Foundation Medicine, Inc.
Form 10-Q
November 12, 2013
Table of Contents

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 September 30, 2013

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** ¨ **No** x

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 ¨
Non-accelerated filer x (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 November 6, 2013 was 28,138,173.

Table of Contents

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 expand existing or develop new relationships with biopharmaceutical partners;

- our ability to increase the commercial success of FoundationOne;

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

- the outcome or success of our clinical trials;

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

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

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

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

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

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

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

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

the impact of the recently completed relocation of our laboratory into our new facility;

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

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

Table of Contents

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

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

other risks and uncertainties, including those listed under Part II, Item 1A. Risk Factors.

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 and elsewhere in this Quarterly Report on Form 10-Q. 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 and our refer to Foundation Medicine, Inc. We own various U.S. federal trademark registrations and applications, and unregistered trademarks and service marks, including Foundation Medicine®, FoundationOne , FoundationOne Heme, and Interactive Cancer Explorer . We also refer to the trademarks of other corporations and organizations in this report.

Table of Contents

FOUNDATION MEDICINE, INC.

REPORT ON FORM 10-Q

For the Quarterly Period Ended September 30, 2013

Table of Contents

FOUNDATION MEDICINE, INC.

Condensed Balance Sheets

(unaudited)

(In thousands, except share and per share data)

	September 30, 2013	December 31, 2012
Assets		
Current assets:		
Cash and cash equivalents	$ 137,927	$ 54,838
Short-term restricted cash	161	
Accounts receivable	4,437	2,195
Inventory	942	803
Prepaid expenses and other current assets	950	550
Total current assets	144,417	58,386
Property and equipment, net	19,480	7,465
Restricted cash	1,725	161
Other assets	54	27
Total assets	$ 165,676	$ 66,039
Liabilities, redeemable convertible preferred stock and stockholders equity (deficit)		
Current liabilities:		
Accounts payable	$ 3,339	$ 1,609
Accrued expenses and other current liabilities	5,022	3,463
Deferred revenue	1,304	1,622
Current portion of deferred rent	149	132
Current portion of notes payable	1,540	1,704
Total current liabilities	11,354	8,530
Deferred revenue, net of current portion	26	156
Notes payable, net of current portion	397	1,441
Deferred rent, net of current portion	11,147	287
Warrant to purchase preferred stock		225
Restricted stock liability	107	139
Commitments and contingencies (Note 8)		
Redeemable convertible preferred stock:		
Series A redeemable convertible preferred stock, $0.0001 par value; no shares and 43,950,000 shares authorized at September 30, 2013 and December 31, 2012, respectively; no shares issued and outstanding at September 30, 2013 and 43,750,000 shares issued and outstanding at December 31, 2012		42,962

(aggregate liquidation preference of $43,750 at December 31, 2012)		
Series B redeemable convertible preferred stock, $0.0001 par value; no shares and 24,762,134 shares authorized at September 30, 2013 and December 31, 2012, respectively; no shares issued and outstanding at September 30, 2013 and 24,762,134 issued and outstanding at December 31, 2012 (aggregate liquidation preference of $55,962 at December 31, 2012)		55,696
Stockholders equity (deficit):		
Preferred Stock, $0.0001 par value, 5,000,000 and no shares authorized at September 30, 2013 and December 31, 2012, respectively; no shares issued and outstanding at September 30, 2013 and December 31, 2012, respectively		
Common stock, $0.0001 par value, 150,000,000 and 96,000,000 shares authorized at September 30, 2013 and December 31, 2012, respectively; 27,336,378 and 2,727,443 shares issued and outstanding at September 30, 2013 and December 31, 2012, respectively	3	
Additional paid-in capital	219,314	3,422
Accumulated deficit	(76,672)	(46,819)
Total stockholders equity (deficit)	142,645	(43,397)
Total liabilities, redeemable convertible preferred stock and stockholders equity (deficit)	$ 165,676	$ 66,039

The accompanying notes are an integral part of these financial statements

Table of Contents

FOUNDATION MEDICINE, INC.

Condensed Statements of Operations and Comprehensive Loss

(unaudited)

(In thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Revenue	$ 8,208	$ 3,037	$ 19,328	$ 5,466
Costs and expenses:				
Cost of revenue	2,858	1,791	7,455	3,621
Selling and marketing	3,038	849	7,724	2,196
General and administrative	6,448	2,134	14,353	5,833
Research and development	6,988	3,567	18,067	10,190
Total costs and expenses	19,332	8,341	47,599	21,840
Loss from operations	(11,124)	(5,304)	(28,271)	(16,374)
Other income (expense):				
Interest expense, net	(61)	(104)	(202)	(325)
Other income (expense), net	(1,278)	(81)	(1,380)	(134)
Total other income (expense), net	(1,339)	(185)	(1,582)	(459)
Net loss	$ (12,463)	$ (5,489)	$ (29,853)	$ (16,833)
Accretion of redeemable convertible preferred stock	(47)	(78)	(139)	(239)
Net loss applicable to common stockholders	$ (12,510)	$ (5,567)	$ (29,992)	$ (17,072)
Net loss per common share applicable to common stockholders, basic and diluted	$ (3.51)	$ (2.39)	$ (9.50)	$ (8.43)
Weighted-average common shares outstanding, basic and diluted	3,565,302	2,331,075	3,158,013	2,025,764
Comprehensive loss	$ (12,463)	$ (5,489)	$ (29,853)	$ (16,833)

The accompanying notes are an integral part of these financial statements

Table of Contents

FOUNDATION MEDICINE, INC.

Condensed Statements of Cash Flows

(unaudited)

(In thousands)

	Nine Months Ended September 30,	
	2013	**2012**
Operating activities		
Net loss	$ (29,853)	$ (16,833)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation expense	3,159	2,071
Change in fair value of warrant liability	1,380	137
Stock-based compensation	4,980	908
Common stock issued in exchange for professional services	4	
Non-cash interest expense	57	82
Changes in operating assets and liabilities:		
Accounts receivable	(2,242)	(1,318)
Inventory	(139)	(363)
Prepaid expenses and other current assets	(400)	(197)
Other assets	(27)	7
Accounts payable	530	(445)
Accrued expenses	600	1,240
Deferred rent	1,653	(80)
Deferred revenue	(448)	987
Net cash used in operating activities	(20,746)	(13,804)
Investing activities		
Purchases of property and equipment	(3,791)	(2,295)
Increase in restricted cash	(1,725)	
Net cash used in investing activities	(5,516)	(2,295)
Financing activities		
Proceeds from issuance of restricted stock and stock option exercises	30	67
Proceeds from issuance of Series A Preferred Stock and related investor rights, net of issuance costs		10,228
Proceeds from issuance of Series B Preferred Stock, net of issuance costs	(10)	42,290
Proceeds from issuance of common stock from initial public offering, net of issuance costs	110,596	
Payments of notes payable	(1,265)	(1,165)
Net cash provided by financing activities	109,351	51,420
Net increase in cash and cash equivalents	83,089	35,321
Cash and cash equivalents at beginning of period	54,838	10,852

Cash and cash equivalents at end of period	$ 137,927	$ 46,173
Supplemental disclosure of cash flow information		
Cash paid for interest	$ 141	$ 241
Supplemental disclosure of non-cash investing and financing activities		
Initial public offering costs include in accounts payable and accrued expenses	$ 656	$
Reclassification of warrant liability to additional paid-in capital	$ 1,605	$
Conversion of convertible preferred stock in common stock	$ 98,788	$
Accretion of convertible preferred stock to redemption value	$ 139	$ 239
Acquisition of property and equipment included in accounts payable and accrued expenses	$ 1,618	$ 99

The accompanying notes are an integral part of these financial statements

Table of Contents

FOUNDATION MEDICINE, INC.

Notes to Condensed Financial Statements

(unaudited)

1. Nature of Business

Foundation Medicine, Inc. (the Company) is a commercial-stage company focused on fundamentally changing the way patients with cancer are treated. The Company derives revenue from selling products enabled by its molecular information platform to physicians and biopharmaceutical companies. This platform includes proprietary methods and algorithms for analyzing tumor tissue samples across all types of cancer, as well as information aggregation and concise reporting capabilities. These products provide genomic information about each patient s individual disease, enabling physicians to optimize treatments in clinical practice and enabling biopharmaceutical companies to develop targeted oncology therapies more effectively. The Company s first clinical product, FoundationOne, which commenced its formal commercial launch in June 2012, is the only commercially available comprehensive molecular information product designed for use in routine patient care.

The interim balance sheet as of September 30, 2013, and the statements of operations and comprehensive loss for the three and nine months ended September 30, 2013 and 2012 and the statements of cash flows for the nine months ended September 30, 2013 and 2012 are unaudited. The unaudited interim financial statements have been prepared on the same basis as the annual financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary to present fairly the Company s financial position as of September 30, 2013 and its results of operations for the three and nine months ended September 30, 2013 and 2012 and cash flows for the nine months ended September 30, 2013 and 2012. The financial data and the other financial information disclosed in these notes to the financial statements related to the three and nine month periods are unaudited. The results of operations for the three and nine months ended September 30, 2013 are not necessarily indicative of the results to be expected for the year ending December 31, 2013 or for any other future annual or interim period. The financial statements should be read in conjunction with the audited financial statements and notes thereto included in the Company s final prospectus for its initial public offering (IPO), that forms a part of the Company s Registration Statement on Form S-1 (File No. 333-190226), which was filed with the SEC pursuant to Rule 424(b)(4) on September 25, 2013 (the Prospectus).

On September 30, 2013, the Company closed its IPO whereby the Company sold 6,772,221 shares of common stock (inclusive of 883,333 shares of common stock sold by the Company pursuant to the full exercise of an overallotment option granted to the underwriters in connection with the offering) at a price of $18.00 per share before underwriting discounts. The shares began trading on the NASDAQ Global Select Market on September 25, 2013. The aggregate net proceeds received by the Company from the offering were $110,596,000. In addition, upon the closing of the IPO, a warrant exercisable for convertible preferred stock was automatically converted into a warrant exercisable for common stock, resulting in the reclassification of the related convertible preferred stock warrant liability of $1,605,000 to additional paid-in capital.

In connection with preparing for the IPO, the Company s Board of Directors and stockholders approved a one-for-four reverse stock split of the Company s outstanding common stock. The Company s historical share and per share information have been retroactively adjusted to give effect to this reverse stock split. Shares of common stock underlying outstanding stock options and other equity instruments were proportionately reduced and the respective exercise prices, if applicable, were proportionately increased in accordance with the terms of the agreements

governing such securities. Upon the closing of the IPO, all outstanding shares of convertible preferred stock converted into 17,128,024 shares of common stock.

Following these transactions, the Company s total issued and outstanding common stock as of September 30, 2013 was 27,336,378 shares. The significant increase in shares as of September 30, 2013 did not have a material impact on the Company s loss per earnings calculation for the three and nine months ended September 30, 2013, but is expected to impact comparability of the Company s loss (earnings) per share calculations the next twelve months in subsequent filings.

2. Summary of Significant Accounting Policies and Basis of Presentation

Summary of accounting policies

There have been no material changes to the significant accounting policies previously disclosed in the Prospectus.

A. Restricted Cash

Restricted cash consists of deposits securing collateral letters of credit issued in connection with the Company s operating leases. The Company had restricted cash of $1,886,000 and $161,000 as of September 30, 2013 and December 31, 2012, respectively.

Table of Contents

B. Inventory

Inventories are stated at the lower of cost or market on a first-in, first-out basis. In order to assess the ultimate realization of inventories, the Company is required to make judgments as to future demand requirements compared to current or committed inventory levels. The Company evaluates its inventories for excess quantities and obsolescence. Inventories that are considered excess or obsolete are expensed.

