Foundation Medicine, Inc.
Form 10-Q
August 13, 2014
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2014

OR

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

For the transition period from _____ to _____

Commission file number: 001-36086

FOUNDATION MEDICINE, INC.

(Exact name of registrant as specified in its charter)

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

150 Second Street

Cambridge MA, 02141

(Address of principal executive offices)(Zip code)

(617) 418-2200

(Registrant s telephone number, including area code)

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

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

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

Large accelerated filer ¨	Accelerated filer ¨
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 August 8, 2014 was 28,260,753.

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FORWARD LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements that involve risks and uncertainties. We make such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. All statements other than statements of historical facts contained in this Quarterly Report on Form 10-Q are forward-looking statements. In some cases, you can identify forward-looking statements by words such as anticipate, believe, contemplate, continue, could, estimate, ex intend, may, plan, potential, predict, project, seek, should, target, will, would, or the negative comparable terminology. These forward-looking statements include, but are not limited to, statements about:

- the evolving treatment paradigm for cancer, including physicians use of molecular information and targeted oncology therapeutics and the market size for molecular information products;
- physicians need for molecular information products and any perceived advantage of our products over those of our competitors, including the ability of our molecular information platform to help physicians treat their patients cancers, our first mover advantage in providing comprehensive molecular information products on a commercial scale or the sustainability of our competitive advantages;
- our ability to generate revenue from sales of products enabled by our molecular information platform to physicians in clinical practice and our biopharmaceutical partners, including our ability to increase adoption of FoundationOne and FoundationOne Heme and expand existing or develop new relationships with biopharmaceutical partners;
- our ability to increase the commercial success of FoundationOne and FoundationOne Heme;
- our plans or ability to obtain reimbursement for FoundationOne and FoundationOne Heme, including expectations as to our ability or the amount of time it will take to achieve successful reimbursement from third-party payors, such as commercial insurance companies and health maintenance organizations, and government insurance programs, such as Medicare and Medicaid;
- the outcome or success of our clinical trials;
- the ability of our molecular information platform to enhance our biopharmaceutical partners ability to develop targeted oncology therapies;
- our ability to comprehensively assess cancer tissue simultaneously for all known genomic alterations across all known cancer-related genes, including our ability to update our molecular information platform to interrogate new cancer genes and incorporate new targeted oncology

therapies and clinical trials;

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

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

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

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

our plans and ability to develop and commercialize new products and improvements to our existing products;

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

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

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

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

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

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

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

- other risks and uncertainties, including those described in Part I, Item 1A, Risk Factors in our Annual Report on Form 10-K for the year ended December 31, 2013 and in Part II, Item 1A, Risk Factors in this Quarterly Report.

Any forward-looking statements in this Quarterly Report on Form 10-Q reflect our current views with respect to future events or to our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under Part I, Item 1A, Risk Factors in our Annual Report on Form 10-K for the year ended December 31, 2013 and under Part II, Item 1A, Risk Factors in this Quarterly Report. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

Unless the context requires otherwise, references in this Quarterly Report to we, us 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.

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FOUNDATION MEDICINE, INC.

REPORT ON FORM 10-Q

For the Quarterly Period Ended June 30, 2014

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FOUNDATION MEDICINE, INC.

Condensed Consolidated Balance Sheets

(unaudited)

(In thousands, except share and per share data)

	June 30, 2014	December 31, 2013
Assets		
Current assets:		
Cash and cash equivalents	$ 97,054	$ 124,293
Accounts receivable	6,067	6,262
Inventory	2,593	1,763
Prepaid expenses and other current assets	1,191	992
Total current assets	106,905	133,310
Property and equipment, net	21,696	22,104
Restricted cash	1,725	1,725
Other assets	321	129
Total assets	$ 130,647	$ 157,268
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable	$ 5,491	$ 7,007
Accrued expenses and other current liabilities	4,747	5,168
Deferred revenue	693	918
Current portion of deferred rent	1,178	1,167
Current portion of notes payable	576	1,499
Total current liabilities	12,685	15,759
Deferred rent, net of current portion	9,592	9,710
Deferred revenue, net of current portion	429	
Restricted stock liability	19	88
Commitments and contingencies (Note 11)		
Stockholders equity:		
Preferred Stock, $0.0001 par value, 5,000,000 shares authorized; no shares issued and outstanding		
Common stock, $0.0001 par value, 150,000,000 shares authorized; 27,971,814 and 27,630,781 shares issued and outstanding at June 30, 2014 and December 31, 2013, respectively	3	3
Additional paid-in capital	223,627	221,471
Accumulated deficit	(115,708)	(89,763)

Total stockholders equity	107,922	131,711
Total liabilities and stockholders equity	$ 130,647	$ 157,268

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

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FOUNDATION MEDICINE, INC.

Condensed Consolidated Statements of Operations and Comprehensive Loss

(unaudited)

(In thousands, except share and per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
Revenue	$ 14,496	$ 5,920	$ 25,951	$ 11,120
Costs and expenses:				
Cost of revenue	6,619	2,219	11,910	4,597
Selling and marketing	7,170	2,875	12,860	4,686
General and administrative	5,825	4,755	11,525	7,905
Research and development	8,645	6,097	15,560	11,079
Total costs and expenses	28,259	15,946	51,855	28,267
Loss from operations	(13,763)	(10,026)	(25,904)	(17,147)
Other income (expense):				
Interest expense, net	(16)	(65)	(41)	(141)
Other expense, net		(96)		(102)
Total other expense, net	(16)	(161)	(41)	(243)
Net loss	$ (13,779)	$ (10,187)	$ (25,945)	$ (17,390)
Accretion of redeemable convertible preferred stock		(42)		(92)
Net loss applicable to common stockholders	$ (13,779)	$ (10,229)	$ (25,945)	$ (17,482)
Net loss per common share applicable to common stockholders, basic and diluted	$ (0.49)	$ (3.34)	$ (0.93)	$ (5.92)
Weighted-average common shares outstanding, basic and diluted	27,876,931	3,065,877	27,804,914	2,950,996
Comprehensive loss	$ (13,779)	$ (10,187)	$ (25,945)	$ (17,390)

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

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FOUNDATION MEDICINE, INC.

