Foundation Medicine, Inc.
Form 10-Q
November 02, 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 September 30, 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 incorporation or organization)	(I.R.S. Employer Identification No.)

150 Second Street

Cambridge, MA 02141

(Address of principal executive offices) (Zip code)

(617) 418-2200

(Registrant's telephone number, including area code)

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

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 October 28, 2016 was 35,058,568.

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 w 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 plans to seek approval from the FDA or other regulatory authorities for certain of our products, as well as our ability to secure such approvals;
- 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;
- our ability to borrow all available amounts under our credit facility with Roche Finance Ltd and our ability to comply with our covenants and other obligations contained in the credit agreement;
- anticipated trends and challenges in our business and the markets in which we operate; and
- other factors discussed elsewhere in this Quarterly Report on Form 10-Q.

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 Excha 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 September 30, 2016

FOUNDATION MEDICINE, INC.

Condensed Consolidated Balance Sheets

(unaudited)

(In thousands, except share and per share data)

	September 30, 2016	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	$77,847	$ 117,763
Marketable securities	90,038	89,607
Accounts receivable, net of allowance of $0 and $171 at September 30, 2016 and December 31, 2015, respectively	6,901	7,362
Receivable due from Roche	6,817	403
Inventory	11,959	7,992
Prepaid expenses and other current assets	2,973	6,517
Total current assets	196,535	229,644
Marketable securities	—	24,939
Property and equipment, net	42,041	41,333
Restricted cash	1,395	1,395
Other assets	2,345	678
Total assets	$242,316	$ 297,989
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$12,005	$ 10,469
Accrued expenses and other current liabilities	22,263	12,822
Deferred revenue	2,156	717
Roche related-party deferred revenue	295	3,742
Current portion of deferred rent	2,250	2,146
Total current liabilities	38,969	29,896
Deferred rent, net of current portion and other non-current liabilities	8,971	10,404
Commitments and contingencies (Note 15)		
Stockholders' equity:		
Preferred stock, $0.0001 par value, 5,000,000 shares authorized; no shares issued and outstanding at September 30, 2016 and December 31, 2015	—	—
Common stock, $0.0001 par value, 150,000,000 shares authorized; 34,996,194 and 34,513,845 shares issued and outstanding at September 30, 2016 and December 31, 2015, respectively	4	3
Additional paid-in capital	503,537	489,480

Accumulated other comprehensive income/(loss)	34	(178)
Accumulated deficit	(309,199)	(231,616)
Total stockholders' equity	194,376	257,689
Total liabilities and stockholders' equity	$242,316	$ 297,989

The accompanying notes are an integral part of these unaudited 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 September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Revenue	$16,325	$20,953	$54,460	$58,557
Related-party revenue from Roche	13,101	4,446	33,581	8,595
Total revenue	29,426	25,399	88,041	67,152
Costs and expenses:				
Cost of revenue	14,729	9,068	36,241	26,934
Cost of Roche related-party revenue	1,217	1,302	3,050	1,302
Selling and marketing	14,654	14,267	42,928	36,630
General and administrative	13,012	9,199	34,739	41,810
Research and development	17,238	12,174	49,194	31,118
Total costs and expenses	60,850	46,010	166,152	137,794
Loss from operations	(31,424)	(20,611)	(78,111)	(70,642)
Other income (expense):				
Interest income	199	15	585	31
Interest expense	(57)	—	(57)	—
Total other income (expense)	142	15	528	31
Net loss	$(31,282)	$(20,596)	$(77,583)	$(70,611)
Other comprehensive (loss) income:				
Unrealized (loss) gain on available-for-sale securities	(25)	—	212	—
Total other comprehensive (loss) income	(25)	—	212	—
Comprehensive loss	$(31,307)	$(20,596)	$(77,371)	$(70,611)
Net loss per common share, basic and diluted	$(0.90)	$(0.60)	$(2.24)	$(2.19)
Weighted-average common shares outstanding, basic and diluted	34,949,785	34,347,593	34,701,013	32,290,972

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

FOUNDATION MEDICINE, INC.

Condensed Consolidated Statements of Cash Flows

(unaudited)

(In thousands)

	Nine Months Ended September 30,	
	2016	2015
Operating activities		
Net loss	$(77,583)	$(70,611)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	11,528	7,523
Stock-based compensation expense	13,526	8,049
Amortization of premiums and discounts on marketable securities	215	—
Provision for doubtful accounts on accounts receivable	—	171
Provision for inventory excess and obsolescence	—	105
Changes in operating assets and liabilities:		
Accounts receivable	461	(348)
Receivable from Roche	(6,414)	—
Inventory	(3,967)	(4,756)
Prepaid expenses and other current assets	3,544	(3,255)
Other assets	(167)	(615)
Accounts payable	5,550	4,269
Accrued expenses and other current liabilities	7,205	4,728
Deferred rent and other non-current liabilities	(1,329)	2,305
Deferred revenue	1,439	115
Roche related-party deferred revenue	(3,447)	—
Net cash used in operating activities	(49,439)	(52,320)
Investing activities		
Purchases of property and equipment	(14,007)	(18,911)
Purchases of marketable securities and other investments	(77,445)	—
Proceeds from maturities of marketable securities	100,453	—
Increase in restricted cash	—	(531)
Net cash provided by (used in) investing activities	9,001	(19,442)
Financing activities		
Proceeds from issuance of common stock to Roche, net of issuance costs	—	245,387
Proceeds from issuance of restricted stock and stock option exercises	522	4,457
Net cash provided by financing activities	522	249,844
Net (decrease)/increase in cash and cash equivalents	(39,916)	178,082
Cash and cash equivalents at beginning of period	117,763	72,080
Cash and cash equivalents at end of period	$77,847	$250,162
Supplemental disclosure of non-cash investing and financing activities		
Deferred financing costs included in accrued expenses and other current liabilities	$331	—
Acquisition of property and equipment included in accounts payable and accrued	$5,052	$5,705

expenses

The accompanying notes are an integral part of these unaudited 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 subsidiaries, Foundation Medicine Securities Corporation and FMI Germany GmbH (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 molecular information products for genomic profiling, FoundationOne for solid tumors, FoundationOne Heme for blood-based cancers, or hematologic malignancies, including leukemia, lymphoma, myeloma, and advanced sarcomas, and FoundationACT, a blood-based (liquid biopsy) assay to measure circulating tumor DNA ("ctDNA"), are 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 developing and commercializing new molecular information products for physicians and biopharmaceutical companies, strengthening its commercial organization, introducing new marketing, education and provider engagement efforts, growing its molecular information knowledgebase, called FoundationCORE, aggressively pursuing reimbursement from regional and national third-party payors, publishing scientific and medical advances, and fostering relationships throughout the oncology community.

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 presentation. 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 as of and 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 unaudited condensed consolidated financial statements are described in the Company's audited consolidated 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, results of operations, and disclosures.

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 or disclosures.

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 September 30, 2016, Roche's ownership was approximately 60.1% 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. In October 2016, the Company elected a new independent director.

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.

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

On June 16, 2016, the Company and Roche entered into the Second Amendment to the R&D Collaboration Agreement, which set forth the terms of an omnibus development program to provide for R&D projects that do not fall within the scope of the other programs already covered by the R&D Collaboration Agreement.

On July 25, 2016, the Company and Roche entered into a Third Amendment to the R&D Collaboration Agreement, which modified certain exclusivity provisions relating to cancer immunotherapy.

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 the 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"). Pursuant to the Ex-U.S. Commercialization Agreement, on April 7, 2016, Roche obtained Ex-U.S. commercialization rights to the Company's existing products and services and to future co-developed products and services. The Company remains solely responsible for commercialization of its products and services within the United States. The selected geographic areas where Roche exercised its commercialization rights constitute the "Roche Territory." For those geographic areas that Roche did not select, the commercialization rights for such geographic areas reverted back 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.

On May 9, 2016, the Company and Roche entered into the First Amendment to the Ex-U.S. Commercialization Agreement, which established procedures for each party to track and inform the other party concerning any adverse events, in the event such adverse events occur.

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.

IVD Collaboration Agreement

On April 6, 2016, the Company entered into a Master IVD Collaboration Agreement (the "IVD Collaboration Agreement") with F. Hoffmann-La Roche Ltd and Roche Molecular Systems, Inc., which memorializes in a definitive agreement the terms set forth in that certain Binding Term Sheet for an In Vitro Diagnostics Collaboration, by and between F. Hoffmann-La Roche Ltd and the Company, 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.

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.

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 September 30, 2016 and December 31, 2015 (in thousands):

	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
September 30, 2016				
Description:				
U.S. government agency securities and treasuries	$ 90,004	$ 35	$ (1)	$ 90,038
Total	$ 90,004	$ 35	$ (1)	$ 90,038
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):

	September 30, 2016	December 31, 2015
Due in one year or less	$ 90,038	$ 89,607
Due after one year through two years	—	24,939
Total	$ 90,038	$ 114,546

The amortized cost of available-for-sale securities is adjusted for amortization of premiums and accretion of discounts to maturity. At September 30, 2016 and December 31, 2015, the balance in the Company's accumulated other comprehensive income/(loss) was composed solely of activity related to the Company's available-for-sale marketable securities. There were no realized gains or losses recognized on the sale or maturity of available-for-sale securities during the three and nine months ended September 30, 2016, and as a result, the Company did not reclassify any amounts out of accumulated other comprehensive income/(loss) for the same period.

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 September 30, 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 September 30, 2016 and December 31, 2015, the Company recorded an allowance for doubtful accounts of $0 and $171,000, respectively.

