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Foundation Medicine, Inc.
Form 10-Q
May 03, 2016

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2016

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 (I.R.S. Employer
incorporation or organization) Identification No.)

150 Second Street

Cambridge, MA 02141

(Address of principal executive offices)(Zip code)

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(617) 418-2200

(Registrant's telephone number, including area code)

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

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 ☒ No ☐

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

Large accelerated filer ☐

Accelerated filer ☒

Non-accelerated filer ☐ (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 ☒

The number of shares outstanding of the registrant's common stock, par value of \$0.0001 per share, as of April 29, 2016 was 34,602,596.

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,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “seek,” “should,” “target,” “will,” “would,” or the negative of these comparable terminology. These forward-looking statements include, but are not limited to, statements about:

- our plans or ability to obtain reimbursement for FoundationOne, FoundationOne Heme, and FoundationACT, 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, FoundationOne Heme, and FoundationACT and expand existing or develop new relationships with biopharmaceutical partners;
- our ability to increase the commercial success of FoundationOne, FoundationOne Heme, and FoundationACT;
- 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 plans and ability to expand our laboratory operations;
- 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 FoundationICE, 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 United States Food and Drug Administration, or FDA, regulation of FoundationOne, FoundationOne Heme, and FoundationACT, and the other tests performed using our molecular information platform;
- our ability to protect and enforce our intellectual property rights, including our trade secret protected proprietary rights in our molecular information platform;
- our anticipated cash needs and our estimates regarding our capital requirements and our needs for additional financing, 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. and Roche's ability to successfully market and sell our products outside of the United States;
- 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 Quarterly Report 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. FoundationACT™, FoundationICE™, FoundationCORE™, PatientMatch™, GeneKit™, Precision Medicine Exchange Consortium™, and SmartTrials™ 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.

FOUNDATION MEDICINE, INC.

REPORT ON FORM 10-Q

For the Quarterly Period Ended March 31, 2016

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FOUNDATION MEDICINE, INC.

Condensed Consolidated Balance Sheets

(unaudited)

(In thousands, except share and per share data)

	March 31, 2016	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	\$86,058	\$ 117,763
Marketable securities	127,441	89,607
Accounts receivable, net of allowance of \$171 at March 31, 2016 and December 31, 2015	8,201	7,362
Receivable due from Roche	2,368	403
Inventory	6,743	7,992
Prepaid expenses and other current assets	5,088	6,517
Total current assets	235,899	229,644
Marketable securities	—	24,939
Property and equipment, net	41,104	41,333
Restricted cash	1,395	1,395
Other assets	2,155	678
Total assets	\$280,553	\$ 297,989
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$8,518	\$ 10,469
Accrued expenses and other current liabilities	14,290	12,822
Deferred revenue	1,797	717
Roche related-party deferred revenue	230	3,742
Current portion of deferred rent	2,184	2,146
Total current liabilities	27,019	29,896
Deferred rent, net of current portion and other non-current liabilities	9,801	10,404
Commitments and contingencies (Note 14)		
Stockholders' equity:		
Preferred stock, \$0.0001 par value, 5,000,000 shares authorized; no shares issued and outstanding at March 31, 2016 and December 31, 2015	—	—
Common stock, \$0.0001 par value, 150,000,000 shares authorized; 34,592,610 and 34,513,845 shares issued and outstanding at March 31, 2016 and December 31, 2015, respectively	3	3
Additional paid-in capital	492,667	489,480
Accumulated other comprehensive loss	(14)	(178)

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Accumulated deficit	(248,923)	(231,616)
Total stockholders' equity	243,733	257,689
Total liabilities and stockholders' equity	\$280,553	\$ 297,989

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

FOUNDATION MEDICINE, INC.

Condensed Consolidated Statements of Operations and Comprehensive Loss

(unaudited)

(In thousands, except share and per share data)

	Three Months Ended March 31,	
	2016	2015
Revenue	\$17,423	\$19,295
Related-party revenue from Roche	12,955	—
Total revenue	30,378	19,295
Costs and expenses:		
Cost of revenue	10,028	8,916
Cost of Roche related-party revenue	1,362	—
Selling and marketing	13,793	9,821
General and administrative	9,224	8,842
Research and development	13,456	8,688
Total costs and expenses	47,863	36,267
Loss from operations	(17,485)	(16,972)
Other income:		
Interest income	178	7
Total other income	178	7
Net loss	\$(17,307)	\$(16,965)
Other comprehensive income:		
Unrealized gain on available-for-sale securities	164	—
Total other comprehensive income	164	—
Comprehensive loss	\$(17,143)	\$(16,965)
Net loss per common share, basic and diluted	\$(0.50)	\$(0.59)
Weighted-average common shares outstanding, basic and diluted	34,537,007	28,609,345

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

FOUNDATION MEDICINE, INC.

Condensed Consolidated Statements of Cash Flows

(unaudited)

(In thousands)

	Three Months Ended March 31,	
	2016	2015
Operating activities		
Net loss	\$(17,307)	\$(16,965)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	3,069	2,206
Stock-based compensation expense	3,039	1,688
Amortization of premiums and discounts on marketable securities	78	—
Changes in operating assets and liabilities:		
Accounts receivable	(839)	(779)
Receivable from Roche	(1,965)	—
Inventory	1,249	316
Prepaid expenses and other current assets	1,429	(398)
Other assets	23	(75)
Accounts payable	2,582	(991)
Accrued expenses and other current liabilities	1,664	3,918
Deferred rent and other non-current liabilities	(563)	320
Deferred revenue	1,080	(157)
Roche related-party deferred revenue	(3,512)	—
Net cash used in operating activities	(9,973)	(10,917)
Investing activities		
Purchases of property and equipment	(7,566)	(2,304)
Purchases of marketable securities and other investments	(31,809)	—
Proceeds from maturities of marketable securities	17,500	—
Increase in restricted cash	—	(1,037)
Net cash used in investing activities	(21,875)	(3,341)
Financing activities		
Proceeds from issuance of restricted stock and stock option exercises	143	3,878
Net cash provided by financing activities	143	3,878
Net decrease in cash and cash equivalents	(31,705)	(10,380)
Cash and cash equivalents at beginning of period	117,763	72,080
Cash and cash equivalents at end of period	\$86,058	\$61,700
Supplemental disclosure of non-cash investing and financing activities		
Acquisition of property and equipment included in accounts payable and accrued expenses	\$2,097	\$5,352

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

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 flagship clinical molecular information products, FoundationOne for solid tumors and FoundationOne Heme for blood-based cancers, or hematologic malignancies, including leukemia, lymphoma, myeloma, and advanced 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 develop and commercialize new molecular information products for physicians and biopharmaceutical companies, strengthen its commercial organization, introduce new marketing, education and provider engagement efforts, grow its molecular information knowledgebase, called FoundationCORE, aggressively pursue reimbursement from regional and national third-party payors, publish scientific and medical advances, and foster relationships throughout the oncology community. Examples of new products that the Company is developing include GeneKit, a cloud-based genomics solutions portal for pathologists and FoundationACT, a blood-based (liquid biopsy) assay to measure circulating tumor DNA (“ctDNA”). The Company launched FoundationACT for research use to its biopharmaceutical partners in December 2015 and commercially to ordering physicians in May 2016.

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, 2015 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 1, 2016. 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, 2015.

2. Summary of Significant Accounting Policies

Summary of accounting policies

The significant accounting policies and estimates used in preparation of the condensed consolidated financial statements are described in the Company's audited financial statements as of and for the year ended December 31, 2015, and the notes thereto, which are included in the Company's Annual Report on Form 10-K. 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, 2015.

Recent Accounting Pronouncements

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

In May 2014, the FASB and the International Accounting Standards Board jointly issued Accounting Standards Update No. 2014-09, Revenue from Contracts with Customers ("ASU 2014-09"), which supersedes the revenue recognition requirements in Accounting Standards Codification 605 ("ASC 605") and most industry-specific guidance. The new standard requires that an entity recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The update also requires additional disclosure about the nature, amount, timing, and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. 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 (January 1, 2017). 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.

In February 2016, the FASB issued ASU 2016-02, Leases ("ASU 2016-02"), to increase transparency and comparability among organizations by recognizing lease assets and lease liabilities, including for operating leases, on the balance sheet and disclosing key information about leasing arrangements. ASU 2016-02 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018. The Company is currently evaluating the impact that adopting ASU 2016-02 will have on its consolidated financial statements.

In March 2016, the FASB issued ASU 2016-09, Improvements to Employee Share-Based Payment Accounting ("ASU 2016-09"). ASU 2016-09 simplifies several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. ASU 2016-09 is effective for fiscal years beginning after December 15, 2016, with early adoption permitted. The adoption of ASU 2016-09 is not expected to have a material effect on the Company's consolidated financial statements or disclosures.

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. Immediately following the closing of the transaction, Roche owned approximately 61.3% of the outstanding shares. As of March 31, 2016, Roche's ownership was approximately 60.8% of the outstanding shares. Upon the closing of the transaction, the size of the Board of Directors of the Company ("Board") 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, as amended (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. 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.

The Company identified allocable consideration of approximately \$85,000,000 related to the molecular information platform program, which was allocated to the individual units of accounting based on the best estimate of selling price (“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 BESP.

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 certain 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 \$6,600,000 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 \$12,000,000 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.

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 \$600,000 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.

