FOUNDATION MEDICINE, INC.

FORM 10-Q
(Quarterly Report)

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 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, 2017

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)**

Registrant's telephone number, including area code: (617) 418-2200

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, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☒
Non-accelerated filer	☐ (Do not check if a smaller reporting company)	Smaller reporting company	☐
Emerging growth company	☒		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

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

As of October 27, 2017, the registrant had 36,252,578 shares of common stock, $0.0001 par value per share, outstanding.

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 words or other comparable terminology. These forward-looking statements include, but are not limited to, statements about:

- our plans or ability to obtain reimbursement coverage and thereafter payment for FoundationOne, FoundationOneHeme, FoundationACT, FoundationFocus CDx *BRCA ,* and FoundationOne CDx, including expectations as to our ability or the amount of time it will take to achieve successful reimbursement coverage and thereafter payment 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' issuance and acceptance of practice guidelines, and the use in clinical practice of molecular information and targeted oncology therapeutics and the market size for molecular information services;
- physicians' need for molecular information services and any perceived advantage of our services 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 services on a commercial scale or the sustainability of our competitive advantages;
- our ability to generate revenue from sales of services enabled by our molecular information platform to physicians in clinical practice and our biopharmaceutical partners, including our ability to increase adoption of our molecular information services, and to maintain and expand existing or to develop new relationships with biopharmaceutical partners;
- our plans and ability to develop, receive approval for, and commercialize new services, including FoundationOne CDx, and improvements to our existing services;
- our ability to increase the commercial success of our molecular information services;
- 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;
- 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 our molecular information service s or future services ;
- our plans to seek approval from the FDA or other regulatory authorities for certain of our services or future services, 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 services 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 subsidiaries. We own various U.S. federal trademark registrations and applications, and unregistered trademarks and service marks. Foundation Medicine®, FoundationOne®, FoundationACT®, Interactive Cancer Explorer®, FoundationICE®, GeneKit®, Once. And for All®, and The Molecular Information Company® are all registered trademarks of Foundation Medicine in the United States, and several of these marks are at various stages of the registration process in other countries. FoundationOne CDx™, FoundationFocus™, FoundationCORE™, PatientMatch™, Precision Medicine Exchange Consortium™, SmartTrials™, and FoundationACCESS™ are also trademarks of Foundation Medicine. 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, 2017

FOUNDATION MEDICINE, INC.
Condensed Consolidated Balance Sheets
(unaudited)

(In thousands, except share and per share data)

	September 30, 2017	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	$ 76,814	$ 63,617
Marketable securities	-	79,402
Accounts receivable	13,293	8,206
Receivable due from Roche	2,203	2,007
Inventory	10,400	10,438
Prepaid expenses and other current assets	4,612	5,251
Total current assets	107,322	168,921
Property and equipment, net	39,136	41,486
Restricted cash	2,305	1,395
Other assets	1,796	2,233
Total assets	$ 150,559	$ 214,035
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 16,178	$ 11,898
Accrued expenses and other current liabilities	28,246	20,578
Deferred revenue	1,702	2,104
Roche related-party deferred revenue	296	3,747
Current portion of deferred rent	1,439	2,324
Total current liabilities	47,861	40,651
Deferred rent, net of current portion and other non-current liabilities	9,261	8,538
Indebtedness to Roche - non-current	30,000	-
Commitments and contingencies (Note 15)		
Stockholders' equity:		
Common stock, $0.0001 par value, 150,000,000 shares authorized; 36,158,558 and 35,281,001 shares issued and outstanding at September 30, 2017 and December 31, 2016, respectively	4	4
Additional paid-in capital	531,593	509,664
Accumulated other comprehensive income (loss)	78	(14)
Accumulated deficit	(468,238)	(344,808)
Total stockholders' equity	63,437	164,846
Total liabilities and stockholders' equity	$ 150,559	$ 214,035

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,	
	2017	2016	2017	2016
Revenue:				
Molecular information services	$ 22,750	$ 13,754	$ 63,121	$ 45,130
Related-party molecular information services from Roche	5,618	4,965	16,642	16,201
Pharma research and development services	3,269	2,571	5,571	9,330
Related-party pharma research and development services from Roche	11,021	8,136	18,656	17,380
Total revenue	42,658	29,426	103,990	88,041
Costs and expenses:				
Cost of molecular information services	17,890	14,729	54,544	36,241
Cost of related-party molecular information services from Roche	1,238	1,217	4,183	3,050
Selling and marketing	16,556	14,654	50,107	42,928
General and administrative	17,001	13,012	49,926	34,739
Research and development	22,399	17,238	68,657	49,194
Total costs and expenses	75,084	60,850	227,417	166,152
Loss from operations	(32,426)	(31,424)	(123,427)	(78,111)
Interest (expense) income, net	(278)	142	(132)	528
Other income	60	—	204	-
Net loss	$ (32,644)	$ (31,282)	$ (123,355)	$ (77,583)
Other comprehensive income (loss):				
Unrealized gain/(loss) on available-for-sale securities	15	(25)	9	212
Foreign currency translation adjustment	(2)	—	83	—
Total other comprehensive income (loss)	13	(25)	92	212
Comprehensive loss	$ (32,631)	$ (31,307)	$ (123,263)	$ (77,371)
Net loss per common share, basic and diluted	$ (0.90)	$ (0.90)	$ (3.45)	$ (2.24)
Weighted-average common shares outstanding, basic and diluted	36,086,169	34,949,785	35,726,711	34,701,013

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,	
	2017	**2016**
Operating activities		
Net loss	$ (123,355)	$ (77,583)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	13,507	11,528
Stock-based compensation expense	18,060	13,526
Amortization of premiums and discounts on marketable securities	17	215
Loss on extinguishment of debt	284	—
Gain on disposal of long-lived assets	(327)	—
Changes in operating assets and liabilities:		
Accounts receivable	(5,087)	461
Receivable from Roche	(196)	(6,414)
Inventory	186	(3,967)
Prepaid expenses and other current assets	670	3,544
Other assets	173	(167)
Accounts payable	5,732	5,550
Accrued expenses and other current liabilities	5,222	7,205
Deferred rent and other non-current liabilities	(163)	(1,329)
Deferred revenue	(403)	1,439
Roche related-party deferred revenue	(3,451)	(3,447)
Net cash used in operating activities	(89,131)	(49,439)
Investing activities		
Purchases of property and equipment	(9,971)	(14,007)
Purchases of marketable securities and other investments	(4,996)	(77,445)
Proceeds from maturities of marketable securities	84,390	100,453
Restricted cash	(909)	—
Net cash provided by investing activities	68,514	9,001
Financing activities		
Proceeds from indebtedness to Roche	30,000	—
Proceeds from stock option exercises	3,805	522
Net cash provided by financing activities	33,805	522
Net increase (decrease) in cash and cash equivalents	13,188	(39,916)
Effect of exchange rate changes on cash and cash equivalents	9	—
Cash and cash equivalents at beginning of period	63,617	117,763
Cash and cash equivalents at end of period	$ 76,814	$ 77,847
Supplemental disclosure of non-cash investing and financing activities		
Cash paid for interest	225	331
Acquisition of property and equipment included in accounts payable and accrued expenses	$ 2,843	$ 5,052

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

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 services that are enabled by its molecular information platform to physicians and biopharmaceutical companies.

The Company's molecular information services for genomic profiling, FoundationOne for solid tumors, FoundationOneHeme for blood-based cancers, or hematologic malignancies, including leukemia, lymphoma, myeloma, pediatric cancers, and advanced sarcomas, FoundationACT, a blood-based (liquid biopsy) assay to measure circulating tumor DNA ("ctDNA"), and FoundationFocus CDx *BRCA* , an FDA approved, companion diagnostic assay to aid in identifying women with ovarian cancer for whom treatment with Rubraca™ (rucaparib) is being considered, 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 services 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, 2016 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 2, 2017 and as subsequently amended on Form 10-K/A filed with the SEC on March 30, 2017. 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, 2016.

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, 2016, 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, 2016.

Reclassifications

Certain reclassifications have been made to the revenue captions of the Condensed Consolidated Statements of Operations and Comprehensive Loss to conform to the current classifications. These reclassifications had no net effect on the Company's consolidated results.

Revenue Recognition

The Company derives revenue from the provision of molecular information services provided to its ordering physicians and biopharmaceutical customers, as well as from pharma research and development services provided to its biopharmaceutical customers. Molecular information services include molecular profiling and the delivery of other molecular information derived from the Company's platform. Pharma research and development services include the development of new platforms and information solutions, including companion diagnostic development. The Company currently receives payments from commercial third-party payors, Medicare, certain hospitals and cancer centers with which it has direct-bill relationships, individual patients, and its biopharmaceutical customers.

The Company recognizes revenue in accordance with FASB ASC Topic 605, *Revenue Recognition* ("ASC 605"). Accordingly, the Company recognizes revenue when all of the following criteria are met: (i) persuasive evidence of an arrangement exists;

(ii) delivery has occurred; (iii) the fee is fixed or determinable; and (iv) collectability is reasonably assured. Criterion (i) is satisfied when the Company ha s an arrangement or contract in place. Criterion (ii) is satisfied when the Company delivers a report to the ordering physician or the biopharmaceutical customer. Determination of criteria (iii) and (iv) are based on management's judgments regarding whethe r the fee is fixed or determinable, and whether the collectability of the fee is reasonably assured.

The Company recognizes revenue on a cash basis when it cannot conclude that criteria (iii) and (iv) have been met. The Company currently recognizes revenue on a cash basis from sales of its molecular information services to certain clinical customers, including payments received from commercial third-party payors, Medicare, and from patients who make co-payments, pay deductibles or from other amounts that the Company has been unable to collect from third-party payors. The Company uses judgment in its assessment of whether the fee is fixed or determinable and whether collectability is reasonably assured in determining when to recognize revenue in the future as it continues to gain payment experience with third-party payors and patients. Accordingly, the Company expects to recognize revenue on a cash basis for these clinical customers until it has sufficient history to reliably estimate payment patterns. The Company's molecular information services are delivered electronically, and as such there are no shipping and handling fees incurred by the Company or billed to customers. The Company's molecular information services are exempt from state sales taxation due to the nature of the services. As a result, the Company does not charge customers state sales tax.

The Company recognizes revenue from the sale of its molecular information services to clinical customers, including certain hospitals, cancer centers, other institutions and patients, at the time results of the test are reported to physicians, if criteria (i) through (iv) above are met.

