Foundation Medicine, Inc.
Form 10-Q
May 11, 2015
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2015

OR

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

For the transition period from _____ to _____

Commission file number: 001-36086

FOUNDATION MEDICINE, INC.

(Exact name of registrant as specified in its charter)

DELAWARE	27-1316416
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

150 Second Street

Cambridge MA, 02141

(Address of principal executive offices)(Zip code)

(617) 418-2200

(Registrant s telephone number, including area code)

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No ¨

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

Large accelerated filer ¨	Accelerated filer x
Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller reporting company ¨

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

The number of shares outstanding of the registrant s common stock, par value of $0.0001 per share, as of May 6, 2015 was 34,266,252.

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FORWARD LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements that involve risks and uncertainties. We make such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. All statements other than statements of historical facts contained in this Quarterly Report on Form 10-Q are forward-looking statements. In some cases, you can identify forward-looking statements by words such as anticipate, believe, contemplate, continue, could, estimate, ex intend, may, plan, potential, predict, project, seek, should, target, will, would, or the negative comparable terminology. These forward-looking statements 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 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 FoundationOne Heme and expand existing or develop new relationships with biopharmaceutical partners;

- our ability to increase the commercial success of FoundationOne and FoundationOne Heme;

- our plans or ability to obtain reimbursement for FoundationOne and FoundationOne Heme, 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;

the acceptance of our publications in peer-reviewed journals or 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 and improvements to our existing products;

anticipated increases in our sales and marketing costs due to expansions in our sales force and marketing activities within and outside of the United States;

our ability to operate outside of the United States in compliance with evolving legal and regulatory requirements;

our ability to meet future anticipated demand by making additional investments in personnel, infrastructure, and systems to scale our laboratory operations;

the expansion of the capabilities of ICE 2, the newest version of our online Interactive Cancer Explorer portal and the development and launch of its associated applications in 2014;

federal, state, and foreign regulatory requirements, including potential FDA regulation of FoundationOne and FoundationOne Heme 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;

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- our anticipated cash needs and our estimates regarding our capital requirements and our needs for additional financing, as well as our ability to obtain such additional financing on reasonable terms;

- our ability to recognize the benefits of our broad strategic collaborations with affiliates of Roche, which closed in April 2015;

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

- other risks and uncertainties, including those described in Part II, Item 1A. Risk Factors in this Quarterly Report.

Any forward-looking statements in this Quarterly Report on Form 10-Q reflect our current views with respect to future events or to our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under Part II, Item 1A. Risk Factors in this Quarterly Report. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

Unless the context requires otherwise, references in this Quarterly Report to we, us , our and Foundation refer to Foundation Medicine, Inc. and our subsidiary. We own various U.S. federal trademark registrations and applications, and unregistered trademarks and service marks. Foundation Medicine®, FoundationOne®, Interactive Cancer Explorer®, Once. And for All®, and The Molecular Information Company® are all registered trademarks of Foundation in the United States, and several of these marks are at various stages of the registration process in other countries. ICE 2 , FoundationCORE and PatientMatch are also trademarks of Foundation. Other trademarks or service marks that may appear in this Quarterly Report are the property of their respective holders. For convenience, we do not use the ® and symbols in each instance in which one of our trademarks appears throughout this Quarterly Report, but this should not be construed as any indication that we will not assert, to the fullest extent under applicable law, our rights thereto.

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FOUNDATION MEDICINE, INC.

REPORT ON FORM 10-Q

For the Quarterly Period Ended March 31, 2015

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FOUNDATION MEDICINE, INC.

Condensed Consolidated Balance Sheets

(unaudited)

(In thousands, except share and per share data)

	March 31, 2015	December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	$ 61,700	$ 72,080
Accounts receivable	10,673	9,894
Inventories	4,493	4,809
Prepaid expenses and other current assets	3,981	2,865
Total current assets	80,847	89,648
Property and equipment, net	25,131	21,015
Restricted cash	1,394	864
Other assets	486	411
Total assets	$ 107,858	$ 111,938
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable	$ 9,416	$ 7,263
Accrued expenses and other current liabilities	12,201	7,414
Deferred revenue	183	340
Current portion of deferred rent	1,586	1,429
Total current liabilities	23,386	16,446
Deferred rent, net of current portion, and other non-current liabilities	9,656	9,323
Total liabilities	33,042	25,769
Commitments and contingencies (Note 11)		
Stockholders equity:		
Preferred Stock, $0.0001 par value, 5,000,000 shares authorized; no shares issued and outstanding		
Common stock, $0.0001 par value, 150,000,000 shares authorized; 29,176,084 and 28,223,958 shares issued and outstanding at March 31, 2015 and December 31, 2014, respectively	3	3
Additional paid-in capital	233,763	228,151
Accumulated deficit	(158,950)	(141,985)
Total stockholders equity	74,816	86,169

Total liabilities and stockholders equity	$ 107,858	$ 111,938

The accompanying notes are an integral part of these condensed consolidated financial statements

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FOUNDATION MEDICINE, INC.

Condensed Consolidated Statements of Operations and Comprehensive Loss

(unaudited)

(In thousands, except share and per share data)

	Three Months Ended March 31,	
	2015	**2014**
Revenue	$ 19,295	$ 11,455
Costs and expenses:		
Cost of revenue	8,916	5,291
Selling and marketing	9,821	5,690
General and administrative	8,842	5,700
Research and development	8,688	6,915
Total costs and expenses	36,267	23,596
Loss from operations	(16,972)	(12,141)
Other income (expense):		
Interest income	7	4
Interest expense		(29)
Total other income (expense), net	7	(25)
Net loss	$ (16,965)	$ (12,166)
Net loss per common share, basic and diluted	$ (0.59)	$ (0.44)
Weighted-average common shares outstanding, basic and diluted	28,609,345	27,733,717
Comprehensive loss	$ (16,965)	$ (12,166)

The accompanying notes are an integral part of these condensed consolidated financial statements

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FOUNDATION MEDICINE, INC.

Condensed Consolidated Statements of Cash Flows

(unaudited)

(In thousands)

	Three Months Ended March 31,	
	2015	**2014**
Operating activities		
Net loss	$ (16,965)	$ (12,166)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	2,206	1,915
Stock-based compensation expense	1,688	696
Non-cash interest expense		7
Changes in operating assets and liabilities:		
Accounts receivable	(779)	(1,699)
Inventory	316	(1,210)
Prepaid expenses and other current assets	(398)	(264)
Other assets	(75)	8
Accounts payable	(991)	(3,279)
Accrued expenses	3,918	1,943
Deferred rent and other non-current liabilities	320	127
Deferred revenue	(157)	481
Net cash used in operating activities	(10,917)	(13,441)
Investing activities		
Purchases of property and equipment	(2,304)	(174)
Increase in restricted cash	(1,037)	
Net cash used in investing activities	(3,341)	(174)
Financing activities		
Proceeds from stock option exercises.	3,878	78
Payments of notes payable		(448)
Net cash provided by (used in) financing activities	3,878	(370)
Net decrease in cash and cash equivalents	(10,380)	(13,985)
Cash and cash equivalents at beginning of period	72,080	124,293
Cash and cash equivalents at end of period	$ 61,700	$ 110,308
Supplemental disclosure of cash flow information		
Cash paid for interest	$	$ 20

Supplemental disclosure of non-cash investing and financing activities		
Acquisition of property and equipment included in accounts payable and accrued expenses	$ 5,352	$ 1,914

The accompanying notes are an integral part of these condensed consolidated financial statements

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FOUNDATION MEDICINE, INC.

Notes to Condensed Consolidated Financial Statements

(unaudited)

1. Nature of Business and Basis of Presentation

Foundation Medicine, Inc. and its wholly-owned subsidiary, Foundation Medicine Securities Corporation (collectively, the Company) is a molecular information company focused on fundamentally changing the way in which patients with cancer are evaluated and treated. We believe an information-based approach to making clinical treatment decisions based on comprehensive genomic profiling will become a standard of care for patients with cancer. We derive revenue from selling products that are enabled by our molecular information platform to physicians and biopharmaceutical companies.

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

The accompanying condensed consolidated financial statements are unaudited. In the opinion of management, the unaudited condensed consolidated financial statements contain all adjustments considered normal and recurring and necessary for their fair statement. Interim results are not necessarily indicative of results to be expected for the year. These interim financial statements have been prepared in accordance with accounting principles generally accepted in the United States for interim financial information and in accordance with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, these condensed consolidated financial statements do not include all of the information and footnotes necessary for a complete presentation of financial position, results of operations, comprehensive loss and cash flows. Our audited consolidated financial statements as of and for the year ended December 31, 2014 included information and footnotes necessary for such presentation and were included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission (SEC), on March 13, 2015. These unaudited condensed consolidated financial statements should be read in conjunction with our audited consolidated financial statements and notes thereto for the year ended December 31, 2014.

2. Summary of Significant Accounting Policies

Summary of accounting policies

There have been no material changes to the significant accounting policies previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2014.

Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board (FASB) or other standard setting bodies and adopted by the Company as of the specified effective date. Unless otherwise discussed, the Company believes that the impact of recently issued standards that are not yet effective will not have a material impact on its financial position or results of operations upon adoption.

In May 2014, the FASB and the International Accounting Standards Board jointly issued Accounting Standards Update No. 2014-09, *Revenue from Contracts with Customers* (ASU 2014-09), which supersedes the revenue recognition requirements in Accounting Standards Codification 605 (ASC 605) and most industry-specific guidance. The new standard requires that an entity recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The update also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. ASU 2014-09 is effective for public entities for annual and interim periods beginning after December 15, 2016, although a deferral of the effective date is now being considered by the FASB. Early adoption is not permitted under accounting principles generally accepted in the United States (GAAP) and retrospective application is permitted but not required. The Company is evaluating the method of adoption and the potential impact this standard may have on its consolidated financial position, results of operations or cash flows.

In August 2014, the FASB issued Accounting Standards Update No. 2014-15, *Disclosure of Uncertainties about an Entity s Ability to Continue as a Going Concern* (ASU 2014-15). ASU 2014-15 requires management to evaluate, at each annual or interim reporting period, whether there are conditions or events that exist that raise substantial doubt about an entity s ability to continue as a going concern within one year after the date the financial statements are issued and provide related disclosures. ASU 2014-15 is effective for annual periods ending after December 15, 2016 and earlier application is permitted. The adoption of ASU 2014-15 is not expected to have a material effect on the Company s consolidated financial statements or disclosures.

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3. Cash and Cash Equivalents

The Company considers all highly liquid investments with original maturity from the date of purchase of three months or less to be cash equivalents. Cash and cash equivalents include bank demand deposits and money market funds that invest primarily in U.S. government treasuries. Cash equivalents are carried at cost, which approximates their fair value.