Roche will reimburse the Company for costs incurred in performing sample profiling and other services relating to Company products sold by Roche in the Roche Territory. These reimbursements will be recognized as revenue in the period the sample profiling or other service has been completed. In addition, Roche will be required to make a one-time milestone payment of \$10,000,000 when the aggregate gross margin on sales of certain of the Company’s products reaches \$100,000,000 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.

Biopharmaceutical Partner

In July 2012, the Company entered into a Master Services Agreement (“Services Agreement”) with a biopharmaceutical partner (“Partner”) to perform sample profiling at the Partner’s request. The Services Agreement established the legal and administrative framework for the partnership between the entities. The Services Agreement also included a right for the Partner to initiate an exclusive negotiation with the Company for the development of a Companion Diagnostic (“CDx”). In March 2014, the Company and Partner expanded the scope of work by executing a Companion Diagnostic Agreement (the “Amended Agreement”), thereby amending the Services Agreement to include the joint development and regulatory approval for a CDx. The Amended Agreement defined the term of the arrangement as the earlier of five years or receipt of certain regulatory approvals of a CDx. The Company concluded that the amendment to the original Services Agreement represented a material modification to the arrangement pursuant to ASC 605 as the Amended Agreement increased total consideration by a significant amount. Additionally, the deliverables under the Amended Agreement changed significantly. At the date of the modification, there was no deferred revenue balance on the consolidated balance sheet related to the original Services Agreement with this Partner.

The Company identified seven deliverables under the Amended Agreement: (i) cross-licenses for access to relevant IP, (ii) obligations to continue to perform sample profiling pursuant to the original Services Agreement, (iii) obligations to perform specific R&D activities for the development of a CDx assay for use in connection with the Partner's product, (iv) obligations to assist in obtaining regulatory approval of the Partner's product at its request, (v) participation on a joint steering committee ("JSC") to manage the overall development of the CDx assay, (vi) obligations to perform analytical validation of the CDx assay, and (vii) obligations to make the CDx assay commercially available, following any required regulatory approval. The obligation to make the CDx assay commercially available is dependent on successful development and regulatory approval. As such, the Company determined that this was a contingent deliverable and therefore arrangement consideration was not allocated to this deliverable.

The Company then determined the following deliverables were separate units of accounting: (i) obligations to continue to perform sample profiling pursuant to the original Services Agreement, (ii) obligations to perform specific R&D activities for the development of a CDx assay for use in connection with the Partner's product and to provide assistance in obtaining regulatory approval of the Partner's product at its request, (iii) obligations to perform analytical validation of the CDx assay, and (iv) obligations to make the CDx assay commercially available, following any regulatory approval obtained. 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 primarily relate to the R&D development activities performed under the Amended Agreement. The Company does not sell the licenses separately as they are closely connected to the R&D development activities and have little value to the Partner without the performance of such activities. The JSC obligations do not have standalone value and are also closely connected to the R&D development activities under the Amended Agreement. The JSC obligations, although considered deliverables under the arrangement, are immaterial in relation to the entire arrangement. Therefore, the licenses and JSC obligations were combined with the R&D development activities, or unit (ii) identified above.

Under the Amended Agreement, the Partner pays a fixed fee for each sample to be profiled; will reimburse the Company for a portion of costs incurred in performing analytical validation of the CDx assay; and will be required to make certain substantive milestone and other payments upon the achievement of specified regulatory and clinical events tied to the development and commercialization of the CDx. The fixed or determinable consideration under the Amended Agreement was allocated to the units of accounting based on the BESP. Consideration allocated to sample profiling is recognized as samples are delivered, which is when the recognition criteria in ASC 605-25 has been satisfied. Consideration allocated to the R&D development activities and the analytical validation work is recognized using the proportional performance method. Both the Company and the Partner expect to negotiate the strategy and specifics of any commercial partnership upon obtaining regulatory approval of a CDx assay, at which point the fair value of any consideration obtained will be assessed.

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-backed securities and treasuries. Cash equivalents are carried at cost, which approximates their fair value.

5. Marketable Securities

The following table summarizes the available-for-sale securities held at March 31, 2016 and December 31, 2015 (in thousands):

	Amortized	Unrealized	Unrealized	
	Cost	Gains	Losses	Fair Value
March 31, 2016				
Description:				
U.S. government agency securities and treasuries	\$ 127,455	\$ 7	\$ (21)) \$ 127,441
Total	\$ 127,455	\$ 7	\$ (21)) \$ 127,441
December 31, 2015				
Description:				
U.S. government agency securities and treasuries	\$ 114,724	\$ —	\$ (178)) \$ 114,546
Total	\$ 114,724	\$ —	\$ (178)) \$ 114,546

The estimated market value of marketable securities by maturity date is as follows (in thousands):

	March 31, 2016	December 31, 2015
Due in one year or less	\$ 127,441	\$ 89,607
Due after one year through two years	—	24,939
Total	\$ 127,441	\$ 114,546

6. Restricted Cash

Restricted cash consists of deposits securing collateral letters of credit issued in connection with the Company's operating leases. As of each of March 31, 2016 and December 31, 2015, the Company had restricted cash of \$1,395,000.

7. 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 each of March 31, 2016 and December 31, 2015, the Company recorded an allowance for doubtful accounts of \$171,000.

Three customer account balances consisting of \$2,368,000, \$1,806,000, and \$1,150,000 were greater than 10% of the total accounts receivable balance representing 22%, 17%, and 11%, respectively, of total accounts receivable at March 31, 2016. Two customer account balances consisting of \$2,423,000 and \$825,000 were greater than 10% of the total accounts receivable balance representing 31% and 11%, respectively, of total accounts receivable at December 31, 2015.

8. Inventory

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

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	March 31, 2016	December 31, 2015
Raw materials	\$ 5,598	\$ 6,604
Work-in-process	1,145	1,388
	\$ 6,743	\$ 7,992

9. Property and Equipment

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

	March 31, 2016	December 31, 2015
Lab equipment	\$ 29,794	\$ 27,883
Computer equipment	10,844	10,542
Software	3,797	3,703
Furniture and office equipment	3,384	3,376
Leasehold improvements	20,154	18,677
Construction in progress	4,220	5,172
	72,193	69,353
Less: accumulated depreciation and amortization	(31,089)	(28,020)
	\$ 41,104	\$ 41,333

Depreciation and amortization expense for the three months ended March 31, 2016 and 2015 was \$3,069,000 and \$2,206,000, respectively. The Company classifies capitalized internal use software in lab equipment, computer equipment and software based on its intended use.

10. Accrued Expenses

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

	March 31, 2016	December 31, 2015
Payroll and employee-related costs	\$ 9,731	\$ 8,375
Professional services	2,569	2,038
Property and equipment purchases	1,001	1,194
Other	989	1,215
	\$ 14,290	\$ 12,822

11. Net Loss per Common Share

Basic net loss per share is calculated by dividing net loss applicable to common stockholders by the weighted-average shares outstanding during the period, without consideration for common stock equivalents. Diluted net loss per share is calculated by adjusting the weighted-average shares outstanding for the dilutive effect of common stock equivalents outstanding for the period, determined using the treasury-stock method and the if-converted method. For purposes of the diluted net loss per share calculation, stock options, and unvested restricted stock are considered to be common stock equivalents, but are excluded from the calculation of diluted net loss per share because their effect would be anti-dilutive. Therefore, basic and diluted net loss per share applicable to common stockholders was the same for all periods presented.

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

	Three Months Ended March 31,	
	2016	2015
Outstanding stock options	1,473,251	1,964,389
Unvested restricted stock	1,038,298	293,211
Total	2,511,549	2,257,600

12. 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 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, marketable securities, restricted cash, accounts receivable, accounts payable, and accrued liabilities. The carrying amount of cash and cash equivalents, restricted cash, 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 March 31, 2016 and December 31, 2015, and indicate the fair value hierarchy of the valuation techniques utilized to determine such fair value (in thousands):

Fair Value Measurement at March 31, 2016				
	Significant			
	Quoted Prices	Other	Significant	
	in Active	Observable	Unobservable	
	Markets	Inputs	Inputs	
	(Level 1)	(Level 2)	(Level 3)	Total
Assets:				
Cash equivalents	\$ 55,630	\$ —	\$ —	\$ 55,630
Marketable securities:				
U.S. government agency securities and treasuries	70,437	57,004	—	127,441
Total assets	\$ 126,067	\$ 57,004	\$ —	\$ 183,071

Fair Value Measurement at December 31, 2015				
	Significant			
	Quoted Prices	Other	Significant	
	in Active	Observable	Unobservable	
	Markets	Inputs	Inputs	
	(Level 1)	(Level 2)	(Level 3)	Total
Assets:				
Cash equivalents	\$ 94,741	\$ 8,400	\$ —	\$ 103,141
Marketable securities:				
U.S. government agency securities and treasuries	54,954	59,592	—	114,546
Total	\$ 149,695	\$ 67,992	\$ —	\$ 217,687

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. Items measured at fair value on a recurring basis during the three months ended March 31, 2016 include marketable securities. The Company did not elect to remeasure any other existing financial assets or liabilities, and did not elect the fair value option for any other financial assets and liabilities transacted during the three months ended March 31, 2016 and 2015.

The fair values of the Company's marketable securities are determined through market and observable sources and have been classified as Level 1 and Level 2. These assets have been initially valued at the transaction price and subsequently valued utilizing third-party pricing services. The pricing services use many inputs to determine value, including reportable trades, benchmark yields, credit spreads, broker/dealer quotes, and other industry and economic events. The Company validates the prices provided by third-party pricing services by reviewing their pricing methods and obtaining market values from other pricing sources. After completing these validation procedures, the Company did not adjust or override any fair value measurements provided by third-party pricing services as of March 31, 2016.