Condensed Consolidated Statements of Cash Flows

(unaudited)

(In thousands)

	Six Months Ended June 30,	
	2014	**2013**
Operating activities		
Net loss	$ (25,945)	$ (17,390)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	4,003	2,073
Change in fair value of warrant liability		103
Stock-based compensation	1,856	1,995
Non-cash interest expense	11	35
Common stock issued in exchange for services		4
Changes in operating assets and liabilities:		
Accounts receivable	194	(1,919)
Inventory	(830)	78
Prepaid expenses and other current assets	(156)	(454)
Other assets	(192)	4
Accounts payable	(2,077)	400
Accrued expenses	(618)	67
Deferred rent	(107)	756
Deferred revenue	204	538
Net cash used in operating activities	(23,657)	(13,710)
Investing activities		
Purchases of property and equipment	(2,969)	(1,298)
Increase in restricted cash		(1,725)
Net cash used in investing activities	(2,969)	(3,023)
Financing activities		
Proceeds from issuance of restricted stock and stock option exercises	229	(4)
Issuance costs related to Series B Preferred Stock		(10)
Issuance costs related to the planned issuance of common stock		(1,292)
Payments of notes payable	(842)	(834)
Net cash used in financing activities	(613)	(2,140)
Net decrease in cash and cash equivalents	(27,239)	(18,873)
Cash and cash equivalents at beginning of period	124,293	54,838
Cash and cash equivalents at end of period	$ 97,054	$ 35,965

Supplemental disclosure of cash flow information		
Cash paid for interest	$ 123	$ 103
Supplemental disclosure of non-cash investing and financing activities		
Accretion of convertible preferred stock to redemption value	$	$ 92
Acquisition of property and equipment included in accounts payable and accrued expenses	$ 627	$ 100

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

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FOUNDATION MEDICINE, INC.

Notes to Condensed Consolidated Financial Statements

(unaudited)

1. Nature of Business and Basis of Presentation

Foundation Medicine, Inc. and its subsidiary (collectively, the Company) is a commercial-stage company focused on leading a transformation in cancer care, where each patient s treatment is informed by a deep understanding of the molecular changes that contribute to their disease. The Company derives revenue from selling both clinical and information products enabled by its molecular information platform to physicians and biopharmaceutical companies.

The company s clinical assays, FoundationOne for solid tumors and FoundationOne Heme for hematologic malignancies, sarcomas and pediatric cancers, provide a fully informative genomic profile to identify the molecular alterations in a patient s cancer and match them with relevant targeted therapies and clinical trials. Foundation Medicine s molecular information platform aims to improve day-to-day care for patients by serving the needs of clinicians, academic researchers and drug developers to help advance the science of molecular medicine in cancer, enabling more efficient and effective development of targeted therapies for cancer care.

The accompanying condensed consolidated financial statements are unaudited. In the opinion of management, the unaudited condensed consolidated financial statements contain all adjustments considered normal and recurring and necessary for their fair statement. Interim results are not necessarily indicative of results to be expected for the year. These interim financial statements have been prepared in accordance with accounting principles generally accepted in the United States for interim financial information and in accordance with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, these condensed consolidated financial statements do not include all of the information and footnotes necessary for a complete presentation of financial position, results of operations, comprehensive loss and cash flows. Our audited consolidated financial statements for the year ended December 31, 2013 included information and footnotes necessary for such presentation and were included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission (SEC), on March 7, 2014. These unaudited condensed consolidated financial statements should be read in conjunction with our audited consolidated financial statements and notes thereto for the year ended December 31, 2013.

2. Summary of Significant Accounting Policies

Summary of accounting policies

There have been no material changes to the significant accounting policies previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2013.

Recent Accounting Pronouncements

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

In May 2014, the FASB issued Accounting Standards Update No. 2014-09, Revenue from Contracts with Customers (ASU 2014-09), which supersedes the revenue recognition requirements in Accounting Standards Codification Topic 605, Revenue Recognition and most industry-specific guidance. The new standard requires that an entity recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. The update also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. ASU 2014-09 is effective for fiscal years, and interim periods within those years, beginning after December 15, 2016 and should be applied retrospectively to each prior reporting period presented or retrospectively with the cumulative effect of initially applying this update recognized at the date of initial application. The Company has not determined yet the potential effects of the adoption of this standard on its consolidated financial position, results of operations or cash flows.

3. Cash and Cash Equivalents

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

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4. 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 $1,725,000 as of June 30, 2014 and December 31, 2013.

5. Inventory

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

	June 30, 2014	December 31, 2013
Raw materials	$ 2,018	$ 1,479
Work-in-process	575	284
	$ 2,593	$ 1,763

6. Property and Equipment

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

	June 30, 2014	December 31, 2013
Lab equipment	$ 13,996	$ 12,193
Computer equipment	5,855	4,772
Software	927	542
Furniture and office equipment	1,641	1,610
Leasehold improvements	12,506	12,213
	34,925	31,330
Less accumulated depreciation and amortization	(13,229)	(9,226)
	$ 21,696	$ 22,104

Depreciation and amortization expense for the three and six months ended June 30, 2014 was $2,088,000 and $4,003,000, respectively, compared to $1,043,000 and $2,073,000 for the three and six months ended June 30, 2013, respectively. The Company classifies capitalized internal use software in Lab Equipment, Computer Equipment and Software based on its intended use.

7. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following (in thousands):

	June 30, 2014	December 31, 2013
Payroll and employee-related costs	$ 3,183	$ 3,258
Professional services	763	1,127
Property and equipment purchases	13	122
Other	788	661
	$ 4,747	$ 5,168

8. Net Loss per Common Share

Basic net loss per share is calculated by dividing net loss applicable to common stockholders by the weighted-average shares outstanding during the period, without consideration for common stock equivalents. Diluted net loss per share is calculated by adjusting the weighted-average shares outstanding for the dilutive effect of common stock equivalents outstanding for the period, determined using the treasury-stock method and the if-converted method. For purposes of the diluted net loss per share calculation, 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.

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Upon closing of the Company s initial public offering 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.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
Denominator:				
Series A Preferred Stock		10,937,500		10,937,500
Series B Preferred Stock		6,190,526		6,190,526
Warrant		50,000		50,000
Outstanding stock options	2,712,402	2,172,892	2,712,402	2,172,892
Unvested restricted stock	414,567	962,203	414,567	962,203
Total	3,126,969	20,313,121	3,126,969	20,313,121

9. Fair Value Measurements

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

Level 1 inputs	Quoted prices in active markets for identical assets or liabilities
Level 2 inputs	Inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly
Level 3 inputs	Unobservable inputs that reflect the company s own assumptions about the assumptions market participants would use in pricing the asset or liability

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

The Company s financial instruments consist of cash and cash equivalents, accounts receivable, accounts payable, accrued liabilities and notes payable. The carrying amount of cash and cash equivalents, accounts receivable, accounts payable, accrued liabilities and notes payable approximate their fair values because of the short-term nature of the instruments or, in the case of the notes payable, because the interest rates the Company believes it could obtain for similar borrowings is similar to its existing interest rates.

