Foundation Medicine, Inc.
Form 10-Q
May 02, 2018

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 March 31, 2018

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 April 27, 2018, the registrant had 37,037,754 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, FoundationOneHeme, FoundationACT, FoundationFocus CDx BRCA, and FoundationOne CDx, including expectations as to our ability or the amount of time it will take to achieve successful reimbursement coverage and thereafter payment from third-party payors, such as commercial insurance companies and health maintenance organizations, and government insurance programs, such as Medicare and Medicaid;
- our ability to generate revenue from sales of FoundationOne CDx in light of our receipt of a final National Coverage Determination in March 2018 that establishes nationwide Medicare coverage for FoundationOne CDx for all solid tumor types when ordered by the patient’s treating physician for Medicare beneficiaries with advanced cancer (i.e., either recurrent, relapsed, refractory, metastatic, or advanced stages III or IV cancer), who either have not been previously tested using FoundationOne CDx for the same primary diagnosis of cancer or are seeking repeat testing with FoundationOne CDx for a new primary cancer diagnosis, and continue to seek further cancer therapy;
- 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 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;
- 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 subsidiaries. We own various U.S. federal trademark registrations and applications, and unregistered trademarks and service marks. Foundation Medicine®, FoundationOne®, FoundationACT®, Interactive Cancer Explorer®, FoundationICE®, GeneKit®, Once. And for All®, and The Molecular Information Company® are all registered trademarks of Foundation Medicine in the United States, and several of these marks are at various stages of the registration process in other countries. FoundationOne CDx™, FoundationFocus™, FoundationCORE™, PatientMatch™, Precision Medicine Exchange Consortium™, SmartTrials™, and FoundationACCESS™ are also trademarks of Foundation Medicine. Other trademarks or service marks that may appear in this Quarterly Report are the property of their respective holders. For convenience, we do not use the ® and ™ symbols in each instance in which one of our trademarks appears throughout this Quarterly Report, but this should not be construed as any indication that we will not assert, to the fullest extent under applicable law, our rights thereto.

FOUNDATION MEDICINE, INC.

REPORT ON FORM 10-Q

For the Quarterly Period Ended March 31, 2018

FOUNDATION MEDICINE, INC.

Condensed Consolidated Balance Sheets

(unaudited)

(In thousands, except share and per share data)

| | March 31, 2018 | December 31, 2017 |
|---|---|---|
| Assets | | |
| Current assets: | | |
| Cash and cash equivalents | $60,293 | $ 71,404 |
| Accounts receivable | 32,222 | 19,967 |
| Receivable due from Roche | 9,099 | 10,159 |
| Inventory | 16,411 | 13,171 |
| Prepaid expenses and other current assets | 13,003 | 9,118 |
| Total current assets | 131,028 | 123,819 |
| Property and equipment, net | 41,607 | 41,119 |
| Restricted cash | 2,305 | 2,305 |
| Other assets | 2,225 | 1,760 |
| Total assets | $177,165 | $ 169,003 |
| Liabilities and stockholders' equity | | |
| Current liabilities: | | |
| Accounts payable | $25,865 | $ 21,926 |
| Accrued expenses and other current liabilities | 22,393 | 36,745 |
| Deferred revenue | 2,867 | 2,212 |
| Roche related-party deferred revenue | 4,801 | 3,742 |
| Current portion of deferred rent | 1,836 | 1,818 |
| Total current liabilities | 57,762 | 66,443 |
| Deferred rent, net of current portion and other non-current liabilities | 10,507 | 10,892 |
| Indebtedness to Roche - non-current | 90,000 | 60,000 |
| Commitments and contingencies (Note 15) | | |
| Stockholders' equity: | | |
| Common stock, $0.0001 par value, 150,000,000 shares authorized; 36,933,569 and 36,541,770 shares issued and outstanding at March 31, 2018 and December 31, 2017, respectively | 4 | 4 |
| Additional paid-in capital | 544,541 | 537,904 |
| Accumulated other comprehensive income (loss) | (177) | 109 |
| Accumulated deficit | (525,472) | (506,349) |
| Total stockholders' equity | 18,896 | 31,668 |
| Total liabilities and stockholders' equity | $177,165 | $ 169,003 |

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

5

FOUNDATION MEDICINE, INC.

Condensed Consolidated Statements of Operations and Comprehensive Loss

(unaudited)

(In thousands, except share and per share data)

| | Three Months Ended March 31, | |
|---|---|---|
| | 2018 | 2017 |
| Revenue: | | |
| Molecular information services | $31,943 | $15,594 |
| Related-party molecular information services from Roche | 14,648 | 5,504 |
| Pharma research and development services | 4,782 | 1,087 |
| Related-party pharma research and development services from Roche | 1,467 | 4,143 |
| Total revenue | 52,840 | 26,328 |
| Costs and expenses: | | |
| Cost of molecular information services | 21,279 | 17,117 |
| Cost of related-party molecular information services from Roche | 5,948 | 900 |
| Selling and marketing | 17,480 | 16,436 |
| General and administrative | 20,695 | 15,277 |
| Research and development | 23,859 | 23,285 |
| Total costs and expenses | 89,261 | 73,015 |
| Loss from operations | (36,421) | (46,687) |
| Interest (expense) income, net | (994) | 90 |
| Other income | — | 144 |
| Net loss | $(37,415) | $(46,453) |
| Other comprehensive loss: | | |
| Unrealized loss on available-for-sale securities | — | (18) |
| Foreign currency translation adjustment | (286) | (17) |
| Total other comprehensive loss | (286) | (35) |
| Comprehensive loss | $(37,701) | $(46,488) |
| Net loss per common share, basic and diluted | $(1.02) | $(1.31) |
| Weighted-average common shares outstanding, basic and diluted | 36,792,980 | 35,426,296 |

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)

| | March 31, 2018 | 2017 |
|---|---|---|
| Operating activities | | |
| Net loss | $ (37,415) | $ (46,453) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation and amortization expense | 5,365 | 4,466 |
| Stock-based compensation expense | 3,208 | 6,399 |
| Amortization of premiums and discounts on marketable securities | — | 14 |
| Gain on disposal of long-lived assets | — | (139) |
| Changes in operating assets and liabilities: | | |
| Accounts receivable | 4,974 | 2,348 |
| Receivable from Roche | 1,059 | (2,863) |
| Inventory | (3,230) | 178 |
| Prepaid expenses and other current assets | (3,143) | (30) |
| Other assets | 108 | 82 |
| Accounts payable | 3,456 | 278 |
| Accrued expenses and other current liabilities | (14,388) | (1,780) |
| Deferred rent and other non-current liabilities | (366) | (571) |
| Deferred revenue | 499 | (120) |
| Roche related-party deferred revenue | 981 | (3,453) |
| Net cash used in operating activities | (38,892) | (41,644) |

| | | |
|---|---|---|
| Investing activities | | |
| Purchases of property and equipment | (5,682) | (3,863) |
| Purchases of marketable securities and other investments | — | (4,996) |
| Proceeds from maturities of marketable securities | — | 34,390 |
| Net cash (used in) provided by investing activities | (5,682) | 25,531 |
| Financing activities | | |
| Proceeds from indebtedness to Roche | 30,000 | — |
| Proceeds from stock option exercises | 3,430 | 1,571 |
| Net cash provided by financing activities | 33,430 | 1,571 |
| Net decrease in cash, cash equivalents, and restricted cash | (11,144) | (14,542) |
| Effect of exchange rate changes on cash and cash equivalents | 33 | — |
| Cash, cash equivalents, and restricted cash at beginning of period | 73,709 | 65,012 |
| Cash, cash equivalents, and restricted cash at end of period | $ 62,598 | $ 50,470 |
| Supplemental disclosure of non-cash investing and financing activities | | |
| Cash paid for interest | $ 891 | $ 75 |
| Acquisition of property and equipment included in accounts payable and accrued expenses | $ 4,528 | $ 696 |

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

7

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 CDx, an FDA-approved broad companion diagnostic assay for solid tumors, FoundationOne for solid tumors, FoundationOneHeme for hematologic malignancies and sarcomas, FoundationACT, a blood-based (liquid biopsy) assay to measure circulating tumor DNA ("ctDNA"), and FoundationFocus CDx BRCA, an FDA-approved, companion diagnostic assay to aid in identifying women with ovarian cancer for whom treatment with Rubraca™ (rucaparib) is being considered, are widely available comprehensive genomic profiles designed for use in the routine care of patients with cancer. Following the FDA's approval of FoundationOne CDx in November 2017, the Centers for Medicare & Medicaid Services ("CMS") issued a final National Coverage Determination, or NCD, in March 2018 that establishes nationwide Medicare coverage for FoundationOne CDx for all solid tumor types when ordered by the patient's treating physician for Medicare beneficiaries with advanced cancer (i.e., either recurrent, relapsed, refractory, metastatic, or advanced stages III or IV cancer), who either have not been previously tested using FoundationOne CDx for the same primary diagnosis of cancer or are seeking repeat testing with FoundationOne CDx for a new primary cancer diagnosis, and continue to seek further cancer therapy.

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, 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, 2017 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 7, 2018. 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, 2017.

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, 2017, and the notes thereto, which are included in the Company's Annual Report on Form 10-K. 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, 2017 are reflected below.

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. All amounts are due to be paid in accordance with the customers agreed upon payment terms and we have not identified the existence of any significant financing components.

Effective January 1, 2018, the Company began recognizing revenue in accordance with FASB ASC Topic 606, Revenue from Contracts with Customers ("ASC 606"). The Company adopted ASC 606 utilizing the modified retrospective method, meaning the cumulative effect of applying the standard was recognized to opening retained earnings as of January 1, 2018. ASC 606 provides for 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.

Performance Obligations

Molecular Information Services

Clinical

Our clinical contracts included within molecular information services typically have a single performance obligation to transfer molecular profiling services to either a patient or a facility. In certain limited contracted scenarios, such as arrangements with academic medical centers, the transaction price is stated within the contract and is therefore fixed consideration. For most of our clinical volume, we identified the patient as the customer in Step 1 of the model and have determined an implied contract exists with the patient in Step 1. As such, a stated contract price does not exist and the transaction price for each contract represents variable consideration. In developing the estimate of variable consideration, we utilize the expected value method under a portfolio approach. Our estimate requires significant judgment and is developed using historical reimbursement data from payors and patients, as well as known current reimbursement trends not reflected in the historical data. As these contracts typically have a single performance obligation, no allocation of the transaction price is required in Step 4 of the model. Control over molecular information services is transferred to our ordering physicians at a point in time. Specifically, we determined the customer obtains control of the promised service upon our delivery of the test results. Certain incremental costs, such as commissions, are incurred in obtaining clinical contracts. We have elected to utilize the practical expedient to expense incremental costs of obtaining a contract that meet the capitalization criteria, as the amortization period of any contract acquisition asset would be one year or less due to the short-term nature of our clinical contracts.

Biopharma

Our biopharma contracts included within molecular information services may include single or multiple performance obligations depending on the contract, and may include different molecular information service offerings, such as molecular profiling, provision of data through either database queries or subscription access to our platform, and clinical trial enrollment assistance, as separately identifiable from other promises in the contracts and therefore distinct performance obligations.

The transaction price in biopharma molecular information service contracts is typically fixed consideration. In certain instances, contracts may include variable consideration. In these contracts, variable consideration is estimated utilizing the expected value method. The primary method used to determine standalone selling price for the biopharma molecular information services is observable standalone selling price. When standalone selling price is not directly observable, the primary method used to estimate standalone selling price for molecular information services is the adjusted market assessment approach, under which we evaluate the market in which we sell the services and estimate the price that a customer in that market would be willing to pay for those services.

Control over biopharma molecular information services from molecular profiling and database queries is transferred to customers at a point in time. We determined the customer obtains control of the promised service upon delivery of the test results or the delivery of responses to database queries to the biopharma partner. Control over biopharma

molecular information services from subscription access to our data platform is transferred to customers ratably over time. We determined that the customer obtains control of the promised service as we host the content throughout the contract term. Control over biopharma molecular information services from clinical trial enrollment assistance is transferred to customers ratably over time. We determined that the customer obtains control of the promised service as we stand ready to perform such services throughout the contract term.

Pharma Research and Development Services

Our biopharma contracts included within pharma research and development services may include single or multiple performance obligations depending on the contract. Research and development ("R&D") services typically represent a single performance obligation as the Company performs a significant integration service for the individual goods or services in the R&D workstream, such as analytical validation and regulatory submissions. The individual promises are not separately identifiable from other promises in the contracts and, therefore, are not distinct. However, in certain contracts, a partner may engage the Company for multiple distinct R&D workstreams which are both capable of being distinct and separately identifiable from other promises in the contracts and, therefore, distinct performance obligations. Additionally, for regulatory contracts in pursuit of approval of a companion diagnostic assay, the Company identifies a performance obligation for commercial availability of the assay subsequent to obtaining regulatory approval.

