Foundation Medicine, Inc.
Form 10-Q
November 03, 2015
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2015

OR

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

For the transition period from _____ to _____

Commission file number: 001-36086

FOUNDATION MEDICINE, INC.

(Exact name of registrant as specified in its charter)

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

150 Second Street

Cambridge, MA 02141

(Address of principal executive offices)(Zip code)

(617) 418-2200

(Registrant s telephone number, including area code)

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

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

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

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

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

The number of shares outstanding of the registrant s common stock, par value of $0.0001 per share, as of November 2, 2015 was 34,451,209.

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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:

- 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 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;

- the outcome or success of our clinical trials;

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

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

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

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

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

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

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

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

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

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

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

federal, state, and foreign regulatory requirements, including potential Food & Drug Administration (FDA) regulation of FoundationOne and FoundationOne Heme and the other tests performed using our molecular information platform;

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

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

our ability to recognize the benefits of our broad strategic collaboration with affiliates of Roche Holdings, Inc., which closed in April 2015;

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

other risks and uncertainties, including those described in Part II, Item 1A. Risk Factors in this Quarterly Report and our prior filings with the SEC.

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

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

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FOUNDATION MEDICINE, INC.

REPORT ON FORM 10-Q

For the Quarterly Period Ended September 30, 2015

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FOUNDATION MEDICINE, INC.

Condensed Consolidated Balance Sheets

(unaudited)

(In thousands, except share and per share data)

	September 30, 2015	December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	$ 250,162	$ 72,080
Accounts receivable, net of allowance of $171 and $0 at September 30, 2015 and December 31, 2014, respectively	10,071	9,894
Inventories	9,460	4,809
Prepaid expenses and other current assets	6,120	2,865
Total current assets	275,813	89,648
Property and equipment, net	36,774	21,015
Restricted cash	1,395	864
Other assets	1,026	411
Total assets	$ 315,008	$ 111,938
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable	$ 11,963	$ 7,263
Accrued expenses and other current liabilities	16,069	7,414
Deferred revenue	455	340
Current portion of deferred rent	2,094	1,429
Total current liabilities	30,581	16,446
Deferred rent, net of current portion, and other non-current liabilities	10,953	9,323
Total liabilities	41,534	25,769
Commitments and contingencies (Note 13)		
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; 34,396,872 and 28,223,958 shares issued and outstanding at September 30, 2015 and December 31, 2014, respectively	3	3
Additional paid-in capital	486,067	228,151
Accumulated deficit	(212,596)	(141,985)

Total stockholders equity	273,474	86,169
Total liabilities and stockholders equity	$ 315,008	$ 111,938

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

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FOUNDATION MEDICINE, INC.

Condensed Consolidated Statements of Operations and Comprehensive Loss

(unaudited)

(In thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Revenue	$ 20,953	$ 16,284	$ 58,557	$ 41,715
Related-party revenue from Roche	4,446	164	8,595	684
Total revenue	25,399	16,448	67,152	42,399
Costs and expenses:				
Cost of revenue	9,068	7,502	26,934	19,412
Cost of Roche related-party revenue	1,302		1,302	
Selling and marketing	14,267	7,893	36,630	20,753
General and administrative	9,199	6,801	41,810	18,326
Research and development	12,174	7,230	31,118	22,790
Total costs and expenses	46,010	29,426	137,794	81,281
Loss from operations	(20,611)	(12,978)	(70,642)	(38,882)
Other income (expense):				
Interest income	15	8	31	14
Interest expense		(10)		(57)
Total other income (expense), net	15	(2)	31	(43)
Net loss	$ (20,596)	$ (12,980)	$ (70,611)	$ (38,925)
Net loss per common share, basic and diluted	$ (0.60)	$ (0.46)	$ (2.19)	$ (1.40)
Weighted-average common shares outstanding, basic and diluted	34,347,593	28,037,349	32,290,972	27,883,244
Comprehensive loss	$ (20,596)	$ (12,980)	$ (70,611)	$ (38,925)

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

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FOUNDATION MEDICINE, INC.

Condensed Consolidated Statements of Cash Flows

(unaudited)

(In thousands)

	Nine Months Ended September 30,	
	2015	**2014**
Operating activities		
Net loss	$ (70,611)	$ (38,925)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization expense	7,523	6,121
Stock-based compensation	8,049	3,475
Provision for doubtful accounts on accounts receivable	171	
Provision for inventory excess and obsolescence	105	
Non-cash interest expense		13
Changes in operating assets and liabilities:		
Accounts receivable	(348)	251
Inventory	(4,756)	(2,431)
Prepaid expenses and other current assets	(3,255)	(475)
Other assets	(615)	(246)
Accounts payable	4,269	1,407
Accrued expenses and other current liabilities	4,728	1,569
Deferred rent and other non-current liabilities	2,305	(236)
Deferred revenue	115	354
Net cash used in operating activities	(52,320)	(29,123)
Investing activities		
Purchases of property and equipment	(18,911)	(7,760)
Increase in restricted cash	(531)	
Net cash used in investing activities	(19,442)	(7,760)
Financing activities		
Proceeds from issuance of common stock to Roche, net of issuance costs	245,387	
Proceeds from issuance of restricted stock and stock option exercises	4,457	349
Payments of notes payable		(1,098)
Net cash provided by (used in) financing activities	249,844	(749)
Net increase (decrease) in cash and cash equivalents	178,082	(37,632)
Cash and cash equivalents at beginning of period	72,080	124,293
Cash and cash equivalents at end of period	$ 250,162	$ 86,661

Supplemental disclosure of cash flow information		
Cash paid for interest	$	$ 150
Supplemental disclosure of non-cash investing and financing activities		
Acquisition of property and equipment included in accounts payable and accrued expenses	$ 5,705	$ 1,312

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

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FOUNDATION MEDICINE, INC.

Notes to Condensed Consolidated Financial Statements

(unaudited)

1. Nature of Business and Basis of Presentation

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

The Company s first clinical products, FoundationOne for solid tumors, and FoundationOne Heme for blood-based cancers, or hematologic malignancies, including leukemia, lymphoma, myeloma, and many sarcomas, are, to its knowledge, the only widely available comprehensive genomic profiles designed for use in the routine care of patients with cancer. To accelerate its commercial growth and enhance its competitive advantage, the Company is continuing to expand its sales force, grow its molecular information knowledgebase, called FoundationCORE, publish scientific and medical advances, foster relationships throughout the oncology community, and develop new clinical and technology products. Examples of new products include the Company s circulating tumor DNA (ctDNA) assay, which is a liquid-biopsy based product anticipated to be launched to our biopharmaceutical partners in the fourth quarter of 2015, and GeneKit, a cloud-based genomics solutions portal for pathologists.

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 unaudited 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. The Company s audited consolidated financial statements as of and for the year ended December 31, 2014 included information and footnotes necessary for such presentation and were included in the Company s Annual Report on Form 10-K filed with the Securities and Exchange Commission (SEC) on March 13, 2015. These unaudited condensed consolidated financial statements should be read in conjunction with the Company s audited consolidated financial statements and notes thereto for the year ended December 31, 2014.

2. Summary of Significant Accounting Policies

Summary of accounting policies

There have been no material changes to the significant accounting policies previously disclosed in the Company s Annual Report on Form 10-K for the year ended December 31, 2014, except as discussed below as a result of the Roche transaction discussed in detail in Note 3.

Multiple-element revenue recognition

The Company analyzes multiple-element arrangements based on the guidance in Financial Accounting Standards Board (FASB) Accounting Standards Codification 605-25, *Revenue Recognition-Multiple-Element Arrangements* (ASC 605-25). Pursuant to the guidance in ASC 605-25, the Company evaluates multiple-element arrangements to determine (1) the deliverables included in the arrangement and (2) whether the individual deliverables represent separate units of accounting or whether they must be accounted for as a combined unit of accounting. This evaluation involves subjective determinations and requires management to make judgments about the individual deliverables and whether such deliverables are separable from the other aspects of the contractual relationship. Deliverables are considered separate units of accounting if: (i) the delivered items have value to the customer on a standalone basis and (ii) the arrangement includes a general right of return relative to the delivered items and delivery or performance of the undelivered items is considered probable and substantially in the control of the Company. In assessing whether an item has standalone value, the Company considers factors such as the research, development and commercialization capabilities of a third party and the availability of the associated expertise in the general marketplace. In addition, the Company considers whether the other party in the arrangement can use the other deliverables for their intended purpose without the receipt of the remaining elements, whether the value of the deliverable is dependent on the undelivered items, and whether there are other vendors that can provide the undelivered elements.

Arrangement consideration that is fixed or determinable is allocated among the separate units of accounting using the relative selling price method. Then, the applicable revenue recognition criteria in ASC 605-25 is applied to each of the separate units of

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accounting in determining the appropriate period and pattern of recognition. The Company determines the selling price of a unit of accounting following the hierarchy of evidence prescribed by ASC 605-25. Accordingly, the Company determines the estimated selling price for units of accounting within each arrangement using vendor-specific objective evidence (VSOE) of selling price, if available, third-party evidence (TPE) of selling price if VSOE is not available, or best estimate of selling price (BESP) if neither VSOE nor TPE is available. The Company typically uses BESP to estimate the selling price, since it generally does not have VSOE or TPE of selling price for its units of accounting under multiple-element arrangements. Determining the BESP for a unit of accounting requires significant judgment. In developing the BESP for a unit of accounting, the Company considers applicable market conditions and estimated costs. The Company validates the BESP for units of accounting by evaluating whether changes in the key assumptions used to determine the BESP will have a significant effect on the allocation of arrangement consideration between multiple units of accounting. The Company recognizes arrangement consideration allocated to each unit of accounting when all of the revenue recognition criteria in ASC 605-25 are satisfied for that particular unit of accounting.

At the inception of an arrangement that includes milestone payments to the Company, the Company evaluates whether each milestone is substantive and at risk to both parties on the basis of the contingent nature of the milestone. This evaluation includes an assessment of whether: (i) the consideration is commensurate with either the Company s performance to achieve the milestone or the enhancement of the value of the delivered items as a result of a specific outcome resulting from the Company s performance to achieve the milestone, (ii) the consideration relates solely to past performance, and (iii) the consideration is reasonable relative to all of the deliverables and payment terms within the arrangement. The Company evaluates factors such as the scientific, clinical, regulatory, commercial, and other risks that must be overcome to achieve the respective milestone and the level of effort and investment required to achieve the respective milestone in making this assessment. There is considerable judgment involved in determining whether a milestone satisfies all of the criteria required to conclude that a milestone is substantive. Generally, once a substantive milestone has been achieved, the Company will recognize revenue related to that milestone using a proportional performance model over the period which the unit of accounting is delivered or based on the level of effort expended to date over the total expected effort, whichever is considered the most appropriate measure of performance. Revenue from commercial milestone payments are accounted for as royalties and recorded as revenue upon achievement of the milestone, assuming all other revenue recognition criteria are met.