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The following tables present information about our assets and liabilities that are measured at fair value on a recurring basis as of June 30, 2014 and December 31, 2013, and indicate the fair value hierarchy of the valuation techniques utilized to determine such fair value (in thousands):

	Fair Value Measurement at June 30, 2014			
	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Assets:				
Cash held in money market funds	$ 96,858	$	$	$ 96,858
Total assets	$ 96,858	$	$	$ 96,858

	Fair Value Measurement at December 31, 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	$ 125,001	$	$	$ 125,001
Total	$ 125,001	$	$	$ 125,001

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 six months ended June 30, 2014 and 2013.

10. Stockholders Equity

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

	June 30, 2014	December 31, 2013
Unvested restricted stock	414,567	517,237
Common stock options	2,712,402	2,314,284

Shares available for issuance under the 2013 Stock Option and Incentive Plan	1,629,742	1,139,244
Shares available for issuance under the 2013 Employee Stock Purchase Plan	788,503	788,503
	5,545,214	4,759,268

In November 2009, the Company issued 2,125,000 shares of common stock to the founders of the Company for consideration equal to the par value per share, the then estimated fair value of the common stock. The founders entered into restricted stock agreements whereby the shares of common stock issued were subject to vesting and became fully vested in 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. The following table shows a roll forward of restricted stock activity outside of the 2010 Stock Plan and the 2013 Stock Plan, as defined and discussed below:

	Number of Shares
Unvested at December 31, 2013	2,606
Granted	
Vested	(2,606)
Unvested at June 30, 2014	

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2010 and 2013 Stock Incentive Plans

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

In 2013, the Company adopted the Foundation Medicine, Inc. 2013 Stock Option and Incentive Plan (the 2013 Stock Plan) under which it may grant restricted and unrestricted stock, restricted stock units, ISOs, non-statutory stock options, stock appreciation rights, cash-based awards, performance share awards and dividend equivalent rights to eligible employees, officers, directors and consultants to purchase up to 1,355,171 shares of common stock. In connection with the establishment of the 2013 Stock Plan, the Company terminated the 2010 Stock Plan and the 512,568 shares available for grant under the 2010 Stock Plan were included in the number of shares authorized under the 2013 Stock Plan. Shares forfeited or repurchased from the 2010 Stock Plan are returned to the 2013 Stock Plan for future issuance. On January 1, 2014, the number of shares reserved and available for issuance under the 2013 Stock Plan increased by 1,125,921 shares of common stock pursuant to a provision in the 2013 Stock Plan that provides that the number of shares reserved and available for issuance will automatically increase each January 1, beginning on January 1, 2014, by 4% of the number of shares of our common stock issued and outstanding on the immediately preceding December 31 or such lesser number as determined by the compensation committee of the Board of Directors.

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

Restricted Stock

The 2010 Stock Plan and the 2013 Stock Plan allow for granting of restricted stock awards. For restricted stock granted to employees, the intrinsic value on the date of grant is recognized as stock-based compensation expense ratably over the period in which the restrictions lapse. For restricted stock granted to non-employees the intrinsic value is remeasured at each vesting date and at the end of the reporting period. The following table shows a roll forward of restricted stock activity pursuant to the 2010 Stock Plan and the 2013 Stock Plan:

	Number of Shares
Unvested at December 31, 2013	72,198
Granted	114,730
Vested	(25,629)
Cancelled	(535)
Unvested at June 30, 2014 (1)	160,764

(1) Excludes 253,803 shares of unvested restricted stock remaining from the early exercise of stock options.

Stock Options

A summary of stock option activity under the 2010 Stock Plan and 2013 Stock Plan for the six months ended June 30, 2014 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, 2013	2,314,284	$ 4.78	8.8	$ 44,236
Granted	564,874	27.98		
Exercised	(123,110)	2.21		
Cancelled	(43,646)	11.05		
Outstanding as of June 30, 2014	2,712,402	$ 9.62	8.6	$ 48,230
Exercisable as of June 30, 2014	776,434	$ 3.38	8.1	$ 18,333

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Certain stock options contain provisions allowing for the early exercise into shares subject to repurchase. At June 30, 2014, 253,803 shares, which were early exercised, remain subject to repurchase by the Company.

The weighted-average fair value of options granted for the six months ended June 30, 2014 was $17.13 per share.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
Cost of revenue	$ 97	$ 5	$ 158	$ 17
Sales and marketing	262	27	406	45
General and administrative	392	1,198	662	1,816
Research and development	409	79	630	117
Total	$ 1,160	$ 1,309	$ 1,856	$ 1,995

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 $988,000 and $1,684,000 during the three and six months ended June 30, 2014, respectively and $193,000 and $304,000 during the three and six months ended June 30, 2013, respectively. The Company recorded total stock-based compensation expense for restricted stock of $172,000 during the three and six months ended June 30, 2014, respectively, and $1,116,000 and $1,691,000 during the three and six months ended June 30, 2013, respectively.

As of June 30, 2014, unrecognized compensation cost of approximately $14,625,000 related to non-vested stock options and restricted stock awards is expected to be recognized over weighted-average periods of 3.4 years.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
Expected volatility	65.4%	67.0%	65.4%	67.1%
Risk-free interest rate	2.20%	1.33%	2.20%	1.35%
Expected option term (in years)	6.25	6.25	6.25	6.25
Expected dividend yield	0.0%	0.0%	0.0%	0.0%

11. Commitments and Contingencies

150 Second Street

In 2013, the Company signed two 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 initially had 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 10.5 months of the lease, having an initial value of $3,300,000. The landlord also agreed to fund up to $9,239,000 in tenant improvements. The Company recorded the tenant improvements as assets and deferred rent on the consolidated balance sheet. Deferred rent is amortized as a reduction in rent expense over the term of the lease agreement. The Company recognizes rent expense on a straight-line basis over the expected lease term. In connection with the Company s termination of the lease at One Kendall Square, the rent abatement was reduced to approximately $1,841,000 and the expected lease term was reduced to 7.5 years. The

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Company began to record rent expense in April 2013 upon gaining access to and control of the 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 June 30, 2014 and December 31, 2013. The Company recorded rent expense of $923,000 and $1,737,000 in the three and six months ended June 30, 2014, respectively, and $556,000 in the three and six months ended June 30, 2013, respectively, associated with this lease.