13. Stockholders' Equity

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

	March 31,	December 31,
	2016	2015
Unvested restricted stock	1,038,298	969,758
Common stock options	1,473,251	1,684,783
Shares available for issuance under the 2013 Stock Option and Incentive Plan	3,139,253	1,694,077
Shares available for issuance under the 2013 Employee Stock Purchase Plan	788,503	788,503
	6,439,305	5,137,121

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, 2016 and 2015, the number of shares reserved and available for issuance under the 2013 Stock Plan increased by 1,380,949 and 1,134,996 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.

The terms of stock award agreements, including vesting requirements, are determined by the Board, 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, 2015	959,864
Granted	121,914
Vested	(20,235)
Cancelled	(28,194)
Unvested at March 31, 2016 ⁽¹⁾	1,033,349

⁽¹⁾ Excludes 4,949 shares of unvested restricted stock remaining from the early exercise of stock options.

Total stock-based compensation expense recognized for restricted stock awards was \$2,113,000 and \$346,000, for the three months ended March 31, 2016 and 2015, respectively.

Stock Options

A summary of stock option activity under the 2010 Stock Plan and the 2013 Stock Plan for the three months ended March 31, 2016 is as follows:

		Weighted- Average	Weighted- Average	Remaining Contractual	Aggregate Intrinsic
	Number of Shares	Exercise Price	Term (In Years)		Value (in thousands)
Outstanding as of December 31, 2015	1,684,783	\$ 17.31	7.7		\$ 13,965
Granted	31,216	19.37			
Exercised	(53,585)	\$ 2.67			
Cancelled	(189,163)	\$ 30.99			
Outstanding as of March 31, 2016	1,473,251	\$ 16.14	7.4		\$ 10,267
Exercisable as of March 31, 2016	845,873	\$ 13.38	7.1		\$ 7,178

Certain stock options contain provisions allowing for the early exercise into shares subject to repurchase. At March 31, 2016, 4,949 shares, which were early exercised, remain subject to repurchase by the Company.

The weighted-average fair value of options granted for the three months ended March 31, 2016 was \$11.00 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 \$926,000 and \$1,342,000 during the three months ended March 31, 2016 and 2015, respectively.

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

	Three Months Ended	
	March 31, 2016	2015
Cost of revenue	\$299	\$203
Selling and marketing	796	445
General and administrative	1,306	688

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Research and development	638	352
Total	\$3,039	\$1,688

As of March 31, 2016, unrecognized compensation cost of approximately \$26,019,000 related to non-vested stock options and restricted stock awards is expected to be recognized over weighted-average periods of 2.0 years.

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

	Three Months Ended	
	March 31, 2016 2015	
Expected volatility	59.2 %	66.8 %
Risk-free interest rate	1.9 %	1.49 %
Expected option term (in years)	6.25	6.25
Expected dividend yield	0.0 %	0.0 %

14. 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 March 31, 2016 and December 31, 2015.

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 funded \$1,020,500 in normal tenant improvements.

The Company recorded \$635,000 of rent expense during each of the three months ended March 31, 2016 and 2015 associated with the Headquarters Lease, as amended.

Ten Canal Park Lease

The Company signed a facility lease (the "Ten Canal Lease") on March 11, 2015 for office space at Ten Canal Park in Cambridge, Massachusetts (the "Leased Space"). The Ten Canal 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 began paying rent of \$172,850 per month, commencing in August 2015, for the first year with scheduled escalating rent payments thereafter, and shall receive up to \$2,070,550 from the landlord for tenant improvements to the Leased Space. In connection with the Ten Canal 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 sheets as of March 31, 2016 and December 31, 2015.

The Company recorded \$404,000 and \$82,000 of rent expense during the three months ended March 31, 2016 and 2015, respectively, associated with the Ten Canal Lease.

Legal Matters

From time to time, the Company is party to litigation arising in the ordinary course of its business. As of March 31, 2016, the Company is not currently a party to any litigation.

15. Related Party Transactions

Roche Holdings, Inc. and its affiliates

Revenue from Roche was \$12,955,000 in the three months ended March 31, 2016, which primarily consisted of payments made for the reserved capacity arrangement, access to the Company's molecular information platform, a \$7,000,000 milestone achieved related to the ctDNA platform development program, and the reimbursement of R&D

costs under the R&D Collaboration Agreement. Roche-related revenue represented 42.6% of the Company's total revenue in the three months ended March 31, 2016. Costs of related party revenue from Roche were \$1,362,000 for the three months ended March 31, 2016, which consisted of costs incurred under the molecular information platform program within the R&D Collaboration Agreement. At March 31, 2016, \$2,368,000 was included in total accounts receivable related to this arrangement. There was no revenue from Roche recorded during the three months ended March 31, 2015.

There were no other material Roche-related transactions in the three months ended March 31, 2016 and 2015.

Other related party transactions

The Company recognized revenue of \$31,000 and \$828,000 during the three months ended March 31, 2016 and 2015, respectively, from an arrangement with an entity affiliated with a member of the Company's Board executed in the year ended December 31, 2013. At March 31, 2016 and December 31, 2015, \$0 and \$825,000, respectively, were included in accounts receivable related to this arrangement.

16. Subsequent Events

Roche Holdings, Inc. and its affiliates

On April 6, 2016, the Company entered into a Master IVD Collaboration Agreement (the “IVD Collaboration Agreement”) with Roche. The IVD Collaboration Agreement memorializes in a definitive agreement the terms set forth in that certain Binding Term Sheet for an In Vitro Diagnostics Collaboration, by and between Roche and the Company (the “IVD Term Sheet”), which was entered into in connection with the Company’s strategic collaboration with Roche.

The IVD Collaboration Agreement provides terms for the Company and Roche to collaborate non-exclusively to develop and commercialize in vitro diagnostic versions of certain existing Company products, including FoundationOne and FoundationOne Heme, and future Company products, including those developed under the R&D Collaboration Agreement.

The IVD Collaboration Agreement expires on April 7, 2020, unless earlier terminated as provided therein. Roche also has the right, in its sole discretion, to extend the term of the IVD Collaboration Agreement for additional two year periods of time during any period of time in which Roche continues to hold at least 50.1% of the Company’s capital stock. Either party may terminate the IVD Collaboration Agreement for an uncured breach of the agreement, or for insolvency or bankruptcy.

In addition, on April 6, 2016, the Company and Roche entered into a First Amendment to the R&D Collaboration Agreement, which reduces certain restrictions on the Company’s activities in immuno-oncology and revises certain criteria for the achievement of a development milestone.

Lease Agreement

On April 18, 2016, the Company entered into a Lease Agreement (the “ARE Lease”) with ARE-7030 Kit Creek, LLC (the “Landlord”) for the lease of approximately 48,236 square feet of office and laboratory space located in a building at 7010 Kit Creek Road, Research Triangle Park, North Carolina (the “Premises”). The term of the ARE Lease commenced on April 18, 2016 and expires on January 31, 2022. Upon certain conditions set forth in the ARE Lease, the Company has the option to extend the ARE Lease for two additional five-year terms.

The Company will pay rent of \$86,423 per month, beginning in January 2017, subject to annual 3% increases beginning February 1, 2018, throughout the term of the ARE Lease. The Company is entitled to an abatement of fixed rent for the first nine months of the term. In addition, the Company, at its election, shall receive up to \$1,205,900 from the Landlord for tenant improvements to the Premises, a certain portion of which may be repayable to the Landlord as specified in the ARE Lease.

Concurrent with the execution of the ARE Lease, the Company entered into an asset purchase agreement whereby it purchased certain laboratory equipment and other assets located at the Premises for cash consideration of approximately \$700,000.

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, 2015. 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 flagship clinical molecular information products, FoundationOne for solid tumors and FoundationOne Heme for blood-based cancers, or hematologic malignancies, including leukemia, lymphoma, myeloma, and advanced 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 develop and commercialize new molecular information products for physicians and biopharmaceutical companies, to strengthen our commercial organization, to introduce new marketing, education and provider engagement efforts, to grow our molecular information knowledgebase, called FoundationCORE, to pursue reimbursement from regional and national third-party payors and government payors, to publish scientific and medical advances, and to foster relationships across the oncology community. We believe our molecular information products address a global market opportunity of \$12-15 billion.

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 should obtain molecular information about their patients' unique cancers to determine the optimal course of treatment.

Since our inception in 2009, we have devoted substantially all of our resources to the development of our molecular information platform, the commercialization of FoundationOne and FoundationOne Heme, and the development of new products such as FoundationACT. We have incurred significant losses since our inception, and as of March 31, 2016 our accumulated deficit was \$248.9 million. We expect to continue to incur operating losses over the near term as we expand our commercial operations, conduct clinical trials, and invest in our molecular information platform and additional products, including FoundationACT, which launched commercially to ordering physicians in May 2016.

Recent Developments

In April 2016, we executed a lease for approximately 48,236 square feet of office and laboratory space located in North Carolina, or the Lease. The term of the Lease commences on April 18, 2016 and expires on January 31, 2022. Upon certain conditions set forth in the Lease, we have the option to extend the Lease for two additional five-year terms. We are still evaluating the testing services to be performed at the North Carolina facility, but we intend to obtain applicable licensure and accreditation before that facility becomes operational. Concurrent with the execution of the Lease, the Company entered into an asset purchase agreement whereby it purchased certain laboratory equipment and other assets for cash consideration of approximately \$0.7 million.