The Company also recognizes royalty revenue in the period of sale of the related product(s), based on the underlying contract terms, provided that the reported sales are reliably measurable and the Company has no remaining performance obligations, assuming all other revenue recognition criteria are met.

For some multiple-element arrangements, the Company will be reimbursed for either all or a portion of the research and development costs incurred. The Company performs research and development services as part of its revenue activities and, therefore, believes such activities are a part of its primary business. Therefore, the Company records these reimbursements as revenue in the statement of operations using a proportional performance model over the period which the unit of accounting is delivered or based on the level of effort expended to date over the total expected effort, whichever is considered the most appropriate measure of performance.

Recent Accounting Pronouncements

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

In May 2014, the FASB and the International Accounting Standards Board jointly issued Accounting Standards Update No. 2014-09, *Revenue from Contracts with Customers* (ASU 2014-09), which supersedes the revenue recognition requirements in Accounting Standards Codification 605 (ASC 605) and most industry-specific guidance. The new standard requires that an entity recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The update also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. In July 2015, the FASB decided to delay the effective date of ASU 2014-09 by one year until January 1, 2018. The FASB also permitted entities to choose to adopt the standard as of the original effective date. The Company intends to adopt ASU 2014-09 on January 1, 2018, and is currently evaluating the method of adoption and the potential impact that ASU 2014-09 may have on its financial position and results of operations.

In August 2014, the FASB issued ASU 2014-15, *Disclosure of Uncertainties about an Entity s Ability to Continue as a Going Concern* (ASU 2014-15). ASU 2014-15 requires management to evaluate, at each annual or interim reporting period, whether there are conditions or events that exist that raise substantial doubt about the Company s ability to continue as a going concern within one year after the date the financial statements are issued and provide related disclosures. ASU 2014-15 is effective for annual periods ending after December 15, 2016 and earlier application is permitted. The adoption of ASU 2014-15 is not expected to have a material effect on the Company s consolidated financial statements or disclosures.

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3. Significant Agreements

Roche Holdings, Inc. and its affiliates

Summary of the Transaction

On January 11, 2015, the Company signed a broad strategic collaboration with Roche Holdings, Inc. and certain of its affiliates (collectively, Roche) to further advance the Company s leadership position in genomic analysis and molecular information solutions in oncology. The transaction, which is a broad multi-part arrangement that includes a research & development (R&D) collaboration, a commercial collaboration, a U.S. medical education collaboration, and an equity investment with certain governance provisions, closed on April 7, 2015.

Under the terms of the transaction, Roche (a) made a primary investment of $250,000,000 in cash through the purchase of 5,000,000 newly issued shares of the Company s common stock at a purchase price of $50.00 per share and (b) completed a tender offer to acquire 15,604,288 outstanding shares of the Company s common stock at a price of $50.00 per share (collectively (a) and (b), the Investment). Immediately following the closing of the transaction, Roche owned approximately 61.3% of the outstanding shares and approximately 57.6% of the outstanding shares on a fully diluted basis. As of September 30, 2015, Roche s ownership was approximately 61.1% of the outstanding shares and approximately 54.1% of the outstanding shares on a fully diluted basis. Upon the closing of the transaction, the size of the Board of Directors of the Company (Board of Directors) was increased to nine, including three designees of Roche. Four existing independent directors and the Company s Chief Executive Officer, Michael Pellini, M.D., have continued as directors, and the Company expects that one new independent director will be added.

The Company assessed the agreements related to each of the R&D collaboration, commercial collaboration, and the U.S. medical education collaboration and determined they should be treated as a single contract for accounting purposes.

Summary of the R&D Collaboration Agreement

Under the terms of the Collaboration Agreement by and among the Company, F. Hoffmann-La Roche Ltd, and Hoffmann-La Roche Inc., dated January 11, 2015 (the R&D Collaboration Agreement), Roche could pay the Company more than $150,000,000 over a period of five years to access its molecular information platform, to reserve capacity for sample profiling, and to fund R&D programs. There was no up-front payment associated with the effectiveness of the R&D Collaboration Agreement. Amounts under the R&D Collaboration Agreement will be received as services are performed and obligations are fulfilled under each platform program. Roche will utilize the Company s molecular information platform to standardize sample profiling conducted as part of its clinical trials, to enable comparability of clinical trial results for R&D purposes, and to better understand the potential for combination therapies. In addition, Roche and the Company will jointly develop solutions related to cancer immunotherapy testing, blood-based genomic analysis using ctDNA assays, and next generation companion diagnostics, each of which represents a distinct platform within the R&D Collaboration Agreement. The R&D Collaboration Agreement is governed by a Joint Management Committee (JMC) formed by an equal number of representatives from the Company and Roche. There are also other sub-committees for each platform that will be established to oversee the day to day responsibilities of the respective platform. The JMC will, among other activities, review and approve R&D plans and establish and set expectations for the other platform sub-committees. The JMC and other sub-committees, although considered deliverables under the arrangement, are immaterial in relation to the entire arrangement and therefore were not considered when allocating consideration.

Molecular Information Platform Program

Under the molecular information platform program within the R&D Collaboration Agreement, the following deliverables were identified: (i) cross-licenses for access to relevant intellectual property (IP), (ii) reserved capacity for sample profiling, (iii) access to the Company s molecular information database, (iv) full-time equivalent persons (FTEs) per year for performance of database queries and delivery of results, and (v) sample profiling above the reserved capacity limit.

The Company determined which deliverables within the arrangement have standalone value from the other undelivered elements, and identified the following separate units of accounting: (i) reserved capacity for sample profiling, (ii) access to the Company s molecular information database and FTEs per year for the performance of database queries and the delivery of results, and (iii) sample profiling above the reserved capacity limit. The cross-licenses grant each party access to relevant IP to perform under the contract or to exploit the deliverables. The licenses are delivered at the inception of the arrangement and relate to development and sample profiling work performed under the platform. The Company does not sell the licenses separately as they are closely connected to the development and sample profiling activities and have little value to Roche without these other deliverables. Therefore, the licenses are combined with the other units of accounting identified under the molecular information platform program and do not have standalone value.

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The Company identified allocable consideration of approximately $85 million related to the molecular information platform program, which was allocated to the individual units of accounting based on the BESP. Revenue related to reserved capacity for sample profiling will be recognized on a straight-line basis as the capacity is available for each individual contract year within the arrangement. The database access and FTE payments will be recognized ratably over the five year contract life. The FTEs will perform database queries and will deliver results of the requested database queries. The value to Roche is not only the access to the database, but also the service being performed by the FTEs. Therefore, the Company concluded the FTEs should be combined with the database access as one unit of accounting. For any sample profiling provided above the reserved capacity, the Company will recognize revenue as the service is provided based on the best estimate of selling price.

Immunotherapy Testing Platform Development Program

Under the immunotherapy testing platform development program within the R&D Collaboration Agreement, the following deliverables were identified: (i) cross-licenses for access to relevant IP, (ii) obligations to perform R&D services for immuno-biomarker discovery and signature identification, and (iii) obligations to provide sample profiling using immunotherapy clinical study assays.

The Company determined which deliverables within the arrangement have standalone value from the other undelivered elements, and identified the following separate units of accounting: (i) obligations to perform R&D services for immuno-biomarker discovery and signature identification and (ii) obligations to provide sample profiling using immunotherapy clinical study assays. The cross-licenses grant each party access to relevant IP of the other party to perform such party s obligations under the contract and to exploit the deliverables. The licenses are delivered at the inception of the arrangement and relate to R&D work performed under the platform. The Company does not sell the licenses separately as they are closely connected to the R&D activities and have little value to Roche without these other deliverables. Therefore, the licenses are combined with the other units of accounting identified under the immunotherapy testing platform development program and do not have standalone value.

Under this platform, Roche will reimburse the Company for R&D costs incurred related to the immuno-biomarker discovery and signature identification activities, as well as costs incurred in the development of immunotherapy assays for clinical studies. In addition, Roche will be required to make certain milestone payments upon the achievement of specified clinical events under the immunotherapy testing platform development program. Clinical milestone payments up to $6.6 million in the aggregate are triggered upon the initiation of Roche clinical trials using immunotherapy assays developed under the R&D Collaboration Agreement and are considered substantive. The R&D reimbursements and clinical milestone payments will be recognized using a proportional performance model when earned by the Company.

Circulating Tumor DNA (ctDNA) Platform Development Program

Under the ctDNA platform development program within the R&D Collaboration Agreement, the following deliverables were identified: (i) cross-licenses for access to relevant IP, (ii) obligations to perform R&D services for the development of a ctDNA clinical trial assay, including its analytical validation, and (iii) sample profiling resulting from the development of a ctDNA clinical assay.

The Company determined which deliverables within the arrangement have standalone value from the other undelivered elements, and identified the following separate units of accounting: (i) obligations to perform R&D services for the development of a ctDNA clinical trial assay and (ii) delivery of clinical sample profiling resulting from the development of a ctDNA clinical assay. The cross-licenses grant each party access to relevant IP of the other party to perform such party s obligations under the contract and to exploit the deliverables. The licenses are delivered

at the inception of the arrangement and relate to R&D work performed under the platform. The Company does not sell the licenses separately as they are closely connected to the R&D activities and have little value to Roche without these other deliverables. Therefore, the licenses are combined with the other units of accounting identified under the ctDNA platform development program and do not have standalone value.

The Company is responsible for all R&D costs under the ctDNA platform development program. Roche will be required to make certain milestone payments upon the achievement of specified events. Milestone payments up to $12.0 million in the aggregate are triggered upon successful analytical validation of a ctDNA assay and delivery of a ctDNA clinical trial assay for use in Roche clinical trials. All milestones are considered substantive and will be recognized using a proportional performance model when earned by the Company.

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Companion Diagnostics (CDx) Development Program

Under the CDx development program within the R&D Collaboration Agreement, the following deliverables were identified: (i) cross-licenses for access to relevant IP and (ii) obligations to perform R&D services for the development of CDx assays for use in connection with certain Roche products.