On June 30, 2014, the Company executed a Second Amendment to the lease amending the lease signed in March 2013, resulting in 8,164 square feet of additional space commencing in November 2014. The Company will begin recording rent expense upon gaining access to and control of the space. The landlord has also agreed to fund up to $1,020,500 in tenant improvements.

Legal Matters

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

12. Related Party Transactions

Since inception, the Company has received consulting and management services from an investor. The Company paid this investor approximately $0 for these services during the three and six months ended June 30, 2014, respectively, and $26,767 and $117,767 for these services during the three and six months ended June 30, 2013, respectively. Of these amounts, $0 and $7,000 of amounts due to the investor were included in accounts payable and accrued expenses at June 30, 2014 and December 31, 2013, respectively.

The Company recognized revenue of $243,000 and $520,000 during the three and six months ended June 30, 2014, respectively, and $162,000 and $526,000 during the three and six months ended June 30, 2013, respectively, from an arrangement with an investor executed in the year ended December 31, 2012. Of these amounts, $355,000 and $0 were included in accounts receivable at June 30, 2014 and December 31, 2013, respectively.

The Company recognized revenue of $98,500 and $130,500 during the three and six months ended June 30, 2014, respectively, and $0 during the three and six months ended 2013, from an arrangement with an entity affiliated with a member of the Company s Board of Directors executed in the year ended December 31, 2013. Of these amounts, $130,500 and $0 were included in accounts receivable at June 30, 2014 and December 31, 2013, respectively.

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

The following discussion of our financial condition and results of operations should be read in conjunction with our condensed consolidated financial statements and notes thereto appearing elsewhere in this Quarterly Report on Form 10-Q and the audited consolidated financial statements and notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2013. This discussion contains forward-looking statements that involve significant risks and uncertainties. As a result of many factors, such as those set forth under Risk Factors in Part I, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2013 and in Part II, Item 1A of this Quarterly Report, our actual results may differ materially from those anticipated in these forward-looking statements.

Overview

We are a commercial-stage company focused on leading a transformation in cancer care, where each patient s treatment is informed by a deep understanding of the molecular changes that contribute to their disease. The Company derives revenue from selling both clinical and information products enabled by its molecular information platform to physicians and biopharmaceutical companies.

The company s clinical assays, FoundationOne for solid tumors and FoundationOne Heme for hematologic malignancies, sarcomas and pediatric cancers, provide a fully informative genomic profile to identify the molecular alterations in a patient s cancer and match them with relevant targeted therapies and clinical trials. Foundation Medicine s molecular information platform aims to improve day-to-day care for patients by serving the needs of clinicians, academic researchers and drug developers to help advance the science of molecular medicine in cancer, enabling more efficient and effective development of targeted therapies for cancer care.

Our first clinical products, FoundationOne, for solid tumors, and FoundationOne Heme, for blood-based cancers, or hematologic malignancies, including leukemia, lymphoma and myeloma, as well as many sarcomas and pediatric cancers, are, to our knowledge, the only commercially available comprehensive molecular information products designed for use in the routine clinical 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 launched FoundationOne Heme in December 2013. 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 more than 18 biopharmaceutical partners to

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enhance the development of targeted oncology therapies. To accelerate our growth and enhance our competitive advantage, we are expanding 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 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, and the development of new products such as FoundationOne Heme. We have incurred significant losses since our inception, and as of June 30, 2014 our accumulated deficit was $115.7 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 products.

Financial Operations Overview

Revenue

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

For many physician orders within the United States, the payment we ultimately receive depends upon the rate of reimbursement from commercial third-party payors and government payors. We are not currently a participating provider with any commercial third-party payors and therefore do not have specific coverage decisions for our products 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. At the end of 2013, we began the process of submitting claims for our tests to Medicare. We may also negotiate rates with patients, if the patient is responsible for payment. Our efforts in obtaining reimbursement based on individual claims, including pursuing appeals or reconsiderations of claim denials, take a substantial amount of time, and bills may not be paid for many months or at all. Furthermore, if a third-party payor denies coverage after final appeal, payment may not be received at all.

We currently recognize revenue on a cash basis from commercial third-party payors and from patients who make co-payments, pay deductibles, or pay other amounts that we have been unable to collect from their third-party payors because the payment is not fixed or determinable and collectability is not reasonably assured, as a result of the fact that we do not have coverage decisions in place and have a limited history of collecting claims. We expect to use judgment in assessing whether the fee is fixed or determinable and whether collectability is reasonably assured as we

continue to gain payment experience with third-party payors and patients. Costs associated with performing tests are recorded as tests are processed. These costs are recorded regardless of when or whether revenue is recognized with respect to those tests. Because we currently recognize revenue on a cash basis from commercial third-party payors, the costs of those FoundationOne and FoundationOne Heme tests are recognized in advance of any associated revenues. Due to the increasing period-to-period test volumes that we have observed to date, our revenue from these payors is lower and our net loss is higher than if we were recognizing revenue from these payors on an accrual basis in the period during which the work was performed and costs were incurred.

There are currently no national coverage decisions that determine whether and how our tests are covered by Medicare. In the absence of national coverage decisions, local Medicare contractors that administer the Medicare program in various regions have some discretion in determining coverage and therefore payment for tests. Our local Medicare contractor, who would process our claims on behalf of Medicare, initially requested that we not submit claims for FoundationOne tests provided to Medicare patients while the contractor assessed the appropriate coverage and payment for FoundationOne as a whole. Based on the volume of our Medicare claims, we began the process of submitting claims to Medicare in November 2013, but we have not generated any revenue from Medicare for our FoundationOne or FoundationOne Heme tests to date. As a result our net loss is higher than if we were recognizing revenue from the sale of our products for patients covered by Medicare. FoundationOne and FoundationOne Heme tests for patients covered by Medicare represented approximately 32% and 29% of total tests reported to physicians in the United States during the six months ended June 30, 2014 and 2013, respectively.