The transaction price can consist of a combination of an upfront fee, performance-based development milestones, cost reimbursement, fixed per sample fees, commercial royalties, and commercial milestones. With the exception of upfront and fixed per sample fees, the other forms of compensation represent variable consideration. Variable consideration in the form of cost reimbursement and commercial royalties is estimated using the expected value method. Variable consideration in the form of development and commercial milestones is estimated using the most likely amount method. All variable consideration is constrained such that it is probable a significant reversal of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. Application of the constraint for variable consideration to milestone payments is an area that requires significant judgment. In making this assessment, the Company evaluates factors such as the scientific, clinical, regulatory, commercial, and other risks that must be managed to achieve the respective milestone and the level of effort and investment required to achieve the respective milestone.

The primary method used to estimate standalone selling price for the R&D service performance obligations is the expected cost plus a margin approach, under which we forecast our expected costs of satisfying each performance obligation and then add an appropriate margin for that distinct good or service. The primary method used to estimate standalone selling price for a commercial availability performance obligation is the adjusted market assessment approach, under which we evaluate the market in which we sell the services and estimate the price that a customer in that market would be willing to pay for those services. The estimation of standalone selling price is an area that requires significant judgment, as it impacts the allocation objective in Step 4 of the model. Revenue will be recognized over time for R&D services and commercial availability services. Specifically, for R&D services we will recognize revenue using an input method to measure progress, utilizing costs incurred to-date relative to total expected costs as our measure of progress. For commercial availability services, we will recognize revenue using an input method to measure progress, resulting in a time-elapsed measure of progress.

The Company performs R&D services as part of its normal activities. The Company records payments for these services as Pharma research and development services revenue in the Consolidated Statements of Operations and Comprehensive Loss. The R&D 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.

Significant Judgments and Contract Estimates

Molecular Information Services

For our clinical molecular information services, we have concluded that an implied contract exists with the patient. This is a significant judgment as contract existence is a requirement to applying the general five-step model of ASC 606.

Accounting for clinical revenue contracts includes estimation of the transaction price, defined as the amount we expect to be entitled to receive in exchange for providing the services under the contract. Due to our out-of-network status with the majority of payors, estimation of the transaction price represents variable consideration. In order to estimate variable consideration, we utilize a portfolio approach in which payors with similar reimbursement experience are grouped into portfolios. Our estimates of variable consideration are based primarily on historical reimbursement data. Certain assumptions will also be adjusted based on known and anticipated factors not reflected in the historical reimbursement data. We monitor these accrual estimates at each reporting period based on actual cash collections in order to assess whether a revision to the estimate is required. Both the initial accrual estimate and any subsequent revision to the estimate contain uncertainty and require the use of judgment in the estimation of the transaction price and application of the constraint for variable consideration.

Pharma Research and Development Services

Accounting for biopharma revenue contracts includes several judgments and estimates which impact the timing and pattern of revenue recognition. Specifically, biopharma contracts require evaluation of separability of promised services, estimation of the transaction price, allocation of the transaction price to performance obligations, and estimation of measure of progress toward complete satisfaction for those performance obligations satisfied over time.

Certain biopharma contracts, typically those for pharma R&D services, contain promises to deliver multiple services. The process for evaluating contracts for material promises, in contrast to immaterial promises or administrative tasks, requires judgment. Once material promises have been identified, we then evaluate whether these promises are both capable of being distinct and distinct within the context of the contract. If both of these criteria are satisfied, a separate performance obligation will be identified. If both criteria are not satisfied, certain promises will be combined in the identification of a combined performance obligation. In assessing whether a promised service is capable of being distinct, the Company considers whether the customer could benefit from the service either on its own or together with other resources that are readily available to the customer, including 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 assessing whether a promised service is distinct within the context of the contract, the Company considers whether we provide a significant integration of the services, whether the services significantly modify or customize one another, or whether the services are highly interdependent or interrelated.

The nature of certain biopharma contracts, primarily contracts for pharma R&D services, requires that the transaction price must be estimated, including application of the constraint to performance-based milestones. The Company evaluates factors such as the scientific, clinical, regulatory, commercial, and other risks that must be managed to achieve the respective milestone and the level of effort and investment required to achieve the respective milestone in making this assessment. Application of the constraint is based on our historical experience with similar milestones, the degree of complexity and uncertainty associated with each milestone, and whether achievement of the milestone is dependent on parties other than the Company. The constraint for variable consideration is applied such that it is probable a significant reversal of revenue will not occur when the uncertainty associated with the contingency is resolved. Application of the constraint for variable consideration is updated at each reporting period as a revision to the estimated transaction price.

Once the transaction price has been estimated, the standalone selling price for each identified performance obligation must be determined in order to allocate the transaction price to performance obligations. Observable standalone selling price is used when available. When an observable price is not available, standalone selling price is estimated using either the adjusted market assessment approach or the expected cost plus a margin approach, utilizing the approach which maximizes the use of observable inputs. Under the adjusted market assessment approach, we utilize pricing on historical similar transactions as well as competitor pricing as relevant inputs. Under the expected cost plus a margin approach, we utilize internal cost models for required personnel and sample resources as the relevant inputs.

Lastly, once the transaction price has been allocated to the identified performance obligations, we must determine the timing and pattern of revenue recognition. For certain biopharma services, particularly pharma R&D services satisfied over time, this requires estimation of the total cost pool in order to determine our measure of progress under the input method. This cost pool is the same cost model utilized to estimate standalone selling price under the expected cost plus a margin approach. At the end of each reporting period, we track actual costs incurred in order to measure progress under the input method and recognize revenue accordingly.

For further discussion on the Company’s revenue recognition, refer to Note 4: Revenue and Note 7: Contract Balances.

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.

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.

The Company adopted ASU 2014-09 Revenue from Contracts with Customers and all related amendments (collectively codified as ASC 606) on January 1, 2018 utilizing the modified retrospective method, meaning the cumulative effect of applying the standard to all contracts that were not completed as of the date of initial application was recognized to opening retained earnings as of January 1, 2018. The Company identified certain differences in accounting for revenue recognition as a result of adoption of ASC 606 which are expected to have a material impact on its financial position or results of operations. These differences are discussed below and any other identified policy differences are not expected to have a material impact on the Company’s financial position or results of operations.

For molecular information services revenue, the Company identified a difference in accounting for certain revenue arrangements from the application of the new revenue accounting standard as compared to the previous revenue accounting standards. Historically, for certain clinical customers, the Company deferred revenue recognition until cash receipt when the price pursuant to the underlying customer arrangement was not fixed and determinable and collectability was not reasonably assured. Under the new standard, this is considered variable consideration. For these arrangements, the Company will record an estimate of the transaction price, subject to the constraint in the new standard for variable consideration, as revenue at the time of delivery. This estimate will be monitored in subsequent periods and adjusted as necessary based on actual collection experience. This will result in earlier revenue recognition as compared to previous revenue recognition.

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

Effective January 1, 2018, the Company recognizes revenue in accordance with ASC 606. Comparative information from prior periods has not been restated and continues to be reported under the accounting standards in effect for those periods.

The cumulative effect of changes made to the Condensed Consolidated Balance Sheet at January 1, 2018 for the adoption of ASC 606 were as follows (in thousands):

| | Balance at December 31, 2017 | Adjustments Due to ASC 606 | Balance at January 1, 2018 |
|---|---|---|---|
| Assets: | | | |
| Accounts receivable | $19,967 | $ 17,243 | $37,210 |
| Prepaid expenses and other current assets | 9,118 | 710 | 9,828 |
| Other assets | 1,760 | 573 | 2,333 |

| | Balance at December 31, 2017 | Adjustments Due to ASC 606 | Balance at January 1, 2018 |
|---|---|---|---|
| Liabilities: | | | |
| Deferred revenue | $2,212 | $ 156 | $2,368 |
| Roche related-party deferred revenue | 3,742 | 78 | 3,820 |

| | Balance at December 31, 2017 | Adjustments Due to ASC 606 | Balance at January 1, 2018 |
|---|---|---|---|
| Equity: | | | |
| Accumulated deficit | $(506,349) | $ 18,292 | $(488,057) |

In accordance with ASC 606 requirements under the modified retrospective method of adoption, the disclosure of the impact of adoption on our Condensed Consolidated Statement of Operations and Condensed Consolidated Balance Sheet was as follows (in thousands):

| | For the three months ended March 31, 2018 | | |
|---|---|---|---|
| | As Reported Under ASC 606 | Effect of Change Higher/(Lower) | Balances Without Adoption of ASC 606 |
| Revenue: | | | |
| Molecular information services | $31,943 | $ 3,212 | $ 35,155 |
| Related-party molecular information services from Roche | 14,648 | (374) | 14,274 |

| | | | |
|---|---|---|---|
| Pharma research and development services | 4,782 | (3,923) | 859 |
| Related-party pharma research and development services from Roche | 1,467 | — | 1,467 |

12

| | March 31, 2018 | | |
|---|---|---|---|
| | As Reported Under ASC 606 | Effect of Change Higher/(Lower) | Balances Without Adoption of ASC 606 |
| Assets: | | | |
| Accounts receivable | $32,222 | $ (14,008) | $18,214 |
| Prepaid expenses and other current assets | 13,003 | (4,771) | 8,232 |
| Other assets | 2,225 | (491) | 1,734 |

| | As Reported Under ASC 606 | Effect of Change Higher/(Lower) | Balances Without Adoption of ASC 606 |
|---|---|---|---|
| Liabilities: | | | |
| Deferred revenue | $2,867 | $ (179) | $2,688 |
| Roche related-party deferred revenue | 4,801 | 286 | 5,087 |

| | As Reported Under ASC 606 | Effect of Change Higher/(Lower) | Balances Without Adoption of ASC 606 |
|---|---|---|---|
| Equity: | | | |
| Accumulated deficit | $(525,472) | $ (19,377) | $(544,849) |

ASC 606 did not have an aggregate impact on the Company's net cash used in operating activities, but resulted in offsetting changes in certain assets and liabilities presented within net cash used in operating activities in the Company's Condensed Consolidated Statement of Cash Flows, as reflected in the above tables.

In January 2016, the FASB issued ASU 2016-01, Recognition and Measurement of Financial Assets and Financial Liabilities ("ASU 2016-01"). ASU 2016-01 provides guidance about how to recognize, measure, present and make disclosures about certain financial assets and financial liabilities under Topic 825. ASU 2016-01 became effective for fiscal years beginning after December 15, 2017. The adoption of ASU 2016-01 did not have a material effect on the Company's consolidated financial statements or disclosures.

In February 2016, the FASB issued ASU 2016-02, Leases ("ASU 2016-02"), to increase transparency and comparability among organizations by recognizing lease assets and lease liabilities, including for operating leases, on the balance sheet and disclosing key information about leasing arrangements. ASU 2016-02 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018. The Company is 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 became effective for fiscal years beginning after December 15, 2017. The adoption of ASU 2016-18 did not 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 2017-09 became effective for fiscal years beginning after December 15, 2017. The adoption of ASU 2017-09 did not have an 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 an R&D collaboration, an ex-U.S. commercial collaboration, a U.S. medical education collaboration, and an equity investment with certain governance provisions, closed on April 7, 2015.

Under the terms of the transaction, Roche (a) made a primary investment of $250,000,000 in cash through the purchase of 5,000,000 newly issued shares of the Company's common stock at a purchase price of $50.00 per share and (b) completed a tender offer to acquire 15,604,288 outstanding shares of the Company's common stock at a price of $50.00 per share. Immediately following the closing of the transaction, Roche owned approximately 61.3% of the outstanding shares. As of March 31, 2018, Roche's ownership was approximately 56.9% 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 February 2017, the Board was increased to ten members. In June 2017, the Board was decreased to nine members when a director retired from the Board at our 2017 annual meeting of stockholders.

The Company assessed the agreements related to each of the R&D collaboration, an ex-U.S. commercial collaboration, and the U.S. medical education collaboration and determined they should be treated as separate contracts 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 promises under the arrangement, are immaterial in relation to the entire arrangement and therefore were not identified as performance obligations.

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. R&D reimbursements and milestone payments will be recognized using an input method measure of progress based on costs incurred by the Company.

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

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

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

On November 1, 2017, the Company and Roche entered into a Sixth 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 promises were identified: (i) cross-licenses for access to relevant intellectual property (“IP”), (ii) sample profiling, (iii) access to the Company’s molecular information database, and (iv) full-time equivalent persons (“FTEs”) per year for performance of database queries and the delivery of results.

The Company assessed which promises within the arrangement are distinct from the other promises, and identified the following separate performance obligations: (i) sample profiling and (ii) access to the Company's molecular information database and FTEs per year for the performance of database queries and the delivery of results. The cross-licenses grant each party access to relevant IP to perform under the contract or to exploit the promised services. 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 promised services. Therefore, the licenses are combined with the other performance obligations identified under the molecular information platform program and are not considered distinct.