Inventory consisted of the following (in thousands):

	September 30, 2013	December 31, 2012
Raw materials	$ 742	$ 406
Work-in-process	200	397
	$ 942	$ 803

C. 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.

3. Property and Equipment

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

	September 30, 2013	December 31, 2012
Lab equipment	$ 10,611	$ 8,163
Computer equipment	4,262	2,904
Software	188	188
Furniture and office equipment	1,315	425
Leasehold improvements	652	474
Construction in progress	10,300	
	27,328	12,154
Less accumulated depreciation and amortization	(7,848)	(4,689)
	$ 19,480	$ 7,465

Depreciation and amortization expense for the three and nine months ended September 30, 2013 and 2012 was $1,086,000, $809,000, $3,159,000 and $2,071,000, respectively. The Company classifies capitalized internal use software in Lab Equipment, Computer Equipment and Software based on its intended use.

Construction in progress primarily relates to leasehold improvements associated with the Company s 150 Second Street, Cambridge, MA lease. The Company received a $9.2 million tenant improvement allowance from the landlord that is being recorded as a lease obligation and is included as a component of long term deferred rent on the balance sheet. The lease incentive obligation will be accreted as a reduction to rent expense over the remaining term of the lease.

4. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	September 30, 2013	December 31, 2012
Payroll and employee-related costs	$ 2,272	$ 1,672
Professional services	1,033	670
Property and equipment purchases	959	977
Inventory purchases	629	
Other	129	144
	$ 5,022	$ 3,463

Table of Contents

5. 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, preferred stock, stock options, unvested restricted stock and warrants are considered to be common stock equivalents, but are excluded from the calculation of diluted net loss per share because their effect would be anti-dilutive. Therefore, basic and diluted net loss per share applicable to common stockholders 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. The convertible preferred stock shares shown in the table below are on a common stock equivalent basis as a result of the reverse stock split described in Note 1.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Denominator:				
Series A Preferred Stock		10,937,500		10,937,500
Series B Preferred Stock		4,701,326		4,701,326
Warrant	50,000	50,000	50,000	50,000
Outstanding stock options	2,308,679	1,033,026	2,308,679	1,033,026
Unvested restricted stock	742,708	1,666,128	742,708	1,666,128
Total	3,101,387	18,387,980	3,101,387	18,387,980

6. 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 Topic 820, *Fair Value Measurements and Disclosures* (ASC 820), establishes a hierarchy of inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the observable inputs be used when available. Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from sources independent of the company. Unobservable inputs are inputs that reflect a company s assumptions about the inputs that market participants would use in pricing the asset or liability, and are developed based on the best information available in the circumstances. The fair value hierarchy applies only to the valuation inputs used in determining the reported fair value of the investments and is not a measure of the investment credit quality. The hierarchy defines three levels of valuation inputs:

Level 1 inputs	Unadjusted quoted prices in active markets for identical assets or liabilities.
Level 2 inputs	Quoted prices for similar assets and liabilities in active markets, quoted prices in markets that are not active, or inputs which are observable, either directly or indirectly, for

	substantially the full term of the asset or liability at the measurement date.
Level 3 inputs	Unobservable inputs that reflect the Company s own assumptions about the assumptions market participants would use in pricing the asset or liability.

The fair value hierarchy prioritizes valuation inputs based on the observable nature of those inputs. Assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. The Company s assessment of the significance of a particular input to the fair value measurement in its entirety requires management to make judgments and consider factors specific to the asset or liability.

The Company s financial instruments consist of cash and cash equivalents, accounts receivable, accounts payable, accrued liabilities, notes payable, and a warrant to purchase certain of its equity instruments. The carrying amount of cash and cash equivalents, accounts receivable, accounts payable, accrued liabilities and notes payable approximate their fair values because of the short-term nature of the instruments or, in the case of the notes payable, because the interest rates the Company believes it could obtain for similar borrowings is similar to its existing interest rates. In conjunction with the closing of the Company s IPO, a warrant exercisable for shares of its Series A Preferred Stock was automatically converted into a warrant exercisable for shares of its common stock, resulting in the reclassification of the related convertible preferred stock warrant liability to additional paid-in capital as the warrant to purchase shares of common stock met the criteria for equity classification. The warrant liability was re-measured to fair value prior to reclassification to additional paid-in capital. As of September 30, 2013, the Company had no outstanding warrant liability.

Table of Contents

The following tables present information about the Company s assets and liabilities that are measured at fair value on a recurring basis as of September 30, 2013 and December 31, 2012, and indicates the fair value hierarchy of the valuation techniques utilized to determine such fair value (in thousands):

	Fair Value Measurement at September 30, 2013			
	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	$ 25,001	$	$	$ 25,001
Total assets	$ 25,001	$	$	$ 25,001

	Fair Value Measurement at December 31, 2012			
	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	$ 37,500	$	$	$ 37,500
Total assets	$ 37,500	$	$	$ 37,500
Liabilities:				
Warrant to purchase preferred stock	$	$	$ 225	$ 225
Total liabilities	$	$	$ 225	$ 225

The following table sets forth a summary of changes in the fair value of the Company s preferred stock warrant liability which represents a recurring measurement that is classified within Level 3 of the fair value hierarchy, wherein fair value is estimated using significant unobservable inputs:

Beginning balance, January 1, 2013	$ 225
Change in fair value[1]	1,380
Reclassification to equity [2]	(1,605)
Ending balance, September 30, 2013	$

(1) The fair value of the warrant is calculated using a Black-Scholes option pricing model. Significant increases or decreases of the inputs could result in significantly higher or lower fair value measurement. Changes in the fair value are recorded as income or expense within other income (expense), net in the accompanying statements of operations.

(2) The warrant was re-measured to fair value and then reclassified to additional paid-in capital on September 30, 2013.

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 and nine months ended September 30, 2013 and 2012.

Table of Contents

7. Redeemable Convertible Preferred Stock and Stockholders Equity (Deficit)

(a) Redeemable Convertible Preferred Stock

Upon closing of the IPO on September 30, 2013, all of the outstanding shares of the Company s convertible preferred stock were converted into 17,128,024 shares of its common stock.

(b) Common Stock

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

	September 30, 2013	December 31, 2012
Series A Preferred Stock		10,937,500
Series B Preferred Stock		6,190,524
Warrant	50,000	50,000
Unvested restricted stock	742,708	1,423,698
Common stock options	2,308,679	1,221,396
Shares available for issuance under the 2010 Stock Plan		252,465
Shares available for issuance under the 2013 Stock Plan	1,164,145	
	4,265,532	20,075,583

In November 2009, the Company issued 2,125,000 shares of common stock to the founders of the Company for consideration equal to the par value per share, the then estimated fair value of the common stock. The founders entered into restricted stock agreements whereby the shares of common stock issued are subject to vesting and become fully vested in 2013. An additional 112,500 shares of common stock subject to repurchase were issued to employees and consultants at fair value during the year ended December 31, 2010. Shares subject to repurchase by the Company are recorded as a liability at their original purchase price. Shares subject to repurchase that were issued to non-employees are revalued at each vesting date and at the end of the reporting period, with changes in fair value recorded as stock-based compensation expense on a straight-line basis. As the Company s right to repurchase the shares lapses, the liability is reclassified as additional paid-in capital. At September 30, 2013, 139,736 of these shares remain subject to repurchase by the Company. The following table shows a roll forward of restricted stock activity outside of the 2010 Stock Plan (as defined below), as discussed below:

	Number of Shares
Unvested at December 31, 2012	547,542
Granted	
Vested	(407,806)
Unvested at September 30, 2013	139,736

Total stock-based compensation expense recognized for restricted stock issued outside of the 2010 Plan was $2,385,000, $335,000, $4,023,000 and $758,000 for the three and nine months ended September 30, 2013 and 2012, respectively. As of September 30, 2013, $3,347,000 of unrecognized compensation expense related to restricted stock is expected to be recognized over weighted average periods of 0.2 years.

2010 and 2013 Stock Incentive Plans

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

Effective upon closing of the IPO, the Company implemented the Foundation Medicine, Inc. 2013 Stock Option and Incentive Plan (the 2013 Stock Plan) under which it may grant restricted stock, incentive stock options (ISOs) and non-statutory stock options to eligible employees, officers, directors and consultants to purchase up to 1,355,171 shares of common stock. In connection with the establishment of the 2013 Stock Plan, the Company terminated the 2010 Stock Plan and the 512,568 shares available for grant under the 2010 Stock Plan were included in the number of shares authorized under the 2013 Stock Plan.

Table of Contents

Terms of stock award agreements, including vesting requirements, are determined by the board of directors, subject to the provisions of the 2010 Stock Plan and the 2013 Stock Plan. Options granted by the Company typically vest over a four-year period. Certain of the options are subject to acceleration of vesting in the event of certain change of control transactions. The options are exercisable from the date of grant for a period of 10 years. For options granted to date, the exercise price equaled the estimated fair value of the common stock as determined by the Board on the date of grant or the Company s IPO price of $18.00 per share.

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. No restricted stock awards have been granted pursuant to the 2013 Stock Plan. The following table shows a roll forward of restricted stock activity pursuant to the 2010 Stock Plan:

	Number of Shares
Unvested at December 31, 2012	123,599
Granted	
Vested	(38,550)
Unvested at September 30, 2013	85,049

All restricted stock issued from the 2010 Stock Plan had a grant date fair value of $0.02 per share. Total stock-based compensation expense recognized for restricted stock issued from the 2010 Stock Plan was $66,000, $10,000, $119,000 and $22,000 for the three and nine months ended September 30, 2013 and 2012, respectively. As of September 30, 2013, $62,000 of unrecognized compensation expense related to restricted stock issued from the 2010 Stock Plan is expected to be recognized over weighted-average periods of 1.9 years.

Stock Options

A summary of stock option activity under the 2010 Stock Plan and 2013 Stock Plan for the nine months ended September 30, 2013 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, 2012	1,221,396	$ 1.29	9.3	$ 3,257

Granted	1,162,344		7.29		
Exercised	(38,317)		0.94		
Cancelled	(36,744)		1.89		
Outstanding as of September 30, 2013	2,308,679	$	4.31	9.0	$ 81,571
Exercisable as of September 30, 2013	447,190	$	1.85	8.5	$ 16,898
Vested and expected to vest at September 30, 2013[(1)]	2,121,286	$	4.26	9.0	$ 75,056

(1) This represents the number of vested options plus the number of unvested options expected to vest at the respective dates, based on unvested options adjusted for estimated forfeitures.

Certain stock options contain provisions allowing for the early exercise into shares subject to repurchase. For the nine months ended September 30, 2013, options to purchase 8,750 shares of common stock were exercised prior to vesting. At September 30, 2013, 519,225 shares, which were early exercised, remain subject to repurchase.

Table of Contents

The weighted-average fair value of options granted for the nine months ended September 30, 2013 was $4.17. The Company recorded total stock-based compensation expense for stock options granted to employees, directors and non-employees from the 2010 and 2013 Stock Plans of $533,000, $56,000, $837,000 and $128,000 during the three and nine months ended September 30, 2013 and 2012, respectively. As of September 30, 2013, unrecognized compensation cost of $4.9 million related to non-vested employee stock-based compensation arrangements is expected to be recognized over weighted-average periods of 2.8 years.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
	(unaudited)			
Cost of revenue	$ 25	$ 7	$ 42	$ 12
Sales and marketing	36	10	81	15
General and administrative	2,588	363	4,379	828
Research and development	336	20	478	53
Total	$ 2,985	$ 400	$ 4,980	$ 908

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 September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Expected volatility	66.2%	68.3%	66.9%	68.7%
Risk-free interest rate	2.05%	0.91%	1.50%	1.33%
Expected option term (in years)	6.25	6.25	6.25	6.25
Expected dividend yield	0.0%	0.0%	0.0%	0.0%

8. Commitments and Contingencies

One Kendall Square

In May 2010, the Company commenced a facility lease which was due to expire in October 2015. On October 9, 2013, the Company executed a lease termination agreement for this facility, and the lease will terminate on the earlier of the date the Company surrenders the facility in accordance with the terms of the facility lease or November 30, 2013 (the Surrender Date). The Company will pay rent, operating expenses and other charges due under the facility lease until the Surrender Date. If the Surrender Date occurs after October 31, 2013, the Company will pay 200% of the amount of rent from November 1, 2013 until the Surrender Date. In exchange for terminating the facility lease, the Company also agreed to pay the landlord a payment equal to two additional months of rent, operating expenses and all other charges due under the facility lease, plus reimburse the landlord for a portion of the brokerage commissions

incurred by the landlord in leasing the facility to a new tenant. The Company recognizes rent expense on a straight-line basis for the full amount of the commitment including the minimum rent increases over the lease term. The Company recorded $219,000, $219,000, $657,000 and $657,000 of rent expense in the three and nine months ended September 30, 2013 and 2012, respectively, associated with this lease.

