is not a U.S. holder.

If a partnership (or an entity or arrangement that is treated as a partnership for U.S. federal income tax purposes) holds our common stock, the tax treatment of a person treated as a partner in the partnership for U.S. federal income tax purposes generally will depend upon the status of the partner and the activities of the partnership. Partnerships and other entities that are treated as partnerships for U.S. federal income tax purposes and persons holding our common stock through a partnership or other entity treated as a partnership for U.S. federal income tax purposes are urged to consult their own tax advisors.

This summary is for general information only and is not intended to be tax advice. Holders of our common stock are urged to consult their own tax advisors concerning the tax considerations related to the acquisition, ownership and disposition of our common stock in light of their particular circumstances, as well as any tax considerations arising under the laws of any other jurisdiction, including any state, local and foreign income and other tax laws.

### **U.S. Holders**

The following discussion is a summary of certain U.S. federal income tax considerations relevant to a U.S. holder of our common stock.

#### Distributions

Distributions with respect to our common stock, if any, generally will be includible in the gross income of a U.S. holder as ordinary dividend income to the extent of our current or accumulated earnings and profits, as determined for U.S. federal income tax purposes. Any portion of a distribution in excess of current and accumulated earnings and profits will be treated as a non-taxable return of capital, up to the U.S. holder s adjusted tax basis in its shares of our common stock with respect to which the distribution was made. Any such distribution in excess of the U.S. holder s adjusted tax basis in its shares will be treated as capital gain and as long-term capital gain if the U.S. holder s holding period exceeds one year. If certain requirements are met (including certain holding period requirements), distributions constituting dividends paid to non-corporate U.S. holders generally will qualify for the reduced tax rate on qualified dividend income.

Distributions constituting dividends for U.S. federal income tax purposes that are paid to U.S. holders that are corporations may qualify for the 70% dividends received deduction, or DRD, which is generally available to corporations that own less than 20% of the voting power or value of the outstanding stock of the distributing corporation. A U.S. holder that is a corporation holding 20% or more of the distributing corporation (by vote and value) may be eligible for an 80% DRD with respect to any such dividends. No assurance can be given that we will have sufficient earnings and profits (as determined for U.S. federal income tax purposes) to cause any distributions to be treated as dividends eligible for a DRD. In addition, a DRD is available only if certain other requirements (including certain holding period requirements) are satisfied, and a DRD may be subject to limitations in certain circumstances, which are not discussed herein.

#### Sale, Exchange, Redemption or Certain Other Taxable Dispositions of Our Common Stock

A U.S. holder of shares of our common stock generally will recognize gain or loss on the taxable sale, exchange, redemption (provided the redemption is treated as a sale or exchange), or other taxable disposition of such shares in an amount equal to the difference between such U.S. holder s amount realized on such disposition and such U.S. holder s adjusted tax basis in its shares of our common stock disposed of. A U.S. holder s amount realized generally will equal the amount of cash and the fair market value of any property received in consideration for the shares of common stock disposed of. Such gain or loss will be capital gain or loss, and will be long-term capital gain or loss if the U.S. holder s holding period for the shares of our common stock disposed of exceeds one year at the time of disposition. The deductibility of capital losses is subject to certain limitations. U.S. holders should consult their tax advisors regarding the treatment of capital gains and capital losses.

#### Medicare Tax on Net Investment Income

An additional 3.8% Medicare tax will be imposed on certain net investment income of certain U.S. holders that are individuals, estates or trusts. Such tax applies to the lesser of (i) the U.S. holder s net investment income for the relevant taxable year and (ii) the excess of the U.S. holder s adjusted gross income (with certain adjustments) over a specified threshold amount. Net investment income generally includes dividends and net gains from the disposition of shares of our common stock. U.S. holders that are individuals, estates or trusts should consult their tax advisors regarding the effect, if any, of the Medicare tax on their ownership and disposition of our common stock.

#### Information Reporting and Backup Withholding Tax

In general, information reporting will apply to payments of dividends on shares of our common stock and proceeds of a disposition of shares of our common stock to U.S. holders, other than certain exempt recipients such as corporations. Under U.S. federal income tax law, dividends and proceeds from the sale of shares of our common stock paid to a U.S. holder (other than an exempt recipient) may be subject to backup withholding at the then applicable rate. Backup withholding generally applies to a U.S. holder if the holder (i) fails to furnish to us or our paying agent a correct social security number or other taxpayer identification number, or TIN, or fails to furnish a certification of exempt status, (ii) has been notified by the IRS that it is subject to backup withholding as a result of the failure to properly report payments of interest or dividends or (iii) under certain circumstances, fails to provide a certified statement, signed under penalty of perjury, that the TIN provided is its correct number and that it is a U.S. holder under the backup withholding rules will be allowed as a credit against such holder s U.S. federal income tax liability and may entitle the holder to a refund, provided that the required information is timely furnished to the IRS. Certain U.S. persons are exempt from backup withholding, including corporations, provided that their exemptions from backup withholding are properly established.

#### Non-U.S. Holders

The following is a summary of certain U.S. federal tax considerations applicable to a non-U.S. holder of our common stock.

#### Distributions

Distributions treated as dividends for U.S. federal income tax purposes (as described above under U.S. Holders Distributions ), if any, that are paid to a non-U.S. holder with respect to shares of our common stock will be subject to U.S. federal withholding tax at a 30% rate (or a lower rate prescribed by an applicable income tax treaty) unless the dividends are effectively connected with the non-U.S. holder s conduct of a trade or business in the United States (and, if required by an applicable income tax treaty, is attributable to a permanent establishment or fixed base maintained in the U.S.). To claim the exemption from withholding with respect to any such effectively connected income, the non-U.S. holder must furnish to us or our paying agent a properly executed IRS Form W-8ECI (or applicable successor form), certifying under penalties of perjury that a dividend paid on our common stock is not subject to withholding tax. The certification requirement also may require a non-U.S. holder to provide its U.S. taxpayer identification number.

If a non-U.S. holder is engaged in a trade or business in the United States and dividends with respect to our common stock are effectively connected with the conduct of such trade or business and, if required by an applicable income tax treaty, are attributable to a U.S. permanent establishment or fixed base, then the non-U.S. holder generally will be subject to U.S. federal income tax on such dividends on a net income basis in the same manner as if received by a U.S. holder (although the dividends will be exempt from the 30% U.S. federal withholding tax, provided the certification requirements are satisfied). In addition, if the non-U.S. holder is a corporation for U.S. federal income tax purposes, such holder may, under certain circumstances, be subject to an additional branch profits tax equal to 30% (or a lower rate prescribed by an applicable income tax treaty) of its effectively connected earnings and profits for the taxable year.

A non-U.S. holder who wishes to claim the benefit of an exemption or reduced rate of U.S. federal withholding tax under an applicable income tax treaty must furnish to us or our paying agent a valid IRS Form W-8BEN (or applicable successor form) certifying, under penalties of perjury, such non-U.S. holder s qualification for the exemption or reduced rate. If a non-U.S. holder is eligible for an exemption

or a reduced rate of U.S. federal withholding tax pursuant to an applicable income tax treaty, it may obtain a refund of any excess amounts withheld by filing an appropriate claim for refund with the IRS.

If a distribution exceeds our current and accumulated earnings and profits, the excess will be treated as a non-taxable return of capital, up to the non-U.S. holder s adjusted tax basis in its shares of our common stock. Any remaining excess will be treated as capital gain, subject to the tax treatment described below in Sale, exchange, redemption or certain other taxable dispositions of our common stock. If we are not able to determine whether or not a distribution will exceed current and accumulated earnings and profits at the time a distribution is made, we may withhold tax on the entire amount of such distribution at the same rate as we would withhold on a dividend. However, a non-U.S. holder may obtain a refund of any excess withholding by filing an appropriate claim for refund with the IRS.

Any distribution described in this section would also be subject to the discussion below in Foreign Account Tax Compliance Act.

#### Sale, Exchange, Redemption or Certain Other Taxable Dispositions of Our Common Stock

Subject to the discussions below regarding backup withholding and the Foreign Account Tax Compliance Act, a non-U.S. holder generally will not be subject to U.S. federal income tax or withholding tax on gain realized upon a sale, exchange or other taxable disposition of shares of our common stock unless: (i) the gain is effectively connected with the conduct of a trade or business in the United States (and, if required by an applicable income tax treaty, is attributable to a U.S. permanent establishment or a fixed base), of the non-U.S. holder; (ii) the non-U.S. holder is a non-resident alien individual who is present in the United States for 183 days or more in the taxable year of that disposition, and certain other conditions are met; or (iii) we are or have been a U.S. real property holding corporation , or a USRPHC, for U.S. federal income tax purposes at any time within the shorter of the five-year period preceding the disposition and the non-U.S. holder sholding period for our common stock, or the relevant period.

If the first exception applies, the non-U.S. holder generally will be subject to U.S. federal income tax on a net basis with respect to such gain in the same manner as if such holder were a resident of the United States. In addition, if the non-U.S. holder is a corporation for U.S. federal income tax purposes, such gains may, under certain circumstances, also be subject to the branch profits tax at a rate of 30% (or at a lower rate prescribed by an applicable income tax treaty).

If the second exception applies, the non-U.S. holder generally will be subject U.S. federal income tax at a rate of 30% tax on the gain from a disposition of our common stock, which may be offset by capital losses allocable to U.S. sources during the taxable year of disposition (even though the non-U.S. holder is not considered a resident of the United States).

With respect to the third exception above, we believe we currently are not, and we do not anticipate becoming, a USRPHC for U.S. federal income tax purposes. Because the determination of whether we are a USRPHC depends on the fair market value of our U.S. real property interests relative to the fair market value of our other trade or business assets and our foreign real property interests, there can be no assurances that we will not become a USRPHC in the future. Generally, a corporation is a USRPHC only if the fair market value of its U.S. real property interests (as defined in the Code) equals or exceeds 50% of the sum of the fair market value of its worldwide real property interests plus its other assets used or held for use in a trade or business. Even if we are or become a USRPHC, a non-U.S. holder would not be subject to U.S. federal income tax on a sale, exchange or other taxable disposition of our common stock by reason of our status as a USRPHC so long as (i) our common stock continues to be regularly traded on an established securities market (within the meaning of Section 897(c)(3) of the Code) during the calendar year in which such disposition occurs and (ii) such

non-U.S. holder does not own and is not deemed to own (directly, indirectly, or constructively) more than 5% of our common stock at any time during the relevant period. If we are a USRPHC and the requirements of (i) or (ii) are not met, gain on the disposition of shares of our common stock generally will be taxed in the same manner as gain that is effectively connected with the conduct of a U.S. trade or business, except that the branch profits tax will not apply.