The Company identified an estimated transaction price of approximately $85,000,000 related to the molecular information platform program, which was allocated to the individual performance obligations based on standalone selling price. Revenue related to sample profiling will be recognized at the point in time at which test results are delivered to Roche. The database access and FTE payments will be recognized using a time-elapsed measure of progress 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 performance obligation.

Immunotherapy Testing Platform Development Program

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

The Company assessed which promises within the arrangement are distinct from the other promises, and identified a single performance obligation for the performance of R&D services for immuno-biomarker discovery and signature identification. 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 promised service. 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 promised services. Therefore, the licenses are combined with the other performance obligation identified under the immunotherapy testing platform development program and are not considered distinct.

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. The R&D reimbursements and clinical milestone payments will be recognized using an input method measure of progress based on costs incurred by the Company.

Circulating Tumor DNA (ctDNA) Platform Development Program

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

The Company assessed which promises within the arrangement are distinct from the other promised services, and identified a single performance obligation for the performance of R&D services for the development of a ctDNA clinical trial 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 promised service. 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 promised services. Therefore, the licenses are combined with the other performance obligation identified under the ctDNA platform development program and are not considered distinct.

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 equal to $12,000,000 in the aggregate were triggered upon successful analytical validation of a ctDNA clinical trial assay and delivery of a ctDNA clinical trial assay for use in Roche clinical trials. All milestones were recognized at the point in time at which benefit transferred to Roche.

Companion Diagnostics (CDx) Development Program

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

The Company assessed which promises within the arrangement are distinct from the other promised services, and identified the following separate performance obligations: (i) obligation to perform R&D services for the development of a CDx assay and (ii) obligation to maintain commercial availability of our assay inclusive of Roche biomarkers. 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 promised services. 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 promised services. Therefore, the licenses are combined with the obligation to perform R&D services for the development of a CDx assay as a single performance obligation.

Under this platform, Roche reimbursed 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 was 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 were triggered upon obtaining FDA approval of a premarket approval application for each CDx product developed under the arrangement. The R&D reimbursements and regulatory milestone payments were recognized using an input method measure of progress based on costs incurred 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 recognized using an input method to measure progress, resulting in a time-elapsed measure of progress.

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 the Ex-U.S. Commercialization Agreement with Roche (as most recently amended and restated in February 2018, the "Ex-U.S. Commercialization Agreement") designed to facilitate the delivery of the Company's services outside the United States ("Ex-U.S.") in partnership with Roche. 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 promises under the arrangement, are immaterial in relation to the entire arrangement and therefore were not identified as performance obligations.

Under the Ex-U.S. Commercialization Agreement, the following promises 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 promises identified will be combined as a single performance obligation under the Ex-U.S. Commercialization Agreement and revenue will be recognized at the point in time test results are delivered 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 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. In the event Roche does not satisfy its specified commercialization obligations under the agreement, including its obligation to launch Company services in specific countries within a specified timeframe, after a cure period, Roche may be required to make penalty payments to the Company. This milestone payment and these penalty payments will be constrained and recognized in their entirety when the associated contingency is resolved as no enforceable right to payment exists until achievement.

The Company is entitled to receive, on a quarterly basis, tiered 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. These payments are recognized in the period when tests are delivered.

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 breach of its material obligations under the agreement. 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.

Summary of the U.S. Education Agreement

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

IVD Collaboration Agreement

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

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

The IVD Collaboration Agreement expires on April 7, 2020, unless earlier terminated as provided therein. Roche also has the right, in its sole discretion, to extend the term of the IVD Collaboration Agreement for additional two-year

periods of time during any period of time in which Roche continues to hold at least 50.1% of the Company's capital stock. Either party may terminate the IVD Collaboration Agreement for an uncured breach of the agreement, or for insolvency or bankruptcy.

Biopharmaceutical Partner

In July 2012, the Company entered into a Master Services Agreement ("Services Agreement") with a biopharmaceutical partner ("Partner") to perform sample profiling at the Partner's request. The Services Agreement established the legal and administrative framework for the partnership between the entities. The Services Agreement also included a right for the Partner to initiate an exclusive negotiation with the Company for the development of a Companion Diagnostic ("CDx"). In March 2014, the Company and Partner expanded the scope of work by executing a Companion Diagnostic Agreement ("Amended Agreement"), thereby amending the Services Agreement to include the joint development and regulatory approval for a CDx. The Amended Agreement defined the term of the arrangement as the earlier of five years or receipt of certain regulatory approvals of a CDx. The Company concluded that the amendment to the original Services Agreement should be treated as a new agreement pursuant to ASC 606 as the Amended Agreement changed both the scope and price of the existing arrangement.

The Company identified six promises 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) obligations to perform analytical validation of the CDx assay, and (vi) obligations to make the CDx assay commercially available, following any required regulatory approval.

The Company then determined the following promises were separate performance obligations: (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, inclusive of analytical validation of the CDx assay, and (iii) 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 promised services. 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 other promised services. Therefore, the licenses are combined with the obligation to perform R&D services for the development of a CDx assay as a single performance obligation.

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 estimated transaction price under the Amended Agreement was allocated to the performance obligations based on standalone selling price. The transaction price allocated to sample profiling is recognized as results of sample profiling are delivered. Consideration allocated to the R&D development activities is recognized using an input method measure of progress based on costs incurred by the Company. 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. Consideration allocated to the commercial availability performance obligation is recognized using a time-elapsed measure of progress.

Under the Amended Agreement, the Company recognized revenue of $2,325,000 and $306,000 for the three months ended March 31, 2018 and 2017, respectively, which was primarily related to sample profiling.

4. Revenue

Refer to Note 2: Summary of Significant Accounting Policies and Note 7: Contract Balances for a complete description of our revenue recognition policy under ASC 606, as well as comparative information demonstrating the impact of ASC 606 on our consolidated financial statements.

We disaggregate our revenue from contracts with customers by type of service, as we believe this best depicts how the nature, amount, timing, and uncertainty of our revenue and cash flows are affected by economic factors. The following tables present our revenue disaggregated by type of service.

By Service Offering – Third Party:

| | Three Months Ended March 31, | |
|---|---|---|
| | 2018 | 2017 |
| Clinical sample profiling services | $15,589 | $10,649 |
| Pharma sample profiling services | 13,106 | 2,454 |
| Other molecular information services | 3,248 | 2,491 |
| Total molecular information services | 31,943 | 15,594 |
| R&D and regulatory services | 4,782 | 1,087 |
| Total pharma research and development services | 4,782 | 1,087 |
| Total revenue | $36,725 | $16,681 |

By Service Offering – Related Party:

| | Three Months Ended March 31, | |
|---|---|---|
| | 2018 | 2017 |
| Clinical sample profiling services | $3,198 | $970 |
| Pharma sample profiling services | 10,450 | 3,534 |
| Other molecular information services | 1,000 | 1,000 |
| Total molecular information services | 14,648 | 5,504 |
| R&D and regulatory services | 1,467 | 4,143 |
| Total pharma research and development services | 1,467 | 4,143 |
| Total revenue | $16,115 | $9,647 |

On March 31, 2018, we had $96.1 million of remaining transaction price allocated to performance obligations which are unsatisfied or partially unsatisfied, of which $51.4 million is associated with related parties. For the $51.4 million associated with related parties, we expect to recognize approximately 58 percent of our remaining transaction price as revenue within the next 12 months following March 31, 2018 and an additional 42 percent in the 12 months thereafter. For the remaining $44.7 million, we expect to recognize approximately 23 percent of our remaining transaction price as revenue within the next 12 months following March 31, 2018, an additional 30 percent in the 12 months thereafter, and the remaining 47 percent thereafter. We have elected to utilize the practical expedient of excluding contracts with an original duration of one year or less. As a result, the majority of our molecular information services contracts are excluded from the calculation and the balance is primarily comprised of transaction price associated with our long-term pharma R&D service contracts, as well as the molecular information platform program within the R&D Collaboration Agreement with Roche.

During the three months ended March 31, 2018, we recognized $1.2 million of revenue from performance obligations satisfied in prior periods, as a result of changes in the estimation of the transaction price for certain arrangements. Changes in the estimation of the transaction price for our clinical molecular information services revenue occur when we adjust our initial estimate based on actual cash collection experience from payors. Changes in the estimation of the transaction price for our pharma research and development services revenue occur based on revisions to our estimate of the constraint for variable consideration of performance-based milestones.

5. 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.

6. Restricted Cash

Restricted cash consists of deposits securing letters of credit issued to lessors as collateral in connection with the Company’s operating leases. As of each March 31, 2018 and December 31, 2017, the Company had restricted cash of $2,305,000.

7. Contract Balances

The timing of revenue recognition, invoicing, and cash collection results in billed accounts receivable, unbilled receivables (contract assets), and deferred revenue (contract liabilities). The Company presents current contract assets within prepaid expenses and other current assets and non-current contract assets within other assets, while accounts receivable and deferred revenue are presented separately on the Condensed Consolidated Balance Sheet. For clinical molecular information services revenue, billing generally occurs at the same time as revenue recognition, meaning the Company does not record unbilled receivables or deferred revenue related to these services. For biopharmaceutical molecular information services revenue, billing generally occurs at the same time as revenue recognition. However, we sometimes receive payment in advance of services being performed. For example, contracts may contain upfront payments or, for our subscription-type arrangements, may call for invoicing at the start of each quarter. Both of these scenarios result in the recording of deferred revenue. For Pharma research and development services, the timing between revenue recognition and invoicing is likely to vary due to the longer-term nature of these contracts. For example, these contracts often contain upfront payments, which results in the recording of deferred revenue to the extent cash is received prior to our performance of the related services. Conversely, these contracts typically contain performance-based milestones. Dependent on our estimation of variable consideration and application of the constraint, we may recognize revenue as we perform toward these milestones but prior to achievement of the milestones, which would result in the recording of contract assets. In all cases, deferred revenue is relieved as we perform under our obligations and revenue is consequently recognized. Contract assets are relieved when milestones are achieved and we invoice the customer, thereby shifting the balances from contract assets to accounts receivable. Revenue recognized in the three months ended March 31, 2018 that was included in the deferred revenue balance as of December 31, 2017 was $3.9 million and

represented primarily revenue from provision of sample profiling services under the reserved capacity arrangement with Roche. As of March 31, 2018, the Company had current unbilled receivables of $4.8 million and non-current unbilled receivables of $0.5 million, as compared to current unbilled receivables of $0.7 million and non-current unbilled receivables of $0.6 million as of January 1, 2018. The Company did not record unbilled receivables for its contract assets prior to adoption of ASC 606 on January 1, 2018.

Two customer account receivable balances consisting of $9,099,000 and $4,687,000 were greater than 10% of the total accounts receivable balance, including receivables due from Roche, representing 22% and 11%, respectively, of total accounts receivable at March 31, 2018. Two customer account balances consisting of $10,159,000 and $8,990,000 were greater than 10% of the total accounts receivable balance, including receivables due from Roche, representing 34% and 30%, respectively, of total accounts receivable at December 31, 2017.

8. Inventory

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

| | March 31, 2018 | December 31, 2017 |
|---|---|---|
| Raw materials | $ 11,655 | $ 8,963 |
| Work-in-process | 4,756 | 4,208 |
| | $ 16,411 | $ 13,171 |

9. Property and Equipment

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

| | March 31, 2018 | December 31, 2017 |
|---|---|---|
| Lab equipment | $ 36,767 | $ 36,533 |
| Computer equipment | 12,256 | 11,808 |
| Software | 11,960 | 10,694 |
| Furniture and office equipment | 5,440 | 3,959 |
| Leasehold improvements | 32,674 | 26,968 |
| Construction in progress | 3,021 | 7,523 |
| Total cost | 102,118 | 97,485 |
| Less: accumulated depreciation and amortization | (60,511) | (56,366) |
| Total property and equipment, net | $ 41,607 | $ 41,119 |

Depreciation and amortization expense for the three months ended March 31, 2018 and 2017 was $5,365,000 and $4,466,000, respectively. The Company classifies capitalized internal use software in lab equipment, computer

equipment and software based on its intended use.

10. Accrued Expenses

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

| | March 31, 2018 | December 31, 2017 |
|---|---|---|
| Payroll and employee-related costs | $ 10,135 | $ 19,630 |
| Professional services | 6,225 | 7,935 |
| Property and equipment purchases | 699 | 688 |
| Other | 5,334 | 8,492 |
| Total accrued expenses and other current liabilities | $ 22,393 | $ 36,745 |

11. Debt

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

The Amendment amends certain provisions of the Existing Credit Facility to provide for an extension of the period during which the Company may borrow funds from three to four years, ending August 2, 2020 (the "Draw Period"), and an increase in the available funds from $100 million to $200 million, of which $80 million was made available immediately and $120 million was made available upon the achievement of certain 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 March 31, 2018.