The Company determined which deliverables within the arrangement have standalone value from the other undelivered elements, and concluded all deliverables under the CDx development program represent a single unit of accounting. The cross-licenses grant each party access to relevant IP of the other party to perform such party s obligations under the contract and to exploit the deliverables. The licenses are delivered at the inception of the arrangement and relate to R&D work performed under the platform. The Company does not sell the licenses separately as they are closely connected to the R&D activities and have little value to Roche without these other deliverables. Therefore, the licenses are combined with the obligation to perform R&D services for the development of a CDx assay as a single unit of accounting.

Under this platform, Roche will reimburse the Company for certain costs incurred related to R&D under the CDx development program with respect to investigational markers. In addition, Roche will be required to make certain milestone payments upon the achievement of specified regulatory and commercial events under the CDx development program. Regulatory milestone payments of $0.6 million are triggered upon obtaining FDA approval of a premarket approval application for each CDx product developed under the arrangement and are considered substantive. The R&D reimbursements and regulatory milestone payments will be recognized using a proportional performance model when earned by the Company. Commercial milestone payments are triggered upon the performance of a specified number of CDx assays for certain commercial clinical diagnostic uses. Any commercial milestone payments received by the Company will be treated similar to royalties and recognized in their entirety when earned.

Termination of the R&D Collaboration Agreement

The R&D Collaboration Agreement may be terminated by either the Company or Roche on a program-by-program basis, upon written notice, in the event of the other party s uncured material breach. Roche may also terminate the entire R&D Collaboration Agreement or an individual program under the R&D Collaboration Agreement for any reason upon written notice to the Company, subject to certain exceptions. If the R&D Collaboration Agreement is terminated, license and IP rights are returned to each party and the Company must return to Roche or dispose of any unused samples delivered for profiling purposes. If Roche terminates the R&D Collaboration Agreement as a result of a breach by the Company, Roche retains the license rights granted to certain IP of the Company, and the Company shall refund to Roche any reserved capacity fees and database access fees previously received by the Company that were unused based on the passage of time up to termination for the given contract year. If the R&D Collaboration Agreement is terminated by Roche without cause, or by the Company due to a breach by Roche, the Company has a right to receive the contractual payments it would have expected to receive for each program had the agreement not been terminated.

Summary of the Ex-U.S. Commercialization Agreement

In addition to the R&D Collaboration Agreement, the Company entered into a commercial collaboration agreement with Roche designed to facilitate the delivery of the Company s products and services outside the United States (Ex-U.S.) in partnership with Roche (the Ex-U.S. Commercialization Agreement). Specifically, Roche will obtain Ex-U.S. commercialization rights to the Company s existing products and services and to future co-developed products and services, and the Company will remain solely responsible for commercialization of its products and services within the United States. Roche will have specified time periods to determine if it desires to exercise its

commercialization rights in selected geographic areas Ex-U.S., which selected geographic areas together constitute the Roche Territory. For those geographic areas that Roche does not select, the commercialization rights for such geographic areas will revert to the Company. The Ex-U.S. Commercialization Agreement is governed by the JMC. There is also a Joint Operational Committee (JOC) that has been established to oversee the activities under the Ex-U.S. Commercialization Agreement. The JMC will have the responsibilities as outlined under the R&D Collaboration Agreement. The JMC and JOC, although considered deliverables under the arrangement, are immaterial in relation to the entire arrangement and therefore were not considered when allocating consideration.

Under the Ex-U.S. Commercialization Agreement, the following deliverables were identified: (i) the right, granted by means of a license, for Roche to market and sell the Company s products in the Roche Territory and (ii) obligations to perform sample profiling and other services relating to Company products and services sold by Roche in the Roche Territory. The Company concluded that the license is delivered at the inception of the arrangement. The Company does not sell the license separately as it is closely connected to the sample profiling and other services and has little value to Roche without these services being performed. Therefore, the deliverables identified will be combined as a single unit of accounting under the Ex-U.S. Commercialization Agreement and revenue will be recognized as the service is performed for each product sold by Roche.

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Roche will be required to make a one-time milestone payment of $10.0 million when the aggregate gross margin on sales of certain of the Company s products reaches $100.0 million in the Roche Territory in any calendar year. Roche may also pay delay fees to the extent Roche fails to launch Company products in specific countries within a specified timeframe. This milestone payment and these fees will be treated similarly to royalties and recognized in their entirety when earned.

The Company will be entitled to receive, on a quarterly basis, tiered royalty payments ranging from the mid-single digits to high-teens based on a percentage of the aggregate gross margin generated on sales of specified products in the Roche Territory during any calendar year. Royalty payments will be recognized in the period when earned.

The Ex-U.S. Commercialization Agreement may be terminated by either the Company or Roche in its entirety or on a country-by-country or product-by-product basis, upon written notice, in the event of the other party s uncured material breach. Roche may also terminate the Ex-U.S. Commercialization Agreement without cause on a product-by-product and/or country-by-country basis, upon written notice to the Company, after the initial five year term. If the Ex-U.S. Commercialization Agreement is terminated, the license and IP rights granted by the Company to Roche terminate. In addition, if Roche terminates the Ex-U.S. Commercialization Agreement as a result of a breach by the Company, Roche may seek damages via arbitration or be eligible to receive either a one-time payment reflecting the value of the terminated products or a royalty on sales of the terminated products based on the royalty Roche would have paid the Company for the terminated products had the Ex-U.S. Commercialization Agreement not been terminated.

Summary of the U.S. Education Agreement

Within the United States, the Company has entered into the U.S. Education Collaboration Agreement (the U.S. Education Agreement) with Genentech, Inc. (Genentech), an affiliate of Roche. Genentech has agreed to engage its pathology education team to provide information and medical education to health care providers regarding comprehensive genomic profiling in cancer. The Company will pay Genentech on a quarterly basis for costs incurred by Genentech in conducting the education activities based on a number of factors. The total amount of payments to be made over the course of the arrangement is immaterial and all payments will be expensed as incurred.

4. Cash and Cash Equivalents

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

5. Restricted Cash

Restricted cash consists of deposits securing collateral letters of credit issued in connection with the Company s operating leases. As of September 30, 2015 and December 31, 2014, the Company had restricted cash of $1,395,000 and $864,000, respectively.

6. Accounts Receivable and Allowance for Doubtful Accounts

The Company s accounts receivable consist primarily of amounts due from biopharmaceutical customers, and from certain hospitals, cancer centers and other institutions with whom it has negotiated price per test (direct bill) relationships for tests performed using its molecular information platform. There are no accounts receivable associated with amounts that are billed to commercial third-party payors or directly to patients, because this revenue is recognized on a cash basis. The Company determines its allowance by considering a number of factors, including the length of time accounts receivable are past due, previous loss history, a specific customer s ability to pay its obligations to the Company, and the condition of the general economy and industry as a whole. As of September 30, 2015 and December 31, 2014, the Company recorded an allowance for doubtful accounts of $171,000 and $0, respectively.

7. Inventories

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):

	September 30, 2015	December 31, 2014
Raw materials	$ 8,564	$ 3,851
Work-in-process	896	958
	$ 9,460	$ 4,809

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8. Property and Equipment

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

	September 30, 2015	December 31, 2014
Lab equipment	$ 23,786	$ 14,843
Computer equipment	9,701	6,673
Software	3,190	2,111
Furniture and office equipment	3,376	1,974
Leasehold improvements	18,783	12,834
Construction in progress	2,881	
	61,717	38,435
Less accumulated depreciation and amortization	(24,943)	(17,420)
	$ 36,774	$ 21,015

Depreciation and amortization expense for the three and nine months ended September 30, 2015 was $2,954,000 and $7,523,000, respectively, compared to $2,118,000 and $6,121,000 for the three and nine months ended September 30, 2014, respectively. The Company classifies capitalized internal use software in Lab Equipment, Computer Equipment and Software based on its intended use.

9. Accrued Expenses and Other Current Liabilities

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

	September 30, 2015	December 31, 2014
Payroll and employee-related costs	$ 7,870	$ 5,011
Professional services	2,185	1,123
Property and equipment purchases	4,410	471
Other	1,604	809
	$ 16,069	$ 7,414

10. Net Loss per Common Share

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

stock equivalents, but are excluded from the calculation of diluted net loss per share because their effect would be anti-dilutive. Therefore, basic and diluted net loss per share applicable to common stockholders was the same for all periods presented.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Outstanding stock options	1,825,633	2,718,335	1,825,633	2,718,335
Unvested restricted stock	945,276	365,741	945,276	365,741
Total	2,770,909	3,084,076	2,770,909	3,084,076

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11. Fair Value Measurements

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

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

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

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

The following tables present information about the Company s assets and liabilities that are measured at fair value on a recurring basis as of September 30, 2015 and December 31, 2014, and indicate the fair value hierarchy of the valuation techniques utilized to determine such fair value (in thousands):

	Fair Value Measurement at September 30, 2015			
	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Assets:				
Cash held in money market funds	$ 193,022	$	$	$ 193,022
Total assets	$ 193,022	$	$	$ 193,022

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

The Company measures eligible assets and liabilities at fair value, with changes in value recognized in the statement of operations and comprehensive loss. Fair value treatment may be elected either upon initial recognition of an eligible asset or liability or, for an existing asset or liability, if an event triggers a new basis of accounting. The Company did not elect to remeasure any of its existing financial assets or liabilities, and did not elect the fair value option for any financial assets and liabilities transacted during the three and nine months ended September 30, 2015 and 2014.

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12. Stockholders Equity

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

	September 30, 2015	December 31, 2014
Unvested restricted stock	945,276	335,933
Common stock options	1,825,633	2,792,021
Shares available for issuance under the 2013 Stock Option and Incentive Plan	1,694,682	1,375,555
Shares available for issuance under the 2013 Employee Stock Purchase Plan	788,503	788,503
	5,254,094	5,292,012

2010 and 2013 Stock Incentive Plans

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

In 2013, in conjunction with its initial public offering, the Company adopted the Foundation Medicine, Inc. 2013 Stock Option and Incentive Plan (the 2013 Stock Plan) under which it may grant restricted and unrestricted stock, restricted stock units, ISOs, non-statutory stock options, stock appreciation rights, cash-based awards, performance share awards and dividend equivalent rights to eligible employees, officers, directors and consultants to purchase up to 1,355,171 shares of common stock. In connection with the establishment of the 2013 Stock Plan, the Company terminated the 2010 Stock Plan and the 512,568 shares which remained available for grant under the 2010 Stock Plan were included in the number of shares authorized under the 2013 Stock Plan. Shares forfeited or repurchased from the 2010 Stock Plan are returned to the 2013 Stock Plan for future issuance. On January 1, 2015 and 2014, the number of shares reserved and available for issuance under the 2013 Stock Plan increased by 1,134,996 and 1,125,921 shares of common stock, respectively, pursuant to a provision in the 2013 Stock Plan that provides that the number of shares reserved and available for issuance will automatically increase each January 1, beginning on January 1, 2014, by 4% of the number of shares of 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, or permissible designee thereof, 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. The options are exercisable from the date of grant for a period of 10 years. The exercise price for stock options granted is equal to the closing price of the Company s common stock on the applicable date of grant.