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We are seeking a positive coverage determination from our Medicare contractor, which, if obtained, will establish a standard for the reimbursement for our Medicare claims. At the end of 2013, we commenced the process of submitting claims to Medicare for FoundationOne tests provided to Medicare patients, and subsequently during the first quarter of 2014 we commenced the process of submitting claims to Medicare for FoundationOne Heme tests provided to Medicare patients. As of June 30, 2014 we have not been reimbursed by our Medicare contractor for the claims that we have submitted, and we are in the process of appealing these unpaid claims. In the future, our Medicare contractor may issue a negative coverage determination for FoundationOne and/or FoundationOne Heme that would apply to future claims or may defer processing a claim pending a coverage or payment determination. If a claim is paid by our Medicare contractor, either upon acceptance of the claim or following a successful appeal of a denied claim, we will generate revenue from Medicare for our testing.

We expect that the current lack of coverage decisions and the uncertainty of reimbursement on a case-by-case basis may continue to negatively impact our revenue and earnings, particularly as FoundationOne and FoundationOne Heme test volumes increase period-to-period. Following our achievement of a coverage decision from a commercial third-party payor or government payor or once we have a sufficient history of claims collections with any such payor that we conclude the fee for FoundationOne and FoundationOne Heme tests for individuals insured by such payor is sufficiently fixed or determinable and collectability is reasonably assured, we will begin to recognize revenue from such payor on an accrual basis. As of June 30, 2014, we had cash and cash equivalents of approximately $97.1 million. We do not believe that the adverse impact 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 the longer term, and our available cash balances and cash flow from claims for reimbursement on behalf of each patient on a case-by-case basis and other operations are insufficient to satisfy our liquidity requirements, we may require additional capital beyond our currently anticipated amounts. Additional capital may not be available on reasonable terms, or at all.

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

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

Revenue from our biopharmaceutical customers 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.

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

Selling and Marketing Expenses

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

During both the three months ended June 30, 2014 and 2013, our selling and marketing expenses represented approximately 49% of our total revenue, and during the six months ended June 30, 2014 and 2013, selling and marketing expenses represented approximately 50% and 42% of our total revenue, respectively. We expect our selling 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, FoundationOne Heme, and any future products we may develop. In the short-term, our selling and marketing costs may also increase as a percentage of total revenues as we make these investments.

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 and FoundationOne Heme, 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.

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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 six months ended June 30, 2014 and 2013, interest income was not material.

Results of Operations

Comparison of Three Months Ended June 30, 2014 and 2013

	Three Months Ended June 30,		Change	
	2014	2013	$	%
	(in thousands, except percentages)			
Statement of Operations Data:				
Revenue	$ 14,496	$ 5,920	$ 8,576	145%
Costs and expenses				
Cost of revenue	6,619	2,219	4,400	198%
Selling and marketing	7,170	2,875	4,295	149%
General and administrative	5,825	4,755	1,070	23%
Research and development	8,645	6,097	2,548	42%
Total costs and expenses	28,259	15,946	12,313	77%
Loss from operations	(13,763)	(10,026)	(3,737)	(37%)
Interest expense, net	(16)	(65)	49	75%
Other (expense) income, net		(96)	96	N/A
Net loss	$ (13,779)	$ (10,187)	$ (3,592)	(35%)

Revenue

Total revenue increased to $14.5 million for the three months ended June 30, 2014 from $5.9 million during the three months ended June 30, 2013. Revenue from FoundationOne and FoundationOne Heme tests reported to our ordering physicians increased to $9.4 million for the three months ended June 30, 2014 from $2.8 million for the three months ended June 30, 2013. The increase was driven by our growing test volumes and expanding commercialization efforts. Revenue from our biopharmaceutical customers increased to $5.1 million for the three months ended June 30, 2014 from $3.1 million for the three months ended June 30, 2013, largely driven by increased activity among our new and existing biopharmaceutical customers.

During the three months ended June 30, 2014, we reported 5,908 tests to ordering physicians, including 948 FoundationOne Heme tests, as compared to 1,626 FoundationOne tests reported during the three months ended June 30, 2013. We also reported 1,261 tests to our biopharmaceutical customers during the three months ended June 30, 2014, as compared to 623 tests during the three months ended June 30, 2013.

The average revenue per test for clinical use that met our revenue recognition criteria during the three months ended June 30, 2014 was approximately $3,600. This average revenue per test does not include 1,594 FoundationOne and FoundationOne Heme tests reported during the period for patients covered by Medicare, 62 tests that were reported and not billed, and 2,546 tests that were reported and billed to commercial third party payors during the period but were not paid during the period. This average revenue per test includes 907 tests reported in prior periods for which revenue was recognized during the three months ended June 30, 2014.

The average revenue per test for clinical use that met our revenue recognition criteria during the three months ended June 30, 2013 was approximately $3,700. This average revenue per test does not include 370 FoundationOne tests reported during the period for patients covered by Medicare and for which claims were not submitted, 26 tests that were reported and not billed, and 732 tests that were reported and billed to commercial third party payors during the period but were not paid during the period. This average revenue per test includes 267 tests reported in prior periods for which revenue was recognized during the three months ended June 30, 2013.

Our average revenue per 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 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

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

The cumulative amount of FoundationOne and FoundationOne Heme tests that have been billed to commercial third-party payors and reported for patients covered by Medicare but for which we have not recognized revenue was 6,153 and 5,228, respectively, as of June 30, 2014. If commercial third-party payors or government payors agree to pay us for these tests in the future, we will recognize revenue for such tests in the period in which our revenue recognition criteria are met. Any revenue that we receive in respect of these previously reported tests will favorably impact our liquidity and results of operations in future periods.

For our biopharmaceutical customer revenue that was based on a negotiated price per test, the average revenue per test was approximately $3,200 and $3,900 for the three months ended June 30, 2014 and 2013, respectively. The decrease in average revenue per test for our biopharmaceutical customers was largely driven by increased test volume for a single contract that contained a volume discount. We expect this average revenue per test for biopharmaceutical customers to remain fairly consistent with prior periods over time. Approximately $2.8 million and $2.2 million of our biopharmaceutical revenue for the three months ended June 30, 2014 and 2013, respectively, represented payments under contracts with multiple element arrangements that were not negotiated on a price per test basis.

Cost of Revenue

Cost of revenue increased to $6.6 million for the three months ended June 30, 2014 from $2.2 million for the three months ended June 30, 2013. This increase was driven by increasing test volumes from our ordering physicians and biopharmaceutical customers. The average cost per test does not differ materially by customer. Additional volume led to higher reagent and consumable costs, additional laboratory personnel-related costs, and higher depreciation expense related to new equipment purchases. During the three months ended June 30, 2014 and 2013, our cost of revenue represented approximately 46% and 37% of our total revenue, respectively. We expect to make additional investments in personnel, infrastructure, and systems to scale our laboratory operations to meet future anticipated demand.