Pursuant to our Ex-U.S. Commercialization Agreement with Roche, as of April 7, 2016, Roche has the exclusive right to commercialize FoundationOne, FoundationOne Heme, any clinical diagnostic products developed under our R&D Collaboration Agreement with Roche, including FoundationACT, and any other products upon mutual agreement, in each case outside of the United States to the extent Roche has not elected to exclude any countries from its territory. We will continue to remain solely responsible for commercialization of our products and services within the United States.

In January 2016, we announced a three-way collaboration with Horizon Healthcare Services and Clinical Outcomes Tracking and Analysis (COTA) to advance precision medicine, improve clinical outcomes, and deliver enhanced value to the healthcare system in the treatment of patients with metastatic non-small cell lung cancer, or NSCLC. Together, the organizations initiated a prospective clinical study measuring changes in survival benefit and total cost savings achieved among patients with previously untreated

metastatic NSCLC who undergo comprehensive genomic profiling with FoundationOne versus other assays. As part of the study design, Horizon Healthcare Services will provide a certain number of its members who participate in the study with coverage for FoundationOne.

We launched our third comprehensive genomic profiling product, FoundationACT (Assay for Circulating Tumor DNA), to our biopharmaceutical partners for research use in December 2015 and commercially to ordering physicians in May 2016. FoundationACT is a blood-based (liquid biopsy) assay to measure ctDNA. We believe FoundationACT will become an important molecular information solution for oncologists because it will provide a new option for comprehensive genomic profiling when tissue biopsy is not feasible. By analyzing cell-free DNA isolated from a patient's blood, we can identify clinically relevant genomic alterations in the cell-free DNA that is ctDNA and match these alterations to targeted therapies and clinical trials.

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, FoundationOne Heme, or FoundationACT 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, FoundationOne Heme, and FoundationACT, in the clinical setting and increase the volume of tests and other services enabled by our molecular information platform that we perform for our biopharmaceutical customers.

For the majority of 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. As of March 31, 2016, we were not a participating provider in any state Medicaid program, and therefore, did not have coverage determinations under which our tests were covered by these Medicaid programs. As of March 31, 2016, we were a participating provider in the Medicare program, but we did not have a coverage determination within the jurisdiction where our operational laboratory facility is located. At the end of 2013, we began the process of submitting claims for our tests to Medicare. We may also negotiate rates with patients, if the patient is responsible for payment. Our efforts in obtaining reimbursement based on individual claims, including pursuing appeals or reconsiderations of claim denials, take a substantial amount of time, and bills may not be paid for many months or at all. Furthermore, if a third-party payor denies coverage after final appeal, payment may not be received at all.

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

We currently have an operating laboratory facility located in Cambridge, Massachusetts, and we are in the process of establishing an operating laboratory facility in the Research Triangle Park, North Carolina. There are currently no national coverage determinations that establish whether and how our tests are covered by Medicare. In the absence of national coverage determinations, local Medicare Administrative Contractors, or MACs, that administer the Medicare program in various regions, have some discretion in determining coverage and payment for tests. For example, several MACs, including Palmetto GBA, or Palmetto, the MAC covering the laboratory in North Carolina that we are now establishing, have issued final local coverage determinations, or LCDs, to cover well-validated comprehensive genomic profiles for a subset of NSCLC patients. The Palmetto LCD became effective July 2015, and specifically included FoundationOne as of October 2015. The local MAC for our Cambridge laboratory, National Government Services, has not elected to follow the same standards for determining coverage. In February 2016, National Government Services announced a final LCD effective April 1, 2016, to provide coverage for hotspot tests of 5 to 50 genes for patients with metastatic NSCLC. We do not believe this LCD reflects coverage for our validated comprehensive genomic profiling products, which includes comprehensive analysis of greater than 50 genes and all classes of alterations, and we will continue to seek a positive coverage

determination from National Government Services, which, if obtained, may establish payment for the Medicare claims we submit to this local MAC covering our laboratory in Massachusetts.

Following discussions with NHIC, Corp., the predecessor to National Government Services, we agreed to not submit claims for FoundationOne tests provided to Medicare patients while this MAC assessed the appropriate coding, coverage, and payment for FoundationOne as a whole. To accommodate this MAC's 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 have not recognized any revenue from Medicare for our tests to date. As a result, our net loss is higher than if we were recognizing revenue from the sale of our tests for patients covered by Medicare. As of March 31, 2016, National Government Services has either denied the claims that we have submitted or not processed and reimbursed us for any of the claims in a manner that we believe is consistent with applicable processing guidelines. We are in the process of appealing these unpaid claims. In the future, a MAC assigned to the jurisdiction in which one of our operational laboratory facilities is located may issue a negative coverage determination for one or more of our tests that would apply to future claims or may defer processing a claim pending a coverage or payment determination. If a claim is paid by a MAC assigned to the jurisdiction in which one of our operational laboratory facilities is located, either upon acceptance of the claim or following a successful appeal of a denied claim, we will generate revenue from Medicare for our testing. It is possible that, once our new laboratory in North Carolina is operational, claims for tests submitted by that location will be reimbursed by Palmetto, the MAC assigned to that jurisdiction. FoundationOne and FoundationOne Heme tests for patients covered by Medicare represented approximately 30% of total tests reported to physicians in the United States during each of the three months ended March 31, 2016 and 2015.

We expect that our current lack of significant coverage decisions and the general uncertainty around reimbursement for our tests will continue to negatively impact our revenue and earnings, both because we will not recognize revenue for tests performed, particularly if our test volumes 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 our 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 March 31, 2016, we had cash, cash equivalents, and marketable securities of approximately \$213.5 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 and marketable security 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 tests 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 Medicare. 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 Financial Accounting Standards Board, or FASB, Accounting Standards Codification Topic 605-25, Revenue Recognition-Multiple-Element Arrangements, or 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 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. 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 domestic revenue to increase over time as we expand our commercial efforts within the United States. 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 could allow us to recognize revenue earlier and potentially increase our overall revenue growth and test volume growth from ordering physicians

within the United States. Outside the United States, volume may decrease in the short-term as commercialization efforts under the Ex-U.S. Commercialization Agreement with Roche get underway. However, we expect volume outside the United States to increase and therefore over time, revenues under the Ex-U.S. Commercialization Agreement are expected to increase as well. 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 exceed revenue from our biopharmaceutical customers, given the higher percentage of patients with cancer who are treated outside of clinical trial settings.

Cost of Revenue and Operating Expenses

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

Cost of Revenue

Cost of revenue consists of personnel expenses, including salaries, bonuses, employee benefits and stock-based compensation expenses, cost of laboratory supplies, depreciation of laboratory equipment and amortization of leasehold improvements, shipping

costs, and certain allocated overhead expenses. We expect these costs will increase in absolute dollars as we increase our sales volume, but will decrease as a percentage of revenue over time as our sales increase and we gain operating efficiencies.

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

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 March 31, 2016 and 2015, our selling and marketing expenses represented approximately 45% and 51%, respectively, of our total revenue. We expect our selling 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, FoundationACT, 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, 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. These costs include additional legal and accounting expenses, 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 and enhanced products and services including FoundationACT, immunotherapy testing, companion diagnostic development, significant product improvements, clinical trials to evaluate the clinical utility of our tests, the development of our FoundationCORE knowledgebase, and various technology applications such as FoundationICE, Patient Match, GeneKit, and SmartTrials. Costs to develop our technology capabilities are recorded as research and development unless they meet the criteria to be capitalized as internal-use software costs. Our research and development activities include the following costs:

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

- clinical trials;
- laboratory supplies; and
- allocated overhead expenses.

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

Interest Income

Interest income consists of interest earned on our cash, cash equivalents, and marketable securities. During the three months ended March 31, 2016 and 2015, interest income was \$0.2 million and \$7,000, respectively.

Results of Operations

Comparison of Three Months Ended March 31, 2016 and 2015

	Three Months Ended		Change	
	March 31, 2016	2015	\$	%
(in thousands, except percentages)				
Statement of Operations Data:				
Revenue	\$17,423	\$19,295	\$(1,872)	(10)%
Related-party revenue from Roche	12,955	—	12,955	100 %
Total revenue	30,378	19,295	11,083	57 %
Costs and expenses				
Cost of revenue	10,028	8,916	1,112	12 %
Cost of Roche related-party revenue	1,362	—	1,362	100 %
Selling and marketing	13,793	9,821	3,972	40 %
General and administrative	9,224	8,842	382	4 %
Research and development	13,456	8,688	4,768	55 %
Total costs and expenses	47,863	36,267	11,596	32 %
Loss from operations	(17,485)	(16,972)	(513)	(3)%
Other income:				
Interest income	178	7	171	2443 %
Total other income	178	7	171	2443 %
Net loss	\$(17,307)	\$(16,965)	\$(342)	(2)%

Revenue

Total revenue increased to \$30.4 million for the three months ended March 31, 2016 from \$19.3 million during the three months ended March 31, 2015. Revenue from tests reported for our ordering physicians decreased to \$10.2 million for the three months ended March 31, 2016 from \$11.1 million for the three months ended March 31, 2015. The decrease in clinical revenue is primarily due to the impact of moving in-network with a large national payor for stage IV NSCLC testing, which causes us to no longer receive payments for other indications that were previously paid by this large national payor on a stacked code basis. We are continuing to work towards broader reimbursement coverage over time, which may include payment for other indications in the future. The increase in revenue from our biopharmaceutical customers to \$20.2 million from \$8.2 million in the three months ended March 31, 2016 and 2015, respectively, was driven by the achievement of a \$7.0 million milestone related to the ctDNA platform development program under the Roche R&D Collaboration Agreement.