Restricted Stock

The 2010 Stock Plan and the 2013 Stock Plan allow for granting of restricted stock awards. For restricted stock granted to employees, the intrinsic value on the date of grant is recognized as stock-based compensation expense

ratably over the period in which the restrictions lapse. For restricted stock granted to non-employees the intrinsic value is remeasured at each vesting date and at the end of the reporting period. The following table shows a roll forward of restricted stock activity pursuant to the 2010 Stock Plan and the 2013 Stock Plan:

	Number of Shares
Unvested at December 31, 2014	219,617
Granted	783,804
Vested	(61,352)
Cancelled	(11,632)
Unvested at September 30, 2015 [1]	930,437

[1] Excludes 14,839 shares of unvested restricted stock remaining from the early exercise of stock options.

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Stock Options

A summary of stock option activity under the 2010 Stock Plan and the 2013 Stock Plan for the nine months ended September 30, 2015 is as follows:

	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (In Years)	Aggregate Intrinsic Value
				(in thousands)
Outstanding as of December 31, 2014	2,792,021	$ 10.82	8.3	$ 35,390
Granted	164,742	45.09		
Exercised	(1,010,085)	4.41		
Cancelled	(121,045)	17.12		
Outstanding as of September 30, 2015	1,825,633	$ 17.04	8.0	$ 12,686
Exercisable as of September 30, 2015	737,282	$ 11.74	7.5	$ 6,986

Certain stock options contain provisions allowing for the early exercise into shares subject to repurchase. At September 30, 2015, 14,839 shares, which were early exercised, remain subject to repurchase by the Company.

The weighted-average fair value of options granted for the nine months ended September 30, 2015 was $26.53 per share. The Company recorded total stock-based compensation expense for stock options granted to employees, directors and non-employees from the 2010 Stock Plan and the 2013 Stock Plan of $1,592,000 and $4,548,000 during the three and nine months ended September 30, 2015, respectively, and $1,407,000 and $3,091,000 during the three and nine months ended September 30, 2014, respectively. The Company recorded total stock-based compensation expense for restricted stock of $2,668,000 and $3,501,000 during the three and nine months ended September 30, 2015, respectively, and $212,000 and $384,000 during the three and nine months ended September 30, 2014, respectively

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Cost of revenue	$ 302	$ 159	$ 690	$ 317
Sales and marketing	1,756	386	2,827	792
General and administrative	1,314	624	2,903	1,286
Research and development	888	450	1,629	1,080
Total	$ 4,260	$ 1,619	$ 8,049	$ 3,475

As of September 30, 2015, unrecognized compensation cost of approximately $32,516,000 related to non-vested stock options and restricted stock awards is expected to be recognized over weighted-average periods of 2.27 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 September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Expected volatility	56.5%	64.5%	63.1%	63.7%
Risk-free interest rate	1.97%	2.15%	1.52%	1.96%
Expected option term (in years)	6.25	6.25	6.25	6.25
Expected dividend yield	0.00%	0.00%	0.00%	0.00%

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13. Commitments and Contingencies

150 Second Street

In 2013, the Company signed two separate facility leases. The first lease commenced in March 2013 and had a one year expected term which was terminated in October 2013. The second lease (the Headquarters Lease) for office and laboratory space at 150 Second Street in Cambridge, Massachusetts commenced in September 2013 and initially had an eight year expected term. The Headquarters Lease is subject to fixed rate escalation increases and the landlord waived the Company s rent obligation for the first 10.5 months of the lease, having an initial value of $3,300,000. The landlord also agreed to fund up to $9,239,000 in tenant improvements. The Company recorded the tenant improvements as leasehold improvements and deferred rent on the consolidated balance sheet. Deferred rent is amortized as a reduction in rent expense over the term of the Headquarters Lease. The Company recognizes rent expense on a straight-line basis over the expected lease term. In connection with the Company s termination of its prior lease at One Kendall Square, the rent abatement was reduced to approximately $1,841,000 and the expected term of the Headquarters Lease was reduced to 7.5 years. The Company began to record rent expense in April 2013 upon gaining access to and control of the space. Upon execution of the Headquarters Lease, the Company paid a security deposit of $1,725,000 which was reduced to approximately $864,000 in 2014. The security deposit is included in restricted cash in the accompanying balance sheet as of September 30, 2015 and December 31, 2014.

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

The Company recorded rent expense of $634,000 and $1,901,000 in the three and nine months ended September 30, 2015, respectively, and $1,069,000 and $2,806,000 in the three and nine months ended September 30, 2014, respectively, associated with the Headquarters Lease, as amended.

Ten Canal Park Lease

The Company signed a facility lease (the Lease) on March 11, 2015 for office space at Ten Canal Park in Cambridge, Massachusetts (the Premises). The Lease commenced on March 12, 2015, which was the date the landlord received the Letter of Credit (as defined in the Lease), and expires on August 31, 2020. The Company will pay rent of $172,850 per month for the first year with scheduled escalating rent payments thereafter, and shall receive up to $1,995,550 from the Landlord for tenant improvements to the Premises. In connection with the Lease, the Company provided a security deposit in the amount of $1,037,000, which was reduced to approximately $530,550 in June 2015. The security deposit is included in restricted cash in the accompanying balance sheet as of September 30, 2015.

The Company recorded rent expense of $377,000 and $876,000 in the three and nine months ended September 30, 2015, respectively, associated with the Lease.

Legal Matters

From time to time, the Company is party to litigation arising in the ordinary course of its business. As of September 30, 2015, the Company is not currently a party to any litigation.

14. Related Party Transactions

Roche Holdings, Inc. and its affiliates

Revenue from Roche was $4,446,000 and $8,595,000 in the three and nine months ended September 30, 2015, respectively, which consisted of payments made for the reserved capacity arrangement and access to the Company s molecular information platform under the R&D Collaboration Agreement. Roche-related revenue represented 17.5% and 12.8% of the Company s total revenue in the three and nine months ended September 30, 2015, respectively. Costs of related party revenue from Roche were $1,302,000 for the three and nine months ended September 30, 2015, which consisted of costs incurred under the molecular information platform program within the R&D Collaboration Agreement.

Revenue from Roche was $164,000 and $684,000 in the three and nine months ended September 30, 2014, respectively, under a previous contractual relationship between Roche and the Company. Roche-related revenue represented 1.0% and 1.6% of the Company s total revenue in the three and nine months ended September 30, 2014, respectively.

There were no other material Roche-related transactions in the three and nine months ended September 30, 2015 and 2014.

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Other related party transactions

The Company recognized revenue of $1,057,000 and $2,369,000 during the three and nine months ended September 30, 2015, respectively, and $272,000 and $402,500 during the three and nine months ended September 2014, respectively, from an arrangement with an entity affiliated with a member of the Board of Directors executed in the year ended December 31, 2013. Of these amounts, $1,090,500 and $419,000 were included in accounts receivable at September 30, 2015 and December 31, 2014, respectively.

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

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

Overview

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

Our first clinical products, FoundationOne for solid tumors, and FoundationOne Heme for blood-based cancers, or hematologic malignancies, including leukemia, lymphoma, myeloma, and many sarcomas, are, to our knowledge, the only widely available comprehensive genomic profiles designed for use in the routine care of patients with cancer. To accelerate our commercial growth and enhance our competitive advantage, we are continuing to expand our sales force, grow our molecular information knowledgebase, called FoundationCORE, publish scientific and medical advances, foster relationships throughout the oncology community, and develop new clinical and technology products. Examples of new products include the Company s circulating tumor DNA (ctDNA) assay, which is a liquid-biopsy based product anticipated to be launched to our biopharmaceutical partners in the fourth quarter of 2015, and GeneKit, a cloud-based genomics solutions portal for pathologists.

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

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, the development of new products such as FoundationOne Heme, and the development of decision support tools. We have incurred significant losses since our inception, and as of September 30, 2015 our accumulated deficit was approximately $213,000,000. We expect to continue to incur operating losses over the near term as we expand our commercial operations, conduct clinical trials, and invest in our molecular information platform and additional products.

Recent Developments

On January 11, 2015, we signed a broad strategic collaboration with affiliates of Roche Holdings, Inc., or Roche, to further advance our leadership position in molecular information solutions. The transaction, which is a broad multi-part agreement that includes an R&D collaboration agreement, a commercial collaboration agreement, a U.S. education agreement, and an equity investment with certain governance provisions, closed on April 7, 2015.

Under the terms of the transaction, Roche (a) made a primary investment of $250,000,000 in cash through the purchase of 5,000,000 newly issued shares of our common stock at a purchase price of $50.00 per share and (b) completed a tender offer to acquire 15,604,288 outstanding shares of our common stock at a price of $50.00 per share. Immediately following the closing, Roche owned approximately 61.3% of our outstanding shares and approximately 57.6% of our outstanding shares on a fully diluted basis. As

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of September 30, 2015, Roche s ownership is approximately 61.1% of our outstanding shares and approximately 54.1% of our outstanding shares on a fully diluted basis. Upon the closing of the transaction, the size of our Board of Directors was increased to nine seats, including three designees of Roche. Four existing independent directors and our Chief Executive Officer, Michael Pellini, M.D. have continued as directors, and we expect that one new independent director will be added.

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

In addition to the R&D collaboration agreement, we entered into a commercial collaboration agreement with Roche for Roche to sell certain of our products outside of the United States. Specifically, Roche will obtain ex-U.S. commercialization rights to our existing products and to future co-developed products, and we will remain solely responsible for commercialization of our products within the United States. In addition, within the United States, we and Roche entered into a U.S. medical education agreement pursuant to which Roche has agreed to engage its medical education team to provide information to pathologists specific to comprehensive genomic profiling in cancer.

Financial Operations Overview

Revenue

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

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

We currently recognize revenue on a cash basis from most commercial third-party payors and from patients who make co-payments, pay deductibles, or pay other amounts that we have been unable to collect from their third-party payors because the payment is not fixed or determinable and collectability is not reasonably assured, as a result of the fact that we do not have coverage decisions in place with most third-party payors 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 most commercial third-party payors, the costs of those FoundationOne and FoundationOne Heme tests are recognized in advance of any associated revenues. Our revenue from these payors is generally lower and our net loss is higher than if we were recognizing revenue from these payors on an accrual basis in the period during which the work was performed and costs were incurred.