4. Restricted Cash

Restricted cash consists of deposits securing collateral letters of credit issued in connection with the Company s operating leases. As of March 31, 2015, the Company had restricted cash of $1,901,000, of which $507,000 is included in prepaid and other current assets in the condensed consolidated balance sheets. As of December 31, 2014, the Company had restricted cash of $864,000.

5. Inventory

Inventories are stated at the lower of cost or market on a first-in, first-out basis and are comprised of the following (in thousands):

	March 31, 2015	December 31, 2014
Raw materials	$ 3,649	$ 3,851
Work-in-process	844	958
	$ 4,493	$ 4,809

6. Property and Equipment

Property and equipment and related accumulated depreciation and amortization are as follows (in thousands):

	March 31, 2015	December 31, 2014
Lab equipment	$ 17,974	$ 14,843
Computer equipment	7,915	6,673
Software	2,374	2,111
Furniture and office equipment	1,974	1,974
Leasehold improvements	12,860	12,834
Construction in progress	1,660	
	44,757	38,435
Less: accumulated depreciation and amortization	(19,626)	(17,420)

	$	25,131	$	21,015

Depreciation and amortization expense for the three months ended March 31, 2015 and 2014 was $2,206,000 and $1,915,000, respectively. The Company classifies capitalized internal use software in Lab Equipment, Computer Equipment and Software based on its intended use.

7. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	March 31, 2015		December 31, 2014	
Payroll and employee-related costs	$	7,964	$	5,011
Professional services		1,876		1,123
Property and equipment purchases		1,345		471
Other		1,016		809
	$	12,201	$	7,414

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8. Net Loss per Common 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 and the if-converted method. For purposes of the diluted net loss per share calculation, stock options, and unvested restricted stock 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 was the same for all periods presented.

The following potential common stock equivalents were not included in the calculation of diluted net loss per common share because the inclusion thereof would be antidilutive.

	Three Months Ended March 31,	
	2015	2014
Outstanding stock options	1,964,389	2,446,648
Unvested restricted stock	293,211	385,210
Total	2,257,600	2,831,858

9. Fair Value Measurements

The Company is required to disclose information on all assets and liabilities reported at fair value that enables an assessment of the inputs used in determining the reported fair values. FASB ASC Topic 820, *Fair Value Measurements and Disclosures* (ASC 820), establishes a hierarchy of inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that 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 a 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 a 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.

The Company s financial instruments consist of cash and cash equivalents, accounts receivable, accounts payable and accrued liabilities. The carrying amount of cash and cash equivalents, accounts receivable, accounts payable and accrued liabilities approximate their fair values because of the short-term nature of the instruments.

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The following tables present information about our assets and liabilities that are measured at fair value on a recurring basis as of March 31, 2015 and December 31, 2014, and indicate the fair value hierarchy of the valuation techniques utilized to determine such fair value (in thousands):

	Fair Value Measurement at March 31, 2015			
	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Assets:				
Cash held in money market funds	$ 38,019	$	$	$ 38,019
Total assets	$ 38,019	$	$	$ 38,019

	Fair Value Measurement at December 31, 2014			
	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Assets:				
Cash held in money market funds	$ 68,016	$	$	$ 68,016
Total	$ 68,016	$	$	$ 68,016

The Company measures eligible assets and liabilities at fair value, with changes in value recognized in the statement of operations and comprehensive loss. Fair value treatment may be elected either upon initial recognition of an eligible asset or liability or, for an existing asset or liability, if an event triggers a new basis of accounting. The Company did not elect to remeasure any of its existing financial assets or liabilities, and did not elect the fair value option for any financial assets and liabilities transacted during the three months ended March 31, 2015 and 2014.

10. Stockholders Equity

The Company has reserved for future issuance the following number of shares of common stock:

	March 31, 2015	December 31, 2014
Unvested restricted stock	293,211	335,933
Common stock options	1,964,389	2,792,021
	2,428,779	1,375,555

Shares available for issuance under the 2013 Stock Option and Incentive Plan		
Shares available for issuance under the 2013 Employee Stock Purchase Plan	788,503	788,503
	5,474,882	5,292,012

2010 and 2013 Stock Incentive Plans

In 2010, the Company adopted the Foundation Medicine, Inc. 2010 Stock Incentive Plan (the 2010 Stock Plan) under which it granted restricted stock, incentive stock options (ISOs) and non-statutory stock options to eligible employees, officers, directors and consultants to purchase up to 1,162,500 shares of common stock. In the year ended December 31, 2013, the Company amended the 2010 Stock Plan to increase the number of shares of common stock available for issuance to 4,232,500.

In 2013, the Company adopted the Foundation Medicine, Inc. 2013 Stock Option and Incentive Plan (the 2013 Stock Plan) under which it may grant restricted and unrestricted stock, restricted stock units, ISOs, non-statutory stock options, stock appreciation rights, cash-based awards, performance share awards and dividend equivalent rights to eligible employees, officers, directors and consultants to purchase up to 1,355,171 shares of common stock. In connection with the establishment of the 2013 Stock Plan, the Company terminated the 2010 Stock Plan and the 512,568 shares which remained available for grant under the 2010 Stock Plan were included in the number of shares authorized under the 2013 Stock Plan. Shares forfeited or repurchased from the 2010 Stock Plan are returned to the 2013 Stock Plan for future issuance. On January 1, 2015 and 2014, the number of shares reserved and available for issuance under the 2013 Stock Plan increased by 1,134,996 and 1,125,921 shares of common stock, respectively, pursuant to a provision in the 2013 Stock Plan that 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 number of shares of our common stock issued and outstanding on the immediately preceding December 31 or such lesser number as determined by the compensation committee of the Board of Directors of the Company (the Board of Directors or the Board).

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The terms of stock award agreements, including vesting requirements, are determined by the Board of Directors, subject to the provisions of the 2010 Stock Plan and the 2013 Stock Plan. Options granted by the Company typically vest over a four-year period. Certain of the options are subject to acceleration of vesting in the event of certain change of control transactions. The options are exercisable from the date of grant for a period of 10 years. The exercise price for stock options granted is equal to the closing price of our common stock on the applicable date of grant.

Restricted Stock

The 2010 Stock Plan and the 2013 Stock Plan allow 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 and the 2013 Stock Plan:

	Number of Shares
Unvested at December 31, 2014	219,617
Granted	23,970
Vested	(16,287)
Cancelled	(581)
Unvested at March 31, 2015 [(1)]	226,719

(1) Excludes 66,492 shares of unvested restricted stock remaining from the early exercise of stock options.

Stock Options

A summary of stock option activity under the 2010 Stock Plan and 2013 Stock Plan for the three months ended March 31, 2015 is as follows:

	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (In Years)	Aggregate Intrinsic Value
				(in thousands)
Outstanding as of December 31, 2014	2,792,021	$ 10.82	8.3	$ 35,390
Granted	104,400	44.62		
Exercised	(886,015)	4.42		
Cancelled	(46,017)	24.22		

Outstanding as of March 31, 2015	1,964,389	$ 15.19	8.4	$	64,660
Exercisable as of March 31, 2015	409,528	$ 8.90	7.6	$	16,057

Certain stock options contain provisions allowing for the early exercise into shares subject to repurchase. At March 31, 2015, 66,492 shares, which were early exercised, remain subject to repurchase by the Company.

The weighted-average fair value of options granted for the three months ended March 31, 2015 was $27.43 per share. The Company recorded total stock-based compensation expense for stock options granted to employees, directors and non-employees from the 2010 Stock Plan and the 2013 Stock Plans of $1,688,000 and $696,000 during the three months ended March 31, 2015 and 2014, respectively.

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The Company recorded stock-based compensation expense in the statements of operations and comprehensive loss as follows (in thousands):

	Three Months Ended March 31,	
	2015	2014
Cost of revenue	$ 203	$ 61
Sales and marketing	445	144
General and administrative	688	270
Research and development	352	221
Total	$ 1,688	$ 696

As of March 31, 2015, unrecognized compensation cost of approximately $16,800,000 related to non-vested stock options and restricted stock awards is expected to be recognized over weighted-average periods of 3.1 years.

The weighted-average assumptions used to estimate the fair value of stock options using the Black-Scholes option pricing model were as follows:

	Three Months Ended March 31,	
	2015	2014
Expected volatility	66.8%	65.5%
Risk-free interest rate	1.49%	2.19%
Expected option term (in years)	6.25	6.25
Expected dividend yield	0.0%	0.0%

11. Commitments and Contingencies

150 Second Street

In 2013, the Company signed two separate facility leases. The first lease commenced in March 2013 and had a one year expected term which was terminated in October 2013. The second lease (the Headquarters Lease) commenced in September 2013 and initially had an eight year expected term. The Headquarters Lease is subject to fixed rate escalation increases and the landlord waived the Company s rent obligation for the first 10.5 months of the lease, having an initial value of $3,300,000. The landlord also agreed to fund up to $9,239,000 in tenant improvements. The Company recorded the tenant improvements as leasehold improvements and deferred rent on the consolidated balance sheet. Deferred rent is amortized as a reduction in rent expense over the term of the Headquarters Lease. The Company recognizes rent expense on a straight-line basis over the expected lease term. In connection with the Company s termination of its prior lease at One Kendall Square, the rent abatement was reduced to approximately $1,841,000 and the expected term of the Headquarters Lease was reduced to 7.5 years. The Company began to record rent expense in April 2013 upon gaining access to and control of the space. Upon execution of the Headquarters Lease, the Company paid a security deposit of $1,725,000 which was reduced to approximately $864,000 in 2014. The security deposit is included in restricted cash in the accompanying balance sheet as of March 31, 2015 and

December 31, 2014.

On June 30, 2014, the Company executed a Second Amendment to Lease amending the Headquarters Lease, resulting in 8,164 square feet of additional space commencing in November 2014. The Company began recording rent expense upon gaining access to and control of the space in July 2014. The landlord has also agreed to fund up to $1,020,500 in normal tenant improvements.

The Company recorded $635,000 and $814,000 of rent expense during the three months ended March 31, 2015 and 2014, respectively, associated with the Headquarters Lease, as amended.

Ten Canal Park Lease

The Company signed a facility lease (the Lease) on March 11, 2015 for office space at Ten Canal Park in Cambridge, Massachusetts (the Premises). The Lease commenced on March 12, 2015, which was the date the landlord received the Letter of Credit (as defined in the Lease), and expires five years after the earlier of the date when the Company first opens for business in the Premises or September 1, 2015. The Company will pay annual rent of $172,850 per month for the first year with scheduled escalating rent payments thereafter, and shall receive up to $1,995,550 from the Landlord for tenant improvements to the Premises. In connection with the Lease, the Company provided a security deposit in the amount of $1,037,000, which will be reduced to $530,550 on the date the Company provides evidence to the landlord of a capital contribution to the Company that results in a net increase in cash in the Company s balance sheet of at least $200 million. The security deposit is included in restricted cash in the accompanying balance sheet as of March 31, 2015.