150 Second Street

In 2013, the Company signed two additional 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 commenced in September 2013 and has an eight year expected term. The second lease is subject to fixed rate escalation increases and the landlord waived the Company s rent obligation for the first three months of the lease, having a value of approximately $3,300,000. As a result, the Company will recognize rent expense on a straight-line basis over the expected lease term. The Company began to record rent expense in April 2013 upon gaining access to and control of the leased space. Upon execution of the lease agreement, the Company paid a security deposit of $1,725,000, which is included in restricted cash as of September 30, 2013. As of September 30, 2013, the future minimum rent payments under the lease total $26,816,000.

Table of Contents

Legal Matters

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

9. Related Party Transactions

Since inception, the Company has received consulting and management services from an investor. The Company paid this investor approximately $1,500, $112,000 and $119,000, $270,000 for these services during the three and nine months ended September 30, 2013 and 2012, respectively. Of these amounts, $0 and $92,000 of amounts due to the investor were included in accounts payable and accrued expenses at September 30, 2013 and December 31, 2012, respectively.

The Company recognized revenue of $164,000, $88,000, $690,000 and $88,000 during the three and nine months ended September 30, 2013 and 2012, respectively, from an arrangement with an investor executed in the year ended December 31, 2012. Of these amounts, $0 and $88,000 were included in accounts receivable at September 30, 2013 and December 31, 2012, respectively.

Table of Contents

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

The following information should be read in conjunction with the unaudited financial information and the notes thereto included in this Quarterly Report on Form 10-Q and the audited financial information and the notes thereto included in the Prospectus that forms a part of our Registration Statement on Form S-1 (File No. 333-190226), which was filed with the Securities and Exchange Commission (the SEC) pursuant to Rule 424(b)(4) on September 25, 2013 (the Prospectus).

Overview

We are a commercial-stage company focused on fundamentally changing the way patients with cancer are treated. We derive revenue from selling products enabled by our molecular information platform to physicians and biopharmaceutical companies. Our platform includes proprietary methods and algorithms for analyzing tumor tissue samples across all types of cancer, as well as information aggregation and concise reporting capabilities. Our products provide genomic information about each patient s individual cancer, enabling physicians to optimize treatments in clinical practice and enabling biopharmaceutical companies to develop targeted oncology therapies more effectively.

FoundationOne, our first clinical product, is, to our knowledge, the only commercially available comprehensive molecular information product designed for use in the routine care of patients with cancer. In November 2011, we first offered for sale FoundationOne for clinical use to a limited network of key oncology thought leaders and their colleagues and leading academic centers. We then commenced our formal commercial launch of FoundationOne for solid tumors in June 2012 and expect to commence our commercial launch of FoundationOne for blood-based cancers, or hematologic malignancies, by early 2014. Prior to commercial sales of FoundationOne for clinical use, we generated revenue from our molecular information platform under relationships with biopharmaceutical partners, starting in December 2010. Our molecular information platform is currently used by 18 biopharmaceutical partners to enhance the development of targeted oncology therapies. To accelerate our growth and enhance our competitive advantage, we are extending our sales force, publishing scientific and medical advances, fostering relationships throughout the oncology community, and developing new products.

We have experienced rapid adoption of FoundationOne. More than 2,100 physicians from large academic centers and community-based practices have ordered FoundationOne since its formal commercial launch in June 2012. We believe this rapid adoption of FoundationOne, accomplished with a nascent sales team, demonstrates the demand for and utility of a single comprehensive product that helps oncologists effectively implement the promise of precision medicine.

Since our inception in 2009, we have devoted substantially all of our resources to the development of our molecular information platform, the commercialization of FoundationOne for solid tumors, and the development of new products such as FoundationOne for hematologic malignancies. We have incurred significant losses since our inception, and as of September 30, 2013, our accumulated deficit was $76.7 million. We expect to continue to incur operating losses over the near term as we expand our commercial operations, conduct clinical trials, and invest in our molecular information platform and additional product offerings.

Recent Developments

On September 30, 2013, we closed our initial public offering (IPO) of our common stock which resulted in the sale of 6,772,221 shares of our common stock at a public offering price of $18.00 per share, before underwriting discounts, including 883,333 shares of common stock issued upon the exercise in full by the underwriters of their option to purchase additional shares at the public offering price to cover over-allotments. We received net proceeds from the

IPO of approximately $110.6 million after deducting underwriting discounts, commissions, and estimated expenses payable by us.

Financial Operations Overview

Revenue

We derive our revenue from selling products that are enabled by our molecular information platform. The information provided in our test results is branded as FoundationOne for our clinical customers and is not branded for our biopharmaceutical customers. 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 for solid tumors in the clinical setting and increase the volume of tests enabled by our molecular information platform that we perform for our biopharmaceutical customers.

Table of Contents

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

We currently recognize revenue on a cash basis from commercial third-party payors and from patients who make co-payments, pay deductibles, or pay other amounts that we have been unable to collect from their third-party payors because the payment is not fixed or determinable and collectability is not reasonably assured, including due to the fact that we do not have coverage decisions in place and have a limited history of collecting claims. We expect to use judgment in assessing whether the fee is fixed or determinable and whether 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 tests are recognized in advance of any associated revenues. Because of the increasing period-to-period FoundationOne test volumes that we have observed to date, our revenue from these payors is lower and our net loss is higher than if we were recognizing revenue from these payors on an accrual basis in the period during which the work was performed and costs were incurred.

There is currently no national coverage decision that determines whether and how our test is covered by Medicare. In the absence of a national coverage decision, local Medicare contractors that administer the Medicare program in various regions have some discretion in determining coverage and therefore payment for tests. Our local Medicare contractor, who would process our claims on behalf of Medicare, requested that we not submit claims for services provided to Medicare patients while the contractor assessed the appropriate coverage and payment for FoundationOne as a whole. Pending the response, no claims have been billed to either Medicare or Medicare patients and we have not generated any revenue from these FoundationOne tests. As a result, while we incur costs to perform these FoundationOne tests, we are not currently generating revenue from the sale of FoundationOne for patients covered by Medicare. Our net loss is therefore higher than if we were recognizing revenue from the sale of FoundationOne for patients covered by Medicare. FoundationOne tests for patients covered by Medicare represented approximately 29% and 26% of total FoundationOne tests ordered by physicians in the United States during the nine months ended September 30, 2013 and 2012, respectively.

We intend to seek a national coverage determination from our Medicare contractor, which, if obtained, will establish a standard for the reimbursement for our Medicare claims. We intend, before the end of 2013, to commence submitting claims to Medicare for FoundationOne tests provided to Medicare patients. The response of the Medicare contractor to the submission of such a claim is uncertain and the claim may be denied or paid, in whole or in part. If a claim is denied or paid in part, we may decide to appeal the denied claim or any denied portion of the claim. Our Medicare contractor may also issue a negative coverage determination for FoundationOne that would apply to future claims or

may defer processing a claim pending a coverage or payment determination. If a claim is paid by our Medicare contractor, either upon acceptance of the claim or following a successful appeal of a denied claim, we will generate revenue from Medicare for FoundationOne testing.

We expect that the current lack of coverage decisions and the uncertainty of reimbursement on a case-by-case basis may continue to negatively impact our revenue and earnings, particularly as FoundationOne test volumes increase period-to-period. Following our achievement of a coverage decision from a commercial third-party payor or government payor or once we have a sufficient history of claims collections with any such payor that we conclude the fee for FoundationOne tests for individuals insured by such payor is sufficiently fixed or determinable and collectability is reasonably assured, we will begin to recognize revenue from such payor on an accrual basis. As of September 30, 2013, we had cash and cash equivalents of approximately $137.9 million. We do not believe that the adverse impacts on our liquidity related to the absence of coverage decisions from commercial third-party payors and government payors will materially adversely affect our business or prospects over at least the next 12 months and likely not for the foreseeable future. If we are not able to obtain coverage decisions from commercial third-party payors and government payors over

Table of Contents

the longer term, however, and our available cash balances and cash flow from claims for reimbursement on behalf of each patient on a case-by-case basis and other operations are insufficient to satisfy our liquidity requirements, we may require additional capital beyond our currently anticipated amounts. Additional capital may not be available on reasonable terms, or at all.

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

We also receive a small portion of revenue from patients who make co-payments and pay deductibles. In addition, while we take on the primary responsibility for obtaining third-party reimbursement on behalf of patients, including appeals for any initial denials, we ultimately do bill patients for amounts that we have been unable to collect from their third-party payors. While we are not currently seeking reimbursement from Medicare or billing Medicare patients, we may decide to provide appropriate notices to patients covered by Medicare to enable us to bill a patient for all or part of a claim that is denied coverage by our Medicare contractor. We offer a comprehensive patient assistance program to support patients whose incomes are below certain thresholds and to allow for extended payment terms, as necessary, given the patient s economic situation.

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

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

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

Sales and Marketing Expenses

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

During the three months ended September 30, 2013 and 2012, our sales and marketing expenses represented approximately 37% and 28%, respectively, of our total revenue, and during the nine months ended September 30, 2013 and 2012, sales and marketing expenses represented approximately 40% of our total revenue for each period. We expect our sales and marketing costs to continue to increase in absolute dollars as we expand our sales force, increase our presence within and outside of the United States, and increase our marketing activities to drive further awareness and adoption of FoundationOne and our future products. In the short-term, our sales and marketing costs may also increase as a percentage of total revenues as we make these investments.

Table of Contents

General and Administrative Expenses

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

We expect that our general and administrative expenses will continue to increase, primarily due to the costs of operating as a public company, including additional legal, accounting, corporate governance, and investor relations 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, the development of our knowledgebase for genomic and clinical data, and the development of our online tools, such as our online portal and mobile applications for Interactive Cancer Explorer. Costs to develop our online tools are recorded as research and development unless they meet the criteria to be capitalized as internal-use software costs. Our research and development activities include the following costs:

- personnel-related expenses such as salaries, bonuses, employee benefits, and stock-based compensation;
- fees for contractual and consulting services;
- costs to manage and synthesize our medical data and to expand our knowledgebase;
- clinical trials;
- laboratory supplies; and
- allocated overhead expenses.

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

Interest Expense, Net

Interest expense, net consists primarily of interest expense on our loan balance and the amortization of debt discounts. Interest income consists of interest earned on our cash and cash equivalents. During the three and nine months ended

September 30, 2013 and 2012, interest income was not material.

Other Expense, Net

Other expense, net consists of changes in the fair value of our preferred stock warrant liability at the end of each reporting period. The warrant was exercised in October 2013.

Table of Contents

Results of Operations

Comparison of Three Months Ended September 30, 2013 and 2012

	Three Months Ended September 30,		Change	
	2013	2012	$	%
	(in thousands, except percentages)			
Statement of Operations Data:				
Revenue	$ 8,208	$ 3,037	$ 5,171	170%
Costs and expenses				
Cost of revenue	2,858	1,791	1,067	60%
Selling and marketing	3,038	849	2,189	258%
General and administrative	6,448	2,134	4,314	202%
Research and development	6,988	3,567	3,421	96%
Total costs and expenses	19,332	8,341	10,991	132%
Loss from operations	(11,124)	(5,304)	(5,820)	(110%)
Interest expense, net	(61)	(104)	(43)	(41%)
Other (expense) income, net	(1,278)	(81)	1,197	1,478%
Net loss	$ (12,463)	$ (5,489)	$ (6,974)	(127%)

Revenue

Total revenue increased to $8.2 million for the three months ended September 30, 2013 from $3.0 million during the three months ended September 30, 2012. Revenue from FoundationOne tests reported for our ordering physicians increased to $4.4 million for the three months ended September 30, 2013 from $0.5 million for the three months ended September 30, 2012 following the formal commercial launch of FoundationOne for solid tumors in June 2012. The increase was driven by our growing test volumes and expanding commercialization efforts. The increase in revenue from our biopharmaceutical customers to $3.8 million from $2.6 million for the three months ended September 30, 2013 and 2012, respectively, resulted from increased business development activity among our new and existing biopharmaceutical customers.