Two customer account balances consisting of $6,817,000 and $1,602,000 were greater than 10% of the total accounts receivable balance, including receivables due from Roche, representing 50% and 12%, respectively, of total accounts receivable at September 30, 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):

	September 30, 2016	December 31, 2015
Raw materials	$ 10,342	$ 6,604
Work-in-process	1,617	1,388
	$ 11,959	$ 7,992

9. Property and Equipment

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

	September 30, 2016	December 31, 2015
Lab equipment	$ 32,499	$ 27,883
Computer equipment	11,481	10,542
Software	5,059	3,703
Furniture and office equipment	3,606	3,376
Leasehold improvements	24,601	18,677
Construction in progress	4,343	5,172
	81,589	69,353
Less: accumulated depreciation and amortization	(39,548)	(28,020)
	$ 42,041	$ 41,333

Depreciation and amortization expense for the three and nine months ended September 30, 2016 was $4,292,000 and $11,528,000, respectively, compared to $2,954,000 and $7,523,000 for the three and nine months ended September 30, 2015, 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):

	September 30, 2016	December 31, 2015
Payroll and employee-related costs	$ 10,757	$ 8,375
Professional services	4,393	2,038
Property and equipment purchases	3,437	1,194
Other	3,676	1,215
	$ 22,263	$ 12,822

11. Debt

On August 2, 2016, the Company entered into a credit facility agreement (the "Roche Credit Facility") with Roche Finance Ltd ("Roche Finance"). Pursuant to the Roche Credit Facility, during the three-year period ending August 2, 2019 (the "Draw Period"), the Company may borrow up to $100,000,000, of which $80,000,000 is available to the Company immediately, subject to certain initial conditions being satisfied, and $20,000,000 will be available upon the achievement of certain milestones. During the Draw Period, the Company shall pay Roche Finance a quarterly commitment fee of 0.3% on the available balance of the Roche Credit Facility. The proceeds from the Roche Credit Facility are intended to be used for product development and commercialization, corporate development, and working capital management. Loans made under the Roche Credit Facility bear interest at 5% per annum.

The Company shall pay Roche Finance, quarterly during the Draw Period, accrued interest on the outstanding principal of the loans. Following the Draw Period, and for five years thereafter, the Company shall pay Roche Finance quarterly equal payments of principal, with accrued interest, until maturity of the Roche Credit Facility on August 2, 2024. The Company may prepay all or a portion of the Roche Credit Facility, subject to certain conditions and prepayment fees, as specified in the Roche Credit Facility.

The Roche Credit Facility is secured by a lien on all of the Company's tangible and intangible personal property, including, but not limited to, shares of its subsidiaries (65% of the equity interests in the case of foreign subsidiaries), intellectual property, insurance, trade and intercompany receivables, inventory and equipment, and contract rights, and all proceeds and products thereof (other than certain excluded assets).

The Roche Credit Facility contains certain affirmative covenants, including, among others, obligations for the Company to provide monthly and annual financial statements, to meet specified minimum cash requirements, to provide tax gross-up and indemnification protection, and to comply with laws. The Roche Credit Facility also contains certain negative covenants, including, among others, restrictions on the Company's ability to dispose of certain assets, to acquire another company or business, to encumber or permit liens on certain assets, to incur additional indebtedness (subject to customary exceptions), and to pay dividends on the Company's common stock. The Company was in compliance with its debt covenants as of September 30, 2016.

The Roche Credit Facility contains customary events of default, including, among others, defaults due to non-payment, bankruptcy, failure to comply with covenants, breaches of a representation and warranty, change of control, or material adverse effect and judgment defaults. Upon the occurrence and continuation of an event of default following applicable notice and cure periods, amounts due under the Roche Credit Facility may be accelerated. The Company had no events of default as of September 30, 2016.

As of September 30, 2016, there were no outstanding balances under the Roche Credit Facility as the Company had not yet drawn down any funds on the available balance.

12. Net Loss per Common Share

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

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

	Three Months Ended September 30,	Nine Months Ended September 30,

	2016	2015	2016	2015
Outstanding stock options	1,303,007	1,825,633	1,303,007	1,825,633
Unvested restricted stock	1,473,483	945,276	1,473,483	945,276
Total	2,776,490	2,770,909	2,776,490	2,770,909

13. 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 September 30, 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 September 30, 2016			
	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Assets:				
Cash equivalents	$45,427	$ —	$ —	$45,427
Marketable securities:				
U.S. government agency securities and treasuries	65,432	24,606	—	90,038
Total assets	$110,859	$ 24,606	$ —	$135,465

	Fair Value Measurement at December 31, 2015			
	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (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 and nine months ended September 30, 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 and nine months ended September 30, 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 September 30, 2016.

14. Stockholders' Equity

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

	September 30, 2016	December 31, 2015
Unvested restricted stock	1,473,483	969,758
Common stock options	1,303,007	1,684,783
Shares available for issuance under the 2013 Stock Option and Incentive Plan	2,470,731	1,694,077
Shares available for issuance under the 2013 Employee Stock Purchase Plan	788,503	788,503
	6,035,724	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, restricted stock, and restricted stock units 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

For restricted stock, including restricted stock units, 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	909,549
Vested	(331,389)
Cancelled	(64,541)
Unvested at September 30, 2016	1,473,483

Total stock-based compensation expense recognized for restricted stock awards was $4,990,000 and $10,863,000 for the three and nine months ended September 30, 2016, respectively, and $2,668,000 and $3,501,000 for the three and nine months ended September 30, 2015, respectively.

Stock Options

A summary of stock option activity under the 2010 Stock Plan and the 2013 Stock Plan for the nine months ended September 30, 2016 is as follows:

	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (In Years)	Aggregate Intrinsic Value (in thousands)
Outstanding as of December 31, 2015	1,684,783	$ 17.31	7.7	$ 13,965
Granted	31,216	19.37		
Exercised	(141,066)	3.71		
Cancelled	(271,926)	30.59		
Outstanding as of September 30, 2016	1,303,007	$ 16.06	7.0	$ 13,005
Exercisable as of September 30, 2016	896,918	$ 13.59	6.7	$ 10,516

The weighted-average fair value of options granted for the nine months ended September 30, 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 $866,000 and $2,663,000 for the three and nine months ended September 30, 2016, respectively, and $1,592,000 and $4,548,000 for the three and nine months ended September 30, 2015, respectively.

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

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2016	2015	2016	2015
Cost of revenue	$668	$302	$1,488	$690
Selling and marketing	1,112	1,756	2,768	2,827
General and administrative	2,800	1,314	6,393	2,903
Research and development	1,276	888	2,877	1,629
Total	$5,856	$4,260	$13,526	$8,049

As of September 30, 2016, unrecognized compensation cost of approximately $31,925,000 related to non-vested stock options and restricted stock awards is expected to be recognized over weighted-average periods of 1.9 years.

The weighted-average assumptions used to estimate the fair value of stock options using the Black-Scholes option pricing model were as follows (there were no stock options granted during the three months ended September 30, 2016):

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2016	2015	2016	2015
Expected volatility	59.2%	56.5%	59.2%	63.1%
Risk-free interest rate	1.9 %	1.97%	1.9 %	1.52%
Expected option term (in years)	6.25	6.25	6.25	6.25
Expected dividend yield	0.0 %	0.0 %	0.0 %	0.0 %

15. Commitments and Contingencies

150 Second Street

In 2013, the Company signed a lease (the “Headquarters Lease”) for approximately 61,591 square feet of office and laboratory space (the “Existing Premises”) at 150 Second Street in Cambridge, Massachusetts (the “Headquarters Building”). The Headquarters Lease commenced in September 2013, and initially had an eight year expected term. The Headquarters Lease is subject to fixed rate escalation increases and the landlord waived the Company’s rent obligation for the first 10.5 months of the lease, having an initial value of $3,300,000. The landlord also agreed to fund up to $9,239,000 in tenant improvements. The Company recorded the tenant improvements as leasehold improvements and deferred rent on the consolidated balance sheet. Deferred rent is amortized as a

reduction in rent expense over the term of the Headquarters Lease. The Company recognizes rent expense on a straight-line basis over the expected lease term. In connection with the Company's termination of its prior lease at One Kendall Square, the rent abatement was reduced to approximately $1,841,000 and the expected term of the Headquarters Lease was reduced to 7.5 years. The Company began to record rent expense in April 2013 upon gaining access to and control of the space. Upon execution of the Headquarters Lease, the Company paid a security deposit of $1,725,000 which was reduced to approximately $864,000 in 2014. The security deposit is included in restricted cash in the accompanying balance sheet as of September 30, 2016 and December 31, 2015.

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

On September 30, 2016, the Company entered into three separate yet related agreements to expand its premises at the Headquarters Building. As a result of these agreements, on the effective date ("Effective Date") for the surrender by bluebird bio, Inc. ("Bluebird") of approximately 53,455 square feet of space leased by Bluebird in the Headquarters Building ("Bluebird Premises"), the Company will become the sole tenant of the Headquarters Building, leasing approximately 123,210 square feet of office and laboratory space. The three agreements include a Third Amendment to Lease with the landlord to the amend the Headquarters Lease ("Third Amendment"), an Assignment and Assumption of Lease (the "Assignment") with Bluebird for the assignment of the lease dated as of June 3, 2013, as amended, between the landlord and Bluebird (the "Bluebird Lease") to the Company, and a Consent to Assignment (the "Consent"), among the landlord, the Company and Bluebird, providing required consents for the assignment of the Bluebird Lease to the Company and providing for financial mitigation for delays by Bluebird in surrendering the Bluebird Premises.

Pursuant to the Assignment, on or after May 1, 2017, Bluebird will surrender the Bluebird Premises. On that date, that is the Effective Date, (i) the Company will become the tenant under the Bluebird Lease, and (ii) the Headquarters Lease will be amended as provided in the Third Amendment. If the Effective Date has not occurred by January 31, 2018, the Company shall have the right to terminate the Assignment, which will effectively terminate the Third Amendment as well. Although Bluebird is under no obligation to surrender the Bluebird Premises, if the Effective Date has not occurred by July 31, 2017, under the Consent from and after August 1, 2017, Bluebird shall be required to pay the Company an amount equal to 100% of the monthly base rent then payable under the Bluebird Lease until the earlier of (a) the Effective Date, or (b) the date that the Company exercises its right to terminate the Assignment.