Selling and Marketing Expenses

Selling and marketing expenses increased to $7.2 million for the three months ended June 30, 2014 from $2.9 million for the three months ended June 30, 2013. The increase was primarily due to an increase of $3.4 million in personnel-related costs related to 53 new employees in our sales, marketing, client service, and reimbursement departments, a $0.6 million increase in travel-related costs, a $0.2 million increase in consulting expense, and a $0.1 million increase in various other expenses.

General and Administrative Expenses

General and administrative expenses increased to $5.8 million for the three months ended June 30, 2014 from $4.8 million for the three months ended June 30, 2013. The increase was primarily due to a $0.6 million combined increase in legal, consulting, audit, and billing fees, a $0.6 million increase in rent and other facilities costs, and a $0.6 million increase in personnel-related costs to support and expand our legal, finance, and human resources infrastructure, offset by a $0.8 million decrease in stock-based compensation expense primarily as a result of restricted stock that was fully vested in 2013.

Research and Development Expenses

Research and development expenses increased to $8.6 million for the three months ended June 30, 2014 from $6.1 million for the three months ended June 30, 2013. The increase was primarily due to a $2.3 million increase in employee and contractor-related expenses, a $0.2 million increase in technology-related investments, and a $0.2 million increase in research-related lab supplies and materials, offset by a $0.2 million decrease in clinical trials expense.

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Interest Expense, Net

Interest expense, net was immaterial each of the three months ended June 30, 2014 and 2013.

Other Expense, Net

Other expense, net was immaterial each of the three months ended June 30, 2014 and 2013.

Comparison of Six Months Ended June 30, 2014 and 2013

	Six Months Ended June 30,		Change	
	2014	2013	$	%
	(in thousands, except percentages)			
Statement of Operations Data:				
Revenue	$ 25,951	$ 11,120	$ 14,831	133%
Costs and expenses				
Cost of revenue	11,910	4,597	7,313	159%
Selling and marketing	12,860	4,686	8,174	174%
General and administrative	11,525	7,905	3,620	46%
Research and development	15,560	11,079	4,481	40%
Total costs and expenses	51,855	28,267	23,588	83%
Loss from operations	(25,904)	(17,147)	(8,757)	(51%)
Interest expense, net	(41)	(141)	100	71%
Other (expense) income, net		(102)	102	N/A
Net loss	$ (25,945)	$ (17,390)	$ (8,555)	(49%)

Revenue

Total revenue increased to $26.0 million for the six months ended June 30, 2014 from $11.1 million during the six months ended June 30, 2013. Revenue from FoundationOne and FoundationOne Heme tests reported to our ordering physicians increased to $16.5 million for the six months ended June 30, 2014 from $5.1 million for the six months ended June 30, 2013. The increase was driven by our growing test volumes and expanding commercialization efforts. The increase in revenue from our biopharmaceutical customers from $6.0 million to $9.4 million for the six months ended June 30, 2013 and 2014, respectively, resulted from increased activity among our new and existing biopharmaceutical customers.

During the six months ended June 30, 2014, we reported 10,610 tests to ordering physicians, including 1,663 FoundationOne Heme tests, as compared to 2,766 FoundationOne tests reported during the six months ended June 30, 2013. We also reported 2,112 and 1,218 tests to our biopharmaceutical customers during the six months ended June 30, 2014 and 2013, respectively.

The average revenue per test for clinical use that met our revenue recognition criteria during the six months ended June 30, 2014 was approximately $3,500. This average revenue per test does not include 2,747 FoundationOne and FoundationOne Heme tests reported during the period for patients covered by Medicare, 181 tests that were reported and not billed, and 4,246 tests that were reported and billed to commercial third party payors during the period but were not paid during the period. This average revenue per test includes 1,293 tests reported in prior periods for which revenue was recognized during the six months ended June 30, 2014.

The average revenue per FoundationOne test for clinical use that met our revenue recognition criteria during the six months ended June 30, 2013 was approximately $3,700. This average revenue per test does not include 611 FoundationOne tests reported during the period for patients covered by Medicare and for which claims were not submitted, 55 tests that were reported and not billed, and 1,117 tests that were reported and billed to commercial third party payors during the period but were not paid during the period. This average revenue per test includes 404 tests reported in prior periods for which revenue was recognized during the six months ended June 30, 2013.

Our average revenue per 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 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

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

The cumulative amount of FoundationOne and FoundationOne Heme tests that have been billed to commercial third-party payors and reported for patients covered by Medicare but for which we have not recognized revenue was 6,153 and 5,228, respectively, as of June 30, 2014. If commercial third-party payors or government payors agree to pay us for these tests in the future, we will recognize revenue for such tests in the period in which our revenue recognition criteria are met. Any revenue that we receive in respect of these previously reported tests will favorably impact our liquidity and results of operations in future periods.

For our biopharmaceutical customer revenue that was based on a negotiated price per test, the average revenue per test was approximately $3,400 and $3,800 for the six months ended June 30, 2014 and 2013, respectively. The decrease in average revenue per test for our biopharmaceutical customers was largely driven by increased test volume for a single contract that contained a large volume discount. We expect this average revenue per test for biopharmaceutical customers to remain fairly consistent with prior periods over time. Approximately $5.7 million and $4.0 million of our biopharmaceutical revenue for the six months ended June 30, 2014 and 2013, respectively, represented payments under contracts with multiple element arrangements that were not negotiated on a price per test basis.

Cost of Revenue

Cost of revenue increased to $11.9 million for the six months ended June 30, 2014 from $4.6 million for the six months ended June 30, 2013. This increase was driven by increasing test volumes from our ordering physicians and biopharmaceutical customers. The average cost per test does not differ materially by customer. Additional volume led to higher reagent and consumable costs, additional laboratory personnel-related costs, and higher depreciation expense related to new equipment purchases. During the six months ended June 30, 2014 and 2013, our cost of revenue represented approximately 46% and 41% of our total revenue, respectively. We expect to make additional investments in personnel, infrastructure, and systems to scale our laboratory operations to meet future anticipated demand.

Sales and Marketing Expenses

Sales and marketing expenses increased to $12.9 million for the six months ended June 30, 2014 from $4.7 million for the six months ended June 30, 2013. The increase was primarily due to an increase of $6.2 million in personnel-related costs related to 53 new employees in our sales, marketing, client service, and reimbursement departments, a $1.0 million increase in travel-related costs, a $0.4 million increase in consulting expense, and a $0.6 million increase in various other expenses.