## Information Reporting and Backup Withholding Tax

We must report annually to the IRS and to each non-U.S. holder the gross amount of the distributions on our common stock paid to such holder and the tax withheld, if any, with respect to such distributions, regardless of whether withholding was required. This information also may be made available under a specific treaty or agreement with the tax authorities in the country in which the non-U.S. holder resides or is established. A non-U.S. holder will generally be subject to backup withholding at the then applicable rate for dividends paid to such holder unless such holder furnishes a valid IRS Form W-8BEN (or such other applicable form and documentation as required by the Code or the Treasury regulations) certifying under penalties of perjury that it is a non-U.S. holder (and the payor does not have actual knowledge or reason to know that such holder is a United States person as defined under the Code), or otherwise establishes an exemption. Dividends paid to non-U.S. holders subject to U.S. federal withholding tax, as described above in Distributions, generally will be exempt from U.S. backup withholding.

Information reporting and, depending on the circumstances, backup withholding will apply to the payment of the proceeds of a sale or other disposition of shares of our common stock by a non-U.S. holder effected by or through the U.S. office of any broker, U.S. or foreign, unless the holder certifies that it is not a United States person (as defined under the Code) and satisfies certain other requirements, or otherwise establishes an exemption. Generally, information reporting and backup withholding will not apply to a payment of disposition proceeds to a non-U.S. holder where the transaction is effected outside the U.S. through a non-U.S. office of a broker. However, for information reporting purposes, dispositions effected through a non-U.S. office of a broker. Prospective investors should consult their own tax advisors regarding the application of the information reporting and backup withholding rules to them.

Copies of the information returns may be made available to the tax authorities in the country in which the non-U.S. holder resides or is incorporated under the provisions of an applicable treaty or agreement.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules may be allowed as a credit against a non-U.S. holder s U.S. federal income tax liability, if any, and may entitle such holder to a refund, provided that an appropriate claim is timely filed with the IRS.

## Foreign Account Tax Compliance Act

Under the Foreign Account Tax Compliance Act, or FATCA, a 30% withholding tax will apply to dividends on, or gross proceeds from the sale or other disposition of, shares of our common stock paid to certain non-U.S. entities (including financial intermediaries) unless various information reporting and due diligence requirements, which are different from and in addition to the certification requirements described elsewhere in this discussion, have been satisfied (generally relating to ownership of by U.S. persons of interests in or accounts with those entities). The withholding rules applicable to payments of dividends on our common stock will be phased in beginning January 1, 2014. The withholding rules will apply to payments of gross proceeds from dispositions of U.S. common stock beginning January 1, 2017.

Holders of our common stock should consult their tax advisors regarding the possible impact of FATCA on their investment in our common stock, including, without limitation, the process and deadlines for meeting the applicable requirements to prevent the imposition of the 30% withholding tax under FATCA.

#### UNDERWRITING

We and the underwriters named below have entered into an underwriting agreement with respect to the shares being offered. Subject to certain conditions, each underwriter has severally agreed to purchase the number of shares indicated in the following table. Goldman, Sachs & Co. and J.P. Morgan Securities, LLC are the representatives of the underwriters.

Underwriters	Number of Shares
Goldman, Sachs & Co.	
J.P. Morgan Securities, LLC	
Leerink Swann, LLC	
Sanford C. Bernstein & Co., LLC	

Total

The underwriters are committed to take and pay for all of the shares being offered, if any are taken, other than the shares covered by the option described below unless and until this option is exercised.

The underwriters have an option to buy up to an additional from us to cover sales by the underwriters of a greater number of shares than the total number set forth in the table above. They may exercise that option for 30 days. If any shares are purchased pursuant to this option, the underwriters will severally purchase shares in approximately the same proportion as set forth in the table above.

The following tables show the per share and total underwriting discounts and commissions to be paid to the underwriters by us. Such amounts are shown assuming both no exercise and full exercise of the underwriters option to purchase additional shares.

Paid by the Company	No Exercise	Full Exercise
Per Share	\$	\$
Total	\$	\$

Shares sold by the underwriters to the public will initially be offered at the initial public offering price set forth on the cover of this prospectus. Any shares sold by the underwriters to securities dealers may be sold at a discount of up to \$ per share from the initial public offering price. After the initial offering of the shares, the representatives may change the offering price and the other selling terms. The offering of the shares by the underwriters is subject to receipt and acceptance and subject to the underwriters right to reject any order in whole or in part.

We and our officers, directors, and holders of substantially all of our common stock, have agreed with the underwriters, subject to certain exceptions, not to dispose of or hedge any of their common stock or securities convertible into or exchangeable for shares of common stock during the period from the date of this prospectus continuing through the date 180 days after the date of the preliminary prospectus related to this offering, except with the prior written consent of the representatives. This agreement does not apply to any existing employee benefit plans. See Shares Available for Future Sale for a discussion of certain transfer restrictions.

Prior to the offering, there has been no public market for the shares. The initial public offering price has been negotiated among us and the representatives. Among the factors to be considered in determining the initial public offering price of the shares, in addition to prevailing market conditions, will be our historical performance, estimates of our business potential and earnings prospects, an assessment of our management and the consideration of the above factors in relation to market valuation of companies in related businesses.

We have filed an application to list the common stock on the NASDAQ Global Market under the symbol FMI .

In connection with the offering, the underwriters may purchase and sell shares of common stock in the open market. These transactions may include short sales, stabilizing transactions and purchases to cover positions created by short sales. Short sales involve the sale by the underwriters of a greater number of shares than they are required to purchase in the offering, and a short position represents the amount of such sales that have not been covered by subsequent purchases. A covered short position is a short position that is not greater than the amount of additional shares for which the underwriters option described above may be exercised. The underwriters may cover any covered short position by either exercising their option to purchase additional shares or purchasing shares in the open market. In determining the source of shares to cover the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase additional shares for which the option described above may be exercised. The underwriters above. Naked short sales are any short sales that create a short position greater than the amount of additional shares for which the option described above may be exercised. The underwriters must cover any such naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the common stock in the open market after pricing that could adversely affect investors who purchase in the offering. Stabilizing transactions consist of various bids for or purchases of common stock made by the underwriters in the open market prior to the completion of the offering.

The underwriters may also impose a penalty bid. This occurs when a particular underwriter repays to the underwriters a portion of the underwriting discount received by it because the representatives have repurchased shares sold by or for the account of such underwriter in stabilizing or short covering transactions.

Purchases to cover a short position and stabilizing transactions, as well as other purchases by the underwriters for their own accounts, may have the effect of preventing or retarding a decline in the market price of our stock, and together with the imposition of the penalty bid, may stabilize, maintain or otherwise affect the market price of the common stock. As a result, the price of the common stock may be higher than the price that otherwise might exist in the open market. The underwriters are not required to engage in these activities and may end any of these activities at any time. These transactions may be effected on NASDAQ, in the over-the-counter market or otherwise.

### **European Economic Area**

In relation to each Member State of the European Economic Area which has implemented the Prospectus Directive, each, a Relevant Member State, each underwriter has represented and agreed that with effect from and including the date on which the Prospectus Directive is implemented in that Relevant Member State, or the Relevant Implementation Date, it has not made and will not make an offer of shares to the public in that Relevant Member State prior to the publication of a prospectus in relation to the shares which has been approved by the competent authority in that Relevant Member State or, where appropriate, approved in another Relevant Member State and notified to the competent authority in that Relevant Member State, all in accordance with the Prospectus Directive, except that it may, with effect from and including the Relevant Implementation Date, make an offer of shares to the public in that Relevant Member State at any time:

(a) to legal entities which are authorised or regulated to operate in the financial markets or, if not so authorised or regulated, whose corporate purpose is solely to invest in securities;

- (b) to any legal entity which has two or more of (1) an average of at least 250 employees during the last financial year; (2) a total balance sheet of more than 43,000,000 and (3) an annual net turnover of more than 50,000,000, as shown in its last annual or consolidated accounts;
- (c) to fewer than 100 natural or legal persons (other than qualified investors as defined in the Prospectus Directive) subject to obtaining the prior consent of the representatives for any such offer; or
- (d) in any other circumstances which do not require the publication by us of a prospectus pursuant to Article 3 of the Prospectus Directive.

For the purposes of this provision, the expression an offer of shares to the public in relation to any shares in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and the shares to be offered so as to enable an investor to decide to purchase or subscribe the shares, as the same may be varied in that Relevant Member State by any measure implementing the Prospectus Directive in that Relevant Member State and the expression Prospectus Directive means Directive 2003/71/EC and includes any relevant implementing measure in each Relevant Member State.

Each underwriter has represented and agreed that:

- (a) it has only communicated or caused to be communicated and will only communicate or cause to be communicated an invitation or inducement to engage in investment activity (within the meaning of Section 21 of the Financial Services and Markets Act 2000, or FSMA) received by it in connection with the issue or sale of the shares in circumstances in which Section 21(1) of the FSMA does not apply to us; and
- (b) it has complied and will comply with all applicable provisions of the FSMA with respect to anything done by it in relation to the shares in, from or otherwise involving the United Kingdom.

The shares may not be offered or sold by means of any document other than (i) in circumstances which do not constitute an offer to the public within the meaning of the Companies Ordinance (Cap.32, Laws of Hong Kong), or (ii) to professional investors within the meaning of the Securities and Futures Ordinance (Cap.571, Laws of Hong Kong) and any rules made thereunder, or (iii) in other circumstances which do not result in the document being a prospectus within the meaning of the Companies Ordinance (Cap.32, Laws of Hong Kong), and no advertisement, invitation or document relating to the shares may be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere), which is directed at, or the contents of which are likely to be accessed or read by, the public in Hong Kong (except if permitted to do so under the laws of Hong Kong) other than with respect to shares which are or are intended to be disposed of only to persons outside Hong Kong or only to professional investors within the meaning of the Securities and Futures Ordinance (Cap. 571, Laws of Hong Kong) and any rules made thereunder.

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the shares may not be circulated or distributed, nor may the shares be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore, or the SFA, (ii) to a relevant person, or any person pursuant to Section 275(1A), and in accordance with the conditions, specified in Section 275 of the SFA or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Where the shares are subscribed or purchased under Section 275 by a relevant person which is: (a) a corporation (which is not an accredited investor) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or (b) a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary is an accredited investor, shares, debentures and units of shares and debentures of that corporation or the beneficiaries rights and interest in that trust shall not be transferable for 6 months after that corporation or that trust has acquired the shares under Section 275 except: (1) to an institutional investor under Section 274 of the SFA or to a relevant person, or any person pursuant to Section 275(1A), and in accordance with the conditions, specified in Section 275 of the SFA; (2) where no consideration is given for the transfer; or (3) by operation of law.

The securities have not been and will not be registered under the Financial Instruments and Exchange Law of Japan, or the Financial Instruments and Exchange Law, and each underwriter has agreed that it will not offer or sell any securities, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan (which term as used herein means any person resident in Japan, including any corporation or other entity organized under the laws of Japan), or to others for re-offering or resale, directly or indirectly, in Japan or to a resident of Japan, except pursuant to an exemption from the registration requirements of, and otherwise in compliance with, the Financial Instruments and Exchange Law and any other applicable laws, regulations and ministerial guidelines of Japan.

The underwriters do not expect sales to discretionary accounts to exceed 5% of the total number of shares offered.

We estimate that our share of the total expenses of the offering, excluding underwriting discounts and commissions, will be approximately \$\$...

We have agreed to indemnify the several underwriters against certain liabilities, including liabilities under the Securities Act.

