Foundation Medicine, Inc.
Form 10-Q
August 01, 2017

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 June 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 July 28, 2017, the registrant had 36,021,729 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 w 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, FoundationOne Heme, FoundationACT, FoundationFocus CDxBRCA, and our universal companion diagnostic assay, 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 our universal companion diagnostic assay, 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;
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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 services 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 subsidiary. 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 in the United States, and several of these marks are at various stages of the registration process in other countries. FoundationFocus™, FoundationCORE™, PatientMatch™, Precision Medicine Exchange Consortium™, SmartTrials™, and FoundationACCESS™ are also trademarks of Foundation. Other trademarks or service marks that may appear in this Quarterly Report are the property of their respective holders. For convenience, we do not use the ® and ™ symbols in each instance in which one of our trademarks appears throughout this Quarterly Report, but this should not be construed as any indication that we will not assert, to the fullest extent under applicable law, our rights thereto.

FOUNDATION MEDICINE, INC.

REPORT ON FORM 10-Q

For the Quarterly Period Ended June 30, 2017

FOUNDATION MEDICINE, INC.

Condensed Consolidated Balance Sheets

(unaudited)

(In thousands, except share and per share data)

	June 30, 2017	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	$36,532	$ 63,617
Marketable securities	34,985	79,402
Accounts receivable	13,645	8,206
Receivable due from Roche	4,082	2,007
Inventory	8,922	10,438
Prepaid expenses and other current assets	5,102	5,251
Total current assets	103,268	168,921
Property and equipment, net	38,713	41,486
Restricted cash	2,305	1,395
Other assets	2,080	2,233
Total assets	$146,366	$ 214,035
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$15,175	$ 11,898
Accrued expenses and other current liabilities	25,269	20,578
Deferred revenue	1,926	2,104
Roche related-party deferred revenue	3,742	3,747
Current portion of deferred rent	1,384	2,324
Total current liabilities	47,496	40,651
Deferred rent, net of current portion and other non-current liabilities	9,354	8,538
Commitments and contingencies (Note 15)		
Stockholders' equity:		
Common stock, $0.0001 par value, 150,000,000 shares authorized; 35,938,814 and 35,281,001 shares issued and outstanding at June 30, 2017 and December 31, 2016, respectively	4	4
Additional paid-in capital	525,041	509,664
Accumulated other comprehensive loss	65	(14)
Accumulated deficit	(435,594)	(344,808)
Total stockholders' equity	89,516	164,846
Total liabilities and stockholders' equity	$146,366	$ 214,035

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

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FOUNDATION MEDICINE, INC.

Condensed Consolidated Statements of Operations and Comprehensive Loss

(unaudited)

(In thousands, except share and per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Molecular information services	$24,777	$17,001	$40,371	$31,376
Related-party molecular information services from Roche	5,520	5,682	11,024	11,236
Pharma research and development services	1,215	3,711	2,302	6,759
Related-party pharma research and development services from Roche	3,492	1,843	7,635	9,244
Total revenue	35,004	28,237	61,332	58,615
Costs and expenses:				
Cost of molecular information services	19,537	11,484	36,654	21,512
Cost of related-party molecular information services from Roche	2,045	471	2,945	1,833
Selling and marketing	17,115	14,481	33,551	28,274
General and administrative	17,648	12,503	32,925	21,727
Research and development	22,973	18,500	46,258	31,956
Total costs and expenses	79,318	57,439	152,333	105,302
Loss from operations	(44,314)	(29,202)	(91,001)	(46,687)
Interest income, net	56	208	146	386
Other income	-	—	144	-
Net loss	$(44,258)	$(28,994)	$(90,711)	$(46,301)
Other comprehensive income:				
Unrealized gain/(loss) on available-for-sale securities	12	73	(6)	237
Foreign currency translation adjustment	102	—	85	—
Total other comprehensive income	114	73	79	237
Comprehensive loss	$(44,144)	$(28,921)	$(90,632)	$(46,064)
Net loss per common share, basic and diluted	$(1.24)	$(0.84)	$(2.55)	$(1.34)
Weighted-average common shares outstanding, basic and diluted	35,660,430	34,613,513	35,544,003	34,575,260

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)

	Six Months Ended June 30,	
	2017	2016
Operating activities		
Net loss	$(90,711)	$(46,301)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	8,841	7,236
Stock-based compensation expense	13,125	7,670
Amortization of premiums and discounts on marketable securities	18	148
Gain on disposal of long-lived assets	(139)	—
Changes in operating assets and liabilities:		
Accounts receivable	(5,439)	(3,056)
Receivable from Roche	(2,076)	(1,627)
Inventory	1,655	(2,168)
Prepaid expenses and other current assets	195	2,688
Other assets	(778)	18
Accounts payable	4,431	4,797
Accrued expenses and other current liabilities	4,184	2,323
Deferred rent and other non-current liabilities	(126)	(991)
Deferred revenue	(178)	467
Roche related-party deferred revenue	(5)	—
Net cash used in operating activities	(67,003)	(28,796)
Investing activities		
Purchases of property and equipment	(6,705)	(11,996)
Purchases of marketable securities and other investments	(4,996)	(77,445)
Proceeds from maturities of marketable securities	49,390	62,453
Net cash provided by (used in) investing activities	37,689	(26,988)
Financing activities		
Proceeds from stock option exercises	2,188	303
Net cash provided by financing activities	2,188	303
Net decrease in cash and cash equivalents	(27,126)	(55,481)
Effect of exchange rate changes on cash and cash equivalents	41	—
Cash and cash equivalents at beginning of period	63,617	117,763
Cash and cash equivalents at end of period	$36,532	$62,282
Supplemental disclosure of non-cash investing and financing activities		
Cash paid for interest	150	—
Acquisition of property and equipment included in accounts payable and accrued expenses	$1,247	$1,941

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

FOUNDATION MEDICINE, INC.

Notes to Condensed Consolidated Financial Statements

(unaudited)

1. Nature of Business and Basis of Presentation

Foundation Medicine, Inc., and its wholly-owned subsidiaries, Foundation Medicine Securities Corporation and FMI Germany GmbH (collectively, the "Company"), is a molecular information company focused on fundamentally changing the way in which patients with cancer are evaluated and treated. The Company believes an information-based approach to making clinical treatment decisions based on comprehensive genomic profiling will become a standard of care for patients with cancer. The Company derives revenue from selling 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, FoundationOne Heme 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 CDxBRCA, 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 has 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 whether 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 CDxBRCA 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 included 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 services to be owned and offered by the Company to its 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 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. The new standard requires that an entity recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. 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. The update also requires additional disclosure about the nature, amount, timing, and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. In 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 guidance 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 engagement of a third-party service provider, to analyze the impact of ASU 2014-09 and the related ASUs across all revenue streams. The Company has substantially 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 second quarter of 2017, the Company began drafting its new accounting policies, including evaluation of any variations in key terms from the baseline contract reviews, and evaluating the new disclosure requirements, including any necessary changes to our business processes, systems, and controls to support the additional required disclosures.

The Company has identified two revenue streams for their contracts with customers: 1) molecular information services and 2) pharma research and development services. For the molecular information services revenue stream, the

Company is in the process of evaluating the application of the new standard to arrangements with certain clinical customers and is not yet able to estimate the anticipated impact to our consolidated financial statements from the application of the new standard. 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. The Company is in the process of evaluating the accounting for these arrangements under the new standard. For the Company's pharma research and development services revenue stream, the Company has not yet identified any significant implementation matters to be resolved, but the Company is in the process of evaluating their application of the new standard and cannot at this time estimate the anticipated impact to our consolidated financial statements from the application of the new standard. For both revenue streams, the Company expects that the disclosures in our notes to the consolidated financial statements related to revenue recognition will be significantly expanded under the new standard.

The Company believes it is following an appropriate timeline to allow for proper recognition, presentation, and disclosure upon adoption effective the beginning of fiscal year 2018. The Company will continue to monitor new customer contracts throughout the remainder of 2017. Additionally, the FASB has issued, and may issue in the future, interpretive guidance which may cause our 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 June 30, 2017, Roche's ownership was approximately 58.5% 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 Pellini, M.D. as the Company's Chief Executive Officer and became a member of the Board. Effective as of Mr. Cox's election, Michael Pellini, M.D. 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.

Molecular Information Platform Program

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

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

The Company identified allocable consideration of approximately $85,000,000 related to the molecular information platform program, which was allocated to the individual units of accounting based on the best estimate of selling price ("BESP"). Revenue related to reserved capacity for sample profiling will be recognized on a straight-line basis as the capacity is available for each individual contract year within the arrangement. The database access and FTE payments will be recognized ratably over the five-year contract life. The FTEs will perform database queries and will deliver results of the requested database queries. The value to Roche is not only the access to the database, but also the service being performed by the FTEs. Therefore, the Company concluded the FTEs should be combined with the database access as one unit of accounting. For any sample profiling provided above the reserved capacity, the Company will recognize revenue as the service is provided based on the BESP.

Immunotherapy Testing Platform Development Program

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

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

Under this platform, Roche will reimburse the Company for certain R&D costs incurred related to the immuno-biomarker discovery and signature identification activities, as well as costs incurred in the development of immunotherapy assays for clinical studies. In addition, Roche will be required to make certain milestone payments upon the achievement of specified clinical events under the immunotherapy testing platform development program. Clinical milestone payments up to $6,600,000 in the aggregate are triggered upon the initiation of Roche clinical trials using immunotherapy assays developed under the R&D Collaboration Agreement and are considered substantive. The R&D reimbursements and clinical milestone payments will be recognized using a proportional performance model when earned by the Company.