General and Administrative Expenses

General and administrative expenses increased to $11.5 million for the six months ended June 30, 2014 from $7.9 million for the six months ended June 30, 2013. The increase was primarily due to a $2.1 million combined increase in legal, consulting, audit, and billing fees, a $1.2 million increase in rent and other facilities costs, and a $1.4 million increase in personnel-related costs to support and expand our legal, finance, and human resources infrastructure, offset by a $1.1 million decrease in stock-based compensation expense primarily as a result of restricted stock that was fully vested in 2013.

Research and Development Expenses

Research and development expenses increased to $15.6 million for the six months ended June 30, 2014 from $11.1 million for the six months ended June 30, 2013. The increase was primarily due to a $3.5 million increase in employee and contractor-related expenses, a $0.2 million increase in rent and other facilities costs, a $0.7 million increase in technology investments related to data management, FoundationOne report design and functionality, and customer interface development, and a $0.1 million increase in research-related lab supplies and materials.

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Interest Expense, Net

Interest expense, net was immaterial each of the six months ended June 30, 2014 and 2013.

Other Expense, Net

Other expense, net was immaterial each of the six months ended June 30, 2014 and 2013.

Liquidity and Capital Resources

We have incurred losses and negative cash flows from operations since our inception in November 2009, and as of June 30, 2014, we had an accumulated deficit of $115.7 million.

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 or FoundationOne Heme from any commercial third-party payors 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, FoundationOne and FoundationOne Heme are not currently covered by Medicare, and we have not received payment on the claims we have submitted to Medicare. If commercial third-party payors or government payors agree to pay us for these tests in the future, we would recognize revenue for such tests in the period in which our revenue recognition criteria are met.

On September 30, 2013, we closed our initial public offering 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 our initial public offering of approximately $110.4 million after deducting underwriting discounts, commissions, and expenses payable by us.

As of June 30, 2014, we had cash and cash equivalents of approximately $97.1 million. Cash in excess of immediate requirements is invested in accordance with our investment policy, primarily with a view to liquidity and capital preservation. These excess funds are held in money market mutual funds consisting of U.S. government-backed securities.

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

Cash Flows

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

	Six Months Ended June 30,	
	2014	2013
	(in thousands)	

Net cash used in:		
Operating activities	$ (23,657)	$ (13,710)
Investing activities	(2,969)	(3,023)
Financing activities	(613)	(2,140)
Net decrease in cash and cash equivalents	$ (27,239)	$ (18,873)

Operating Activities

Net cash used in operating activities in all periods resulted primarily from our net losses adjusted for non-cash charges and changes in components of working capital. The net cash used in operating activities was $23.7 million for the six months ended June 30, 2014 compared to $13.7 million for the six months ended June 30, 2013. The increase in cash used in operating activities was driven primarily by an increase in net loss of $8.6 million, and a $3.1 million increase in cash utilized to support working capital requirements, partially offset by an increase in depreciation expense of $1.9 million between the respective periods.

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Investing Activities

Net cash used in investing activities for the six months ended June 30, 2014 was $3.0 million and consisted solely of purchases of property and equipment. Net cash used in investing activities for the six months ended June 30, 2013 was $3.0 million and consisted of an increase in restricted cash of $1.7 million related to our new laboratory and office facilities, and purchases of property and equipment of $1.3 million.

Financing Activities

Net cash used in financing activities for the six months ended June 30, 2014 was $0.6 million and consisted primarily of $0.8 million of loan principal payments, partially offset by $0.2 million of proceeds from the exercise of stock options. Net cash used in financing activities for the six months ended June 30, 2013 was $2.1 million comprised of loan principal payments totaling $0.8 million and $1.3 million in issuance costs related to the planned issuance of common stock in our initial public offering.

Operating Capital Requirements

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

Based on our current business plan, we believe our current cash and cash equivalents and anticipated cash flow from operations will be sufficient to meet our anticipated cash requirements over 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 selling and marketing activities and continue to invest in new product offerings. As sales of our products grow, we expect our accounts receivable balance to increase. Any increase in accounts payable and accrued expenses may not 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 our Annual Report on Form 10-K for the year ended December 31, 2013 and in Part II, Item 1A, Risk Factors in this Quarterly Report, we may seek to sell common or preferred equity or convertible debt securities, enter into an additional credit facility or another form of third-party funding, or seek other debt financing. The sale of equity and convertible debt securities may result in dilution to our stockholders and those securities may have rights senior to those of our common shares. If we raise additional funds through the issuance of preferred stock, convertible debt securities or other debt financing, these securities or other debt could contain covenants that would restrict our operations. Any other third-party funding arrangement could require us to relinquish valuable rights. We may require additional capital beyond our currently anticipated amounts. Additional capital may not be available on reasonable terms, or at all.

These estimates are forward-looking statements and involve risks and uncertainties and actual results could vary materially and negatively as a result of a number of factors, including the factors discussed in Part I, Item 1A, Risk Factors in our Annual Report on Form 10-K for the year ended December 31, 2013 and in Part II, Item 1A, Risk Factors in this Quarterly Report. We have based our estimates on assumptions that may prove to be wrong and we could utilize our available capital resources sooner than we currently expect. If we cannot expand our operations or otherwise capitalize on our business opportunities because we lack sufficient capital, our business, financial condition, and results of operations could be materially adversely affected.

Contractual Obligations and Commitments

The following summarizes our principal contractual obligations as of June 30, 2014 that have changed significantly since December 31, 2013 and the effects such obligations are expected to have on our liquidity and cash flow in future periods. Contractual obligations that were presented in our Annual Report on Form 10-K for the year ended December 31, 2013, but omitted below, represent those that have not changed significantly since that date.

	Total	2014	2015-2016	2017-2018	Thereafter
			(in thousands)		
Operating lease obligations [1] [2]	$ 29,024	$ 1,812	$ 8,481	$ 8,785	$ 9,946

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

(2) In April 2014, we leased 1,975 square feet for office space in Palo Alto, California under an operating lease that expires in May 2016.

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

There have been no material changes to our critical accounting policies from those described in Part II, Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations included in our Annual Report on Form 10-K for the year ended December 31, 2013.

Item 3. Quantitative and Qualitative Disclosures about Market Risks

There were no material changes during the quarter ended June 30, 2014 with respect to the information appearing in Part II, Item 7A. Quantitative and Qualitative Disclosures About Market Risk, included in our Annual Report on Form 10-K for the year ended December 31, 2013.