The underwriters and their respective affiliates are full service financial institutions engaged in various activities, which may include sales and trading, commercial and investment banking, advisory, investment management, investment research, principal investment, hedging, market making, brokerage and other financial and non-financial activities and services. Certain of the underwriters and their respective affiliates have provided, and may in the future provide, a variety of these services to the issuer and to persons and entities with relationships with the issuer, for which they received or will receive customary fees and expenses.

In the ordinary course of their various business activities, the underwriters and their respective affiliates, officers, directors and employees may purchase, sell or hold a broad array of investments and actively trade securities, derivatives, loans, commodities, currencies, credit default swaps and other financial instruments for their own account and for the accounts of their customers, and such investment and trading activities may involve or relate to assets, securities and/or instruments of the issuer (directly, as collateral securing other obligations or otherwise) and/or persons and entities with relationships with the issuer. The underwriters and their respective affiliates may also communicate independent investment recommendations, market color or trading ideas and/or publish or express independent research views in respect of such assets, securities or instruments and may at any time hold, or recommend to clients that they should acquire, long and/or short positions in such assets, securities and instruments.

## LEGAL MATTERS

The validity of the shares of common stock offered by this prospectus will be passed upon for us by Goodwin Procter LLP, Boston, Massachusetts. Certain legal matters will be passed upon for the underwriters by Ropes & Gray LLP, Boston, Massachusetts.

### EXPERTS

The financial statements of Foundation Medicine, Inc. at December 31, 2011 and 2012, and for each of the two years in the period ended December 31, 2012, appearing in this Prospectus and Registration Statement have been audited by Ernst & Young LLP, independent registered public accounting firm, as set forth in their report thereon appearing elsewhere herein, and are included in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

## WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1 (File Number 333-190226) under the Securities Act with respect to the common stock we are offering by this prospectus. This prospectus does not contain all of the information included in the registration statement. For further information pertaining to us and our common stock, you should refer to the registration statement and to its exhibits. Whenever we make reference in this prospectus to any of our contracts, agreements or other documents, the references are not necessarily complete, and you should refer to the exhibits attached to the registration statement for copies of the actual contract, agreement or other document.

Upon the closing of the offering, we will be subject to the informational requirements of the Securities Exchange Act of 1934 and will file annual, quarterly and current reports, proxy statements and other information with the SEC. You can read our SEC filings, including the registration statement, over the Internet at the SEC s website at www.sec.gov. You may also read and copy any document we file with the SEC at its public reference facility at 100 F Street, N.E., Room 1580, Washington, D.C. 20549.

You may also obtain copies of the documents at prescribed rates by writing to the Public Reference Section of the SEC at 100 F Street, N.E., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the operation of the public reference facilities.

# FOUNDATION MEDICINE, INC.

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## **Report of Independent Registered Public Accounting Firm**

The Board of Directors and Stockholders of

Foundation Medicine, Inc.

We have audited the accompanying balance sheets of Foundation Medicine, Inc. (the Company) as of December 31, 2011 and 2012, and the related statements of operations and comprehensive loss, redeemable convertible preferred stock and stockholders deficit, and cash flows for the years then ended. 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 financial position of Foundation Medicine, Inc. at December 31, 2011 and 2012, and the results of its operations and its cash flows for the years then ended, in conformity with U.S. generally accepted accounting principles.

/s/ Ernst & Young LLP

Boston, Massachusetts

June 24, 2013, except for Note 14,

as to which the date is August 16, 2013

# FOUNDATION MEDICINE, INC.

## **Balance Sheets**

## (In thousands, except share and per share data)

Assets	Decem 2011	ber 31, 2012	June 30, 2013 (una	Pro Forma June 30, 2013 udited)
Current assets:				
Cash and cash equivalents	\$ 10,852	\$ 54,838	\$ 35,965	\$ 35,965
Accounts receivable	278	2,195	4,114	4,114
Inventory	318	803	725	725
Prepaid expenses and other current assets	313	550	1,004	1,004
Total current assets	11,761	58,386	41,808	41,808
Property and equipment, net	6,106	7,465	7,260	7,260
Restricted cash	161	161	1,886	1,886
Other assets	37	27	1,315	1,315
Total assets	\$ 18,065	\$ 66,039	\$ 52,269	\$ 52,269
Liabilities, redeemable convertible preferred stock and stockholders (deficit) equity				
Current liabilities:				
Accounts payable	\$ 1,369	\$ 1,609	\$ 2,109	\$ 2,109
Accrued expenses	1,039	3,463	3,530	3,530
Deferred revenue	154	1,622	2,090	2,090
Current portion of deferred rent	109	132	141	141
Current portion of notes payable	1,569	1,704	1,712	1,712
Total current liabilities	4,240	8,530	9,582	9,582
Deferred revenue, net of current portion		156	226	226
Notes payable, net of current portion	3,041	1,441	634	634
Deferred rent, net of current portion	419	287	1,504	1,504
Warrant to purchase preferred stock	94	225	328	
Restricted stock liability	119	139	106	106
Commitments and contingencies (Note 12)				
Redeemable convertible preferred stock, \$0.0001 par value per share:				
Series A redeemable convertible preferred stock; 33,700,000 shares authorized at December 31, 2011, 43,950,000 shares authorized at December 31, 2012 and June 30, 2013; 33,500,000 shares issued and outstanding at December 31, 2011, 43,750,000 shares issued and outstanding at December 31, 2012 and June 30, 2013, and no shares issued and outstanding at June 30, 2013 (pro forma) (aggregate liquidation				
preference of \$43,750 at December 31, 2012 and June 30, 2013) Series B redeemable convertible preferred stock; 24,762,134 shares authorized at December 31, 2012 and June 30, 2013; no shares issued and outstanding at December 31, 2011, 24,762,134 issued and outstanding at	32,455	42,962	43,045	
December 31, 2012 and June 30, 2013 and no shares issued and outstanding at June 30, 2013 (pro forma) (aggregate liquidation preference of \$55,962 at December 31, 2012 and June 30, 2013)		55,696	55,695	
Stockholders (deficit) equity: Common stock, \$0.0001 par value, 52,700,000 shares authorized at December 31, 2011, and 96,000,000 shares authorized at December 31, 2012 and June 30, 2013; 6,606,501, 10,909,771 and 12,761,284 shares issued and outstanding at December 31, 2011 and 2012 and June 30, 2013, respectively, and 81,273,418				
shares issued and outstanding at June 30, 2013 (pro forma)	1	1	1	8
Additional paid-in capital	2,122	3,421	5,357	104,349
Accumulated deficit	(24,426)	(46,819)	(64,209)	(64,140)
Total stockholders (deficit) equity	(22,303)	(43,397)	(58,851)	40,217

Total liabilities, redeemable convertible preferred stock and stockholders (deficit) equity

The accompanying notes are an integral part of these financial statements

# FOUNDATION MEDICINE, INC.

## Statements of Operations and Comprehensive Loss

(In thousands, except share and per share data)

	Years Ende 2011	d Decemb	oer 31, 2012		Six 2012	Months End June 30,	ed 2013
	2011		2012			(unaudited)	2013
Revenue	\$ 2,057	\$	10,645	\$	2,429		11,120
Costs and expenses:							
Cost of revenue	258		5,681		1,830	)	4,597
Sales and marketing	1,555		3,454		1,347	1	4,686
General and administrative	6,992		8,644		3,699	)	7,905
Research and development	9,023		14,777		6,623	5	11,079
Total costs and expenses	17,828		32,556		13,499	)	28,267
Loss from operations	(15,771)		(21,911)		(11,070	))	(17,147)
Other income (expense):							
Interest expense, net	(421)		(421)		(221	)	(141)
Other expense, net	(845)		(61)		(53	5)	(102)
Total other expense, net	(1,266)		(482)		(274	-)	(243)
Net loss	\$ (17,037)	\$	(22,393)	\$	(11,344	) \$	(17,390)
Accretion of redeemable convertible preferred stock	(296)		(286)		(162	2)	(92)
Net loss applicable to common stockholders	\$ (17,333)	\$	(22,679)	\$	(11,506	<b>5</b> ) \$	(17,482)
Net loss per common share applicable to common stockholders, basic and diluted	\$ (3.52)	\$	(2.62)	\$	(1.54	\$) \$	(1.48)
Weighted-average common shares outstanding, basic and diluted	4,930,634		8,667,326	ĩ	7,485,723	; ]	1,803,985
Pro forma net loss per common share applicable to common stockholders, basic and diluted (unaudited)		\$	(0.41)			\$	(0.22)
Pro forma weighted-average common shares outstanding, basic and diluted (unaudited)		5	5,642,878			٤	30,516,119
Comprehensive loss	\$ (17,037)	\$	(22,393)	\$	(11,344	•) \$	(17,390 )

The accompanying notes are an integral part of these financial statements

# FOUNDATION MEDICINE, INC.

## Statements of Redeemable Convertible Preferred Stock and Stockholders (Deficit) Equity

(In thousands, except share and per share data)

	Series Redeem Convert Preferred	able ible	Series Redeema Converti Preferred S	ible ble	Common S		Additional Paid-In	Accumulated	Total Stockholders (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Deficit	Equity
Balance at December 31, 2010	7,000,000	\$ 5,821		\$	3,651,625	\$	\$	\$ (7,389)	
Issuance of Series A redeemable convertible preferred stock, net of issuance costs of \$162	26,500,000	26,338							
Settlement of Series A investor rights obligation Accretion of redeemable convertible							2,331		2,331
preferred stock to redemption value Vesting of restricted stock		296			2,954,876	1	(296) 14		(296) 15
Stock-based compensation expense Net loss							73	(17,037)	73 (17,037)
Balance at December 31, 2011 Issuance of Series A redeemable	33,500,000	32,455			6,606,501	1	2,122	(24,426)	(22,303)
convertible preferred stock, net of issuance costs of \$22	10,250,000	10,228							
Issuance of Series B redeemable convertible preferred stock, net of issuance costs of \$273	., ,	-, -	24,762,134	55,689					
Accretion of redeemable convertible									
preferred stock to redemption value		279		7			(286)		(286)
Vesting of restricted stock					4,303,270		50		50
Stock-based compensation expense Net loss							1,535	(22,393)	1,535 (22,393)
Balance at December 31, 2012	43,750,000	42,962	24,762,134	55,696	10,909,771	1	3,421	(46,819)	(43,397)
Issuance costs related to Series B preferred stock offering <i>(unaudited)</i>				(10)					
Accretion of redeemable convertible preferred stock to redemption value (unaudited)		83		9			(92)		(92)
Issuance of common stock in exchange for services ( <i>unaudited</i> )					2,534		4		4
Exercise of stock options (unaudited)					15,000		3		3
Vesting of restricted stock (unaudited)					1,833,979		26		26
Stock-based compensation expense (unaudited)							1,995	(17.200)	1,995
Net loss (unaudited)								(17,390)	(17,390)
Balance at June 30, 2013 ( <i>unaudited</i> )	43,750,000	43,045	24,762,134	55,695	12,761,284	1	5,357	(64,209)	(58,851)
Conversion of redeemable convertible preferred stock into common stock ( <i>unaudited</i> )	(43,750,000)	(43,045)	(24,762,134)	(55,695)	68,512,134	7	98,664	69	98,740
Reclassification of warrant to purchase redeemable convertible preferred stock into warrant to	(15,750,000)	(15,045)	(21,702,104)	(55,075)	00,012,134	,	328	07	328