On the Effective Date, pursuant to the Third Amendment, (i) the Company will be entitled to a partial abatement of base rent payable under the Headquarters Lease for each of the first two calendar months following the Effective Date (provided the Company is not in default under the Third Amendment or the Bluebird Lease), (ii) the term of the Headquarters Lease shall be extended through April 30, 2024, (iii) the Company shall have the right to extend the term for one subsequent five-year period, (iv) the Company will pay annual base rent on the Existing Premises (ranging from $70.51 to $83.42 per square foot) in accordance with the rent schedule attached to the Third Amendment, with semi-annual adjustments beginning in January and July of each calendar year, and (v) the landlord will provide up to $2,500,000 in tenant improvement allowances to improve the Headquarters Building, including the Existing Premises, the Bluebird Premises and the lobby. Pursuant to the Assignment, the Company will assume the Bluebird Lease and will pay annual base rent on the Bluebird Premises (ranging from $62.83 to $72.84 per square foot) in accordance with the Bluebird Lease.

As of the Effective Date, the Third Amendment also requires the Company to increase its security deposit by amending the letter of credit for the Headquarters Lease to $1,771,009, and to amend the terms of the letter of credit to serve as security for both the Third Amendment and the Bluebird Lease.

The Company recorded $634,000 of rent expense during each of the three months ended September 30, 2016 and 2015, respectively, and $1,901,000 of rent expense during each of the nine months ended September 30, 2016 and 2015, respectively 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 Ten Canal 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 $1,995,550 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 September 30, 2016 and December 31, 2015.

The Company recorded $407,000 and $1,222,000 of rent expense during the three and nine months ended September 30, 2016, respectively, and $377,000 and $876,000 in the three and nine months ended September 30, 2015, respectively, associated with the Ten Canal Lease.

Research Triangle Park Lease Agreement

On April 18, 2016, the Company entered into a facility 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. The Company was not obligated to provide a security deposit in connection with signing the ARE Lease.

The Company recorded $240,000 and $435,000 of rent expense during the three and nine months ended September 30, 2016, respectively, associated with the ARE Lease.

Penzberg, Germany Lease

On September 9, 2016, the Company entered into a facility lease agreement (the "Penzberg Lease") with Roche Diagnostics, GmbH ("Roche Diagnostics") for the lease of office and laboratory space located in Penzberg, Germany (the "Leased Premises"). The initial term of the Penzberg Lease commenced on September 9, 2016 and expires on September 8, 2021. Upon certain conditions set forth in the Penzberg Lease, the Company has the option to extend the term of the Penzberg Lease for additional two-year terms. Commencing March 1, 2017, but not later than May 1, 2017, at the request of the Company, the Penzberg Lease shall be expanded to include additional space as described in the Penzberg Lease.

The Company began paying rent of approximately $22,000 per month in September 2016 ("Base Rent"). Base Rent will increase upon the Company taking possession of the additional space in 2017, but the rate of the Base Rent is fixed through December 31, 2017. Commencing January 1, 2018, Base Rent may be adjusted by Roche Diagnostics up to a maximum increase of 2% per annum, compared with Base Rent for the immediately preceding year. The Company is not obligated to provide a security deposit in connection with the Penzberg Lease.

The Company recorded $16,000 of rent expense during the three and nine months ended September 30, 2016 associated with the Penzberg Lease.

Legal Matters

From time to time, the Company is party to litigation arising in the ordinary course of its business. As of September 30, 2016, the Company is not currently a party to any significant litigation.

16. Related Party Transactions

Roche Holdings, Inc. and its affiliates

Revenue from Roche was $13,101,000 and $33,581,000 in the three and nine months ended September 30, 2016, respectively. Included in the $13,101,000 recognized from Roche in the three months ended September 30, 2016 was a $5,000,000 milestone achieved under the ctDNA Platform Development Program, $4,446,000 of revenue earned under the Molecular Information Platform Program, $3,136,000 from the reimbursement of R&D costs under the CDx Development and Immunotherapy Testing Platform Development Programs, and $519,000 of other Roche-related revenue. Included in the $33,581,000 recognized from Roche in the nine months ended September 30, 2016 was $15,031,000 from revenue earned under the Molecular Information Platform Program, $12,000,000 in milestones achieved under the ctDNA Platform Development Program, $5,380,000 from the reimbursement of R&D costs under the CDx Development and Immunotherapy Testing Platform Development Programs, and $1,170,000 of other Roche-related revenue. Roche-related revenue represented 45% and 38% of the Company’s total revenue in the three and nine months ended September 30, 2016, respectively. Costs of related-party revenue from Roche were $1,217,000 and $3,050,000 for the three and nine months ended September 30, 2016, respectively, which consisted of costs incurred under the Molecular Information Platform Program

and costs related to the delivery of products outside of the United States under the Ex-U.S. Commercialization Agreement. At September 30, 2016, $6,817,000 and $295,000 was included in total accounts receivable and deferred revenue, respectively, related to this arrangement. At December 31, 2015, $403,000 and $3,742,000 was included in total accounts receivable and deferred revenue, respectively, related to this arrangement.

Revenue from Roche was $4,446,000 and $8,595,000 in the three and nine months ended September 30, 2015, respectively, which consisted of revenue earned under the Molecular Information Platform Program within the R&D Collaboration Agreement. Roche-related revenue represented 18% and 13% of the Company's total revenue in the three and nine months ended September 30, 2015, respectively. Costs of related party revenue from Roche were $1,302,000 for the three and nine months ended September 30, 2015, which consisted of costs incurred under the Molecular Information Platform Program.

There were no other material Roche-related balances included in the condensed consolidated financial statements at September 30, 2016, or for the three and nine months ended September 30, 2016 and 2015.

Other related party transactions

The Company recognized revenue of $334,000 and $1,486,000 during the three and nine months ended September 30, 2016, respectively, and $1,057,000 and $2,369,000 during the three and nine months ended September 30, 2015, respectively, from an arrangement with an entity affiliated with a member of the Company's Board executed during the year ended December 31, 2013. At September 30, 2016 and December 31, 2015, $303,000 and $825,000, respectively, were included in accounts receivable related to this arrangement.

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 unaudited 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 and research in a concise and user-friendly fashion. Our products provide genomic information about and contextualized to 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 and leadership position in providing comprehensive genomic profiling and molecular information products on a commercial scale.

Our clinical molecular information products, FoundationOne for solid tumors, FoundationOne Heme for blood-based cancers, or hematologic malignancies, including leukemia, lymphoma, myeloma, and advanced sarcomas, and FoundationACT, a blood-based (liquid biopsy) assay to measure circulating tumor DNA, or ctDNA, are widely available comprehensive genomic profiles designed for use in the routine care of patients with cancer and in research. To accelerate commercial growth and enhance competitive advantage, we are continuing to develop and commercialize new molecular information products for physicians and biopharmaceutical companies, strengthen our commercial organization, introduce new marketing, education and provider engagement efforts, grow our molecular information knowledgebase, called FoundationCORE, aggressively pursue reimbursement from government payors, and regional and national third-party payors, publish scientific and medical advances, and foster relationships throughout 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 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 September 30, 2016 our accumulated deficit was $309.2 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.

FoundationOne, FoundationOne Heme, and FoundationACT have been commercialized as laboratory developed tests, or LDTs, which are subject to the Clinical Laboratory Improvement Amendments of 1988, or CLIA, and are not currently regulated as medical devices under the Federal Food, Drug and Cosmetic Act. In addition to those LDTs, we are working with biopharmaceutical partners, such as Clovis Oncology, Inc., or Clovis, to develop FDA-approved companion diagnostics for use in connection with their products.

In addition, we are seeking FDA approval for FoundationOne, with an indication for use as a companion diagnostic across a diverse range of solid tumors. We believe our work developing companion diagnostic assays with our biopharmaceutical partners accelerates our progress in this area, and is a key component of our strategy to develop a universal companion diagnostic assay. If approved, FoundationOne could be the first FDA-approved comprehensive genomic profiling assay to incorporate multiple companion diagnostics to support precision medicine in oncology, and would be a key differentiator for the Company.

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 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. The laboratory commenced conducting services in the third quarter of 2016. Concurrent with the execution of the Lease, we purchased certain laboratory equipment from the former tenant of the office and laboratory space 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.

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 could 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.

The Company is now working with the FDA and the U.S. Centers for Medicare & Medicaid Services, or CMS, in a process called Parallel Review. The Parallel Review program is intended to facilitate the development and FDA review of innovative new products that have the potential to improve outcomes. Our goal is to obtain approval of a Premarket Approval Application, or PMA, from the FDA and, in parallel, a favorable National Coverage Determination, or NCD, from CMS for Medicare reimbursement for FoundationOne. The FDA and CMS accepted our application for Parallel Review of FoundationOne in the second quarter of 2016. We cannot predict whether the PMA for FoundationOne will be approved by the FDA, or whether the NCD will be granted by CMS. In addition, during the second quarter of 2016, the FDA accepted our request to review FoundationOne under the Expedited Access Pathway, or EAP program, a voluntary program for sponsors of breakthrough devices. As a participant in the EAP program, the FDA will endeavor to work with the Company, as the sponsor of FoundationOne, to reduce the time and cost of the approval decision, including the implementation of priority review, interactive review, senior management involvement, and assignment of a case manager.

On August 2, 2016, we entered into a credit facility agreement, or the Roche Credit Facility, with Roche Finance Ltd, or Roche Finance. Pursuant to the Roche Credit Facility, during the three-year period ending August 2, 2019, or the Draw Period, we may borrow up to $100 million, of which $80 million is available to us immediately, subject to certain initial conditions being satisfied, and $20 million will be available upon the achievement of certain milestones. During the Draw Period, we shall pay Roche Finance a quarterly commitment fee of 0.3% on the available balance of the Roche Credit Facility. Loans made under the Roche Credit Facility bear interest at 5% per annum. We shall pay Roche Finance, quarterly during the Draw Period, accrued interest on the outstanding principal of the loans. Following the Draw Period, and for five years thereafter, we shall pay Roche Finance quarterly equal payments of principal, with accrued interest, until maturity of the Roche Credit Facility on August 2, 2024.