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. In designing and evaluating our disclosure controls and procedures, our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures as of the end of the period covered by this report. Based on

this evaluation, our principal executive officer and principal financial officer have concluded that, as of June 30, 2014, our disclosure controls and procedures were effective at the reasonable assurance level.

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

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Changes in Internal Control Over Financial Reporting

During the quarter ended June 30, 2014, 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.

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PART II OTHER INFORMATION

Item 1. Legal Proceedings

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

Item 1A. Risk Factors

The following information updates, and should be read in conjunction with, the factors discussed in Part I, Item 1A, Risk Factors in our Annual Report on Form 10-K for the year ended December 31, 2013, which could materially affect our business, financial condition or future results. The risks described in our Annual Report on Form 10-K, as updated in this Quarterly Report, are not the only risks facing our Company. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition or operating results.

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

In June 2014, we agreed to lease additional space at our corporate headquarters location. We intend to build a new laboratory in a portion of this additional space to support development of companion diagnostic tests. If we are delayed in building the new laboratory or if we never complete construction and validation, this could result in our inability to meet certain timelines for developing companion diagnostic tests for our partners, which could result in harm to our reputation.

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

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

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

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

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

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

As a result, there is significant uncertainty surrounding whether the use of products that incorporate new technology, such as FoundationOne and FoundationOne Heme, will be eligible for coverage by commercial third-party payors and government payors or, if eligible for coverage, what the reimbursement rates will be for those products. The fact that a diagnostic product has been approved for reimbursement in the past, for any particular indication or in any particular

jurisdiction, does not guarantee that such a diagnostic product will remain approved for reimbursement or that similar or additional diagnostic products will be approved in the future. 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 demonstrating improved outcomes.

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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, FoundationOne Heme, or future molecular information products we develop. Our strategy to achieve broad reimbursement coverage is focused on demonstrating the clinical utility and economic benefits of FoundationOne and FoundationOne Heme, including engagement with key members of the oncology community and increasing physician demand, but there is no assurance that we will succeed in any of these areas or that, even if we do succeed, we will receive favorable reimbursement decisions. If adequate third-party reimbursement is unavailable, we may not be able to maintain price levels sufficient to realize an appropriate return on investment in product development. Furthermore, if a commercial third-party payor or government payor denies coverage, it may be difficult for us to collect from the patient, and we may not be successful.

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

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

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

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

Under the risk-based approach described in the guidance documents, the FDA would rely upon its existing medical device classification system to evaluate the risk of LDTs. The FDA would require that laboratories providing LDTs, subject to certain limited exemptions, comply with notification or registration and listing requirements within six months after the guidance documents are finalized. The FDA s premarket review requirements would begin twelve months after finalization of the guidance documents for the highest risk tests, including LDTs with the same intended use as a companion diagnostic or LDTs with the same intended use as an FDA-approved Class III medical device.

Premarket review for other LDTs classified as high-risk by the FDA would be phased in over the next four years. During this period, LDTs could remain on the market while the FDA reviewed the applications or notifications for such tests.

The FDA s draft guidance documents for LDTs have yet to be published or finalized. Assuming the FDA publishes the draft guidance documents, it will accept comments from the public for a period of time before deciding whether to issue final guidance documents implementing the same or modified versions of the draft guidance documents. There is no timeframe in which the FDA must issue final guidance documents.

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

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requirements of the FDA could result in enforcement action, including receiving untitled or warning letters, fines, injunctions, or civil or criminal penalties. In addition, we could be subject to a recall or seizure of current or future products, operating restrictions, partial suspension or total shutdown of production. Any such enforcement action would have a material adverse effect on our business, financial condition and operations.

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

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, we recently received approval from the New York State Department of Health for FoundationOne and FoundationOne Heme. If we do not maintain these licenses or if our approval is revoked, our business would suffer. Moreover, several other states require that we hold licenses to test specimens from patients in those states. Other states 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. If we are unable to comply with existing laws and regulations or changes to the laws and regulations, our business could be materially and adversely affected.

Any sanction imposed under CLIA, its implementing regulations, or state or foreign laws or regulations governing licensure, or our failure to renew a CLIA certificate, a state or foreign license, or accreditation, could have a material adverse effect on our business. Most CLIA deficiencies are not classified as condition-level deficiencies, and there are no adverse effects upon the laboratory operations as long as the deficiencies are corrected. Remediation of these deficiencies are routine matters, with corrections occurring within several hours or weeks. More serious CLIA

deficiencies could rise to the level of condition-level deficiencies, and CMS has the authority to impose a wide range of sanctions, including revocation of the CLIA certification along with a bar on the ownership or operation of a CLIA, certified laboratory by any owners or operators of the deficient laboratory. There is an administrative hearing procedure that can be pursued by the laboratory in the event of imposition of such sanctions, during which the sanctions are stayed, but the process can take a number of years to complete. If we were to lose our CLIA certification or CAP accreditation, we would not be able to operate our clinical reference laboratory and conduct our molecular tests, which would result in material harm to our business and results of operations.

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

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

amendments to HIPAA under the 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;

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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.

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

Use of Proceeds from Initial Public Offering of Common Stock

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

We raised approximately $110.4 million in net proceeds after deducting underwriting discounts and commissions of approximately $8.5 million and other offering expenses of approximately $3.0 million. None of these expenses consisted of direct or indirect payments made by us to directors, officers or persons owning 10% or more of our common stock or to their associates, or to our affiliates. There has been no material change in 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 June 30, 2014, the remainder of the net proceeds is included as cash and cash equivalents.

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Item 6. Exhibits

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

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SIGNATURES

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

FOUNDATION MEDICINE, INC.

Date: August 12, 2014

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

Date: August 12, 2014

By: /s/ Jason Ryan
Jason Ryan
Senior Vice President, Finance
(Principal Financial Officer)

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Exhibit No.	Exhibit Index
10.1	Second Amendment to Lease, by and between the Company and 150 Second Street, LLC, dated June 30, 2014. (incorporated by reference to Exhibit 10.1 to the Company s Current Report on Form 8-K filed on July 2, 2014).
31.1*	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101***	Interactive Data Files regarding (a) our Condensed Consolidated Balance Sheets as of June 30, 2014 and December 31, 2013 (b) our Condensed Consolidated Statements of Operations and Comprehensive Loss for the Three and Six Months Ended June 30, 2014 and 2013, (c) our Condensed Consolidated Statements of Cash Flows for the Six Months Ended June 30, 2014 and 2013 and (d) the Notes to such Condensed Consolidated 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.