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purchase common stock (unaudited)			
Pro forma balance at June 30, 2013 ( <i>unaudited</i> )	\$ \$	81,273,418 \$ 8 \$ 104,349	\$ (64,140) \$ 40,217

The accompanying notes are an integral part of these financial statements

# FOUNDATION MEDICINE, INC.

## **Statements of Cash Flows**

## (In thousands)

	Years Ended December 31,		Six Months Ended June 30,		
	2011 2012		2012	2013	
			(unau	dited)	
Operating activities					
Net loss	\$ (17,037)	\$ (22,393)	\$ (11,344)	\$ (17,390)	
Adjustments to reconcile net loss to cash used in operating activities:	1.500	<b>2</b> 00 4	1.0/0	0.070	
Depreciation and amortization expense	1,520	2,894	1,262	2,073	
Change in fair value of investor rights obligation	1,067	101	50	100	
Change in fair value of warrant liability	34	131	52	103	
Stock-based compensation	73	1,535	508	1,995	
Common stock issued in exchange for services	111	104	50	4	
Non-cash interest expense	111	104	59	35	
Changes in operating assets and liabilities:	072	(1.017)	(1.0(2))	(1.010)	
Accounts receivable	973	(1,917)	(1,863)	(1,919)	
Inventory	(318)	(485)	(296)	78	
Prepaid expenses and other current assets	(70)	(237)	(275)	(454)	
Other assets	(8)	10	(170)	4	
Accounts payable	(338)	147	(179)	400	
Accrued expenses	580	1,447	642	67	
Deferred rent	376	(109)	(52)	756	
Deferred revenue	(1,096)	1,624	484	538	
Net cash used in operating activities	(14,133)	(17,249)	(11,002)	(13,710)	
Investing activities					
Purchases of property and equipment	(5,410)	(3,183)	(1,678)	(1,298)	
Increase in restricted cash				(1,725)	
Net cash used in investing activities	(5,410)	(3,183)	(1,678)	(3,023)	
Financing activities					
Proceeds from issuance of restricted stock and stock option exercises	114	70	(4)	(4)	
Proceeds from issuance of Series A Preferred Stock and related investor rights, net					
of issuance costs	26,338	10,228	10,228		
Proceeds from issuance of Series B Preferred Stock, net of issuance costs		55,689		(10)	
Issuance costs related to planned issuance of common stock				(1,292)	
Proceeds from issuance of notes payable	2,974				
Payments of notes payable	(440)	(1,569)	(769)	(834)	
Net cash provided by (used in) financing activities	28,986	64,418	9,455	(2,140)	
Net increase (decrease) in cash and cash equivalents	9,443	43,986	(3,225)	(18,873)	
Cash and cash equivalents at beginning of period	1,409	10,852	10,852	54,838	
Cash and cash equivalents at end of period	\$ 10,852	\$ 54,838	\$ 7,627	\$ 35,965	
Supplemental disclosure of cash flow information					
Cash paid for interest	\$ 308	\$ 305	\$ 169	\$ 103	
Supplemental disclosure of non-cash investing and financing activities					
Supplemental discostre of non-cash investing and infancing activities	\$ 2,331	\$	\$	\$	
Settement of investor rights obligation	φ 2,331	φ	φ	φ	
Accretion of convertible preferred stock to redemption value	\$ 296	\$ 286	\$ 162	\$ 92	

Acquisition of property and equipment included in accounts payable and accrued						
expenses	\$ 816	9	1,070	\$ 562	\$	100
-						

The accompanying notes are an integral part of these financial statements

## FOUNDATION MEDICINE, INC.

#### Notes to Financial Statements

#### Years Ended December 31, 2011 and 2012

#### and Six Months Ended June 30, 2012 and 2013

(Information as of June 30, 2013 and for the six months ended June 30, 2012 and 2013 is unaudited)

#### 1. Nature of Business

Foundation Medicine, Inc. (the Company ) is a commercial-stage company focused on fundamentally changing the way patients with cancer are treated. The Company s proprietary molecular information platform generates actionable genomic information about a patient s individual disease, enabling physicians to optimize treatments in clinical practice and enabling biopharmaceutical companies to develop targeted oncology therapies more effectively. The Company s first clinical product, FoundationOne, which commenced its formal commercial launch in June 2012, is the only commercially available comprehensive molecular information product designed for use in routine patient care.

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 cash resources of \$54,838,000 at December 31, 2012 will be sufficient to allow the Company to fund its current operating plan through January 1, 2014, and into the foreseeable future. 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 other sources of capital.

#### 2. Summary of Significant Accounting Policies

#### A. Basis of Presentation

The Company s financial statements have been prepared in conformity with generally accepted accounting principles in the United States of America (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).

## 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 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 financial statements include revenue recognition, the fair value of liability-classified warrants, accrued expenses, the determination of the fair value of stock awards issued, stock-based compensation expense, and the valuation allowance on the company s deferred tax asset.

## FOUNDATION MEDICINE, INC.

#### Notes to Financial Statements

The Company utilizes significant estimates and assumptions in determining the fair value of its Common Stock. The Company utilized various valuation methodologies in accordance with the framework of the 2004 American Institute of Certified Public Accountants Technical Practice Aid, *Valuation of Privately-Held Company Equity Securities Issued as Compensation*, to estimate the fair value of its Common Stock. Each valuation methodology includes estimates and assumptions that require the Company s judgment. These estimates and assumptions include a number of objective and subjective factors, including external market conditions, the prices at which the Company sold shares of preferred stock, the superior rights and preferences of securities senior to the Company s common stock at the time and the likelihood of achieving a liquidity event, such as an initial public offering or sale. Significant changes to the key assumptions used in the valuations could result in different fair values of common stock at each valuation date.

#### C. Unaudited Interim Presentation

The accompanying interim balance sheet as of June 30, 2013, the statements of operations and comprehensive loss and cash flows for the six months ended June 30, 2012 and 2013 and the statement of redeemable convertible preferred stock and stockholders deficit for the six months ended June 30, 2013 and the related footnote disclosures are unaudited. These unaudited interim financial statements have been prepared in accordance with GAAP. In management s opinion, the unaudited interim financial statements have been prepared on the same basis as the audited financial statements and include all adjustments, which include only normal recurring adjustments necessary for the fair presentation of its statement of financial position as of June 30, 2013 and its statements of operations and comprehensive loss and cash flows for the six months ended June 30, 2012 and 2013. The results for the six months ended June 30, 2013 are not necessarily indicative of the results expected for the full fiscal year.

#### D. Unaudited Pro Forma Presentation

In 2013, the Company s board of directors (the Board ) authorized management of the Company to pursue the filing of a registration statement with the Securities and Exchange Commission (SEC) for the Company to sell shares of its common stock to the public. Immediately prior to the consummation of this offering, all outstanding shares of redeemable convertible preferred stock will automatically convert into common stock and a warrant exercisable for redeemable convertible preferred stock will convert into a warrant exercisable for common stock. The unaudited pro forma balance sheet information as of June 30, 2013 assumes the conversion of all outstanding redeemable convertible preferred stock as of that date into 68,512,134 shares of common stock, resulting in the reclassification of the related redeemable convertible preferred stock warrant liability to additional paid-in capital. The unaudited pro forma net loss per share applicable to common stock into shares of common stock outstanding redeemable convertible preferred stock outstanding, including the pro forma effect of the conversion of all outstanding redeemable convertible preferred stock outstanding, including the pro forma effect of the conversion of all outstanding redeemable convertible preferred stock into shares of common stock, as if such conversion had occurred at the beginning of the respective periods, or the date of issuance, if later. The impact of the accretion of the redeemable convertible preferred stock has been excluded from the determination of net loss applicable to common stockholders used to compute pro forma net loss per share. Upon conversion of the redeemable convertible preferred stock are not entitled to receive undeclared dividends.

## FOUNDATION MEDICINE, INC.

#### Notes to Financial Statements

#### E. 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.

#### F. 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 genomic 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 two customers, was \$0, \$788,000, \$298,000 and \$715,000 for the years ended December 31, 2011 and 2012 and the six months ended June 30, 2012 and 2013, respectively.

## G. Cash and Cash Equivalents

The Company considers all highly liquid investments with original or remaining 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 market value.

## H. 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 direct-bill relationships for tests performed using its molecular information. 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 O). 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, 2011 and 2012 or at June 30, 2013.

Two accounts consisting of \$148,000 and \$94,000 represented 53% and 34%, respectively, of accounts receivable at December 31, 2011. Three accounts consisting of \$784,000, \$469,000 and \$436,000 represented 36%, 21% and 20%, respectively, of accounts receivable at December 31, 2012. Two accounts consisting of \$1,963,000 and 588,000 represented 48%, and 14%, respectively, of accounts receivable at June 30, 2013.

## FOUNDATION MEDICINE, INC.

#### Notes to Financial Statements

#### I. 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, 2011 and 2012 and June 30, 2013, inventory consisted of the following:

	I	December 31,			ne 30,
	2011		2012 ousands)	2	2013
Raw materials	\$ 318	\$	406	\$	532
Work-in-process			397		193
	\$ 318	\$	803	\$	725

#### J. Deferred Issuance Costs

Deferred issuance costs, which primarily consist of direct incremental legal and accounting fees relating to the potential IPO, are capitalized. The deferred issuance costs will be offset against IPO proceeds upon the consummation of the offering. In the event the offering is terminated, deferred issuance costs will be expensed. \$0, \$0 and \$1,292,000 were capitalized and deferred as of December 31, 2011 and 2012 and June 30, 2013.

#### K. 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:

	Estimated Useful Life
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
	and an abtained for internal case in sheding anternal dise

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 the future net undiscounted cash flows 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 exceed 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 through June 30, 2013. (See Note 3)

### FOUNDATION MEDICINE, INC.

#### Notes to Financial Statements

#### L. Grants

In March 2011, the Company received notification from the Internal Revenue Service (IRS) that it had been awarded a grant in the amount of \$244,479 pursuant to the qualifying therapeutic discovery grant program established by the IRS and the Secretary of Health and Human Services under the Patient Protection and Affordable Care Act of 2010. The grant was made with respect to certain of the Company's qualifying research and development programs. The Company received the full amount related to the grant during 2011, and this amount was recorded as other income in the statement of operations and comprehensive loss for the year ended December 31, 2011.

#### M. Restricted Cash

Restricted cash consists of deposits securing collateral letters of credit issued in connection with the Company s operating leases. As of December 31, 2011 and 2012 and June 30, 2013, the Company had restricted cash of \$161,000, \$161,000 and \$1,886,000, respectively.

#### N. 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 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 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 5)

#### O. 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.

## FOUNDATION MEDICINE, INC.

#### Notes to Financial Statements

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. Criteria (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 the collectability of the fee is reasonably assured.