The Roche Credit Facility contains customary events of default, including, among others, defaults due to non-payment, bankruptcy, failure to comply with covenants, breaches of representations and warranties, a change of control, a material adverse effect and judgment defaults. Upon the occurrence and continuation of an event of default following applicable notice and cure periods, amounts due under the Roche Credit Facility may be accelerated. The Company had no events of default under the Roche Credit Facility as of March 31, 2018.

As of March 31, 2018, the Company had $90 million in borrowings outstanding and $110 million of unused and available credit under the Roche Credit Facility. Interest expense was $1.2 million and $0.1 million for the three months ended March 31, 2018 and 2017, respectively.

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 March 31, | |
|---|---|---|
| | 2018 | 2017 |
| Outstanding stock options | 478,132 | 1,059,795 |
| Unvested restricted stock | 914,648 | 1,468,022 |
| Total | 1,392,780 | 2,527,817 |

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, restricted cash, accounts receivable, accounts payable, accrued liabilities, and debt. The carrying amount of cash and cash equivalents, restricted cash, accounts receivable, accounts payable, and accrued liabilities approximate their fair values because of the short-term nature of the instruments. The fair value of our outstanding debt balance approximates the carrying value as of the balance sheet date. The principal amount of our outstanding debt balance at March 31, 2018 and December 31, 2017 was $90.0 million and $60.0 million, respectively.

The following tables present information about the Company's assets and liabilities that are measured at fair value on a recurring basis as of March 31, 2018 and December 31, 2017, and indicate the fair value hierarchy of the valuation

techniques utilized to determine such fair value (in thousands):

| | Fair Value Measurement at March 31, 2018 | | | |
|---|---|---|---|---|
| | Quoted Prices in Active Markets (Level 1) | Significant Other Observable Inputs (Level 2) | Significant Unobservable Inputs (Level 3) | Total |
| Assets: | | | | |
| Cash equivalents | $ 25,263 | $ — | $ — | $ 25,263 |
| Total assets | $ 25,263 | $ — | $ — | $ 25,263 |
| Liabilities: | | | | |
| Indebtedness to Roche | $ — | $ 90,000 | $ — | $ 90,000 |
| Total liabilities | $ — | $ 90,000 | $ — | $ 90,000 |

| | Fair Value Measurement at December 31, 2017 | | | |
|---|---|---|---|---|
| | Quoted Prices in Active Markets (Level 1) | Significant Other Observable Inputs (Level 2) | Significant Unobservable Inputs (Level 3) | Total |
| Assets: | | | | |
| Cash equivalents | $ 25,183 | $ — | $ — | $ 25,183 |
| Total assets | $ 25,183 | $ — | $ — | $ 25,183 |
| Liabilities: | | | | |
| Indebtedness to Roche | $ — | $ 60,000 | $ — | $ 60,000 |
| Total liabilities | $ — | $ 60,000 | $ — | $ 60,000 |

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 at March 31, 2018 include cash equivalents and indebtedness to Roche. The Company did not elect to remeasure any other existing financial assets or liabilities, and did not elect the fair value option for any other financial assets and liabilities transacted during the three months ended March 31, 2018 and 2017.

14. Stockholders' Equity

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

| | March 31, 2018 | December 31, 2017 |
|---|---|---|
| Unvested restricted stock | 914,648 | 1,164,040 |
| Common stock options | 478,132 | 666,717 |
| Shares available for issuance under the 2013 Stock Option and Incentive Plan | 4,781,183 | 3,273,334 |
| Shares available for issuance under the 2013 Employee Stock Purchase Plan | 788,503 | 788,503 |
| | 6,962,466 | 5,892,594 |

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, 2018 and 2017, the number of shares reserved and available for issuance under the 2013 Stock Plan increased by 1,461,671 and 1,403,616 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, 2017 | 1,164,040 |
| Granted | 43,905 |
| Vested | (207,016) |
| Forfeited | (86,281) |
| Unvested at March 31, 2018 | 914,648 |

Total stock-based compensation expense recognized for restricted stock awards was $2,997,000 and $5,639,000 for the three months ended March 31, 2018 and 2017, respectively.

Stock Options

A summary of stock option activity under the 2010 Stock Plan and the 2013 Stock Plan for the three months ended March 31, 2018 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, 2017 | 666,717 | $ 19.53 | 5.6 | $ 32,450 |
| Granted | — | — | | |

| | | | | |
|---|---|---|---|---|
| Exercised | (184,783) | 18.56 | | |
| Forfeited | (3,802 ) | 25.40 | | |
| Outstanding as of March 31, 2018 | 478,132 | $ 19.86 | 5.3 | $ 28,159 |
| Exercisable as of March 31, 2018 | 440,089 | $ 18.74 | 5.1 | $ 26,409 |

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 $211,000 and $760,000 for the three months ended March 31, 2018 and 2017, respectively.

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

| | Three Months Ended March 31, | |
|---|---|---|
| | 2018 | 2017 |
| Cost of revenue | $238 | $1,095 |
| Selling and marketing | 912 | 1,220 |
| General and administrative | 1,281 | 2,778 |
| Research and development | 777 | 1,306 |
| Total | $3,208 | $6,399 |

As of March 31, 2018, unrecognized compensation cost of approximately $23,510,000 related to non-vested stock options and restricted stock awards is expected to be recognized over weighted-average period of 2.3 years.

15. Commitments and Contingencies

Legal Matters

From time to time, we are a party to litigation arising in the ordinary course of its business. On July 28, 2017, a purported stockholder of the Company filed a putative class action in the U.S. District Court for the District of Massachusetts, against the Company and certain of its current and former executives, captioned Mahoney v. Foundation Medicine, Inc., et al., No. 1:17-cv-11394. The complaint alleges violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 thereunder based on allegedly false and misleading statements and omissions 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. On December 22, 2017, the plaintiffs filed an amended class action complaint alleging 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 and omissions concerning providing 2015 financial guidance and other statements during the class period concerning demand and reimbursement for certain of the Company's tests. On February 20, 2018, the Company moved to dismiss the complaint for failure to state a claim, which plaintiffs opposed on April 23, 2018. We believe this case is without merit and, therefore, continue to vigorously defend ourselves against the allegations.

16. Related Party Transactions

Roche Holdings, Inc. and its affiliates

Related-party molecular information services revenue from Roche for the three months ended March 31, 2018 and 2017 was $14,648,000 and $5,504,000, 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 March 31, 2018 and 2017 was $1,467,000 and $4,143,000, 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 $5,948,000 and $900,000 for the three months ended March 31, 2018 and 2017, 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 March 31, 2018, $9,099,000 and $4,801,000 was included in total accounts receivable and deferred revenue, respectively, related to this arrangement with Roche. At December 31, 2017, $10,159,000 and $3,742,000 was included in total accounts receivable and deferred revenue, respectively, related to this arrangement with Roche. As of March 31, 2018, the Company had $90 million in borrowings outstanding under the Roche Credit Facility. There were no other material Roche-related balances included in the condensed consolidated financial statements as of March 31, 2018 or December 31, 2017, or for the three months ended March 31, 2018 and 2017.

17. Subsequent Events

On April 26, 2018, we announced a three-party collaboration with Roche and Dian Diagnostics Group, Co., Ltd. ("Dian") to integrate our comprehensive genomic profiling ("CGP") assays into clinical patient care in mainland China. Under the collaboration, Dian becomes the exclusive clinical sequencing partner in China for FoundationOne, FoundationACT and FoundationOneHeme, enabling the delivery of molecular information services by these tests for patients in China. Roche will maintain commercial exclusivity for our molecular information services in China, and in cooperation with Dian will continue its current in-county activities to support the broad integration of CGP into clinical care.

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, 2017. 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 molecular information 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 clinical molecular information services, which include FoundationOne CDx, a U.S. Food & Drug Administration, or FDA, approved broad companion diagnostic assay for solid tumors, FoundationOne for solid tumors, FoundationOneHeme for blood-based cancers, or hematologic malignancies, and sarcomas, FoundationACT, a blood-based (liquid biopsy) assay to measure circulating tumor DNA, or ctDNA, and FoundationFocus CDx BRCA, an FDA-approved companion diagnostic assay to aid in identifying women with ovarian cancer for whom treatment with Rubraca™ (rucaparib) is being considered, are widely available comprehensive genomic profiles designed for use in the routine care of patients with cancer and in research.

Following the FDA's approval of FoundationOne CDx in November 2017, the Centers for Medicare & Medicaid Services, or CMS, issued a final National Coverage Determination, or NCD, in March 2018 that establishes nationwide Medicare coverage for FoundationOne CDx for all solid tumor types when ordered by the patient's treating physician for Medicare beneficiaries with advanced cancer (i.e., either recurrent, relapsed, refractory, metastatic, or advanced stages III or IV cancer), who either have not been previously tested using FoundationOne CDx for the same primary diagnosis of cancer or are seeking repeat testing with FoundationOne CDx for a new primary cancer diagnosis, and continue to seek further cancer therapy.

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, to strengthen our commercial organization, to introduce new marketing, education and provider engagement efforts, to grow our molecular information knowledgebase, FoundationCore, to pursue reimbursement from government payors and regional and national third-party commercial payors, to publish scientific and medical advances, and to foster relationships throughout the oncology community.

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, FoundationOneHeme, FoundationACT and FoundationFocus CDx BRCA, and the development of new services such as FoundationOne CDx. We have incurred

significant losses since our inception, and as of March 31, 2018 our accumulated deficit was $525.5 million. We expect to continue to incur operating losses over the near term as we expand our commercial operations, including supporting the commercial launch of FoundationOne CDx, invest in our molecular information platform and additional services, and continue to scale our technology and data infrastructure.

FoundationOne, FoundationOneHeme, and FoundationACT have been commercialized as laboratory developed tests, or LDTs, which are subject to the Clinical Laboratory Improvement Amendments of 1988, or CLIA, and are not currently regulated as medical devices under the Federal Food, Drug and Cosmetic Act. FoundationFocus CDx BRCA and FoundationOne CDx are FDA-approved companion diagnostic assays. 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 and a significant differentiator for our business.

Recent Developments

On March 13, 2018, we and Guardant Health, Inc., or Guardant, announced an agreement to settle false advertising challenges that we and Guardant had filed against each other under the Lanham Act related to advertising for their respective liquid genomic profiling assays. Under the terms of the settlement, the lawsuit and counterclaims will be dismissed with prejudice. We and Guardant also agreed to create a rapid-resolution process in the event of further advertising-related disputes.

On March 16, 2018, we announced that Chugai Pharmaceutical Co., Ltd., or Chugai, an affiliate of Roche, filed for regulatory approval from the Ministry of Health, Labour and Welfare (MHLW) for FoundationOne CDx in Japan. Pursuant to an agreement with Roche, Chugai will also lead commercial efforts in Japan for FoundationOne CDx and our other comprehensive genomic profiling, or CGP, assays.

On March 18, 2018, we announced that the Centers for Medicare & Medicaid Services (CMS) issued a final National Coverage Determination (NCD) for patients who receive next generation sequencing (NGS) testing with an assay that meets the coverage criteria, including FoundationOne CDx. The final NCD establishes nationwide Medicare coverage for FoundationOne CDx for all solid tumor types when ordered by the patient's treating physician for Medicare beneficiaries with advanced cancer (i.e., either recurrent, relapsed, refractory, metastatic, or advanced stages III or IV cancer), who either have not been previously tested using FoundationOne CDx for the same primary diagnosis of cancer or are seeking repeat testing with FoundationOne CDx for a new primary cancer diagnosis, and continue to seek further cancer therapy.

On March 30, 2018, we announced commercial availability in the United States of FoundationOne CDx.

On April 11, 2018, we announced the presentation of new findings at the American Association for Cancer Research Annual Meeting. The data concerns the use of both tissue- and blood-based CGP to advance personalized cancer care and to inform the use of targeted and immunotherapy treatment approaches. Presentations included new data regarding the use of FoundationOne CDx, FoundationOne and FoundationACT, and data regarding the use of our blood-based clinical trial assay to measure tumor mutational burden, or bTMB, as part of an investigational study now being conducted by an affiliate of Roche.

On April 26, 2018, we announced that the FDA granted a Breakthrough Device designation (formerly known as the Expedited Access Pathway program) for our new liquid biopsy assay. This new assay, which is an expanded version of FoundationACT, is expected to include more than 70 genes, to incorporate multiple companion diagnostics and to include genomic biomarkers for microsatellite instability, or MSI, and bTMB, and will provide treating physicians with information helpful in determining the use of targeted oncology therapies, including immunotherapies.

On April 26, 2018, we announced a three-party collaboration with Roche and Dian Diagnostics Group, Co., Ltd., or Dian, to integrate our CGP assays into clinical patient care in mainland China. Under the collaboration, Dian becomes the exclusive clinical sequencing partner in China for FoundationOne, FoundationACT and FoundationOneHeme, enabling the delivery of molecular information services with these tests for patients in China. Roche will maintain commercial exclusivity for our molecular information services in China, and in cooperation with Dian will continue its current in-county activities to support the broad integration of CGP into clinical care.