During the three months ended March 31, 2016, we reported 8,985 tests to ordering physicians, including 1,028 FoundationOne Heme tests, as compared to 7,854 tests reported during the three months ended March 31, 2015, including 969 FoundationOne Heme tests. We also reported 2,622 and 1,596 tests to our biopharmaceutical customers during the three months ended March 31, 2016 and 2015, respectively.

The average revenue per test for clinical use that met our revenue recognition criteria during the three months ended March 31, 2016 was approximately \$3,100. This average revenue per test does not include 2,464 FoundationOne and FoundationOne Heme tests reported during the period for patients covered by Medicare, 77 tests that were reported and not billed, and 5,029 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 1,925 tests reported in prior periods for which revenue was recognized during the three months ended March 31, 2016.

The average revenue per test for clinical use that met our revenue recognition criteria during the three months ended March 31, 2015 was approximately \$3,400. This average revenue per test does not include 2,022 FoundationOne and FoundationOne Heme tests reported during the period for patients covered by Medicare, 65 tests that were reported and not billed, and 4,127 tests that were reported and billed to commercial third-party payors during the period but were not paid during the period. This average revenue per test includes 1,621 tests reported in prior periods for which revenue was recognized during the three months ended March 31, 2015.

Our average revenue per test excludes tests for which we have not yet recognized revenue. Because we recognize revenue on a cash basis from commercial third-party payors and from patients who make co-payments, 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, 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 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 remain consistent with 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 22,513 and 20,087, respectively, as of March 31, 2016. If commercial third-party payors or government payors agree to pay us for these tests in the future, we will recognize revenue for such tests in the period in which our revenue recognition criteria are met. Any revenue that we receive in respect of these previously reported tests will favorably impact our liquidity and results of operations in future periods.

For our biopharmaceutical customer revenue that was based on a negotiated price per test, the average revenue per test was approximately \$3,400 and \$3,900 for the three months ended March 31, 2016 and 2015, respectively. We expect this average revenue per test for biopharmaceutical customers to remain fairly consistent with prior periods over time. Approximately \$17.8 million and \$4.2 million of our biopharmaceutical revenue for the three months ended March 31, 2016 and 2015, respectively, represented payments under contracts with multiple-element arrangements that were not negotiated on a price per test basis.

Cost of Revenue

Total cost of revenue, including the cost of Roche related-party revenue, increased to \$11.4 million for the three months ended March 31, 2016 from \$8.9 million for the three months ended March 31, 2015. 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, facilities costs, and higher depreciation expense related to new equipment purchases. During the three months ended March 31, 2016 and 2015, our total cost of revenue represented approximately 37% 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 \$13.8 million for the three months ended March 31, 2016 from \$9.8 million for the three months ended March 31, 2015. The increase was primarily due to an increase of \$2.4 million in personnel-related costs for employees in our sales, marketing, client service, and reimbursement departments to support our commercialization efforts, a \$1.2 million increase in travel-related and rent and other facilities costs, and a \$0.4 million increase in marketing costs.

General and Administrative Expenses

General and administrative expenses increased to \$9.2 million for the three months ended March 31, 2016 from \$8.8 million for the three months ended March 31, 2015. The increase was primarily due to a \$0.9 million increase in

personnel costs to support and expand our legal, finance, and human resources infrastructure and a \$0.5 million increase in combined consulting, audit, and billing fees, partially offset by a \$1.0 million decrease in legal fees compared to the prior period in which legal fees were higher than normal due to the closing of the Roche transaction.

Research and Development Expenses

Research and development expenses increased to \$13.5 million for the three months ended March 31, 2016 from \$8.7 million for the three months ended March 31, 2015. The increase was primarily due to a \$3.0 million increase in employee and contractor-related expenses, a \$0.7 million increase in laboratory management expenses, a \$0.7 million increase in rent and other facilities costs, and a \$0.4 million increase in laboratory supply costs, including reagents utilized in research and development activities.

Interest Income

Interest income was \$178,000 and \$7,000 for the three months ended March 31, 2016 and 2015, respectively.

Liquidity and Capital Resources

We have incurred losses and negative cash flows from operations since our inception in November 2009, and as of March 31, 2016, we had an accumulated deficit of \$248.9 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 our existing tests 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, none of our existing tests are currently covered by Medicare, and Medicare has either denied the claims that we have submitted or not processed and reimbursed us for any of these claims in a manner that we believe is consistent with applicable processing guidelines. If commercial third-party payors or government payors agree to pay us for any of these tests in the future, we would recognize revenue for any such tests in the period in which our revenue recognition criteria are met.

As of March 31, 2016, we had cash, cash equivalents, and marketable securities of approximately \$213.5 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 U.S. government agency securities, U.S. treasuries, and money market mutual funds consisting of U.S. government-backed securities and treasuries.

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

Cash Flows

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

	Three Months Ended	
	March 31, 2016	2015
	(in thousands)	
Net cash (used in) provided by:		
Operating activities	\$(9,973)	\$(10,917)
Investing activities	(21,875)	(3,341)
Financing activities	143	3,878
Net decrease in cash and cash equivalents	\$(31,705)	\$(10,380)

Operating Activities

Net cash used in operating activities in all periods resulted primarily from our net losses adjusted for non-cash charges and changes in components of working capital. The net cash used in operating activities was \$10.0 million for the three months ended March 31, 2016 compared to \$10.9 million for the three months ended March 31, 2015. The

decrease in cash used in operating activities was driven primarily by a \$1.4 million increase in stock-based compensation expense and a \$0.9 million increase in depreciation and amortization expense, partially offset by a \$1.0 million increase in cash utilized to support working capital requirements between the respective periods.

Investing Activities

Net cash used in investing activities for the three months ended March 31, 2016 was \$21.9 million and consisted of purchases of marketable securities and other investments of \$31.8 million, partially offset by \$17.5 million in proceeds received from maturities of marketable securities and \$7.6 million in purchases of property and equipment. Net cash used in investing activities for the three months ended March 31, 2015 was \$3.3 million and consisted of \$2.3 million in purchases of property and equipment and a \$1.0 million increase in restricted cash related to a letter of credit issued in connection with our execution of the lease for Ten Canal Park.

Financing Activities

Net cash provided by financing activities for the three months ended March 31, 2016 and 2015 was \$0.1 million and \$3.9 million, respectively, and consisted solely of proceeds received 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, FoundationOne Heme, and FoundationACT, 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 March 31, 2016 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 utilize our available capital resources sooner than we currently expect. If we cannot expand our operations or otherwise capitalize on our business opportunities because we lack sufficient capital, our business, financial condition, and results of operations could be materially adversely affected.

Contractual Obligations and Commitments

During the three months ended March 31, 2016, there were no material changes to our contractual obligations and commitments described under “Management’s Discussion and Analysis of Financial Condition and Results of Operations” included in our Annual Report on Form 10-K for the year ended December 31, 2015.

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, 2015.

Item 3. Quantitative and Qualitative Disclosures about Market Risks

There were no material changes during the quarter ended March 31, 2016 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, 2015.

Item 4. Controls and Procedures

Management’s Evaluation of our Disclosure Controls and Procedures

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

Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures as of the end of the period covered by this Quarterly Report. Based on this evaluation, our principal executive officer and principal financial officer have concluded that, as of March 31, 2016, our disclosure controls and procedures were effective at the reasonable assurance level.

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

Changes in Internal Control Over Financial Reporting

During the quarter ended March 31, 2016, 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 March 31, 2016, 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 I, Item 1A, “Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2015, which could materially affect our business, financial condition or future results. The risks described in our Annual Report on Form 10-K, as updated in this Quarterly Report, are not the only risks we face. 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

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

We believe our commercial success is dependent upon our ability to successfully market and sell our first molecular information products, FoundationOne for solid tumors, FoundationOne Heme for blood-based cancers, or hematologic malignancies, and FoundationACT, our blood-based (liquid biopsy) assay to measure ctDNA, which we launched commercially to ordering physicians in May 2016, to physicians in clinical practice, to continue to expand our current relationships and develop new relationships with biopharmaceutical partners, and to develop and commercialize new molecular information products. The demand for our existing products may decrease or may not continue to increase at historical rates for a number of reasons, including among others increased competition from companies that offer similar molecular diagnostic tests. In addition, FoundationOne and FoundationOne Heme have coverage decisions from only a few commercial third-party payors and do not have coverage contracts with or coverage decisions from most commercial third-party payors or any government payors, including Medicare. FoundationACT does not yet have coverage contracts with or coverage decisions from any commercial third-party payors or any government payors. Certain commercial third-party payors have declined to reimburse FoundationOne and FoundationOne Heme because they have designated our products as experimental and investigational. This designation is customarily assigned to a product or service by a third-party payor pending the development of clinical information deemed sufficient to support a positive coverage decision. During this assessment period our products do not have the benefit of a positive coverage decision or a coverage contract from these third-party payors, resulting, in the aggregate, in a material loss of revenue to us. We have generally experienced revenue growth from the sale of each of FoundationOne and FoundationOne Heme to physicians since their formal commercial launches in June 2012 and December 2013, respectively. We may not be able to grow our revenues or maintain existing revenue levels for a number of reasons, including because increased competition and lack of positive coverage decisions or coverage contracts from government or third-party payors may make it less likely that physicians will order our products.