The Company recognizes revenue on a cash basis when it cannot conclude that criterion (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 patients who make co-payments, pay deductibles or other amounts that the Company has been unable to collect from third-party payors. 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 our products. As a result, the Company does not charge customers state sales tax. The Company expects to use 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 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 over a defined period. The Company recognizes revenue upon delivery of the test results, or over the period the testing volume is provided, as appropriate.

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, and in assessing whether each deliverable is a separate unit of accounting. 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 \$1,750,000 of revenue, represented 85% of the Company s total revenue for the year ended December 31, 2011. Two customer arrangements, consisting of \$4,233,000 and \$1,339,000 of revenue, represented 40% and 13%, respectively, of the Company s revenue for the year ended December 31, 2012. Two customer arrangements, consisting of \$1,058,000 and \$544,000 of revenue, represented 44% and 22%, respectively, of the

## FOUNDATION MEDICINE, INC.

#### Notes to Financial Statements

Company s revenue for the six months ended June 30, 2012. One customer arrangement, consisting of \$3,425,000 of revenue, represented 31% of the Company s revenue for the six months ended June 30, 2013.

#### P. 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.

## Q. Redeemable Convertible Preferred Stock

The carrying value of the Company s Series A and Series B redeemable convertible preferred stock (individually, the Series A Preferred Stock and the Series B Preferred Stock , and collectively, the Preferred Stock ) is adjusted by periodic accretions such that the carrying value will equal the redemption amount at the redemption date. The carrying value is also adjusted to reflect dividends, when and if declared by the Board. The Board has not declared any dividends since inception.

### R. 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 the input of and 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 a public market for the trading of its common stock and a 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 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

## FOUNDATION MEDICINE, INC.

#### Notes to Financial Statements

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 9)

### S. 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. (See Note 19)

#### T. 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 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.

The amounts in the table below were excluded from the calculation of diluted weighted-average shares outstanding, prior to the use of the treasury stock method, due to their anti-dilutive effect:

	Year Ended D	Six Months Ended June 30,	
	2011	2012	2013
Series A Preferred Stock	33,500,000	43,750,000	43,750,000
Series B Preferred Stock		24,762,134	24,762,134
Series A Preferred Stock warrant	200,000	200,000	200,000
Outstanding stock options	607,750	4,885,629	8,691,566
Unvested restricted stock	9,406,010	5,694,792	3,850,813

43,713,760 79,292,555 81,254,513

The calculations for the unaudited pro forma basic and diluted net loss per share assume the conversion of all outstanding shares of Preferred Stock into shares of common stock, as if the

## FOUNDATION MEDICINE, INC.

#### Notes to Financial Statements

conversions had occurred at the beginning of the period or at the date of issuance if such shares were issued during the period. The impact of the accretion of the Preferred Stock has been excluded from the determination of pro forma net loss applicable to common stockholders. The holders of Preferred Stock are not entitled to receive undeclared dividends upon such conversion.

## U. Comprehensive Income (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 has been disclosed in the accompanying statements of operations and comprehensive loss and equals the Company s net loss for all periods presented.

#### V. 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.

## W. 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.

#### X. Subsequent Events

The Company considers events or transactions that occur after the balance sheet date but prior to the issuance of the financial statements to provide additional evidence relative to certain estimates or to identify matters that require additional disclosure. (See Note 14)

## FOUNDATION MEDICINE, INC.

#### Notes to Financial Statements

### 3. Property and Equipment

Property and equipment and related accumulated depreciation and amortization are as follows:

	December 31,		June 30,	
	2011	2012 (in thousands)	2013	
Lab equipment	\$ 5,166	\$ 8,163	\$ 9,176	
Computer equipment	1,024	2,904	3,021	
Software	144	188	188	
Furniture and office equipment	411	425	678	
Leasehold improvements	440	474	475	
Construction in progress	717		484	
	7,902	12,154	14,022	
Less accumulated depreciation and amortization	(1,796)	(4,689)	(6,762)	
	\$ 6,106	\$ 7,465	\$ 7,260	

Depreciation and amortization expense for the years ended December 31, 2011 and 2012 and the six months ended June 30, 2012 and 2013 was \$1,520,000, \$2,894,000, \$1,262,000 and \$2,073,000, 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, 2011 and 2012 and the six months ended June 30, 2012 and 2013 was \$0, \$221,000, \$25,000 and \$451,000, respectively. The remaining unamortized capitalized internal use software costs at December 31, 2011 and 2012 and June 30, 2012 and 2013 were \$0, \$1,157,000, \$879,000 and \$927,000, respectively.

### 4. Accrued Expenses

Accrued expenses consisted of the following:

	Decer 2011	nber 31, 2012 (in thousands	June 30, 2013
Payroll and employee-related costs	\$ 285	\$ 1,672	\$ 1,773
Professional services	328	670	1,534
Equipment purchases	179	977	
Other	247	144	223
	\$ 1,039	\$ 3,463	\$ 3,530

#### 5. 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.

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The Company s financial instruments consist of cash and cash equivalents, accounts receivable, accounts payable, accrued liabilities, notes payable, and a warrant to purchase Series A Preferred Stock. The carrying amount of cash and cash equivalents, accounts receivable, accounts payable,

## FOUNDATION MEDICINE, INC.

## Notes to Financial Statements

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 is similar to its existing interest rates. The fair value measurements of the Company s cash held in money market funds and warrant liability at December 31, 2011 and 2012 and June 30, 2013 is summarized in the table below:

	Fair Value Measurement at December 31, 2011			l		
	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2) (in th	Unobs Inj	ificant cervable puts vel 3)	T	otal
Assets:			, i i			
Cash held in money market funds	\$ 8,500	\$	\$		\$ 8	,500
Total	\$ 8,500	\$	\$		\$ 8	,500
Liabilities:						
Warrant to purchase preferred stock	\$	\$	\$	94	\$	94
Total	\$	\$	\$	94	\$	94

	Fa Quoted Prices in Active Markets (Level 1)	ir Value Measurem Significant Other Observable Inputs (Level 2) (in th	ent at December Significan Unobservat Inputs (Level 3) ousands)	t ole
Assets:			,	
Cash held in money market funds	\$ 37,500	\$	\$	\$ 37,500
Total	\$ 37,500	\$	\$	\$ 37,500
Liabilities:				
Warrant to purchase preferred stock	\$	\$	\$ 22	5 \$ 225
Total	\$	\$	\$ 22	5 \$ 225

Fair Value Measurement at June 30, 2013				
Quoted Prices	Significant	Significant	Total	
in Active	Other	Unobservable		
Markets (Level 1)	Observable Inputs	Inputs		

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		(Level 2)	(Level 3	5)	
Assets:		(in th	ousands)		
Cash held in money market funds	\$ 34,000	\$	\$	\$	5 34,000
Total	\$ 34,000	\$	\$	\$	34,000
Liabilities:					
Warrant to purchase preferred stock	\$	\$	\$ 3	328 \$	328
Total	\$	\$	\$ 3	328 \$	328

# FOUNDATION MEDICINE, INC.

#### Notes to Financial Statements

The following table sets forth a summary of changes in the fair value of the Company s preferred stock warrant liability which represents a recurring measurement that is classified within Level 3 of the fair value hierarchy, wherein fair value is estimated using significant unobservable inputs (See Note 6):

	Year End	led December 31,		hs Ended e 30,
	2011	2012	2012	2013
		(in th	nousands)	
Beginning balance	\$ 60	\$ 94	\$ 94	\$ 225
Change in fair value	34	131	53	103
Ending balance	\$ 94	\$ 225	\$ 147	\$ 328

This liability represents a warrant to purchase Series A Preferred Stock that was issued in conjunction with the loan agreement, as more fully described in Note 6. The fair value of the warrant is calculated using a Black-Scholes option pricing model. See Note 6 for further discussion, as well as for a summary of the significant inputs and assumptions used to determine the fair value of the warrant.

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 in the years ended December 31, 2011 and 2012 and the six months ended June 30, 2013.

#### 6. 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 Loan Agreement ). 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 makes 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 is secured by certain property and equipment. The final payments are amortized over the term of the advances and recorded in interest expense. Based on the current advances outstanding at June 30, 2013, the final payment will be made on December 31, 2014. At December 31, 2011 and 2012 and June 30, 2013, there was \$4,610,000, \$3,145,000 and \$2,346,000, respectively, outstanding under the Loan Agreement, which includes \$87,000, \$154,000 and \$197,000, respectively, of deferred interest payments due upon maturity of the loan.

Future principal payments under the Loan Agreement are as follows:

	December 31, 2012 (in thousands)
2013	\$ 1,704
2013 2014	1,287
	\$ 2,991

# FOUNDATION MEDICINE, INC.

#### Notes to Financial Statements

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 and June 30, 2013, the warrant is exercisable for 200,000 shares of Series A Preferred Stock. The warrant has an eight-year term and has not yet been exercised as of December 31, 2012 or June 30, 2013. In accordance with ASC 480-10, *Distinguishing Liabilities from Equity*, the freestanding warrant for the Company s redeemable convertible preferred shares is recognized as a liability and recorded at fair value. The initial fair value of the warrant of \$60,000 was recorded as a liability and a discount to notes payable and is being accreted to interest expense over the term of the notes.

On December 31, 2011 and 2012 and on June 30, 2013, the warrant was revalued, resulting in increases of \$34,000, \$131,000 and \$103,000, respectively. The warrant liability will be reported at fair value until the warrants are either exercised or expire. The fair value of the warrant was calculated using the Black-Scholes valuation model with the following assumptions:

		Year Ended December 31,		Six Months Ended June 30,	
	2011	2012	2012	2013	
Expected volatility	68.6%	68.0%	68.8%	67.5%	
Risk-free interest rate	1.35%	0.72%	1.11%	1.41%	
Expected life (in years)	6.85	5.85	6.36	5.36	
Expected dividend vield	%	%	%	%	

Reasonable changes in the assumptions used to value the warrant would not have a material impact on the liability balance at the end of any reporting period presented.

#### 7. Redeemable Convertible Preferred Stock

As of December 31, 2012 and June 30, 2013, the authorized capital stock of the Company included 68,712,134 shares of preferred stock, \$0.0001 par value, of which 43,950,000 shares are designated Series A Preferred Stock and 24,762,134 are designated Series B Preferred Stock.

In March 2010, the Company issued 7,000,000 shares of Series A Preferred Stock for cash proceeds of \$7,000,000 (the Series A financing). In accordance with the terms of the Series A Preferred Stock Purchase Agreement for the Series A financing, the Company committed to sell up to an additional 18,000,000 shares of Series A Preferred Stock to existing holders of Series A Preferred Stock (Series A Investors) and to new investors, if any, for total proceeds of \$18,000,000 upon the achievement of pre-defined milestones.