Circulating Tumor DNA (ctDNA) Platform Development Program

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

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

The Company 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 are triggered upon successful analytical validation of a ctDNA assay and delivery of a ctDNA clinical trial assay for use in Roche clinical trials. All milestones 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 development program represent a single unit of accounting. The cross-licenses grant each party access to relevant IP of the other party to perform such party's obligations under the contract and to exploit the deliverables. The licenses are delivered at the inception of the arrangement and relate to R&D work performed under the platform. The Company does not sell the licenses separately as they are closely connected to the R&D activities and have little value to Roche without these other deliverables. Therefore, the licenses are combined with the obligation to perform R&D services for the development of a CDx assay as a single unit of accounting.

Under this platform, Roche will reimburse the Company for certain costs incurred related to R&D under the CDx development program with respect to 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 digits 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.

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 FoundationOne Heme, 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 assay commercially available is dependent on successful development and regulatory approval. As such, the Company determined that this was a contingent deliverable and therefore arrangement consideration was not allocated to this deliverable.

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

Under the Amended Agreement, the Partner pays a fixed fee for each sample to be profiled; will reimburse the Company for a portion of costs incurred in performing analytical validation of the CDx assay; and will be required to make certain substantive milestone and other payments upon the achievement of specified regulatory and clinical events tied to the development and commercialization of the CDx. The fixed or determinable consideration under the Amended Agreement was allocated to the units of accounting based on the BESP. Consideration allocated to sample profiling is recognized as 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 $830,000 and $1,300,000 for the three and six months ended June 30, 2017, respectively, and $4,040,000 and $6,864,000 for the three and six months ended June 30, 2016, respectively. Revenue for the three and six months ended June 30, 2017 primarily related to sample profiling and royalties earned on the Partner's commercial product sales. Revenue for the three and six months ended June 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 June 30, 2017 and December 31, 2016 (in thousands):

	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
June 30, 2017				
Description:				
U.S. government agency securities and treasuries	$ 35,000	$ —	$ (15)	$ 34,985
Total	$ 35,000	$ —	$ (15)	$ 34,985
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):

	June 30, 2017	December 31, 2016
Due in one year or less	$34,985	$ 79,402
Due after one year through two years	—	—
Total	$34,985	$ 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 six months ended June 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 each of June 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.

Two customer account balances consisting of $5,535,000 and $4,082,000 were greater than 10% of the total accounts receivable balance, including receivables due from Roche, representing 31% and 23%, respectively, of total accounts receivable at June 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):

	June 30, 2017	December 31, 2016
Raw materials	$ 6,256	$ 8,293
Work-in-process	2,666	2,145
	$ 8,922	$ 10,438

9. Property and Equipment

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

	June 30, 2017	December 31, 2016
Lab equipment	$37,591	$ 34,727
Computer equipment	11,534	11,534
Software	7,642	5,429
Furniture and office equipment	3,854	3,638
Leasehold improvements	25,644	24,730
Construction in progress	2,917	4,512
	89,182	84,570
Less: accumulated depreciation and amortization	(50,469)	(43,084)
	$38,713	$ 41,486

Depreciation and amortization expense for the three and six months ended June 30, 2017 was $4,375,000 and $8,841,000, respectively, and for the three and six months ended June 30, 2016 was $4,167,000 and $7,236,000, 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):

	June 30, 2017	December 31, 2016
Payroll and employee-related costs	$14,140	$ 13,044
Professional services	3,966	2,221
Property and equipment purchases	423	115
Other	6,740	5,198
	$25,269	$ 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 effectiveness of the Amendment is subject to certain customary closing conditions.

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 June 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 a representation and warranty, change of control, or material adverse effect and judgment defaults. Upon the occurrence and continuation of an event of default following applicable notice and cure periods, amounts due under the Roche Credit Facility may be accelerated. The Company had no events of default under the Roche Credit Facility as of June 30, 2017.

As of June 30, 2017, there were no outstanding balances under the Roche Credit Facility as the Company had not yet drawn down any funds on the available balance.

12. Net Loss per Common Share

Basic net loss per share is calculated by dividing net loss applicable to common stockholders by the weighted-average shares outstanding during the period, without consideration for common stock equivalents. Diluted net loss per share is calculated by adjusting the weighted-average shares outstanding for the dilutive effect of common stock equivalents

outstanding for the period, determined using the treasury-stock method and the if-converted method. For purposes of the diluted net loss per share calculation, stock options, and unvested restricted stock are considered to be common stock equivalents, but are excluded from the calculation of diluted net loss per share because their effect would be anti-dilutive. Therefore, basic and diluted net loss per share applicable to common stockholders was the same for all periods presented.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Outstanding stock options	1,012,833	1,384,000	1,012,833	1,384,000
Unvested restricted stock	1,524,058	1,546,882	1,524,058	1,546,882
Total	2,536,891	2,930,882	2,536,891	2,930,882

13. Fair Value Measurements

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

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

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

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

The following tables present information about the Company's assets and liabilities that are measured at fair value on a recurring basis as of June 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 June 30, 2017			
	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Assets:				

Cash equivalents	$ 15,895	$ —	$ —	$ 15,895
Marketable securities:				
U.S. government agency securities and treasuries	29,990	4,995	—	34,985
Total assets	$ 45,885	$ 4,995	$ —	$ 50,880

	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 six months ended June 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 six months ended June 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 June 30, 2017.

14. Stockholders' Equity

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

	June 30, 2017	December 31, 2016
Unvested restricted stock	1,524,058	1,297,054
Common stock options	1,012,833	1,267,329
Shares available for issuance under the 2013 Stock Option and Incentive Plan	3,170,156	2,398,031
Shares available for issuance under the 2013 Employee Stock Purchase Plan	788,503	788,503
	6,495,550	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	719,896
Vested	(417,977)
Cancelled	(74,915)
Unvested at June 30, 2017	1,524,058

Total stock-based compensation expense recognized for restricted stock awards was $6,071,000 and $11,710,000 for the three and six months ended June 30, 2017, respectively, and $3,760,000 and $5,873,000 for the three and six months ended June 30, 2016, respectively.

Stock Options

A summary of stock option activity under the 2010 Stock Plan and the 2013 Stock Plan for the six months ended June 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	(239,836)	9.12		
Cancelled	(14,660)	24.34		
Outstanding as of June 30, 2017	1,012,833	$ 17.79	6.2	$ 22,795
Exercisable as of June 30, 2017	840,484	$ 15.98	6.1	$ 20,294

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 $655,000 and $1,415,000 for the three and six months ended June 30, 2017, respectively, and $871,000 and $1,797,000 for the three and six months ended June 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 June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Cost of revenue	$563	$521	$1,658	$820
Selling and marketing	1,297	860	2,517	1,656
General and administrative	3,159	2,287	5,937	3,593
Research and development	1,707	963	3,013	1,601
Total	$6,726	$4,631	$13,125	$7,670

As of June 30, 2017, unrecognized compensation cost of approximately $32,436,000 related to non-vested stock options and restricted stock awards is expected to be recognized over weighted-average periods of 2.3 years.

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

	Six Months Ended June 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

150 Second Street

In 2013, the Company signed a lease (the "Headquarters Lease") for approximately 61,591 square feet of office and laboratory space (the "Existing Premises") at 150 Second Street in Cambridge, Massachusetts (the "Headquarters Building"). The Headquarters Lease commenced in September 2013, and initially had an eight year expected term. The Headquarters Lease is subject to fixed rate escalation increases and the landlord waived the Company's rent obligation for the first 10.5 months of the lease, having an initial value of $3,300,000. The landlord also agreed to fund up to $9,239,000 in tenant improvements. The Company recorded the tenant improvements as leasehold improvements and deferred rent on the consolidated balance sheet. Deferred rent is amortized as a reduction in rent expense over the term of the Headquarters Lease. The Company recognizes rent expense on a straight-line basis over the expected lease term. In connection with the Company's termination of its prior lease at One Kendall Square, the rent abatement was reduced to approximately $1,841,000 and the expected term of the Headquarters Lease was reduced to 7.5 years. The Company began to record rent expense in April 2013 upon gaining access to and control of the space. Upon execution of the Headquarters Lease, the Company paid a security deposit of $1,725,000 which was reduced to approximately $864,000 in 2014. The security deposit is included in restricted cash in the accompanying balance sheet as of June 30, 2017 and December 31, 2016.

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

On September 30, 2016, the Company entered into three separate yet related agreements to expand its premises at the Headquarters Building. In connection with these agreements, on May 1, 2017 ("Effective Date"), bluebird bio, Inc. ("Bluebird") surrendered approximately 53,455 square feet of space previously leased by Bluebird in the Headquarters Building ("Bluebird Premises"), and the Company became the sole tenant of the Headquarters Building, leasing approximately 123,210 square feet of office and laboratory space. The three agreements include a Third Amendment to Lease with the landlord to amend the Headquarters Lease ("Third Amendment"), an Assignment and Assumption of

Lease (the "Assignment") with Bluebird for the assignment of the lease dated as of June 3, 2013, as amended, between the landlord and Bluebird (the "Bluebird Lease") to the Company, and a Consent to Assignment (the "Consent"), among the landlord, the Company and Bluebird, providing required consents for the assignment of the Bluebird Lease to the Company.