There are currently no local or national coverage decisions that determine whether and how our tests are covered by Medicare. In the absence of national coverage decisions, local Medicare contractors that administer the Medicare program in various regions have some discretion in determining coverage and, therefore, payment for tests. For example, while one leading Medicare contractor

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covering another region issued a decision to cover well-validated comprehensive genomic profiles for cancer effective July 2015, our local Medicare contractor has not yet elected to follow the same standards for determining coverage at this time. 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 31% of total tests reported to physicians in the United States during each of the nine months ended September 30, 2015 and 2014.

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 September 30, 2015, our Medicare contractor has not correctly processed and reimbursed us for any of the claims that we have submitted, and we are in the process of appealing these unpaid claims. In the future, our Medicare contractor may issue a negative coverage determination for FoundationOne and/or FoundationOne Heme that would apply to future claims or may defer processing a claim pending a coverage or payment determination. If a claim is paid by our Medicare contractor, either upon acceptance of the claim or following a successful appeal of a denied claim, we will generate revenue from Medicare for our testing.

We expect that our current lack of significant coverage decisions and the general uncertainty around reimbursement for our products will continue to negatively impact our revenue and earnings, both because we will not recognize revenue for tests performed, particularly if FoundationOne and FoundationOne Heme test volumes continue to increase period-to-period, and because the absence of Medicare or other significant coverage decisions may lead physicians to not order a meaningful number of tests. Following our achievement of a coverage decision from a commercial third-party payor or a government payor or once we have a sufficient history of claims collections with any such payor that we conclude the fees for FoundationOne and FoundationOne Heme tests for individuals insured by such payor are sufficiently fixed or determinable and collectability is reasonably assured, we will begin to recognize revenue from such payor on an accrual basis. As of September 30, 2015, we had cash and cash equivalents of approximately $250.2 million. If we are not able to obtain coverage decisions from additional commercial third-party payors and government payors over the longer term, and our available cash balances and cash flows from operations are insufficient to satisfy our liquidity requirements, we may require additional capital beyond our currently anticipated amounts. Additional capital may not be available on reasonable terms, or at all, and may be subject to the prior consent of Roche pursuant to our Investor Rights Agreement with Roche, dated January 11, 2015, or the Investor Rights Agreement.

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

We also receive a small portion of revenue from patients who make co-payments and pay deductibles. In addition, while we take on the primary responsibility for obtaining third-party reimbursement on behalf of patients, including appeals for any initial denials, we ultimately do bill patients for amounts that we have been unable to collect from their third-party payors. We initiated the process to seek reimbursement from Medicare at the end of 2013, and we may also decide to provide appropriate notices to patients covered by Medicare to enable us to bill a patient for all or part of a claim that is denied coverage by our Medicare contractor. We offer a comprehensive patient assistance program to support patients whose incomes are below certain thresholds and to allow for extended payment terms, as

necessary, given the patient s economic situation.

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

Certain of our arrangements include multiple deliverables. We analyze multiple-element arrangements based on the guidance in ASC 605-25. Pursuant to the guidance in ASC 605-25, we evaluate multiple-element arrangements to determine (1) the deliverables included in the arrangement and (2) whether the individual deliverables represent separate units of accounting or whether they must be accounted for as a combined unit of accounting. This evaluation involves subjective determinations and requires management to make judgments about the individual deliverables and whether such deliverables are separable from the other aspects of the contractual relationship. Deliverables are considered separate units of accounting provided that: (i) the delivered items have value to the customer on a standalone basis and (ii) if the arrangement includes a general right of return relative to the delivered items and delivery or performance of the undelivered items is considered probable and substantially in our control. In assessing whether an item has standalone value, we consider factors such as the research, development and commercialization capabilities of a third party and the

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availability of the associated expertise in the general marketplace. In addition, we consider whether the other party in the arrangement can use the other deliverables for their intended purpose without the receipt of the remaining elements, whether the value of the deliverable is dependent on the undelivered items and whether there are other vendors that can provide the undelivered elements.

Arrangement consideration that is fixed or determinable is allocated among the separate units of accounting using the relative selling price method. Then, the applicable revenue recognition criteria in ASC 605-25 is applied to each of the separate units of accounting in determining the appropriate period and pattern of recognition. We determine the selling price of a unit of accounting following the hierarchy of evidence prescribed by ASC 605-25. Accordingly, we determine the estimated selling price for units of accounting within each arrangement using vendor-specific objective evidence, or VSOE, of selling price, if available, third-party evidence, or TPE, of selling price if VSOE is not available, or best estimate of selling price, or BESP, if neither VSOE nor TPE is available. We typically use BESP to estimate the selling price, since we generally do not have VSOE or TPE of selling price for our units of accounting under multiple-element arrangements. Determining the BESP for a unit of accounting requires significant judgment. In developing the BESP for a unit of accounting, we consider applicable market conditions and estimated costs. We validate the BESP for units of accounting by evaluating whether changes in the key assumptions used to determine the BESP will have a significant effect on the allocation of arrangement consideration between multiple units of accounting. We recognize arrangement consideration allocated to each unit of accounting when all of the revenue recognition criteria in ASC 605-25 are satisfied for that particular unit of accounting.

At the inception of an arrangement that includes milestone payments, we evaluate whether each milestone is substantive and at risk to both parties on the basis of the contingent nature of the milestone. This evaluation includes an assessment of whether: (i) the consideration is commensurate with either our performance to achieve the milestone or the enhancement of the value of the delivered items as a result of a specific outcome resulting from our performance to achieve the milestone, (ii) the consideration relates solely to past performance and (iii) the consideration is reasonable relative to all of the deliverables and payment terms within the arrangement. We evaluate factors such as the scientific, clinical, regulatory, commercial and other risks that must be overcome to achieve the respective milestone and the level of effort and investment required to achieve the respective milestone in making this assessment. There is considerable judgment involved in determining whether a milestone satisfies all of the criteria required to conclude that a milestone is substantive. Generally, once a substantive milestone has been achieved, we will recognize revenue related to that milestone using a proportional performance model over the period which the unit of accounting is delivered or based on the level of effort expended to date over the total expected effort, whichever is considered the most appropriate measure of performance. Revenue from commercial milestone payments are accounted for as royalties and recorded as revenue upon achievement of the milestone, assuming all other revenue recognition criteria are met.

We also recognize royalty revenue in the period of sale of the related product(s), based on the underlying contract terms, provided that the reported sales are reliably measurable and we have no remaining performance obligations, assuming all other revenue recognition criteria are met.

For some multiple-element arrangements, we are reimbursed for either all or a portion of the research and development costs incurred. We perform research and development services as part of our revenue activities and, therefore, believe such activities are a part of our primary business. Therefore, we record these reimbursements as revenue in the statement of operations using a proportional performance model over the period which the unit of accounting is delivered or based on the level of effort expended to date over the total expected effort, whichever is considered the most appropriate measure of performance.

We expect our revenue to increase over time as we expand our commercial efforts within the United States, and outside the United States pursuant to our Ex-U.S. Commercialization Agreement with F. Hoffmann-La Roche Ltd, dated January 11, 2015. Positive reimbursement decisions from additional commercial third-party payors and government payors, such as Medicare and Medicaid, would eliminate much of the uncertainty around payment and, should allow us to recognize revenue earlier and increase our overall revenue growth and test volume 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.

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Cost of Revenue

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

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

Selling and Marketing Expenses

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

During the three months ended September 30, 2015 and 2014, our selling and marketing expenses represented approximately 56% and 48%, respectively, of our total revenue, and during the nine months ended September 30, 2015 and 2014, selling and marketing expenses represented approximately 55% and 49%, respectively, of our total revenue. We expect our sales and marketing expenses to continue to increase in absolute dollars as we expand our sales force, grow our client service infrastructure, and increase our marketing and medical affairs activities to drive further awareness and adoption of FoundationOne, FoundationOne Heme, and any future products we may develop.

General and Administrative Expenses

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

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

Research and Development Expenses

Our research and development expenses consist primarily of costs incurred for the development of new products and services for use in molecular information, immunotherapy, circulating tumor DNA and companion diagnostics, significant product improvements, clinical trials to evaluate the clinical utility of FoundationOne and FoundationOne Heme, the development of our FoundationCORE knowledgebase, and the development of technology tools such as

ICE 2, the newest version of our online Interactive Cancer Explorer portal, and GeneKit. Costs to develop our technology capabilities are recorded as research and development unless they meet the criteria to be capitalized as internal-use software costs. Our research and development activities include the following costs:

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

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

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Other income (expense), net

Other income (expense) includes interest income and interest expense. Interest income results from interest earned on our cash and cash equivalents. During the three and nine months ended September 30, 2015 and 2014, interest income was not material. Interest expense consists primarily of interest expense on our loan balance and the amortization of debt discounts. Our loan balance was paid in full during the year ended December 31, 2014.

Results of Operations

Comparison of Three Months Ended September 30, 2015 and 2014

	Three Months Ended September 30,		Change	
	2015	2014	$	%
	(in thousands, except percentages)			
Statement of Operations Data:				
Revenue	$ 20,953	$ 16,284	$ 4,669	29%
Related-party revenue from Roche	4,446	164	4,282	2,611%
Total revenue	25,399	16,448	8,951	54%
Costs and expenses				
Cost of revenue	9,068	7,502	1,566	21%
Cost of Roche related-party revenue	1,302		1,302	100%
Selling and marketing	14,267	7,893	6,374	81%
General and administrative	9,199	6,801	2,398	35%
Research and development	12,174	7,230	4,944	68%
Total costs and expenses	46,010	29,426	16,584	56%
Loss from operations	(20,611)	(12,978)	(7,633)	(59%)
Other income (expense):				
Interest income	15	8	7	88%
Interest expense		(10)	10	100%
Total other income (expense), net	15	(2)	17	850%
Net loss	$ (20,596)	$ (12,980)	$ (7,616)	(59%)

Revenue

Total revenue increased to $25.4 million for the three months ended September 30, 2015 from $16.4 million during the three months ended September 30, 2014. Revenue from FoundationOne and FoundationOne Heme tests reported to our ordering physicians increased to $13.7 million for the three months ended September 30, 2015 from $9.8 million for the three months ended September 30, 2014. The increase was driven by our growing test volume in prior periods that resulted in stronger cash collections during the current period. The increase in revenue from our biopharmaceutical customers to $11.7 million for the three months ended September 30, 2015 from $6.7 million for

the three months ended September 30, 2014 resulted from increased business development activity among our new and existing biopharmaceutical customers and a broadening of the services we offer to existing clients, including $4.4 million in revenue from our R&D collaboration agreement with Roche.