On September 9, 2016, we entered into a facility lease agreement, or the Penzberg Lease, with Roche Diagnostics, GmbH, or Roche Diagnostics, for the lease of office and laboratory space located in Penzberg, Germany. The initial term of the Penzberg Lease commenced on September 9, 2016 and expires on September 8, 2021. Upon certain conditions set forth in the Penzberg Lease, we have the option to extend the Penzberg Lease for additional two-year terms. Commencing March 1, 2017 but not later than May 1, 2017, we may request expansion of the Penzberg Lease to include additional space as described in the Penzberg Lease.

On September 30, 2016, we entered into three agreements related to the expansion of our headquarters located at 150 Second Street, Cambridge, Massachusetts, or the Headquarters Building. As a result of these agreements, on the Effective Date, or Effective Date, we will assume the lease for approximately 53,455 square feet of space leased by bluebird bio, Inc., or Bluebird, in the Headquarters Building, or the Bluebird Premises. Combined with 69,755 square

feet currently leased by us, we will become the sole tenant of the Headquarters Building, leasing approximately 123,210 square feet of office and laboratory space, or the Combined Premises. On the Effective Date, the term of our lease of the Combined Premises shall be extended through April 30, 2024, and we will have the right to extend the term for one subsequent five-year period. If the Effective Date has not occurred by January 31, 2018, we shall have the right to terminate our agreement to assume control of the Bluebird Premises and our agreement to extend the term of the lease for the remaining space to April 30, 2024. Although Bluebird is under no obligation to surrender the Bluebird Premises, if the Effective Date has not occurred by July 31, 2017, from and after August 1, 2017, Bluebird shall be required to pay us an amount equal to 100% of the monthly base rent then payable by Bluebird under its lease until the earlier of (i) the Effective Date, or (ii) the date that we exercise our right to terminate the assignment of the Bluebird lease.

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 to 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 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 September 30, 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 September 30, 2016, we were a participating provider in the Medicare program. A local coverage determination, or LCD, exists for certain patients with non-small cell lung cancer, or NSCLC, within the jurisdiction where our Research Triangle Park, North Carolina laboratory facility is located. An LCD that reflects coverage for our validated comprehensive genomic profiling products does not exist within the jurisdiction where our Cambridge, Massachusetts 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 during the second and third quarters of 2016, we established a second operating laboratory facility in Research Triangle Park, North Carolina. Although we are in the process of seeking an NCD for FoundationOne as part the Parallel Review process, there are currently no NCDs that establish whether and how our tests are covered by Medicare. In the absence of NCDs, 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 our laboratory in North Carolina that recently became operational, have issued final 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. On September 29, 2016, Palmetto expanded the LCD for Medicare beneficiaries diagnosed with stage IIIB or stage IV NSCLC to eliminate the limitation requiring covered patients to be non-smokers or former light smokers. The expanded LCD, or the Expanded LCD, also expanded requirements for the collection of data in a registry, although the registry, the specific data to be submitted to the registry, and the permitted uses of such data, have not yet been

established. 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 include comprehensive analysis of greater than 50 genes and all classes of alterations. We intend to 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 submitted these claims for FoundationOne and FoundationOne Heme tests to National Government Services using a miscellaneous CPT code, and have not recognized any revenue from Medicare for those claims 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 September 30, 2016, National Government Services has either denied the FoundationOne or FoundationOne Heme claims that we have submitted or not processed and reimbursed us for 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 August

2016, we began submitting claims for FoundationACT tests associated with our Cambridge, Massachusetts laboratory to National Government Services using stacked CPT codes, and as of September 30, 2016, we have recognized a small amount of revenue from those claims.

In the future, a MAC having jurisdiction over any one of our operational laboratory facilities could issue a negative coverage determination for one or more of our tests that would apply to future claims and that MAC could defer processing claims 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 claims submitted by our new laboratory in North Carolina for tests that are referred to our laboratory facility in Cambridge and that comply with the criteria of the Expanded LCD, will be reimbursed by Palmetto, the MAC assigned to North Carolina. FoundationOne, FoundationOne Heme, and FoundationACT tests for patients covered by Medicare represented approximately 30% and 31% of total tests reported to physicians in the United States during the nine months ended September 30, 2016 and 2015, respectively.

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 September 30, 2016, we had cash, cash equivalents, and marketable securities of approximately $167.9 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, and the Roche Credit Facility.

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 continues to proceed. In addition, under our Ex-U.S. Commercialization Agreement with Roche, we are now being reimbursed by Roche for the cost of each test and a portion of the resulting gross margin, as compared to the direct-sales, patient pay model under which we had been previously operating for international volume, which we expect will reduce our average revenue per test for patients outside the United States. 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, third-party laboratory 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 September 30, 2016 and 2015, our selling and marketing expenses represented approximately 50% and 56%, respectively, of our total revenue and during the nine months ended September 30, 2016 and 2015, selling and marketing expenses represented approximately 49% and 55%, 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, 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 and nine months ended September 30, 2016, interest income was $0.2 million and $0.6 million, respectively, and $15,000 and $31,000 during the three and nine months ended September 30, 2015, respectively.

Interest Expense

Interest expense consists primarily of the amortization of deferred financing costs, and the quarterly commitment fee on the available balance under the Roche Credit Facility. During the three and nine months ended September 30, 2016, interest expense was $0.1 million.

Results of Operations

Comparison of Three Months Ended September 30, 2016 and 2015

	Three Months Ended			
	September 30,		Change	
	2016	2015	$	%
	(in thousands, except percentages)			
Statement of Operations Data:				
Revenue	$16,325	$20,953	$(4,628)	(22)%
Related-party revenue from Roche	13,101	4,446	8,655	195 %
Total revenue	29,426	25,399	4,027	16 %
Costs and expenses				
Cost of revenue	14,729	9,068	5,661	62 %
Cost of Roche related-party revenue	1,217	1,302	(85)	(7)%
Selling and marketing	14,654	14,267	387	3 %
General and administrative	13,012	9,199	3,813	41 %
Research and development	17,238	12,174	5,064	42 %
Total costs and expenses	60,850	46,010	14,840	32 %
Loss from operations	(31,424)	(20,611)	(10,813)	(52)%
Other income (expense):				
Interest income	199	15	184	1227%
Interest expense	(57)	—	(57)	100 %
Total other income (expense)	142	15	127	847 %
Net loss	$(31,282)	$(20,596)	$(10,686)	(52)%

Revenue

Total revenue increased to $29.4 million for the three months ended September 30, 2016 from $25.4 million during the three months ended September 30, 2015. Revenue from tests reported for our ordering physicians decreased to $8.7 million for the three months ended September 30, 2016 from $13.7 million for the three months ended September 30, 2015. The decrease in revenue was driven by several factors, including, moving in-network with a large national payor for stage IV NSCLC testing, which has resulted in no longer receiving payments for other indications that were previously paid by this large national payor on a stacked code basis, and in payment delays for the covered indication; a transition from billing certain medical institutions directly to billing their patients' insurance plans, which resulted in fewer tests paid during the period for those patients; a modest revenue decline due to our Ex-U.S. Commercialization Agreement with Roche, under which, beginning on April 7, 2016, international tests are now reimbursed by Roche at cost plus a portion of the resulting gross margin, as compared to the direct-sales, patient pay model under which we

had previously been operating for international volume; and increased examination of out-of-network claims by commercial third-party payors which resulted in payment delays and fewer tests paid. The increase in revenue from our biopharmaceutical customers to $20.7 million from $11.7 million in the three months ended September 30, 2016 and 2015, respectively, resulted from increased business development activity among our new and existing biopharmaceutical customers, including a $5.0 million milestone achieved under the Roche R&D Collaboration, and a broadening of the services we offer to existing clients.

Included in the $29.4 million of total revenue for the three months ended September 30, 2016 was $13.1 million of related-party revenue from Roche, which was comprised of (i) a $5.0 million milestone achieved under the ctDNA Platform Development Program, (ii) $4.5 million from revenue earned under the Molecular Information Platform Program, (iii) $3.1 million from the reimbursement of R&D costs under the CDx Development and Immunotherapy Testing Platform Development Programs, and (iv) $0.5 million of other Roche-related revenue.

Included in the $25.4 million of total revenue for the three months ended September 30, 2015 was $4.4 million of related-party revenue from Roche, all of which resulted from revenue earned under the Molecular Information Platform Program.

During the three months ended September 30, 2016, we reported 11,627 tests to ordering physicians, including 1,325 FoundationOne Heme tests and 904 FoundationACT tests, as compared to 8,012 tests reported during the three months ended

September 30, 2015, including 1,012 FoundationOne Heme tests. We also reported 2,245 and 2,676 tests to our biopharmaceutical customers during the three months ended September 30, 2016 and 2015, respectively.

The average revenue per test sold in the United States for clinical use that met our revenue recognition criteria during the three months ended September 30, 2016 was approximately $2,800. This average revenue per test does not include tests reported under the Roche Ex-U.S. Commercialization Agreement, given that those tests are now reimbursed by Roche at cost plus a portion of the resulting gross margin. This average revenue per test also does not include 3,278 tests reported during the period for patients covered by Medicare, 130 tests that were reported and not billed, and 6,535 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 1,732 tests reported in prior periods for which revenue was recognized during the three months ended September 30, 2016.

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

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 broad coverage decisions across large numbers of third-party payors, 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 a substantial majority of 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, FoundationOne Heme, and FoundationACT 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 31,401 and 26,106, respectively, as of September 30, 2016.