On the Effective Date, the Headquarters Lease was amended as provided in the Third Amendment. Pursuant to the Third Amendment: (i) the Company was entitled to a partial abatement of base rent payable under the Headquarters Lease for each of the first two calendar months following the Effective Date (provided the Company was not in default under the Third Amendment or the Bluebird Lease), (ii) the term of the Headquarters Lease was extended through April 30, 2024, (iii) the Company has the right to extend the term for one subsequent five-year period, (iv) the Company will pay annual base rent on the Existing Premises (ranging from $70.51 to $83.42 per square foot) in accordance with the rent schedule attached to the Third Amendment, with semi-annual adjustments beginning in January and July of each calendar year, and (v) the landlord will provide up to $2,500,000 in tenant improvement allowances to improve the Headquarters Building, including the Existing Premises, the Bluebird Premises and the lobby. Pursuant to the Assignment, the Company assumed the Bluebird Lease and will pay annual base rent on the Bluebird Premises (ranging from $62.83 to $72.84 per square foot) in accordance with the Bluebird Lease. The Third Amendment also requires the Company to increase its security deposit by amending the letter of credit for the Headquarters Lease to $1,771,009, and to amend the terms of the letter of credit to serve as security for both the Third Amendment and the Bluebird Lease.

Palo Alto, CA

On April 21, 2017, the Company entered into a Second Amendment to Lease (the "Palo Alto Amendment") with PAOC, LLC ("PAOC") amending the lease between the Company and PAOC for the lease of approximately 1,975 square feet of office space located in a building at 525 University Avenue, Palo Alto, California. The Palo Alto Amendment extended the term of the lease for a period of 60 months, expiring on April 30, 2022.

The Company will pay rent of $17,775 per month, beginning in June 2017, subject to annual 3% increases beginning May 1, 2018, throughout the term of the amended lease. The Company is entitled to an abatement of fixed rent for the month of May 2017.

Legal Matters

From time to time, the Company is party to litigation arising in the ordinary course of its business. As of June 30, 2017, the Company was not currently a party to any significant litigation. 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.

16. Related Party Transactions

Roche Holdings, Inc. and its affiliates

Related-party molecular information services revenue from Roche for the three months ended June 30, 2017 and 2016 was $5,520,000 and $5,682,000, respectively, and $11,024,000 and $11,236,000 for the six months ended June 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 June 30, 2017 and 2016 was $3,492,000 and $1,843,000, respectively, and $7,635,000 and $9,244,000 for the six months ended June 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 $2,045,000 and $471,000 for the three months ended June 30, 2017 and 2016, respectively, and $2,945,000 and $1,833,000 for six months ended June 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 June 30, 2017, $4,082,000 and $3,742,000 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. There were no other material Roche-related balances included in the condensed consolidated financial statements as of June 30, 2017 or December 31, 2016, or for the three and six months ended June 30, 2017 and 2016.

Other related party transactions

The Company recognized revenue of $64,000 and $149,000 for the three and six months ended June 30, 2017, respectively, and $1,121,000 and $1,152,000 during the three and six months ended June 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 June 30, 2017 and December 31, 2016, there was $149,000 and $0, respectively, included in accounts receivable related to this arrangement.

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

The following discussion of our financial condition and results of operations should be read in conjunction with our 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 selling 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, FoundationOne Heme for blood-based cancers, or hematologic malignancies, including leukemia, lymphoma, myeloma, and sarcomas, FoundationACT (Assay for Circulating Tumor DNA), a blood-based (liquid biopsy) assay to measure circulating tumor DNA, or ctDNA, and FoundationFocus CDxBRCA, a 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, the commercialization of FoundationOne and FoundationOne Heme, and the development of new tests such as FoundationACT and FoundationFocus CDxBRCA. We have incurred significant losses since our inception, and as of June 30, 2017 our accumulated deficit was $435.6 million. We expect to continue to incur operating losses over the near term as we expand our commercial operations, conduct clinical trials, invest in our molecular information platform and additional services, including our universal companion diagnostic, and invest in our infrastructure.

FoundationOne, FoundationOne Heme, and FoundationACT have been commercialized as laboratory developed tests, or LDTs, which are subject to the Clinical Laboratory Improvement Amendments of 1988, or CLIA, and are not currently regulated as medical devices under the Federal Food, Drug and Cosmetic Act. In addition to FoundationFocus CDxBRCA, we are seeking FDA approval for our universal companion diagnostic assay based on

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

On September 30, 2016, we entered into three agreements related to the expansion of our headquarters located at 150 Second Street, Cambridge, Massachusetts, or the Headquarters Building. On May 1, 2017, or the Effective Date, we assumed the lease for approximately 53,455 square feet of space leased by bluebird bio, Inc., or Bluebird, in the Headquarters Building, or the Bluebird Premises. Combined with 69,755 square feet currently leased by us, we have become the sole tenant of the Headquarters Building, leasing approximately 123,210 square feet of office and laboratory space, or the Combined Premises. On the Effective Date, the term of our lease of the Combined Premises was extended through April 30, 2024. We will have the right to extend the term for one subsequent five-year period.

In January 2017, we began submitting claims to Palmetto GBA, or Palmetto, the Company's Medicare Administrative Contractor, or MAC, in North Carolina, 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 non-small cell lung cancer, or NSCLC, claims submitted under Palmetto's local coverage determination, or LCD, based upon the allowable rate of $3,416 per test.

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 June 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. As of June 30, 2017, we became 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.

During 2016 we established a second laboratory facility in Research Triangle Park, North Carolina. Although we are in the process of seeking an NCD for our universal companion diagnostic assay based on our FoundationOne platform as part the Parallel Review process, there are currently no NCDs that establish whether and how our tests are covered by Medicare. In the absence of NCDs, local MACs that administer the Medicare program in various regions have some discretion in determining coverage, the reimbursement 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 patients 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 FoundationOne Heme tests for Medicare patients with dates of service on or after November 1, 2013. We have submitted these claims for FoundationOne and FoundationOne Heme tests to National Government Services using a miscellaneous CPT code, and have not recognized any revenue from Medicare for those claims to date.

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 institution. As of June 30, 2017, National Government Services has either denied the FoundationOne or FoundationOne Heme claims that we have submitted, or not processed and reimbursed us

for the claims in a manner that we believe is consistent with applicable processing guidelines. 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 June 30, 2017, we have recognized revenue from those claims.

FoundationOne, FoundationOne Heme, FoundationACT, and FoundationFocus CDxBRCA tests for patients covered by Medicare, including those patients that fell under the 14-Day Rule, represented approximately 29% of total tests reported to physicians in the United States during the three months ended June 30, 2017 and 2016, respectively, and 30% of total tests reported to physicians in the United States during the six months ended June 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 June 30, 2017, we had cash, cash equivalents, and marketable securities of approximately $71.5 million. If we are not able to obtain coverage decisions from additional commercial third-party payors and government payors over the longer term, and our available cash and marketable 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, provided that the reported sales are reliably measurable and we have no remaining performance obligations, assuming all other revenue recognition criteria are met. To date, royalty 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, FoundationOne Heme, FoundationACT and FoundationFocus CDxBRCA 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, FoundationOne Heme 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 June 30, 2017 and 2016, our selling and marketing expenses represented approximately 49% and 51%, respectively, of our total revenue and during the six months ended June 30, 2017 and 2016, selling and marketing expenses represented approximately 55% and 48%, 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 Income, Net

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

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Results of Operations

Comparison of Three Months Ended June 30, 2017 and 2016

	Three Months Ended June 30,		Change	
	2017	2016	$	%
	(in thousands, except percentages)			
Statement of Operations Data:				
Molecular information services	$24,777	$17,001	$7,776	46 %
Related-party molecular information services from Roche	5,520	5,682	(162)	(3)%
Pharma research and development services	1,215	3,711	(2,496)	(67)%
Related-party pharma research and development services from Roche	3,492	1,843	1,649	89 %
Total revenue	35,004	28,237	6,767	24 %
Costs and expenses				
Cost of molecular information services	19,537	11,484	8,053	70 %
Cost of related-party molecular information services from Roche	2,045	471	1,574	334%
Selling and marketing	17,115	14,481	2,634	18 %
General and administrative	17,648	12,503	5,145	41 %
Research and development	22,973	18,500	4,473	24 %
Total costs and expenses	79,318	57,439	21,879	38 %
Loss from operations	(44,314)	(29,202)	(15,112)	(52)%
Interest income, net	56	208	(152)	(73)%
Net loss	$(44,258)	$(28,994)	$(15,264)	(53)%

Revenue

Molecular Information Services

Molecular information services revenue, including Roche related-party revenue, increased to $30.3 million for the three months ended June 30, 2017 from $22.7 million during the three months ended June 30, 2016. Revenue from tests reported to our ordering physicians increased to $12.9 million for the three months ended June 30, 2017 from $9.4 million for the three months ended June 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 $17.4 million from $13.3 million for the three months ended June 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 $5.5 million and $5.7 million for the three months ended June 30, 2017 and 2016, respectively, the majority of which is revenue earned under the Molecular Information Platform Program.

During the three months ended June 30, 2017, we reported a total of 15,924 tests to ordering physicians, including 1,608 FoundationOne Heme tests, 1,594 FoundationACT tests, and 280 FoundationFocus CDxBRCA tests as compared to 10,286 tests reported during the three months ended June 30, 2016, including 1,248 FoundationOne Heme tests and 174 FoundationACT tests.