Our biopharmaceutical partners may decide to decrease or discontinue their use of our molecular information platform due to changes in research and product development plans, failures in their clinical trials, financial constraints, or utilization of internal molecular testing resources or molecular tests performed by other parties, which are circumstances outside of our control. In addition, biopharmaceutical companies may decline to do business with us or decrease or discontinue their use of our molecular information platform due to our broad strategic collaboration with certain affiliates of Roche and the fact that Roche is our largest stockholder and beneficially owns a majority of our

outstanding stock. In addition to reducing our revenue, if our biopharmaceutical partners decide to decrease or discontinue their use of our molecular information platform, this may reduce our exposure to early stage research that facilitates the incorporation of newly developed information about cancer into our molecular information platform and products.

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

If our sole operational laboratory facility becomes damaged or inoperable, if we are required to vacate our laboratory facility, or if we are delayed in obtaining or unable to obtain additional laboratory space, our ability to conduct our genomic analyses, pursue our research and development efforts or our companion diagnostics partnerships, and fulfill our contractual obligations may be jeopardized.

We currently derive substantially all of our revenue from tests conducted at a single laboratory facility located in Cambridge, Massachusetts. Our facility and equipment could be harmed or rendered inoperable by natural or man-made disasters, including war,

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

In April 2016, we executed a lease for an additional laboratory facility in North Carolina. Establishing a laboratory facility, and transitioning some of our testing operations to this new laboratory, could disrupt overall laboratory operations, resulting in our inability to meet customer turnaround time expectations. Establishing this new laboratory facility could be delayed, including delays caused by operational issues or delays associated with the transfer of current licenses or the issuance of new licenses or other approvals necessary to allow our clinical laboratory operations to commence at the new facility. Any delay could result in slower realization of laboratory efficiencies anticipated from operating an additional laboratory facility. Adverse consequences resulting from a delay in establishing this new laboratory or an interruption of our overall laboratory operations, could harm relationships with our customers and regulators, and our reputation, and could affect our ability to generate revenue.

We may also construct, acquire or enter into relationships with third parties to procure additional laboratory space inside and outside the United States to support our existing and new tests. Our Ex-U.S. Commercialization Agreement with Roche contemplates that we will provide additional laboratory space in Europe and Asia to perform genomic sequencing for FoundationOne and FoundationOne Heme in those geographies. In addition, our R&D Collaboration Agreement with Roche contemplates that we will collaborate with Roche on multiple programs related to the development of products and services for use in molecular information, immunotherapy, ctDNA, and companion diagnostics. If we are unable to obtain or are delayed in obtaining new laboratory space to support these commercialization and development efforts, we could fail to meet certain contractual obligations and agreed upon timelines with certain of our biopharmaceutical partners, including Roche, or provide existing products and develop and launch new products in certain territories, which could result in harm to our business and reputation, and adversely affect our business, financial condition and results of operations.

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

New product development involves a lengthy and complex process, and we may be unable to successfully commercialize FoundationACT or any other products we may develop on a timely basis, or at all, and the development and commercialization of additional products may negatively affect the commercialization of existing products.

FoundationACT, our blood-based (liquid biopsy) assay to measure ctDNA, which we launched commercially to ordering physicians in May 2016, will take time to successfully commercialize, and there can be no assurance that this product will be successful in the evaluation of cancers for a variety of technical and market reasons. Our future molecular information products, which are in various stages of early development, will take time to develop and commercialize, if we are able to commercialize them at all. There can be no assurance that our new products will be capable of reliably identifying relevant genomic alterations in various forms of cancer. Before we can commercialize

any new products, we will need to expend significant funds in order to:

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

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

- failure of the product to perform as expected at the research or development stage;
- lack of validation data; or
- failure to demonstrate the clinical utility of the product.

As we develop products, we will have to make significant investments in product development, marketing, and selling resources. In addition, the commercialization of newer products, such as FoundationACT, may also negatively affect the sales of

existing products, such as FoundationOne or FoundationOne Heme, where the diagnostic applications overlap, to the extent physicians decide to order the newer product in lieu of our existing products.

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

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

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

We have limited experience in marketing and selling FoundationOne Heme, which launched in December 2013, and FoundationACT, which was launched for research use to our biopharmaceutical partners in December 2015 and commercially to ordering physicians in May 2016. We may not be able to market, sell, or distribute our existing products or other products we may develop effectively enough to support our planned growth.

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

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

Pursuant to our Ex-U.S. Commercialization Agreement with Roche, as of April 2016, Roche has the exclusive right to commercialize FoundationOne, FoundationOne Heme, any clinical diagnostic products developed under our R&D Collaboration Agreement with Roche, including FoundationACT, and any other products upon mutual agreement, in each case outside of the United States to the extent Roche has not elected to exclude any countries from its territory. Subject to satisfaction of certain performance milestones, the Ex-U.S. Commercialization Agreement will remain in effect for five years and may be extended by Roche for additional two-year periods. Roche has the right to terminate the agreement without cause upon six months' written notice after the initial five year term, and either party may terminate the agreement in the event of breach by the other party. During the term of the Ex-U.S. Commercialization Agreement, we are relying on Roche's efforts to sell and market FoundationOne, FoundationOne Heme, FoundationACT, and potentially other future molecular information products outside of the United States, and if Roche's sales and marketing efforts are not successful, we may not achieve significant market acceptance of our

products outside the United States, which would materially and adversely impact our business operations.

For any jurisdictions outside of the United States that Roche elects to exclude from its territory, if we believe a significant market opportunity for our products exists, we intend to enlist distribution partners and local laboratories to assist with sales, distribution, and customer support. We may not be successful in finding, attracting, and retaining distribution partners or laboratories, or we may not be able to enter into such arrangements on favorable terms. Sales practices utilized by our distribution partners that are locally acceptable may not comply with sales practices standards required under United States laws that apply to us, which could create additional compliance risk. If these additional sales and marketing efforts are not successful, we may not achieve significant market acceptance for our products in these markets, which could harm our business.

Compliance with changing European privacy laws could require us to incur significant costs or experience significant business disruption and failure to so comply could result in an adverse impact on our business.

In Europe, 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, or the Directive, and Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector (as amended by Directive 2009/136/EC), or the ePrivacy-Directive, has

required European Union, or EU, member states to implement data protection laws to meet strict privacy requirements. Violations of these requirements can result in administrative measures, including fines, or criminal sanctions.

Among other requirements, the Directive regulates transfers of personally identifiable data that is subject to the Directive, or Personal Data, to third countries, such as the United States, that have not been found to provide adequate protection to such Personal Data. We have in the past relied upon 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 Personal Data by data controllers in the European Economic Area, or the EEA, to the United States. 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 requirements set forth in the Directive (and member states' implementations thereof) regarding the transfer of Personal Data outside of the EEA.

Recently, it was announced that negotiators from Europe and the United States reached political agreement on a successor to the Safe Harbor framework that will be referred to as the EU-US Privacy Shield. However, it is likely to be months before all of the details regarding EU-US the Privacy Shield program are finalized and a procedure is introduced to allow interested companies to participate in the program. In addition, there continue to be concerns about whether the EU-US Privacy Shield might face additional challenges. On April 13, 2016, the Article 29 Working Party, a body made up of a representative from the data protection authority of each EU member State, expressed "strong concerns" about the adequacy of the EU-US Privacy Shield. In its draft adequacy decision, the Working Party noted that the framework does not incorporate some of the key principles of the EU data protection regime. Accordingly, it is quite possible that the EU-US Privacy Shield may face further challenges and undergo some substantive changes before companies are able to register and participate in it. While the details regarding the Privacy Shield program continue to evolve, we will continue to face uncertainty as to whether our efforts to comply with our obligations under European privacy laws will be sufficient. If we are investigated by a European data protection authority, we may face fines and other penalties. Any such investigation or charges by European data protection authorities could have a negative effect on our existing business and on our ability to attract and retain new customers.

In light of the ECJ opinion in the Schrems case, we anticipate undertaking efforts to conform transfers of Personal Data from the EEA based on current regulatory obligations, the guidance of data protection authorities, and evolving best practices. Despite these efforts, we may be unsuccessful in establishing conforming means of transferring such data from the EEA, including due to ongoing legislative activity, which may vary the current data protection landscape.

We may also 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 in the Schrems case and the current data protection obligations imposed on them by certain data protection authorities. Such customers may also view any alternative approaches to compliance as being too costly, too burdensome, too legally uncertain or otherwise objectionable and therefore decide not to do business with us.

We and our customers are at risk of enforcement actions taken by certain EU data protection authorities until such point in time that we may be able to ensure that all transfers of Personal Data to us from the EEA are conducted in compliance with all applicable regulatory obligations, the guidance of data protection authorities, and evolving best practices. We may find it necessary to establish systems to maintain Personal Data originating from the EU in the EEA, which may involve substantial expense and may cause us to need to divert resources from other aspects of our business, all of which may adversely affect our business.

The Directive will be replaced in time with the recently adopted European General Data Protection Regulation, which is expected to enter into force in 2018, and which will impose additional obligations and risk upon our business and which will increase substantially the penalties to which we could be subject in the event of any non-compliance, including fines of up to 10,000,000 Euros or up to 2% of the total worldwide annual turnover for certain comparatively minor offenses, or up to 20,000,000 Euros or up to 4% of the total worldwide annual turnover for more serious offenses. We may incur substantial expense in complying with the new obligations to be imposed by the European General Data Protection Regulation and we may be required to make significant changes in our business operations, all of which may adversely affect our revenues and our business overall.