During the three months ended September 30, 2015, we reported 8,012 tests to ordering physicians, including 1,012 FoundationOne Heme tests, as compared to 6,428 tests reported during the three months ended September 30, 2014, including 1,036 FoundationOne Heme tests. We also reported 2,676 tests to our biopharmaceutical customers during the three months ended September 30, 2015, as compared to 1,465 tests during the three months ended September 30, 2014.

The average revenue per test for clinical use that met our revenue recognition criteria during the three months ended September 30, 2015 was approximately $3,200. This average revenue per test does not include 2,153 FoundationOne and FoundationOne Heme tests reported during the period for patients covered by Medicare, 71 tests that were reported and not billed, and 3,727 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 2,205 tests reported in prior periods for which revenue was recognized during the three months ended September 30, 2015.

The average revenue per test for clinical use that met our revenue recognition criteria during the three months ended September 30, 2014 was approximately $3,600. This average revenue per test does not include 1,685 FoundationOne and

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FoundationOne Heme tests reported during the period for patients covered by Medicare, 51 tests that were reported and not billed, and 3,135 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 1,130 tests reported in prior periods for which revenue was recognized during the three months ended September 30, 2014.

Our average revenue per test excludes tests for which we have not yet recognized revenue. Because we recognize revenue on a cash basis from most commercial third-party payors and from patients who make co-payments, and our efforts to obtain payment for individual claims can take a substantial amount of time, there is typically a significant lag between the time the test is reported and the time we actually recognize the revenue from such test. As a result, if we were to include tests for which we have not recognized revenue in our average revenue per test calculation for a particular period, it would imply that we will not receive any revenue for such tests. Despite our lack of coverage decisions, we have been reasonably successful in securing reimbursement from many commercial third-party payors for tests reported in prior periods. With respect to tests reported for patients covered by Medicare, we commenced the process of submitting claims to Medicare for these tests in November 2013 and have not yet been reimbursed based on properly processed submissions 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 17,235 and 15,375, respectively, as of September 30, 2015. If commercial third-party payors or government payors agree to pay us for these tests in the future, we will recognize revenue for such tests in the period in which our revenue recognition criteria are met. Any revenue that we receive in respect of these previously reported tests will favorably impact our liquidity and results of operations in future periods.

For our biopharmaceutical customer revenue that was based on a negotiated price per test, the average revenue per test was approximately $3,600 and $3,100 for the three months ended September 30, 2015 and 2014, respectively. We expect this average revenue per test for biopharmaceutical customers to remain fairly consistent with prior periods over time. Approximately $6.6 million and $2.7 million of our biopharmaceutical revenue for the three months ended September 30, 2015 and 2014, respectively, represented payments under contracts with multiple-element arrangements that were not negotiated on a price per test basis.

Cost of Revenue

Cost of revenue increased to $10.4 million, including $1.3 million in costs of Roche related-party revenue, for the three months ended September 30, 2015 from $7.5 million for the three months ended September 30, 2014. This increase was driven by increasing test volumes from our ordering physicians and biopharmaceutical customers. The average cost per test does not differ materially by customer. Additional volume led to higher reagent and consumable costs, additional laboratory personnel-related costs, and higher depreciation expense related to new equipment purchases. During the three months ended September 30, 2015 and 2014, our total cost of revenue represented approximately 41% and 46% 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 $14.3 million for the three months ended September 30, 2015 from $7.9 million for the three months ended September 30, 2014. The increase was primarily due to an increase of $3.5 million in personnel-related costs, including a $0.9 million non-recurring stock-based compensation charge, for new employees in our sales, marketing, client service, and reimbursement departments to support our commercialization efforts, a $1.9 million increase in travel-related and rent and other facilities costs, and a $0.9 million increase in marketing costs.

General and Administrative Expenses

General and administrative expenses increased to $9.2 million for the three months ended September 30, 2015 from $6.8 million for the three months ended September 30, 2014. The increase was primarily due to $1.8 million increase in personnel costs to support and expand our legal, finance, and human resources infrastructure and a $0.4 million combined increase in legal, consulting, audit, and billing fees.

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Research and Development Expenses

Research and development expenses increased to $12.2 million for the three months ended September 30, 2015 from $7.2 million for the three months ended September 30, 2014. The increase was primarily due to a $1.8 million increase in employee and contractor-related expenses, $1.3 million increase in laboratory supply costs, including reagents utilized in research and development activities, a $0.8 million increase in rent and other facilities costs, a $0.6 million increase in laboratory management expenses, and a $0.4 million increase in clinical trial costs.

Other income (expense), net

Other income (expense) includes interest income and interest expense. Interest income was $15,000 and $8,000 for the three months ended September 30, 2015 and 2014, respectively. Interest expense was $0 and $10,000 for the three months ended September 30, 2015 and 2014, respectively. The decrease in interest expense was due to the elimination of our outstanding loan balance, as the loan amount was paid in full in December 2014.

Comparison of Nine Months Ended September 30, 2015 and 2014

	Nine Months Ended September 30,		Change	
	2015	2014	$	%
	(in thousands, except percentages)			
Statement of Operations Data:				
Revenue	$ 58,557	$ 41,715	$ 16,842	40%
Related-party revenue from Roche	8,595	684	7,911	1,157%
Total revenue	67,152	42,399	24,753	58%
Costs and expenses				
Cost of revenue	26,934	19,412	7,522	39%
Cost of Roche related-party revenue	1,302		1,302	100%
Selling and marketing	36,630	20,753	15,877	77%
General and administrative	41,810	18,326	23,484	128%
Research and development	31,118	22,790	8,328	37%
Total costs and expenses	137,794	81,281	56,513	70%
Loss from operations	(70,642)	(38,882)	(31,760)	(82%)
Other income (expense):				
Interest income	31	14	17	121%
Interest expense		(57)	57	100%
Total other income (expense), net	31	(43)	74	172%
Net loss	$ (70,611)	$ (38,925)	$ (31,686)	(81%)

Revenue

Total revenue increased to $67.2 million for the nine months ended September 30, 2015 from $42.4 million during the nine months ended September 30, 2014. Revenue from FoundationOne and FoundationOne Heme tests reported to our ordering physicians increased to $37.2 million for the nine months ended September 30, 2015 from $26.3 million for the nine months ended September 30, 2014. The increase was driven by our growing test volume in prior periods that resulted in stronger cash collections during the current period. The increase in revenue from our biopharmaceutical customers to $30.0 million from $16.1 million for the nine months ended September 30, 2015 and 2014, respectively, resulted from increased business development activity among our new and existing biopharmaceutical customers and a broadening of the services we offer to existing clients, including $8.6 million in revenue from our R&D collaboration with Roche.

During the nine months ended September 30, 2015, we reported 24,712 tests to ordering physicians, including 3,018 FoundationOne Heme tests, as compared to 17,038 tests to ordering physicians reported during the nine months ended September 30, 2014, including 2,699 FoundationOne Heme tests. We also reported 5,723 and 3,577 tests to our biopharmaceutical customers during the nine months ended September 30, 2015 and 2014, respectively.

The average revenue per test for clinical use that met our revenue recognition criteria during the nine months ended September 30, 2015 was approximately $3,300. This average revenue per test does not include 6,531 FoundationOne and

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FoundationOne Heme tests reported during the period for patients covered by Medicare, 192 tests that were reported and not billed, and 9,373 tests that were reported and billed to commercial third-party payors during the period but which were not paid during the period. This average revenue per test includes 2,609 tests reported in prior periods for which revenue was recognized during the nine months ended September 30, 2015.

The average revenue per test for clinical use that met our revenue recognition criteria during the nine months ended September 30, 2014 was approximately $3,500. This average revenue per test does not include 4,432 FoundationOne and FoundationOne Heme tests reported during the period for patients covered by Medicare, 232 tests that were reported and not billed, and 6,353 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 1,395 tests reported in prior periods for which revenue was recognized during the nine months ended September 30, 2014.

Our average revenue per test excludes tests for which we have not yet recognized revenue. Because we recognize revenue on a cash basis from most commercial third-party payors and from patients who make co-payments, and our efforts to obtain payment for individual claims can take a substantial amount of time, there is typically a significant lag between the time the test is reported and the time we actually recognize the revenue from such test. As a result, if we were to include tests for which we have not recognized revenue in our average revenue per test calculation for a particular period, it would imply that we will not receive any revenue for such tests. Despite our lack of coverage decisions, we have been reasonably successful in securing reimbursement from many commercial third-party payors for tests reported in prior periods. With respect to tests reported for patients covered by Medicare, we commenced 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 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 17,235 and 15,375, respectively, as of September 30, 2015. If commercial third-party payors or government payors agree to pay us for these tests in the future, we will recognize revenue for such tests in the period in which our revenue recognition criteria are met. Any revenue that we receive in respect of these previously reported tests will favorably impact our liquidity and results of operations in future periods.

For our biopharmaceutical customer revenue that was based on a negotiated price per test, the average revenue per test was approximately $3,700 and $3,200 for the nine months ended September 30, 2015 and 2014, respectively. We expect this average revenue per test for biopharmaceutical customers to remain fairly consistent with prior periods over time. Approximately $18.0 million and $8.4 million of our biopharmaceutical revenue for the nine months ended September 30, 2015 and 2014, respectively, represented payments under contracts with multiple-element arrangements that were not negotiated on a price per test basis.

Cost of Revenue

Cost of revenue increased to $28.2 million, including $1.3 million in costs of Roche related-party revenue, for the nine months ended September 30, 2015 from $19.4 million for the nine months ended September 30, 2014. This increase was driven by increasing test volumes from our ordering physicians and biopharmaceutical customers. The average

cost per test does not differ materially by customer. Additional volume led to higher reagent and consumable costs, additional laboratory personnel-related costs, and higher depreciation expense related to new equipment purchases. During the nine months ended September 30, 2015 and 2014, our total cost of revenue represented approximately 42% and 46% 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 $36.6 million for the nine months ended September 30, 2015 from $20.8 million for the nine months ended September 30, 2014. The increase was due to an increase of $7.9 million in personnel-related costs, including a $0.9 million non-recurring stock-based compensation charge, for new employees in our sales, marketing, client service, and reimbursement departments to support our commercialization efforts, a $4.1 million increase in marketing costs, a $2.4 million increase in rent and other facilities costs, and a $1.4 million increase in travel-related costs.