The average revenue per comprehensive genomic profiling test for clinical use that met our revenue recognition criteria during the three months ended June 30, 2017 was approximately $2,500, as compared to $3,000 during the

three months ended June 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, the exclusion of international tests that had previously been paid at a higher self-pay rate and are now paid through our Roche Ex-U.S. Commercialization Agreement, 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 three months ended June 30, 2017 was 4,778, including 3,156 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 three months ended June 30, 2016 was 3,024, including 1,729 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 4,762 and 1,895 tests to our biopharmaceutical customers during the three months ended June 30, 2017 and 2016, respectively, and the average revenue per test sold was approximately $3,400 and $4,200 for the same periods.

Pharma Research and Development Services

Pharma research and development services revenue, including Roche related-party revenue, decreased to $4.7 million for the three months ended June 30, 2017 from $5.6 million during the three months ended June 30, 2016. The decrease was primarily driven by the timing of research and development projects with our non-Roche biopharma customers.

Related-party pharma research and development services for Roche includes related-party revenue from Roche of $3.5 million and $1.8 million for the three months ended June 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 $21.6 million for the three months ended June 30, 2017 from $12.0 million for the three months ended June 30, 2016. The increase was driven by a 55% 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 June 30, 2017 and 2016, our total cost of molecular information services revenue represented approximately 71% and 53% of our total molecular information services revenue, respectively.

Cost of related-party molecular information services from Roche was $2.0 million and $0.5 million for the three months ended June 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 $17.1 million for the three months ended June 30, 2017 from $14.5 million for the three months ended June 30, 2016. The increase was primarily due to an increase of $1.6 million in

personnel-related costs for employees in our sales, marketing, client service, and reimbursement departments to support our commercialization efforts, and a $1.0 million increase in consulting and marketing-related costs.

General and Administrative Expenses

General and administrative expenses increased to $17.6 million for the three months ended June 30, 2017 from $12.5 million for the three months ended June 30, 2016. The increase was primarily due to a $1.7 million increase in personnel costs to support and expand our executive, legal, finance, and human resources infrastructure, a $2.9 million combined increase in legal, consulting, and other professional services costs, and a $0.5 million increase in rent and other facilities costs.

Research and Development Expenses

Research and development expenses increased to $23.0 million for the three months ended June 30, 2017 from $18.5 million for the three months ended June 30, 2016. The increase was attributed to a $3.4 million increase in employee and contractor-related expenses, $2.8 million in consulting related costs, and a $0.4 million increase in system related costs, offset by a $2.1 million decrease in lab supplies and clinical trial and related expenses.

Interest Income, Net

Interest income was $142,000 and $208,000 for the three months ended June 30, 2017 and 2016, respectively. Interest expense was $86,000 and $0 for the three months ended June 30, 2017 and 2016, respectively, and was primarily related to the amortization of deferred financing costs and the commitment fee on the available balance under the Roche Credit Facility.

Comparison of Six Months Ended June 30, 2017 and 2016

	Six Months Ended June 30,		Change	
	2017	2016	$	%
	(in thousands, except percentages)			
Statement of Operations Data:				
Molecular information services	$40,371	$31,376	$8,995	29 %
Related-party molecular information services from Roche	11,024	11,236	(212)	(2)%
Pharma research and development services	2,302	6,759	(4,457)	(66)%
Related-party pharma research and development services from Roche	7,635	9,244	(1,609)	(17)%
Total revenue	61,332	58,615	2,717	5 %
Costs and expenses				
Cost of molecular information services	36,654	21,512	15,142	70 %
Cost of related-party molecular information services from Roche	2,945	1,833	1,112	61 %
Selling and marketing	33,551	28,274	5,277	19 %
General and administrative	32,925	21,727	11,198	52 %
Research and development	46,258	31,956	14,302	45 %
Total costs and expenses	152,333	105,302	47,031	45 %
Loss from operations	(91,001)	(46,687)	(44,314)	(95)%
Interest income	146	386	(240)	62 %
Other income	144	—	144	100%
Net loss	$(90,711)	$(46,301)	$(44,410)	(96)%

Revenue

Molecular Information Services

Molecular information services revenue, including Roche related-party revenue, increased to $51.4 million for the six months ended June 30, 2017 from $42.6 million during the six months ended June 30, 2016. Revenue from tests reported to our ordering physicians increased to $24.6 million for the six months ended June 30, 2017 from $19.6 million for the six months ended June 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 $26.8 million from $23.0 million for the six months ended June 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 $11.0 million and $11.2 million for the six months ended June 30, 2017 and 2016, respectively, the majority of which is revenue earned under the Molecular Information Platform Program.

During the six months ended June 30, 2017, we reported a total of 29,857 tests to ordering physicians, including 2,892 FoundationOne Heme tests, 2,949 FoundationACT tests, and 569 FoundationFocus CDxBRCA tests as compared to 19,271 tests reported during the six months ended June 30, 2016, including 2,276 FoundationOne Heme tests and 174 FoundationACT tests.

The average revenue per comprehensive genomic profiling test for clinical use that met our revenue recognition criteria during the six months ended June 30, 2017 was approximately $2,600, as compared to $3,000 during the six months ended June 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, the exclusion of international tests that had previously been paid at a higher self-pay rate and are now paid through our Roche Ex-U.S. Commercialization Agreement, 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 six months ended June 30, 2017 was 8,872, including 3,882 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 six months ended June 30, 2016 was 6,364, including 2,694 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 6,564 and 4,517 tests to our biopharmaceutical customers during the three months ended June 30, 2017 and 2016, respectively, and the average revenue per test sold was approximately $3,400 and $4,300, for the same periods.

Pharma Research and Development Services

Pharma research and development services, including Roche related-party revenue, decreased to $9.9 million for the six months ended June 30, 2017 from $16.0 million during the six months ended June 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 $7.6 million and $9.2 million for the six months ended June 30, 2017 and 2016, respectively. The decrease 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 $39.6 million for the six months ended June 30, 2017 from $23.3 million for the six months ended June 30, 2016. The increase was

driven by a 55% 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 six months ended June 30, 2017 and 2016, our total cost of molecular information services revenue represented approximately 77% and 55% of our total molecular information services revenue, respectively.

Cost of related-party molecular information services from Roche was $2.9 million and $1.8 million for the six months ended June 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 $33.5 million for the six months ended June 30, 2017 from $28.3 million for the six months ended June 30, 2016. The increase was primarily due to an increase of $3.9 million in personnel-related costs for employees in our sales, marketing, client service, and reimbursement departments to support our commercialization efforts, and a $1.6 million increase in consulting and marketing-related costs, partially offset by a $0.3 million decrease in facilities costs.

General and Administrative Expenses

General and administrative expenses increased to $32.9 million for the six months ended June 30, 2017 from $21.7 million for the six months ended June 30, 2016. The increase was primarily due to a $5.2 million combined increase in legal, consulting, and other professional services costs, a $4.8 million increase in personnel costs to support and expand our executive, legal, finance, and human resources infrastructure, and a $1.2 million increase in rent and other facilities costs. Included in G&A is an immaterial share-based compensation modification expense related to Dr. Pellini's resignation as CEO in February 2017.

Research and Development Expenses

Research and development expenses increased to $46.3 million for the six months ended June 30, 2017 from $32.0 million for the six months ended June 30, 2016. The increase was attributed to a $7.0 million increase in employee and contractor-related expenses, $4.7 million increase in consulting costs, $3.0 million increase in reagent costs for analytical validation activities to support our universal companion diagnostic and other companion diagnostic work, and a $1.4 million increase in system related expenses, offset by a $1.6 million decrease in clinical trial costs and $0.2 million decrease in facilities costs.

Interest Income, Net

Interest income was $317,000 and $386,000 for the six months ended June 30, 2017 and 2016, respectively. Interest expense was $171,000 and $0 for the six months ended June 30, 2017 and 2016, respectively, and was primarily related to the amortization of deferred financing costs and the commitment fee on the available balance under the Roche Credit Facility.

Other Income

Other income during the six months ended June 30, 2017 was $144,000 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 June 30, 2017, we had an accumulated deficit of $435.6 million.

We have funded our operations principally from the sale of common stock, preferred stock and revenue from clinical testing and our biopharmaceutical partners. Since we have received 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 June 30, 2017, we had cash, cash equivalents, and marketable securities of approximately $71.5 million. Cash in excess of immediate requirements is invested in accordance with our investment policy, primarily with a view to liquidity and capital preservation. These excess funds are held in U.S. government agency securities, U.S. treasuries, and money market mutual funds consisting of U.S. government-backed securities and treasuries.

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

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, 2026. As of June 30, 2017, there were no outstanding loans under the Roche Credit Facility as we had not yet drawn down any funds on the available balance.

Cash Flows

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

	Six Months Ended June 30,	
	2017	2016
	(in thousands)	
Net cash (used in) provided by:		
Operating activities	$(67,003)	$(28,796)
Investing activities	37,689	(26,988)
Financing activities	2,188	303
Net decrease in cash and cash equivalents	$(27,126)	$(55,481)

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 $67.0 million for the six months ended June 30, 2017 compared to $28.8 million for the six months ended June 30, 2016. The increase in cash used in operating activities was driven primarily by an increase in net loss of $44.4 million, $0.6 million used for working capital requirements, a $0.3 million gain on disposal of long lived assets and amortization of premiums on marketable securities, partially offset by an increase in stock-based compensation expense of $5.5 million and a $1.6 million increase in depreciation and amortization expense.