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The Company recorded $82,000 of rent expense during the three months ended March 31, 2015 associated with the Lease.

Legal Matters

The Company, from time to time, is party to litigation arising in the ordinary course of its business. Although the outcomes of these legal proceedings are inherently difficult to predict, the Company s 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

The Company recognized revenue of $0 and $277,000 during the three months ended March 31, 2015 and 2014, respectively, from an arrangement with an investor executed in the year ended December 31, 2012. There was no balance included in accounts receivable at March 31, 2015 and December 31, 2014, respectively, in connection with this arrangement.

The Company recognized revenue of $828,000 and $0 during the three months ended March 31, 2015 and 2014 from an arrangement with an entity affiliated with a member of the Company s Board of Directors executed in the year ended December 31, 2013. At March 31, 2015 and December 31, 2014, $776,000 and $419,000, respectively, were included in accounts receivable related to this arrangement.

13. Subsequent Events

On January 11, 2015, we signed a broad strategic collaboration with Roche Holdings, Inc. and certain of its affiliates (Roche) to further advance our leadership position in molecular information solutions. The transaction, which is a broad multi-part agreement that includes a research & development (R&D) collaboration, commercial collaborations, and an equity investment with certain governance provisions, closed on April 7, 2015 following the completion of a public tender offer in which Roche purchased 15,604,288 of our outstanding shares at a price of $50.00 per share, and Roche s primary investment in the Company of $250,000,000 in cash through the purchase of 5,000,000 newly issued shares at a price of $50.00 per share.

Under the terms of the Collaboration Agreement by and among us, F. Hoffman-La Roche Ltd, and Hoffman-La Roche Inc., dated January 11, 2015 (the R&D collaboration agreement), Roche could pay potentially more than $150,000,000 over five years to access our molecular information platform and to fund R&D programs. Roche will utilize our molecular information platform to standardize its clinical trial testing, to enable comparability of clinical trial results for R&D purposes, and to better understand the potential for combination therapies. In addition, Roche and the Company will jointly develop information solutions related to blood-based monitoring and evaluation, cancer immunotherapy, and next generation companion diagnostics.

In addition to the R&D collaboration agreement, we entered into commercial collaboration agreements with Roche designed to broaden its reach across international clinical and molecular information markets. Specifically, Roche will obtain ex-U.S. commercialization rights to our existing products and to future co-developed products, and we will remain solely responsible for commercialization of its products within the United States. In addition, within the United States, Roche has agreed to engage its medical education team to provide information to pathologists specific to comprehensive genomic profiling in cancer.

Under the terms of the transaction, Roche (a) made a primary investment of $250,000,000 in cash through the purchase of 5,000,000 newly issued shares of our common stock at a purchase price of $50.00 per share and (b) completed a tender offer to acquire 15,604,288 outstanding shares of our common stock at a price of $50.00 per share (collectively (a) and (b), the Investment). Immediately following the closing, Roche owned approximately 61% of our outstanding shares and approximately 57% of our outstanding shares on a fully diluted basis. Upon the closing of the transaction, the size of our Board of Directors was increased to nine seats, including three designees of Roche. Four existing independent directors and our Chief Executive Officer, Michael Pellini, M.D. are continuing as directors, and one new independent director will be added.

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Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations

The following discussion of our financial condition and results of operations should be read in conjunction with our condensed consolidated financial statements and notes thereto appearing elsewhere in this Quarterly Report on Form 10-Q and the audited consolidated financial statements and notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2014. This discussion contains forward-looking statements that involve significant risks and uncertainties. As a result of many factors, such as those set forth under Risk Factors in Part II, Item 1A. of this Quarterly Report, our actual results may differ materially from those anticipated in these forward-looking statements.

Overview

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

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

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

Since our inception in 2009, we have devoted substantially all of our resources to the development of our molecular information platform, the commercialization of FoundationOne, and the development of new products such as FoundationOne Heme. We have incurred significant losses since our inception, and as of March 31, 2015 our accumulated deficit was $159,000,000. 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 products.

Recent Developments

On January 11, 2015, we signed a broad strategic collaboration with Roche to further advance our leadership position in molecular information solutions. The transaction, which is a broad multi-part agreement that includes an R&D collaboration agreement, commercial collaborations, and an equity investment with certain governance provisions, closed on April 7, 2015 following the completion of a public tender offer in which Roche purchased 15,604,288 of our outstanding shares at a price of $50.00 per share, and Roche s primary investment in the Company of $250,000,000 in cash through the purchase of 5,000,000 newly issued shares at a price of $50.00 per share.

Under the terms of the R&D collaboration agreement, Roche could pay potentially more than $150,000,000 over five years to access our molecular information platform and to fund R&D programs. Roche will utilize our molecular information platform to standardize its clinical trial testing, to enable comparability of clinical trial results for R&D purposes, and to better understand the potential for combination therapies. In addition, Roche and the Company will jointly develop information solutions related to blood-based monitoring and evaluation, cancer immunotherapy, and next generation companion diagnostics.

In addition to the R&D collaboration agreement, we entered into commercial collaboration agreements with Roche designed to broaden its reach across international clinical and molecular information markets. Specifically, Roche will obtain ex-U.S. commercialization rights to our existing products and to future co-developed products, and we will remain solely responsible for commercialization of its products within the United States. In addition, within the United States, Roche has agreed to engage its medical education team to provide information to pathologists specific to comprehensive genomic profiling in cancer.

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Under the terms of the transaction, Roche (a) made a primary investment of $250,000,000 in cash through the purchase of 5,000,000 newly issued shares of our common stock at a purchase price of $50.00 per share and (b) completed a tender offer to acquire 15,604,288 outstanding shares of our common stock at a price of $50.00 per share. Immediately following the closing, Roche owned approximately 61% of our outstanding shares and approximately 57% of our outstanding shares on a fully diluted basis. Upon the closing of the transaction, the size of our Board of Directors was increased to nine seats, including three designees of Roche. Four existing independent directors and our Chief Executive Officer, Michael Pellini, M.D. are continuing as directors, and one new independent director will be added.

Financial Operations Overview

Revenue

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

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

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

period during which the work was performed and costs were incurred.

There are currently no local or national coverage decisions that determine whether and how our tests are covered by Medicare. In the absence of national coverage decisions, local Medicare contractors that administer the Medicare program in various regions have some discretion in determining coverage and, therefore, payment for tests. Our local Medicare contractor, who would process our claims on behalf of Medicare, initially requested that we not submit claims for FoundationOne tests provided to Medicare patients while the contractor assessed the appropriate coverage and payment for FoundationOne as a whole. Based on the volume of our Medicare claims, we began the process of submitting claims to Medicare in November 2013, but we have not generated any revenue from Medicare for our FoundationOne or FoundationOne Heme tests to date. As a result, our net loss is higher than if we were recognizing revenue from the sale of our products for patients covered by Medicare. FoundationOne and FoundationOne Heme tests for patients covered by Medicare represented approximately 30% and 31% of total tests reported to physicians in the United States during the three months ended March 31, 2015 and 2014, respectively.

We are seeking a positive coverage determination from our Medicare contractor, which, if obtained, will establish a standard for the reimbursement for our Medicare claims. At the end of 2013, we commenced the process of submitting claims to Medicare for FoundationOne tests provided to Medicare patients, and subsequently during the first quarter of 2014 we commenced the process of

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submitting claims to Medicare for FoundationOne Heme tests provided to Medicare patients. As of March 31, 2015, we have not been reimbursed by our Medicare contractor for any of the claims that we have submitted, and we are in the process of appealing these unpaid claims. In the future, our Medicare contractor may issue a negative coverage determination for FoundationOne and/or FoundationOne Heme that would apply to future claims or may defer processing a claim pending a coverage or payment determination. If a claim is paid by our Medicare contractor, either upon acceptance of the claim or following a successful appeal of a denied claim, we will generate revenue from Medicare for our testing.

We expect that the current lack of coverage decisions and the uncertainty of reimbursement on a case-by-case basis will continue to negatively impact our revenue and earnings, particularly as FoundationOne and FoundationOne Heme test volumes increase period-to-period. Following our achievement of a coverage decision from a commercial third-party payor or a government payor or once we have a sufficient history of claims collections with any such payor that we conclude the fee for FoundationOne and FoundationOne Heme tests for individuals insured by such payor is sufficiently fixed or determinable and collectability is reasonably assured, we will begin to recognize revenue from such payor on an accrual basis. As of March 31, 2015, we had cash and cash equivalents of approximately $61.7 million. We received gross proceeds of $250.0 million from the Roche equity investment on April 7, 2015. If we are not able to obtain coverage decisions from additional commercial third-party payors and government payors over the longer term, and our available cash balances and cash flows from 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, and may be subject to the prior consent of Roche pursuant to our Investor Rights Agreement by and between the Company and Roche Holdings, Inc., dated January 11, 2015 (the Investor Rights Agreement).

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. We initiated the process to seek reimbursement from Medicare at the end of 2013, and we may also decide to provide appropriate notices to patients covered by Medicare to enable us to bill a patient for all or part of a claim that is denied coverage by our Medicare contractor. We offer a comprehensive patient assistance program to support patients whose incomes are below certain thresholds and to allow for extended payment terms, as necessary, given the patient s economic situation.

Revenue from our biopharmaceutical customers is based on a negotiated price per test or on the basis of agreements to provide certain testing volumes 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, assuming all other revenue recognition criteria have been met. Certain of our arrangements include multiple deliverables. We evaluate these deliverables pursuant to ASC 605-25 *Revenue Recognition: Multiple-Element Arrangements* to determine if they represent separate units of accounting. We then allocate the non-contingent consideration to the units of accounting using the relative selling price model, and recognize revenue as appropriate based upon the nature of the deliverable.

We expect our revenue to increase over time as we expand our commercial efforts within the United States, and outside the United States pursuant to the Ex-U.S. Commercialization Agreement by and between the Company and F. Hoffman-La Roche Ltd, a wholly-owned subsidiary of Roche, dated January 11, 2015 (the ex-U.S. commercialization agreement). Positive reimbursement decisions from additional commercial third-party payors and government payors, such as Medicare and Medicaid, would eliminate much of the uncertainty around payment and, should allow us to

recognize revenue earlier and increase our overall revenue growth from ordering physicians within the United States. We also expect to grow our biopharmaceutical customer base. Over time, we expect that our revenue from ordering physicians within and outside of the United States will significantly exceed revenue from our biopharmaceutical customers, given the higher percentage of patients with cancer who are treated outside of clinical trial settings.

Cost of Revenue and Operating Expenses

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

Cost of Revenue

Cost of revenue consists of personnel expenses, including 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.

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

During the three months ended March 31, 2015 and 2014, our sales and marketing expenses represented approximately 51% and 50%, respectively, of our total revenue. We expect our sales and marketing expenses to continue to increase in absolute dollars as we expand our sales force, grow our client service infrastructure, and increase our marketing and medical affairs activities to drive further awareness and adoption of FoundationOne, FoundationOne Heme, and any future products we may develop.