Revenue from sales of the Company's services to biopharmaceutical customers are based on a negotiated price per test or on the basis of an agreement to provide certain testing volume, data access, or pharma research and development services over a defined period. The Company recognizes revenue upon delivery of the test results, or over the period in which pharma research and development services are provided, as appropriate.

The Company performs pharma research and development services for its biopharmaceutical customers utilizing its molecular information platform. Contracts for pharma customers are primarily analyzed as multiple-element arrangements given the nature of the service deliverables. For pharma research and development services performed, the Company is compensated in various ways, including (1) through the reimbursement of costs incurred; (2) through non-refundable regulatory and other developmental milestone payments; and (3) through royalty and sales milestone payments. For some multiple-element arrangements, including the R&D Collaboration agreement with Roche, the Company will be reimbursed for either all or a portion of the research and development costs incurred. The Company performs pharma research and development services as part of its normal activities. The Company records these payments as Pharma research and development services revenue in the Consolidated Statements of Operations and Comprehensive Loss, 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. The research and development costs incurred by the Company under these arrangements are included as Research and development expenses in the Company's Consolidated Statements of Operations and Comprehensive Loss given these costs are related to the development of new services to be owned and offered by the Company to its customers.

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

Arrangement consideration that is fixed or determinable is allocated among the separate units of accounting using the relative selling price method. Then, the applicable revenue recognition criteria in ASC 605-25 is applied to each of the separate units of accounting in determining the appropriate period and pattern of recognition. The Company determines the selling price of a unit of accounting following the hierarchy of evidence prescribed by ASC 605-25. Accordingly, the Company determines the estimated selling price for units of accounting within each arrangement using vendor-specific objective evidence ("VSOE") of selling price, if available, third-party evidence ("TPE") of selling price if VSOE is not available, or best estimate of selling price ("BESP") if neither VSOE nor TPE is available. The Company typically uses BESP to estimate the selling price, since it generally does not have VSOE or TPE of selling price for its units of accounting under multiple-element arrangements. Determining the BESP for a unit of accounting requires significant judgment. In developing the BESP for a unit of accounting, the Company considers applicable market conditions

and estimated costs . The Company validates the BESP for units of accounting by evaluating whether changes in the key assumptions used to determine the BESP will have a significant effect on the allocation of arrangement consideration between multiple units of accounting. The Company recognizes arrangement consideration allocated to each unit of accounting when all of the revenue recognition criteria in ASC 605-25 are satisfied for that particular unit of accounting.

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

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

Cost of Revenue

Cost of molecular information services generally consists of specific reagents, specific consumable lab supplies, and shared costs that are allocated to the Company's molecular information services – its FoundationOne, FoundationOne Heme, FoundationACT and FoundationFocus CDx *BRCA* tests – either on a direct or indirect basis, resulting in an overall cost for each specific test. The shared costs that are allocated to each test include personnel expenses (comprised of salaries, bonuses, employee benefits and stock-based compensation expenses), depreciation of laboratory equipment and amortization of leasehold improvements, shipping costs, third-party laboratory costs, and certain overhead expenses.

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 the Company currently recognizes revenue on a cash basis from commercial third-party payors and patients who make co-payments, pay deductibles or pay other amounts that the Company has been unable to collect from their insurers, the costs of those tests are often recognized in advance of any associated revenues.

Cost of Related-party molecular information services from Roche is generally derived by taking the cost per test described above and applying it to each of the FoundationOne, FoundationOne Heme and FoundationACT tests processed for Roche. Costs of Related-party molecular information services from Roche are associated with performing molecular information services for Roche under both the (i) molecular information platform program within the Company's R&D Collaboration Agreement with Roche, and (ii) the Company's Ex-U.S. Commercialization Agreement with Roche. Revenues from tests performed by the Company under the molecular information platform and the Ex-U.S. Commercialization Agreement are recognized in the Related-party molecular information services from Roche caption within the Company's Consolidated Statements of Operations and Comprehensive Loss.

Research and Development Expenses

Research and development expenses consist primarily of costs incurred for the development of new and enhanced services, immunotherapy testing, companion diagnostic development, significant service improvements, clinical trials to evaluate the clinical utility of the Company's services, the development of our FoundationCORE knowledgebase, and various technology applications such as FoundationICE and Patient-Match. Costs to develop the Company's technology capabilities are recorded as research and development unless they meet the criteria to be capitalized as internal-use software costs. The Company's 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.

Costs incurred for the performance of pharma research and development services requested by the Company's biopharmaceutical customers, including non-molecular information services costs incurred under the R&D Collaboration Agreement with Roche, are include d as Research and development expenses in the Consolidated Statements of Operations and Comprehensive Loss, given that these costs are related to the development of new servic es to be owned and offered by the Company to its customers. Revenues from these s ervices are recognized in the Pharma research and development services and Related-party pharma research and development service s from Roche captions within the Company's Consolidated Statements of Operations and Comprehensive Loss.

Recent Accounting Pronouncements

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

In May 2014, the FASB issued Accounting Standards Update No. 2014-09, Revenue from Contracts with Customers ("ASU 2014-09"), which supersedes the revenue recognition requirements in Accounting Standards Codification 605 ("ASC 605") and most industry-specific guidance. ASU 2014-09 requires that an entity recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration the entity expects to receive in exchange for those goods or services. To achieve this core principle, ASU 2014-09 includes provisions within a five-step model that includes identifying the contract with a customer, identifying the performance obligations in the contract, determining the transaction price, allocating the transaction price to the performance obligations, and recognizing revenue when, or as, an entity satisfies a performance obligation. ASU 2014-09 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 August 2015, the FASB decided to delay the effective date of ASU 2014-09 through the issuance of an additional ASU, which revised the effective date for ASU 2014-09 to annual and interim periods beginning on or after December 15, 2017, with early adoption permitted, but not earlier than the original effective date of annual and interim periods beginning on or after December 15, 2016, for public entities. In May 2014, the FASB and International Accounting Standards Board formed The Joint Transition Resource Group for Revenue Recognition ("TRG"), consisting of financial statement preparers, auditors, and users, to seek feedback on potential issues related to the implementation of the new revenue standard. As a result of feedback from the TRG, the FASB issued additional ASUs throughout 2016 to provide clarification, implementation guidance, and practical expedients to address some of the challenges of implementation. The new ASUs have the same effective date and transition requirements as ASU 2014-09. We refer to these ASUs which comprise Accounting Standards Codification 606 ("ASC 606") and Accounting Standards Codification 340-40 ("ASC 340-40") collectively as the "new standard".

The Company intends to adopt the new standard on January 1, 2018 utilizing the modified retrospective method, meaning the cumulative effect of applying the standard will be recognized to opening retained earnings at the date of initial application. The Company has a project team in place, including a third-party service provider, to analyze the impact of the new standard across all revenue streams. The Company has completed a diagnostic review of current accounting policies and a sample of existing baseline contracts to identify potential differences that would result from applying the requirements under the new standard. In the third quarter of 2017, the Company substantially completed preparation of its new accounting policies, including evaluation of any variations in key terms from the baseline contract reviews. The Company identified two revenue streams for its contracts with customers: (1) molecular information services, and (2) pharma research and development services.

For the molecular information services revenue stream, for certain revenue arrangements the Company has identified a difference in accounting applying the new standard as compared to applying the current accounting standards. Currently, for certain clinical customers, the Company will defer revenue recognition until cash receipt when the price pursuant to the underlying customer arrangement is not fixed and determinable and collectability is not reasonably assured. Under the new standard, this is considered variable consideration. For these arrangements, the Company will record an estimate of the transaction price, subject to the constraint in the new standard for variable consideration, as revenue at the time of delivery. This estimate will be monitored in subsequent periods and adjusted as necessary based on actual collection experience. This will result in earlier revenue recognition as compared to current revenue recognition. The Company currently anticipates this will result in a material impact to the transition adjustment to retained earnings and is in the process of evaluating the impact to the amount of revenue recorded on a quarterly basis subsequent to adoption on January 1, 2018. The Company is in the process of implementing any necessary changes to business processes, systems, and controls to support the recording and subsequent monitoring of these estimates.

For the pharma research and development services revenue stream, the Company has identified a difference in accounting for certain contracts from the application of the new standard as compared to current revenue accounting standards. Currently, for arrangements with regulatory and other developmental milestone payments, the Company will constrain revenue recognition based on the right to invoice the customer. Under the new standard, for these arrangements, the Company will constrain revenue such that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. Based on the facts and circumstances associated with each milestone, this could result in a change to the timing and pattern of revenue recognition as compared to current accounting policy. The Company is

evaluating the anticipated imp act to the transition adjustment to retained earnings, which will be dependent on the work performed towards, and potential achievement of, milestones not yet achieved as of December 31, 2017.

For both revenue streams, the Company expects disclosure contained in the notes to the consolidated financial statements relating to revenue recognition will expand under the new standard. The Company is evaluating the new disclosure requirements, including any necessary changes to business processes, systems, and controls to support the additional required disclosures.

The Company believes it is following an appropriate timeline to allow for proper recognition, presentation, and disclosure of the new standard following the January 1, 2018 effective date. The Company will continue to monitor new and existing customer contracts throughout the remainder of 2017 for potential impact on its evaluation. Additionally, the FASB has issued, and may issue in the future, interpretive guidance which may cause the Company's evaluation to change.

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, forfeiture rates, and classification on the statement of cash flows. ASU 2016-09 became effective for fiscal years beginning after December 15, 2016. The adoption of ASU 2016-09 resulted in an immaterial forfeiture rate adjustment, which was recorded in accumulated deficit upon adoption of the standard on January 1, 2017 .

Effective as of January 1, 2017, the Company adopted a change in accounting policy in accordance with ASU 2016-09 to account for excess tax benefits and tax deficiencies as income tax expense or benefit, treated as discrete items in the reporting period in which they occur, and to recognize previously unrecognized deferred tax assets that arose directly from (or the use of which was postponed by) tax deductions related to equity compensation in excess of compensation recognized for financial reporting. The recognition of the federal and state excess tax benefit net operating losses increased the net operating loss deferred tax asset by $14.9 million. No prior periods were restated as a result of this change in accounting policy as the Company maintains a valuation allowance against its deferred tax assets, which also increased by $14.9 million after adoption.

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 (See Note 12), 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 still performing its assessment of ASU 2016-02, however expects that substantially all of its operating lease commitments will be subject to the new guidance.