Investing Activities

Net cash provided by investing activities for the six months ended June 30, 2017 was $37.7 million and consisted of $49.4 million in proceeds received from maturities of marketable securities, partially offset by $5.0 million in purchases of marketable securities and other investments, and $6.7 million in purchases of property and equipment. Net cash used in investing activities for the six months ended June 30, 2016 was $27.0 million and primarily consisted of purchases of marketable securities and other investments of $77.4 million, partially offset by $62.4 million in proceeds received from maturities of marketable securities and $12.0 million in purchases of property and equipment.

Financing Activities

Net cash provided by financing activities was $2.2 million and $0.3 million for the six months ended June 30, 2017 and 2016, respectively, which 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, invest in clinical trials, 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 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. 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. Based on our current business plan, we believe our cash and cash equivalents as of June 30, 2017, the availability of borrowings under the Roche Credit Facility, which we expect to access in 2017, and anticipated cash flows from operations will be sufficient to meet our anticipated cash requirements for at least the 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 expect our operating and capital expenditures to increase as we increase our headcount, expand our selling and marketing activities and continue to invest in new service offerings. If sales of our services grow, we expect our accounts receivable balance to increase. Any increase in accounts payable and accrued expenses may not completely offset increases in accounts receivable, which could result in greater working capital requirements.

If our available cash balances, 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 June 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]	$76,604	$6,019	$ 24,770	$ 22,825	$ 22,990

[1] On May 1, 2017, we became the sole tenant of the Headquarters Building at 150 Second Street, Cambridge, Massachusetts, leasing approximately 123,210 square feet under an operating lease that 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.

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 six months ended June 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 June 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 June 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. As of June 30, 2017, we were not party to any significant litigation. 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 Report for the quarter ended March 31, 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

We rely on a limited number of suppliers or, in some cases, sole suppliers, for some of our laboratory instruments and materials and may not be able to find replacements or immediately transition to alternative suppliers.

We rely on several sole suppliers, including Illumina, Inc., or Illumina, for certain laboratory substances used in the chemical reactions incorporated into our processes, or reagents, sequencers, equipment, and other materials which we use in our laboratory operations. The terms upon which we are able to purchase these supplies and materials from any supplier could be adversely affected by our broad strategic collaboration with Roche and the fact that Roche is our largest stockholder and beneficially owns a majority of our outstanding stock. An interruption in our laboratory operations could occur if we encounter delays or difficulties in securing these reagents, sequencers, or other laboratory materials, and if we cannot then obtain an acceptable substitute. Any such interruption could negatively impact research and development, launches of new products, and significantly affect our business, financial condition, results of operations, and reputation.

We rely on Illumina as the sole supplier of sequencers and various associated reagents, and as the sole provider of maintenance and repair services for these sequencers. Any disruption in Illumina's operations could impact our supply chain and laboratory operations of our molecular information platform and our ability to conduct our business and generate revenue.

We believe that there are only a few other equipment manufacturers that are currently capable of supplying and servicing the equipment necessary for our laboratory operations, including sequencers and various associated reagents. The use of equipment or materials furnished by these replacement suppliers would require us to significantly alter our laboratory operations. Transitioning to a new supplier would be time-consuming and expensive, may result in interruptions in our laboratory operations, would likely affect the performance specifications of our laboratory operations, and would require that we revalidate our existing assays. There can be no assurance that we would be able

to secure alternative equipment, reagents, and other materials, and bring such equipment, reagents, and materials on line and revalidate them without experiencing interruptions in our workflow. In the case of an alternative supplier for Illumina, there can be no assurance that replacement sequencers and various associated reagents would be available or would meet our quality control and performance requirements for our laboratory operations. If we should encounter delays or difficulties in securing, reconfiguring, or revalidating the equipment and reagents we require for our assays, our business, financial condition, results of operations and reputation could be adversely affected.

If we cannot compete successfully with our competitors, including new entrants in the market, we may be unable to increase or sustain our revenue or achieve and sustain profitability.

While personalized genomic diagnostics is a relatively new area of science, we face intense competition from companies that offer tests or have conducted research to profile genes and gene expression in various cancers. Our principal competition comes from diagnostic companies that offer molecular diagnostic tests that capture only a single-marker or hotspot panel tests that capture a limited number of the most well-known gene alterations, as well as academic research centers, diagnostic companies and next generation sequencing, or NGS, platform developers that are offering or developing NGS-based testing. In addition, there are an increasing number of sophisticated commercial competitors who are selling hot spot panel or NGS-based tests that they are marketing

as comparable to, and/or more cost effective than, our existing tests.

Our competitors include laboratory companies such as Bio-Reference Laboratories, Inc., Laboratory Corporation of America Holdings, Quest Diagnostics Incorporated, Caris Life Sciences, Guardant Health, NeoGenomics Laboratories, Genomic Health, Myriad Genetics, Personal Genome Diagnostics, as well as laboratories outside the United States. In addition, companies such as Abbott Laboratories, Qiagen N.V., Nanostring Technologies, Sophia Genetics, and Sequenom, Inc. manufacture or may manufacture diagnostic testing kits that are competitive with our tests or that may be viewed as substitutes for our tests by current or potential customers. There are also a significant number of early stage companies that may develop tests which compete with our tests. Recently, some of these competitors have been increasingly marketing their tests as comparable to, and/or more cost effective than, our tests, and if such marketing strategies are successful, they could result in physicians determining not to order our tests which, in turn, would have an adverse effect on our revenue, financial condition, and results of operations. As competition in our market increases, we may be subject to increased litigation risk, including in connection with our marketing practices and other promotional activities.

Many hospitals and academic medical centers may also seek to perform the type of molecular testing we perform at their own facilities. As such, our competition may include entities such as the MD Anderson Cancer Center, Memorial Sloan-Kettering Cancer Center, University of Michigan, Baylor Medical Genetics Laboratories, Washington University in St. Louis, University of Washington, Intermountain Healthcare, and other academic hospitals and research centers inside and outside the United States.

Illumina, Thermo Fisher, Qiagen N.V., and other companies market NGS platforms that are being sold directly to research centers, biopharmaceutical companies, and clinical laboratories. While these platforms have been largely utilized in research and development settings or testing for non-cancer conditions, many of these companies have launched and will likely continue to commercialize products for focused application in the clinical oncology market. We believe some diagnostic platform providers will seek to place sequencing machines in laboratories and to develop NGS-based laboratory-developed tests, or LDTs, for use in clinical oncology, including by seeking to decrease the cost, size, and complexity of their platforms. In addition, Illumina has received approval by the FDA for an in vitro diagnostic kit for metastatic colorectal cancer and Thermo Fisher has received FDA approval for a multi-gene, NGS-based assay for non-small cell lung cancer. Both FDA approved products can be used for clients who have purchased, respectively, Illumina’s and Thermo Fisher’s platforms. We believe other diagnostic platform providers may develop additional FDA approved diagnostic kits for clinical use by clients who have purchased their platforms, potentially including kits designed to identify genetic alterations in samples of solid tumors or blood-based cancers. Also, many private companies are developing information technology-based tools to support the integration of NGS testing into the clinical setting. The successful development and marketing of these products by diagnostic platform providers could enable some of our potential customers to perform clinical-grade, comprehensive genomic analyses, which could have a material adverse effect on our business and financial condition. These companies may also use their patent portfolios, developed in connection with developing their tests, to allege that our products infringe their patents, and we could face litigation with respect to such allegations and the validity of such patents.

Because our proprietary molecular information platform consists largely of trade-secret protected technology and know-how and has only limited patent protection, new and existing companies inside and outside the United States could seek to develop molecular tests that compete with ours. These competitors could have technological, financial, and market access advantages that are not currently available to us and they could develop and commercialize competing services faster than we are able to do so. Additional competition, including price competition, could have a material adverse impact on our net revenues and profitability.

Reimbursement and Regulatory Risks Relating to Our Business

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

In both domestic and many international markets, sales of our existing and any future services we develop will depend, in large part, upon the availability of reimbursement from third-party payors. These third-party payors include government healthcare programs in various markets, such as Medicare and Medicaid in the United States, managed care providers, accountable care organizations, private health insurers, and other organizations. In particular, we believe that obtaining a positive local coverage decision, or LCD, or national coverage determination, or NCD, and a favorable Medicare reimbursement rate for each of our existing services, and any future services we develop, across substantially all medically indicated cancers will be a necessary element in achieving material commercial success. Physicians and patients may not order our services unless commercial third-party payors and government payors authorize coverage and pay for all, or a substantial portion, of the rates established for our services, and certain commercial third-party payors may not agree to reimburse our existing services or future services if the Centers for Medicare & Medicaid Services, or CMS, or the Medicare administrative contractors, or MACs, assigned to the jurisdictions in which our operational laboratory facilities are located do not issue positive coverage decisions for such services.

There is currently no NCD that determines whether and how our services are covered by Medicare. In the second quarter of 2016, the FDA and CMS accepted our universal companion diagnostic assay based on our FoundationOne platform for the Parallel

Review program. This program provides concurrent review of a medical device by the FDA for marketing approval and by CMS for an NCD to facilitate patient access to innovative medical devices. We cannot predict whether CMS will grant a favorable NCD for this assay, and if coverage is provided, whether such coverage will be sufficiently broad to make the test commercially viable. Moreover, we cannot predict whether the Medicare reimbursement rate established for this test will be favorable at the time of the initial rate determination or any time thereafter. In the absence of an NCD, local MACs that administer the Medicare program in various regions have some discretion in determining coverage for tests.