The right of the investors (the Investor Rights Obligation ) to purchase Series A Preferred Stock represented a freestanding financial instrument. As such, the Company accounted for the Investor Rights Obligation as a liability. The Company adjusted the carrying value of the liability to its estimated fair value at each reporting date through the closing of the final tranche of the Series A financing. Increases or decreases in the fair value of the liability was determined using a valuation model, which considers the probability of achieving the pre-defined milestones, the entity s cost of capital, the estimated period the rights will be outstanding, consideration received for the instrument with the rights, the number of shares to be issued to satisfy the rights, the price of such shares and any changes in the fair value of the underlying instrument. At the date of

# FOUNDATION MEDICINE, INC.

#### Notes to Financial Statements

issuance in March 2010, the Company recorded the Investor Rights Obligation at its initial estimated fair value of \$1,300,000. The change in fair value of the Investor Rights Obligation was \$1,067,000 for the year ended December 31, 2011, and was recorded as other expense in the accompanying statement of operations and comprehensive loss.

In early 2011, the Company issued 6,000,000 shares of Series A Preferred Stock for gross proceeds of \$6,000,000. In August 2011, the Company issued 15,000,000 shares of Series A Preferred Stock for gross proceeds of \$15,000,000 and committed to sell an additional 5,500,000 shares of Series A Preferred Stock to one of its Series A Investors for proceeds of \$5,500,000, which was completed in October 2011. The carrying value of the Investor Rights Obligation was settled in additional paid-in capital at the respective settlement dates throughout 2011, resulting in an increase of \$2,331,000 to additional paid-in capital.

In April of 2012, the Company issued 10,250,000 shares of Series A Preferred Stock at \$1.00 per share, for gross proceeds of \$10,250,000.

In September 2012, the Company issued 18,805,304 shares of Series B Preferred Stock at \$2.26 per share, for gross proceeds of \$42,500,000 (the Series B financing ). In December 2012, the Company issued 5,956,830 shares of Series B Preferred Stock for gross proceeds of \$13,462,000.

In connection with the Series B financing in September 2012, the Company amended certain rights and privileges of the Series A Investors. The Company adopted a qualitative policy pursuant to which it assessed whether the amendment fundamentally changed the nature of the preferred shares in order to determine the appropriate accounting treatment. The Company has accounted for the impact of the amendment as a modification of the Series A Preferred Stock due to the limited impact of the amended terms on the economic expectations of both the Company and the holders of the Series A Preferred Stock. The amendment included the forfeiture of accrued dividends and the removal of the Series A Preferred Stock liquidation preference above the original issue price, among other changes. The Company concluded that the removal of these rights led to a decrease in the fair value of the Series A Preferred Stock. Accordingly, the Company has not recorded the change in the statement of operations and comprehensive loss.

The rights, preferences, and privileges of the Preferred Stock are as follows:

#### Conversion

Shares of Preferred Stock are convertible into common stock on a one-for-one basis, adjustable for certain dilutive events. Conversion is at the option of the holders of Preferred Stock, although a conversion is automatic upon the earlier of (A) the consummation of a firm-commitment underwritten public offering resulting in (i) gross proceeds to the Company of at least \$30,000,000, (ii) at a price per share at least equal to \$2.49 (as adjusted for stock splits, stock dividends, combinations, subdivisions, recapitalizations, or certain dilutive events) and (iii) the listing of the common stock on a nationally recognized securities exchange or trading system, or (B) the consent of at least 60% of the holders of the Series A Preferred Stock with respect to the shares of Series A Preferred Stock, or at least two-thirds of the holders of the Series B Preferred Stock with respect to the shares of Series B Preferred Stock.

The Company performs assessments of all terms and features of its redeemable convertible preferred stock in order to identify any potential embedded features that would require bifurcation or any beneficial conversion features. As part of this analysis, the Company assessed the economic characteristics and risks of its Preferred Stock, including conversion, liquidation and redemption

# FOUNDATION MEDICINE, INC.

#### Notes to Financial Statements

features, as well as dividend and voting rights. Based on the Company s determination that each series of its Preferred Stock is an equity host, the Company determined that the features of the Preferred Stock are most closely associated with an equity host, and, although the Preferred Stock includes conversion features, such conversion features do not require bifurcation as a derivative liability.

The Company accounts for potentially beneficial conversion features under ASC 470-20, *Debt with Conversion and other Options*. At the time of each of the issuances of Preferred Stock, the common stock into which the Series A Preferred Stock and B Preferred Stock is convertible had a fair value less than the effective conversion price of the Preferred Stock and as such, there was no intrinsic value on the respective commitment dates.

## Dividends

Holders of the Preferred Stock are entitled to receive dividends when, as and if declared by the Board.

## Liquidation Preference

Holders of the Preferred Stock have preferences to the assets of the Company in the event of any voluntary or involuntary liquidation or dissolution of the Company, including a change of control. Upon such an event, the holders of the Preferred Stock are entitled to receive, on a pari passu basis, an amount per share equal to their respective original purchase price (as adjusted for stock splits, stock dividends, combinations, subdivisions, recapitalizations, or certain dilutive events), plus any dividends declared but unpaid thereon.

#### Voting Rights

Holders of the Preferred Stock are entitled to vote as a single class with the holders of common stock, and shall have one vote for each equivalent common share into which the Preferred Stock is convertible. A two-thirds vote of the holders of Preferred Stock is required in order to amend the certificate of incorporation and the bylaws, pay or declare any dividends (except dividends payable solely in shares of common stock), reclassify common stock or establish another class of stock, create or authorize additional shares of Preferred Stock, effect a sale, liquidation or merger of the Company, repurchase or redeem any capital stock, or engage in any action which would adversely affect the holders of the Preferred Stock. A 60% vote of the holders of the Series A Preferred Stock is required to amend the Series A Preferred Stock.

#### Redemption

At any time on or after September 10, 2017, within 60 days of the receipt of a written request from the holders of at least two-thirds of the shares of the Preferred Stock, all of the outstanding shares of Preferred Stock are redeemable at a price equal to the greater of the respective original purchase price per share (as adjusted for stock splits, stock dividends, combinations, subdivisions, recapitalizations, or certain dilutive events) plus all declared but unpaid dividends, or the fair market value as determined by an independent third-party. If the Company does not have sufficient funds available to redeem the Preferred Stock on the redemption date, the Company shall redeem a pro rata portion of each holder s shares of Preferred Stock out of funds available and shall redeem the

# FOUNDATION MEDICINE, INC.

# Notes to Financial Statements

remaining shares as soon as practicable after the Company has funds available. The balance of any unpaid amounts at the redemption date shall accrue interest at 12% per annum.

As the Preferred Stock may become redeemable upon an event that is outside of the control of the Company, the Preferred Stock has been classified outside of permanent equity.

# 8. Stockholders (Deficit) Equity 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. 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.

The Company has reserved for future issuance the following number of shares of common stock:

	December 31, 2012	June 30, 2013
Series A Preferred Stock	43,750,000	43,750,000
Series B Preferred Stock	24,762,134	24,762,134
Series A Preferred Stock Warrant	200,000	200,000
Unvested restricted stock	5,694,792	3,850,813
Common stock options	4,885,629	8,691,566
Shares available for issuance under the 2010 Plan	1,009,808	1,968,871
	80,302,363	83,223,384

# FOUNDATION MEDICINE, INC.

#### Notes to Financial Statements

In November 2009, the Company issued 8,500,000 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 are subject to vesting and become fully vested in 2013. An additional 450,000 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. At December 31, 2012 and June 30, 2013, 2,190,104 and 1,100,000 of these shares, respectively, remain potentially subject to repurchase by the Company, and therefore are not considered outstanding for accounting purposes. The following table shows a roll forward of restricted stock activity outside of the 2010 Stock Plan, as discussed below:

	Number of Shares
Unvested at December 31, 2011	4,365,104
Granted	
Vested	(2,175,000)
Unvested at December 31, 2012	2,190,104
Granted	
Vested	(1,090,104)
Unvested at June 30, 2013	1,100,000

Total stock-based compensation expense recognized for restricted stock issued outside of the 2010 Plan was \$62,000, \$1,284,000, \$424,000 and \$1,638,000 for the years ended December 31, 2011 and 2012 and the six months ended June 30, 2012 and 2013, respectively. As of December 31, 2012 and June 30, 2013, \$2,168,000 and \$1,958,000, respectively, of unrecognized compensation expense related to restricted stock is expected to be recognized over weighted average periods of 0.9 and 0.4 years, respectively.

## 2010 Stock Incentive Plan

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 4,650,000 shares of common stock. In the years ended December 31, 2011 and 2012 and the six months ended June 30, 2013, the Company amended the 2010 Stock Plan to increase the number of shares of common stock available for issuance to 8,650,000, 12,150,000 and 16,930,000, respectively. As of December 31, 2012 and June 30, 2013 there were 1,009,808 and 1,968,871 awards, respectively, available for future grant under the 2010 Stock Plan.

Terms of stock award agreements, including vesting requirements, are determined by the board of directors, subject to the provisions of the 2010 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

# FOUNDATION MEDICINE, INC.

#### Notes to Financial Statements

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 on the date of grant.

## Restricted Stock

The 2010 Stock Plan allows for granting of restricted stock awards. For restricted stock 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 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:

	Number of Shares
Unvested at December 31, 2011	760,833
Granted	
Vested	(266,458)
Unvested at December 31, 2012	494,375
Granted	
Vested	(102,812)
Unvested at June 30, 2013	391,563

All restricted stock issued from the 2010 Stock Plan had a grant date fair value of \$0.02 per share. Total stock-based compensation expense recognized for restricted stock issued from the 2010 Stock Plan was \$2,000, \$36,000, \$12,000 and \$53,000 for the years ended December 31, 2011 and 2012 and the six months ended June 30, 2012 and 2013, respectively. As of December 31, 2012 and June 30, 2013, \$44,000 and \$40,000, respectively, of unrecognized compensation expense related to restricted stock issued from the 2010 Stock Plan is expected to be recognized over weighted-average periods of 2.5 and 2.0 years, respectively.

# FOUNDATION MEDICINE, INC.

# Notes to Financial Statements

Stock Options

A summary of stock option activity under the 2010 Stock Plan for the year ended December 31, 2012 and the six months ended June 30, 2013, is as follows:

	Number of Shares	Weighted- Average Remaining Weighted- Average Exercise Price (In Years) (in thousands, except share numbers)		Average Remaining Contractual Term (In Years)	Aggregate Intrinsic Value	
Outstanding as of December 31, 2011	607,750	\$	0.02			
Granted	5,014,629		0.33			
Exercised	(620,657)		0.13		\$	535
Cancelled	(116,093)		0.09			
Outstanding as of December 31, 2012	4,885,629	\$	0.32	9.3	\$	3,282
Granted	3,886,500		1.30			
Exercised	(15,000)		0.21		\$	24
Cancelled	(65,563)		0.65			
Outstanding as of June 30, 2013	8,691,566	\$	0.76	9.2	\$	8,900
Exercisable as of December 31, 2012	570,957	\$	0.17	8.9	\$	475
Vested and expected to vest at December 31, 2012(1)	4,454,162	\$	0.32	9.3	\$	3,001
Exercisable as of June 30, 2013	1,443,722	\$	0.25	8.6	\$	2,216
Vested and expected to vest at June 30, 2013(1)	7,966,782	\$	0.75	9.2	\$	8,231

(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.