General and Administrative Expenses

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

We expect that our general and administrative expenses will continue to increase, primarily due to the costs associated with increased infrastructure and headcount, as well as the costs associated with the closing and implementation of the Roche transaction. These costs include additional legal and accounting expenses, higher directors and officers insurance premiums, and an increase in billing costs related to our anticipated increase in revenues.

Research and Development Expenses

Our research and development expenses consist primarily of costs incurred for new product research and development, significant product improvements, clinical trials to evaluate the clinical utility of FoundationOne and FoundationOne Heme, the development of our FoundationCORE knowledgebase, and the development of technology tools such as ICE 2. Costs to develop our technology capabilities are recorded as research and development unless they meet the criteria to be capitalized as internal-use software costs. Our research and development activities include the following costs:

- personnel-related expenses such as salaries, bonuses, employee benefits, and stock-based compensation;
- fees for contractual and consulting services;

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

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 Income/Expense

Interest income consists of interest earned on our cash and cash equivalents. During the three months ended March 31, 2015 and 2014, interest income was not material. Interest expense consists primarily of interest expense on our loan balance and the amortization of debt discounts. Our loan balance was paid in full during the year ended December 31, 2014.

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Results of Operations

Comparison of Three Months Ended March 31, 2015 and 2014

	Three Months Ended March 31,		Change	
	2015	2014	$	%
	(in thousands, except percentages)			
Statement of Operations Data:				
Revenue	$ 19,295	$ 11,455	$ 7,840	68%
Costs and expenses				
Cost of revenue	8,916	5,291	3,625	69%
Selling and marketing	9,821	5,690	4,131	73%
General and administrative	8,842	5,700	3,142	55%
Research and development	8,688	6,915	1,773	26%
Total costs and expenses	36,267	23,596	12,671	54%
Loss from operations	(16,972)	(12,141)	(4,831)	40%
Other income (expense):				
Interest income	7	4	3	75%
Interest expense		(29)	29	100%
Total other income (expense)	7	(25)	32	128%
Net loss	$ (16,965)	$ (12,166)	$ (4,799)	(39%)

Revenue

Total revenue increased to $19.3 million for the three months ended March 31, 2015 from $11.5 million during the three months ended March 31, 2014. Revenue from FoundationOne and FoundationOne Heme tests reported to our ordering physicians increased to $11.1 million for the three months ended March 31, 2015 from $7.1 million for the three months ended March 31, 2014. The increase was driven by our growing test volumes and expanding commercialization efforts. The increase in revenue from our biopharmaceutical customers to $8.2 million from $4.3 million in the three months ended March 31, 2015 and 2014, respectively, resulted from increased business development activity among our new and existing biopharmaceutical customers.

During the three months ended March 31, 2015, we reported 7,854 tests to ordering physicians, including 969 FoundationOne Heme tests, as compared to 4,702 tests reported during the three months ended March 31, 2014, including 715 FoundationOne Heme tests. We also reported 1,596 and 851 tests to our biopharmaceutical customers during the three months ended March 31, 2015 and 2014, respectively.

The average revenue per test for clinical use that met our revenue recognition criteria during the three months ended March 31, 2015 was approximately $3,400. This average revenue per test does not include 2,022 FoundationOne and FoundationOne Heme tests reported during the period for patients covered by Medicare, 65 tests that were reported

and not billed, and 4,127 tests that were reported and billed to commercial third-party payors during the period but were not paid during the period. This average revenue per test includes 1,621 tests reported in prior periods for which revenue was recognized during the three months ended March 31, 2015.

The average revenue per FoundationOne test for clinical use that met our revenue recognition criteria during the three months ended March 31, 2014 was approximately $3,400. This average revenue per test does not include 1,153 FoundationOne and Foundation One Heme tests reported during the period for patients covered by Medicare and for which claims were not submitted, 119 tests that were reported and not billed, and 2,141 tests that were reported and billed to commercial third-party payors during the period but were not paid during the period. This average revenue per test calculation includes 827 tests reported in prior periods for which revenue was recognized during the three months ended March 31, 2014.

Our average revenue per test excludes tests for which we have not yet recognized revenue. Because we recognize revenue on a cash basis from most commercial third-party payors and from patients who make co-payments, and our efforts to obtain payment for individual claims can take a substantial amount of time, there is typically a significant lag between the time the test is reported and the time we actually recognize the revenue from such test. As a result, if we were to include tests for which we have not recognized revenue in our average revenue per test calculation for a particular period, it would imply that we will not receive any revenue for such tests. Despite our lack of coverage decisions, we have been reasonably successful in securing reimbursement from many commercial third-party payors for tests reported in prior periods. With respect to tests reported for patients covered by Medicare, we commenced

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the process of submitting claims to Medicare for these tests in November 2013 and have not yet been reimbursed for these claims. We also expect to record revenue from patients who make co-payments, pay deductibles, or pay other amounts that we have been unable to collect from third-party payors. While receipt of payment from third-party payors and patients in respect of these claims is not currently fixed or determinable and collectability is not reasonably assured, we do expect to record revenue in the future for some of the tests reported in this period. However, it is difficult to predict future revenue from the previously reported FoundationOne and FoundationOne Heme tests because we are in an early stage of commercialization and we have limited payment history. As a result, we cannot be certain that the revenue per test we recognize in the future will equal or exceed the average revenue per test reported above.

The cumulative amount of FoundationOne and FoundationOne Heme tests that have been billed to commercial third-party payors and reported for patients covered by Medicare but for which we have not recognized revenue was 12,977 and 10,866, respectively, as of March 31, 2015. If commercial third-party payors or government payors agree to pay us for these tests in the future, we will recognize revenue for such tests in the period in which our revenue recognition criteria are met. Any revenue that we receive in respect of these previously reported tests will favorably impact our liquidity and results of operations in future periods.

For our biopharmaceutical customer revenue that was based on a negotiated price per test, the average revenue per test was approximately $3,900 and $3,700 for the three months ended March 31, 2015 and 2014, respectively. We expect this average revenue per test for biopharmaceutical customers to remain fairly consistent with prior periods over time. Approximately $4.2 million and $2.9 million of our biopharmaceutical revenue for the three months ended March 31, 2015 and 2014, respectively, represented payments under contracts with multiple element arrangements that were not negotiated on a price per test basis.

Cost of Revenue

Cost of revenue increased to $8.9 million for the three months ended March 31, 2015 from $5.3 million for the three months ended March 31, 2014. This increase was driven by increasing test volumes from our ordering physicians and biopharmaceutical customers. The average cost per test does not differ materially by customer. Additional volume led to higher reagent and consumable costs, additional laboratory personnel-related costs, and higher depreciation expense related to new equipment purchases. During each of the three months ended March 31, 2015 and 2014, our cost of revenue represented approximately 46% of our total revenue. We expect to make additional investments in personnel, infrastructure, and systems to scale our laboratory operations to meet future anticipated demand.

Sales and Marketing Expenses

Sales and marketing expenses increased to $9.8 million for the three months ended March 31, 2015 from $5.7 million for the three months ended March 31, 2014. The increase was primarily due to an increase of $2.1 million in personnel-related costs related to new employees in our sales, marketing, client service, and reimbursement departments to support increased volume, a $1.4 million increase in marketing costs, a $0.3 million increase in travel-related costs, and a $0.3 million increase in various other expenses.

General and Administrative Expenses

General and administrative expenses increased to $8.8 million for the three months ended March 31, 2015 from $5.7 million for the three months ended March 31, 2014. The increase was primarily due to a $1.1 million combined increase in legal, consulting, audit, and billing fees, a $1.4 million increase in personnel costs to support and expand our legal, finance, and human resources infrastructure, and a $0.6 million increase in rent and other facilities costs.

Research and Development Expenses

Research and development expenses increased to $8.7 million for the three months ended March 31, 2015 from $6.9 million for the three months ended March 31, 2014. The increase was primarily due to a $0.9 million increase in employee and contractor-related expenses and a $0.9 million increase in laboratory supply costs, including reagents utilized in research and development activities.

Interest Income/Expense

Interest income was $7,000 and $4,000 for the three months ended March 31, 2015 and 2014, respectively. Interest expense was $0 and $29,000 for the three months ended March 31, 2015 and 2014, respectively. The decrease in interest expense was due to the elimination of our outstanding loan balance, as the loan amount was paid in full in December 2014.

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Liquidity and Capital Resources

We have incurred losses and negative cash flows from operations since our inception in November 2009, and as of March 31, 2015, we had an accumulated deficit of $159.0 million.

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

As of March 31, 2015, we had cash and cash equivalents of approximately $61.7 million. Cash in excess of immediate requirements is invested in accordance with our investment policy, primarily with a view to liquidity and capital preservation. These excess funds are held in money market mutual funds consisting of U.S. government-backed securities.

In April 2015, the Roche transaction was consummated, and we received an additional $250,000,000 in gross proceeds from the sale of 5,000,000 shares of common stock to Roche at a price of $50.00 per share. We believe this incremental capital should be sufficient to meet our anticipated cash requirements for the foreseeable future, although we may consider raising additional capital to pursue strategic investments or for other purposes, subject to certain consent rights of Roche contained in our Investor Rights Agreement.

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:

	Three Months Ended March 31,	
	2015	2014
	(in thousands)	
Net cash (used in) provided by:		
Operating activities	$ (10,917)	$ (13,441)
Investing activities	(3,341)	(174)
Financing activities	3,878	(370)
Net decrease in cash and cash equivalents	$ (10,380)	$ (13,985)

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 $10.9 million for the three months ended March 31, 2015 compared to $13.4 million for the three months ended March 31, 2014. The decrease in cash used in operating activities was driven primarily by a $6.0 million decrease in cash utilized to support working capital requirements due to increased accounts payable and accrued expense balances, and a $1.0 million increase in stock-based compensation expense, partially offset by an increase in net loss of $4.8 million between the respective periods.

Investing Activities

Net cash used in investing activities for the three months ended March 31, 2015 was $3.3 million and consisted of $2.3 million in purchases of property and equipment and a $1.0 million increase in restricted cash related to a letter of credit issued in connection with signing the Ten Canal Park lease agreement. Net cash used in investing activities for the three months ended March 31, 2014 was $0.2 million and consisted solely of purchases of property and equipment.

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Financing Activities

Net cash provided by financing activities for the three months ended March 31, 2015 was $3.9 million and consisted solely of proceeds received from the exercise of stock options. Net cash used in financing activities for the three months ended March 31, 2014 was $0.4 million comprised primarily of loan principal payments.