In November 2016, the FASB issued ASU 2016-18, *Restricted Cash* ("ASU 2016-18"). ASU 2016-18 provides guidance on the classification of restricted cash and cash equivalents in the statement of cash flows. Although it does not provide a definition of restricted cash or restricted cash equivalents, it states that amounts generally described as restricted cash and restricted cash equivalents should be included with cash and cash equivalents when reconciling the beginning-of-period and end-of period total amounts shown on the statement of cash flows. ASU 2016-18 is effective for interim and annual reporting periods beginning after December 15, 2017. Early adoption is permitted, including adoption in an interim period. The adoption of ASU 2016-18 is not expected to have a material effect on the Company's consolidated financial statements or disclosures.

In May 2017, the FASB issued ASU 2017-09, *Scope of Modification Accounting* ("ASU 2017-09"). ASU 2017-09 provides guidance about which terms or conditions of a share-based payment award require an entity to apply modification accounting in Topic 718. ASU 2017-18 is effective for interim and annual reporting periods beginning after December 15, 2017. Early adoption is permitted, including adoption in an interim period. The adoption of ASU 2017-09 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, 2017, Roche's ownership was approximately 58.1% 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. In October 2016, Michael Dougherty was

appointed as a member of the Board to fill the existing vacancy. In February 2017, the Board was increased to ten members when Troy Cox succeeded Michael Pellin i, M.D. as the Company's Chief Executive Officer and became a member of the Board. Effective a s of Mr. Cox's election, Dr. Pellini became Chairman of the Board .

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. For the new R&D projects contemplated during 2016 under the Second Amendment to the R&D Collaboration Agreement, Roche will reimburse the Company for certain R&D costs incurred for the agreed upon work. In addition, Roche will be required to make certain milestone payments upon the achievement of specified clinical events up to $13,000,000 in the aggregate. All milestone payments are considered substantive. The R&D reimbursements and clinical milestone payments will be recognized using a proportional performance model when earned by the Company .

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.

On December 20, 2016, the Company and Roche entered into a Fourth Amendment to the R&D Collaboration Agreement, which further modified certain exclusivity provisions relating to cancer immunotherapy.

On September 8, 2017, the Company and Roche entered into a Fifth Amendment to the R&D Collaboration Agreement, which reduced certain exclusivity provisions relating to blood-based tumor mutational burden assays.

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 wil l 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 was responsible for all R&D costs under the ctDNA platform development program. Roche was required to make certain milestone payments upon the achievement of specified events. Milestone payments up to $12,000,000 in the aggregate were 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 were considered substantive and were 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 deve lopment 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 in ception 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 approved and 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 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 services and to future co-developed services. The Company remains solely responsible for commercialization of its 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 does not select, the commercialization rights for such geographic areas revert 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 services in the Roche Territory and (ii) obligations to perform sample profiling and other services relating to Company 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 test sold by Roche.

Roche will reimburse the Company for costs incurred in performing sample profiling and other services relating to Company services 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 services 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 services 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 is entitled to receive, on a quarterly basis, tiered royalty payments ranging from the mid-single digit s to high-teens based on a percentage of the aggregate gross margin generated on sales of specified services in the Roche Territory during any calendar year. Royalty payments are 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 services 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.

On October 17, 2017, the Company and Roche entered into the Second Amendment to the Ex-U.S. Commercialization Agreement, which added FoundationACT to the collaboration and modified certain pricing terms and delivery obligations.

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 tests, including FoundationOne and FoundationOneHeme, and future Company tests, 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 ("Amended Agreement"), thereby amending the Services Agreement to include the joint development and regulatory approval for a CDx. The Amended Agreement defined the term of the arrangement as the earlier of five years or receipt of certain regulatory approvals of a CDx. The Company concluded that the amendment to the original Services Agreement represented a material modification to the arrangement pursuant to ASC 605 as the Amended Agreement increased total consideration by a significant amount. Additionally, the deliverables under the Amended Agreement changed significantly. At the date of the modification, there was no deferred revenue balance on the consolidated balance sheet related to the original Services Agreement with this Partner.

The Company identified seven deliverables under the Amended Agreement: (i) cross-licenses for access to relevant IP, (ii) obligations to continue to perform sample profiling pursuant to the original Services Agreement, (iii) obligations to perform specific

R&D activities for the development of a CDx assay for use in connection with the Partner's product , (iv) obligations to assist in obtaining regulatory approval of the Partner's product at its request, (v) participation on a 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 as say 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 results of sample profiling 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. As of December 31, 2016, the CDx assay had achieved regulatory approval and the regulatory and development obligations under the Amended Agreement had been completed.

Under the Amended Agreement, the Company recognized revenue of $3,414,000 and $4,714,000 for the three and nine months ended September 30, 2017, respectively, and $2,089,000 and $8,953,000 for the three and nine months ended September 30, 2016, respectively. Revenue for the three and nine months ended September 30, 2017 primarily related to sample profiling and royalties earned on the Partner's commercial product sales. Revenue for the three and nine months ended September 30, 2016 primarily related to sample profiling and milestone payments received upon the achievement of specified regulatory and clinical events tied to the R&D development activities of the CDx.

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, 2017 and December 31, 2016 (in thousands):

	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
September 30, 2017				
Description:				
U.S. government agency securities and treasuries	$ —	$ —	$ —	$ —
Total	$ —	$ —	$ —	$ —
December 31, 2016				
Description:				
U.S. government agency securities and treasuries	$ 79,411	$ —	$ (9)	$ 79,402
Total	$ 79,411	$ —	$ (9)	$ 79,402

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

	September 30, 2017	December 31, 2016
Due in one year or less	$ —	$ 79,402
Due after one year through two years	—	—
Total	$ —	$ 79,402

The amortized cost of available-for-sale securities is adjusted for amortization of premiums and accretion of discounts to maturity. There were no realized gains or losses recognized on the sale or maturity of available-for-sale securities during the nine months ended September 30, 2017 and 2016, respectively, and as a result, the Company did not reclassify any amounts out of accumulated other comprehensive 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 September 30, 2017 and December 31, 2016, the Company had restricted cash of $2,305,000 and $1,395,000, respectively.

7. Accounts Receivable

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.

Four customer account balances consisting of $3,197,000, $2,203,000, $1,994,000, and $1,589,000 were greater than 10% of the total accounts receivable balance, including receivables due from Roche, representing 21%, 14%, 13%, and 10%, respectively, of total accounts receivable at September 30, 2017. Three customer account balances consisting of $2,079,000, $2,007,000 and $1,319,000 were greater than 10% of the total accounts receivable balance, including receivables due from Roche, representing 20%, 20% and 13%, respectively, of total accounts receivable at December 31, 2016.

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, 2017	December 31, 2016
Raw materials	$ 6,709	$ 8,293
Work-in-process	3,691	2,145
	$ 10,400	$ 10,438

9. Property and Equipment

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

	September 30, 2017	December 31, 2016
Lab equipment	$ 34,738	$ 34,727
Computer equipment	11,688	11,534
Software	9,640	5,429
Furniture and office equipment	3,854	3,638
Leasehold improvements	25,992	24,730
Construction in progress	5,206	4,512
	91,118	84,570
Less: accumulated depreciation and amortization	(51,982)	(43,084)
	$ 39,136	$ 41,486

Depreciation and amortization expense for the three and nine months ended September 30, 2017 was $4,666,000 and $13,507,000, respectively, and for the three and nine months ended September 30, 2016 was $4,292,000 and $11,528,000, respectively. The Company classifies capitalized internal use software in lab equipment, computer equipment and software based on its intended use.

10. Accrued Expenses

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

	September 30, 2017	December 31, 2016
Payroll and employee-related costs	$ 15,271	$ 13,044
Professional services	3,208	2,221
Property and equipment purchases	2,378	115
Other	7,389	5,198
	$ 28,246	$ 20,578

11. Debt

On July 31, 2017, the Company entered into an Amendment Letter Agreement (the "Amendment") with Roche Finance Ltd ("Roche Finance"), amending the Credit Facility Agreement, dated August 2, 2016, between the Company and Roche (the "Existing Credit Facility" and, as amended, the "Roche Credit Facility").

The Amendment amends certain provisions of the Existing Credit Facility to provide for an extension of the period during which the Company may borrow funds from three to four years, ending August 2, 2020 (the "Draw Period"), and an increase in the available funds from $100 million to $200 million, of which $80 million is available immediately, $70 million will be available upon the achievement of certain milestones, and $50 million will be available upon the achievement of certain additional milestones. Pursuant to the Amendment, loans made under the Roche Credit Facility will bear interest at 6.5% per annum, as compared to 5% under the Existing Credit Facility. The Company shall pay Roche quarterly during the Draw Period and for six months thereafter accrued interest on the outstanding principal of the loans. Beginning six months after the Draw Period and for five years thereafter, the Company shall pay Roche quarterly equal payments of principal, with accrued interest, in arrears until maturity of the Roche Credit Facility on February 2, 2026 (the "Final Maturity Date"). The Company shall also pay Roche a quarterly commitment fee of 0.4% per annum on the available commitment until the end of the Draw Period, as compared to 0.3% under the Existing Credit Facility. The other provisions of the Existing Credit Facility remain substantially unchanged. The proceeds from the Roche Credit Facility are intended to be used for research and development and commercialization, corporate development, and working capital management.

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 services 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 covenants under the Roche Credit Facility as of September 30, 2017.

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 representations and warranties, a change of control, a 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 under the Roche Credit Facility as of September 30, 2017.

As of September 30, 2017, the Company had $30 million in cash borrowings outstanding under the Roche Credit Facility. Interest expense was $0.4 million and $0.5 million for the three and nine months ended September 30, 2017, respectively, and $0.1 million for both the three and nine months ended September 30, 2016. Interest expense for the three and nine months ended September 30, 2017 included a $0.3 million loss on extinguishment of debt due to the write-off of unamortized deferred financing costs in conjunction with the amendment to the Roche Credit Facility.

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,	
	2017	2016	2017	2016
Outstanding stock options	849,953	1,303,007	849,953	1,303,007
Unvested restricted stock	1,386,942	1,473,483	1,386,942	1,473,483
Total	2,236,895	2,776,490	2,236,895	2,776,490

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, accrued liabilities, and debt. 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 fair value of our outstanding debt balance approximates the carrying value as of the balance sheet date. The principal amount of our outstanding debt balance at September 30, 2017 and December 31, 2016 was $30.0 million and $0, respectively.