During the three months ended September 30, 2013 and 2012, we reported 2,577 and 492 FoundationOne tests, respectively, for ordering physicians, and 965 and 307 tests, respectively, for our biopharmaceutical customers.

The average revenue per FoundationOne test for clinical use that met our revenue recognition criteria during the three months ended September 30, 2013 was approximately $3,300. This average revenue per test does not include 573 FoundationOne tests reported during the period for patients covered by Medicare and for which claims were not yet submitted, 59 tests that were reported and not billed, and 1,019 tests that were reported and billed to commercial third party payors during the period but were not paid during the period. This average revenue includes 392 tests reported in prior periods for which revenue was recognized during the three months ended September 30, 2013.

The average revenue per FoundationOne test for clinical use that met our revenue recognition criteria during the three months ended September 30, 2012 was approximately $3,500. This average revenue per test does not include 100 FoundationOne tests reported during the period for patients covered by Medicare and for which claims were not submitted, 13 tests that were reported and not billed, and 283 tests that were reported and billed to commercial third party payors during the period but were not paid during the period. This average revenue includes 51 tests reported in prior periods for which revenue was recognized during the three months ended September 30, 2012.

Our average revenue per FoundationOne test excludes tests for which we have not yet recognized revenue. Because we recognize revenue on a cash basis from commercial third-party payors and from patients who make co-payments, and our efforts to obtain payment for individual claims can take a substantial amount of time, there is typically a significant lag between the time the FoundationOne test is reported and the time we actually recognize the revenue from such test. As a result, if we were to include tests for which we have not recognized revenue in our average revenue per test calculation for a particular period, it would imply that we will not receive any revenue for such tests. Despite our lack of coverage decisions, we have been reasonably successful in securing reimbursement from commercial third-party payors for tests reported in prior periods. Similarly with respect to tests reported for patients covered by Medicare, we intend to submit claims to Medicare for these tests before the end of 2013. We also expect to record revenue from patients who make co-payments, pay deductibles, or pay other amounts that we have been unable to collect from third-party payors. While receipt of payment from third-party payors, Medicare, and patients in respect of these claims is not

Table of Contents

currently fixed and determinable and collectability is not reasonably assured, we do expect to record revenue in the future for tests reported in this period. However, it is difficult to predict future revenue from the previously reported FoundationOne tests because the test is in an early stage of commercialization and we have limited payment history. As a result, we cannot be certain that the revenue per test we recognize in the future will equal or exceed the average revenue per test reported above.

We billed commercial third-party payors for the 1,019 and 283 FoundationOne tests referenced above that were reported during the three months ended September 30, 2013 and 2012, respectively, at $5,800 per test, the current list price for FoundationOne. This represents a maximum potential revenue to us of $5.9 million and $1.6 million, if collected in full. We will continue to make requests for payment and/or appeal payment decisions made by commercial third-party payors. Because we are in an early stage of commercialization, we have limited payment experience, and it is therefore difficult to predict future revenue from the previously reported FoundationOne tests.

Pending receipt of definitive direction from our Medicare contractor, we have not submitted claims to Medicare for the 573 and 100 FoundationOne tests reported for the three months ended September 30, 2013 and 2012 for patients covered by Medicare nor have we billed Medicare patients for these tests. Based upon the current $5,800 per test list price for FoundationOne, the 573 and 100 tests we reported for Medicare patients for the three months ended September 30, 2013 and 2012, respectively, represent a maximum potential revenue to us of $3.3 million and $0.6 million, if collected in full. We currently expect to submit claims to Medicare for FoundationOne tests previously reported by us for patients covered by Medicare; however, we will continue to assess our ability to bill Medicare or Medicare patients for these tests, pending receipt of definitive direction from our Medicare contractor. Notwithstanding our current intentions to seek payment for these tests, our Medicare contractor may deny our claim, in whole or in part, we may never receive any revenue from any of the 573 and 100 FoundationOne tests that we reported during the three months ended September 30, 2013 and 2012 for patients covered by Medicare and even if we do receive revenue from these tests, we do not expect to receive the full $5,800 list price per test.

If commercial third-party payors or government payors agree to pay us for these FoundationOne tests in the future, we will recognize revenue for such FoundationOne tests in the period in which our revenue recognition criteria are met. Any revenue that we receive in respect of these previously reported FoundationOne tests will favorably impact our liquidity and results of operations in future periods.

The cumulative amount of FoundationOne tests that have been billed to commercial third-party payors and reported for patients covered by Medicare but for which we have not recognized revenue was 1,981 and 1,585, respectively, as of September 30, 2013. If commercial third-party payors or government payors agree to pay us for these FoundationOne tests in the future, we will recognize revenue for such FoundationOne tests in the period in which our revenue recognition criteria are met. Any revenue that we receive in respect of these previously reported FoundationOne tests will favorably impact our liquidity and results of operations in future periods.

For our biopharmaceutical customer revenue that was based on a negotiated price per test, the average revenue per test was approximately $3,700 and $3,900 for the three months ended September 30, 2013 and 2012, respectively. We expect this average revenue per test for biopharmaceutical customers to remain fairly consistent over time. Approximately $2.4 million and $1.6 million of our biopharmaceutical revenue for the three months ended September 30, 2013 and 2012, respectively, represented payments under contracts with multiple element arrangements that were not negotiated on a price per test basis.

Cost of Revenue

Cost of revenue increased to $2.9 million for the three months ended September 30, 2013 from $1.8 million for the three months ended September 30, 2012. This increase was driven by increasing test volumes from our ordering physicians and biopharmaceutical customers. The average cost per test does not differ materially by customer. Additional volume led to higher reagent and consumable costs, additional laboratory personnel-related costs, and higher depreciation expense related to new equipment purchases. During the three months ended September 30, 2013 and 2012, our cost of revenue represented approximately 35% and 59%, respectively, of our total revenue. We expect to make additional investments in personnel, infrastructure, and systems to scale our laboratory operations to meet future anticipated demand. As a result, our cost of revenue as a percentage of total revenue could increase in the short-term.

Sales and Marketing Expenses

Sales and marketing expenses increased to $3.0 million for the three months ended September 30, 2013 from $0.8 million for the three months ended September 30, 2012. The increase was primarily due to an increase of $1.6 million in personnel-related costs related to 21 new employees in our sales, marketing, client service, and reimbursement departments, a $0.2 million increase in consulting, and a $0.4 million increase in various other expenses.

Table of Contents

General and Administrative Expenses

General and administrative expenses increased to $6.4 million for the three months ended September 30, 2013 from $2.1 million for the three months ended September 30, 2012. The increase was primarily due to a $2.2 million increase in stock-based compensation, a $0.6 million increase in other employee-related expenses to support and expand our legal, finance, and human resources infrastructure, a $0.2 million increase in legal fees, a $0.2 million increase in audit and tax fees and a $1.1 million increase in overhead and billing fees.

Research and Development Expenses

Research and development expenses increased to $7.0 million for the three months ended September 30, 2013 from $3.6 million for the three months ended September 30, 2012. The increase was primarily due to a $1.2 million increase in employee and contractor-related expenses, including a $0.3 million increase in stock-based compensation, a $0.8 million increase in technology investments related to data management, FoundationOne report design and functionality, and customer interface development, a $0.6 million increase in facilities, a $0.3 million increase in clinical trial expenses, and a $0.5 million increase in overhead allocations and other expenses.

Interest Expense, Net

Interest expense, net was $0.1 million for the three months ended September 30, 2013 and 2012.

Other Expense, Net

Other expense, net increased to $1.3 million for the three months ended September 30, 2013 from $0.1 million for the three months ended September 30, 2012. We recorded $1.3 million of other expense associated with the change in the fair value of our warrant liability immediately before it converted into a warrant to purchase common stock and was reclassified into additional paid-in capital.

Table of Contents

Comparison of Nine Months Ended September 30, 2013 and 2012

	Nine Months Ended September 30,		Change	
	2013	2012	$	%
	(in thousands, except percentages)			
Statement of Operations Data:				
Revenue	$ 19,328	$ 5,466	$ 13,862	254%
Costs and expenses				
Cost of revenue	7,455	3,621	3,834	106%
Selling and marketing	7,724	2,196	5,528	252%
General and administrative	14,353	5,833	8,520	146%
Research and development	18,067	10,190	7,877	77%
Total costs and expenses	47,599	21,840	25,759	118%
Loss from operations	(28,271)	(16,374)	(11,897)	(73%)
Interest expense, net	(202)	(325)	(123)	(38%)
Other (expense) income, net	(1,380)	(134)	1,246	930%
Net loss	$ (29,853)	$ (16,833)	$ (13,020)	(77%)

Revenue

Total revenue increased to $19.3 million for the nine months ended September 30, 2013 from $5.5 million during the nine months ended September 30, 2012. Revenue from FoundationOne tests reported for our ordering physicians increased to $9.5 million for the nine months ended September 30, 2013 from $1.0 million for the nine months ended September 30, 2012 following the formal commercial launch of FoundationOne for solid tumors in June 2012. The increase was driven by increased adoption of FoundationOne and our expanding commercialization efforts. The increase in revenue from our biopharmaceutical customers was $9.8 million from $4.5 million for the nine months ended September 30, 2013 and 2012, respectively, resulted from increased activity among our new and existing biopharmaceutical customers.

During the nine months ended September 30, 2013 and 2012, we reported 5,343 and 872 FoundationOne tests for ordering physicians and 2,183 and 786 tests for our biopharmaceutical customers, respectively.

The average revenue per FoundationOne test for clinical use that met our revenue recognition criteria during the nine months ended September 30, 2013 was approximately $3,500. This average revenue per test does not include 1,184 FoundationOne tests reported during the period for patients covered by Medicare and for which claims were not yet submitted, 114 tests that were reported and not billed, and 1,744 tests that were reported and billed to commercial third party payors during the period but were not paid during the period. This average revenue includes 404 tests reported in prior periods for which revenue was recognized during the nine months ended September 30, 2013.

The average revenue per FoundationOne test for clinical use that met our revenue recognition criteria during the nine months ended September 30, 2012 was approximately $3,800. This average revenue per test does not include 172 FoundationOne tests reported during the period for patients covered by Medicare and for which claims were not

submitted, 28 tests that were reported and not billed, and 420 tests that were reported and billed to commercial third party payors during the period but were not paid during the period. This average revenue includes 4 tests reported in prior periods for which revenue was recognized during the nine months ended September 30, 2012.

Our average revenue per FoundationOne test excludes tests for which we have not yet recognized revenue. Because we recognize revenue on a cash basis from commercial third-party payors and from patients who make co-payments, and our efforts to obtain payment for individual claims can take a substantial amount of time, there is typically a significant lag between the time the FoundationOne test is reported and the time we actually recognize the revenue from such test. As a result, if we were to include tests for which we have not recognized revenue in our average revenue per test calculation for a particular period, it would imply that we will not receive any revenue for such tests. Despite our lack of coverage decisions, we have been reasonably successful in securing reimbursement from commercial third-party payors for tests reported in prior periods. Similarly with respect to tests reported for patients covered by Medicare, we intend to submit claims to Medicare for these tests before the end of 2013. We also expect to receive revenue from patients who make co-payments, pay deductibles, or pay other amounts that we have been unable to collect from

Table of Contents

third-party payors. While receipt of payment from third-party payors, Medicare, and patients in respect of these claims is not currently fixed and determinable and collectability is not reasonably assured, we do expect to receive revenue in the future for tests reported in this period. However, it is difficult to predict future revenue from the previously reported FoundationOne tests because the test is in an early stage of commercialization and we have limited payment history. As a result, we cannot be certain that the revenue per test we recognize in the future will equal or exceed the average revenue per test reported above.