Operating Capital Requirements

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

In April 2015, the Roche transaction was consummated and we received an additional $250,000,000 in gross proceeds from the sale of 5,000,000 shares of common stock to Roche at a price of $50.00 per share. Based on our current business plan, we believe our cash and cash equivalents as of March 31, 2015, cash proceeds from the sale of common stock to Roche, and anticipated cash flows from operations will be sufficient to meet our anticipated cash requirements over the next 12 months and for the foreseeable future. We may consider raising additional capital to pursue strategic investments or for other reasons, subject to certain consent rights of Roche contained in our Investor Rights Agreement. In the future, we expect our operating and capital expenditures to increase as we increase our headcount, expand our selling and marketing activities and continue to invest in new product offerings. As sales of our products grow, we expect our accounts receivable balance to increase. Any increase in accounts payable and accrued expenses may not completely offset increases in accounts receivable, which could result in greater working capital requirements.

If our available cash balances and anticipated cash flow from operations are insufficient to satisfy our liquidity requirements, including because of lower demand for our products as a result of lower than currently expected rates of reimbursement from commercial third-party payors and government payors or other risks described in Part II, Item 1A. Risk Factors in this Quarterly Report, we may seek to sell common or preferred equity or convertible debt securities, enter into a credit facility or another form of third-party funding, or seek other debt financing. The sale of equity and convertible debt securities may result in dilution to our stockholders and those securities may have rights senior to those of our common stock. If we raise additional funds through the issuance of equity, convertible debt securities or other debt financing, these securities or other debt could contain covenants that would restrict our operations, and certain of these transactions will be subject to the prior consent of Roche as set forth in our Investor Rights Agreement. 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 Part II, Item 1A. Risk Factors in this Quarterly Report. 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 summarizes our principal contractual obligations as of March 31, 2015 that have changed significantly since December 31, 2014 and the effects such obligations are expected to have on our liquidity and cash flow in future periods. Contractual obligations that were presented in our Annual Report on Form 10-K for the year ended December 31, 2014, but omitted below, represent those that have not changed significantly since that date.

	Total	2015	2016-2017	2018-2019	Thereafter
			(in thousands)		
Operating lease obligations [1]	$ 38,003	$ 4,936	$ 12,812	$ 13,415	$ 6,840

[1] In March 2015, we leased 38,411 square feet for office space in Cambridge, Massachusetts under an operating lease that expires in August 2020.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

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Application of Critical Accounting Policies

We have prepared our condensed consolidated financial statements in accordance with accounting principles generally accepted in the United States. Our preparation of these condensed consolidated financial statements requires us to make estimates, assumptions, and judgments that affect the reported amounts of assets, liabilities, expenses, and related disclosures at the date of the condensed consolidated financial statements, as well as revenue and expenses recorded during the reporting periods. We evaluate our estimates and judgments on an ongoing basis. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results could therefore differ materially from these estimates under different assumptions or conditions.

There have been no material changes to our critical accounting policies from those described in Part II, Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations included in our Annual Report on Form 10-K for the year ended December 31, 2014.

Item 3. Quantitative and Qualitative Disclosures about Market Risks

There were no material changes during the quarter ended March 31, 2015 with respect to the information appearing in Part II, Item 7A. Quantitative and Qualitative Disclosures About Market Risk, included in our Annual Report on Form 10-K for the year ended December 31, 2014.

Item 4. Controls and Procedures

Management s Evaluation of our Disclosure Controls and Procedures

We maintain disclosure controls and procedures (as defined in Rules 13a-15(e) or 15d-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act)) that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is (1) recorded, processed, summarized, and reported within the time periods specified in the SEC s rules and forms and (2) accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures as of the end of the period covered by this Quarterly Report. Based on this evaluation, our principal executive officer and principal financial officer have concluded that, as of March 31, 2015, our disclosure controls and procedures were effective at the reasonable assurance level.

We continue to review and document our disclosure controls and procedures, including our internal controls and procedures for financial reporting, and may from time to time make changes aimed at enhancing their effectiveness and to ensure that our systems evolve with our business.

Changes in Internal Control Over Financial Reporting

During the quarter ended March 31, 2015, there were no changes in our internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15(d)-15(f) promulgated under the Exchange Act, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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PART II OTHER INFORMATION

Item 1. Legal Proceedings

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

Item 1A. Risk Factors

We operate in a rapidly changing environment that involves a number of risks that could materially affect our business, financial condition or future results, some of which are beyond our control. The risk factors described below pertain to us following the closing of our series of transactions with affiliates of Roche on April 7, 2015, as described elsewhere in this Quarterly Report on Form 10-Q. These risk factors should be carefully considered although the risks described below are not the only risks facing us. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition or operating results and could cause the market price of our common stock to fluctuate or decline. The risk factors set forth below with an asterisk (*) next to the title are new risk factors or risk factors containing changes, which may be material, from the risk factors previously disclosed in Item 1A of our Annual Report on Form 10-K for the fiscal year ended December 31, 2014, as filed with the SEC.

Risks Relating to Our Business and Strategy

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

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

Our biopharmaceutical partners may decide to decrease or discontinue their use of our molecular information platform due to changes in research and product development plans, failures in their clinical trials, financial constraints, or utilization of internal molecular testing resources or molecular tests performed by other parties, which are

circumstances outside of our control, as well as due to our broad strategic collaboration with certain affiliates of Roche and the fact that Roche is our largest stockholder and beneficially owns a majority of our outstanding stock. In addition to reducing our revenue, if our biopharmaceutical partners decide to decrease or discontinue their use of our molecular information platform, this may reduce our exposure to early stage research that facilitates the incorporation of newly developed information about cancer into our molecular information platform, FoundationOne and FoundationOne Heme.

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

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

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

- our ability to convince the medical community of the clinical utility of our products and their potential advantages over existing molecular tests;
- the willingness of physicians and patients to utilize our products; and
- the agreement by commercial third-party payors and government payors to reimburse our products, the scope and amount of which will affect patients willingness or ability to pay for our products and likely heavily influence physicians decisions to recommend our products.

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

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

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

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

We rely on several sole suppliers, including Illumina, 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. The terms upon which we are able to purchase these supplies and materials from any supplier could be adversely affected by our broad strategic collaboration with Roche and the fact that Roche is our largest stockholder and beneficially owns a majority of our outstanding stock. 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 significantly alter our laboratory operations. Transitioning to a new supplier would be time consuming and expensive, may result in interruptions in our laboratory operations, would likely affect the performance specifications of our laboratory operations, and would require that we revalidate FoundationOne and FoundationOne Heme. There can be no assurance that we will be able to secure alternative equipment, reagents, and other materials, and bring such equipment, reagents, and materials on line and revalidate them without experiencing interruptions in our workflow. In the case of an alternative supplier for Illumina, there can be no assurance that replacement sequencers and various associated reagents will be available or will meet our quality control and performance requirements for our laboratory operations. If we should encounter delays or difficulties in securing, reconfiguring, or revalidating the equipment and reagents we require for our products, our business, financial condition, results of operations and reputation could be adversely affected.

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

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

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We are building additional laboratory space at our corporate headquarters to support the development of companion diagnostic tests and new product development, including the development of a circulating tumor DNA assay. Our R&D collaboration agreement with Roche contemplates that we will collaborate with Roche on multiple programs related to the development of products and services for use in molecular information, immunotherapy, circulating tumor DNA and companion diagnostics. If we are delayed in building new laboratory space to support these development efforts, or if we never complete construction and validation, this delay could result in our inability to meet agreed upon timelines with certain of our biopharmaceutical partners, including Roche, which could cause us to breach our agreements or result in harm to our business and reputation. In addition, if we are delayed in building this additional laboratory space, or if we never complete construction and validation, this delay could impact our ability to develop and launch new products, which could adversely affect our business, financial condition and results of operations.

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

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

As our volume grows, including any potential increases in volume due to our collaboration with Roche, 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 technicians and other scientific and technical personnel to process higher volumes of our molecular information products. Portions of our process are not automated and will require additional personnel to scale. We will also need to purchase additional equipment, some of which can take several months or more to procure, setup, and validate, and increase our software and computing capacity to meet increased demand. There is no assurance that any of these increases in scale, expansion of personnel, equipment, software and computing capacities, or process enhancements will be successfully implemented, or that we will have adequate space in our laboratory facility to accommodate such required expansion.

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

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

FoundationOne Heme, which we launched in December 2013 for hematologic cancers, including leukemia, lymphoma and myeloma, as well as pediatric cancers and many sarcomas, will take time to successfully commercialize. There can be no assurance that FoundationOne Heme will be successful in the evaluation of blood-based cancers for a variety of technical and market reasons. Our other new molecular information products,

including a circulating tumor DNA assay, which are in various stages of early development, will take time to develop and commercialize, if we are able to commercialize them at all. There can be no assurance that our new products will be capable of reliably identifying relevant genomic alterations in various forms of cancer. Before we can commercialize any new products, we will need to expend significant funds in order to:

- conduct substantial research and development, including validation studies and potentially clinical trials;
- build additional laboratory space for new products, including a circulating tumor DNA assay;
- further develop and scale our laboratory processes to accommodate different products; and
- 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.

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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, including new entrants in the market, 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, Molecular Health, Caris Life Sciences, Guardant Health, Paradigm, NeoGenomics Laboratories, as well as companies such as Abbott Laboratories, Qiagen N.V., and Sequenom, Inc. that manufacture or may manufacture diagnostic testing kits. In addition, companies such as Genomic Health, Inc. and Myriad Genetics, Inc. have well-established commercial organizations that sell molecular diagnostic tests for cancer to physicians and may develop tests which compete with FoundationOne or FoundationOne Heme.

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

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

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

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

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

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

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

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

In addition, our FoundationOne and FoundationOne Heme reports match identified genomic alterations with FDA-approved targeted therapies or relevant clinical trials of targeted therapies. If a patient or clinical physician who orders FoundationOne or FoundationOne Heme is unable to obtain, or be reimbursed for the use of, targeted therapies because they are not indicated in the FDA-approved product label for treatment of a patient s cancer, the patient is unable to enroll in an identified clinical trial due to the enrollment criteria of the trial, or some other reason, the patient or ordering clinical physician may conclude the FoundationOne or FoundationOne Heme report does not contain actionable information. If physicians do not believe FoundationOne or FoundationOne Heme consistently generates actionable information about their patients cancers, they may be less likely to order our products, our reputation could be harmed, and our business and results of operations could suffer.

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

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

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

We deploy our molecular information platform to analyze tissue samples provided by biopharmaceutical partners from their clinical trials. We have entered into agreements with biopharmaceutical companies in the cancer field including, for example, Agios Pharmaceuticals, Inc., ARIAD Pharmaceuticals, Inc., Array BioPharma Inc., AstraZeneca UK Limited, Celgene Corporation, Clovis Oncology, Inc., Eisai Co., Ltd., Johnson & Johnson, Novartis, and Sanofi, among others, as well as our broad collaboration with Roche which closed in April 2015. In each of the years ended December 31, 2014, 2013, and 2012, our alliance with Novartis accounted for more than 10% of our revenue. We expect that our broad collaboration with Roche will account for a material portion of revenue in future years. The revenue attributable to Novartis or Roche may also fluctuate in the future, which could have an adverse effect on our financial condition and results of operations. In addition, the termination of this relationship could result in a temporary or permanent loss of revenue to us.