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, 2017 and December 31, 2016 , and indicate the fair value hierarchy of the valuation techniques utilized to determine such fair value (in thousands):

	Fair Value Measurement at September 30, 2017			
	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Assets:				
Cash equivalents	$ 25,119	$ —	$ —	$ 25,119
Marketable securities:				
U.S. government agency securities and treasuries	—	—	—	—
Total assets	$ 25,119	$	$ —	$ 25,119

	Fair Value Measurement at December 31, 2016			
	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Assets:				
Cash equivalents	$ 56,147	$ —	$ —	$ 56,147
Marketable securities:				
U.S. government agency securities and treasuries	71,999	7,403	—	$ 79,402
Total	$ 128,146	$ 7,403	$ —	$ 135,549

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, 2017 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, 2017 and 2016.

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, 2017.

14. Stockholders' Equity

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

	September 30, 2017	December 31, 2016
Unvested restricted stock	1,386,942	1,297,054
Common stock options	849,953	1,267,329
Shares available for issuance under the 2013 Stock Option and Incentive Plan	3,250,408	2,398,031
Shares available for issuance under the 2013 Employee Stock Purchase Plan	788,503	788,503
	6,275,806	5,750,917

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, 2017 and 2016, the number of shares reserved and available for issuance under the 2013 Stock Plan increased by 1,403,616 and 1,379,782 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, 2016	1,297,054
Granted	775,819
Vested	(520,098)
Cancelled	(165,833)
Unvested at September 30, 2017	1,386,942

Total stock-based compensation expense recognized for restricted stock awards was $4,435,000 and $16,145,000 for the three and nine months ended September 30, 2017 respectively, and $4,990,000 and $10,863,000 for the three and nine months ended September 30, 2016, 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, 2017 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, 2016	1,267,329	$ 16.22	6.6	$ 8,355
Granted	—	—		
Exercised	(366,044)	11.28		
Cancelled	(51,332)	24.39		
Outstanding as of September 30, 2017	849,953	$ 17.86	5.9	$ 19,500
Exercisable as of September 30, 2017	746,590	$ 16.43	5.8	$ 18,061

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 $500,000 and $1,915,000 for the three and nine months ended September 30, 2017, respectively, and $866,000 and $2,663,000 for the three and nine months ended September 30, 2016, respectively.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Cost of revenue	$ 294	$ 668	$ 1,952	$ 1,488
Selling and marketing	824	1,112	3,341	2,768
General and administrative	2,872	2,800	8,809	6,393
Research and development	945	1,276	3,958	2,877
Total	$ 4,935	$ 5,856	$ 18,060	$ 13,526

As of September 30, 2017, unrecognized compensation cost of approximately $29,100,000 related to non-vested stock options and restricted stock awards is expected to be recognized over weighted-average periods of 2.2 years.

There were no stock options granted during the three and nine months ended September 30, 2017 and three months ended September 30, 2016. The weighted-average assumptions used to estimate the fair value of stock options using the Black-Scholes option pricing model for the nine months ended September 30, 2016 were as follows:

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

15. Commitments and Contingencies

Legal Matters

From time to time, the Company is party to litigation arising in the ordinary course of its business. On July 28, 2017, a purported stockholder of the Company filed a putative class action in the U.S. District Court for the District of Massachusetts, against the Company and certain of its current and former executives, captioned Mahoney v. Foundation Medicine, Inc., et al., No. 1:17-cv-11394. The complaint alleges violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 thereunder based on allegedly false and misleading statements when providing 2015 financial guidance. The lawsuit seeks among other things, unspecified compensatory damages in connection with the Company's allegedly inflated stock price between February 26, 2014 and November 3, 2015, interest, attorneys' fees and costs, and unspecified equitable/injunctive relief.

16. Related Party Transactions

Roche Holdings, Inc. and its affiliates

Related-party molecular information services revenue from Roche for the three months ended September 30, 2017 and 2016 was $5,618,000 and $4,965,000, respectively, and $16,642,000 and $16,201,000 for the nine months ended September 30, 2017 and 2016, respectively, which was earned under the Molecular Information Platform Program and ex-U.S. Commercialization Agreement.

Related-party pharma research and development services revenue from Roche for the three months ended September 30, 2017 and 2016 was $11,021,000 and $8,136,000, respectively, and $18,656,000 and $17,380,000 for the nine months ended September 30, 2017 and 2016, respectively, from the reimbursement of R&D costs under the CDx Development, Immunotherapy Testing Platform Development and other programs.

Costs of related-party molecular information services from Roche were $1,238,000 and $1,217,000 for the three months ended September 30, 2017 and 2016, respectively, and $4,183,000 and $3,050,000 for the nine months ended September 30, 2017 and 2016, respectively, which consisted of costs incurred under the Molecular Information Platform Program and costs related to the delivery of services outside of the United States under the Ex-U.S. Commercialization Agreement.

At September 30, 2017, $2,203,000 and $296,000 was included in total accounts receivable and deferred revenue, respectively, related to this arrangement. At December 31, 2016, $2,007,000 and $3,747,000 was included in total accounts receivable and deferred revenue, respectively, related to this arrangement. As of September 30, 2017, the Company had $30 million in cash borrowings outstanding under the Roche Credit Facility. There were no other material Roche-related balances included in the condensed consolidated financial statements as of September 30, 2017 or December 31, 2016, or for the three and nine months ended September 30, 2017 and 2016.

Other related party transactions

The Company recognized revenue of $247,000 and $396,000 for the three and nine months ended September 30, 2017, respectively, and $334,000 and $1,486,000 during the three and nine months ended September 30, 2016, respectively, from an arrangement with an entity affiliated with a former member of the Company’s Board executed during the year ended December 31, 2013. At September 30, 2017 and December 31, 2016, there was $215,000 and $0, respectively, 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, 2016. 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 offering services that are enabled by our molecular information platform to physicians and biopharmaceutical companies. Our platform includes proprietary methods and algorithms for analyzing specimens across all types of cancer, and for incorporating that information into clinical care in a concise and user-friendly fashion. Our services provide genomic information about each patient's individual cancer, enabling physicians to optimize treatments in clinical practice and biopharmaceutical companies to develop targeted oncology therapies more effectively. We believe we have a significant first mover advantage in providing a portfolio of comprehensive genomic profiling and molecular information services on a commercial scale.

Our suite of molecular information services including FoundationOne for solid tumors, FoundationOneHeme for blood-based cancers, or hematologic malignancies, FoundationACT, a blood-based assay to measure circulating tumor DNA, or ctDNA, and FoundationFocus CDx *BRCA* , an FDA approved companion diagnostic assay to aid in identifying women with ovarian cancer for whom treatment with Rubraca™ (rucaparib) is being considered, 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 our competitive advantage, we are continuing to develop and commercialize new molecular information services for physicians and biopharmaceutical companies, strengthen our commercial organization, introduce new marketing, education and provider engagement efforts, grow our molecular information knowledgebase, FoundationCORE, aggressively pursue reimbursement from government payors and regional and national commercial payors, publish scientific and medical advances, and foster relationships throughout the oncology community. We believe our molecular information services address a global market opportunity of $12-15 billion.

Since our inception in 2009, we have devoted substantially all of our resources to the development of our molecular information platform and portfolio of services. We have incurred significant losses since our inception, and as of September 30, 2017 our accumulated deficit was $468.2 million. We expect to continue to incur operating losses over the near term as we expand our commercial operations, invest in our molecular information platform and additional services, including FoundationOne CDx, and invest in our infrastructure.

FoundationOne, FoundationOneHeme, 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 FoundationFocus CDx *BRCA* , which is FDA approved, we are seeking FDA approval for FoundationOne CDx for use as a companion diagnostic across multiple solid tumor types. 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 FoundationOne CDx. If approved, FoundationOne CDx could be the first FDA approved comprehensive genomic profiling assay that incorporates multiple companion diagnostics in a single platform, which we believe would be an additional key differentiator for us.

Recent Developments

We are 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 services 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 CDx. The FDA and CMS accepted our application for Parallel Review of this assay in the second quarter of 2016. We cannot predict whether the PMA for this assay 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 CDx 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 has indicated that they will endeavor to work with us to reduce the time and cost of the approval decision for our assay including the implementation of priority review, interactive review, senior management involvement, and assignment of a case manager. We have been submitting to the FDA data in support of our PMA in separate modules as part of a rolling data submission process, and we have been in engaged in regular communications with CMS in support of the NCD. In June 2017, we submitted

our final PMA module to the FDA , and in July 2017 we submitted a dossier o f data and information to CMS. We anticipate a decision from the FDA on our PMA, and a decision from CMS on a draft NCD , during the fourth quarter of 2017.

Financial Operations Overview

Revenue

We derive revenue from the provision of molecular information services provided to our ordering physicians and biopharmaceutical customers, as well as from pharma research and development services provided to our biopharmaceutical customers. Molecular information services include molecular profiling and the delivery of other molecular information derived from our platform. Pharma research and development services include the development of new platforms and information solutions, including companion diagnostic development. We currently receive payments from commercial third-party payors, Medicare, certain hospitals and cancer centers with which we have direct-bill relationships, individual patients, and our biopharmaceutical customers.

We recognize revenue in accordance with FASB ASC Topic 605, *Revenue Recognition* ("ASC 605"). Accordingly, we recognize revenue when all of the following criteria are met: (i) persuasive evidence of an arrangement exists; (ii) delivery has occurred; (iii) the fee is fixed or determinable; and (iv) collectability is reasonably assured. Criterion (i) is satisfied when we have an arrangement or contract in place. Criterion (ii) is satisfied when we deliver a report to the ordering physician or the biopharmaceutical customer. Determination of criteria (iii) and (iv) are based on management's judgments regarding whether the fee is fixed or determinable, and whether the collectability of the fee is reasonably assured.

We recognize revenue on a cash basis when we cannot conclude that criteria (iii) and (iv) have been met. We currently recognize revenue on a cash basis from sales of our molecular information services to certain clinical customers, including payments received from commercial third-party payors, Medicare, and from patients who make co-payments, pay deductibles or from other amounts that we have been unable to collect from third-party payors. We use judgment in our assessment of whether the fee is fixed or determinable and whether collectability is reasonably assured in determining when to recognize revenue in the future as we continue to gain payment experience with third-party payors and patients. Accordingly, we expect to recognize revenue on a cash basis for these clinical customers until we have sufficient history to reliably estimate payment patterns. Our molecular information services are delivered electronically, and as such there are no shipping and handling fees incurred by us or billed to customers. Our molecular information services are exempt from state sales taxation due to the nature of the services. As a result, we do not charge customers state sales tax.

We recognize revenue from the sale of our molecular information services to clinical customers, including certain hospitals, cancer centers, other institutions and patients, at the time results of the test are reported to physicians, if criteria (i) through (iv) above are met.