On May 2, 2018, we announced a comprehensive gene expression profiling program to support precision oncology clinical research and development. This initiative will provide support for the Company's biopharma partners in the efficient identification of known and novel genomic and expression-based biomarkers of response for investigational and approved personalized cancer therapies, including new and existing cancer immunotherapies.

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.

Effective January 1, 2018, the Company began recognizing revenue in accordance with FASB ASC Topic 606, Revenue from Contracts with Customers, or ASC 606. The Company adopted ASC 606 using the modified retrospective method of adoption, meaning the cumulative effect of applying ASC 606 has been recognized to accumulated deficit at January 1, 2018, the date of adoption of ASC 606, and prior comparative periods will not be recast to reflect ASC 606. As a result, revenue for the three months ended March 31, 2017 is presented in accordance with FASB ASC Topic 605, Revenue Recognition, or ASC 605, whereas revenue for the three months ended March 31, 2018 is presented under ASC 606. ASC 606 provides a five-step model for recognizing revenue 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.

Our clinical contracts included within molecular information services typically have a single performance obligation to transfer molecular profiling services to either a patient or a facility. In certain limited contracted scenarios, such as arrangements with academic medical centers, the transaction price is stated within the contract and is therefore fixed consideration. For most of our clinical volume, we identified the patient as the customer in Step 1 of the model and have determined an implied contract exists with the patient. As such, a stated contract price does not exist and the transaction price for each contract represents variable consideration. In developing the estimate of variable consideration, we utilize the expected value method under a portfolio approach. Our estimate requires significant judgement and is developed using historical reimbursement data from payors and patients, as well as known current reimbursement trends not reflected in the historical data. As these contracts typically have a single performance obligation, no allocation of the transaction price is required in Step 4 of the model. Molecular information services are transferred to our ordering physicians at a point in time. Specifically, we determined the customer obtains control of the promised service upon our delivery of the test results. Certain incremental costs, such as commissions, are incurred in obtaining clinical contracts. We have elected to utilize the practical expedient method to expense incremental costs of obtaining a contract that meet the capitalization criteria, as the amortization period of any contract acquisition asset would be one year or less due to the short-term nature of our clinical contracts.

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. As a result, for most of our commercial third-party payors we are not a contracted provider and, therefore, do not have specific coverage decisions from those third-party payors for our specific 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, to our knowledge are not specific to us, and 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, which entities process our claims and pay us directly at negotiated rates. Further, coverage and payment for reimbursement claims for our services are determined by each third-party payor on a case-by-case basis.

As of March 31, 2018, we were not a participating provider in any state Medicaid program, and therefore, did not have coverage determinations under which our tests were covered by these Medicaid programs. We are a participating provider in the Medicare program.

For tests that we offer that are not subject to an NCD, local Medicare Administrative Contractors, or MACs, that administer the Medicare program in various regions may, in their discretion but subject to Medicare rules, determine coverage, rates of reimbursement and payment.

The local MAC for our laboratory in Cambridge, Massachusetts is National Government Services which succeeded the previous local MAC NHIC, Corp., or NHIC. In connection with the launch of FoundationOne, our first commercial test, and following discussions with NHIC, we agreed to not submit claims for FoundationOne tests provided to Medicare patients while NHIC assessed the appropriate coding, coverage, and payment for FoundationOne as a whole. To accommodate NHIC's request, we deferred the submission of claims until November 2013, when we commenced the process of submitting claims to National Government Services for FoundationOne and FoundationOneHeme tests for Medicare patients with dates of service on or after November 1, 2013. We have submitted these claims for FoundationOne and FoundationOneHeme tests to National Government Services using a miscellaneous CPT code, and have not recognized revenue from Medicare for those claims to date. National Government Services, issued a final Local Coverage Determination, or LCD, effective April 1, 2016, to provide coverage for hotspot tests of 5 to 50 genes for patients with metastatic non-small cell lung cancer, or NSCLC. We do not believe this LCD reflects coverage for our CGP services, which include comprehensive analysis of greater than 50

genes and all classes of alterations. As of March 31, 2018, National Government Services has either denied the FoundationOne or FoundationOneHeme claims that we have submitted using stacked CPT codes, 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 March 31, 2018, we have recognized revenue from many of those claims.

The local MAC for our laboratory in Research Triangle Park, North Carolina, is Palmetto GBA, or Palmetto. In May 2016, Palmetto issued a final LCD, or Palmetto LCD, to cover highly validated comprehensive genomic profiling received by Medicare patients initially diagnosed with Stage IIIB and Stage IV NSCLC and who otherwise meet the eligibility criteria of the Palmetto LCD.

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. In December 2016, Palmetto originally 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, respectively. In March 2018, Palmetto re-issued revised versions of these draft LCDs, and is accepting public comments on such drafts until May 10, 2018. If finalized as proposed, FoundationOne will be covered by Medicare when provided to patients with these conditions consistent with the terms of these LCDs.

In accordance with an exception to Medicare's Date of Service rule, commonly known as the 14-Day Rule, for a subset of Medicare claims we are required to bill the ordering institution directly instead of submitting claims to Medicare. We have recognized revenue associated with these bills upon receipt of payment from the institution.

We expect that our current lack of broad coverage decisions among commercial third-party payors, the fact that we are currently a contracted provider with only a few commercial third-party payors and the general uncertainty around reimbursement for our tests will continue to negatively impact our revenue and earnings. For Medicare tests we offer that are not subject to an NCD, 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.

As of March 31, 2018, we had cash and cash equivalents of approximately $60.3 million. If we are not able to obtain additional coverage decisions over the longer term, and our available cash and cash equivalents 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. As of March 31, 2018, under the Credit Facility Agreement with Roche Finance Ltd dated August 2, 2016, as amended by the Amendment Letter Agreement with Roche Finance Ltd, dated July 31, 2017, or the Roche Credit Facility, we have $110 million of unused and available credit. Additional capital may not be available on reasonable terms, or at all, and may be subject to the prior consent of Roche pursuant to the Roche Credit Facility and our Investor Rights Agreement with Roche dated January 11, 2015.

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 bill patients for amounts that are determined to be due from the patient. We initiated the process to seek reimbursement from Medicare at the end of 2013, and as part of the Medicare reimbursement process, we seek advance beneficiary notices, or ABNs, from Medicare patients to enable us to bill a Medicare patient for all or part of a claim that is denied coverage by Medicare. We offer a comprehensive patient assistance program to provide financial support to patients whose incomes are below certain thresholds, and we also may allow for extended payment terms, as necessary, given the patient's economic situation.

Our biopharma contracts included within molecular information services may include single or multiple performance obligations depending on the contract, and may include different molecular information service offerings, such as molecular profiling, provision of data through either database queries or subscription access to our platform, and clinical trial enrollment assistance, as separately identifiable from other promises in the contracts and therefore distinct performance obligations.

The transaction price in biopharma molecular information service contracts is typically fixed consideration. In certain instances, contracts may include variable consideration. In these contracts, variable consideration is estimated utilizing the expected value method. The primary method used to determine standalone selling price for the biopharma molecular information services is observable standalone selling price. When standalone selling price is not directly observable, the primary method used to estimate standalone selling price for molecular information services is the adjusted market assessment approach, under which we evaluate the market in which we sell the services and estimate the price that a customer in that market would be willing to pay for those services.

Control over biopharma molecular information services from molecular profiling and database queries is transferred to customers at a point in time. We determined the customer obtains control of the promised service upon delivery of the test results or the delivery of responses to database queries to the biopharma partner. Control over biopharma molecular information services from subscription access to our data platform is transferred to customers ratably over time. We determined that the customer obtains control of the promised service as we host the content throughout the

contract term. Control over biopharma molecular information services from clinical trial enrollment assistance is transferred to customers ratably over time. We determined that the customer obtains control of the promised service as we stand ready to perform such services throughout the contract term.

Pharma research and development services may include single or multiple performance obligations dependent on the contract. Research and development, or R&D, services typically represent a single performance obligation as the Company performs a significant integration service for the individual goods or services in the research and development workstream, such as analytical validation and regulatory submissions. The individual promises are not separately identifiable from other promises in the contracts and, therefore, are not distinct. However, in certain contracts, a partner may engage the Company for multiple distinct R&D workstreams which are both capable of being distinct and separately identifiable from other promises in the contracts and, therefore, distinct performance obligations. Additionally, for regulatory contracts in pursuit of approval of a companion diagnostic assay, the Company identifies a performance obligation for commercial availability of the assay subsequent to obtaining regulatory approval.

The transaction price can consist of a combination of an upfront fee, performance-based development milestones, cost reimbursement, fixed per sample fees, commercial royalties, and commercial milestones. With the exception of upfront and fixed per sample fees, the other forms of compensation represent variable consideration. Variable consideration in the form of cost reimbursement and commercial royalties is estimated using the expected value method. Variable consideration in the form of development and commercial milestones is estimated using the most likely amount method. All variable consideration is constrained such that it is probable a significant reversal of cumulative revenue recognized will not occur when the uncertainty associated with the

variable consideration is subsequently resolved. Application of the constraint for variable consideration to milestone payments is an area that requires significant judgment. In making this assessment, the Company evaluates factors such as the scientific, clinical, regulatory, commercial, and other risks that must be managed to achieve the respective milestone and the level of effort and investment required to achieve the respective milestone.

The primary method used to estimate standalone selling price for the R&D service performance obligations is the expected cost plus a margin approach, under which we forecast our expected costs of satisfying each performance obligation and then add an appropriate margin for that distinct good or service. The primary method used to estimate standalone selling price for a commercial availability performance obligation is the adjusted market assessment approach, under which we evaluate the market in which we sell the services and estimate the price that a customer in that market would be willing to pay for those services. The estimation of standalone selling price is an area that requires significant judgment, as it impacts the allocation objective in Step 4 of the model. Revenue will be recognized over time for R&D services and commercial availability services. Specifically, for R&D services we will recognize revenue using an input method to measure progress, utilizing costs incurred to-date relative to total expected costs as our measure of progress. For commercial availability services, we will recognize revenue using an input method to measure progress, resulting in a time-elapsed measure of progress.

The Company performs R&D 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. The R&D 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.

Cost of Molecular Information Services Revenue and Operating Expenses

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

Cost of Molecular Information Services Revenue

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

Cost of Related-Party Molecular Information Services Revenue from Roche

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

Selling and Marketing Expenses

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

During the three months ended March 31, 2018 and 2017, our selling and marketing expenses represented approximately 33% and 62%, respectively, of our total revenue. We expect our selling and marketing expenses to continue to increase in absolute dollars as we grow our client service infrastructure, 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, 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 biomarker-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 FoundationSmartTrials. Costs to develop our technology capabilities are recorded as research and development unless they meet the criteria to be capitalized as internal-use software costs. Our research and development activities include the following costs:

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

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

Interest (Expense) Income, Net

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

Other Income

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

Results of Operations

Comparison of Three Months Ended March 31, 2018 and 2017

| | Three Months Ended March 31, | | Change | |
|---|---|---|---|---|
| | 2018 | 2017 | $ | % |
| | (in thousands, except percentages) | | | |
| Statement of Operations Data: | | | | |
| Revenue: | | | | |
| Molecular information services | $31,943 | $15,594 | $16,349 | 105 % |
| Related-party molecular information services from Roche | 14,648 | 5,504 | 9,144 | 166 % |
| Pharma research and development services | 4,782 | 1,087 | 3,695 | 340 % |
| Related-party pharma research and development services from Roche | 1,467 | 4,143 | (2,676) | (65)% |
| Total revenue | 52,840 | 26,328 | 26,512 | 101 % |
| Costs and expenses | | | | |
| Cost of molecular information services | 21,279 | 17,117 | 4,162 | 24 % |
| Cost of related-party molecular information services from Roche | 5,948 | 900 | 5,048 | 561 % |
| Selling and marketing | 17,480 | 16,436 | 1,044 | 6 % |
| General and administrative | 20,695 | 15,277 | 5,418 | 35 % |
| Research and development | 23,859 | 23,285 | 574 | 2 % |
| Total costs and expenses | 89,261 | 73,015 | 16,246 | 22 % |
| Loss from operations | (36,421) | (46,687) | 10,266 | 22 % |
| Interest (expense) income, net | (994) | 90 | (1,084) | 1204% |
| Other income | — | 144 | (144) | 100 % |
| Net loss | $(37,415) | $(46,453) | $9,038 | 19 % |

Revenue

Molecular Information Services

Molecular information services revenue for the three months ended March 31, 2018 and 2017, respectively, were comprised of the following:

| | Three Months Ended March 31, | | Change | |
|---|---|---|---|---|
| | 2018 | 2017 | $ | % |
| | (in thousands, except percentages) | | | |
| Clinical: | | | | |
| Molecular information services | $15,589 | $10,649 | $4,940 | 46 % |
| Related-party molecular information services from Roche | 3,198 | 970 | 2,228 | 230% |
| Total clinical revenue | 18,787 | 11,619 | 7,168 | 62 % |
| Pharma: | | | | |
| Molecular information services | 16,354 | 4,945 | 11,409 | 231% |
| Related-party molecular information services from Roche | 11,450 | 4,534 | 6,916 | 153% |
| Total pharma revenue | 27,804 | 9,479 | 18,325 | 193% |

| | | | | |
|---|---|---|---|---|
| Total molecular information services revenue | $46,591 | $21,098 | $25,493 | 121% |

32

Molecular information services revenue, including Roche related-party revenue, increased to $46.6 million for the three months ended March 31, 2018 from $21.1 million during the three months ended March 31, 2017. Revenue from tests reported to our ordering physicians increased to $18.8 million for the three months ended March 31, 2018 from $11.6 million for the three months ended March 31, 2017. The increase in revenue was partly driven by the increase in the number of tests reported for patients located in the United States, Medicare payments for FoundationOne for eligible patients with NSCLC under the Palmetto LCD, and an increase in revenue recorded under our Roche Ex-U.S. Commercialization Agreement. The change to accrual basis revenue under ASC 606 was not the driver of the increase in revenue from tests reported to our ordering physicians, as cash basis clinical revenue under ASC 605 in the three months ended March 31, 2018 would have been approximately $22.0 million, inclusive of certain one-time catch up payments.