We billed commercial third-party payors for the 1,744 and 420 FoundationOne tests referenced above that were reported during the nine months ended September 30, 2013 and 2012, respectively, at $5,800 per test, the current list price for FoundationOne. This represents a maximum potential revenue to us of $10.1 million and $2.4 million, if collected in full. We will continue to make requests for payment and/or appeal payment decisions made by commercial third-party payors. Because we are in an early stage of commercialization, we have limited payment experience, and it is therefore difficult to predict future revenue from the previously reported FoundationOne tests.

Pending receipt of definitive direction from our Medicare contractor, we have not submitted claims to Medicare for the 1,184 and 172 FoundationOne tests reported for the nine months ended September 30, 2013 and 2012 for patients covered by Medicare nor have we billed Medicare patients for these tests. Based upon the current $5,800 per test list price for FoundationOne, the 1,184 and 172 tests we reported for Medicare patients for the nine months ended September 30, 2013 and 2012, respectively, represent a maximum potential revenue to us of $6.9 and $1.0 million, if collected in full. We currently expect to submit claims to Medicare for FoundationOne tests previously reported by us for patients covered by Medicare; however, we will continue to assess our ability to bill Medicare or Medicare patients for these tests, pending receipt of definitive direction from our Medicare contractor. Notwithstanding our current intentions to seek payment for these tests, our Medicare contractor may deny our claim, in whole or in part, we may never receive any revenue from any of the 1,184 and 172 FoundationOne tests that we reported during the nine months ended September 30, 2013 and 2012 for patients covered by Medicare and even if we do receive revenue from these tests, we do not expect to receive the full $5,800 list price per test.

If commercial third-party payors or government payors agree to pay us for these FoundationOne tests in the future, we will recognize revenue for such FoundationOne tests in the period in which our revenue recognition criteria are met. Any revenue that we receive in respect of these previously reported FoundationOne tests will favorably impact our liquidity and results of operations in future periods.

For our biopharmaceutical customer revenue that was based on a negotiated price per test, the average revenue per test was approximately $3,700 for each of the nine months ended September 30, 2013 and 2012. We expect this average revenue per test for biopharmaceutical customers to remain fairly consistent over time. Approximately $6.4 million and $2.4 million of our biopharmaceutical revenue for the nine months ended September 30, 2013 and 2012, respectively, represented payments under contracts with multiple element arrangements that were not negotiated on a price per test basis.

Cost of Revenue

Cost of revenue increased to $7.5 million for the nine months ended September 30, 2013 from $3.6 million for the nine months ended September 30, 2012. This increase was driven by increasing test volumes from our ordering physicians and biopharmaceutical customers. During the nine months ended September 30, 2013 and 2012, our cost of revenue represented approximately 39% and 66%, respectively, of our total revenue.

Sales and Marketing Expenses

Sales and marketing expenses increased to $7.7 million for the nine months ended September 30, 2013 from $2.2 million for the nine months ended September 30, 2012. The increase was primarily due to an increase of $4.1 million in personnel-related costs related to the expansion of our sales, marketing, client service and reimbursement teams, a $0.6 million increase in consulting, and a $0.8 million increase in various other expenses.

General and Administrative Expenses

General and administrative expenses increased to $14.4 million for the nine months ended September 30, 2013 from $5.8 million for the nine months ended September 30, 2012. The increase was due to $3.6 million in stock-based compensation, a $1.8 million increase in other employee-related expenses to support and expand our legal, finance, and human resources infrastructure, $1.5 million in increased facilities costs, a $0.6 million increase in legal fees, a $0.4 million increase in billing fees and a $0.7 million increase in overhead and other expenses.

Table of Contents

Research and Development Expenses

Research and development expenses increased to $18.1 million for the nine months ended September 30, 2013 from $10.2 million for the nine months ended September 30, 2012. The increase was primarily due to a $2.8 million increase in employee and contractor-related expenses primarily due to increased headcount, including a $0.4 million increase in stock-based compensation, a $1.1 million increase in facilities, a $2.1 million increase in technology infrastructure, a $1.2 million increase in clinical trial expenses, and a $0.7 million increase in overhead and other expenses.

Interest Expense, Net

Interest expense, net was $0.2 million and $0.3 million for the nine months ended September 30, 2013 and 2012, respectively.

Other Expense, Net

Other expense, net was $1.4 million and $0.1 million for the nine months ended September 30, 2013 and 2012, respectively. The increase is due to the change in the fair value of our warrant liability immediately before it converted into a warrant to purchase common stock and was reclassified into additional paid-in capital.

Liquidity and Capital Resources

We have incurred losses and negative cash flows from operations since our inception in November 2009, and as of September 30, 2013, we had an accumulated deficit of $76.7 million. We expect that our sales and marketing, research and development, and general and administrative expenses will continue to increase. We expect these increased costs to be funded by our product revenue, subject to the rate of reimbursement we receive from commercial third-party payors and government payors and by our existing cash and cash equivalents.

We have funded our operations principally from the sale of common stock and preferred stock, product revenue and the incurrence of indebtedness. Since we have not received a coverage decision for FoundationOne from any commercial third-party payor and have a limited history of collecting claims, we currently recognize revenue on a cash basis from commercial third-party payors. We will continue to make requests for payment and/or appeal payment decisions made by commercial third-party payors. In addition, we currently expect to submit claims to Medicare for FoundationOne tests previously reported by us for patients covered by Medicare and we may receive payment for a portion of these FoundationOne tests, although our requests for payments could be denied in whole. If commercial third-party payors or government payors agree to pay us for these FoundationOne tests in the future, we will recognize revenue for such FoundationOne tests in the period in which our revenue recognition criteria are met. Any revenue that we receive in respect of these previously performed FoundationOne tests will favorably impact our liquidity in future periods.

In November 2010, we entered into a loan and security agreement, or the loan and security agreement, with Lighthouse Capital Partners, or Lighthouse, for $5.0 million, which was fully drawn by June 21, 2011. As of September 30, 2013, $1.9 million of principal and deferred interest payments were outstanding under the loan and security agreement. Under the terms of the loan and security agreement, we are precluded from entering into certain financing, restructuring and other transactions, including disposing of certain assets, and are subject to various non-financial covenants, including requirements that we maintain standard levels of insurance, maintain our assets in good condition, and file all required tax returns. The loan and security agreement also restricts our ability to pay dividends without the prior written consent of Lighthouse. We believe we were in compliance with all covenants

under the loan and security agreement as of September 30, 2013.

As of September 30, 2013, we had cash and cash equivalents of approximately $137.9 million. Cash in excess of immediate requirements is invested in accordance with our investment policy, primarily with a view to liquidity and capital preservation. These excess funds are held in money market mutual funds consisting of U.S. government-backed securities.

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

Table of Contents

Cash Flows

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

	Nine Months Ended September 30,	
	2013	2012
	(in thousands)	
Net cash (used in) provided by:		
Operating activities	$ (20,746)	$ (13,804)
Investing activities	(5,516)	(2,295)
Financing activities	109,351	51,420
Net increase in cash and cash equivalents	$ 83,089	$ 35,321

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 $20.7 million for the nine months ended September 30, 2013 compared to $13.8 million for the nine months ended September 30, 2012. The increase in cash used in operating activities was driven primarily by an increase in net loss of $13.0 million for the nine months ended September 30, 2013 as compared to the nine months ended September 30, 2012, offset by increases in stock-based compensation expense of $4.1 million and depreciation of $1.1 million between the respective periods.

Investing Activities

Net cash used in investing activities consisted of purchases of fixed assets and an increase in restricted cash related to a security deposit. Net cash used in investing activities for the nine months ended September 30, 2013 was $5.5 million and consisted of an increase in restricted cash of $1.7 million related to our new laboratory and office facilities, and purchases of property and equipment of $3.8 million. Net cash used in investing activities for the nine months ended September 30, 2012 was $2.3 million and consisted solely of purchases of property and equipment.

Financing Activities

Net cash provided by financing activities for the nine months ended September 30, 2013 was $109.4 million and reflects the net proceeds from our IPO of $110.6 million, offset in part by $1.3 million in loan principal payments. Net cash provided by financing activities for the nine months ended September 30, 2012 was $51.4 million and reflects the sale of our Series A preferred stock for net proceeds of $10.2 million and the sale of our Series B preferred stock for net proceeds of $42.3 million, offset in part by $1.2 million in 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 for solid tumors, launch FoundationOne for hematologic malignancies, invest in clinical trials, innovate our molecular

information platform, and develop new product offerings. Our liquidity requirements have and will continue to consist of sales and marketing expenses, research and development expenses, capital expenditures, working capital, debt service, and general corporate expenses. As demand for FoundationOne continues to increase from physicians and biopharmaceutical companies, we anticipate that our capital expenditure requirements will also increase in order to build additional capacity. We expect that our planned expenditures will be funded from our ongoing operations and from our existing cash and cash equivalents.

Based on our current business plan, we believe our current cash and cash equivalents and anticipated cash flow from operations, will be sufficient to meet our anticipated cash requirements over at least the next 12 months and for the foreseeable future. We may consider raising additional capital to expand our business, to pursue strategic investments, to take advantage of financing opportunities, or for other reasons. In the future, we expect our operating and capital expenditures to increase as we increase our headcount, expand our sales and marketing activities and continue to invest in new product offerings. As sales of FoundationOne grow, we expect our accounts receivable balance to increase. Any increase in accounts payable and accrued expenses may not be completely offset by increases in accounts receivable, which could result in greater working capital requirements.

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

Table of Contents

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 of this Quarterly Report on Form 10-Q. 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

During the three months ended September 30, 2013, there were no material changes to our contractual obligations and commitments described under Management s Discussion and Analysis of Financial Condition and Results of Operations included in our Prospectus.

Off-Balance Sheet Arrangements

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

Application of Critical Accounting Policies

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

There have been no material changes to our critical accounting policies from those described in Management s Discussion and Analysis of Financial Condition and Results of Operations included in our Prospectus.

Item 3. Quantitative and Qualitative Disclosures about Market Risks

We are exposed to market risk related to changes in interest rates. As of September 30, 2013 and December 31, 2012 we had cash and cash equivalents of $137.9 million and $54.8 million, respectively, a portion of which is held in money market mutual funds consisting of U.S. government-backed securities. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our investments are in short-term securities. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, an immediate one percent change in interest rates would not have a material effect on the fair market value of our portfolio. We do not have any derivative financial instruments or derivative commodity instruments.

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, or 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.

Based on this evaluation, 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 report. 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 principal executive officer and principal financial officer have concluded based upon the evaluation described above that, as of September 30, 2013, our disclosure controls and procedures were effective at the reasonable assurance level.

Table of Contents

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 September 30, 2013, there have been 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 Securities Exchange Act of 1934, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II OTHER INFORMATION

Item 1A. Risk Factors

Risks Relating to Our Business and Strategy

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

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

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

We are currently not profitable. Even if we succeed in increasing adoption of FoundationOne by physicians, maintaining and creating relationships with our existing and new biopharmaceutical partners and developing and commercializing additional molecular information products, we may not be able to generate sufficient revenue to achieve profitability.

FoundationOne may never achieve significant commercial market acceptance.

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

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

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

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

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

Table of Contents

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

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

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

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

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

If our sole laboratory facility becomes damaged or inoperable or we are required to vacate our laboratory facility, our ability to conduct our genomic analyses and pursue our research and development efforts may be jeopardized.

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

Even in the unlikely event we are able to find a third party with such qualifications to enable us to conduct our molecular tests, we may be unable to negotiate commercially reasonable terms.

In October 2013, we finished moving our laboratory into a new facility at our new corporate headquarters in Cambridge, Massachusetts. Our laboratory operations in the new corporate headquarters may achieve slower realization of laboratory efficiencies than we anticipate, resulting in our inability to meet customer turnaround time expectations.

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

Table of Contents

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

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

As additional products are commercialized, such as FoundationOne Heme, we will need to incorporate new equipment, implement new technology systems and laboratory processes, and hire new personnel with different qualifications. For example, we are now scaling up our RNA sequencing capabilities and we believe we will be the first company to perform RNA sequencing for clinical testing at our clinical scale. Failure to manage this growth or transition could result in turnaround time delays, higher product costs, declining product quality, deteriorating customer service, and slower responses to competitive challenges. A failure in any one of these areas could make it difficult for us to meet market expectations for our products, and could damage our reputation and the prospects for our business.