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

We currently have limited international operations, but our business strategy incorporates plans for significant international expansion through our collaboration with Roche. Pursuant to our Ex-U.S. Commercialization Agreement with Roche, as of April 2016, Roche has the exclusive right to commercialize FoundationOne, FoundationOne Heme, any clinical diagnostic products developed under our R&D Collaboration Agreement with Roche, including FoundationACT, and any other products upon mutual agreement, in each case outside of the United States to the extent Roche has not elected to exclude any countries from its territory.

Subject to satisfaction of certain performance milestones, the Ex-U.S. Commercialization Agreement will remain in effect for five years and may be extended by Roche for additional two-year periods. Roche has the right to terminate the agreement without cause upon six months' written notice after the initial five year term, and either party may terminate the agreement in the event of breach by the other party. Until Roche assumes full responsibility for commercialization of our products in a given country outside of the United States, we may continue to rely on pre-existing distributor relationships to conduct physician and patient association outreach activities in such country.

Doing business internationally involves a number of risks, including:

- multiple, conflicting, and changing laws and regulations such as data protection laws, privacy regulations, tax laws, export and import restrictions, employment laws, regulatory requirements (including requirements related to patient consent, testing of genetic material and reporting the results of such testing) and other governmental approvals, permits, and licenses;
- failure by us, Roche or our distributors to obtain regulatory approvals for the manufacture, sale, and use of our products in various countries;
- additional, potentially relevant third-party patent rights;
- complexities and difficulties in obtaining protection for and enforcing our intellectual property;
- difficulties in staffing and managing foreign operations;
- complexities associated with obtaining reimbursement from and managing multiple payor reimbursement regimes, government payors, or patient self-pay systems;
- logistics and regulations associated with preparing, shipping, importing and exporting tissue samples, including infrastructure conditions, transportation delays, and customs;
- limits in our ability to penetrate international markets if we are not able to conduct our molecular tests locally;
- financial risks, such as the impact of local and regional financial crises on demand and payment for our products, and exposure to foreign currency exchange rate fluctuations;
- natural disasters, political and economic instability, including wars, terrorism, and political unrest, outbreak of disease, boycotts, curtailment of trade, and other business restrictions; and
- regulatory and compliance risks that relate to maintaining accurate information and control over sales and distribution activities that may fall within the purview of the U.S. Foreign Corrupt Practices Act, or FCPA, including its books and records provisions, or its anti-bribery provisions.

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

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

International customers have ordered, or may, in the future, order our products, and we are, therefore, subject to the FCPA, which prohibits companies and their intermediaries from making payments in violation of law to non-U.S. government officials for the purpose of obtaining or retaining business or securing any other improper advantage. Our current reliance on third-party distributors and Roche to sell our products internationally demands a high degree of vigilance in maintaining our policy against participation in corrupt activity, because these entities could be deemed to be our agents, and we could be held responsible for their actions. Other U.S. companies in the medical device and pharmaceutical field have faced criminal penalties under the FCPA for allowing their agents to deviate from appropriate practices in doing business with these individuals. We are also subject to similar anti-bribery laws in the jurisdictions in which we operate, including the United Kingdom's Bribery Act of 2010, which prohibits commercial bribery and makes it a crime for companies to fail to prevent bribery. These laws are complex and far-reaching in nature, and, as a result, we cannot assure you that we would not be required in the future to alter one or more of our practices to be in compliance with these laws, any changes in these laws, or the interpretation thereof. Any violations

of these laws, or allegations of such violations, could disrupt our operations, involve significant management distraction, involve significant costs and expenses, including legal fees, and could result in a material adverse effect on our business, prospects, financial condition, or results of operations. We could also suffer severe penalties, including criminal and civil penalties, disgorgement, and other remedial measures.

Reimbursement and Regulatory Risks Relating to Our Business

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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 our existing products 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 our existing and any future 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 local or national coverage determination and favorable reimbursement rate from CMS or the applicable MAC, for each of our existing products across all medically indicated tumor types will be a necessary element in achieving material commercial success. Physicians and patients may not order our products unless commercial third-party payors and government payors authorize such ordering and pay for all, or a substantial portion, of the list price, and certain commercial third-party payors may not agree to reimburse our existing products if CMS or the MACs assigned to the jurisdictions in which our operational laboratory facilities are located do not issue a positive coverage decision.

There is currently no national coverage determination that determines whether and how our products 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 and following discussions with NHIC, Corp., the predecessor to National Government Services, the MAC for our Cambridge, Massachusetts laboratory, we agreed to not submit claims for services provided to Medicare patients while this MAC assessed the appropriate coding, coverage, and payment for FoundationOne as a whole. To accommodate this MAC's 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 associated with our Cambridge, Massachusetts laboratory to National Government Services using a miscellaneous CPT code. When submitting claims for molecular services or procedures that do not have specific CPT codes, providers may submit those claims using a CPT code, referred to as the miscellaneous molecular 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 National Government Services using stacked molecular CPT codes in the manner currently used in submitting claims to commercial third-party payors. The use of a miscellaneous molecular 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 processed payments from Medicare for the claims submitted in a manner that we believe is consistent with applicable processing guidelines. The response to date of National Government Services to the submission of our claims has been to deny payment, or in a few limited instances to make payment following erroneous application of the applicable processing guidelines, which we have refunded or intend to refund, and we have decided to appeal these claims. The response to these appeals is uncertain.

The MAC assigned to the jurisdiction in which we have an operational laboratory facility may deny paying a claim submitted by that facility pending a coverage or payment determination. Even if we do receive payments from the MAC on appeal, 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, the MAC may issue a non-coverage determination for one or more of our existing products and/or clinically indicated tumor types that would apply to future claims. Although we would have the opportunity to submit additional materials in support of a positive coverage determination for our products to the MAC and to CMS through the Office of Medicare Hearings and Appeals (OMHA) on appeal, there is no guarantee that the MAC or CMS will provide us with a positive coverage decision or reverse a non-coverage decision that it already issued.

If CMS does not issue a positive national coverage determination, or MACs assigned to the jurisdiction in which one of our operational laboratory facilities is located does not issue an LCD, with respect to one or more of our products and/or clinically indicated tumor types, or if a MAC denies reimbursement of one or more of these products, withdraws its coverage policies after reimbursement is obtained, reviews and adjusts the rate of reimbursement, or stops paying for one or more of these products 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.

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, one or more of our existing products may reduce, suspend, revoke, or discontinue payments or coverage at any time, including those payors that designate one or more of our existing products and/or clinically indicated tumor types 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, FoundationOne Heme, and FoundationACT, 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 and/or clinically indicated tumor types will be approved in the future. We have had claims for reimbursement denied by certain commercial third-party payors, in some cases because they have designated FoundationOne and FoundationOne Heme as experimental and investigational. Reimbursement of NGS-based cancer tests by commercial third-party payors and government payors may depend on a number of factors, including a payor's determination that our existing and future products 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 and health economic studies demonstrating improved outcomes and cost effectiveness.

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 our existing and future products. Our strategy to achieve broad reimbursement coverage is focused on demonstrating the clinical utility and economic benefits of our products 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 March 2015, Palmetto, a MAC that would cover our North Carolina laboratory when it becomes operational, published a final LCD effective July 6, 2015 outlining guidelines for coverage of well-validated comprehensive genomic profiles for certain patients diagnosed with NSCLC. The Palmetto website lists FoundationOne as a covered test under these guidelines, effective as of October 1, 2015. There are also several MACs that are assigned to jurisdictions in which we do not currently operate that have issued final LCDs to cover well-validated comprehensive genomic profiles for a subset of NSCLC patients. National Government Services, the MAC that covers our Massachusetts laboratory, has elected not to follow these guidelines from Palmetto and instead issued their own LCD, which became effective April 1, 2016, to provide coverage for hotspot tests of 5 to 50 genes for patients with metastatic NSCLC. We do not believe this LCD from National Government Services reflects coverage for our validated comprehensive genomic profiling products, which include greater than 50 genes.

We have executed a lease for an additional laboratory facility in North Carolina. This North Carolina laboratory facility is not operational. Many factors exist that could delay or limit our ability to establish an operating laboratory at this facility. If we are able to commence clinical laboratory operations at this facility, the types of testing services that we may perform at this facility remain to be determined. Such determination will be subject to the existence and limitations of applicable licensees and approvals and our ability to meet laboratory and product requirements and to accommodate logistical and commercial needs in the test ordering and fulfillment process. As part of our clinical operations, we are still considering the services we expect to perform at our North Carolina laboratory and in our existing Massachusetts laboratory. If our North Carolina laboratory becomes operational, and this laboratory submits claims for testing from patients covered by Medicare, those claims will be subject to applicable Medicare rules and

practices, including the rules and practice of Palmetto, the MAC for the jurisdiction in which the North Carolina laboratory is located. We expect to engage in conversations with Palmetto regarding the potential for coverage and payment by Palmetto for tests from patients covered by Medicare submitted by our North Carolina laboratory. There is no certainty that Palmetto will provide coverage for such Medicare patients, and if coverage is provided, that such coverage will result in payments for claims submitted by our North Carolina laboratory.

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 reimbursement for one or more of our existing products for 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.