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General and Administrative Expenses

General and administrative expenses increased to $41.8 million for the nine months ended September 30, 2015 from $18.3 million for the nine months ended September 30, 2014. The increase was due to $14.4 million in advisor fees related to closing the Roche transaction, a $4.9 million increase in personnel costs to support and expand our legal, finance, and human resources infrastructure, a $2.5 million combined increase in legal, consulting, audit, and billing fees, and a $1.7 million increase in rent and other facilities costs.

Research and Development Expenses

Research and development expenses increased to $31.1 million for the nine months ended September 30, 2015 from $22.8 million for the nine months ended September 30, 2014. The increase was due to a $3.1 million increase in employee and contractor-related expenses, $3.0 million increase in laboratory supply costs, including reagents utilized in research and development activities, a $1.2 million increase in laboratory management expenses, a $0.8 million increase in rent and other facilities costs, and a $0.2 million increase in clinical trial costs.

Other income (expense), net

Other income (expense) includes interest income and interest expense. Interest income was $31,000 and $14,000 for the nine months ended September 30, 2015 and 2014, respectively. Interest expense was $0 and $57,000 for the nine months ended September 30, 2015 and 2014, respectively. The decrease in interest expense was due to the elimination of our outstanding loan balance, as the loan amount was paid in full in December 2014.

Liquidity and Capital Resources

We have incurred losses and negative cash flows from operations since our inception in November 2009, and as of September 30, 2015, we had an accumulated deficit of $212.6 million.

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

As of September 30, 2015, we had cash and cash equivalents of approximately $250.2 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 primarily 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:

	Nine Months Ended September 30,	
	2015	2014
	(in thousands)	
Net cash (used in) provided by:		
Operating activities	$ (52,320)	$ (29,123)
Investing activities	(19,442)	(7,760)
Financing activities	249,844	(749)
Net increase (decrease) in cash and cash equivalents	$ 178,082	$ (37,632)

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Operating Activities

Net cash used in operating activities for the nine months ended September 30, 2015 and September 30, 2014 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 $52.3 million for the nine months ended September 30, 2015 compared to $29.1 million for the nine months ended September 30, 2014. The increase in cash used in operating activities was driven primarily by an increase in net loss of $31.7 million, which included $14.4 million in advisor fees related to closing the Roche transaction, partially offset by an increase in stock-based compensation expense of $4.6 million, a $2.3 million increase in cash provided by changes in working capital, and an increase in depreciation and amortization expense of $1.4 million.

Investing Activities

Net cash used in investing activities for the nine months ended September 30, 2015 was $19.4 million and primarily consisted of purchases of property and equipment. Net cash used in investing activities for the nine months ended September 30, 2014 was $7.8 million and consisted solely of purchases of property and equipment.

Financing Activities

Net cash provided by financing activities for the nine months ended September 30, 2015 was $249.8 million and consisted of $245.4 million of proceeds received from the issuance of common stock related to the Roche transaction, net of issuance costs, as well as $4.4 million from the exercise of stock options during the period. Net cash used in financing activities for the nine months ended September 30, 2014 was $0.7 million and was comprised of $1.1 million in loan principal payments, offset by $0.4 million of proceeds from the exercise of stock options.

Operating Capital Requirements

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

In April 2015, the Roche transaction was consummated and we received $250.0 million in gross proceeds from the sale of 5,000,000 shares of our common stock to Roche at a price of $50.00 per share. Based on our current business plan, we believe our cash and cash equivalents as of September 30, 2015 and anticipated cash flows from operations will be sufficient to meet our anticipated cash requirements over the next 12 months and for the foreseeable future. We may consider raising additional capital to pursue strategic investments or for other reasons, subject to certain consent rights of Roche contained in the Investor Rights Agreement. In the future, we expect our operating and capital expenditures to increase as we increase our headcount, expand our selling and marketing activities and continue to invest in new product offerings. If sales of our products grow, we expect our accounts receivable balance to increase. Any increase in accounts payable and accrued expenses may not completely offset increases in accounts receivable, which could result in greater working capital requirements.

If our available cash balances and anticipated cash flow from operations are insufficient to satisfy our liquidity requirements, including because of lower demand for our products, lower than currently expected rates of reimbursement from commercial third-party payors and government payors, increased competition from other providers of molecular diagnostic tests or other risks described in Part II, Item 1A. Risk Factors in this Quarterly Report and our prior filings with the SEC, we may seek to sell common or preferred equity or convertible debt securities, enter into a credit facility or another form of third-party funding, or seek other debt financing. The sale of equity and convertible debt securities may result in dilution to our stockholders and those securities may have rights senior to those of our common stock. If we raise additional funds through the issuance of equity, convertible debt securities or other debt financing, these securities or other debt could contain covenants that would restrict our operations, and certain of these transactions will be subject to the prior consent of Roche as set forth in the Investor Rights Agreement. Any other third-party funding arrangement could require us to relinquish valuable rights. We may require additional capital beyond our currently anticipated amounts. Additional capital may not be available on reasonable terms, or at all.

These estimates are forward-looking statements and involve risks and uncertainties and actual results could vary materially and negatively as a result of a number of factors, including the factors discussed in Part II, Item 1A. Risk Factors in this Quarterly Report and our prior filings with the SEC. We have based our estimates on assumptions that may prove to be wrong and we could

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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 September 30, 2015 that have changed significantly since December 31, 2014 and the effects such obligations are expected to have on our liquidity and cash flow in future periods. Contractual obligations that were presented in our Annual Report on Form 10-K for the year ended December 31, 2014, but omitted below, represent those that have not changed significantly since that date.

	Total	2015	2016-2017	2018-2019	Thereafter
			(in thousands)		
Operating lease obligations [1]	$ 34,493	$ 1,599	$ 12,818	$ 13,422	$ 6,654

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

Off-Balance Sheet Arrangements

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

Application of Critical Accounting Policies

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

There have been no material changes to our critical accounting policies from those described in Part II, Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations included in our Annual Report on Form 10-K for the year ended December 31, 2014, except as related to multiple-element revenue recognition as a result of the Roche transaction discussed in detail throughout this document.

Item 3. Quantitative and Qualitative Disclosures about Market Risks

There were no material changes during the quarter ended September 30, 2015 with respect to the information appearing in Part II, Item 7A. Quantitative and Qualitative Disclosures About Market Risk, included in our Annual Report on Form 10-K for the year ended December 31, 2014.

Item 4. Controls and Procedures

Management s Evaluation of our Disclosure Controls and Procedures

We maintain disclosure controls and procedures (as defined in Rules 13a-15(e) or 15d-15(e) under the Securities Exchange Act of 1934, as amended, 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.

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Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures as of the end of the period covered by this Quarterly Report. Based on this evaluation, our principal executive officer and principal financial officer have concluded that, as of September 30, 2015, our disclosure controls and procedures were effective at the reasonable assurance level.

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

Changes in Internal Control Over Financial Reporting

During the quarter ended September 30, 2015, there were no changes in our internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15(d)-15(f) promulgated under the Exchange Act, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we are party to litigation arising in the ordinary course of its business. As of September 30, 2015, we were not party to any litigation.

Item 1A. Risk Factors

The following information updates, and should be read in conjunction with, the factors discussed in Part II, Item 1A, Risk Factors in our Quarterly Report on Form 10-Q for the quarters ended March 31, 2015 and June 30, 2015, as filed with the SEC, which could materially affect our business, financial condition or future results. The risks described in our Quarterly Report on Form 10-Q for the quarters ended March 31, 2015 and June 30, 2015, as updated in this Quarterly Report, are not the only risks facing us. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition or operating results.

Risks Relating to Our Business and Strategy

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

In the ordinary course of our business, we and our third-party billing and collections provider collect and store sensitive data, including legally protected health information, personally identifiable information, intellectual property, and proprietary business information owned or controlled by ourselves or our customers, payors, and biopharmaceutical partners. We manage and maintain our applications and data utilizing a combination of on-site systems, managed data center systems, and cloud-based data center systems. We also communicate, and facilitate the exchange of, sensitive patient data to customers through our ICE 2 portal and other applications, such as GeneKit. These applications and data encompass a wide variety of business-critical information including research and development information, commercial information, and business and financial information. We face four primary

risks relative to protecting this critical information, including: unauthorized access risk; inappropriate disclosure risk; inappropriate modification risk; and the risk of our being unable to adequately monitor our controls over the first three risks.

The secure processing, storage, maintenance, and transmission of this critical information is vital to our operations and business strategy, and we devote significant resources to protecting such information. Although we take measures to protect sensitive information from unauthorized access or disclosure, our information technology and infrastructure, and that of our third-party billing and collections provider, may be vulnerable to attacks by hackers or viruses or breached due to personnel error, malfeasance, or other disruptions. Any such breach or interruption could compromise our networks, and the information stored there could be accessed by unauthorized parties, publicly disclosed, lost, or stolen. Any such access, disclosure, or other loss of information could result in governmental investigations, class action legal claims or proceedings, liability under laws that protect the privacy of personal information, such as the Health Insurance Portability and Accountability Act, or HIPAA, and regulatory penalties. Although we have implemented security measures and a formal, dedicated enterprise security program to prevent unauthorized access to patient data, the ICE 2 portal and GeneKit, which are currently accessible through online portals and may, in the future, be accessible through dedicated mobile applications, give broad access to physicians, at which point we lose ability to control access, and there is no guarantee we can absolutely protect our online portals or our mobile applications, from breach. Unauthorized access, loss, or dissemination could also

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disrupt our operations, including our ability to conduct our analyses, provide test results, bill payors or patients, process claims and appeals, provide customer assistance services, conduct research and development activities, collect, process, and prepare company financial information, provide information about our products and other patient and physician education and outreach efforts through our website, manage the administrative aspects of our business, and damage our reputation, any of which could adversely affect our business.