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 services 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. An LCD that reflects coverage for our validated comprehensive genomic profiling services does not exist within the jurisdiction where our Cambridge, Massachusetts laboratory facility is located. As of September 30, 2017, 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. We are a participating provider in the Medicare program on a limited basis. In addition, an LCD exists for certain patients with NSCLC who meet the LCD eligibility requirements and receive FoundationOne testing, at least in part, at our Research Triangle Park, North Carolina laboratory facility. We also receive payments from 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 have a laboratory facility located in Cambridge, Massachusetts. The local MAC for our Cambridge laboratory, National Government Services, has elected not 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 services, 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.

D uring 2016 we established a second laboratory facility in Research Triangle Park, North Carolina. Although we are in the process of seeking an NCD for FoundationOne CDx as part the Paral lel Review process, there are currently no NCDs that establish whether and how our tests are covered by Medicare. In the absence of NCDs, local MACs that administer the Medicare program in various regions have some discretion in determining coverage, the r eimbursement rate, and payment for tests. Palmetto, the MAC covering our laboratory in North Carolina, issued a final LCD , the Palmetto LCD, to cover well-validated comprehensive genomic profiles for initially diagnosed Stage IIIB and Stage IV NSCLC patien ts who meet the eligibility criteria.

In January 2017, we began submitting claims to Palmetto for FoundationOne test requisitions where components of our testing services were performed in our North Carolina facility. In March 2017, we began receiving payment for eligible NSCLC claims submitted under the Palmetto LCD based upon the allowable rate of $3,416 per test. On December 22, 2016, Palmetto issued three draft LCDs for the use of comprehensive genomic profiling to guide treatment in patients with metastatic colorectal cancer; with metastatic melanoma; and with advanced primary peritoneal, fallopian tube and ovarian cancer. These draft LCDs are past the prescribed public comment periods and are awaiting finalization.

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 FoundationOneHeme tests for Medicare patients with dates of service on or after November 1, 2013. We have submitted these claims for FoundationOne and FoundationOneHeme tests to National Government Services using a miscellaneous CPT code, and have not recognized any revenue from Medicare for those claims to date.

There are a subset of Medicare patients that fall under the Medicare 14-Day Rule, requiring us to bill the ordering institution directly instead of billing Medicare. We have recognized some revenue for these patients upon receipt of payment from the instit ution. As of September 30, 2017, National Government Services has either denied the FoundationOne or FoundationOneHeme 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. 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, 2017, we have recognized revenue from some of those claims.

FoundationOne, FoundationOneHeme, FoundationACT, and FoundationFocus CDx *BRCA* tests for patients covered by Original Medicare, including those patients that fell under the 14-Day Rule, represented approximately 29% and 31% of total tests reported to physicians in the United States during the three months ended September 30, 2017 and 2016, respectively, and 30% of total tests reported to physicians in the United States during the nine months ended September 30, 2017 and 2016.

We expect that our current lack of broad 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. In the future, a MAC having jurisdiction over any one of our laboratory facilities could issue a negative coverage determination for one or more of our tests that would apply to future claims for tests performed at the relevant facility 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 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. 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 anticipate that we will begin to recognize revenue from such payor on an accrual basis.

As of September 30, 2017, we had cash and cash equivalents of approximately $76.8 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 securities balances, cash flows from operations, and available borrowings 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 Credit Facility Agreement with Roche Finance Ltd dated August 2, 2016, as amended by the Amendment Letter Agreement with Roche Finance Ltd, or Roche Finance, dated July 31, 2017, or Roche Credit Facility.

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 insurance providers. 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 sales of our services to biopharmaceutical customers are based on a negotiated price per test or on the basis of an agreement to provide certain testing volume, data access, or pharma research and development services over a defined period. We recognize revenue upon delivery of the test results, or over the period in which pharma research and development services are provided, as appropriate.

Contracts for pharma customers are primarily analyzed as multiple-element arrangements given the nature of the service deliverables. For pharma research and development services performed, we are compensated in various ways, including (1) through the reimbursement of costs incurred; (2) through non-refundable regulatory and other developmental milestone payments; and (3) through royalty and sales milestone payments. For some multiple-element arrangements, including the R&D Collaboration agreement with Roche, we will be reimbursed for either all or a portion of the research and development costs incurred. We perform pharma research and development services as part of our normal activities. We record these payments as pharma research and development services revenue in the Consolidated Statements of Operations and Comprehensive Loss, using a proportional performance model over the period in 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. The research and development costs incurred by us under these arrangements are included as Research and development expenses in our Consolidated Statements of Operations and Comprehensive Loss given these costs are related to the development of new services to be owned and offered by us to our customers.

We analyze multiple-element arrangements based on the guidance in FASB ASC Topic 605-25, *Revenue Recognition-Multiple-Element Arrangements* ("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 if: (i) the delivered items have value to the customer on a standalone basis and (ii) the arrangement includes a general right of return relative to the delivered items and delivery or performance of the undelivered items is considered probable and substantially within 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 ("VSOE") of selling price, if available, third-party evidence ("TPE") of selling price if VSOE is not available, or best estimate of selling price ("BESP") if neither VSOE nor TPE is available. 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 to us, 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 service(s), based on the underlying contract terms, pro vided that the reported sales are reliably measurable and we have no remaining performance obligations, assuming all other revenue recognition criteria are met. To date, royalt y revenue recognized by us has been immaterial.

Cost of Molecular Information Services Revenue and Operating Expenses

We allocate certain overhead expenses, such as rent, utilities, and depreciation to cost of molecular information services 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 Molecular Information Services Revenue

Cost of molecular information services revenue generally consists of specific reagents, specific consumable lab supplies, and shared costs that are allocated to our molecular information services – our FoundationOne, FoundationOneHeme, FoundationACT and FoundationFocus CDx *BRCA* tests – either on a direct or indirect basis, resulting in an overall cost for each specific test. The shared costs that are allocated to each test include personnel expenses (comprised of salaries, bonuses, employee benefits and stock-based compensation expenses), depreciation of laboratory equipment and amortization of leasehold improvements, shipping costs, third-party laboratory costs, and certain overhead expenses.

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.

Cost of Related-Party Molecular Information Services Revenue from Roche

Cost of Related-party molecular information services revenue from Roche is generally derived by taking the cost per test described above and applying it to each of the FoundationOne, FoundationOneHeme and FoundationACT tests processed for Roche. Costs of Related-party molecular information services revenue from Roche are associated with performing molecular information services for Roche under both the (i) molecular information platform program within our R&D Collaboration Agreement with Roche, and (ii) our Ex-U.S. Commercialization Agreement with Roche. Revenues from tests performed by us under the molecular information platform and the Ex-U.S. Commercialization Agreement are recognized in the Related-party molecular information services from Roche caption within our Consolidated Statements of Operations and Comprehensive Loss.

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, 2017 and 2016, our selling and marketing expenses represented approximately 39% and 50%, respectively, of our total revenue and during the nine months ended September 30, 2017 and 2016, selling and marketing expenses represented approximately 48% and 49%, 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 our current molecular information services, and any future services we may develop.

General and Administrative Expenses

Our general and administrative expenses include costs for our executive, accounting and finance, legal, corporate information technology, 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, including ongoing litigation involving a patent infringement claim asserted by us, and an increase in billing costs related to our anticipated increase in revenues.

Research and Development Expenses

Research and development expenses consist primarily of costs incurred for the development of new and enhanced services, immunotherapy testing, companion diagnostic development, significant service improvements, clinical trials to evaluate the clinical utility of our services, the development of our FoundationCORE knowledgebase, and various technology applications such as FoundationICE and Patient-Match. 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.

Costs incurred for the performance of pharma research and development services requested by our biopharmaceutical customers, including non-molecular information services costs incurred under the R&D Collaboration Agreement with Roche, are included as Research and development expenses in the Consolidated Statements of Operations and Comprehensive Loss, given these costs are related to the development of new services to be owned and offered by us to our customers. Revenues from these services are recognized in the pharma research and development services and related-party pharma research and development services from Roche captions within our Consolidated Statements of Operations and Comprehensive Loss.

Interest (Expense) Income, Net

Interest (expense) income, net includes interest expense and interest income. Interest expense consists primarily of the amortization of deferred financing costs, the quarterly commitment fee on the available balance under the Roche Credit Facility, and interest expense on outstanding borrowings under the Roche Credit Facility. Interest income is earned on our cash, cash equivalents, and marketable securities.

Other Income

Other income includes the gain on disposal of certain long-lived assets and foreign exchange transactions.

Results of Operations

Comparison of Three Months Ended September 30, 2017 and 2016

	Three Months Ended September 30,		Change	
	2017	2016	$	%
	(in thousands, except percentages)			
Statement of Operations Data:				
Revenue:				
Molecular information services	$ 22,750	$ 13,754	$ 8,996	65%
Related-party molecular information services from Roche	5,618	4,965	653	13%
Pharma research and development services	3,269	2,571	698	27%
Related-party pharma research and development services from Roche	11,021	8,136	2,885	35%
Total revenue	42,658	29,426	13,232	45%
Costs and expenses				
Cost of molecular information services	17,890	14,729	3,161	21%
Cost of related-party molecular information services from Roche	1,238	1,217	21	2%
Selling and marketing	16,556	14,654	1,902	13%
General and administrative	17,001	13,012	3,989	31%
Research and development	22,399	17,238	5,161	30%
Total costs and expenses	75,084	60,850	14,234	23%
Loss from operations	(32,426)	(31,424)	(1,002)	(3)%
Interest income (expense), net	(278)	142	(420)	(296)%
Other income	60	—	60	100%
Net loss	$ (32,644)	$ (31,282)	$ (1,362)	(4)%

Revenue

Molecular Information Services

Molecular information services revenue, including Roche related-party revenue, increased to $28.4 million for the three months ended September 30, 2017 from $18.7 million during the three months ended September 30, 2016. Revenue from tests reported to our ordering physicians increased to $13.1 million for the three months ended September 30, 2017 from $8.7 million for the three months ended September 30, 2016. The increase in revenue was partly driven by Medicare payments for FoundationOne for eligible patients with non-small cell lung cancer under the Palmetto LCD, higher test volumes, and an increase in revenue recorded under our Roche Ex-U.S. Commercialization Agreement. Molecular information services revenue from our biopharma customers increased to $15.3 million from $10.0 million for the three months ended September 30, 2017 and 2016, respectively, and was driven by increased testing volume from new and existing customers.