A MAC assigned to a jurisdiction in which we have an operational laboratory facility may deny a claim submitted by us related to that facility. Even if we do receive coverage from a MAC on appeal of a denied claim, the reimbursement rate may be lower than we expect, and if such rate is then adopted by commercial third-party payors, it would have an adverse effect on our revenues and results of operations. In addition, a MAC may, insofar as such determination is not inconsistent with an NCD, issue an LCD for one or more of our existing or future services, and/or for one or more clinically indicated tumor types involved with such services, that would apply to future claims. Although we would have the opportunity to submit additional materials in support of a positive LCD for our services to the MAC (or to CMS through the Office of Medicare Hearings and Appeals for claims-level appeals), there is no guarantee that the MAC or CMS will provide us with any additional positive LCDs or claims decisions, reverse any previously issued negative LCDs or claims decisions, or maintain any previously issued positive LCDs. In these circumstances, we may be required to receive a signed advance beneficiary notice, or ABN, from Medicare patients in order to be paid directly by the patient for non-covered services.

If CMS issues a negative NCD, or a MAC assigned to the jurisdiction in which one of our operational laboratory facilities is located issues a negative LCD, with respect to one or more of our services and/or clinically indicated tumor types, or if a MAC establishes patient eligibility conditions, data collection obligations or other requirements in addition to the stated requirements of the related LCD that are difficult and/or costly to satisfy, or if a MAC denies reimbursement of one or more of these services in claims not covered by an NCD or LCD, our revenue and results of operations would be adversely affected because we may not be able to satisfy such requirements, our costs in meeting reimbursement requirements may increase or we will not receive revenue or will receive decreased revenue for tests performed. Similarly, if CMS or a MAC withdraws or negatively changes its coverage policies after deciding to cover one or more of our services, our revenue and results of operations would be adversely affected. Physicians may be less likely to order a test for a patient if the test is not subject to a positive coverage determination such that the patient could ultimately be responsible for all or substantially all of the cost of the test. We may also be less likely to receive a positive coverage determination by commercial third-party payors insofar as Medicare identifies one or more of our tests as non-covered in an NCD or LCD.

Commercial third-party payors and government payors are increasingly attempting to contain healthcare costs by demanding price discounts, by limiting coverage on which diagnostic services they will pay for and the amounts that they will pay for new molecular diagnostic services, and by creating conditions to reimbursement, such as conditioning coverage upon participation in clinical evidence development involving research studies and the collection of physician decision impact and patient outcomes data. Because of these cost-containment trends, commercial third-party payors and government payors that currently provide or in the future may provide reimbursement for one or more of our services may reduce, suspend, revoke, or discontinue payments or coverage at any time, including those payors that designate one or more of our existing services and/or clinically indicated tumor types as experimental and investigational. Payors may also create conditions to coverage or contract with third-party vendors to manage laboratory benefit coverage, in both cases creating burdens for ordering physicians and patients that may make our services more difficult to sell. The percentage of submitted claims that are ultimately paid, the length of time to receive payment on claims, and the average reimbursement of those paid claims, is likely to vary from period to period.

As a result, there is significant uncertainty surrounding whether the use of services that incorporate new technology, such as our portfolio of molecular information services, will be eligible for coverage by commercial third-party payors and government payors or, if eligible for coverage, what the reimbursement rates will be for these services. The fact that a diagnostic service has been approved for reimbursement in the past, or has received FDA approval, for any particular indication or in any particular jurisdiction, does not guarantee that such diagnostic service will remain covered or that similar or additional diagnostic services and/or clinically indicated tumor types will be covered in the future. We have had claims for reimbursement denied by certain commercial third-party payors, in some cases because they have designated some or all of FoundationOne, FoundationOne Heme and FoundationACT as experimental and investigational. Reimbursement of next generation sequencing-based cancer tests by commercial third-party payors and government payors may depend on a number of factors, including a payor's determination that our existing and future services are:

- not experimental or investigational;
- medically reasonable and necessary;
- appropriate for the specific patient;
- cost effective;
- supported by peer-reviewed publications;

- included in clinical practice guidelines and pathways; and
- supported by clinical utility and health economic studies demonstrating improved outcomes and cost effectiveness.

As a result, our efforts to receive reimbursement on behalf of patients will take a substantial amount of time, and various commercial third-party payors and government payors may never cover or provide adequate payment for our existing and future services. Our strategy to achieve broad reimbursement and coverage is focused on demonstrating the clinical utility and economic benefits of our services, including engagement with key members of the oncology community and increasing physician demand, but there is no assurance that we will succeed in any of these areas or that, even if we do succeed, we will receive favorable coverage and reimbursement decisions. If adequate third-party coverage and reimbursement is unavailable, we may not be able to maintain volume and price levels sufficient to realize an appropriate return on investment in research and development. Furthermore, if a commercial third-party payor or government payor denies coverage and payment, it may be difficult for us to collect from the patient, and we may not be successful in doing so.

Our North Carolina laboratory became commercially operational in September 2016. We are conducting specific testing services at this facility and are still in the process of determining what other types of services we may conduct at this facility. Such determination will be subject to the existence and limitations of applicable licenses and approvals, to our ability to meet laboratory and testing requirements, and to our ability to accommodate logistical and commercial needs in the test ordering and fulfillment process. Since we are conducting services at our North Carolina laboratory, we have begun to submit claims to Palmetto GBA for patients with non-small cell lung cancer, or NSCLC, tumor types who receive FoundationOne testing and who meet the eligibility requirements of the Palmetto LCD, and who meet data collection obligations or other requirements otherwise established by Palmetto. These claims will be subject to applicable Medicare rules and practices of Palmetto. We could be required to repay any payments received from Palmetto to the extent Palmetto determines that any of the claims for which we have received payment do not meet the requirements of its LCD.

We are engaged in conversations with Palmetto regarding the potential for coverage and payment by Palmetto for FoundationOne claims submitted by our North Carolina laboratory for Medicare patients having tumor types other than NSCLC, as well as coverage and payment for FoundationOne Heme testing. In December 2016, Palmetto issued three draft LCDs for the use of comprehensive genomic profiling to guide treatment in patients with metastatic colorectal cancer; metastatic melanoma; and advanced primary peritoneal, fallopian tube and ovarian cancer. However, these draft LCDs may be delayed, may never be finalized, or if the LCDs are finalized, the coverage established therein may not result in payment for claims submitted by our North Carolina laboratory. There is no certainty that Palmetto will provide coverage for such Medicare patients, and if coverage is provided, that such coverage will result in payments for claims submitted by our North Carolina laboratory. We may also be required to obtain an executed ABN form for non-covered tumor types in order to bill Medicare beneficiaries directly, which may have a negative impact on test utilization and our revenue and profitability.

We are currently considered a “non-contracted provider” by many commercial third-party payors because we have not entered into specific contracts to provide reimbursement for one or more of our existing services for their covered patients, and as a result we take on primary responsibility for obtaining reimbursement on behalf of patients. If we were to become a contracted provider with additional commercial third-party payors in the future, the amount of overall reimbursement we receive may decrease if coverage is furnished for only a limited number of tumor types and/or we are reimbursed less money per test performed at a contracted rate than at a non-contracted rate, which could have a negative impact on our revenue. We may also be unable to collect payments from patients beyond the amount that is paid by their coverage with the relevant provider, and we will experience lost revenue as a result. In addition, coverage in a specific tumor type such as NSCLC could also result in our inability to receive payment for other non-covered tumor types, resulting in lost volume and revenue. Finally, our contracts with current and any additional third-party payors will be subject to renewal, and the renewal process could result in lower reimbursement rates or elimination of reimbursement to us if the parties fail to agree to the terms of renewal and the contract is terminated.

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

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

The FDA does not currently regulate most laboratory developed tests, or LDTs, such as FoundationOne, FoundationOne Heme, and FoundationACT. The FDA historically took the position that, although such LDTs are medical devices, it would exercise enforcement discretion by not requiring compliance with the Federal Food, Drug, and Cosmetic Act, or the FDCA, or its regulations. However, in June 2010, the FDA announced that it intended to no longer exercise enforcement discretion for LDTs and in October

2014, the FDA published two draft guidance documents that, if finalized, would implement a regulatory approach for most LDTs. In the draft guidance documents, the FDA stated that it had serious concerns regarding the lack of independent review of the evidence of clinical validity of LDTs and asserted that the requirements under the Clinical Laboratory Improvement Amendments of 1988, or CLIA, do not address the clinical validity of any LDT. The draft guidance documents proposed to impose a risk-based, phased-in approach for LDTs similar to the existing framework for in vitro diagnostic devices. In November 2016, the FDA announced that it would not finalize the draft guidance documents for LDTs prior to the end of the Obama administration.

In January 2017, the FDA released a discussion paper synthesizing public comments on the 2014 draft guidance documents and outlining an updated possible approach to regulation of LDTs. The discussion paper has no legal status and does not represent a final version of the LDT draft guidance documents. In the discussion paper, the FDA states that there is "a growing consensus that additional oversight of LDTs is necessary." Similar to the FDA's 2014 draft guidance, the FDA's discussion paper proposes a risk-based framework that would require most LDTs to comply with most of the FDA's regulatory requirements for medical devices. Unlike the draft guidance, however, the discussion paper proposes to exempt most currently marketed LDTs from premarket review, requiring only new or substantially modified tests to be approved or cleared by the agency. In addition, the FDA proposed requiring LDTs to comply with only a subset of the medical device quality system regulations, or QSRs, and proposed other changes from the 2014 draft guidance. We cannot predict whether the FDA will take action to regulate LDTs under the new administration or what approach the FDA will seek to take.

Legislative proposals have been introduced in Congress or publicly circulated, each of which would implement differing approaches to the regulation of LDTs. We cannot predict whether any of these legislative proposals will be enacted into law or the impact such new legal requirements would have on our business.