For our biopharmaceutical customer revenue that was based on a negotiated price per test, the average revenue per test was approximately $3,600 during each of the three months ended September 30, 2016 and 2015. We expect this average revenue per test for biopharmaceutical customers to remain fairly consistent with prior periods over time with fluctuations primarily resulting from test mix in a given period. Approximately $18.6 million and $6.6 million of our biopharmaceutical revenue for the three months ended September 30, 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 $15.9 million for the three months ended September 30, 2016 from $10.4 million for the three months ended September 30, 2015. This increase was driven by increasing test volumes from our ordering physicians and biopharmaceutical customers as well as costs incurred at our North Carolina laboratory. 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 September 30, 2016 and 2015, our total cost of revenue represented approximately 54% and 41% of our total revenue, respectively. We expect to make additional investments in personnel, infrastructure, and systems to scale our laboratory operations to meet future anticipated demand.

Selling and Marketing Expenses

Selling and marketing expenses increased to $14.7 million for the three months ended September 30, 2016 from $14.3 million for the three months ended September 30, 2015. The increase was primarily due to an increase of $0.8 million in consulting costs and $0.7 million in personnel-related costs for employees in our sales, marketing, client service, and reimbursement departments to support our commercialization efforts, partially offset by a combined $1.1 million decrease in marketing-related, travel, and other facilities costs.

General and Administrative Expenses

General and administrative expenses increased to $13.0 million for the three months ended September 30, 2016 from $9.2 million for the three months ended September 30, 2015. The increase was primarily due to a $1.8 million increase in personnel costs to support and expand our legal, finance, and human resources infrastructure, a $1.2 million combined increase in legal, consulting, and audit costs, and a $0.8 million increase in rent and other facilities costs.

Research and Development Expenses

Research and development expenses increased to $17.2 million for the three months ended September 30, 2016 from $12.2 million for the three months ended September 30, 2015. The increase was primarily due to a $2.6 million increase in employee and contractor-related expenses, a $0.9 million increase in laboratory supply costs, including reagents utilized in research and development activities, a $0.8 million increase in consulting costs, a $0.5 million increase in clinical trial expenses, and a $0.2 million increase in laboratory management and facilities costs.

Interest Income

Interest income was $0.2 million and $15,000 for the three months ended September 30, 2016 and 2015, respectively. The increase in interest income was due to interest earned on our marketable securities.

Interest Expense

Interest expense was $0.1 million for the three months ended September 30, 2016. Interest expense was primarily related to the amortization of deferred financing costs and the commitment fee on the available balance under the Roche Credit Facility.

Comparison of Nine Months Ended September 30, 2016 and 2015

	Nine Months Ended September 30,		Change	
	2016	2015	$	%
	(in thousands, except percentages)			
Statement of Operations Data:				
Revenue	$54,460	$58,557	$(4,097)	(7)%
Related-party revenue from Roche	33,581	8,595	24,986	291 %
Total revenue	88,041	67,152	20,889	31 %
Costs and expenses				
Cost of revenue	36,241	26,934	9,307	35 %
Cost of Roche related-party revenue	3,050	1,302	1,748	134 %
Selling and marketing	42,928	36,630	6,298	17 %
General and administrative	34,739	41,810	(7,071)	(17)%
Research and development	49,194	31,118	18,076	58 %
Total costs and expenses	166,152	137,794	28,358	21 %
Loss from operations	(78,111)	(70,642)	(7,469)	(11)%
Other income:				
Interest income	585	31	554	1787%
Interest expense	(57)	—	(57)	100 %
Total other income	528	31	497	1603%
Net loss	$(77,583)	$(70,611)	$(6,972)	(10)%

Revenue

Total revenue increased to $88.0 million for the nine months ended September 30, 2016 from $67.2 million during the nine months ended September 30, 2015. Revenue from tests reported for our ordering physicians decreased to $28.3 million for the nine months ended September 30, 2016 from $37.2 million for the nine months ended September 30, 2015. The decrease in revenue was driven by several factors, including, moving in-network with a large national payor for stage IV NSCLC testing, which has resulted in no longer receiving payments for other indications that were previously paid by this large national payor on a stacked code basis, and in payment delays from the payor for the indication covered; a transition from billing certain medical institutions directly to billing their patients' insurance plans, which resulted in fewer tests paid during the period for those patients; a modest revenue decline due to our Ex-U.S. Commercialization Agreement with Roche, under which, beginning on April 7, 2016, international tests are now reimbursed by Roche at cost plus a portion of the resulting gross margin, as compared to the direct-sales, patient pay model under which we had previously been operating for international volume; and increased examination of out-of-network claims by commercial third-party payors which resulted in payment delays and fewer tests paid. The increase in revenue from our biopharmaceutical customers to $59.7 million from $30.0 million in the nine months ended September 30, 2016 and 2015, respectively, was primarily driven by increased business development activity among our new and existing biopharmaceutical customers and by the achievement of $12.0 million in milestones related to the ctDNA Platform Development Program under the Roche R&D Collaboration Agreement.

Included in the $88.0 million of total revenue for the nine months ended September 30, 2016 was $33.6 million of related-party revenue from Roche, which was comprised of (i) 15.0 million from revenue earned under the Molecular Information Platform Program, (ii) $12.0 million in milestones achieved under the ctDNA Platform Development Program, (iii) $5.4 million from the reimbursement of R&D costs under the CDx Development and Immunotherapy

Testing Platform Development Programs, and (iv) $1.2 million of other Roche-related revenue.

Included in the $67.2 million of total revenue for the nine months ended September 30, 2015 was $8.6 million of related-party revenue from Roche, all of which resulted from revenue earned under the Molecular Information Platform Program.

During the nine months ended September 30, 2016, we reported 30,898 tests to ordering physicians, including 3,601 FoundationOne Heme tests and 1,078 FoundationACT tests, as compared to 24,712 tests reported during the nine months ended September 30, 2015, including 2,699 FoundationOne Heme tests. We also reported 6,762 and 5,723 tests to our biopharmaceutical customers during the nine months ended September 30, 2016 and 2015, respectively.

The average revenue per test sold in the United States for clinical use that met our revenue recognition criteria during the nine months ended September 30, 2016 was approximately $2,900. This average revenue per test does not include tests reported under the Roche Ex-U.S. Commercialization Agreement, given that those tests are now reimbursed by Roche at cost plus a portion of the

resulting gross margin. This average revenue per test also does not include 8,483 tests reported during the period for patients covered by Medicare, 342 tests that were reported and not billed, and 14,984 tests that were reported and billed to commercial third-party payors during the period but were not paid during the period. This average revenue per test includes 2,992 tests reported in prior periods for which revenue was recognized during the nine months ended September 30, 2016.

The average revenue per test for clinical use that met our revenue recognition criteria during the nine months ended September 30, 2015 was approximately $3,300. This average revenue per test does not include 6,531 FoundationOne and FoundationOne Heme tests reported during the period for patients covered by Medicare, 192 tests that were reported and not billed, and 9,373 tests that were reported and billed to commercial third-party payors during the period but which were not paid during the period. This average revenue per test includes 2,609 tests reported in prior periods for which revenue was recognized during the nine months ended September 30, 2015.

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 broad coverage decisions across large numbers of third-party payors, 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 a substantial majority of 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 31,401 and 26,106, respectively, as of September 30, 2016.

For our biopharmaceutical customer revenue that was based on a negotiated price per test, the average revenue per test was approximately $3,800 and $3,700 for the nine months ended September 30, 2016 and 2015, respectively. We expect this average revenue per test for biopharmaceutical customers to remain fairly consistent with prior periods over time. Approximately $50.0 million and $18.0 million of our biopharmaceutical revenue for the nine months ended September 30, 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 $39.3 million for the nine months ended September 30, 2016 from $28.2 million for the nine months ended September 30, 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 nine months ended September 30, 2016 and 2015, our total cost of revenue represented approximately 45% and 42% 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 $42.9 million for the nine months ended September 30, 2016 from $36.6 million for the nine months ended September 30, 2015. The increase was primarily due to an increase of $5.7 million in personnel-related costs for employees in our sales, marketing, client service, and reimbursement departments to support our commercialization efforts, and a $1.2 million increase in consulting costs, partially offset by a $0.6 million decrease in marketing-related and other facilities costs.

General and Administrative Expenses

General and administrative expenses decreased to $34.7 million for the nine months ended September 30, 2016 from $41.8 million for the nine months ended September 30, 2015. The decrease was primarily due to the one-time $14.4 million expense for advisor fees related to closing the Roche transaction recorded during the nine months ended September 30, 2015, partially offset by a $5.0 million increase in personnel costs to support and expand our legal, finance, and human resources infrastructure, a $1.3 million increase in rent and other facilities costs, and a $1.0 million combined increase in legal and consulting costs.

Research and Development Expenses

Research and development expenses increased to $49.2 million for the nine months ended September 30, 2016 from $31.1 million for the nine months ended September 30, 2015. The increase was primarily due to a $7.5 million increase in employee and contractor-related expenses, a $4.4 million increase in laboratory supply costs, including reagents utilized in research and development activities, a $2.2 million increase in laboratory management and facilities costs, a $2.1 million increase in consulting costs, and a $1.9 million increase in clinical trial expenses.

Interest Income

Interest income was $0.6 million and $31,000 for the nine months ended September 30, 2016 and 2015, respectively. The increase in interest income was due to interest earned on our marketable securities.

Interest Expense

Interest expense was $0.1 million for the nine months ended September 30, 2016. Interest expense was primarily related to the amortization of deferred financing costs and the commitment fee associated with the Roche Credit Facility.

Liquidity and Capital Resources

We have incurred losses and negative cash flows from operations since our inception in November 2009, and as of September 30, 2016, we had an accumulated deficit of $309.2 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 a limited number of 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, few of our existing tests are currently covered by Medicare, and Medicare has either denied the substantial majority of claims that we have submitted or not processed and reimbursed us for 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 September 30, 2016, we had cash, cash equivalents, and marketable securities of approximately $167.9 million. Cash in excess of immediate requirements is invested in accordance with our investment policy, primarily with a view to liquidity and capital preservation. These excess funds are held in 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.