Molecular information services revenue from our biopharma customers increased to $27.8 million from $9.5 million for the three months ended March 31, 2018 and 2017, respectively, and was driven by increased testing volume from new and existing customers.

Related-party molecular information services revenue from Roche was $14.6 million and $5.5 million for the three months ended March 31, 2018 and 2017, respectively, the majority of which is revenue earned under the Molecular Information Platform Program and Ex-U.S. Commercialization Agreement.

During the three months ended March 31, 2018, we reported a total of 21,861 CGP tests for clinical use to ordering physicians, including 2,005 FoundationOneHeme tests, 2,123 FoundationACT tests, and 48 FoundationFocus CDx BRCA tests as compared to 13,933 tests reported during the three months ended March 31, 2017, including 1,284 FoundationOneHeme tests, 1,355 FoundationACT tests, and 289 FoundationFocus CDx BRCA tests.

For CGP tests delivered in the US for clinical use during the three months ended March 31, 2018, we estimate we will be paid on approximately 29% of these tests at an average rate of approximately $2,600 when paid. Despite our lack of broad coverage decisions across many commercial third-party payors, we have been partially successful in securing reimbursement from these payors. However, it is difficult to predict future reimbursement as a result of variable reimbursement payments and continuously developing coverage decisions.

We delivered the results of 7,184 and 1,802 tests to our biopharmaceutical customers during the three months ended March 31, 2018 and 2017, respectively, and the average revenue per test sold was approximately $3,200 and $3,500 for the same periods.

Pharma Research and Development Services

Pharma research and development services revenue, including Roche related-party revenue, increased to $6.2 million for the three months ended March 31, 2018 from $5.2 million during the three months ended March 31, 2017. The increase was primarily driven by revenue earned under R&D service agreements with our various biopharma partners. Pharma research and development services revenue under ASC 605 for the three months ended March 31, 2018 would have totaled approximately $2.3 million. The increase of approximately $3.9 million of revenue recorded under ASC 606 results from recognition during the quarter of companion diagnostic development services performed for a biopharma customer prior to achievement of the related contractual milestones. Under ASC 605, revenue recognition was limited by the right to invoice upon achievement of such milestones.

Related-party pharma research and development services for Roche includes related-party revenue from Roche of $1.5 million and $4.1 million for the three months ended March 31, 2018 and 2017, respectively. The decrease was primarily driven by a decrease in revenue earned under the Companion Diagnostic (CDx) Development Program and was not affected by the adoption of ASC 606.

Cost of Molecular Information Services

Cost of molecular information services revenue, including Roche related-party revenue, increased to $27.2 million for the three months ended March 31, 2018 from $18.0 million for the three months ended March 31, 2017. The increase was driven by a 57% increase in tests reported to our ordering physicians. Additional volume led to higher reagent and consumable costs, additional laboratory personnel-related costs and facilities costs, and higher depreciation expense related to new equipment purchases. During the three months ended March 31, 2018 and 2017, our total cost of molecular information services revenue represented approximately 58% and 85% of our total molecular information services revenue, respectively.

Cost of related-party molecular information services from Roche was $5.9 million and $0.9 million for the three months ended March 31, 2018 and 2017, respectively. The increase was primarily driven by an increase in the number of tests delivered under the Molecular Information Platform Program and Ex-US Commercialization Agreement.

Selling and Marketing Expenses

Selling and marketing expenses increased to $17.5 million for the three months ended March 31, 2018 from $16.4 million for the three months ended March 31, 2017. The increase was primarily due to an increase of $0.9 million in personnel-related costs for employees in our sales, marketing, client service and reimbursement departments to support our commercialization efforts, and a $0.2 million increase in rent and other facility costs.

General and Administrative Expenses

General and administrative expenses increased to $20.7 million for the three months ended March 31, 2018 from $15.3 million for the three months ended March 31, 2017. The increase was primarily due to an increase of $4.4 million in legal costs, and a $1.0 increase in rent and other facility costs.

Research and Development Expenses

Research and development expenses increased to $23.9 million for the three months ended March 31, 2018 from $23.3 million for the three months ended March 31, 2017. The increase was primarily attributed to a $2.2 million increase in personnel-related costs and $1.5 million in consulting related costs, offset by a $3.1 million decrease in laboratory supplies.

Interest (Expense) Income, Net

Interest expense was $1.2 million and $0.1 million for the three months ended March 31, 2018 and 2017, respectively. The increase was primarily related to interest incurred on the Roche Credit Facility which was first drawn on in the third quarter of 2017. Interest income was $0.2 million for both the three months ended March 31, 2018 and 2017.

Other Income

Other income during the three months ended March 31, 2017 was $0.1 million 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 March 31, 2018, we had an accumulated deficit of $525.5 million.

We have funded our operations principally from the sale of common stock, preferred stock, borrowings under our credit facilities, and revenue from molecular information services and pharma research and development services. We have a limited number of coverage decisions for our existing tests from commercial third-party payors and have a limited history of collecting claims. We will continue to make requests for payment and/or appeal payment decisions made by commercial third-party payors. As of March 31, 2018, we had cash, cash equivalents, and restricted cash of approximately $62.6 million.

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. As of March 31, 2018, we have $90 million in borrowings outstanding and $110 million currently available under the facility. During the Draw Period, we are paying 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 are obligated to 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 are obligated to pay Roche Finance quarterly equal payments of principal, with accrued interest, until maturity of the Roche Credit Facility on February 2, 2026.

Cash Flows

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

| | Three Months Ended March 31, | |
|---|---|---|
| | 2018 | 2017 |
| | (in thousands) | |
| Net cash used in operating activities | $(38,892) | $(41,644) |
| Net cash (used in) provided by investing activities | (5,682) | 25,531 |
| Net cash provided by financing activities | 33,430 | 1,571 |
| Net decrease in cash, cash equivalents, and restricted cash | (11,144) | (14,542) |
| Effect of exchange rate changes on cash and cash equivalents | 33 | - |
| Cash, cash equivalents, and restricted cash at beginning of period | 73,709 | 65,012 |
| Cash, cash equivalents, and restricted cash at end of period | $62,598 | $50,470 |

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 $38.9 million for the three months ended March 31, 2018 compared to $41.6 million for the three months ended March 31, 2017. The decrease in cash used in operating activities was driven primarily by a decrease in net loss of $9.0 million and a $0.9 million increase in depreciation and amortization expense partially offset by a $4.1 million increase in cash used for working capital and a decrease in stock-based compensation expense of $3.2 million.

Investing Activities

Net cash used in investing activities for the three months ended March 31, 2018 was $5.7 million and primarily consisted of purchases of property and equipment. Net cash provided in investing activities for the three months ended March 31, 2017 was $25.5 million and consisted of $34.4 million in proceeds received from maturities of marketable securities, partially offset by $5.0 million in purchases of marketable securities and other investments, and $3.9 million in purchases of property and equipment.

Financing Activities

Net cash provided by financing activities was $33.4 million for the three months ended March 31, 2018 and consisted of $30 million in cash borrowings under the Roche Credit Facility and $3.4 million in proceeds received from the exercise of stock options. Net cash provided by financing activities was $1.6 million for the three months ended March 31, 2017 and consisted solely of proceeds received from the exercise of stock options.

Operating Capital Requirements

We expect to incur additional operating losses in the near future and our operating expenses will increase as we seek regulatory approval of certain services, scale our technology infrastructure, expand our sales force, increase our marketing efforts to drive market adoption of our molecular information services, innovate our molecular information platform, and develop new service offerings. Our liquidity requirements have consisted of, and will continue to consist of, selling and marketing expenses, research and development expenses, capital expenditures, working capital and general corporate expenses. If demand for our services continues to increase, we anticipate that our capital expenditure

requirements will also increase in order to build additional capacity. We expect that our planned expenditures will be funded from our ongoing operations, from our existing cash and cash equivalents, and borrowings under the Roche Credit Facility.

In April 2015, the Roche transaction was consummated, and we received $250.0 million in gross proceeds from the sale of 5,000,000 shares of our common stock to Roche at a price of $50.00 per share. On July 31, 2017, we amended the Roche Credit Facility. Pursuant to the Roche Credit Facility, as amended, during the Draw Period, we may borrow up to $200 million. We have currently borrowed $90 million and have immediate access to an additional $110 million. 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 March 31, 2018, the availability of borrowings under the Roche Credit Facility, and anticipated cash flows from operations will be sufficient to meet our

anticipated cash requirements for at least the next twelve 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 March 31, 2018 that have changed significantly since December 31, 2017 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, 2017, but omitted below, represent those that have not changed significantly since that date.

| | Total | 2018 | 2019-2020 | 2021-2022 | Thereafter |
|---|---|---|---|---|---|
| | (in thousands) | | | | |
| Long-term debt obligations [1] | 90,000 | - | - | 31,500 | 58,500 |
| Interest [1] | 35,596 | 5,417 | 12,660 | 10,450 | 7,069 |
| Total | $125,596 | $5,417 | $ 12,660 | $ 41,950 | $ 65,569 |

[1] 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 March 31, 2018, we had $90 million in borrowings outstanding under the Roche Credit Facility. For further details on the Roche Credit Facility, refer to footnote 11 in the Notes to the Condensed Consolidated Financial Statements.

Off-Balance Sheet Arrangements

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

Application of Critical Accounting Policies

We have prepared our consolidated financial statements in accordance with accounting principles generally accepted in the United States. Our preparation of these 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 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, 2017, beyond the adoption of ASC 606 described in Note 2: Summary of Significant Accounting Policies.

Item 3. Quantitative and Qualitative Disclosures about Market Risks

There were no material changes during the three months ended March 31, 2018, 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, 2017.

Item 4. Controls and Procedures

Management's Evaluation of our Disclosure Controls and Procedures

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

Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures as of the end of the period covered by this Quarterly Report. Based on this evaluation, our principal executive officer and principal financial officer have concluded that, as of March 31, 2018, 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

In the first quarter of 2018, we added and/or modified certain internal controls and processes in conjunction with adopting the new revenue recognition standard in January 2018 under the modified retrospective approach. These changes primarily relate to the implementation of accrual basis revenue recognition for our clinical molecular information services revenue, including identification of portfolios, estimation and constraint of variable consideration to support accrual estimates of revenue upon test delivery, and subsequent monitoring of cash collections to support re-estimation of variable consideration at each reporting period (changes in estimated transaction price). There have not been any additional changes in our internal control over financial reporting (as defined in Rule 13a 15(f) and 15d 15(f) of the Exchange Act) during the quarter ended March 31, 2018 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 a party to litigation arising in the ordinary course of its business. On July 28, 2017, a purported stockholder of the Company filed a putative class action in the U.S. District Court for the District of Massachusetts, against the Company and certain of its current and former executives, captioned Mahoney v. Foundation Medicine, Inc., et al., No. 1:17-cv-11394. The complaint alleges violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 thereunder based on allegedly false and misleading statements and omissions 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. On December 22, 2017, the plaintiffs filed an amended class action complaint alleging 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 and omissions concerning providing 2015 financial guidance and other statements during the class period concerning demand and reimbursement for certain of the Company's tests. On February 20, 2018, the Company moved to dismiss the complaint for failure to state a claim, which plaintiffs opposed on April 23, 2018. We believe this case is without merit and, therefore, continue to vigorously defend ourselves against the allegations.

Item 1A. Risk Factors

Investing in our common stock involves a high degree of risk. The risk factors described below pertain to us as of the date hereof and should be read in conjunction with the risk factors included in Part I, Item 1A, "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2017. The risk factors included in this Quarterly Report and our Annual Report should be carefully considered although these risks 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. If any such risks or uncertainties actually occur, it could adversely affect our business, financial condition or results of operations, and could cause the market price of our common stock to fluctuate or decline.