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

For tests that are subject to FDA regulation, we may not be able to obtain timely approvals for our tests or otherwise comply with FDA regulatory requirements, which could delay or prevent us from commercializing our tests or subject us to enforcement action and harm our business.

If the FDA takes action to finalize and implement a regulatory system for LDTs, or if legislation is enacted that subjects LDTs to FDA regulation, we would need to comply with FDA regulatory requirements for our LDTs, including FoundationOne, FoundationOne Heme, FoundationACT, or any future LDTs intended for clinical use. We currently also market Foundation Focus CDxBRCA which was approved by the FDA in December 2016 as a companion diagnostic to aid in identifying women with ovarian cancer for whom treatment with Rubraca™ (rucaparib) is being considered. In addition, we are developing a universal companion diagnostic test that we submitted to the FDA for approval in 2017. Foundation Focus CDxBRCA and our universal companion diagnostic are regulated by the

FDA as Class III medical devices.

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

If a product is classified as a Class III medical device, that product would likely be required to be approved by the FDA under a premarket approval, or PMA, which must be supported by valid scientific evidence to demonstrate a reasonable assurance of safety and effectiveness of the subject service, typically including the results of human clinical trials that demonstrate the clinical validity of that product. During the review of our PMAs, the FDA may indicate areas in which the FDA believes additional data or information is necessary to reach a decision on the application. We may need to expend significant time and resources in responding to such FDA

requests, which could include performing additional testing or developing new data to support the PMA. Depending on the nature of the requests, we may not be able to provide the data or information that the FDA believes necessary to resolve the deficiencies.

For devices not subject to a PMA, we may be required to submit either a de novo reclassification request or, if classified as a Class II medical device, a premarket notification or 510(k). Under the 510(k) process, we must demonstrate that our assays are substantially equivalent in technological characteristics and intended use to legally-marketed predicate devices. If we are unable to identify an appropriate predicate that is substantially equivalent to our device, we would be required to submit a PMA or a de novo reclassification request. The FDA's 510(k) clearance process usually takes from four to twelve months, but it can take longer. Under the de novo process, we may request that the FDA classify a low or moderate risk device that lacks an appropriate predicate as a Class I or Class II device. The de novo process typically requires the development of clinical data and usually takes between six to twelve months from the time of submission of the de novo application, but can take longer.

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

After approval, products subject to FDA regulation are required to comply with post-market requirements. Among the requirements, we and our suppliers must comply with the FDA's QSRs, which set forth requirements for manufacturers of devices, including the methods and documentation for the design, control testing, quality assurance, labeling, packaging, storage, and shipping of our devices. Our limited experience complying with these requirements may lead to operational challenges as we increase the scale of our QSR-compliant operations and develop and refine our policies and procedures for evaluating and mitigating issues we encounter with our processes. Further, if there are any modifications made to our PMA-approved marketed products, a PMA supplement may be required to be submitted to, and approved by, the FDA before the modified device may be marketed. Additionally, the FDA requires that manufacturers of medical devices report adverse events, including when they learn that their devices may have caused or contributed to a death or serious injury, and when they become aware that their device has malfunctioned and would be likely to cause or contribute to a death or serious injury if the malfunction were to recur. Other post-market requirements include post-approval studies, facility registration, product listing, recalls, corrections and removals, and restrictions on advertising and promotion. These requirements could subject our business to further regulatory risks and costs. The FDA enforces the requirements of the Federal FDCA through announced and unannounced inspections. Failure to comply with the FDA's view of our satisfaction of applicable regulatory requirements could require us to expend time and resources to respond to the FDA's observations and to implement corrective and preventive actions, as appropriate. If we cannot resolve such issues to the satisfaction of the FDA, we may be subject to enforcement actions, including untitled or warning letters, fines, injunctions, or civil or criminal penalties. In addition, we could be subject to a recall or seizure of current or future products, operating restrictions, a partial suspension, or a total shutdown of production. Any such enforcement action would have a material adverse effect on our business, financial condition, and operations.

In August 2016, the FDA granted our request to review our universal companion diagnostic assay based on our FoundationOne platform under the Expedited Access Pathway, or EAP, program because it met the three criteria necessary for inclusion in the program, one of which is the large unmet need for comprehensive genomic profiling of tumors. Once accepted into the EAP program, the FDA will work with the device sponsor to try to reduce the time and cost from development to an approval decision. Elements of the EAP program may include priority review, interactive

review, senior management involvement, and assignment of a case manager. We cannot predict whether the PMA for our universal companion diagnostic assay based on our FoundationOne platform will be approved by the FDA, nor can we predict whether any indications for which our universal companion diagnostic assay is approved will be sufficient to make the test commercially viable.

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 CDxBRCA or our universal companion diagnostic assay based on our FoundationOne platform 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. CMS then established and published for 2016 an NLA for some of these codes, including the code associated with testing for 5-50 genes as calculated by determining the median price as provided by the MACs for the applicable code. If CMS reduces reimbursement for the new CPT codes for individual genes or fails to price favorably new multi-gene panel codes which cover our services, or if commercial payors who often base pricing on Medicare fee schedules reduce non-contracted payment rates below the new NLA amount for CPT codes corresponding to individual genes, mandate use of the new sequencing-based panel CPT codes, or decide to stop payment on specific CPT codes altogether, our revenue could be adversely affected.

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

PAMA requires certain clinical laboratories meeting a threshold of Medicare revenues to report private payor payment rates and corresponding test volumes. 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 and CMS's current intention to implement as of January 1, 2018. 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 our universal companion diagnostic may be paid 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. Our average commercial payor reimbursement for our tests, including, if approved by the FDA, our universal companion diagnostic, starting in 2018 could be adversely affected depending upon if and how commercial

payors adopt 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.

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 FDA 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 level, 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.

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

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

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

We are also required to maintain a license for our Massachusetts laboratory facility to perform testing in Massachusetts. Massachusetts laws establish standards for day-to-day operation of our clinical laboratory, including the training and skills required of personnel and quality control over and above that required by CLIA. We are also licensed to perform testing in our Massachusetts laboratory facility by the states of California, Pennsylvania, Maryland, Florida, Rhode Island, and New York, where we have received a permit from the New York State Department of Health to perform FoundationOne and FoundationOne Heme testing and deliver the related test report for specimens originating from New York.

Our North Carolina laboratory facility became commercially operational in September 2016 and currently conducts limited testing activities. We are currently evaluating whether additional services will be conducted at this facility in the future. We have obtained the necessary licensure for the activities currently performed at this facility and are in the process of obtaining additional licensure to allow for potential expansion of services provided. If, after acquiring laboratory licenses for our Massachusetts and North Carolina facilities, we do not maintain these licenses or if our approvals are revoked, our business would suffer. In addition, other states may adopt similar licensure requirements in the future.

We will become subject to additional regulations in foreign jurisdictions as we and Roche expand international distribution of our services and seek to expand clinical laboratory operations outside the United States. International regulation may require prior review or approval of our services, may impose limits on the export of tissue, data or personal information necessary for us to perform our tests, and, as we establish laboratory operations outside the United States, may require us to obtain licenses and other operating permits. This additional regulation may affect our

ability to provide our services and to conduct laboratory operations outside of the United States. If we are unable to comply with existing laws and regulations or changes to the laws and regulations, our business could be materially adversely affected.

We are also subject to the Health Insurance Portability and Accountability Act, or HIPAA, under which the Department of Health and Human Services established comprehensive federal standards with respect to the privacy and security of protected health information and requirements for the use of certain standardized electronic transactions; certain of our services, including our online portals, FoundationICE, Insights, and GeneKit, are subject to these standards and requirements. Amendments to HIPAA under the Health Information Technology for Economic and Clinical Health Act, or the HITECH Act, and related regulatory amendments, which strengthen and expand HIPAA privacy and security standards, increase penalties for violators, extend enforcement authority to state attorneys general, and impose requirements for breach notification.

We furnish to biopharmaceutical partners and academic researchers genomic information that has been de-identified in accordance with HIPAA and relevant international health information privacy regulations. We may also furnish our biopharmaceutical partners and academic researchers with identifiable genomic information for research purposes, so long as such disclosure has been approved by an institutional review board or other ethical or privacy review board. The laws of certain states and countries may require specific consent from the individual either to retain or utilize certain genetic information for research or other purposes even if such information has been de-identified, or may require that we obtain a waiver of such consent from an ethical or privacy review board. Even where we furnish to biopharmaceutical partners and academic researchers genomic information that has been de-identified in accordance with applicable laws and regulations, biopharmaceutical partners or academic researchers may use technology

or other methods to link that de-identified genomic information to the patient from whom it was obtained in contravention of one or more applicable laws and regulations. Similarly, as we expand our decision support applications and offerings, such as SmartTrials, we may encounter greater regulatory risk, such as compliance with HIPAA and other regulations governing the use of protected health information and the promotion of FDA approved drugs. A finding that we have failed to comply with any such laws and any remedial activities required to ensure compliance with such laws could cause us to incur substantial costs, to be subject to unfavorable publicity or public opinion, to change our business practices, or to limit the retention or use of genetic information in a manner that, individually or collectively, could be adverse to our business.