Related-party molecular information services revenue from Roche was $5.6 million and $5.0 million for the three months ended September 30, 2017 and 2016, respectively, the majority of which is revenue earned under the Molecular Information Platform Program.

During the three months ended September 30, 2017, we reported a total of 17,474 tests to ordering physicians, including 1,478 FoundationOneHeme tests, 1,488 FoundationACT tests, and 110 FoundationFocus CDx *BRCA* tests as compared to 11,627 tests reported during the three months ended September 30, 2016, including 1,325 FoundationOneHeme tests and 904 FoundationACT tests.

The average revenue per comprehensive genomic profiling test for clinical use that met our revenue recognition criteria during the three months ended September 30, 2017 was approximately $2,600, as compared to $2,800 during the three months ended September 30, 2016. 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 decrease was driven by lower out-of-network payments from commercial third-party payers.

The total number of clinical tests paid, excluding tests performed under the Roche Ex-U.S. Commercialization Agreement, during the three months ended September 30, 2017 was 4,561, including 2,924 tests that were reported in prior periods. The total

number of clinical tests pa id , excluding tests performed under the Roche Ex-U.S. Commercialization Agreement, during the three mont hs ended September 30, 2016 was 2,969, including 1,73 9 tests that were reported in prior periods.

The average revenue per test sold for clinical use that met our revenue recognition criteria 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. 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 as a result of unpredictable reimbursement payments, physician ordering patterns, continuously developing coverage decisions, and a limited payment history for some services. As a result, we cannot be certain that the average revenue per test sold for clinical use that met our revenue recognition in the future will remain consistent with the average reported above.

We delivered the results of 2,817 and 2,245 tests to our biopharmaceutical customers during the three months ended September 30, 2017 and 2016, respectively, and the average revenue per test sold was approximately $3,300 and $3,600 for the same periods.

Pharma Research and Development Services

Pharma research and development services revenue, including Roche related-party revenue, increased to $14.3 million for the three months ended September 30, 2017 from $10.7 million during the three months ended September 30, 2016. The increase was primarily driven by revenue driven by a $10.0 million milestone achieved under the Roche R&D Collaboration Agreement.

Related-party pharma research and development services for Roche includes related-party revenue from Roche of $11.0 million and $8.1 million for the three months ended September 30, 2017 and 2016, respectively. The increase was driven by revenue earned under the Immunotherapy Testing Platform Development Program and under the Companion Diagnostic (CDx) Development Program.

Cost of Molecular Information Services

Cost of molecular information services revenue, including Roche related-party revenue, increased to $19.1 million for the three months ended September 30, 2017 from $15.9 million for the three months ended September 30, 2016. The increase was driven by a 50% increase in tests reported to our ordering physicians, and costs related to our North Carolina laboratory that became operational in the third quarter of 2016. 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, 2017 and 2016, our total cost of molecular information services revenue represented approximately 67% and 85% of our total molecular information services revenue, respectively.

Cost of related-party molecular information services from Roche was $1.2 million for both the three months ended September 30, 2017 and 2016. The costs were driven by testing performed under the Molecular Information Platform Program.

Selling and Marketing Expenses

Selling and marketing expenses increased to $16.6 million for the three months ended September 30, 2017 from $14.7 million for the three months ended September 30, 2016. The increase was primarily due to an increase of $1.8 million in personnel-related costs for employees in our sales, marketing, client service, and reimbursement departments to support our commercialization efforts.

General and Administrative Expenses

General and administrative expenses increased to $17.0 million for the three months ended September 30, 2017 from $13.0 million for the three months ended September 30, 2016. The increase was primarily due to a $1.8 million increase in personnel costs to support and expand our executive, legal, finance, and human resources infrastructure, which includes a $1.2 million one-time equity-based compensation charge, a $1.2 million increase in rent and other facility costs, and a $1.0 million combined increase in legal, consulting, and other professional services costs.

Research and Development Expenses

Research and development expenses increased to $22.4 million for the three months ended September 30, 2017 from $17.2 million for the three months ended September 30, 2016. The increase was primarily attributed to a $2.7 million increase in employee and contractor-related expenses and $2.3 million in consulting related costs.

Interest (Expense) Income, Net

Interest expense was $0.4 and $0.1 million for the three months ended September 30, 2017 and 2016, respectively. The increase was primarily related to a $0.3 million loss on extinguishment of debt due to the write-off of unamortized deferred financing costs in conjunction with the amendment to the Roche Credit Facility. Interest income was $0.1 million and $0.2 million for the three months ended September 30, 2017 and 2016, respectively.

Other Income

Other income during the three months ended September 30, 2017 was $60,000 and related to foreign exchange transactions.

Comparison of Nine Months Ended September 30, 2017 and 2016

	Nine Months Ended September 30,		Change	
	2017	2016	$	%
	(in thousands, except percentages)			
Statement of Operations Data:				
Revenue:				
Molecular information services	$ 63,121	$ 45,130	$ 17,991	40%
Related-party molecular information services from Roche	16,642	16,201	441	3%
Pharma research and development services	5,571	9,330	(3,759)	(40)%
Related-party pharma research and development services from Roche	18,656	17,380	1,276	7%
Total revenue	103,990	88,041	15,949	18%
Costs and expenses				
Cost of molecular information services	54,544	36,241	18,303	51%
Cost of related-party molecular information services from Roche	4,183	3,050	1,133	37%
Selling and marketing	50,107	42,928	7,179	17%
General and administrative	49,926	34,739	15,187	44%
Research and development	68,657	49,194	19,463	40%
Total costs and expenses	227,417	166,152	61,265	37%
Loss from operations	(123,427)	(78,111)	(45,316)	(58)%
Interest income (expense), net	(132)	528	(660)	125%
Other income	204	—	204	100%
Net loss	$ (123,355)	$ (77,583)	$ (45,772)	(59)%

Revenue

Molecular Information Services

Molecular information services revenue, including Roche related-party revenue, increased to $79.8 million for the nine months ended September 30, 2017 from $61.3 million during the nine months ended September 30, 2016. Revenue from tests reported to our ordering physicians increased to $37.6 million for the nine months ended September 30, 2017 from $28.3 million for the nine months ended September 30, 2016. The increase in revenue was partly driven by Medicare payments for FoundationOne for eligible patients with non-small cell lung cancer under the Palmetto LCD, higher test volumes, and an increase in revenue recorded under our Roche Ex-U.S. Commercialization Agreement. Molecular information services revenue from our biopharma customers increased to $42.1 million from $33.0 million for the nine months ended September 30, 2017 and 2016, respectively, and was driven by increased testing volume from new and existing customers.

Related-party molecular information services revenue from Roche was $16.6 million and $16.2 million for the nine months ended September 30, 2017 and 2016, respectively, the majority of which is revenue earned under the Molecular Information Platform Program.

During the nine months ended September 30, 2017 , we reported a total of 47,331 tests to ordering ph ysicians , including 4,370 FoundationOne Heme tests, 4,437 FoundationACT tests, and 679 FoundationFocus CDx *B RCA* tests as compared to 30,898 tests reported during the nine months ended September 30, 2016 , including 3,601 FoundationOne Heme tests and 1,078 FoundationACT tests.

The average revenue per comprehensive genomic profiling test for clinical use that met our revenue recognition criteria during the nine months ended September 30, 2017 was approximately $2,600, as compared to $2,900 during the nine months ended September 30, 2016. 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 decrease was driven by non-contracted payments from commercial third-party payers and non-contracted payments from our Medicare administrator contractor in New England, National Government Services, for our FoundationACT test.

The total number of clinical tests paid, excluding tests performed under the Roche Ex-U.S. Commercialization Agreement, during the nine months ended September 30, 2017 was 13,433, including 4,371 tests that were reported in prior periods. The total number of clinical tests paid, excluding tests performed under the Roche Ex-U.S. Commercialization Agreement, during the nine months ended September 30, 2016 was 9,333, including 2,992 tests that were reported in prior periods.

The average revenue per test sold for clinical use that met our revenue recognition criteria 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. 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 as a result of unpredictable reimbursement payments, physician ordering patterns, continuously developing coverage decisions, and a limited payment history for some services. As a result, we cannot be certain that the average revenue per test sold for clinical use that met our revenue recognition in the future will remain consistent with the average reported above.

We delivered the results of 9,381 and 6,762 tests to our biopharmaceutical customers during the nine months ended September 30, 2017 and 2016, respectively, and the average revenue per test sold was approximately $3,400 and $3,800, for the same periods.

Pharma Research and Development Services

Pharma research and development services, including Roche related-party revenue, decreased to $24.2 million for the nine months ended September 30, 2017 from $26.7 million during the nine months ended September 30, 2016. The decrease was primarily driven by the timing of research and development projects with our non-Roche biopharma customers and the associated recognition of certain regulatory milestones.

Related-party pharma research and development services for Roche includes related-party revenue from Roche of $18.7 million and $17.4 million for the nine months ended September 30, 2017 and 2016, respectively. The increase was driven by the timing of various research and development projects under the Roche R&D Collaboration Agreement.

Cost of Molecular Information Services

Cost of molecular information services revenue, including Roche related-party revenue, increased to $58.7 million for the nine months ended September 30, 2017 from $39.3 million for the nine months ended September 30, 2016. The increase was driven by a 53% increase in tests reported to our ordering physicians, and costs related to our North Carolina laboratory that became operational in the third quarter of 2016. 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, 2017 and 2016, our total cost of molecular information services revenue represented approximately 73% and 64% of our total molecular information services revenue, respectively.

Cost of related-party molecular information services from Roche was $4.2 million and $3.1 million for the nine months ended September 30, 2017 and 2016, respectively. This increase was driven by additional testing performed under the Molecular Information Platform Program.

Selling and Marketing Expenses

Selling and marketing expenses increased to $50.1 million for the nine months ended September 30, 2017 from $42.9 million for the nine months ended September 30, 2016. 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 $1.7 million increase in consulting and marketing-related costs, partially offset by a $0.2 million decrease in facilities costs.

General and Administrative Expenses

General and administrative expenses increased to $49.9 million for the nine months ended September 30, 2017 from $34.7 million for the nine months ended September 30, 2016. The increase was primarily due to a $6.6 million increase in personnel costs to support and expand our executive, legal, finance, and human resources infrastructure, a $6.3 million combined increase in legal, consulting, and other professional services costs, and a $2.3 million increase in rent and other facilities costs.