On August 2, 2016, we entered into the Roche Credit Facility with Roche Finance. Pursuant to the Roche Credit Facility, during the Draw Period, we may borrow up to $100 million, of which $80 million is available to us immediately, subject to certain initial conditions being satisfied, and $20 million will be available upon the achievement of certain milestones. During the Draw Period, we shall pay Roche Finance a quarterly commitment fee of 0.3% on the available balance of the Roche Credit Facility. Loans made under the Roche Credit Facility bear interest at 5% per annum. We shall pay Roche Finance, quarterly during the Draw Period, accrued interest on the outstanding principal of the loans. Following the Draw Period, and for five years thereafter, we shall pay Roche Finance quarterly equal payments of principal, with accrued interest, until maturity of the Roche Credit Facility on August 2, 2024. As of September 30, 2016, there were no outstanding loans under the Roche Credit Facility as we had not yet drawn down any funds on the available balance.

Cash Flows

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

	Nine Months Ended September 30,	
	2016	2015
	(in thousands)	
Net cash (used in) provided by:		
Operating activities	$(49,439)	$(52,320)
Investing activities	9,001	(19,442)
Financing activities	522	249,844
Net (decrease) increase in cash and cash equivalents	$(39,916)	$178,082

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 $49.4 million for the nine months ended September 30, 2016 compared to $52.3 million for the nine months ended September 30, 2015. The decrease in cash used in operating activities was driven primarily by a $5.5 million increase in stock-based compensation expense, a $4.0 million increase in depreciation and amortization expense, and a $0.4 million increase in cash provided by working capital requirements, partially offset by a $7.0 million increase in net loss.

Investing Activities

Net cash provided by investing activities for the nine months ended September 30, 2016 was $9.0 million and consisted of $100.4 million in proceeds received from maturities of marketable securities, partially offset by $77.4 million in purchases of marketable securities and other investments, and $14.0 million in purchases of property and equipment. Net cash used in investing activities for the nine months ended September 30, 2015 was $19.4 million and primarily consisted of purchases of property and equipment.

Financing Activities

Net cash provided by financing activities for the nine months ended September 30, 2016 was $0.5 million and consisted solely of proceeds received from the exercise of stock options. Net cash provided by financing activities for the nine months ended September 30, 2015 was $249.8 million and consisted of $245.4 million of proceeds received from the issuance of common stock related to the Roche transaction, net of issuance costs, as well as $4.4 million from the exercise of stock options during the period.

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, seek regulatory approval for certain of our products, innovate our molecular information platform, and develop new product offerings. Our liquidity requirements

have and will continue to consist of selling and marketing expenses, research and development expenses, capital expenditures, working capital and general corporate expenses. If demand for our products continues to increase, we anticipate that our capital expenditure requirements will also increase in order to build additional capacity. We expect that our planned expenditures will be funded from our ongoing operations and from our existing cash and cash equivalents.

In April 2015, the Roche transaction was consummated, and we received $250.0 million in gross proceeds from the sale of 5,000,000 shares of our common stock to Roche at a price of $50.00 per share. Based on our current business plan, we believe our cash and cash equivalents as of September 30, 2016, the availability of proceeds under the Roche Credit Facility, 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 and the Roche Credit Facility. 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 another 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 and the Roche Credit Facility. 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

The following summarizes our principal contractual obligations as of September 30, 2016 that have changed significantly since December 31, 2015 and the effects such obligations are expected to have on our liquidity and cash flow in future periods. Contractual obligations that were presented in our Annual Report on Form 10-K for the year ended December 31, 2015, but omitted below, represent those that have not changed significantly since that date.

	Total	2016	2017-2018	2019-2020	Thereafter
	(in thousands)				
Operating lease obligations [1] [2]	$36,575	$3,257	$ 15,666	$ 15,464	$ 2,188

(1) In April 2016, we leased 48,236 square feet for office and laboratory space in Research Triangle Park, North Carolina under an operating lease that expires in January 2022.

(2) In September 2016, we leased office and laboratory space in Penzberg, Germany under an operating lease that expires in September 2021.

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 September 30, 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 September 30, 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 September 30, 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 September 30, 2016, we were not party to any significant 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 our Quarterly Reports for the quarters ended March 31, 2016 and June 30, 2016, and 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 that we launched commercially to ordering physicians in May 2016, to physicians in clinical practice, to continue to expand our current relationships and to 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, FoundationOne Heme, and FoundationACT have positive 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, with the exception of an LCD in the Palmetto jurisdiction which covers FoundationOne for certain patients with NSCLC. Certain commercial third-party payors have designated some or all of FoundationOne, FoundationOne Heme and FoundationACT as experimental and investigational and have declined to reimburse these products. 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 historically 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; however, that has not been the case in recent periods. For the three and nine months ended September 30, 2016, we saw a decrease in revenue from the sale of our products to physicians. This decline was driven primarily by several factors. A large national payor commenced "in-network" coverage for FoundationOne and FoundationOne Heme for patients with stage IV NSCLC testing. This coverage determination has resulted in us no longer receiving payments for other indications that were previously paid by this large national payor on a stacked code basis, and in payment delays from this payor for the NSCLC indication. A second factor is our transition from billing certain medical institutions directly for testing performed for patients of the institutions to billing the patients' insurance plans. This transition has resulted in fewer tests being paid for these patients during the periods. A third factor is a modest revenue decline due to the

commencement on April 7, 2016 of sales by Roche under our Ex-U.S. Commercialization Agreement with Roche. Sales of international tests are now paid by Roche (at cost plus a portion of the resulting gross margin), as compared to payments by patients at list prices under a self-pay model. A final factor is the increased examination of out-of-network claims by commercial third-party payors, which has resulted in payment delays and fewer tests being paid. The continuation of these factors, and other factors, including 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, and may affect our ability to grow our revenues or maintain existing revenue levels.

Our biopharmaceutical partners may decide to decrease or discontinue their use of our molecular information platform due to changes in research and product development plans, failures in their clinical trials, financial constraints, the regulatory environment, reimbursement landscape, 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 one or more of our operational laboratory facilities becomes damaged or inoperable, if we are required to vacate any of our laboratory facilities, 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 performed 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 perform 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, which is now operational. Transitioning some of our services to this new laboratory could disrupt overall laboratory operations and could require adjustments to meet regulatory requirements, resulting in our inability to meet customer turnaround time expectations. Any delays in this transition could result in slower realization of laboratory efficiencies anticipated from operating an additional laboratory facility. Adverse consequences resulting from 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 outside of the United States. We are in the process of establishing a laboratory facility in Penzberg, Germany. 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 or establishing 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.

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

We anticipate continued growth in our business operations both inside and outside the United States. Our laboratory facility in North Carolina recently became operational, we are in the process of establishing a laboratory facility in Penzberg, Germany, and we recently executed agreements to expand our facilities in Cambridge, Massachusetts. 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 implementation in a timely and efficient manner could adversely affect our operations.

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.

In February 2016, negotiators from Europe and the United States reached political agreement on a successor to the Safe Harbor framework that is being referred to as the EU-US Privacy Shield and a draft adequacy decision was presented by the European Commission on February 29, 2016. 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 opinion on the 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, the EU-US Privacy Shield was subject to further negotiations and revisions. On May 26, 2016 the European Parliament adopted a resolution and on July 8, 2016 the European Member States representatives approved the final version of the EU-US Privacy Shield, paving the way for the adoption of the decision by the European Commission. On July 12, 2016, the U.S. Department of Commerce announced that the EU-US Privacy Shield program would be open to registrants as of August 1, 2016. However, there continue to be concerns about whether the EU-US Privacy Shield will face additional challenges (such as the Safe Harbor framework). We expect that for the immediate future, 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 are 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 entered into force on May 25, 2016 and will apply from May 25, 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. Our Ex-U.S. Commercialization Agreement with Roche also contemplates that we will provide additional laboratory space in Europe and Asia to perform genomic sequencing for FoundationOne and FoundationOne Heme in those geographies, and we are currently in the process of establishing a laboratory facility in Penzberg, Germany. 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. Since Roche has the exclusive right to commercialize FoundationOne, FoundationOne Heme and any clinical diagnostic product developed under our R&D Collaboration Agreement with Roche, including FoundationACT, our ability to achieve commercial success outside the United States, including growing test volume and revenue, obtaining coverage decisions from commercial and government payors, and developing and operating a sustainable international commercial infrastructure, relies to a significant extent on the performance of Roche. Further, 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 and new distributor relationships to conduct commercial activities in such country, and our ability to achieve commercial success in such countries will significantly rely on the performance of such distributor relationships.

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 perform 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, 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. In addition, any failure to comply with applicable legal and regulatory obligations could impact us in a variety of ways that include, but are not limited to, significant criminal, civil and administrative penalties, including imprisonment of individuals, fines and penalties, denial of export privileges, seizure of shipments, and restrictions on certain business activities. Also,

the failure to comply with applicable legal and regulatory obligations could result in the disruption of our activities in these countries.

Our international operations could be affected by changes in laws, trade regulations, labor and employment regulations, and procedures and actions affecting approval, production, pricing, reimbursement and marketing of our products, as well as by inter-governmental disputes. Any of these changes could adversely affect our business.

Our success internationally will depend, in part, on our ability to develop and implement policies and strategies that are effective in anticipating and managing these and other risks in the countries in which we do business. Failure to manage these and other risks may have a material adverse effect on our operations in any particular country and on our business as a whole.

Reimbursement and Regulatory Risks Relating to Our Business

If commercial third-party payors or government payors fail to provide coverage or adequate reimbursement, or if there is a decrease in the amount of reimbursement for 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 LCD or NCD and a favorable reimbursement rate from CMS or the applicable MAC, for each of our existing products across substantially 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 NCD that determines whether and how our products are covered by Medicare. In the second quarter of 2016, the FDA and CMS accepted FoundationOne for the Parallel Review program, which provides for concurrent review of medical devices for FDA approval and an NCD from CMS to facilitate patient access to innovative medical devices. We cannot predict whether CMS will grant an NCD for FoundationOne, and if coverage is provided, if the reimbursement rate will be favorable. In the absence of an NCD, 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 stacked CPT codes for FoundationACT and using a miscellaneous CPT code for FoundationOne and FoundationOne Heme. 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. 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 payments from National Government Services for the claims submitted for FoundationOne or FoundationOne Heme which we believe were processed in a manner that 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. We only recently began submitting claims for FoundationACT to National Government Services.