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

- The federal Anti-Kickback Statute, which prohibits knowingly and willfully offering, paying, soliciting, or receiving remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing, arranging for, or recommending of an item or service that is reimbursable, in whole or in part, by a federal healthcare program;
- the federal Stark physician self-referral law, which prohibits a physician from making a referral for certain designated health services covered by a federal healthcare program, including laboratory and pathology services, if the physician or an immediate family member has a financial relationship with the entity providing the designated health services, unless the financial relationship falls within an applicable exception to the prohibition;
- the federal False Claims Act, which imposes liability on any person or entity that, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment to the federal government;
- the federal Civil Monetary Penalties Law, which prohibits, among other things, the offering or transfer of remuneration to a Medicare or other federal or state healthcare program beneficiary if the person knows or should know it is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of services reimbursable by Medicare or other federal or state healthcare program, unless an exception applies;
- other federal and state fraud and abuse laws, such as anti-kickback laws, prohibitions on self-referral, fee-splitting restrictions, prohibitions on the provision of services at no or discounted cost to induce physician or patient adoption, and false claims acts, which may extend to services reimbursable by any third-party payor, including private insurers;
- the prohibition on reassignment of Medicare clinical laboratory claims, which, subject to certain exceptions, precludes the reassignment of such Medicare claims to any other party;
- the rules regarding billing for diagnostic tests reimbursable by the Medicare program, which in certain circumstances prohibit laboratories from charging the Medicare program directly for services provided to hospital inpatients and outpatients, and also prohibit a physician or other supplier from marking up the price of the technical component or professional component of certain diagnostic tests ordered by the physician or other supplier and supervised or performed by a physician who does not "share a practice" with the billing physician or supplier;
- state laws that prohibit other specified practices, such as billing physicians for testing that they order; waiving coinsurance, copayments, deductibles, and other amounts owed by patients; billing a state Medicaid program at a price that is higher than what is charged to one or more other payors;
- federal and state laws regulating lobbying activities, including the disclosure of payments made in connection with such activities; and
- similar foreign laws and regulations that apply to us in the countries in which we operate.

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

Intellectual Property Risks Related to Our Business

If we are unable to protect the confidentiality of our trade secrets, know-how, and other confidential and proprietary information, our business and competitive position would be harmed.

In addition to patent protection, we also rely upon copyright and trade secret protection, as well as non-disclosure agreements

and invention assignment agreements with our employees, consultants and third parties, to protect our confidential and proprietary information. For example, significant elements of some of our tests, including aspects of sample preparation, computational-biological algorithms, and related processes and software, are based on unpatented trade secrets and know-how that are not publicly disclosed. In addition to contractual measures, we try to protect the confidential nature of our proprietary information using physical and technological security measures. Such measures may not, for example, in the case of misappropriation of intellectual rights by an employee, consultant, or third party with authorized access, provide adequate protection for our proprietary information. Our security measures may not prevent an employee, consultant, or third party from misappropriating our trade secrets and providing them to a competitor, and recourse we take against such misconduct may not provide an adequate remedy to protect our interests fully. Enforcing a claim that a party illegally disclosed or misappropriated intellectual property can be difficult, expensive, and time-consuming, and the outcome is unpredictable. Due to variation in the degree of protection afforded to intellectual property of this nature under the laws and regulations applicable to different international markets where our services are sold under our Ex-US Commercialization Agreement with Roche, our ability to pursue and obtain an adequate remedy may depend significantly on the jurisdiction in which the misconduct takes place and our ability to enforce a favorable judgment against the offending party in a jurisdiction in which such party has substantial assets. In addition, trade secrets may be independently developed by others in a manner that could prevent legal recourse by us. If any of our confidential or proprietary information, such as our trade secrets, were to be disclosed or misappropriated, or if any such information were independently developed by a competitor, our competitive position could be harmed.

The Roche Credit Facility contains restrictions that limit our flexibility in operating our business.

In July 2017, we entered into an amendment, or the Credit Facility Amendment, to our secured credit facility agreement with Roche Finance, an affiliate of Roche, as amended, the Roche Credit Facility. As amended by the Credit Facility Amendment, we may borrow up to $200 million under the Roche Credit Facility. The Roche Credit Facility is secured by a lien on all of our assets, including shares of our subsidiaries, our intellectual property, insurance, trade and intercompany receivables, inventory and equipment and contract rights. The Roche Credit Facility requires us to meet specified minimum cash requirements and contains various affirmative and negative covenants that limit our ability to engage in specified types of transactions. These covenants limit our ability to, among other things:

- sell, lease, transfer or otherwise dispose of certain assets;
- acquire another company or business or enter into a merger or similar transaction with third parties;
- incur additional indebtedness, subject to customary exceptions;
- encumber or permit liens on certain assets; and
- pay dividends on our common stock.

Our Board or management team could believe that taking any one of these actions would be in our best interests and the best interests of our stockholders. As such, if we are unable to complete any of these actions because Roche Finance does not provide its consent, it could adversely impact our business and results of operations.

In the event of a default, including, among other things, our failure to make any payment when due or our failure to comply with any provision of the Roche Credit Facility, Roche Finance could elect to declare all amounts outstanding to be immediately due and payable and terminate all commitments to extend further credit. If we are unable to repay those amounts, Roche Finance could proceed against the collateral granted to them to secure such indebtedness.

Roche Finance’s interests as a lender may not always be aligned with our interests, or with Roche’s interests as a stockholder. If our interests come into conflict with those of Roche Finance, including in the event of a default under the Roche Credit Facility, Roche Finance may choose to act in its self-interest, which could adversely affect the success of our current and future collaborative efforts with Roche.

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 June 30, 2017, we had an accumulated deficit of $435.6 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.

We may need to raise additional capital to fund our existing operations, develop our molecular information platform, commercialize new services, and expand our operations.

If our available cash balances, available borrowings under the Roche Credit Facility, which we expect to access in 2017, and anticipated cash flow from operations are insufficient to satisfy our liquidity requirements, including because of lower demand for our services as a result of lower than currently expected rates of reimbursement from commercial third-party payors and government payors or other risks described in this Quarterly Report and our Annual Report, we may seek to sell common or preferred equity or convertible debt securities, enter into another credit facility or another form of third-party funding, or seek other debt financing.

We may consider raising additional capital in the future to expand our business, to pursue strategic investments, to take advantage of financing opportunities, or for other reasons, including to:

- increase our sales and marketing efforts to drive market adoption of our services and address competitive developments;
- fund development and marketing efforts of any future services;
- further expand our laboratory operations domestically and outside of the United States;
- expand our technologies into other types of cancers;
- acquire, license or invest in technologies, including information technologies;
- acquire or invest in complementary businesses or assets; and
- finance capital expenditures and general and administrative expenses.

Our present and future funding requirements will depend on many factors, including:

- our ability to achieve revenue growth;
- our rate of progress in establishing reimbursement arrangements with domestic and international commercial third-party payors and government payors;
- the cost of expanding our laboratory operations and offerings, including our sales and marketing efforts;
- our rate of progress in, and cost of the sales and marketing activities associated with, establishing adoption of and reimbursement for our services;
- our rate of progress in, and cost of research and development activities associated with, services in research and early development;
- the effect of competing technological and market developments;
- costs related to international expansion; and
- the potential cost of and delays in research and development as a result of any regulatory oversight applicable to our services.

The various ways we could raise additional capital carry potential risks and are, in certain cases as set forth in the Investor Rights Agreement and Roche Credit Facility, subject to the prior consent of Roche. If we raise funds by issuing equity securities, dilution to our stockholders could result. Any equity securities issued also could provide for rights, preferences, or privileges senior to those of holders of our common stock. If we raise funds by issuing debt securities, those debt securities would have rights, preferences, and privileges senior to those of holders of our common stock. The terms of debt securities issued or borrowings pursuant to a credit agreement, like the Roche Credit Facility, could impose significant restrictions on our operations. If we raise funds through collaborations and licensing arrangements, we might be required to relinquish significant rights to our platform technologies or services, or grant licenses on terms that are not favorable to us.

Additional equity or debt financing might not be available on reasonable terms, if at all. If we cannot secure additional funding when needed, we may have to delay, reduce the scope of, or eliminate one or more research and development programs or sales and marketing initiatives. In addition, we may have to work with a partner on one or more of our development programs, which could lower the economic value of those programs to us. Lastly, if we are unable to

obtain the requisite amount of financing needed to fund our planned operations, it could have a material adverse effect on our business and ability to continue operating as a going concern.

Risks Related to Our Common Stock

We are recently the subject of securities litigation, which could result in substantial costs and may divert our management's attention.

From time to time, the Company is party to litigation arising in the ordinary course of its business. As of June 30, 2017, the Company was not currently a party to any significant litigation. 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, interest, attorneys' fees and costs, and unspecified equitable/injunctive relief for a class period of February 26, 2014 through November 3, 2015. The Company believes these claims are meritless and intends to vigorously defend itself against the claims made in this lawsuit.

Item 6. Exhibits

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

SIGNATURES

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

FOUNDATION MEDICINE, INC.

Date: August 1, 2017 By: /s/ Troy Cox
Troy Cox
Chief Executive Officer
(Principal Executive Officer)

Date: August 1, 2017 By: /s/ Jason Ryan
Jason Ryan
Chief Financial Officer
(Principal Financial Officer)

Exhibit No.	Exhibit Index
10.1*#	Amendment #2 to the Supply, Service, and Support Agreement, by and between the Company and Illumina, Inc., dated April 11, 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 June 30, 2017 and December 31, 2016, (b) our Condensed Consolidated Statements of Operations and Comprehensive Loss for the Three and Six Months Ended June 30, 2017 and 2016, (c) our Condensed Consolidated Statements of Cash Flows for the Six Months Ended June 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.