Risks Relating to Our Business and Strategy

If one or more of our laboratory facilities become damaged or inoperable, if we are required to vacate any of our laboratory facilities, or if we are delayed in obtaining or unable to obtain additional laboratory space or delayed in commencing operations in our laboratory facilities, our ability to conduct our molecular information services, pursue our research and development efforts or our companion diagnostics partnerships, and fulfill our contractual obligations may be jeopardized.

Our revenue is primarily derived from testing services performed at our laboratory facilities. Our facilities and equipment could be harmed or rendered inoperable by natural or man-made disasters, including war, fire, earthquake, power loss, communications or internet failure or interruption, or terrorism, which may render it difficult or impossible for us to operate our molecular information platform for some period of time. The inability to perform our molecular tests or to reduce the backlog of analyses that could develop if one or more of our laboratories become inoperable, for even a short period of time, may result in the loss of customers or harm to our reputation, and we may be unable to regain those customers or repair our reputation in the future. Furthermore, our facilities and the equipment we use to perform our research and development work could be unavailable or costly and time-consuming to repair or replace. It would be difficult, time-consuming, and expensive to rebuild any of our facilities or license or transfer our proprietary technology to a third party, particularly in light of the licensure and accreditation requirements for commercial laboratories like ours. Even in the unlikely event we are able to find a third party with such

qualifications to enable us to perform our molecular tests, we may be unable to negotiate commercially reasonable terms with such third parties. Adverse consequences resulting from an interruption of our overall laboratory operations could harm relationships with our customers and regulatory authorities, and our reputation, and could affect our ability to generate revenue.

We may also construct, acquire, or enter into relationships with third parties to procure additional laboratory space inside and outside the United States to support our existing and new tests. Our R&D Collaboration Agreement with Roche contemplates that we will collaborate with Roche on multiple programs related to the development of services for use in molecular information, immunotherapy, circulating tumor DNA, or ctDNA, and companion diagnostics and that we will provide additional laboratory space in Europe and Asia to perform genomic sequencing outside of the United States. In October 2017, our laboratory facility in Penzberg, Germany became operational. In April 2018, we announced our collaboration with Roche and Dian Diagnostics Group Co., Ltd., or Dian, pursuant to which Dian became the exclusive clinical sequencing partner in mainland China for FoundationOne, FoundationAct, and FoundationOneHeme to support Roche’s continued commercialization activities of our testing services in China. If our collaboration with Roche and Dian in China is unsuccessful, we are unable to obtain or are delayed in obtaining or establishing new laboratory space to support our commercialization and development efforts, or if our ex-United States laboratory operations are harmed or are rendered inoperable, we could fail to meet certain contractual obligations and agreed upon timelines with certain

biopharmaceutical partners, including Roche, or provide existing services and develop and launch new services in certain territories, which could result in harm to our business and reputation, and adversely affect our business, financial condition, and results of operations. As we continue to transition some of our services to new laboratories, we could experience disruptions in overall laboratory operations and could require adjustments to meet regulatory requirements, resulting in our inability to meet customer turnaround time expectations. Any delays in this transition could result in slower realization of laboratory efficiencies anticipated from operating an additional laboratory facility. Adverse consequences resulting from an interruption of our overall laboratory operations could harm relationships with our customers and regulators, and our reputation, and could affect our ability to generate revenue.

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

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

We anticipate continued growth in our business operations both inside and outside the United States. Our laboratory facilities in North Carolina and Penzberg, Germany are operational, we have executed agreements to expand our facilities in Cambridge, Massachusetts, and we recently announced a collaboration with Roche and Dian to support Roche's continued commercialization activities of our services in China. This expansion and any future growth could create strain on our organizational, administrative, and operational infrastructure, including laboratory operations, quality control, customer service, and sales force management. We may not be able to maintain the quality or expected turnaround times of our services or satisfy customer demand as it grows. Our ability to manage our growth properly will require us to continue to improve our operational, financial, and managerial controls, as well as our reporting systems and procedures. We plan to implement new enterprise software systems in a number of areas affecting a broad range of business processes and functional areas. The time and resources required to implement these new systems is uncertain, and failure to complete implementation in a timely and efficient manner could adversely affect our operations.

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

Our business strategy incorporates plans for significant international expansion through our collaboration with Roche. Pursuant to our Ex-U.S. Commercialization Agreement with Roche, in April 2016, Roche obtained the exclusive right to commercialize FoundationOne and FoundationOneHeme, in October 2017, the exclusive right to commercialize FoundationACT, and in February 2018, the exclusive right to commercialize FoundationOne CDx, in each case outside of the United States. Additionally, if terms are agreed upon between us and Roche, Roche may obtain the exclusive right to commercialize any new clinical diagnostic services developed under the R&D Collaboration Agreement, or upon mutual agreement any of our other services, in each case outside of the United States to the extent Roche has not elected to exclude any countries from its territory.

Our laboratory facility in Penzberg, Germany became operational in 2017. In addition, our Ex-U.S. Commercialization Agreement contemplates that we will provide laboratory space in Asia to perform genomic sequencing for FoundationOne, FoundationOneHeme, and FoundationACT. In April 2018, we announced our collaboration with Roche and Dian, pursuant to which Dian became our exclusive clinical sequencing partner in mainland China, to support Roche's continued commercialization activities of our services in China. Subject to satisfaction of certain performance milestones, the Ex-U.S. Commercialization Agreement will remain in effect until April 2020 and may be extended by Roche for additional two-year periods. Roche has the right to terminate the

agreement without cause upon six months' prior written notice after the initial five-year term, and either party may terminate the agreement in the event of breach by the other party. Since Roche has the exclusive right to commercialize FoundationOne, FoundationOneHeme, FoundationACT, FoundationOne CDx, and, if terms are agreed upon between us and Roche, any new clinical diagnostic services developed under the R&D Collaboration Agreement, our ability to achieve commercial success outside the United States, including growing test volume and revenue, obtaining coverage decisions from commercial and government payors, and developing and operating a sustainable international commercial infrastructure, relies to a significant extent on the performance of Roche.

Doing business internationally involves a number of risks, including:

- multiple, potentially conflicting, and changing laws and regulations such as data protection laws, privacy regulations, tax laws, export and import restrictions, employment laws, regulatory requirements (including requirements related to patient consent, testing of genetic material, and reporting the results of such testing) and other governmental approvals, permits, and licenses, or government delays in issuing such approvals, permits, and licenses;
- failure by us, Roche, or other authorized third parties to obtain and maintain regulatory approvals for the marketing, promotion, manufacture, sale, and use of our services in various countries;
- transition and management of our former distribution relationships in various countries;
- additional, potentially relevant third-party intellectual property rights;

- complexities and difficulties in obtaining protection for and enforcing our intellectual property and defending ourselves against third-party claims of infringement of our intellectual property (including those elements of our intellectual property that we will make available to Dian as part of our collaboration with Roche and Dian in China), as the laws of some foreign jurisdictions, including China, may not provide sufficient protection of our intellectual property rights;
- difficulties in staffing and managing foreign operations or overseeing the staffing and management of foreign operations run by third parties;
- complexities associated with obtaining reimbursement from and managing multiple payor reimbursement regimes, government payors, or patient self-pay systems;
- logistics and regulations associated with preparing, shipping, importing, and exporting tissue and blood samples, including infrastructure conditions, transportation delays, and customs;
- limits in our ability to penetrate international markets if we are not able to perform our molecular tests locally or, in the converse, if we are required to expend significant resources to establish infrastructure in such markets and/or perform our molecular tests locally in such markets;
- financial risks, such as the impact of local and regional financial crises on demand and payment for our services, and exposure to foreign currency exchange rate fluctuations;
- natural disasters, political, and economic instability, including wars, terrorism, and political unrest, outbreak of disease, boycotts, curtailment of trade, and other business restrictions; and
- regulatory and compliance risks that relate to maintaining accurate information and control over sales and distribution activities that may fall within the purview of the United States Foreign Corrupt Practices Act, or FCPA, including its books and records provisions, or its anti-bribery provisions.

Any of these factors could significantly harm our future international expansion and operations and, consequently, our revenue and results of operations. The difference in regulations under United States law and the laws of foreign countries may be significant and, in order to comply with the laws of foreign countries, we may have to implement global changes to our services or business practices. Such changes may result in additional expense to us and either reduce or delay development of our services, commercialization, or sales. In addition, any failure to comply with applicable legal and regulatory obligations could impact us in a variety of ways that include, but are not limited to, significant criminal, civil, and administrative penalties, including imprisonment of individuals, fines and penalties, denial of export privileges, seizure of shipments, and restrictions on certain business activities. Also, the failure to comply with applicable legal and regulatory obligations could result in the disruption of our activities in these countries.

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

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

Reimbursement and Regulatory Risks Relating to Our Business

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.

Overview

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 adequate 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. We believe that obtaining a positive Medicare Local Coverage Determination, or LCD, or National Coverage Determination, or NCD, and a favorable Medicare reimbursement rate, and obtaining the agreement of established commercial third-party payors to provide coverage and adequate payment, 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 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.

Commercial third-party payors and government payors are increasingly attempting to contain healthcare costs by lowering reimbursement rates, limiting coverage of diagnostic services, and creating conditions of reimbursement, such as requiring participation in clinical evidence development involving research studies and the collection of physician decision impact and patient outcomes data. Certain commercial third-party payors may not agree to reimburse our existing services or future services if 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, and pay for, such services. As a result 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 propose and/or actually reduce, suspend, revoke, or discontinue payments or coverage at any time. Payors may also create conditions for coverage or may contract with third-party vendors to manage laboratory benefits, in both cases creating administrative hurdles 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.

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, has received FDA approval, or has obtained coverage for any particular indication or in any particular jurisdiction, does not guarantee that such diagnostic service will remain covered and/or reimbursed or that similar or additional diagnostic services and/or clinically indicated tumor types will be covered and/or reimbursed 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, FoundationOneHeme, and FoundationACT as experimental and investigational. Reimbursement of next generation sequencing, or NGS, -based cancer tests by commercial third-party payors and government payors may depend on a number of factors, including a payor’s determination that our existing and future 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 pursue coverage 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 are 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.

Government Payors

In the second quarter of 2016, the FDA and CMS accepted FoundationOne CDx for the Parallel Review program. The Parallel Review 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. In November 2017, the FDA approved

FoundationOne CDx for detection of substitutions, insertion and deletion alterations, and copy number alterations in 324 genes and select gene rearrangements, as well as genomic signatures including microsatellite instability and tumor mutational burden, using DNA isolated from formalin-fixed paraffin embedded tumor tissue specimens. FoundationOne CDx is intended as a companion diagnostic for patients with metastatic non-small cell lung cancer, or NSCLC, melanoma, colorectal cancer, ovarian cancer, or breast cancer to identify those patients who may benefit from treatment with one of 17 on-label targeted therapies in accordance with FDA-approved therapeutic product labeling. Additionally, FoundationOne CDx is intended to provide tumor mutation profiling to be used by qualified health care professionals in accordance with professional guidelines in oncology for cancer patients with solid malignant neoplasms.

Following FDA's approval of FoundationOne CDx in November 2017, CMS issued a final NCD in March 2018 that establishes nationwide Medicare coverage for FoundationOne CDx for all solid tumor types when ordered by the patient's treating physician for Medicare beneficiaries with advanced cancer (i.e., either recurrent, relapsed, refractory, metastatic, or advanced stages III or IV cancer), who either have not been previously tested using FoundationOne CDx for the same primary diagnosis of cancer or are seeking repeat testing with FoundationOne CDx for a new primary cancer diagnosis, and continue to seek further cancer therapy. We

cannot guarantee that the Medicare reimbursement rate established for this test will be favorable at the time of the initial rate determination or any time thereafter. If the Medicare reimbursement rate is unfavorable, we could experience a negative impact on revenue.

The final NCD establishes nationwide Medicare coverage NGS tests for advanced cancer that have been approved or cleared by the FDA as a companion diagnostic, and applies to all local MACs and Medicare Advantage plans. For NGS-based tests other than those that have been approved or cleared by the FDA as a companion diagnostic (i.e., tests offered as LDTs or FDA-approved or cleared tests that are not a companion diagnostic), the final NCD allows the local MACs to continue determining coverage for such tests insofar as patients meet the patient criteria outlined in the final NCD (i.e., either recurrent, relapsed, refractory, metastatic, or advanced stages III or IV cancer, and who either have not been previously tested using the same NGS test for the same primary diagnosis of cancer or are seeking repeat testing with the same NGS test for a new primary cancer diagnosis, and continue to seek further cancer therapy). As such, FoundationOne will continue to be covered by Medicare when provided to patients with NSCLC consistent with the current terms of the LCD issued by Palmetto GBA, or Palmetto. Palmetto is the MAC for the jurisdiction in which our North Carolina laboratory is located. The MolDx Program was developed by Palmetto to serve various functions, including establishing coverage and reimbursement for molecular diagnostic tests that fall under Palmetto's purview. In May 2015, Palmetto's MolDx Program published a final LCD, or the Palmetto LCD, which included reimbursement for comprehensive genomic profiles for highly validated testing in an initial subset of patients diagnosed with NSCLC. The Palmetto website listed FoundationOne as a covered test under this LCD effective October 1, 2015.