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

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In addition, certain biopharmaceutical companies, including those with which we currently have agreements, may choose not to do business with us or may seek out other partners for molecular information, due to our broad strategic collaboration with Roche and the fact that Roche is our largest stockholder and beneficially owns a majority of our outstanding stock, particularly if they are actual or potential competitors with Roche. If we are unable to continue to grow our business with biopharmaceutical companies, our business and results of operations would be adversely affected.

From time to time, we expect to engage in discussions with biopharmaceutical companies regarding commercial opportunities. There is no assurance that any of these discussions will result in a commercial agreement, or if an agreement is reached, that the resulting engagement will be successful or that clinical studies conducted as part of the engagement will produce successful outcomes. Speculation in the industry about our existing or potential engagements with biopharmaceutical companies can be a catalyst for adverse speculation about us, our products, and our technology, which can result in harm to our reputation and our business.

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

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

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

We have limited experience in marketing and selling FoundationOne, which had its formal commercial launch in June 2012, and FoundationOne Heme, which launched in December 2013. We may not be able to market, sell, or distribute FoundationOne, FoundationOne Heme, or other products we may develop effectively enough to support our planned growth.

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.

Pursuant to our ex-U.S. commercialization agreement with Roche, commencing in April 2016, Roche will have the exclusive right to commercialize our existing clinical diagnostic testing products, FoundationOne and FoundationOne Heme, any clinical diagnostic products developed under our R&D collaboration agreement with Roche, and any other products upon mutual agreement, in each case outside of the United States to the extent Roche has not elected to exclude any countries from its territory. Subject to satisfaction of certain performance milestones, the ex-U.S. commercialization agreement will remain in effect for five years and may be extended by Roche for additional two-year periods. Roche shall have the right to terminate the agreement without cause upon six months written notice after the initial five year term, and either party may terminate the agreement in the event of breach by the other party. During the term of the ex-U.S. commercialization agreement, we will be relying on Roche s efforts to sell and market FoundationOne and FoundationOne Heme outside of the United States, and if Roche s sales and marketing efforts are not successful, we may not achieve significant market acceptance of our products outside the United States, which would materially and adversely impact our business operations.

For any jurisdictions outside of the United States that Roche elects to exclude from its territory, if we believe a significant market opportunity for our products exists, we intend to enlist distribution partners and local laboratories to assist with sales, distribution, and customer support. 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 partners 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 these additional sales and marketing efforts are not successful, we may not achieve significant market acceptance for our products in these markets, which could harm our business.

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**** The loss of any member of our senior management team or our inability to attract and retain highly skilled scientists, clinicians, and salespeople, or the diversion of management s attention due to the implementation of our collaboration with Roche, 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 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. In addition, our obligation to repurchase shares of our common stock pursuant to Roche s anti-dilution protections set forth in the Investor Rights Agreement may result in changes to our equity compensation programs, which could impact our ability to attract and retain key personnel. Recruitment and retention difficulties can limit our ability to support our research and development and sales programs. All of our employees are at will, which means that either we or the employee may terminate their employment at any time.

The implementation of our broad strategic collaboration with Roche may also divert management s focus and resources from other strategic opportunities and operational matters. In addition, this implementation could cause management and employee disruption, resulting in the possible loss of key management, sales and marketing, technical or other personnel. If we experience any of these implementation-related issues, our business could be harmed.

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

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

We maintain product and professional liability insurance, but this insurance may not fully protect us from the financial impact of defending against product liability or professional liability claims. Any product liability or professional liability claim brought against us, with or without merit, could increase our insurance rates or prevent us from securing insurance coverage in the future. Additionally, any product liability lawsuit could damage our reputation or cause current clinical or biopharmaceutical partners to terminate existing agreements and potential clinical or biopharmaceutical partners to seek other partners, any of which could impact our results of operations.

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

We depend on information technology and telecommunications systems for significant elements of our operations, including our laboratory information management system, our computational biology system, our knowledge management system, our customer reporting, and our ICE 2 portal. We have installed, and expect to expand, a number of enterprise software systems that affect a broad range of business processes and functional areas, including, for example, systems handling human resources, financial controls and reporting, contract management, regulatory compliance, and other infrastructure operations. In addition to the aforementioned business systems, we intend to extend the capabilities of both our preventative and detective security controls by augmenting the monitoring and alerting functions, the network design, and the automatic countermeasure operations of our technical systems. These information technology and telecommunications systems support a variety of functions, including laboratory operations, test validation, sample tracking, quality control, customer service support, billing and reimbursement, research and development activities, scientific and medical curation, 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. Failures or significant downtime of our information technology or telecommunications systems, or those used by our third-party service providers, could prevent us from conducting our comprehensive genomic analyses, preparing and providing reports and data to pathologists and oncologists, billing payors, processing reimbursement appeals, handling patient or physician inquiries, conducting research and development activities, and managing the administrative aspects of our business. Any disruption or loss of information technology or telecommunications systems on which critical aspects of our operations depend could have an adverse effect on our business.

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Security breaches, loss of data, and other disruptions could compromise sensitive information related to our business or prevent us from accessing critical information and expose us to liability, which could adversely affect our business and our reputation.

In the ordinary course of our business, we and our third-party billing and collections provider collect and store sensitive data, including legally protected health information, personally identifiable information, intellectual property, and proprietary business information owned or controlled by ourselves or our customers, payors, and biopharmaceutical partners. We manage and maintain our applications and data utilizing a combination of on-site systems, managed data center systems, and cloud-based data center systems. We also communicate, and facilitate the exchange of, sensitive patient data to customers through our ICE 2 portal. These applications and data encompass a wide variety of business-critical information including research and development information, commercial information, and business and financial information. We face four primary risks relative to protecting this critical information, including: unauthorized access risk; inappropriate disclosure risk; inappropriate modification risk; and the risk of our being unable to adequately monitor our controls over the first three risks.

The secure processing, storage, maintenance, and transmission of this critical information is vital to our operations and business strategy, and we devote significant resources to protecting such information. Although we take measures to protect sensitive information from unauthorized access or disclosure, our information technology and infrastructure, and that of our third-party billing and collections provider, may be vulnerable to attacks by hackers or viruses or breached due to personnel error, malfeasance, or other disruptions. Any such breach or interruption could compromise our networks, and the information stored there could be accessed by unauthorized parties, publicly disclosed, lost, or stolen. Any such access, disclosure, or other loss of information could result in governmental investigations, class action legal claims or proceedings, liability under laws that protect the privacy of personal information, such as the Health Insurance Portability and Accountability Act, 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, the ICE 2 portal, which is currently accessible through our online portal and will, in the future, be accessible through dedicated mobile applications, gives broad access to physicians, at which point we lose ability to control access, and there is no guarantee we can absolutely protect our online portal or our mobile applications, from breach. Unauthorized access, loss, or dissemination could also disrupt our operations, including our ability to conduct our analyses, provide test results, bill payors or patients, process claims and appeals, provide customer assistance services, conduct research and development activities, collect, process, and prepare company financial information, provide information about our products and other patient and physician education and outreach efforts through our website, manage the administrative aspects of our business, and damage our reputation, any of which could adversely affect our business.

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

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

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

Our business strategy may, from time to time, include pursuing acquisitions of businesses and assets. We also may pursue strategic alliances and joint ventures that leverage our proprietary molecular information platform and industry experience to expand our offerings or distribution. We have no experience with acquiring other companies. Negotiating these transactions and the formation

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of strategic alliances or joint ventures can be time consuming, difficult and expensive, and our ability to close these transactions may be subject to third-party approvals, including, in some cases, the approval of Roche pursuant to the terms of our Investor Rights Agreement, as well as governmental authorities, which are beyond our control. In addition, some third parties may choose not to enter into partnership arrangements with us because of our relationship with Roche. Consequently, we may not be able to complete such transactions on favorable terms or at all, and we can make no assurance that these transactions, once undertaken and announced, will close.

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

To finance any acquisitions or joint ventures, we may choose to issue shares of our common stock as consideration, which could dilute the ownership of our stockholders, if the issuance does not trigger our repurchase obligations under the Investor Rights Agreement, and be subject to the prior consent of Roche, which might not be given. 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, or if Roche does not provide consent for transactions requiring their approval, 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 plans for significant international expansion through our collaboration with Roche. Pursuant to our ex-U.S. commercialization agreement with Roche, commencing in April 2016, Roche will have the exclusive right to commercialize our existing clinical diagnostic testing products, FoundationOne and FoundationOne Heme, any clinical diagnostic products developed under our R&D collaboration agreement with Roche, and any other products upon mutual agreement, in each case outside of the United States to the extent Roche has not elected to exclude any countries from its territory. Subject to satisfaction of certain performance milestones, the ex-U.S. commercialization agreement will remain in effect for five years and may be extended by Roche for additional two-year periods. Roche shall have the right to terminate the agreement without cause upon six months written notice after the initial five year term, and either party may terminate the agreement in the event of breach by the other party. Until Roche assumes responsibility for commercialization of our products outside of the United States, we intend to continue to rely on distributor relationships to conduct physician and patient association outreach activities and to expand payor relationships outside of the United States.

Doing business internationally involves a number of risks, including:

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

and licenses;

failure by us, Roche 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.

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

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

International customers have ordered, or may, in the future, order FoundationOne or FoundationOne Heme, and we are, therefore, subject to the FCPA, which prohibits companies and their intermediaries from making payments in violation of law to non-U.S. government officials for the purpose of obtaining or retaining business or securing any other improper advantage. Our current reliance on third-party distributors to sell FoundationOne and FoundationOne Heme internationally demands a high degree of vigilance in maintaining our policy against participation in corrupt activity, because these distributors could be deemed to be our agents, and we could be held responsible for their actions. Other U.S. companies in the medical device and pharmaceutical field have faced criminal penalties under the FCPA for allowing their agents to deviate from appropriate practices in doing business with these individuals. We are also subject to similar anti-bribery laws in the jurisdictions in which we operate, including the United Kingdom s Bribery Act of 2010, which 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, any changes in these laws, or the interpretation thereof. Any violations of these laws, or allegations of such violations, could disrupt our operations, involve significant management distraction, involve significant costs and expenses, including legal fees, and could result in a material adverse effect on our business, prospects, financial condition, or results of operations. We could also suffer severe penalties, including criminal and civil penalties, disgorgement, and other remedial measures.