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

In the European Union, or EU, where companies must meet specified privacy and security standards, Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data, commonly referenced as the Data Protection Directive, and EU member state implementations of the Data Protection Directive, require comprehensive information privacy and security protections for consumers with respect to personally identifiable information, collected about them. We have relied on adherence to the U.S. Department of Commerce s Safe Harbor Privacy Principles and compliance with the U.S.-EU and U.S.-Swiss Safe Harbor Frameworks as agreed to and set forth by the U.S. Department of Commerce, and the European Union and Switzerland, which established a means for legitimating the transfer of personally identifiable information by U.S. companies doing business in Europe from the European Economic Area to the U.S. As a result of the October 6, 2015 European Union Court of Justice, or ECJ, opinion in Case C-362/14 (Schrems v. Data Protection Commissioner) regarding the adequacy of the U.S.-EU Safe Harbor Framework, the U.S.-EU Safe Harbor Framework is no longer deemed to be a valid method of compliance with restrictions set forth in the Data Protection Directive (and member states implementations thereof) regarding the transfer of data outside of the European Economic Area. In light of the ECJ opinion in Case C-362/14, we anticipate engaging in efforts to legitimize data transfers from the European Economic Area by the end of the January 2016 grace period. We may be unsuccessful in establishing legitimate means of transferring data from the European Economic Area, we may experience hesitancy, reluctance, or refusal by European or multi-national customers to continue to use our services due to the potential risk exposure to such customers as a result of the ECJ ruling, and we and our customers are at risk of enforcement actions taken by an EU data protection authority until such point in time that we ensure that all data transfers to us from the European Economic Area are legitimized. We may find it necessary to establish systems to maintain EU-origin data in the European Economic Area, which may involve substantial expense and distraction from other aspects of our business.

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

with these regulations in each country, or complying with these various laws could cause us to incur substantial costs or require us to change our business practices and compliance procedures in a manner adverse to our business.

Reimbursement and Regulatory Risks Relating to Our Business

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

In both domestic and many international markets, sales of FoundationOne, FoundationOne Heme or any future molecular information products we develop will depend, in large part, upon the availability of reimbursement from third-party payors. These third-party payors include government healthcare programs such as Medicare, managed care providers, accountable care organizations, private health insurers, and other organizations. In particular, we believe that obtaining a positive national coverage decision and favorable reimbursement rate from the Centers for Medicare & Medicaid Services, or CMS, for FoundationOne and FoundationOne Heme will be a necessary element in achieving material commercial success. Physicians and patients may not order FoundationOne and FoundationOne Heme unless commercial third-party payors and government payors authorize such ordering and

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pay for all, or a substantial portion, of the list price, and certain commercial third-party payors may not agree to reimburse FoundationOne and FoundationOne Heme if CMS or our local Medicare Administrative Contractor, or MAC, does not issue a positive coverage decision.

There is currently no national coverage decision that determines whether and how our tests are covered by Medicare. In the absence of a national coverage determination, local MACs that administer the Medicare program in various regions have some discretion in determining coverage and, therefore, payment for tests. At the time FoundationOne was launched in 2012, our local MAC, National Government Services, 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 for FoundationOne and FoundationOne Heme tests for Medicare patients with dates of service on or after November 1, 2013.

We are submitting claims to National Government Services using a miscellaneous Current Procedural Terminology, or CPT, code. When submitting claims for services or procedures that do not have specific CPT codes, providers may submit those claims using a CPT code, referred to as the miscellaneous CPT code, to provide the means of reporting and tracking services and procedures until a more specific CPT code is established. We are not submitting claims to CMS using stacked CPT codes in the manner currently used in submitting claims to commercial third-party payors. The use of a miscellaneous CPT code for claims submitted to CMS may decrease the likelihood of reimbursement given that a miscellaneous CPT code is a single CPT code that does not represent an identified service or procedure. We have not received any correctly processed 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 both because we will not receive revenue for tests performed but also because physicians may be less likely to order a test for a patient if the test is not subject to a coverage determination such that the patient could ultimately be responsible for all or substantially all of the cost of the test.

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

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

FoundationOne and/or FoundationOne Heme may reduce, suspend, revoke, or discontinue payments or coverage at any time, including those payors that designate FoundationOne and/or FoundationOne Heme as experimental and investigational. The percentage of submitted claims that are ultimately paid, the length of time to receive payment on claims, and the average reimbursement of those paid claims, is likely to vary from period to period.

As a result, there is significant uncertainty surrounding whether the use of products that incorporate new technology, such as FoundationOne and FoundationOne Heme, will be eligible for coverage by commercial third-party payors and government payors or, if eligible for coverage, what the reimbursement rates will be for these 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 diagnostic product will remain approved for reimbursement or that similar or additional diagnostic products will be approved in the future. We have had claims for reimbursement denied by certain commercial third-party payors, in some cases because they have designated FoundationOne and FoundationOne Heme as experimental and investigational. In addition, in March 2015, Palmetto GBA, a Medicare administrative contractor published a final local coverage determination effective July 6, 2015 outlining guidelines for coverage of well-validated comprehensive genomic profiles, which we believe would include FoundationOne, for certain patients diagnosed with non-small cell lung cancer, or NSCLC. However, to date, Palmetto has not issued a formal coverage decision for FoundationOne. In addition, our local MAC, National Government Services, has elected not to follow these guidelines from Palmetto

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GBA and instead issued their own draft local coverage decision, or LCD, for patients with NSCLC on October 1, 2015. Pending the outcome of the finalized LCD, FoundationOne may or may not be covered by National Government Services for this subset or any other subset of patients with cancer. Reimbursement of NGS-based cancer products by commercial third-party payors and government payors may depend on a number of factors, including a payor s determination that FoundationOne, FoundationOne Heme, or products enabled by our molecular information platform are:

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

As a result, our efforts to receive reimbursement on behalf of patients will take a substantial amount of time, and various commercial third-party payors and government payors may never cover or provide adequate authorization for orders or 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 authorization for ordering and reimbursement is unavailable, we may not be able to maintain volume and 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 and payment, it may be difficult for us to collect from the patient, and we may not be successful.

In addition, we are currently considered a non-contracted provider by all but a few 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 with additional commercial third-party payors in the future, the amount of overall reimbursement we receive may decrease if we were to be required to limit test ordering and/or 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. We may also be unable to collect payments from patients beyond that which is paid by their coverage, and will experience lost revenue as a result. In addition, coverage in a specific tumor type such as NSCLC may result

in our inability to accept orders and non-payment for other non-covered tumor types, resulting in lost volume and revenue. Finally, our contracts with current and any additional third-party payors will be subject to renewal, and the renewal process could result in lower reimbursement rates or elimination of reimbursement to us if the parties fail to agree to the terms of renewal and the contract is terminated.

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 utilization and pricing. Utilization and cost control initiatives could decrease the volume of orders and payment that we would receive for any products in the future, which would limit our revenue and profitability.

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

The FDA does not currently regulate most laboratory developed tests, or LDTs, such as FoundationOne and FoundationOne Heme. The FDA historically has taken the position that, although such LDTs are medical devices, it exercises enforcement discretion by not requiring compliance with its regulations. However, 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. In October 2014, the FDA published two draft guidance documents that, if finalized, would implement a regulatory approach for most LDTs. In the draft guidance documents, the FDA stated that it had serious concerns regarding the lack of independent review of the evidence of clinical validity of LDTs and asserted that the requirements under the Clinical Laboratory Improvement Amendments, or CLIA, do not address the clinical validity of any LDT. If published and finalized in the same form, the guidance documents would impose a risk-based, phased-in approach for LDTs similar to the existing *in vitro* diagnostic devices framework.

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

If classified as Class III medical devices, our tests would likely be required to be approved by the FDA under a premarket approval application or PMA, which must be supported by valid scientific evidence to demonstrate a reasonable assurance of safety and effectiveness of the subject product, typically including the results of human clinical trials that demonstrate the clinical utility of our tests. If classified as Class II medical devices, we would need to submit premarket notifications or 510(k)s that demonstrate that our tests are substantially equivalent in technological characteristics and intended use to legally marketed predicate devices. If we are unable to identify an appropriate predicate that is substantially equivalent to our device, we would be required to submit a PMA or a de novo reclassification request.

Until premarket review is required for a test, the LDT could remain on the market while the FDA reviews the applications or premarket notifications for such test. In addition, once a premarket application is submitted to FDA or FDA issues a 510(k) clearance order, the laboratory must also comply with FDA s quality system regulation.

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

The FDA s draft guidance documents for LDTs were published on October 3, 2014, and the FDA accepted comments from the public through February 2, 2015. The FDA will consider such comments before deciding whether to issue final guidance documents implementing the same or a modified version of the regulatory approach described in the draft guidance documents. There is no time frame in which the FDA must issue final guidance documents. Although the FDA included a final guidance on its framework for regulating LDTs as part of a list of priority guidance

documents it intended to issue in fiscal year 2015 (which ended September 2015), the FDA has not yet issued a final guidance. Legislative proposals have been introduced in Congress or publicly circulated, each of which would implement differing approaches to the regulation of LDTs. We cannot predict whether any of these legislative proposals will be enacted into law or the impact such new legal requirements would have on our business.

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

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Risks Relating to Our Financial Condition and Capital Requirements

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

We have historically incurred substantial net losses, including a net loss of $52.2 million in 2014. From our inception in 2009 through September 30, 2015, we had an accumulated deficit of $212.6 million. We expect our losses to continue as a result of ongoing research and development expenses and increased selling and marketing costs. These losses have had, and will continue to have, an adverse effect on our working capital, total assets, and stockholders equity. Because of the numerous risks and uncertainties associated with our research, development, and commercialization efforts, we are unable to predict when we will become profitable, and we may never become profitable. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our inability to achieve and then maintain profitability would negatively affect our business, financial condition, results of operations, and cash flows.

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, or IPO, was registered under the Securities Act of 1933, as amended, pursuant to registration statements on Form S-1 (File No. 333-190226), which was filed with the SEC on July 29, 2013 and amended subsequently and declared effective by the SEC on September 24, 2013, and Form S-1MEF (File No. 333-191333), which was filed with the SEC on September 24, 2013 and automatically effective upon filing.

We raised approximately $110.4 million in net proceeds after deducting underwriting discounts and commissions of approximately $8.5 million and other offering expenses of approximately $3.0 million. There has been no material change in the planned use of proceeds from our IPO as described in our final prospectus filed with the SEC on September 25, 2013 pursuant to Rule 424(b)(4). We invested the funds received in cash equivalents and other short-term investments in accordance with our investment policy, and as of September 30, 2015, the remainder of the net proceeds is included as cash and cash equivalents.

Item 6. Exhibits

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

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SIGNATURES

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

FOUNDATION MEDICINE, INC.

Date: November 3, 2015

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

Date: November 3, 2015

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

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Exhibit

No.	Exhibit Index
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 September 30, 2015 and December 31, 2014 (b) our Condensed Consolidated Statements of Operations and Comprehensive Loss for the Three and Nine Months Ended September 30, 2015 and 2014, (c) our Condensed Consolidated Statements of Cash Flows for the Nine Months Ended September 30, 2015 and 2014 and (d) the Notes to such Condensed Consolidated Financial Statements.

* Filed herewith.
** Furnished herewith.