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

FoundationOne Heme, for which we expect to commence our commercial launch by early 2014, will take time to commercialize, and its launch may be delayed or may not be successful. There can be no assurance that FoundationOne 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, which are in various stages of early development, will take time to develop and commercialize, if we are able to commercialize them at all. There can be no assurance that our new products will be capable of reliably identifying relevant genomic alterations in forms of cancer other than cancers found in solid tumors. Before we can commercialize any new products, we will need to expend significant funds in order to:

- conduct substantial research and development, including validation studies and potentially clinical trials;
- further develop and scale our laboratory processes to accommodate different products; and
- further develop and scale our infrastructure to be able to analyze increasingly large amounts of data.

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

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

lack of validation data; or

failure to demonstrate the clinical utility of the product.

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

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

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

Table of Contents

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

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

In addition to developing kits, certain diagnostic companies also provide NGS platforms. Illumina, Life Technologies Corporation, and other companies develop NGS platforms that are being sold directly to research centers, biopharmaceutical companies and clinical laboratories. While many of the applications for these platforms are focused on the research and development markets and others are focused on testing for non-cancer conditions, each of these companies has launched and will continue to commercialize products focused on the clinical oncology market. We believe diagnostic platform providers will seek to place sequencing machines in laboratories to develop NGS-based laboratory-developed tests, or LDTs. In addition, we believe these companies will also develop their own FDA-approved diagnostic kits, which can be sold to the clients who have purchased their platforms. Also, many private companies are developing information technology-based tools to support the integration of NGS testing into the clinical setting. These companies may also use their patent portfolios, developed in connection with developing their tests, to allege that FoundationOne infringes their patents, and we could face litigation with respect to such allegations and the validity of such patents.

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

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

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

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

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

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

Table of Contents

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, such as the Memorial Sloan-Kettering Cancer Center, Vanderbilt-Ingram Cancer Center and The US Oncology Network. If these key thought leaders determine that our molecular information platform, FoundationOne or other products that we develop are not clinically effective or that alternative technologies are more effective, or if they elect to use internally developed products, we would encounter significant difficulty validating our testing platform, driving adoption, or establishing our molecular information platform and FoundationOne as a standard of care, which would limit our revenue growth and our ability to achieve profitability.

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

We deploy our molecular information platform to analyze tissue samples provided by biopharmaceutical partners from their clinical trials. We have entered into agreements with biopharmaceutical companies in the cancer field including, for example, Agios Pharmaceuticals, Inc., ARIAD Pharmaceuticals, Inc., Array BioPharma Inc., AstraZeneca UK Limited, Celgene Corporation, Clovis Oncology, Inc., Eisai Co., Ltd., Johnson & Johnson, Novartis, and Sanofi, among others. In each of the years ended December 31, 2011 and 2012 and the nine months ended September 30, 2013, our alliance with Novartis accounted for more than 10% of our revenue. The revenue attributable to Novartis may also fluctuate in the future, which could have an adverse effect on our financial condition and results of operations. In addition, the termination of this relationship could result in a temporary or permanent loss of revenue to us.

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

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

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

We anticipate growth in our business operations. This future growth could create strain on our organizational, administrative and operational infrastructure, including laboratory operations, quality control, customer service, and

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

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

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

Table of Contents

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

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

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

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

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

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

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

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

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

Table of Contents

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

We may pursue acquisitions of businesses and assets. We also may pursue strategic alliances and joint ventures that leverage our proprietary molecular information platform and industry experience to expand our offerings or distribution. We have no experience with acquiring other companies and limited experience with forming strategic partnerships. We may not be able to find suitable partners or acquisition candidates, and we may not be able to complete such transactions on favorable terms, if at all. If we make any acquisitions, we may not be able to integrate these acquisitions successfully into our existing business, and we could assume unknown or contingent liabilities. Any future acquisitions also could result in the incurrence of debt, contingent liabilities or future write-offs of intangible assets or goodwill, any of which could have a material adverse effect on our financial condition, results of operations, and cash flows. Integration of an acquired company also may disrupt ongoing operations and require management resources that we would otherwise focus on developing our existing business. We may experience losses related to investments in other companies, which could have a material negative effect on our results of operations and financial condition. We may not realize the anticipated benefits of any acquisition, technology license, strategic alliance, or joint venture.

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

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

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

- multiple, conflicting and changing laws and regulations such as privacy regulations, tax laws, export and import restrictions, employment laws, regulatory requirements, and other governmental approvals, permits, and licenses;
- failure by us or our distributors to obtain regulatory approvals for the use of our products in various countries;
- additional potentially relevant third-party patent rights;
- complexities and difficulties in obtaining protection and enforcing our intellectual property;

difficulties in staffing and managing foreign operations;

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

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

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

financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our products, and exposure to foreign currency exchange rate fluctuations;

natural disasters, political and economic instability, including wars, terrorism, and political unrest, outbreak of disease, boycotts, curtailment of trade, and other business restrictions; and

regulatory and compliance risks that relate to maintaining accurate information and control over sales and distributors activities that may fall within the purview of the U.S. Foreign Corrupt Practices Act, or FCPA, its books and records provisions, or its anti-bribery provisions.

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

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

International customers may currently order FoundationOne and we are subject to the FCPA, which prohibits companies and their intermediaries from making payments in violation of law to non-U.S. government officials for the purpose of obtaining or retaining business or securing any other improper advantage. Our reliance on independent distributors to sell FoundationOne internationally demands a high degree of vigilance in maintaining our policy against

Table of Contents

participation in corrupt activity, because these distributors could be deemed to be our agents, and we could be held responsible for their actions. Other U.S. companies in the medical device and pharmaceutical field have faced criminal penalties under the FCPA for allowing their agents to deviate from appropriate practices in doing business with these individuals. We are also subject to similar anti-bribery laws in the jurisdictions in which we operate, including the United Kingdom s Bribery Act of 2010, which went into effect in the third quarter of 2011, which also prohibits commercial bribery and makes it a crime for companies to fail to prevent bribery. These laws are complex and far-reaching in nature, and, as a result, we cannot assure you that we would not be required in the future to alter one or more of our practices to be in compliance with these laws or any changes in these laws or the interpretation thereof. Any violations of these laws, or allegations of such violations, could disrupt our operations, involve significant management distraction, involve significant costs and expenses, including legal fees, and could result in a material adverse effect on our business, prospects, financial condition, or results of operations. We could also suffer severe penalties, including criminal and civil penalties, disgorgement, and other remedial measures.

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

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

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

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

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

Table of Contents

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

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

The secure processing, storage, maintenance, and transmission of this critical information is vital to our operations and business strategy, and we devote significant resources to protecting such information. Although we take measures to protect sensitive information from unauthorized access or disclosure, our information technology and infrastructure, and that of our third-party billing and collections provider, may be vulnerable to attacks by hackers or viruses or breached due to employee error, malfeasance, or other disruptions. Any such breach or interruption could compromise our networks and the information stored there could be accessed by unauthorized parties, publicly disclosed, lost, or stolen. Any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, such as the Health Insurance Portability and Accountability Act of 1996, or HIPAA, and regulatory penalties. Although we have implemented security measures and a formal, dedicated enterprise security program to prevent unauthorized access to patient data, Interactive Cancer Explorer, which is currently accessible through our online portal and will also soon be accessible through our mobile applications, gives broad access to physicians, at which point we lose ability to control access, and there is no guarantee we can continue to protect our online portal or will be able to protect our mobile applications from breach. Unauthorized access, loss or dissemination could also disrupt our operations, including our ability to conduct our analyses, provide test results, bill payors or patients, process claims and appeals, provide customer assistance services, conduct research and development activities, collect, process, and prepare company financial information, provide information about our products and other patient and physician education and outreach efforts through our website, manage the administrative aspects of our business, and damage our 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 the HIPAA regulations. In the event of a significant breach, the reporting requirements could include notification to the general public.

In addition, the interpretation and application of consumer, health-related, and data protection laws in the United States, Europe and elsewhere are often uncertain, contradictory, and in flux. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices. If so, this could result in government-imposed fines or orders requiring that we change our practices, which could adversely affect our business. In addition, these privacy regulations may differ from country to country, and may vary based on whether testing is performed in the United States or in the local country. Complying with these various laws could cause us to incur substantial costs or require us to change our business practices and compliance procedures in a manner adverse to our business.

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

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

Table of Contents

impact on our business, financial condition, and results of operations. Additionally, the instability has resulted in diminished liquidity and credit availability in the market, which could impair our ability to access capital if required or adversely affect our operations. In the event of further economic slowdown, investment in biopharmaceutical research and development may also experience a corresponding slowdown.

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

Our activities currently require the use of hazardous chemicals. We cannot eliminate the risk of accidental contamination or injury to employees or third parties from the use, storage, handling, or disposal of these materials. In the event of contamination or injury, we could be held liable for any resulting damages, and any liability could exceed our resources or any applicable insurance coverage we may have. Additionally, we are subject on an ongoing basis to federal, state, and local laws and regulations governing the use, storage, handling, and disposal of these materials and specified waste products. The cost of compliance with these laws and regulations may become significant and could negatively affect our operating results.

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

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

- sell, transfer, lease or dispose of certain assets;
- encumber or permit liens on certain assets;
- make certain restricted payments, including paying dividends on, or repurchasing or making distributions with respect to, our common stock; and
- enter into certain transactions with affiliates.

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

Reimbursement and Regulatory Risks Relating to Our Business

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

In both domestic and foreign markets, sales of FoundationOne or any future molecular information products we develop will depend, in large part, upon the availability of reimbursement from third-party payors. These third-party

payors include government healthcare programs such as Medicare, managed care providers, private health insurers, and other organizations. In particular, we believe that obtaining a positive national coverage decision and favorable reimbursement rate from the Centers for Medicare and Medicaid Services, or CMS, for FoundationOne will be a necessary element in achieving material commercial success. Physicians and patients may not order FoundationOne unless commercial third-party payors and government payors pay for all, or a substantial portion, of the list price, and certain commercial third-party payors may not agree to reimburse FoundationOne if CMS does not issue a positive coverage decision.

There is currently no national coverage decision that determines whether and how our test is covered by Medicare. In the absence of a national coverage decision, local Medicare contractors that administer the Medicare program in various regions have some discretion in determining coverage and therefore payment for tests. Our local Medicare contractor, who would process our claims on behalf of Medicare, requested that we not submit claims for services provided to Medicare patients while the contractor assessed the appropriate coverage and payment for FoundationOne as a whole. Pending the response, no claims have been billed to either Medicare or Medicare patients. Accordingly, we do not currently receive any payment for FoundationOne provided to patients covered by Medicare. If CMS does not issue a positive national coverage decision with respect to FoundationOne, or if CMS denies reimbursement of FoundationOne, withdraws its coverage policies after reimbursement is obtained, reviews and adjusts the rate of reimbursement, or stops paying for FoundationOne altogether, our revenue and results of operations would be adversely affected.

We intend, before the end of 2013, to commence submitting claims to CMS for FoundationOne tests provided to Medicare patients. We will inform our Medicare contractor prior to submitting these claims for services provided to Medicare patients. The response of the Medicare contractor to the submission of such a claim is uncertain and the claim may be denied or paid, in whole or in part. If a claim is denied or paid in part, we may decide to appeal the denied claim or

Table of Contents

any denied portion of the claim. Alternatively, CMS may defer processing a claim pending a coverage or payment determination. Even if we do receive payments from CMS, the reimbursement rate may be lower than we expect, and if such rate is then adopted by commercial third-party payors, it would have an adverse effect on our revenues and results of operations. In addition, CMS may issue a negative coverage determination for FoundationOne that would apply to future claims. Although we would have the opportunity to submit additional materials to CMS in support of a positive coverage determination for FoundationOne, there is no guarantee that CMS would provide us with a positive coverage decision or reverse a negative coverage decision that it already issued.

Commercial third-party payors and government payors are increasingly attempting to contain healthcare costs by demanding price discounts or rebates and limiting both coverage on which diagnostic products they will pay for and the amounts that they will pay for new molecular diagnostic products. Because of the cost-containment trends, commercial third-party payors and government payors that currently provide reimbursement for, or in the future cover, FoundationOne may reduce, suspend, revoke, or discontinue payments or coverage at any time.