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

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

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

Continuing concerns over United States health care reform legislation, geopolitical issues, the availability and cost of credit, and government stimulus programs in the United States and other countries have contributed to volatility for the global economy. If the economic climate does not improve, our business, including our access to patient samples and the addressable market for molecular information products that we may successfully develop, as well as the financial condition of our suppliers and our commercial third-party payors, could be adversely affected, resulting in a negative impact on our business, financial condition, and results of operations. 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.

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

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

Reimbursement and Regulatory Risks Relating to Our Business

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

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

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

We are submitting claims to National Government Services using a miscellaneous Current Procedural Terminology, or CPT, code. When submitting claims for services or procedures that do not have specific CPT codes, providers may submit those claims using a CPT code, referred to as the miscellaneous CPT code, to provide the means of reporting and tracking services and procedures until a more specific CPT code is established. We are not submitting claims to CMS using stacked CPT codes in the manner currently used in submitting claims to commercial third-party payors. The use of a miscellaneous CPT code for claims submitted to CMS may decrease the likelihood of reimbursement given that a miscellaneous CPT code is a single CPT code that does not represent an identified service or procedure. We have not received any payments for FoundationOne or FoundationOne Heme provided to patients covered by Medicare to date. If CMS does not issue a positive national coverage determination, or National Government Services does not issue a local coverage determination, with respect to FoundationOne and/or FoundationOne Heme, or if

National Government Services denies reimbursement of FoundationOne and/or FoundationOne Heme, withdraws its coverage policies after reimbursement is obtained, reviews and adjusts the rate of reimbursement, or stops paying for FoundationOne and/or FoundationOne Heme altogether, our revenue and results of operations would be adversely affected.

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

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

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

- not experimental or investigational;
- medically necessary;
- appropriate for the specific patient;
- cost effective;
- supported by peer-reviewed publications;
- included in clinical practice guidelines; and
- supported by clinical utility studies demonstrating improved outcomes.

As a result, our efforts to receive reimbursement on behalf of patients will take a substantial amount of time, and various commercial third-party payors and government payors may never cover or provide adequate payment for FoundationOne, FoundationOne Heme, or future molecular information products we develop. Our strategy to achieve broad reimbursement coverage is focused on demonstrating the clinical utility and economic benefits of FoundationOne and FoundationOne Heme, including engagement with key members of the oncology community and

increasing physician demand, but there is no assurance that we will succeed in any of these areas or that, even if we do succeed, we will receive favorable reimbursement decisions. If adequate third-party reimbursement is unavailable, we may not be able to maintain price levels sufficient to realize an appropriate return on investment in product development. Furthermore, if a commercial third-party payor or government payor denies coverage, it may be difficult for us to collect from the patient, and we may not be successful.

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

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

Changes in the way that the FDA regulates products developed, manufactured, validated, and performed by laboratories like ours could result in additional expense in offering our current and any future products or even possibly delay or suspend development, manufacture, or commercialization of such products.

While the FDA currently exercises its enforcement discretion for laboratory developed tests, or LDTs, by not requiring compliance with its regulations, on July 31, 2014, the FDA announced that it intends to change this policy. The FDA previously announced in June 2010 that it intended to no longer exercise enforcement discretion for LDTs and subsequently stated that it would publish guidance documents describing an approach to regulating LDTs. Pursuant to the Food and Drug Administration Safety and

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Innovation Act of 2012, the FDA was required to notify Congress at least 60 days prior to publishing any guidance documents implementing a new regulatory policy for LDTs. On July 31, 2014, the FDA provided the required notification, including draft guidance documents, to Congress and in October 2014, the FDA formally published the draft guidance documents. In the draft guidance documents, the FDA stated that it had serious concerns regarding the lack of independent review of the evidence of clinical validity of LDTs and asserted that the requirements under the Clinical Laboratory Improvement Amendments, or CLIA, do not address the clinical validity of any LDT. If published and finalized in the same form, the guidance documents would impose a risk-based, phased-in approach for LDTs similar to the existing *in vitro* diagnostic devices framework.

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

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

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

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

In addition, we could be subject to a recall or seizure of current or future products, operating restrictions, a partial suspension or a total shutdown of production. Any such enforcement action would have a material adverse effect on our business, financial condition and operations.

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

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

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

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

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

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

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

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

Additionally, in April 2014 the Protecting Access to Medicare Act of 2014, or the Act, was enacted into law which reforms the Medicare payment system for clinical laboratory tests paid through the CLFS. The Act rescinds CMS statutory authority to make adjustments to future payments for tests based on technological changes, which CMS had intended to apply to certain test codes on the CLFS beginning in calendar year 2015. Beginning in January 2017, Medicare payment for clinical diagnostic laboratory tests will be established by a market-based payment system. Under this new methodology, CMS will establish Medicare payment for each test based on the weighted median of the payment rates for private payors for the test. The Act creates a new class of Advanced Diagnostic Laboratory Tests

defined as sole source multi-analyte tests with a unique algorithm yielding a single result or a test that is cleared or approved by FDA or other such criteria developed by the Secretary of Health and Human Services. For Medicare payment prior to 2017, the Act creates a transitional period for both new and existing tests. Our average commercial payor reimbursement starting in 2017 could be adversely affected depending upon if and how payors adopt this new CMS pricing methodology and resulting rates.

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

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 CLIA, a federal law that regulates clinical laboratories that perform testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention, or treatment of disease. CLIA regulations mandate specific standards in the areas of personnel qualifications, administration, and participation in proficiency testing, patient test management, quality control, quality assurance, and inspections. We have a current certificate of accreditation under CLIA to conduct our genomic analyses through our accreditation by CAP. To renew this certificate, we are subject to survey and inspection every two years. Moreover, CLIA inspectors may make unannounced inspections of our clinical reference laboratory at any time.

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

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

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

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, ICE 2;

amendments to HIPAA under the Health Information Technology for Economic and Clinical Health Act (HITECH Act), which strengthen and expand HIPAA privacy and security compliance requirements,

increase penalties for violators, extend enforcement authority to state attorneys general, and impose requirements for breach notification;

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

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

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

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

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

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

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

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

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

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

Intellectual Property Risks Related to Our Business

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

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

We could incur substantial costs and divert the attention of our management and technical personnel in defending ourselves against any of these claims. Any adverse ruling or perception of an adverse ruling in defending ourselves against these claims could have a material adverse impact on our cash position and stock price. Furthermore, parties making claims against us may be able to obtain injunctive or other relief, which could block our ability to develop, commercialize, and sell products, and could result in the award of substantial damages against us. In the event of a successful claim of infringement or misappropriation against us, we may be required to pay damages and obtain one or more licenses from third parties, or be prohibited from selling certain products, all of which could have a material adverse impact on our cash position and business and financial condition.

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

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

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

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

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

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

the defense or settlement of these claims could have a material adverse impact on our business.

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

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

Obtaining and maintaining a strong patent position is important to our business. Many of our patent applications are in the early stages of prosecution. Patent law relating to the scope of claims in the technology fields in which we operate is complex and uncertain,

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

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

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

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

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

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

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

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

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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 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 Related to Our Relationship with Roche

**** We may not fully realize the anticipated benefits of our broad strategic collaboration with Roche or realize them in the expected time frame.***

Implementation of the collaboration agreements and related corporate governance agreements with Roche may result in material unanticipated problems, expenses, liabilities, competitive responses, loss of customer relationships, and diversion of management s attention, including, among others:

- difficulties in achieving anticipated business opportunities and growth prospects;
- difficulties in managing the expanded operations of a more complex company;

challenges related to adhering to our obligations to repurchase shares pursuant to Roche s anti-dilution protections contained in the Investor Rights Agreement;

challenges resulting from increased complexities in accounting and tax matters related to our obligations under the Investor Rights Agreement and Tax Sharing Agreement by and between the Company and Roche Holdings, Inc., dated January 11, 2015 (the Tax Sharing Agreement), including our compliance with certain financial, accounting and tax reporting obligations, practices and procedures, and the transition to a new independent public company accounting firm;

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

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

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

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

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

Immediately following the closing of our transactions with Roche, Roche owned approximately 61% of our outstanding common stock. As a result, until such time as Roche and its affiliates hold shares representing less, and potentially a material portion less, than a majority of the votes entitled to be cast by the holders of our outstanding common stock at a stockholder meeting, Roche generally will have the ability to control the outcome of any matter submitted for the vote of our stockholders, except in certain circumstances set forth in our certificate of incorporation, bylaws and the Investor Rights Agreement.

The interests of Roche may not coincide with the interests of our other stockholders. Roche s ability, subject to the limitations in our certificate of incorporation, bylaws and the Investor Rights Agreement, to control all matters submitted to our stockholders for approval limits the ability of other stockholders to influence corporate matters and, as a result, we may take actions that our minority stockholders do not view as beneficial. As a result, the market price of our common stock could be adversely affected.

In addition, the existence of a majority stockholder will have the effect of making it more difficult for a third party to acquire, or discouraging a third party from seeking to acquire, our business. A third party would be required to negotiate any such transaction with Roche, and the interests of Roche with respect to such transaction may be different from the interests of our other stockholders. In particular, it is possible that our minority stockholders may not receive a control premium for their shares upon any eventual sale of our Company. In addition, the performance of Roche or speculation about the possibility of future actions Roche may take in connection with us may adversely affect our share price.

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

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

make any voluntary bankruptcy filings. Our Board of Directors or management team could believe that taking any one of these actions would be in the best interests of our Company and its stockholders. As such, if we are unable to complete any of these actions because Roche does not provide its consent, it could adversely impact and our business and results of operations.

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

In addition, the Transaction Agreement by and between the Company and Roche Holdings, Inc., dated January 11, 2015 (the Transaction Agreement) provides for us to indemnify Roche for breaches of the Transaction Agreement by us subject to negotiated limitations. If we are required to indemnify Roche for any such breaches, it could have a material adverse impact on our results of operations.

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**** Roche s majority ownership of our Company and contractual restrictions on their ability to purchase and sell our common stock could have a material negative impact on the liquidity of our common stock.***

Immediately following the closing of our transactions with Roche on April 7, 2015, Roche owned approximately 61% of our outstanding common stock. In addition, under the terms of the Investor Rights Agreement, for three years following the closing, Roche is restricted from acquiring additional shares, except in order to offset dilution and maintain its aggregate percentage ownership in the Company at no less than 50.5% of the outstanding shares of our common stock on a fully diluted basis. The Investor Rights Agreement also requires us to establish a stock repurchase program designed to maintain Roche s percentage ownership interest in our common stock. This ownership and these provisions will likely result in a less liquid trading market for our shares. This lack of liquidity may make it more difficult for investors to transact in our shares and the price of our stock may suffer as a result.