Certain stock options contain provisions allowing for the early exercise into shares subject to repurchase. For the year ended December 31, 2012 and the six months ended June 30, 2013, 479,250 and no options, respectively, were exercised prior to vesting. At December 31, 2012 and June 30, 2013, 3,010,313 and 2,359,250 shares, which were early exercised, respectively, remain subject to repurchase, and therefore are not considered outstanding for accounting purposes.

The weighted-average fair value of options granted for the year ended December 31, 2012 and the six months ended June 30, 2013 was \$0.27 and \$0.80 per share, respectively. The Company recorded total stock-based compensation expense for stock options granted to employees, directors and non-employees from the 2010 Stock Plan of \$9,000, \$215,000, \$72,000 and \$304,000 during the year, ended December 31, 2011, 2012 and the six months ended June 30, 2012 and 2013, respectively. As of December 31, 2012 and June 30, 2013, unrecognized compensation cost of \$1,078,000 and \$3,578,000, respectively, related to non-vested employee stock-based compensation arrangements is expected to be recognized over weighted-average periods of 3.2 and 3.3 years, respectively.

# FOUNDATION MEDICINE, INC.

#### Notes to Financial Statements

The Company recorded stock-based compensation expense in the statements of operations and comprehensive loss as follows:

		s Ended nber 31, 2012	En Jun 2012 (unau	Ionths Ided Ie 30, 2013 Idited)
			usands)	
Cost of revenue	\$ 1	\$ 22	\$5	\$ 17
Sales and marketing		31	5	45
General and administrative	69	1,388	465	1,816
Research and development	3	94	33	117
Total	\$73	\$ 1,535	\$ 508	\$ 1,995

The weighted-average assumptions used to estimate the fair value of stock options using the Black-Scholes option pricing model were as follows:

		Years Ended December 31,		Six Months Ended June 30,	
	2011	2012	2012	2013	
Expected volatility	67.1%	68.8%	69.0%	67.1%	
Risk-free interest rate	2.56%	1.29%	1.35%	1.35%	
Expected option term (in years)	6.25	6.25	6.25	6.25	
Expected dividend yield	%	%	%	%	

#### 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.

For the years ended December 31, 2011 and 2012, the Company did not have a current or deferred income tax expense or benefit.

As of December 31, 2012 the Company had federal and state net operating loss carryforwards of approximately \$39,883,000 and \$39,146,000, respectively, which were available to reduce future taxable income. The net operating loss carryforwards expire at various times beginning in 2029 for federal purposes and 2014 for state purposes. The Company also had federal and state tax credits of approximately \$344,000 and \$758,000, 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 2024 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

# FOUNDATION MEDICINE, INC.

#### **Notes to Financial Statements**

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 recorded any reserves for uncertain tax positions as of December 31, 2011 or 2012. 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, 2012, 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:

	Decer	nber 31,
	2011 (in the	2012 Dusands)
Deferred tax assets:		
Net operating loss carryforwards	\$ 8,669	\$ 15,616
Research and development credits	649	845
Deferred revenue	60	697
Accrued bonus	86	593
Deferred rent	207	164
Other	13	68
Gross deferred tax assets	9,684	17,983
Deferred tax liability	(16)	(28)
Valuation allowance	(9,668)	(17,955)
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, 2011 and 2012, respectively, because the Company s management has determined that is it more likely than not that these assets will not be fully realized. The increase in the valuation allowance of \$8,287,000 in 2012 primarily relates to the net loss incurred by the Company during that period.

# FOUNDATION MEDICINE, INC.

## Notes to Financial Statements

A reconciliation of the income tax expense at the federal statutory tax rate to the Company s effective income tax rate follows:

	Year Ended De	cember 31,
	2011	2012
Statutory tax rate	34.0%	34.0%
State taxes, net of federal benefit	4.9	4.8
Permanent differences	(2.3)	(2.5)
Research and development credit	2.9	1.1
Other	(0.6)	(0.3)
Change in valuation allowance	(38.9)	(37.1)
Effective tax rate	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 agreement has an initial two year term beginning on the amendment date, during which Customer shall pay the Company \$14,200,000. The Customer may elect to extend the agreement for one additional year during which the Customer would pay the Company an additional \$7,900,000. The Company identified three deliverables under the agreement: provision of one full-time project manager, participation on a joint steering committee and the provision of sufficient laboratory capacity to test a minimum number of samples provided by Customer. The Company assessed the agreement as a multiple-element arrangement pursuant to ASC 605-25 *Revenue Recognition: Multiple-Element Arrangements*, and determined the deliverables were not separable due to a lack of stand-alone value for certain deliverables. The deliverables did not have standalone value as a result of the fact that the provision of a full-time project manager and the participation on a joint steering committee 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 services. Thus, the arrangement is accounted for as a single unit of accounting and revenue is being recognized over the initial two-year performance period. The Company recognized revenue of \$4,233,000 and \$3,425,000 for the year ended December 31, 2012 and the six months ended June 30, 2013, respectively.

# 11. Commitments and Contingencies

One Kendall Square

In May 2010, the Company commenced a facility lease which expires in October 2015. The lease is subject to fixed rate escalation increases. As a result, the Company recognizes rent expense on a straight-line basis for the full amount of the commitment including the minimum rent increases over the lease term. The future minimum rental payments under the lease are included in the future minimum rental payments below. The Company recorded \$803,000, \$875,000, \$438,000 and \$438,000 of rent expense in the years ended December 31, 2011 and 2012 and the six months ended June 30, 2012 and 2013, respectively, associated with this lease.

# FOUNDATION MEDICINE, INC.

#### Notes to Financial Statements

#### 150 Second Street

In 2013, the Company signed two additional facility leases. The first lease commenced in March 2013 and has a one year expected term. The second lease commences in September 2013 and has an eight year expected term. The second lease is subject to fixed rate escalation increases and the landlord waived \$3,300,000 of the Company s rent obligation. As a result, the Company will recognize rent expense on a straight-line basis over the expected lease term. The Company began recording rent expense in April 2013 upon gaining access to and control of the space. The landlord has also agreed to fund up to \$9,200,000 million in tenant improvements. The Company records the tenant improvements as assets and deferred rent on the balance sheet. Deferred rent is amortized as a reduction in rent expense over the term of the lease agreement. Upon execution of the lease agreement, the Company paid a security deposit of \$1,725,000, which is included in restricted cash as of June 30, 2013. The future minimum rent payments under the leases total \$27,028,000.

As of December 31, 2012, the minimum future rent payments under the Company s lease agreements are as follows:

	(in thousa	(in thousands)	
2013	\$ 1,	,007	
2014	1,	,030 863	
2015		863	
Total minimum lease payments	\$ 2.	,900	

Total minimum lease payments

## 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 paid this investor approximately \$535,000, \$362,000 and \$117,767 for these services during the years ended December 31, 2011 and 2012 and the six months ended June 30, 2013, respectively. Of these amounts, \$4,000, \$92,000 and \$1,000 of amounts due to the investor were included in accounts payable and accrued expenses at December 31, 2011 and 2012 and June 30, 2013, respectively.

The Company recognized revenue of \$287,000 and \$526,000 in the year ended December 31, 2012 and the six months ended June 30, 2013, respectively, from an arrangement with an investor executed in the year ended December 31, 2012. Of these amounts, \$88,000 and \$0 were included in accounts receivable at December 31, 2012 and June 30, 2013, respectively.

#### 13. 401(k) Savings Plan

The Company maintains a defined contribution savings plan covering all eligible U.S. employees under Section 401(k) of the Internal Revenue Code. Company contributions to the plan may be made at the discretion of the Board. To date, the Company has not made any contributions to the plan.

# FOUNDATION MEDICINE, INC.

#### Notes to Financial Statements

# 14. Subsequent Events

The Company has completed an evaluation of all subsequent events after the audited balance sheet date of December 31, 2012 and the unaudited balance sheet date of June 30, 2013 through June 24, 2013, the date this Registration Statement on Form S-1 was confidentially submitted to the SEC, to ensure that this filing includes appropriate disclosure of events both recognized in the financial statements as of December 31, 2012 and June 30, 2013, and events which occurred subsequently but were not recognized in the financial statements. Except as described below, the Company has concluded that no subsequent event has occurred that requires disclosure.

## Supply Agreement

In July 2013, the Company entered into a Supply, Service and Support Agreement with Illumina, Inc., under which the Company agreed to purchase a minimum quantity of reagents and other consumables and access to services and capital equipment over a five-year term. The Company s minimum purchase commitment over the term of the agreement is approximately \$6,100,000 as of the effective date.

Shares

# Foundation Medicine, Inc.

Common Stock

Goldman, Sachs & Co.

J.P. Morgan

Leerink Swann

Sanford C. Bernstein

# PART II

## **Information Not Required in Prospectus**

#### Item 13. Other Expenses of Issuance and Distribution.

The following table sets forth the fees and expenses, other than underwriting discounts and commissions, payable in connection with the registration of the common stock hereunder. All amounts are estimates except the SEC registration fee.

	<b>A</b> 11 <b>B</b> C
SEC registration fee	\$ 11,765
FINRA filing fee	*
NASDAQ listing fee	*
Blue Sky fees and expenses	*
Printing and engraving expenses	*
Legal fees and expenses	*
Accounting fees and expenses	*
Transfer agent and registrar fees and expenses	*
Miscellaneous	*
Total	\$

*	To be provided by amendment
Item 14. Indemnification of Directors	and Officers.

Section 145 of the Delaware General Corporation Law, or the DGCL, authorizes a corporation to indemnify its directors and officers against liabilities arising out of actions, suits and proceedings to which they are made or threatened to be made a party by reason of the fact that they have served or are currently serving as a director or officer to a corporation. The indemnity may cover expenses (including attorneys fees) judgments, fines and amounts paid in settlement actually and reasonably incurred by the director or officer in connection with any such action, suit or proceeding. Section 145 permits corporations to pay expenses (including attorneys fees) incurred by directors and officers in advance of the final disposition of such action, suit or proceeding. In addition, Section 145 provides that a corporation has the power to purchase and maintain insurance on behalf of its directors and officers against any liability asserted against them and incurred by them in their capacity as a director or officer, or arising out of their status as such, whether or not the corporation would have the power to indemnify the director or officer against such liability under Section 145.

We have adopted provisions in our certificate of incorporation and bylaws to be in effect at the completion of this offering that limit or eliminate the personal liability of our directors to the fullest extent permitted by the DGCL, as it now exists or may in the future be amended. Consequently, a director will not be personally liable to us or our stockholders for monetary damages or breach of fiduciary duty as a director, except for liability for:

any breach of the director s duty of loyalty to us or our stockholders;

any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;

any unlawful payments related to dividends or unlawful stock purchases, redemptions or other distributions; or

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any transaction from which the director derived an improper personal benefit.

These limitations of liability do not alter director liability under the federal securities laws and do not affect the availability of equitable remedies such as an injunction or rescission.

In addition, our bylaws provide that:

we will indemnify our directors, officers and, in the discretion of our board of directors, certain employees to the fullest extent permitted by the DGCL, as it now exists or may in the future be amended; and

we will advance reasonable expenses, including attorneys fees, to our directors and, in the discretion of our board of directors, to our officers and certain employees, in connection with legal proceedings relating to their service for or on behalf of us, subject to limited exceptions.