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

not experimental or investigational;

medically necessary;

appropriate for the specific patient;

cost-effective;

supported by peer-reviewed publications;

included in clinical practice guidelines; and

supported by clinical utility studies.

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

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

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

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

Table of Contents

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

While the FDA currently exercises its enforcement discretion for LDTs by not enforcing its regulations, the FDA has stated that it has a mandate to regulate in this field and that it may address LDT regulation using a risk-based, phased-in approach similar to the existing *in vitro* diagnostic framework. In particular, as recently as June 2013, the Commissioner of the FDA has stated that the FDA is working to make sure that the accuracy and clinical validity of high-risks tests are established before they come to market. Thus, the FDA may seek to more actively regulate, including requiring clearance or approval of, our molecular information products in the future. Moreover, the FDA could disagree with our assessment that FoundationOne is a LDT, including FoundationOne Heme that we are developing with Memorial Sloan-Kettering Cancer Center, and could require us to seek clearance or approval to offer FoundationOne for clinical use. If the FDA requires us to seek clearance or approval to offer FoundationOne or any of our future products for clinical use, we may not be able to obtain such approvals on a timely basis, or at all. Failure to comply with applicable regulatory requirements can result in enforcement action by the FDA, which may include any of the following sanctions: warning letters; fines; injunctions; civil or criminal penalties; recall or seizure of current or future products; operating restrictions; partial suspension or total shutdown of production; denial of applications; or challenges to clearances or approvals. In July 2010, the FDA s Office of In-Vitro Diagnostic Device Evaluation and Safety held a public meeting to discuss oversight of LDTs. The FDA highlighted the lack of standardized clinical validation at the test level under current CLIA regulatory guidelines and noted that CLIA does not require post-market surveillance or monitoring of LDTs. The comment period for providing the FDA with written comments expired on August 15, 2010, but the FDA has not yet published additional guidance on the oversight of LDTs. We cannot provide any assurance that FDA regulation, including premarket review, will not be required for our molecular information products. If premarket review is required, our business could be negatively impacted if we are required to stop selling molecular information products pending their clearance or approval or the launch of any new products that we develop could be delayed by new requirements.

In addition, in June 2011, the FDA issued draft guidance regarding the sale and use of products labeled for research use only. Among other things, the draft guidance advises manufacturers to cease the sale of research use only products to customers that the manufacturer knows use the product for clinical diagnostic purposes. Certain of the reagents and other products we use in FoundationOne are labeled as research use only products. If the FDA were to enforce this June 2011 draft guidance, certain of our suppliers may cease selling research use only products to us and any failure to obtain an acceptable substitute could significantly and adversely affect our business, financial condition and results of operations.

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

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively referred to as the Affordable Care Act, was enacted in the United States, which made a number of substantial changes in the way health care is financed by both governmental and private insurers. Among other things, the Affordable Care Act:

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

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

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

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

Table of Contents

In addition, many of the Current Procedure Terminology, or CPT, procedure codes that we use to bill our products were recently revised by the American Medical Association, effective January 1, 2013. In the Final Rule, CMS announced that it has decided to keep the new molecular codes on the Clinical Laboratory Fee Schedule, rather than move them to the Physician Fee Schedule as some stakeholders had urged. CMS has also announced that for 2013 it will price the new codes using a gapfilling process by which it will refer the codes to the Medicare contractors to allow them to determine an appropriate price. Our reimbursement could be adversely affected by CMS action in this area. If it reduces reimbursement for the new test codes, then our revenue will be adversely affected. There can be no guarantees that Medicare and other payors will establish positive or adequate coverage policies or reimbursement rates.

We cannot predict whether future health care initiatives will be implemented at the federal or state level, or how any future legislation or regulation may affect us. The taxes imposed by the new federal legislation and the expansion of government s role in the U.S. health care industry as well as changes to the reimbursement amounts paid by payors for our product and future products or our medical procedure volumes may reduce our profits and have a materially adverse effect on our business, financial condition, results of operations, and cash flows. Moreover, Congress has proposed on several occasions to impose a 20% coinsurance on patients for clinical laboratory tests reimbursed under the clinical laboratory fee schedule, which would require us to bill patients for these amounts. Because of the relatively low reimbursement for many clinical laboratory tests, in the event that Congress were to ever enact such legislation, the cost of billing and collecting for these tests would often exceed the amount actually received from the patient and effectively increase our costs of billing and collecting.

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

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

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

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

Table of Contents

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Table of Contents

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

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

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

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

We have implemented measures to ensure that all clinical data and genetic and other biological samples that we receive from our biopharmaceutical partners have been collected from subjects who have provided appropriate informed consent for purposes which extend to our product development activities. We seek to ensure these data and samples are provided to us on a subject de-identified manner. We also have measures in place to ensure that the subjects from whom the data and samples are collected do not retain or have conferred on them any proprietary or commercial rights to the data or any discoveries derived from them. Our biopharmaceutical partners conduct clinical trials in a number of different countries, and, to a large extent, we rely upon them to comply with the subject s informed consent and with local law and international regulation. The collection of data and samples in many different countries results in complex legal questions regarding the adequacy of informed consent and the status of genetic material under a large number of different legal systems. The subject s informed consent obtained in any particular country could be challenged in the future, and those informed consents could prove invalid, unlawful, or otherwise inadequate for our purposes. Any findings against us, or our biopharmaceutical partners, could deny us access to or force us to stop using some of our clinical samples, which would hinder our molecular information product development efforts. We could become involved in legal challenges, which could consume our management and financial resources.

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

Genomic testing, like that conducted using our molecular information platform and FoundationOne, has raised ethical, legal, and social issues regarding privacy and the appropriate uses of the resulting information. Governmental authorities could, for social or other purposes, limit or regulate the use of genomic information or genomic testing or

prohibit testing for genetic predisposition to certain conditions, particularly for those that have no known cure. Similarly, these concerns may lead patients to refuse to use genomic tests even if permissible.

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

Table of Contents

Intellectual Property Risks Related to Our Business

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

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

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

In addition, we may be unable to obtain these licenses at a reasonable cost, if at all. We could therefore incur substantial costs related to royalty payments for licenses obtained from third parties, which could negatively affect our gross margins. Moreover, we could encounter delays in product introductions while we attempt to develop alternative methods or products. Defense of any lawsuit or failure to obtain any of these licenses on favorable terms could prevent us from commercializing products, and the prohibition of sale of any of our products would materially affect our ability to grow and maintain profitability and have a material adverse impact on our business.

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

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

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

On July 3, 2012, the USPTO issued a memorandum to patent examiners providing interim guidelines for examining process claims for patent eligibility in view of the Supreme Court decision in *Prometheus*. The guidance indicates that claims directed to a law of nature, a natural phenomenon, or an abstract idea that do not meet the eligibility requirements should be rejected as non-statutory subject matter. We cannot assure you that our efforts to seek patent protection for our technology and products will not be negatively impacted by the decisions described above, rulings in other cases or changes in guidance or procedures issued by the USPTO.

We cannot fully predict what impact the Supreme Court s decisions in *Prometheus* and *Myriad* may have on the ability of biopharmaceutical companies or other entities to obtain or enforce patents relating to genes or genomic discoveries in the future. Despite the USPTO memorandum described above, the *Prometheus* decision is new and the contours of when certain method claims allegedly directed to laws of nature or natural phenomenon meet the patent eligibility requirements are not clear and may take many years to develop via interpretation in the courts. There are many patents claiming diagnostic methods based on similar or related correlations that issued before *Prometheus*, and although some of these patents may be invalid under the standard set forth in *Prometheus*, until successfully challenged, these patents are presumed valid and enforceable, and certain third parties could allege that we infringe, or request that we obtain a license to, these patents. Whether based on patents issued prior to or after *Prometheus*, we could have to defend ourselves against claims of patent infringement, or choose to license rights, if available, under patents claiming such

Table of Contents

methods. Moreover, although the Supreme Court has held in *Myriad* that isolated genomic DNA is not patent-eligible subject matter, certain third parties could allege that activities that we may undertake infringe other classes of gene-related patent claims, and we could have to defend ourselves against these claims by asserting non-infringement and/or invalidity positions, or pay to obtain a license to these claims. In any of the foregoing or in other situations involving third-party intellectual property rights, if we are unsuccessful in defending against claims of patent infringement, we could be forced to pay damages or be subjected to an injunction that would prevent us from utilizing the patented subject matter in question if we are unable to obtain a license on reasonable terms. Such outcomes could materially affect our ability to offer our products and have a material adverse impact on our business. Even if we are able to obtain a license or successfully defend against claims of patent infringement, the cost and distraction associated with the defense or settlement of these claims could have a material adverse impact on our business.

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

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

Obtaining and maintaining a strong patent position is important to our business. Our patent applications are in the early stages of prosecution and none have yet issued as patents. Patent law relating to the scope of claims in the technology fields in which we operate is complex and uncertain, so we cannot be assured that we will be able to obtain or maintain patent rights, or that the patent rights we may obtain will be valuable, provide an effective barrier to competitors or otherwise provide competitive advantages. Others have filed, and in the future are likely to file, patent applications that are similar or identical to ours or those of our licensors. To determine the priority of inventions, or demonstrate that we did not derive our invention from another, we may have to participate in interference or derivation proceedings in the USPTO or in court that could result in substantial costs in legal fees and could substantially affect the scope of our patent protection. We cannot be assured our patent applications will prevail over those filed by others. Also, our intellectual property rights may be subject to other challenges by third parties. Patents we obtain could be challenged in litigation or in administrative proceedings such as *ex parte* reexam, *inter partes* review, or post grant review in the United States or opposition proceedings in Europe or other jurisdictions.

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

competitive position could suffer.

Legal actions to enforce our patent rights can be expensive and may involve the diversion of significant management time. In addition, these legal actions could be unsuccessful and could also result in the invalidation of our patents or a finding that they are unenforceable. We may or may not choose to pursue litigation or interferences against those that have infringed on our patents, or used them without authorization, due to the associated expense and time commitment of monitoring these activities. If we fail to protect or to enforce our intellectual property rights successfully, our competitive position could suffer, which could harm our results of operations.

Table of Contents

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

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

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

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

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

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

Third parties may in the future make claims challenging the inventorship or ownership of our intellectual property. For example, we rely on certain third parties to provide us with tissue samples and biological materials that we use to conduct our genomic analyses. We have written agreements with collaborators that provide for the ownership of intellectual property arising from our collaborations. These agreements provide that we must negotiate certain commercial rights with collaborators with respect to joint inventions or inventions made by our collaborators that arise from the results of the collaboration. In some instances, there may not be adequate written provisions to address

clearly the resolution of intellectual property rights that may arise from a collaboration. If we cannot successfully negotiate sufficient ownership and commercial rights to the inventions that result from our use of a third-party collaborator s materials where required, or if disputes otherwise arise with respect to the intellectual property developed with the use of a collaborator s samples, we may be limited in our ability to capitalize on the market potential of these inventions. In addition, we may face claims by third parties that our agreements with employees, contractors, or consultants obligating them to assign intellectual property to us are ineffective, or in conflict with prior or competing contractual obligations of assignment, which could result in ownership disputes regarding intellectual property we have developed or will develop and interfere with our ability to capture the commercial value of such inventions. Litigation may be necessary to resolve an ownership dispute, and if we are not successful, we may be precluded from using certain intellectual property, or may lose our exclusive rights in that intellectual property. Either outcome could have an adverse impact on our business.

Table of Contents

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

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

Risks Relating to Our Financial Condition and Capital Requirements

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

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

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

We have historically incurred substantial net losses, including a net loss of $22.4 million in 2012. From our inception in 2009 through September 30, 2013, we had an accumulated deficit of $76.7 million. We expect our losses to continue as a result of ongoing research and development expenses and increased sales and marketing costs. These losses have had, and will continue to have, an adverse effect on our working capital, total assets, and stockholders equity. Because of the numerous risks and uncertainties associated with our research, development, and commercialization efforts, we are unable to predict when we will become profitable, and we may never become profitable. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our inability to achieve and then maintain profitability would negatively affect our business, financial condition, results of operations, and cash flows.