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 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 NCD, 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, by limiting coverage on which diagnostic products they will pay for and the amounts that they will pay for new molecular diagnostic products, and by creating conditions to reimbursement, such as coverage eligibility requirements based upon clinical evidence development involving research studies and the collection of patient outcomes data. Because of these cost-containment trends, commercial third-party payors and government payors that currently provide or in the future may provide reimbursement for one or more of our 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. Payors may also create conditions to coverage that create burdens for ordering physicians and patients that may make our products more difficult to sell. 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 some or all of FoundationOne, FoundationOne Heme and FoundationACT 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 doing so.

In March 2015, Palmetto, a MAC whose jurisdiction includes our North Carolina laboratory, 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 listed FoundationOne as a covered test under these guidelines, effective as of October 1, 2015. On September 29, 2016, Palmetto expanded the LCD for NSCLC patients with stage IIIB or stage IV NSCLC, eliminating a limitation requiring covered patients to be non-smokers or former light smokers. This LCD also includes expanded requirements for the collection of data in a registry, although the registry, the specific data to be submitted to the registry, and the permitted uses of such data, have not yet been established. 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.

Our North Carolina laboratory facility recently became operational. We are conducting some services at this facility and are still in the process of determining what other types of services we may conduct at this facility. Such determination will be subject to the existence and limitations of applicable licenses and approvals, to our ability to meet laboratory and product requirements, and to our ability to accommodate logistical and commercial needs in the test ordering and fulfillment process. Since we are conducting services at our North Carolina laboratory, once we are able to meet the criteria of the Expanded LCD, including the requirement to submit data to a registry, we intend to submit claims from patients covered by Medicare to Palmetto, the MAC for the jurisdiction in which the North Carolina laboratory is located. These claims will be subject to applicable Medicare rules and practices of Palmetto. We expect to engage in conversations with Palmetto regarding the potential for coverage and payment by Palmetto for claims submitted by our North Carolina laboratory for Medicare patients having tumor types other than NSCLC. 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.

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

The FDA does not currently regulate most laboratory developed tests, or LDTs, such as FoundationOne, FoundationOne Heme, and FoundationACT. The FDA historically took the position that, although such LDTs are medical devices, it would exercise enforcement discretion by not requiring compliance with the Federal Food, Drug, and Cosmetic Act, or the FDCA, or its regulations. However, in June 2010, the FDA announced that it intended to no longer exercise enforcement discretion for LDTs and subsequently stated that it would publish guidance documents describing an approach to regulating LDTs. In October 2014, the FDA published two draft guidance documents that, if finalized, would implement a regulatory approach for most LDTs. In the draft guidance documents, the FDA stated that it had serious concerns regarding the lack of independent review of the evidence of clinical validity of LDTs and asserted that the requirements under CLIA do not address the clinical validity of any LDT. If published and finalized in the same form, the guidance documents would impose a risk-based, phased-in approach for LDTs similar to the existing framework for in vitro diagnostic devices.

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

in enforcement period. Premarket review of moderate-risk (Class II) LDTs would be phased-in over a period of four years following completion of the premarket review period for LDTs classified as high-risk.

For LDTs that are marketed before such time as the FDA begins requiring premarket review for that type or class of LDT, the LDT could remain on the market while the FDA reviews the applications or premarket notifications for such test. In addition, once a premarket application is submitted to the FDA or the FDA issues a 510(k) clearance order, the laboratory must also comply with the FDA's quality system regulation.

The FDA's draft guidance documents for LDTs were published on October 3, 2014, and the FDA accepted comments from the public through February 2, 2015. The FDA will consider such comments before deciding whether to issue final guidance documents implementing the same or a modified version of the regulatory approach described in the draft guidance documents. While there is no time frame in which the FDA must issue final guidance documents, the FDA included a final guidance on its framework for regulating LDTs as part of a list of priority guidance documents it intends to issue in fiscal year 2016. Legislative proposals have been introduced in Congress or publicly circulated, each of which would implement differing approaches to the regulation of LDTs. We cannot predict whether any of these legislative proposals will be enacted into law or the impact such new legal requirements would have on our business.

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

For tests that are subject to FDA regulation, we may not be able to obtain timely approvals for our tests or otherwise comply with FDA regulatory requirements.

If the FDA's proposed framework for regulating LDTs is finalized and implemented, or if legislation is enacted that subjects LDTs to FDA regulation, we would need to comply with FDA regulatory requirements for our LDTs, including FoundationOne, FoundationOne Heme, FoundationACT, or any future LDTs intended for clinical use. In addition, we are developing both individual and universal companion diagnostic tests, both of which will be regulated by the FDA as medical devices, regardless of the FDA's actions with respect to LDTs more generally.

For products that are subject to FDA requirements, including requirements for premarket clearance or approval, we may not be able to obtain such clearance or approvals on a timely basis, or at all. Our business could be negatively impacted if we are required to stop selling molecular information products pending their clearance or approval, or the launch of any new products that we develop could be delayed. The cost of conducting clinical trials and otherwise developing data and information to support premarket applications may be significant. In order to conduct a clinical investigation involving human subjects for the purpose of demonstrating the safety and effectiveness of a device, a sponsor of an investigation must, among other things, apply for and obtain institutional review board, or IRB, approval of the proposed investigation. In addition, if the clinical study involves a "significant risk" (as defined by the

FDA) to human health, the sponsor of the investigation must also submit and obtain FDA approval of an investigational device exemption, or IDE, application. We or the applicable study sponsor, as applicable, may not be able to obtain FDA and/or IRB approval to undertake clinical trials in the United States for any new devices we intend to market in the United States.

If classified as Class III medical devices, our products would likely be required to be approved by the FDA under a PMA, which must be supported by valid scientific evidence to demonstrate a reasonable assurance of safety and effectiveness of the subject product, typically including the results of human clinical trials that demonstrate the clinical utility of our products. During the review of our PMAs, the FDA may indicate areas in which the FDA believes additional data or information is necessary to reach a decision on the application. We may need to expend significant time and resources in responding to such FDA requests, which could include performing additional testing or developing new data to support the PMA. Depending on the nature of the requests, we may not be able to provide the data or information that the FDA believes necessary to resolve the deficiencies.

For devices not subject to a PMA, we may be required to submit either a de novo reclassification request or, if classified as Class II medical devices, a premarket notifications or 510(k). Under the 510(k) process, we must demonstrate that our products are substantially equivalent in technological characteristics and intended use to legally-marketed predicate devices. If we are unable to identify an appropriate predicate that is substantially equivalent to our device, we would be required to submit a PMA or a de novo

reclassification request. The FDA's 510(k) clearance process usually takes from four to twelve months, but it can take longer. Under the de novo process, we may request that the FDA classify a low or moderate risk device that lacks an appropriate predicate as a Class I or Class II device. The de novo process typically requires the development of clinical data and usually takes between six to twelve months from the time of submission of the de novo application, but can take longer.

In addition, as part of its review of a PMA, the FDA may conduct preapproval inspections pursuant to the FDA's Bioresearch Monitoring (BIMO) program. During such inspections, FDA investigators may review the data and information supporting our PMA applications or may review the procedures and systems used to design or manufacture the device that is under review. The FDA may indicate areas where additional data or information is necessary, or areas where corrective or preventive actions should be implemented. We may need to expend significant time and resources in responding to such FDA requests, and depending on the nature of the requests, we may not be able to provide the data or information or implement the actions that the FDA believes are necessary.

After approval, products subject to FDA regulation are required to comply with post-market requirements, including facility registration, product listing, quality system requirements, adverse event reporting, recalls, corrections and removals, restrictions on advertising and promotion, and other requirements. These requirements could subject our business to further regulatory risks and costs. The FDA enforces the requirements of the FDCA through announced and unannounced inspections. Failure to comply with the FDA's view of our satisfaction of applicable regulatory requirements could require us to expend time and resources to respond to the FDA's observations and to implement corrective and preventive actions, as appropriate. If we cannot resolve such issues to the satisfaction of the FDA, we may be subject to enforcement actions, including untitled or warning letters, fines, injunctions, or civil or criminal penalties. In addition, we could be subject to a recall or seizure of current or future products, operating restrictions, a partial suspension or a total shutdown of production. Any such enforcement action would have a material adverse effect on our business, financial condition and operations.

The FDA recently granted our request to review FoundationOne under the Expedited Access Pathway, or EAP, program because it met the three criteria necessary for inclusion in the program, one of which is the large unmet need for comprehensive genomic profiling of tumors. Once accepted into the EAP program, the FDA will work with the device sponsor to try to reduce the time and cost from development to an approval decision. Elements of the EAP program may include priority review, interactive review, senior management involvement, and assignment of a case manager. We cannot predict whether the PMA for FoundationOne will be approved by the FDA.

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

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

- requires each medical device manufacturer and importer to pay an excise tax equal to 2.3% of the sale price for its taxable medical devices. In 2015, Congress imposed a 2-year moratorium on this medical device tax, so that medical device sales during the period between January 1, 2016 and December 31, 2017 are exempt from the tax. Absent further legislative action, the tax will be automatically reinstated for medical device sales starting on January 1, 2018. If the tax is reinstated and if our products become regulated as medical devices, we could be required to begin paying this tax on the sales of our products for which we submit a marketing application, such as a 510(k) or PMA, to the FDA; and
- mandates a reduction in payments for clinical laboratory services paid under the Medicare Clinical Laboratory Fee Schedule, or CLFS, of 1.75% for the years 2011 through 2015. In addition, a productivity adjustment is made to the

fee schedule payment amount.