We have entered into indemnification agreements with each of our directors and intend to enter into such agreements with certain of our executive officers. These agreements provide that we will indemnify each of our directors, certain of our executive officers and, at times, their affiliates to the fullest extent permitted by Delaware law. We will advance expenses, including attorneys fees (but excluding judgments, fines and settlement amounts), to each indemnified director, executive officer or affiliate in connection with any proceeding in which indemnification is available and we will indemnify our directors and officers for any action or proceeding arising out of that person s services as a director or officer brought on behalf of us and/or in furtherance of our rights. Additionally, each of our directors may have certain rights to indemnification, advancement of expenses and/or insurance provided by their affiliates, which indemnification relates to and might apply to the same proceedings arising out of such director s ervices as a director referenced herein. Nonetheless, we have agreed in the indemnification agreements that our obligations to those same directors are primary and any obligation of the affiliates of those directors to advance expenses or to provide indemnification for the expenses or liabilities incurred by those directors are secondary.

We also maintain general liability insurance which covers certain liabilities of our directors and officers arising out of claims based on acts or omissions in their capacities as directors or officers, including liabilities under the Securities Act.

The underwriting agreement filed as Exhibit 1.1 to this registration statement provides for indemnification of us and our directors and officers by the underwriters against certain liabilities under the Securities Act and the Exchange Act.

# Item 15. Recent Sales of Unregistered Securities.

The following list sets forth information as to all securities we have sold since January 1, 2010, which were not registered under the Securities Act.

- 1. On September 10, 2012, we issued an aggregate of 18,805,304 shares of our Series B preferred stock to 19 investors for aggregate consideration of approximately \$42.5 million. On December 28, 2012, we issued an aggregate of 5,956,830 shares of our Series B preferred stock to five investors for aggregate consideration of approximately \$13.5 million.
- 2. On November 1, 2010, we issued a Preferred Stock Purchase Warrant to Lighthouse Capital Partners VI, L.P., exercisable for an aggregate of up to 200,000 shares of our Series A preferred stock.
- 3. On March 30, 2010, we issued an aggregate of 7,000,000 shares of our Series A preferred stock to one investor for aggregate consideration of approximately \$7.0 million. On February 7, 2011, we issued an aggregate of 1,000,000 shares of our Series A preferred stock to one existing investor for aggregate consideration of approximately \$1.0 million. On March 30, 2011, we issued an aggregate of 5,000,000 shares of our Series A preferred stock to one existing investor for aggregate consideration of approximately \$5.0 million. On October 14, 2011, we issued an aggregate of 5,500,000 shares of our Series A preferred stock to one existing investor for aggregate consideration of approximately \$5.5 million. On August 8, 2011, we issued an aggregate of 10,000,000 shares of our Series A preferred

stock to one investor for aggregate consideration of approximately \$10.0 million. On August 23, 2011, we issued an aggregate of 5,000,000 shares of our Series A preferred stock to one investor for aggregate consideration of approximately \$5.0 million. On April 18, 2012, we issued an aggregate of 10,250,000 shares of our Series A preferred stock to four existing investors for aggregate consideration of approximately \$10.3 million.

- 4. Between August 5, 2010 and July 31, 2013, we have granted stock options to purchase an aggregate of 14,841,129 shares of our common stock with exercise prices ranging from \$0.02 to \$1.78 per share to our employees, consultants and directors pursuant to our 2010 Plan. Of these, options covering an aggregate of 350,656 shares were cancelled without being exercised.
- 5. We sold an aggregate of 5,764,657 shares of common stock to employees, directors and consultants for cash consideration in the aggregate amount of \$187,018.14 upon the exercise of stock options.

We deemed the offers, sales and issuances of the securities described in paragraphs (1) through (3) above to be exempt from registration under the Securities Act, in reliance on Section 4(2) of the Securities Act, including Regulation D and Rule 506 promulgated thereunder, regarding transactions by an issuer not involving a public offering. All purchasers of securities in transactions exempt from registration pursuant to Regulation D represented to us that they were accredited investors and were acquiring the shares for investment purposes only and not with a view to, or for sale in connection with, any distribution thereof and that they could bear the risks of the investment and could hold the securities for an indefinite period of time. The purchasers received written disclosures that the securities had not been registered under the Securities Act and that any resale must be made pursuant to a registration statement or an available exemption from such registration.

We deemed the grants of stock options described in paragraph (4) and the issuances of shares of common stock upon the exercise of stock options described in paragraph (5) as exempt pursuant to Section 4(2) of the Securities Act or to be exempt from registration under the Securities Act in reliance on Rule 701 of the Securities Act as offers and sales of securities under compensatory benefit plans and contracts relating to compensation in compliance with Rule 701. Each of the recipients of securities in any transaction exempt from registration either received or had adequate access, through employment, business or other relationships, to information about us.

All certificates representing the securities issued in the transactions described in this Item 15 included appropriate legends setting forth that the securities had not been offered or sold pursuant to a registration statement and describing the applicable restrictions on transfer of the securities. There were no underwriters employed in connection with any of the transactions set forth in this Item 15.

# Item 16. Exhibits and Financial Statement Schedules.

(a) Exhibits:

The exhibits to the registration statement are listed in the Exhibit Index to this registration statement and are incorporated herein by reference.

(b) Financial Statements Schedules:

Schedules have been omitted because the information required to be set forth therein is not applicable or is shown in the financial statements or notes thereto.

# Item 17. Undertakings.

Insofar as indemnification for liabilities arising under the Securities Act of 1933, as amended, or the Act, may be permitted to directors, officers and controlling persons of the Registrant pursuant to the foregoing provisions, or otherwise, the Registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is therefore unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer or controlling person of the Registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

The Registrant hereby undertakes that:

- (a) The Registrant will provide to the underwriter at the closing as specified in the underwriting agreement, certificates in such denominations and registered in such names as required by the underwriter to permit prompt delivery to each purchaser.
- (b) For purposes of determining any liability under the Securities Act of 1933, as amended, the information omitted from a form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in the form of prospectus filed by the Registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act of 1933, as amended, shall be deemed to be part of this registration statement as of the time it was declared effective.
- (c) For the purpose of determining any liability under the Securities Act of 1933, as amended, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

# SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused this Amendment No. 2 to Registration Statement on Form S-1 to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Cambridge, Commonwealth of Massachusetts, on August 16, 2013.

## FOUNDATION MEDICINE, INC.

By: /s/ Michael J. Pellini, M.D. Michael J. Pellini, M.D.

President and Chief Executive Officer

Pursuant to the requirements of the Securities Act of 1933, as amended, this Amendment No. 2 to Registration Statement has been signed by the following person in the capacities and on the date indicated.

Name	Title	Date
/s/ Michael J. Pellini, M.D.	President, Chief Executive Officer and Director ( <i>Principal Executive Officer</i> )	August 16, 2013
Michael J. Pellini, M.D.		
/s/ Jason Ryan	Vice President, Finance (Principal Financial and Accounting Officer)	August 16, 2013
Jason Ryan		
*	Director	August 16, 2013
Alexis Borisy		
*	Director	August 16, 2013
Brook Byers		
*	Director	August 16, 2013
Evan Jones		

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Name	Title	Date
*	Director	August 16, 2013
Mark Levin		
*	Director	August 16, 2013
David Schenkein, M.D.		
*	Director	August 16, 2013
Krishna Yeshwant, M.D.		

\* Pursuant to Power of Attorney

By: /s/ Michael J. Pellini, M.D. Michael J. Pellini, M.D.

Attorney-in-Fact

# EXHIBIT INDEX

Exhibit No.	Exhibit Index	
1.1*		
1.1** 3.1**	Form of Underwriting Agreement Fifth Amended and Restated Certificate of Incorporation of the Registrant, as amended and currently in effect	
3.2	Form of Sixth Amended and Restated Certificate of Incorporation of the Registrant (to be effective upon completion of this	
5.2	offering)	
3.3**	Bylaws of the Registrant, as amended and currently in effect	
3.4	Form of Amended and Restated Bylaws of the Registrant (to be effective upon completion of this offering)	
4.1*	Form of Common Stock certificate of the Registrant	
4.2**	Warrant to Purchase Preferred Stock of the Registrant, dated as of November 1, 2010, issued to Lighthouse Capital Partners VI,	
4.3**	L.P. Second Amended and Restated Investors Rights Agreement, by and between the Registrant and the Investors named therein,	
т.5	dated as of June 20, 2013.	
5.1*	Opinion of Goodwin Procter LLP	
10.1 **	Amended and Restated 2010 Stock Incentive Plan and forms of agreements thereunder	
10.2 *	2013 Stock Option and Incentive Plan and forms of agreements thereunder	
10.3 *	Executive Employee Offer Letter issued by the Registrant to Michael J. Pellini, dated as of March 14, 2011.	
10.4 **	Executive Employee Offer Letter issued by the Registrant to Kevin Krenitsky, dated as of March 7, 2013.	
10.5 **	Executive Employee Offer Letter issued by the Registrant to Robert W. Hesslein, dated as of March 7, 2013.	
10.6 **	Executive Employee Offer Letter issued by the Registrant to Jason Ryan, dated as of March 7, 2013.	
10.7 *	Executive Employee Offer Letter issued by the Registrant to Steven J. Kafka, dated as of March 7, 2013.	
10.8	Form of Indemnification Agreement, to be entered into between the Registrant and its directors and officers	
10.9**	Lease Agreement, by and between the Registrant and RB Kendall Fee, LLC, dated as of July 13, 2010.	
10.10**	Lease, by and between the Registrant and 150 Second Street, LLC, dated as of February 4, 2013.	
10.11**	Lease, by and between the Registrant and 150 Second Street, LLC, dated as of March 27, 2013.	
10.12**	Loan and Security Agreement, by and between the Registrant and Lighthouse Capital Partners VI, L.P., dated as of November 1, 2010, as amended.	
10.13#	Supply and Support Agreement, by and between the Registrant and Illumina, Inc., effective as of July 25, 2013.	
10.14#	Laboratory Master Services Agreement, by and between the Registrant and Novartis Pharmaceuticals Corporation, dated as of	
10.15*	November 21, 2011, as amended.	
10.15*	Executive Employee Offer Letter issued by the Registrant to Vincent A. Miller, dated as of March 7, 2013.	
10.16 * 21.1**	2013 Employee Stock Purchase Plan. Subsidiaries of the Registrant	
23.1	Consent of Ernst & Young LLP	
23.2*	Consent of Goodwin Procter LLP (included in Exhibit 5.1)	
24.1**	Power of Attorney (included in page II-5)	
27.1	Tower of Automety (included in page 11-5)	
	* To be included by amendment	
	** Previously filed.	
	Indicates a management contract or any compensatory plan, contract or arrangement.	
<ul> <li># Application has been made to the Securities and Exchange Commission for confidential treatment of certain provisions. Omitted material for which confidential treatment has been requested was filed separately with the Securities and Exchange Commission.</li> </ul>		
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