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

If our available cash balances, net proceeds from our initial public offering, and anticipated cash flow from operations are insufficient to satisfy our liquidity requirements including because of lower demand for our 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 on Form 10-Q, we may seek to sell common or preferred equity or convertible debt securities, enter into an additional credit facility or another form of third-party funding, or seek other

debt financing.

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

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

Table of Contents

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

- our ability to achieve revenue growth;
- our rate of progress in establishing reimbursement arrangements with domestic and international commercial third-party payors and government payors;
- the cost of expanding our laboratory operations and offerings, including our sales and marketing efforts;
- our rate of progress in, and cost of the sales and marketing activities associated with, establishing adoption of and reimbursement for FoundationOne;
- our rate of progress in, and cost of research and development activities associated with, products in research and early development;
- the effect of competing technological and market developments;
- costs related to international expansion; and
- the potential cost of and delays in product development as a result of any regulatory oversight applicable to our products.

The various ways we could raise additional capital carry potential risks. If we raise funds by issuing equity securities, dilution to our stockholders could result. Any equity securities issued also could provide for rights, preferences, or privileges senior to those of holders of our common stock. If we raise funds by issuing debt securities, those debt securities would have rights, preferences, and privileges senior to those of holders of our common stock. The terms of debt securities issued or borrowings pursuant to a credit agreement could impose significant restrictions on our operations. If we raise funds through collaborations and licensing arrangements, we might be required to relinquish significant rights to our platform technologies or products, or grant licenses on terms that are not favorable to us.

The credit markets and the financial services industry have experienced a period of unprecedented turmoil and upheaval characterized by the bankruptcy, failure, collapse, or sale of various financial institutions and an unprecedented level of intervention from the United States federal government. These events have generally made equity and debt financing more difficult to obtain. Accordingly, additional equity or debt financing might not be available on reasonable terms, if at all. In addition, our current loan and security agreement with Lighthouse restricts our ability to raise funds through additional debt or other financing options. If we cannot secure additional funding when needed, we may have to delay, reduce the scope of, or eliminate one or more research and development programs or sales and marketing initiatives. In addition, we may have to work with a partner on one or more of our development programs, which could lower the economic value of those programs to us.

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

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

To comply with the requirements of being a public company, we may need to undertake various actions, including implementing new internal controls and procedures and hiring new accounting or internal audit staff. The Sarbanes-Oxley Act requires that we maintain effective disclosure controls and procedures and internal control over financial reporting. We are continuing to develop and refine our disclosure controls and other procedures that are designed to ensure that information required to be disclosed by us in the reports that we file with the SEC is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms, and that information required to be disclosed in reports under the Securities Exchange Act of 1934, or the Exchange Act, is accumulated and communicated to our

Table of Contents

principal executive and financial officers. Our current controls and any new controls that we develop may become inadequate and weaknesses in our internal control over financial reporting may be discovered in the future. Any failure to develop or maintain effective controls could adversely affect the results of periodic management evaluations and annual independent registered public accounting firm attestation reports regarding the effectiveness of our internal control over financial reporting that we may be required to include in our periodic reports we will file with the SEC under Section 404 of the Sarbanes-Oxley Act, harm our operating results, cause us to fail to meet our reporting obligations, or result in a restatement of our prior period financial statements. In the event that we are not able to demonstrate compliance with the Sarbanes-Oxley Act, that our internal control over financial reporting is perceived as inadequate or that we are unable to produce timely or accurate financial statements, investors may lose confidence in our operating results and the price of our ordinary shares could decline. In addition, if we are unable to continue to meet these requirements, we may not be able to remain listed on the NASDAQ Global Select Market.

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

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

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

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

Risks Related to Our Common Stock

We expect that our stock price may fluctuate significantly.

The initial public offering of our common stock was completed in September 2013 at a price of $18.00 per share. There has been a public market for our common stock for only a short period of time. Although our common stock is listed on the NASDAQ Global Select Market, an active public market for our common stock may not be sustained.

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

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

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

competition from existing products or new products that may emerge;

Table of Contents

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

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

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

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

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

additions or departures of key management or scientific personnel;

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

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

announcement or expectation of additional debt or equity financing efforts;

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

general economic and market conditions.

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

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

Investment funds affiliated with Third Rock Ventures and Kleiner Perkins Caufield & Byers, and Google Ventures 2011, L.P., along with our executive officers and directors, beneficially own, in the aggregate, shares representing more than a majority of our outstanding capital stock as of September 30, 2013. If these stockholders were to choose to act together, as a result of their stock ownership, they could influence our management and affairs and control all matters submitted to our stockholders for approval, including the election of directors and approval of any merger, consolidation, or sale of all or substantially all of our assets. This concentration of ownership may have the effect of delaying or preventing a change in control of our company and might affect the market price of our common stock.

A significant portion of our total outstanding shares of common stock are restricted from immediate resale but may be sold into the market in the near future, which could cause our stock price to decline.

A significant number of our outstanding shares are subject to a180-day contractual lock-up and other legal restrictions on resale pursuant to lock-up agreements that our officers, directors and a significant majority of our stockholders executed in connection with our initial public offering. If these stockholders sell, or indicate an intent to sell, substantial amounts of our common stock in the public market after the expiration of the lock-up period, the trading price of our common stock could decline significantly and could decline below the initial public offering price.

After the lock-up agreements pertaining to our initial public offering expire and based on shares outstanding as of September 30, 2013, an additional 21,295,533 shares will be eligible for sale in the public market. In addition, upon issuance, the 2,150,117 shares subject to outstanding options under our 2010 stock option plan, the 1,355,171 shares subject to outstanding options or reserved for future issuance under our 2013 stock option plan and the 788,503 shares reserved for future issuance under our employee stock purchase plan will become eligible for sale in the public market in the future, subject to certain legal and contractual limitations. Moreover, 180 days after the completion of our initial public offering, holders of approximately 17,178,024 shares of our common stock will have the right to require us to register these shares under the Securities Act of 1933, as amended, or the Securities Act, pursuant to an investors rights agreement. If our existing stockholders sell substantial amounts of our common stock in the public market, or if the public perceives that such sales could occur, this could have an adverse impact on the market price of our common stock, even if there is no relationship between such sales and the performance of our business.

Table of Contents

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

We will have considerable discretion in the application of the net proceeds from our initial public offering. We intend to use the net proceeds from our initial public offering for expansion of our commercial and laboratory operations, ongoing and new clinical trials, supporting our molecular information platform, and for working capital and other general corporate purposes. We may use the net proceeds for purposes that do not yield a significant return or any return at all for our stockholders. In addition, we may invest the net proceeds from our initial public offering in a manner that does not produce income or that loses value.

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

We are an emerging growth company, as defined in the Jumpstart our Business Startups Act of 2012, or the JOBS Act, and we intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies including not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-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 shareholder approval of any golden parachute payments not previously approved. In addition, Section 107 of the JOBS Act also provides that an emerging growth company can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act of 1933, as amended, or the Securities Act, for complying with new or revised accounting standards. In other words, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. However, we are electing not to take advantage of such extended transition period, and as a result we will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth companies. Section 107 of the JOBS Act provides that our decision to not take advantage of the extended transition period for complying with new or revised accounting standards is irrevocable. We cannot predict if investors will find our common stock less attractive because we may rely on any of the exemptions available under the JOBS Act. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We may take advantage of these reporting exemptions until we are no longer an emerging growth company. We will remain an emerging growth company until the earliest of (i) the last day of the fiscal year in which we have total annual gross revenue of $1.0 billion or more; (ii) the last day of our fiscal year following the fifth anniversary of the date of the completion of our initial public offering; (iii) the date on which we have issued more than $1.0 billion in nonconvertible debt during the previous three years; and (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC.

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

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

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

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

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

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

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

Table of Contents

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

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

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

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

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

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

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

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

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

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

Unregistered Sales of Equity Securities

Upon closing of our initial public offering, all of the outstanding shares of our convertible preferred stock were converted into 17,128,024 shares of common stock. The shares of common stock issued pursuant to such conversion were issued in reliance on the exemption from registration provided by Section 3(a)(9) of the Securities Act, which exemption is available for transactions involving securities exchanged by the issuer with its existing security holders exclusively where no commission or other remuneration is paid or given directly or indirectly for soliciting such exchange.

During the quarter ended September 30, 2013, we issued and sold an aggregate of 34,567 shares of common stock to certain employees and consultants for cash consideration in the aggregate amount of $32,933 upon the exercise of stock options. These issuances were undertaken in reliance upon the exemption from registration requirements of Rule 701 of the Securities Act as offers and sales of securities under compensatory benefit plans and contracts relating to compensation in compliance with Rule 701.

No underwriters were used in the foregoing transactions.

Table of Contents

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 was registered under the Securities Act pursuant to registration statements on Form S-1 (File No. 333-190226), which was filed with the SEC on July 29, 2013 and amended subsequently and declared effective by the SEC on September 24, 2013, and Form S-1MEF (File No. 333-191333), which was filed with the SEC on September 24, 2013 and automatically effective upon filing. Following the sale of the shares in connection with the closing of our initial public offering, the offering terminated. The offering did not terminate before all the securities registered in the registration statements were sold. Goldman, Sachs & Co. and J.P. Morgan Securities LLC acted as joint book-running managers of the offering, and Leerink Swann LLC and Sanford C. Bernstein & Co., LLC acted as co-managers of the offering.

We raised approximately $110.6 million in net proceeds after deducting underwriting discounts and commissions of approximately $8.5 million and other offering expenses of approximately $2.8 million. None of these expenses consisted of direct or indirect payments made by us to directors, officers or persons owning 10% or more of our common stock or to their associates, or to our affiliates. There has been no material change in the planned use of proceeds from our initial public offering 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 September 30, 2013, the entire amount 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.

Table of Contents

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: November 12, 2013

By: /s/ Michael J. Pellini, M.D.

Michael J. Pellini, M.D.

President and Chief Executive Officer

(Principal Executive Officer)

Date: November 12, 2013

By: /s/ Jason Ryan

Jason Ryan

Vice President, Finance

(Principal Finance and Accounting Officer)

Table of Contents

Exhibit No.	Exhibit Index
3.1	Sixth Amended and Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1 of the Company s Form 8-K filed on October 2, 2013)
3.2	Amended and Restated Bylaws of the Company (incorporated by reference to Exhibit 3.2 of the Company s Form 8-K filed on October 2, 2013)
4.1	Form of Common Stock certificate of the Company (incorporated by reference to Exhibit 4.1 to the Company s Registration Statement on Form S-1 (File No. 333-190226) filed on July 29, 2013)
10.1	2013 Stock Option and Incentive Plan and forms of agreements thereunder (incorporated by reference to Exhibit 10.2 to the Company s Registration Statement on Form S-1 (File No. 333-190226) filed on July 29, 2013)
10.2	Executive Employee Offer Letter issued by the Company to Michael J. Pellini, dated as of September 9, 2013 (incorporated by reference to Exhibit 10.3 to the Company s Registration Statement on Form S-1 (File No. 333-190226) filed on July 29, 2013)
10.3	Supply and Support Agreement, by and between the Company and Illumina, Inc., effective as of July 25, 2013 (incorporated by reference to Exhibit 10.13 to the Company s Registration Statement on Form S-1 (File No. 333-190226) filed on July 29, 2013)
10.4	Form of Indemnification Agreement, to be entered into between the Company and its directors and officers (incorporated by reference to Exhibit 10.8 to the Company s Registration Statement on Form S-1 (File No. 333-190226) filed on July 29, 2013)
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 Balance Sheets as of September 30, 2013 and December 31, 2012 (b) our Condensed Statements of Operations and Comprehensive Loss for the Three and Nine Months Ended September 30, 2013 and 2012, (c) our Condensed Statements of Cash Flows for the Nine Months Ended September 30, 2013 and 2012 and (d) the Notes to such Condensed Financial Statements.

* Filed herewith.
** Furnished herewith.
*** As provided in Rule 406T of Regulation S-T, this information is furnished and not filed for purposes of Sections 11 and 12 of the Securities Act and Section 18 of the Securities Exchange Act.