For tests we may offer that are not subject to an NCD, local MACs that administer the Medicare program in various regions have discretion in determining coverage for tests, subject to Medicare rules. 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 if the service is not currently priced on the Medicare Clinical Laboratory Fee Schedule, or CLFS, 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 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 circumstances of non-coverage under an NCD or LCD, we may be required to obtain 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 CMS under an NCD or a MAC under an LCD establishes patient eligibility conditions, data collection obligations or other requirements 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.

In September 2016, we began receiving test requisitions and samples from commercial customers at our North Carolina facility and performing components of FoundationOne and FoundationOneHeme testing at the facility. In accordance with CMS guidance, in January 2017, we began submitting an initial set of claims to Palmetto for FoundationOne test requisitions received in our North Carolina facility. We submitted these claims using miscellaneous Current Procedural Terminology, or CPT, codes with unique McKesson Z Code identifiers. In March 2017, we received our first payments for claims under the Palmetto LCD. Payment for all claims processed to date by Palmetto has been made based upon the allowable rate of $3,416 per test. Although we are performing components of our testing services for FoundationOneHeme in our North Carolina facility, Palmetto has provided guidance that CGP testing not covered by an LCD is explicitly non-covered, including FoundationOneHeme; therefore, we are seeking to obtain signed ABNs from Medicare patients who receive FoundationOneHeme testing. We 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, our ability to meet laboratory and testing requirements, and our ability to accommodate logistical and commercial needs in the test ordering and fulfillment process.

In parallel, we have been 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 testing. In December 2016, Palmetto originally 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, respectively. In March 2018, Palmetto re-issued revised versions of these draft LCDs, and is accepting public comments on such drafts until May 10, 2018. If finalized as proposed, FoundationOne will be covered by Medicare when provided to patients with these conditions consistent with the terms of these LCDs. However, these draft LCDs may be delayed, may never be finalized, or if the LCDs are finalized, the coverage established by such LCDs 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 are also currently seeking to obtain as part of the test order process a signed ABN from Medicare patients for non-covered tumor types in order to allow us to bill Medicare patients directly. The process of procuring signed ABNs may affect the turn-around-time for test report delivery, and may have a negative impact on test utilization, our revenue and our profitability.

Commercial Payors

We are currently considered an “out-of-network provider” by many commercial third-party payors because we have not entered into specific contracts to provide one or more of our existing services for their health plan beneficiaries, and as a result, patients may have higher out-of-pocket costs for our services and be subject to health plan requirements such as prior authorization. Physicians may be less likely to order our tests if patients have higher out-of-pocket costs or administrative hurdles, which would in turn have a negative effect on revenue and results of operations. 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 patient out-of-pocket payments amounts directly from patients, and may experience lost revenue as a result. In addition, a payor’s decision to cover our services only 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.

Policy Considerations

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 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.

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

Affordable Care Act

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 two-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. In 2018, Congress extended the moratorium to medical device sales made during the period between January 1, 2018 and December 31, 2019. Absent further legislative action, the tax will be automatically reinstated for medical device sales starting on January 1, 2020. If the tax is reinstated, sales of our services that are regulated as medical devices, such as FoundationFocus CDx BRCA or FoundationOne CDx, 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 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 CLFS rather than move them to the Physician Fee Schedule. CMS then announced that for 2013, it would price the new codes using a “gap filling” process. Under this approach, CMS referred the CPT codes to the MACs to allow them to determine an appropriate price. CMS then calculated the median of the pricing provided by the MACs to establish and publish a National Limitation Amount, or NLA, by CPT code for 2014.

In 2014, the AMA approved and implemented new CPT codes for genomic sequencing-based panel tests in cancer, effective January 1, 2015. In 2015, CMS used a "gap filling" process to price some of these new codes, which involved referring the new codes to the MACs to allow them to determine and submit to CMS an appropriate price. For 2016, CMS established and published an NLA for some of these codes, including the code associated with testing for 5-50 genes as calculated by determining the median price as provided by the MACs for the applicable code. If CMS reduces reimbursement for the CPT codes for individual genes or fails to price favorably multi-gene panel codes upon which commercial payors may base rates, or if commercial payors who often base pricing on Medicare fee schedules reduce non-contracted payment rates below the NLA amounts for CPT codes corresponding to individual genes, mandate use of the sequencing-based panel CPT codes, or decide to stop payment on specific CPT codes altogether, our revenue could be adversely affected. For 2018, CMS established and published an NLA for the CPT code associated with testing for over 51 genes as calculated based on the weighted median of the payment rates for private payors for such code.

Effective April 1, 2018, the AMA established a unique Proprietary Laboratory Analysis code that is specific to our FoundationOne CDx test. No Medicare payment rate has yet been established for this code.

Protecting Access to Medicare Act

In April 2014 the Protecting Access to Medicare Act of 2014, or PAMA, was enacted into law. Section 216 of PAMA reforms the Medicare payment system for clinical laboratory tests paid through the CLFS. PAMA establishes a market-based payment system for Medicare payment for clinical diagnostic laboratory tests. Under this new methodology, CMS will establish Medicare payment for each test based on the weighted median of the private payor rates for the test. PAMA also creates a new class of test called the Advanced Diagnostic Laboratory Test, or ADLT, defined as a test offered and furnished only 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 United States Secretary of Health and Human Services.

PAMA requires certain clinical laboratories meeting a threshold of Medicare revenues to report private payor rates and corresponding test volumes. We did not meet this threshold during the January 1, 2016 to June 30, 2016 data collection period and therefore were not required to report this data in 2017, however, we anticipate that we will be required to report data during future reporting periods. 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. As outlined in the Final Rule, CMS implemented the new payment system on January 1, 2018. CMS 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. In March 2018, CMS also published additional sub-regulatory guidance describing an application process for ADLTs. While we believe that FoundationOne CDx meets the requirements for designation as a new ADLT, it is possible that CMS will determine that FoundationOne CDx does not meet the requirements for classification as a new ADLT, or that the requirements of the ADLT application process could create delays for us submitting or billing under PAMA. A delay in or denial of an application for the designation of FoundationOne CDx as a new ADLT could materially change our approach to commercializing FoundationOne CDx and could negatively affect reimbursement and therefore revenue. Depending upon if and how commercial payors adopt, or are otherwise influenced by, this new Medicare pricing methodology and the payment rates, our average and weighted median commercial payor rate for our tests, including FoundationOne CDx, could be adversely affected.

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 192 physician practices in 32 states, as well as 14 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.

Medicare 14-Day Rule

Certain Medicare billing policy requirements for clinical laboratory tests impact our ability to bill Medicare directly, and under certain circumstances, require us to bill and collect payments from hospitals for tests that we perform for inpatient or outpatient Medicare patients. Prior to January 1, 2018, under the so-called “14-Day Rule,” tests performed on specimens collected from hospital inpatients or outpatients, where those tests are ordered less than 14 days following the date of the patient's discharge from the hospital, could not be billed by us to Medicare directly; instead we had to bill the hospital for the test.

In November 2017, CMS finalized the 2018 Hospital Outpatient Prospective Payment System Final Rule, which allows us to directly bill Medicare more frequently. Specifically, under the revised billing rules, a laboratory that performs molecular pathology tests on specimens collected during a hospital outpatient stay may bill Medicare directly for such tests if the test was performed following a hospital outpatient's discharge from the hospital outpatient department. To the extent these revisions to Medicare’s billing policy permit us to bill Medicare directly for tests previously billed to hospitals under the 14-Day Rule, we will no longer bill hospitals for such tests. We continue to be subject to the 14-Day Rule, and therefore remain obligated to bill the hospital insofar as we

perform tests on specimens collected during a hospital inpatient stay. Hospitals may assert that they are not required to pay these bills, or they may delay in paying these bills. In these cases, for hospitals who disclaim responsibility for our bills or delay payment of our bills under the 14-Day Rule, we may undertake collection activities, and as a result of such efforts, we may accept payments from hospitals that are less than the original invoice or we may be unable to collect from hospitals any payments at all. The management of this collection activity, and the acceptance of payment amounts less than the amount of such bills, involves a number of risks, including our ability to meet the requirements of applicable financial accounting principles and controls and healthcare regulations. If we are not successful in managing this collection activity in a manner that meets our obligations, we could be deemed to be in violation of accounting principles or health care regulation, which in turn, could lead to the assertion of claims against us and a resulting adverse effect on our operating results and reputation.

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. Most notably, Congress enacted legislation in 2017 that eliminates the ACA's "individual mandate" beginning in 2019, which may significantly impact the number of covered lives participating in exchange plans. 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.

Risks Relating to Our Financial Condition and Capital Requirements

Changes in estimates as a result of the adoption of recently adopted financial accounting standards may cause an adverse impact to our reported results of operations.

In May 2014, the Financial Accounting Standards Board issued new revenue recognition rules under Accounting Standards Codification Topic 606, Revenue from Contracts with Customers, or ASC 606, which is effective for interim and annual periods beginning after December 31, 2017. We have adopted the new standard effective January 1, 2018 using the modified retrospective method. The adoption of ASC 606 is complex and requires the use of significant judgment in certain areas which could have a material effect on our financial statements.

In order to comply with the requirements of ASC 606, we added and/or modified certain internal controls and processes in the first quarter of 2018 in conjunction with adopting the new revenue recognition standard. In particular, accounting for clinical molecular information services revenue on an accrual basis under ASC 606 requires substantially more estimation by us as compared to recognizing revenue on a cash basis. This additional estimation could cause increased variability and uncertainty in our financial reporting and projections, which could have a material impact on our business. For example, accounting for clinical revenue on an accrual basis could result in true-ups in future periods as our reimbursement experience changes.

If we are not successful in our execution of the updated policies, procedures, information systems and internal controls over financial reporting which we implemented in the first quarter of 2018 to effectively record revenue under ASC 606, the revenue that we recognize and the related disclosures that we provide in our financial statements may not be complete or accurate, which could cause investors to lose confidence in our financial reporting, or cause us to fail to

meet our reporting obligations, all of which could have an adverse effect on our reputation and operating results.

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 $161.5 million in 2017. From our inception in 2009 through March 31, 2018, we had an accumulated deficit of $525.5 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.

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, we are a party to litigation arising in the ordinary course of its business. On July 28, 2017, a purported stockholder of the Company filed a putative class action in the U.S. District Court for the District of Massachusetts, against the Company and certain of its current and former executives, captioned Mahoney v. Foundation Medicine, Inc., et al., No. 1:17-cv-11394. The complaint alleges violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 thereunder based on allegedly false and misleading statements and omissions 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. On December 22, 2017, the plaintiffs filed an amended class action complaint alleging 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 and omissions concerning providing 2015 financial guidance and other statements during the class period concerning demand and reimbursement for certain of the Company's tests. On February 20, 2018, the Company moved to dismiss the complaint for failure to state a claim, which plaintiffs opposed on April 23, 2018. We believe this case is without merit and, therefore, continue to vigorously defend ourselves against the allegations.

Item 6. Exhibits

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

| Exhibit No. | Exhibit Index |
|---|---|
| 10.1*# | Amended and Restated Ex-US Commercialization Agreement, by and between the Company and F. Hoffmann-La Roche Ltd, dated February 28, 2018. |
| 10.2* | Executive Employee Offer Letter by and between the Company and Michael Doherty, dated December 5, 2016, as amended. |
| 10.3* | Executive Employee Offer Letter by and between the Company and Konstantin Fiedler, dated May 1, 2018. |
| 10.4* | Executive Employee Offer Letter by and between the Company and Melanie Nallicheri, dated September 12, 2016. |
| 31.1* | Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. |
| 31.2* | Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. |
| 32.1** | Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. |
| 101 | Interactive Data Files regarding (a) our Condensed Consolidated Balance Sheets as of March 31, 2018 and December 31, 2017, (b) our Condensed Consolidated Statements of Operations and Comprehensive Loss for the Three Months Ended March 31, 2018 and 2017, (c) our Condensed Consolidated Statements of Cash Flows for the Three Months Ended March 31, 2018 and 2017, 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.

SIGNATURES

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

FOUNDATION MEDICINE, INC.

Date: May 2, 2018 By: /s/ Troy Cox
Troy Cox
President and Chief Executive Officer
(Principal Executive Officer)

Date: May 2, 2018 By: /s/ Jason Ryan
Jason Ryan
Chief Financial Officer
(Principal Financial Officer)