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

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

We are also required to maintain a license to conduct testing in Massachusetts. Massachusetts laws establish standards for day-to-day operation of our clinical laboratory, including the training and skills required of personnel and quality control over and above that required by CLIA. We are also licensed to conduct testing by the states of California, Pennsylvania, Maryland, Florida, Rhode Island, and in New York, where we have received a permit from the New York State Department of Health to conduct FoundationOne and FoundationOne Heme testing and deliver the related test report for specimens originating from New York. We executed in April, 2016, a lease for an additional laboratory facility in North Carolina, and we intend to conduct testing at this laboratory. We are still evaluating the testing services to be performed at the North Carolina laboratory, but we intend to obtain applicable licensure and accreditation to enable the laboratory to become operational. If, after acquiring laboratory licenses, we do not maintain these licenses or if our approval is revoked, our business would suffer. Moreover, other states may adopt similar requirements in the future. We may be subject to regulation in foreign jurisdictions as we expand international distribution of our products and seek to expand clinical laboratory operations outside the United States. International regulation may require prior review or approval of our products or services, may impose limits on the export of tissue, data or personal information necessary for us to perform our tests, and, as we establish laboratory operations outside the United States, may require us to obtain licenses and other operating permits. This additional regulation may affect our ability to provide our products and services and to conduct laboratory operations outside of the United States. If we are unable to comply with existing laws and regulations or changes to the laws and regulations, our business could be materially adversely affected.

Any sanction imposed under CLIA, its implementing regulations, or state or foreign laws or regulations governing licensure, or our failure to renew a CLIA certificate, a state or foreign license, or accreditation, could have a material adverse effect on our business. Most CLIA deficiencies are not classified as “condition-level” deficiencies, and there are

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

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

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

- HIPAA, which established comprehensive federal standards with respect to the privacy and security of protected health information and requirements for the use of certain standardized electronic transactions, particularly with respect to our online portals, FoundationICE and GeneKit;
- amendments to HIPAA under the Health Information Technology for Economic and Clinical Health Act, or the HITECH Act, and related regulatory amendments, which strengthen and expand HIPAA privacy and security compliance requirements, increase penalties for violators, extend enforcement authority to state attorneys general, and impose requirements for breach notification;
- the federal Anti-Kickback Statute, which prohibits knowingly and willfully offering, paying, soliciting, or receiving remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing, arranging for, or recommending of an item or service that is reimbursable, in whole or in part, by a federal health care program;
- the federal Stark physician self-referral law, which prohibits a physician from making a referral for certain designated health services covered by the Medicare program, including laboratory and pathology services, if the physician or an immediate family member has a financial relationship with the entity providing the designated health services, unless the financial relationship falls within an applicable exception to the prohibition;
- the federal False Claims Act, which imposes liability on any person or entity that, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment to the federal government;
- the federal Civil Monetary Penalties Law, which prohibits, among other things, the offering or transfer of remuneration to a Medicare or state health care program beneficiary if the person knows or should know it is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of services reimbursable by Medicare or a state health care program, unless an exception applies;
- other federal and state fraud and abuse laws, such as anti-kickback laws, prohibitions on self-referral, fee-splitting restrictions, prohibitions on the provision of products at no or discounted cost to induce physician or patient adoption, and false claims acts, which may extend to services reimbursable by any third-party payor, including private insurers;
- the prohibition on reassignment of Medicare claims, which, subject to certain exceptions, precludes the reassignment of Medicare claims to any other party;
- the rules regarding billing for diagnostic tests reimbursable by the Medicare program, which in certain circumstances prohibit laboratories from charging the Medicare program directly for services provided to hospital inpatients, and also prohibit a physician or other supplier from marking up the price of the technical component or professional component of a diagnostic test ordered by the physician or other supplier and supervised or performed by a physician who does not "share a practice" with the billing physician or supplier;
 - state laws that prohibit other specified practices, such as billing physicians for testing that they order; waiving coinsurance, copayments, deductibles, and other amounts owed by patients; billing a state Medicaid program at a price that is higher than what is charged to one or more other payors; and
- similar foreign laws and regulations that apply to us in the countries in which we operate.

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

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

information product development efforts.

We provide products and services, including molecular testing, as a vendor to our biopharmaceutical partners in connection with clinical trials. We have implemented measures to ensure that all clinical data and genetic and other biological samples that we receive in connection with clinical trials from our biopharmaceutical partners have been collected from subjects who have provided

appropriate informed consent for purposes which extend to our product development activities. We seek to ensure that these data and samples are provided to us on a subject de-identified manner.

We also act as a sponsor of clinical trials in connection with data analyses we perform, which are frequently conducted in collaboration with biopharmaceutical partners. We seek and receive approval from an ethical review board, or “Institutional Review Board”, for projects that meet the definition of “human subjects research,” which includes review and approval of processes for subject informed consent and authorization for use of personal information or waivers thereof.

In all our clinical trial-related activities, we also have measures in place to ensure that the subjects from whom the data and samples are collected do not retain or have conferred on them any proprietary or commercial rights to the data or any discoveries derived from them. Our biopharmaceutical partners conduct clinical trials in a number of different countries, and, to a large extent, and particularly when we are acting as a vendor in connection with a project sponsored by our biopharmaceutical partners, we rely upon them to comply with the subject’s informed consent and with applicable local laws and international regulations. The collection of data and samples in many different countries results in complex legal questions regarding the adequacy of informed consent and the status of genetic material under a large number of different legal systems. The subject’s informed consent obtained in any particular country could be challenged in the future, and those informed consents could prove invalid, unlawful, or otherwise inadequate for our purposes. Any findings against us, or our biopharmaceutical partners, could deny us access to or force us to stop using some of our clinical data or samples, which would hinder our molecular information product development efforts. We could become involved in legal challenges, which could consume our management and financial resources.

If we experience any of a number of possible unforeseen events in connection with clinical trials, our ability to conduct further clinical trials of, obtain regulatory approval of or commercialize future products and services or improvements to existing products and services, could be delayed or prevented.

We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to conduct further clinical trials, obtain regulatory approval or commercialization of future products and services or improvements to existing products and services. Unforeseen events that could delay or prevent our ability to conduct clinical trials, obtain regulatory approval or commercialize future products and services or improvements to existing products and services include:

- regulators or institutional review boards may not authorize us, our investigators or our biopharmaceutical partners to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may have delays in reaching or fail to reach agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;
- clinical trials of our future product or services candidates, or improvements to our existing products or services, may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- the number of patients, or amount of data, required for clinical trials of our future product or services candidates, or improvements to our existing products or services may be larger than we anticipate, patient enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials at a higher rate than we anticipate;
- our failure to conduct our clinical trials in accordance with applicable regulatory requirements of the FDA and of other countries;
- we are unable to develop any companion diagnostic tests and/or obtain regulatory approval to market any such test on a timely basis, or at all;
-

we may decide, or regulators or institutional review boards may require us, or our investigators, or our biopharmaceutical partners to, suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements,

- a finding that the participants are being exposed to unacceptable risks to their health or the privacy of their health information associated with our future product or services candidates, or improvements to our existing products or services;
- the cost of clinical trials of future product or services candidates, or improvements to our existing products or services, may be greater than we anticipate; and
- the supply or quality of materials or data necessary to conduct clinical trials of future product or services candidates, or improvements to our existing products or services, may be insufficient or inadequate.

Item 5. Other Information

On April 18, 2016, we entered into a Lease Agreement, or the Lease, with ARE-7030 Kit Creek, LLC, or the Landlord, for the lease of approximately 48,236 square feet of office and laboratory space located in a building at 7010 Kit Creek Road, Research Triangle Park, North Carolina, or the Premises. The term of the Lease commenced on April 18, 2016 and expires on January 31, 2022. Upon certain conditions set forth in the Lease, we have the option to extend the Lease for two additional five-year terms.

We will pay annual rent of \$21.50 per rentable square foot, or \$86,422.83 per month, subject to annual 3% increases beginning February 1, 2018, throughout the term of the Lease. We are entitled to an abatement of fixed rent for the first nine months of the term. In addition, at our election, we may receive up to \$1,205,900 from the Landlord for tenant improvements to the Premises, a certain portion of which may be repayable to the Landlord as specified in the Lease.

The Lease includes customary provisions concerning insurance obligations, covenants, indemnities, and events of default. Subject to certain limitations, our obligations under the Lease may be accelerated upon the occurrence of certain uncured events of default.

The foregoing description of the Lease does not purport to be complete and is qualified in its entirety by reference to the Lease, a complete copy of which is filed hereto as Exhibit 10.1 and is incorporated herein by reference. Concurrent with the execution of the Lease, we entered into an asset purchase agreement whereby we purchased certain laboratory equipment and other assets located at the Premises for cash consideration of \$0.7 million.

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.

SIGNATURES

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

FOUNDATION MEDICINE,
INC.

Date: May 3, 2016 By: /s/ Michael J.
Pellini, M.D.
Michael J. Pellini,
M.D.
Chief Executive
Officer
(Principal Executive
Officer)

Date: May 3, 2016 By: /s/ Jason Ryan
Jason Ryan
Chief Financial
Officer
(Principal Financial
Officer)

Exhibit

No. Exhibit Index

- 10.1* Lease Agreement, by and between the Company and ARE-7030 Kit Creek, LLC, dated April 18, 2016
- 31.1* Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 31.2* Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 32.1** Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- 101 Interactive Data Files regarding (a) our Condensed Consolidated Balance Sheets as of March 31, 2016 and December 31, 2015, (b) our Condensed Consolidated Statements of Operations and Comprehensive Loss for the Three Months Ended March 31, 2016 and 2015, (c) our Condensed Consolidated Statements of Cash Flows for the Three Months Ended March 31, 2016 and 2015, and (d) the Notes to such Condensed Consolidated Financial Statements.

*Filed herewith.

**Furnished herewith.