On April 1, 2013, cuts to the federal budget were implemented, known as sequestration, resulting in a 2% annual cut in Medicare payments for all services, including clinical laboratory testing. Congress has since extended this 2% Medicare sequester through fiscal year 2025. At this time, it remains uncertain how long the cuts will be continued.

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

In 2014, the AMA approved and implemented new CPT codes for genomic sequencing-based panel tests in cancer, effective January 1, 2015. In 2015, CMS used a "gap filling" process to price some of these new codes, which involved referring the new codes to the MACs to allow them to determine and submit to CMS an appropriate price if they deemed a code to be a covered service. CMS then established and published for 2016 an NLA for some of these codes, including the code associated with testing for 5-50 genes as calculated by determining the median price as provided by the MACs for the applicable code. If CMS reduces reimbursement for the new CPT codes for individual genes or fails to price new multi-gene panel codes which cover our products, or if commercial payors who often base pricing on Medicare fee schedules reduce non-contracted payment rates below the new NLA amount for CPT codes corresponding to individual genes, mandate use of the new sequencing-based panel CPT codes, or decide to stop payment on specific CPT codes altogether, our revenue could be adversely affected.

Additionally, in April 2014 the Protecting Access to Medicare Act of 2014, or PAMA, was enacted into law. Section 216 of PAMA reforms the Medicare payment system for clinical laboratory tests paid through the CLFS. PAMA establishes a market-based payment system for Medicare payment for clinical diagnostic laboratory tests. Under this new methodology, CMS will establish Medicare payment for each test based on the weighted median of the payment rates for private payors for the test. PAMA also creates a new class of test called the Advanced Diagnostic Laboratory Test, or ADLT, defined as a test offered and furnished by a single laboratory that is not sold for use by a laboratory other than the original developing laboratory and is either a (1) multi-biomarker test of DNA, RNA or proteins with a unique algorithm yielding a single, patient-specific result, (2) test that is cleared or approved by the FDA, or (3) test meeting other similar criteria established by the Secretary of Health and Human Services.

PAMA requires certain clinical laboratories meeting a threshold of Medicare revenues to report private payor payment rates and corresponding test volumes. PAMA also directed CMS to establish parameters to implement PAMA by June 30, 2015 and requires the market-based payment system to start on January 1, 2017. On June 17, 2016 CMS issued the Medicare Clinical Diagnostic Laboratory Tests Payment System Final Rule, or the Final Rule, to implement the laboratory test payment provisions of PAMA. Because the issuance of the Final Rule was delayed, CMS delayed the market-based payment rates until January 1, 2018. The agency has issued sub-regulatory guidance on data collection and reporting and on additional topics, including a list of specific billing codes for which laboratories must report data. CMS is expected to publish additional sub-regulatory guidance describing how PAMA will be implemented, including an application process for ADLTs. At this time, the full impact of the implementation of PAMA on new and existing tests is uncertain. Our average commercial payor reimbursement starting in 2018 could be adversely affected depending upon if and how commercial payors adopt this new Medicare pricing methodology and the payment rates.

Finally, the Center for Medicare and Medicaid Innovation announced on June 29, 2016 the launch of the Oncology Care Model, or OCM, beginning on July 1, 2016. The OCM is a five-year voluntary program that includes 195 physician practices in 31 states, as well as 16 private payors. Under the OCM, participating practices receive performance based payments on the basis of how their prices for 6-month "episodes" of cancer care triggered by receipt of chemotherapy compare to "benchmark" prices for similar episodes. These benchmarks are based on the historical data for the period of January 2012 through June 2015. The model may impact the utilization of our tests among those practices participating in OCM.

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

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

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

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 College of American Pathologists accreditation, we would not be able to operate our clinical laboratory and perform our molecular tests, which would result in material harm to our business and results of operations.

We are also required to maintain a license for our Massachusetts laboratory facility to perform 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 perform testing in our Massachusetts laboratory facility by the states of California, Pennsylvania, Maryland, Florida, Rhode Island, and New York, where we have received a permit from the New York State Department of Health to perform FoundationOne and FoundationOne Heme testing and deliver the related test report for specimens originating from New York.

Our North Carolina laboratory facility recently became operational, and we are still evaluating the services to be conducted at this facility. We have obtained or are in the process of obtaining all required state licensures for such activities at this facility. If, after acquiring laboratory licenses for our Massachusetts and North Carolina facilities, we do not maintain these licenses or if our approvals are revoked, our business would suffer. In addition, other states may adopt similar licensure requirements in the future.

We believe that our LDTs comply with the FDA's regulatory policies for LDTs. In October 2014, the FDA issued draft guidance documents stating that the agency intends to regulate LDTs using a risk-based, phased-in approach and will continue exercising enforcement discretion until the draft guidance is finalized and, even after finalized, during the period in which the phased-in approach is implemented. We continue to evaluate the services that will be transitioned to our North Carolina laboratory and will assess whether any tests associated with such services are consistent with the FDA's statements that the design and performance of an LDT should take place in a single clinical laboratory. In the event that the agency takes the position that any of our tests do not meet this standard, the FDA has stated that it intends to continue exercising enforcement discretion and will apply the same risk-based, phased-in approach described in its October 2014 draft guidance document to any such test that is offered by a CLIA-certified laboratory. Any such phased-in approach would not begin until after the October 2014 draft guidance is finalized. The FDA has also stated that, regardless of its enforcement discretion policy and the proposed phased-in approach, the FDA may take enforcement action to protect the public health if, for example, an LDT presents a significant risk to public health.

We will become subject to additional regulations in foreign jurisdictions as we and Roche 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.

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. We may also furnish our biopharmaceutical partners and academic researchers

with identifiable genomic information for research purposes, so long as such disclosure has been approved by an institutional review board or other ethical or privacy review board. The laws of certain states and countries may require specific consent from the individual either to retain or utilize certain genetic information for research or other purposes even if such information has been de-identified, or may require that we obtain a waiver of such consent from an ethical or privacy review board. 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 be subject to unfavorable publicity or public opinion, 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.

In addition to CLIA and HIPAA, 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, under which the Department of Health and Human Services 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; certain of our services, including our online portals, FoundationICE and GeneKit, are subject to these standards and requirements;
- 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 standards, 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 a federal healthcare 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 other federal 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 other federal or 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 clinical laboratory claims, which, subject to certain exceptions, precludes the reassignment of such 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 outpatients, and also prohibit a physician or other supplier from marking up the price of the technical component or professional component of certain diagnostic tests 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 healthcare 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 we or our biopharmaceutical partners 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 or our biopharmaceutical partners 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;
- the therapeutic agents that we are developing companion diagnostic tests for may be associated with negative or inconclusive results in clinical trials, and our biopharmaceutical partners may decide to deprioritize or abandon these therapeutic agent programs, or regulators may require them to abandon these therapeutic agent programs or impose onerous changes or requirements;
- clinical trials of our biopharmaceutical partners' therapeutic agents that we are developing companion diagnostic tests for may suggest or demonstrate that these therapeutic agents are not as efficacious and/or as safe as other similar therapeutic agents or a companion diagnostic test is not essential to determine which patients would benefit from these therapeutic agents;
- 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.

Risks Relating to Our Financial Condition and Capital Requirements

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

We have historically incurred substantial net losses, including a net loss of $89.6 million in 2015. From our inception in 2009 through September 30, 2016, we had an accumulated deficit of $309.2 million. We expect our losses to continue as a result of not being broadly contracted with commercial payors, ongoing research and development expenses and increased selling and marketing costs. These losses have had, and will continue to have, an adverse effect on our working capital, total assets, and stockholders' equity. Because of the numerous risks and uncertainties associated with our research, development, and commercialization efforts, we are unable to predict when we will become profitable, and we may never become profitable. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our inability to achieve and then maintain profitability would negatively affect our business, financial condition, results of operations, and cash flows.

Item 6. Exhibits

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

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SIGNATURES

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

FOUNDATION MEDICINE, INC.

Date: November 2, 2016 By: /s/ Michael J. Pellini, M.D.
Michael J. Pellini, M.D.
Chief Executive Officer
(Principal Executive Officer)

Date: November 2, 2016 By: /s/ Jason Ryan
Jason Ryan
Chief Financial Officer
(Principal Financial Officer)

Exhibit No.	Exhibit Index
10.1	Credit Facility Agreement, by and between the Company and Roche Finance Ltd., dated August 2, 2016 (incorporated by reference to Exhibit 10.1 of the Company's Form 8-K filed on August 2, 2016).
10.2*#	Third Amendment to Collaboration Agreement, by and among the Company, F. Hoffmann-La Roche Ltd and Hoffman-La Roche Inc., dated July 25, 2016.
10.3	Third Amendment to Lease, by and between the Company and ARE-MA Region No. 50, LLC, dated September 30, 2016 (incorporated by reference to Exhibit 10.1 of the Company's Form 8-K filed on October 5, 2016).
10.4	Consent to Assignment, by and among ARE-MA Region No. 50, LLC, bluebird bio, Inc., and the Company dated September 30, 2016 (incorporated by reference to Exhibit 10.2 of the Company's Form 8-K filed on October 5, 2016).
10.5	Assignment and Assumption of Lease, by and between the Company and bluebird bio, Inc., dated September 30, 2016 (incorporated by reference to Exhibit 10.3 of the Company's Form 8-K filed on October 5, 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 September 30, 2016 and December 31, 2015, (b) our Condensed Consolidated Statements of Operations and Comprehensive Loss for the Three and Nine Months Ended September 30, 2016 and 2015, (c) our Condensed Consolidated Statements of Cash Flows for the Nine Months Ended September 30, 2016 and 2015, and (d) the Notes to such Condensed Consolidated Financial Statements.

*Filed herewith.
**Furnished herewith.
#

Confidential treatment has been requested for certain information contained in this exhibit. Such information has been omitted and filed separately with the Securities and Exchange Commission.

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