**** The independent members of our Board of Directors, who are not our employees and are not Roche designees, do not represent a majority of our Board of Directors.***

We have determined that the directors designated by Roche, who represent a minority on our Board of Directors, and our Chief Executive Officer are not independent directors under NASDAQ Rule 5605(a)(2). NASDAQ Rule 5605(b) requires that a majority of the board of directors of NASDAQ listed companies be comprised of independent directors. In connection with the closing of our transactions with Roche, the size of our Board of Directors was increased to nine seats. The Board currently consists of three directors designated by Roche, or the Roche Designees, and five of our directors who served prior to the closing, including our Chief Executive Officer. We intend that the vacancy on the Board will be filled in accordance with the Investor Rights Agreement with an independent director to be agreed upon by us and Roche.

Four members of our Board are independent under NASDAQ Rule 5605(a)(2), which does not constitute a majority of our Board of Directors at this time. However, due to Roche s majority ownership of our stock, we intend to rely upon the Controlled Company exemption from the majority Board independence requirement of NASDAQ Rule 5605(b) set forth in NASDAQ Rule 5615(c)(2) until the new independent director is appointed to the Board. If we are not able to identify and appoint a new independent director to our Board in a timely fashion, the perception of our Company as an independent entity could be diminished and our business could be harmed.

Risks Relating to Our Financial Condition and Capital Requirements

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

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

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

We have historically incurred substantial net losses, including a net loss of $52.2 million in 2014. From our inception in 2009 through March 31, 2015, we had an accumulated deficit of $159.0 million. We expect our losses to continue as a result of ongoing research and development expenses and increased selling and marketing costs. These losses have had, and will continue to have, an adverse effect on our working capital, total assets, and stockholders equity. Because of the numerous risks and uncertainties associated with our research, development, and commercialization efforts, we are unable to predict when we will become profitable, and we may never become profitable. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our inability to achieve and then maintain profitability would negatively affect our business, financial condition, results of operations, and cash flows.

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

If our available cash balances, net proceeds from our IPO and the investment from Roche, 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 Quarterly Report, we may seek to sell common or preferred equity or convertible debt securities, enter into a credit facility or another form of third-party funding, or seek other debt financing.

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

- increase our sales and marketing efforts to drive market adoption of FoundationOne and FoundationOne Heme and address competitive developments;
- fund development and marketing efforts of any future products;
- further expand our clinical laboratory operations;
- expand our technologies into other types of cancers;
- acquire, license or invest in technologies, including information technologies;
- acquire or invest in complementary businesses or assets; and
- finance capital expenditures and general and administrative expenses.

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

- our ability to achieve revenue growth;
- our rate of progress in establishing reimbursement arrangements with domestic and international commercial third-party payors and government payors;
- the cost of expanding our laboratory operations and offerings, including our sales and marketing efforts;

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

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

the effect of competing technological and market developments;

costs related to international expansion; and

the potential cost of and delays in product development as a result of any regulatory oversight applicable to our products.

The various ways we could raise additional capital carry potential risks and are, in certain cases set forth in the Investor Rights Agreement, subject to the prior consent of Roche. 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. Accordingly, additional equity or debt financing might not be available on reasonable terms, if at all. If we cannot secure additional funding when needed, we may have to delay, reduce the scope of, or eliminate one or more research and development programs or sales and marketing initiatives. In addition, we may have to work with a partner on one or more of our development programs, which could lower the economic value of those programs to us.

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

As a public company, we incur significant legal, accounting, and other expenses due to our compliance with regulations and disclosure obligations applicable to us, including compliance with the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, as well as rules implemented by the SEC, and the NASDAQ Stock Market, or NASDAQ. The SEC and other regulators have continued to adopt new rules and regulations and make additional changes to existing regulations that require our compliance. In July 2010, the

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

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

We are required to comply with certain of the SEC rules that implement Section 404 of the Sarbanes-Oxley Act, which requires management to certify financial and other information in our quarterly and annual reports and provide an annual management report on the effectiveness of our internal control over financial reporting. This assessment needs to include the disclosure of any material weaknesses in our internal control over financial reporting identified by our management or our independent registered public accounting firm. We are just beginning the costly and challenging process of compiling the system and processing documentation needed to comply with such requirements. We may not be able to complete our evaluation, testing, and any required remediation in a timely fashion. During the evaluation and testing process, if we identify one or more material weaknesses in our internal control over financial reporting, we will be unable to assert that our internal control over financial reporting is effective.

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

reporting, we could lose investor confidence in the accuracy and completeness of our financial reports, which could have a material adverse effect on the price of our common stock.

In addition, adherence to our obligations to repurchase shares of our common stock pursuant to Roche s anti-dilution protections in the Investor Rights Agreement may be costly and, require substantial resources and efforts. Furthermore, adherence to our other obligations under the Investor Rights Agreement and the Tax Sharing Agreement, including our compliance with certain financial, accounting and tax reporting obligations, may be costly and time consuming, require substantial resources and efforts, and result in changes to our existing business practices.

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 transactions with Roche that closed in April 2015 may have resulted in an ownership change 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 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.

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Risks Related to Our Common Stock

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

There has been a public market for our common stock for only a short period of time. Although our common stock is listed on the NASDAQ Global Select Market, an active public market for our common stock may not be sustained, due to the ownership of a majority of our outstanding stock by Roche and contractual restrictions on Roche s and our ability to transact our shares set forth in the Investor Rights Agreement.

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

- actual or anticipated fluctuations in our financial condition and operating results;
- actual or anticipated changes in our growth rate relative to our competitors;
- competition from existing products or new products that may emerge;
- announcements by us, our biopharmaceutical partners, or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations, or capital commitments;
- failure to meet or exceed financial estimates and projections of the investment community or that we provide to the public;
- 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;

the perception of us in the marketplace as an independent entity;

the performance of Roche or speculation about the possibility of future actions Roche may take in connection with us; 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 our 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.

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

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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 any of the exemptions available under the JOBS Act. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We may take advantage of these reporting exemptions until we are no longer an emerging growth company. We will remain an emerging growth company until the earliest of (i) the last day of the fiscal year in which we have total annual gross revenue of $1.0 billion or more; (ii) December 31, 2018; (iii) the date on which we have issued more than $1.0 billion in nonconvertible debt during the previous three years; and (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC.

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

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

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

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

**** Our relationship with Roche and anti-takeover provisions contained in our certificate of incorporation and bylaws, as well as provisions of Delaware law, could impair a takeover attempt.***

Immediately following the closing of our transactions with Roche, Roche beneficially owned approximately 61% of our outstanding common stock. As a result, until such time as Roche and its affiliates hold shares representing less, and potentially a material portion less, than a majority of the votes entitled to be cast by the holders of our outstanding common stock at a stockholder meeting, Roche generally will have the ability to control the outcome of matters submitted for the vote of our stockholders related to a proposed takeover attempt. The existence of a majority stockholder will have the effect of making it more difficult for a third party to acquire, or discouraging a third party from seeking to acquire, our business. A third party would be required to negotiate any such transaction with Roche, and the interests of Roche with respect to such transaction may be different from the interests of our other stockholders. In particular, it is possible that our minority stockholders may not receive a control premium for their shares upon any eventual sale of our Company.

Our certificate of incorporation, bylaws, and Delaware law contain provisions which could have the effect of rendering more difficult, delaying or preventing an acquisition deemed undesirable by our Board of Directors. Our

corporate governance documents include provisions:

- 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.

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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.

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

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

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

Use of Proceeds from Initial Public Offering of Common Stock

On September 30, 2013, we closed the sale of 6,772,221 shares of common stock to the public (inclusive of 883,333 shares of common stock sold by us pursuant to the full exercise of an overallotment option granted to the underwriters) at a price of $18.00 per share, before underwriting discounts. The offer and sale of the shares in our initial public offering (IPO) was registered under the Securities Act of 1933 pursuant to registration statements on Form S-1 (File No. 333-190226), which was filed with the SEC on July 29, 2013 and amended subsequently and declared effective by the SEC on September 24, 2013, and Form S-1MEF (File No. 333-191333), which was filed with the SEC on September 24, 2013 and automatically effective upon filing.

We raised approximately $110.4 million in net proceeds after deducting underwriting discounts and commissions of approximately $8.5 million and other offering expenses of approximately $3.0 million. There has been no material change in the planned use of proceeds from our IPO as described in our final prospectus filed with the SEC on September 25, 2013 pursuant to Rule 424(b)(4). We invested the funds received in cash equivalents and other short-term investments in accordance with our investment policy, and as of March 31, 2015, the remainder of the net proceeds is included as cash and cash equivalents.

Item 6. Exhibits

The exhibits filed as part of this Quarterly Report on Form 10-Q are set forth on the Exhibit Index, which is incorporated herein by reference.

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf on the date set forth below by the undersigned thereunto duly authorized.

FOUNDATION MEDICINE, INC.

Date: May 11, 2015

By: /s/ Michael J. Pellini, M.D.
Michael J. Pellini, M.D.
Chief Executive Officer
(Principal Executive Officer)

Date: May 11, 2015

By: /s/ Jason Ryan
Jason Ryan
Chief Financial Officer
(Principal Financial Officer)

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Exhibit No.	Exhibit Index
2.1	Transaction Agreement, by and between the Company and Roche Holdings, Inc., dated January 11, 2015 (1)
4.1	Investor Rights Agreement, by and between the Company and Roche Holdings, Inc., dated January 11, 2015 (1)
4.2	Amendment to Second Amended and Restated Investors Rights Agreement, by and between the Company and the Investors named therein, dated January 11, 2015 (1)
10.1	Tax Sharing Agreement, by and between the Company and Roche Holdings, Inc., dated January 11, 2015 (1)
10.2	Deed of Lease, by and between the Company and BCSP Cambridge Ten Property LLC, dated March 11, 2015 (2)
10.3	Collaboration Agreement, by and among the Company, F. Hoffman-La Roche Ltd and Hoffman-La Roche Inc., dated January 11, 2015 (3)
10.4	Ex-US Commercialization Agreement, by and between the Company and F. Hoffmann-La Roche Ltd, dated January 11, 2015 (3)
10.5	US Education Collaboration Agreement, by and between the Company and Genentech, Inc., dated January 11, 2015 (3)
10.6	Binding Term Sheet for an In Vitro Diagnostics Collaboration, by and between the Company and F. Hoffman-La Roche Ltd, dated January 11, 2015 (3)
31.1*	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	Interactive Data Files regarding (a) our Condensed Consolidated Balance Sheets as of March 31, 2015 and December 31, 2014 (b) our Condensed Consolidated Statements of Operations and Comprehensive Loss for the Three Months Ended March 31, 2015 and 2014, (c) our Condensed Consolidated Statements of Cash Flows for the Three Months Ended March 31, 2015 and 2014 and (d) the Notes to such Condensed Consolidated Financial Statements.

* Filed herewith.
** Furnished herewith.
(1) Incorporated by reference from the Company s Current Report on Form 8-K filed on January 12, 2015.
(2) Incorporated by reference from the Company s Current Report on Form 8-K filed on March 12, 2015.
(3) Incorporated by reference from the Company s Current Report on Form 8-K/A filed on February 2, 2015.

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