Research and Development Expenses

Research and development expenses increased to $68.7 million for the nine months ended September 30, 2017 from $49.2 million for the nine months ended September 30, 2016. The increase was primarily attributed to a $9.7 million increase in employee and contractor-related expenses and $6.9 million increase in consulting costs.

Interest (Expense) Income, Net

Interest expense was $0.5 million and $0.1 million for the nine months ended September 30, 2017 and 2016, respectively. The increase was primarily related to a $0.3 million loss on extinguishment of debt due to the write-off of unamortized deferred financing costs in conjunction with the amendment to the Roche Credit Facility. Interest income was $0.4 million and $0.6 million for the nine months ended September 30, 2017 and 2016, respectively.

Other Income

Other income during the nine months ended September 30, 2017 was $204,000 and related to a gain on disposal of certain long-lived assets and foreign exchange transactions.

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, 2017, we had an accumulated deficit of $468.2 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, although we submit for reimbursement to Medicare when appropriate, to date, we have received limited payments. In March 2017, we began receiving payment for eligible non-small cell lung cancer claims submitted under Palmetto's LCD. If commercial third-party payors or government payors agree to pay us for any of these services 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, 2017, we had cash and cash equivalents of approximately $76.8 million. Cash in excess of immediate requirements is invested in accordance with our investment policy, primarily with a view to liquidity and capital preservation. These excess funds are held in money market mutual funds.

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.

Pursuant to the Roche Credit Facility, which was amended on July 31, 2017, during the four-year period ending August 2, 2020, or the Draw Period, we may borrow up to $200 million, of which $80 million is available immediately, $70 million will be available upon the achievement of certain milestones, and $50 million will be available upon the achievement of certain additional milestones. During the Draw Period, we shall pay Roche Finance a quarterly commitment fee of 0.4% on the available balance of the Roche Credit Facility. Loans made under the Roche Credit Facility bear interest at 6.5% per annum. We shall pay Roche Finance, quarterly during the Draw Period and for six months thereafter, accrued interest on the outstanding principal of the loans. Beginning six months after 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 February 2, 202 6 . As of September 30, 2017 , we had $30 million in cash borrowings outstanding under the Roche Credit Facility .

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,	
	2017	2016
	(in thousands)	
Net cash (used in) provided by:		
Operating activities	$ (89,131)	$ (49,439)
Investing activities	68,514	9,001
Financing activities	33,805	522
Net increase (decrease) in cash and cash equivalents	$ 13,188	$ (39,916)

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 $89.1 million for the nine months ended September 30, 2017 compared to $49.4 million for the nine months ended September 30, 2016. The increase in cash used in operating activities was driven primarily by an increase in net loss of $45.8 million and a $0.3 million gain on disposal of long lived assets, partially offset by an increase in stock-based compensation expense of $4.5 million, a $2.0 million increase in depreciation and amortization expense, and a $0.3 million non-cash loss on extinguishment of debt due to the write-off of unamortized deferred financing costs.

Investing Activities

Net cash provided by investing activities for the nine months ended September 30, 2017 was $68.5 million and consisted of $84.4 million in proceeds received from maturities of marketable securities, partially offset by $10.0 million in purchases of property and equipment, $5.0 million in purchases of marketable securities and other investments, and $0.9 million in deposits securing collateral letters of credit issued in connection with the Company’s operating leases. Net cash provided in 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.

Financing Activities

Net cash provided by financing activities was $33.8 million for the nine months ended September 30, 2017 and consisted of $30 million in cash borrowings under the Roche Credit Facility and $3.8 million in proceeds received from the exercise of stock options. Net cash provided by financing activities was $0.5 million for the nine months ended September 30, 2016 and consisted solely of proceeds received from the exercise of stock options.

Operating Capital Requirements

We expect to incur additional operating losses in the near future and our operating expenses will increase as we seek regulatory approval of certain services, scale our technology infrastructure, expand our sales force, increase our marketing efforts to drive market adoption of our molecular information services, innovate our molecular information platform, and develop new service offerings. Our liquidity requirements have consisted of, 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 services 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, from our existing cash and cash equivalents, and borrowings under the Roche Credit Facility.

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. On July 31, 2017, we amended the Roche Credit Facility. Pursuant to the Roche Credit Facility, as amended, during the four-year period ending August 2, 2020, or the Draw Period, we expect to borrow up to $200 million, of which $80 million is available immediately, $70 million will be available upon the

achievement of certain milestones, and $50 million will be available upon the achievement of certain additional milestones . During the Draw Period, we shall pay Roche Finance a quarterly commitment fee of 0. 4 % on the available balance of the Roche Credit Facility. Loans made under the Roche Credit Facility bear interest at 6. 5% per annum. We shall pay Roche Finance, quarterly during the Draw Period and for six months thereafter , accrued interest on the outstanding principal of the loans. B eginning six months a fter 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 February 2, 202 6 . Based on our current business plan, we believe our cash and cash equivalents as of September 30, 2017 , the availability of borrowings u nder the Roche Credit Facility , and anticipated cash flows from operations will be sufficient to meet our anticipated cash requirements for at least t he next 12 months . 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 expec t our operating and capital expenditures to increase as we increase our headcount, expand our selling and marketing activities and continue to invest in new se rvice offerings. If sales of our services grow, we expect our accounts receivable balance to incr ease. 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, anticipated cash flow from operations, and available borrowings are insufficient to satisfy our liquidity requirements, including because of lower demand for our services, 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. 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, 2017 that have changed significantly since December 31, 2016 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, 2016, but omitted below, represent those that have not changed significantly since that date.

	Total	2017	2018-2019	2020-2021	Thereafter
			(in thousands)		
Operating lease obligations (1) (2)	$ 73,596	$ 3,011	$ 24,770	$ 22,825	$ 22,990
Long-term debt obligations (3)	30,000	-	-	4,500	25,500
Interest (3)	13,790	309	5,260	4,353	3,868
Total	$ 117,386	$ 3,320	$ 30,030	$ 31,678	$ 52,358

(1) On May 1, 2017, we became the sole tenant of the Headquarters Building at 150 Second Street, Cambr idge, Massachusetts, leasing approximately 123,210 square feet under an operating lease t hat expires in April 2024.

(2) On April 21, 2017, we leased 1,975 square feet for office space in Palo Alto, California under an operating lease that expires in April 2022.

(3) We shall pay Roche Finance a quarterly commitment fee of 0.4% on the available balance of the Roche Credit Facility. Loans made under the Roche Credit Facility bear interest at 6.5% per annum. We shall pay Roche Finance, quarterly during the Draw Period and for six months thereafter, accrued interest on the outstanding principal of the loans. Beginning six months after 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 February 2, 2026. As of September 30, 2017, we had $30 million in cash borrowings outstanding under the Roche Credit Facility. For further details on the Roche Credit Facility, refer to footnote 11 in the Notes to the Condensed Consolidated Financial Statements.

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, 2016.

Item 3. Quantitative and Qualitative Disclosures about Market Risks

There were no material changes during the nine months ended September 30, 2017, 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, 2016.

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, 2017, 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, 2017, 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. On July 28, 2017, a purported stockholder of the Company filed a putative class action in the U.S. District Court for the District of Massachusetts, against us and certain of our current and former executives, captioned Mahoney v. Foundation Medicine, Inc., et al., No. 1:17-cv-11394. The complaint alleges violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 thereunder based on allegedly false and misleading statements when providing 2015 financial guidance. The lawsuit seeks among other things, unspecified compensatory damages in connection with the Company's allegedly inflated stock price between February 26, 2014 and November 3, 2015, interest, attorneys' fees and costs, and unspecified equitable/injunctive relief.

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, 2016, 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, 2017, June 30, 2017 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

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 a significant portion of our revenue from tests performed at our 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. As we continue to transition some of our services to this new laboratory, we could experience disruptions in 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. For example, in September 2016, we executed a lease for additional laboratory space in Cambridge, Massachusetts. 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 recently opened our 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 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 services and develop and launch new services 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 ou r 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.

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

Our future molecular information services, including FoundationOne CDx, our comprehensive genomic profiling assay that incorporates multiple companion diagnostics, which is currently under review by the FDA and CMS, and other services in various stages of early development, will take time to develop and commercialize, if we are able to commercialize them at all. There can be no assurance that our new services will be capable of reliably identifying relevant genomic alterations in various forms of cancer. Before we can commercialize any new services, we will need to expend significant funds in order to:

- conduct substantial research and development, including validation studies and potentially clinical trials;
- build additional laboratory space for new services;
- further develop and scale our laboratory processes to accommodate different services;
- further develop and scale our infrastructure to be able to analyze increasingly large amounts of data; and
- in the case of services for which we are seeking FDA approval, pursue such FDA approval.

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

- failure of the service to perform as expected at the research or development stage;
- lack of validation data;
- failure to demonstrate the clinical utility of the service; or
- in the case of services for which we are seeking or have received FDA approval, the inability to obtain FDA approval or the loss of FDA approval.

As we develop services, we will have to make significant investments in services development, marketing, and selling resources. In addition, the commercialization of newer services, such as FoundationOne CDx, may negatively affect the sales of existing services or create confusion with existing services, such as FoundationOne, where the diagnostic applications overlap. Physicians may decide to order a newer service in lieu of an existing serivce or may be confused as to which service to order.

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 is operational, we recently opened our laboratory facility in Penzberg, Germany, and we have executed agreements to expand our facilities in Cambridge, Massachusetts. This expansion and any 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 services 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.

The loss or transition of any member of our senior management team or our inability to attract and retain highly skilled scientists, clinicians, and salespeople, or the diversion of management's attention due to the continued implementation of our collaboration with Roche, could adversely affect our business.

Our success depends on the skills, experience and performance of key members of our senior management team. The individual and collective efforts of these employees will be important as we continue to develop our molecular information platform and additional services, and as we expand our commercial activities. The loss or incapacity of existing members of our senior management team could adversely affect our operations if we experience difficulties in hiring qualified successors. Effective February 6, 2017, Troy Cox succeeded Michael J. Pellini, M.D. as our Chief Executive Officer. Effective August 11, 2017, Dave Daly resigned as our Chief Commercial Officer. We have hired a new Chief Commercial Officer, Tom Civik, who will begin his employment with us in November 2017. The complexity inherent in integrating a new key member of the senior management team with existing senior management may limit the effectiveness of any such successor or otherwise adversely affect our business. Leadership transitions can

be inherently difficult to manage and may cause uncertainty or a disruption to our business or may increase the likelihood of turnover in other key officers and employees. Specifically, a leadership transition in the commercial team may cause uncertainty or a disruption to our commercial organization, which may impact our ability to achieve sales and revenue targets.

All members of our senior management team have employment agreements; however, the existence of an employment agreement does not guarantee the retention of the employee for any period of time. We may make use of retention agreements, as we implemented with Steven Kafka, our President and Chief Operating Officer, in January 2017, to mitigate the risk of losing a member of our senior management at a time that would adversely affect key strategic initiatives or our operations as a whole, however, we cannot guarantee that the incentives provided under such retention agreement will be effective in retaining the relevant member of senior management. We do not maintain "key person" insurance on any of our employees.

Our research and development programs and laboratory operations depend on our ability to attract and retain highly skilled scientists and technicians. We may not be able to attract or retain qualified scientists and technicians in the future due to the intense competition for qualified personnel among life science businesses, particularly in Cambridge, Massachusetts, and potentially at our locations in North Carolina and Penzberg, Germany. We also face competition from universities and public and private research institutions in recruiting and retaining highly qualified scientific personnel. We may have difficulties locating, recruiting, or retaining qualified sales people. In addition, our obligation to repurchase shares of our common stock pursuant to Roche's anti-dilution protections set forth in the Investor Rights Agreement may result in changes to our equity compensation programs, which could impact our ability to attract and retain key personnel. Recruitment and retention difficulties can limit our ability to support our research and development and sales programs. All of our employees are at will, which means that either we or the employee may terminate their employment at any time.

The continued implementation of our broad strategic collaboration with Roche may also divert management's focus and resources from other strategic opportunities and operational matters. In addition, this implementation could cause management and employee disruption, resulting in the possible loss of key management, sales and marketing, technical or other personnel. If we experience any of these implementation-related issues, our business could be harmed.

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.

Our business strategy incorporates plans for significant international expansion through our collaboration with Roche. Pursuant to our Ex-U.S. Commercialization Agreement with Roche, beginning in April 2016, Roche obtained the exclusive right to commercialize FoundationOne and FoundationOneHeme, and beginning in October 2017, the exclusive right to commercialize FoundationACT. Additionally, if terms are agreed upon between us and Roche, Roche may obtain the exclusive right to commercialize any new clinica l diagnostic services developed under the R&D Collaboration Agreement, or upon mutual agreement any of our other services, 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, FoundationOneHeme, and FoundationACT in those geographies, and we recently opened our laboratory facility in Penzberg, Germany. Subject to satisfaction of certain performance milestones, the Ex-U.S. Commercialization Agreement will remain in effect until April 2020 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, FoundationOneHeme, FoundationACT, and if terms are agreed upon between us and Roche, any new clinical diagnostic services developed under the R&D Collaboration Agreement, 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.

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, or government delays in issuing such approvals, permits, and licenses;
- failure by us or Roche to obtain regulatory approvals for the manufacture, sale, and use of our services in various countries;
- transition and management of our former distribution relationships in various countries;
- additional, potentially relevant third-party intellectual property 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 services, and exposure to foreign currency exchange rate fluctuations;
- natural disasters, political and economic instability, including wars, terrorism, and political unrest, outbreak of disease, boycotts, curtailment of trade, and other business restrictions; and
- regulatory and compliance risks that relate to maintaining accurate information and control over sales and distribution activities that may fall within the purview of the U.S. Foreign Corrupt Practices Act, or FCPA, including its books and records provisions, or its anti-bribery provisions.

Any of these factors could significantly harm our future international expansion and operations and, consequently, our revenue and results of operations. The difference in regulations under U.S. law and the laws of foreign countries may be significant and, in order to comply with the laws of foreign countries, we may have to implement global changes to our services or business practices. Such changes may result in additional expense to us and either reduce or delay development of our services, commercialization or sales. 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 services, 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

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, as subsequently amended, 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, sales of our services that are regulated as medical devices, such as Foundation Focus CDx *BRCA* or FoundationOne CDx, following a positive determination by the FDA under the Parallel Review program, would be subject to this tax.

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 Current Procedural Terminology, or CPT, procedure codes for molecular pathology tests that we use to bill our services 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 Clinical Laboratory Fee Schedule, or 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. For 2016, CMS established and published 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 CPT codes for individual genes or fails to price favorably mu lti-gene panel codes upon which commercial payors may base rates, or if commercial payors who often base pricing on Medicare fee schedules reduce non-contracted payment rates below the NLA amounts for CPT codes corresponding to individual genes, mandate us e of the 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 private payor rates 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 rates and corresponding test volumes. We did not meet this threshold during the January 1, 2016 to June 30, 2016 data collection period and therefore are not required to report this data in 2017. In June 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. Under the Final Rule, CMS has indicated that Section 216 of PAMA will be implemented as of January 1, 2018. Given the complexity of implementation of the new payment system and recommendations made by a number of stakeholders in the laboratory community that implementation be delayed to address certain concerns about the integrity and completeness of the data reported, there is a possibility that implementation of PAMA would be delayed notwithstanding the Final Rule's January 1, 2018 effective date. If PAMA were delayed, this may have an impact on the method of calculation, the timing for commencement of payment, and the amount of such payments for FoundationOne CDx under the Medicare program. 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. For 2018, we anticipate that CMS will establish and publish an NLA for the CPT code associated with testing for over 51 genes as calculated by establishing a Medicare payment for each test based on the weighted median of the payment rates for private payors for the test code. Our average commercial payor rate for our tests, including, if approved by the FDA, FoundationOne CDx, starting in 2018 could be adversely affected depending upon if and how commercial payors adopt, or are otherwise influenced by, this new Medicare pricing methodology and the payment rates.

The Center for Medicare and Medicaid Innovation announced in June 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 190 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.

Certain Medicare billing policy requirements for clinical laboratory tests impact our ability to bill Medicare directly, and under certain circumstances, requires us to bill and collect payments from hospitals for tests that we perform for inpatient or outpatient Medicare patients. Under the so-called "14-Day Rule," CMS currently requires hospitals to bill Medicare for tests performed on specimens collected from hospital inpatients or outpatients, where those tests are ordered less than 14 days following the date of the patient's discharge from the hospital. When we perform tests that fall within this policy, we cannot bill Medicare directly and instead must bill the hospital, which bills Medicare. Hospitals may assert that they are not required to pay these bills, or they may delay in paying these bills. For hospitals who disclaim responsibility for our bills or delay payment of our bills under the 14-Day Rule, we may undertake collection activities, and as a result of such efforts, we may accept payments from hospitals that are less than the original invoice or we may be unable to collect from hospitals any payments at all.

In the 2018 Hospital Outpatient Prospective Payment System Proposed Rule, issued on July 13, 2017, CMS proposes revisions to the Medicare 14-Day Rule. The proposed revisions would allow the performing laboratory to bill Medicare directly for certain tests performed on specimens collected from hospital outpatients, even when those tests are ordered less than 14 days after the date of specimen collection. CMS is expected to announce the adoption of these proposed revisions and changes to this billing policy later in 2017, and if adopted, these changes could go into effect as early as January 1, 2018. To the extent revisions to Medicare's billing policy would permit us to bill Medicare directly for tests previously billed to hospitals under the 14-Day Rule, we would no longer bill hospitals for such tests. If we bill Medicare directly and do not bill hospitals under the 14-Day Rule, our business and financial condition could be affected since we will no longer receive revenue for Medicare tests billed to hospitals under the 14-Day Rule for Medicare outpatients.

Finally, the recent presidential and congressional elections in the U.S. could result in significant changes in, and uncertainty with respect to, legislation, regulation and government policy that could significantly impact our business and the healthcare industry.

While it is not possible to predict whether and when any such changes will occur, a variety of initiatives to repeal or significantly reform key provisions of the ACA have been introduced in Congress or otherwise proposed. Other potentially significant changes in policy include the possibility of modifications and elimination of programs and reductions in staffing at the F DA and CMS, and initiatives to contain or reduce governmental spending in the healthcare area, including Medicare and Medicaid reimbursement. We cannot predict what future healthcare initiatives will be introduced or implemented at the federal or state lev el, or how any future legislation or regulation may affect us. Any 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 services, may reduce our profits and have a material adverse effect on our business, financial condition, results of operations, and cash flows.

Intellectual Property Risks Related to Our Business

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

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

Monitoring infringement and misappropriation of intellectual property can be difficult and expensive, and we may not be able to detect every instance of infringement or misappropriation of our proprietary rights. Even if we do detect infringement or misappropriation of our proprietary rights, proceedings to enforce our intellectual property rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate. In addition, changes in the law and legal decisions by courts in the United States and foreign countries may affect our ability to obtain adequate protection for our technology and the enforcement of intellectual property.

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 $113.2 million in 2016. From our inception in 2009 through September 30, 2017 , we had an accumulated deficit of $468.2 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.

Exhibit No.	Exhibit Index
10.1	Amendment Letter Agreement, by and between the Company and Roche Finance Ltd., dated July 31, 2017 (incorporated by reference to Exhibit 10.1 of the Company's Form 8-K filed on August 1, 2017).
10.2#	Fifth Amendment to Collaboration Agreement, by and among the Company, F. Hoffmann-La Roche Ltd and Hoffman-La Roche Inc., dated September 8, 2017 (incorporated by reference to Exhibit 10.1 of the Company's Form 8-K filed on September 13, 2017).
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, 2017 and December 31, 2016, (b) our Condensed Consolidated Statements of Operations and Comprehensive Loss for the Three and Nine Months Ended September 30, 2017 and 2016, (c) our Condensed Consolidated Statements of Cash Flows for the Nine Months Ended September 30, 2017 and 2016, and (d) the Notes to such Condensed Consolidated Financial Statements.

* Filed herewith.

** Furnished herewith.

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

SIGNAT URES

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 1, 2017

By: /s/ Troy Cox
Troy Cox
Chief Executive Officer
(Principal Executive Officer)

Date: November 1, 2017

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

Exhibit 31.1

CERTIFICATIONS

I, Troy Cox, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Foundation Medicine, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 1, 2017

/s/ Troy Cox
Troy Cox
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATIONS

I, Jason Ryan, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Foundation Medicine, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 1, 2017

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

Exhibit 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Each of the undersigned officers of Foundation Medicine, Inc. (the "Company") hereby certifies to his knowledge that the Company's Quarterly Report on Form 10-Q for the period ended September 30, 2017 (the "Report"), as filed with the Securities and Exchange Commission on the date hereof, fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended, and that the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 1, 2017

/s/ Troy Cox
Troy Cox
Chief Executive Officer
(Principal Executive Officer)

Date: November 1, 2017

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