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# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION
**WASHINGTON, D.C. 20549**

# FORM 10-Q

**(Mark One)**

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

**For the quarterly period ended March 31, 2020**

**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 001-36156**

# VERACYTE, INC.
(Exact name of registrant as specified in its charter)

| **Delaware** | **20-5455398** |
|---|---|
| (State or other jurisdiction of incorporation or organization) | (I.R.S. Employer Identification No.) |

**6000 Shoreline Court, Suite 300**
**South San Francisco, California 94080**
(Address of principal executive offices, zip code)

**(650) 243-6300**
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

| **Title of each class** | **Trading Symbol(s)** | **Name of each exchange on which registered** |
|---|---|---|
| Common Stock, par value, $0.001 per share | VCYT | The Nasdaq Stock Market LLC |

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 o

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted 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 such files). Yes ☒ No o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a 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 x | Accelerated filer o |
| Non-accelerated filer o | 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. o

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 30, 2020, there were 50,053,437 shares of common stock, par value $0.001 per share, outstanding.

**VERACYTE, INC.**
**INDEX**

## PART I. — FINANCIAL INFORMATION

### Item 1. Condensed Financial Statements

**VERACYTE, INC.**

**Condensed Consolidated Balance Sheets**

**(unaudited)**

**(In thousands, except share and per share amounts)**

| | March 31, 2020 | December 31, 2019 (See Note 1) |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 153,132 | $ 159,317 |
| Accounts receivable | 19,091 | 19,329 |
| Supplies | 6,094 | 6,806 |
| Prepaid expenses and other current assets | 3,045 | 2,235 |
| Total current assets | 181,362 | 187,687 |
| Property and equipment, net | 8,788 | 8,933 |
| Right-of-use assets - operating lease | 8,576 | 8,808 |
| Finite-lived intangible assets, net | 63,744 | 65,019 |
| Goodwill | 2,725 | 2,725 |
| Restricted cash | 603 | 603 |
| Other assets | 1,302 | 1,437 |
| Total assets | $ 267,100 | $ 275,212 |
| **Liabilities and Stockholders' Equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 7,665 | $ 2,328 |
| Accrued liabilities | 10,079 | 13,734 |
| Current portion of operating lease liability | 1,450 | 1,407 |
| Total current liabilities | 19,194 | 17,469 |
| Long-term debt | 748 | 694 |
| Acquisition-related contingent consideration | 5,604 | 6,088 |
| Operating lease liability, net of current portion | 11,132 | 11,506 |
| Total liabilities | 36,678 | 35,757 |
| Commitments and contingencies | | |
| Stockholders' equity: | | |
| Preferred stock, $0.001 par value; 5,000,000 shares authorized, no shares issued and outstanding as of March 31, 2020 and December 31, 2019 | — | — |
| Common stock, $0.001 par value; 125,000,000 shares authorized, 49,999,923 and 49,625,341 shares issued and outstanding as of March 31, 2020 and December 31, 2019, respectively | 50 | 50 |
| Additional paid-in capital | 488,773 | 486,090 |
| Accumulated deficit | (258,401) | (246,685) |
| Total stockholders' equity | 230,422 | 239,455 |
| Total liabilities and stockholders' equity | $ 267,100 | $ 275,212 |

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

**VERACYTE, INC.**

**Condensed Consolidated Statements of Operations and Comprehensive Loss**

**(Unaudited)**

**(In thousands, except share and per share amounts)**

| | Three Months Ended March 31, | |
|---|---|---|
| | 2020 | 2019 |
| Revenue: | | |
| Testing revenue | $ 26,991 | $ 25,389 |
| Product revenue | 3,409 | — |
| Biopharmaceutical revenue | 722 | 4,140 |
| Total Revenue | 31,122 | 29,529 |
| Operating expenses: | | |
| Cost of testing revenue | 10,568 | 8,513 |
| Cost of product revenue | 1,559 | — |
| Cost of biopharmaceutical revenue | 116 | — |
| Research and development | 4,407 | 3,435 |
| Selling and marketing | 17,584 | 12,477 |
| General and administrative | 7,813 | 6,904 |
| Intangible asset amortization | 1,275 | 267 |
| Total operating expenses | 43,322 | 31,596 |
| Loss from operations | (12,200) | (2,067) |
| Interest expense | (55) | (303) |
| Other income, net | 539 | 453 |
| Net loss and comprehensive loss | $ (11,716) | $ (1,917) |
| Net loss per common share, basic and diluted | $ (0.24) | $ (0.05) |
| Shares used to compute net loss per common share, basic and diluted | 49,792,631 | 41,168,593 |

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

**VERACYTE, INC.**

**Condensed Consolidated Statements of Stockholders' Equity**

**(Unaudited)**

**(In thousands)**

| | Common Stock | | Additional Paid-in Capital | Accumulated Deficit | Total Stockholders' Equity |
|---|---|---|---|---|---|
| | Shares | Amount | | | |
| Balance at December 31, 2019 | 49,625 | $ 50 | $ 486,090 | $ (246,685) | $ 239,455 |
| Issuance of common stock upon exercise of stock options and vesting of restricted stock units | 314 | — | 981 | — | 981 |
| Issuance of common stock under employee stock purchase plan (ESPP) | 61 | — | 1,101 | — | 1,101 |
| Tax portion of vested restricted stock units | — | — | (2,304) | | (2,304) |
| Stock-based compensation expense (employee) | — | — | 2,551 | — | 2,551 |
| Stock-based compensation expense (ESPP) | — | — | 354 | — | 354 |
| Net loss and comprehensive loss | — | — | — | (11,716) | (11,716) |
| Balance at March 31, 2020 | 50,000 | $ 50 | $ 488,773 | $ (258,401) | $ 230,422 |

| | Common Stock | | Additional Paid-in Capital | Accumulated Deficit | Total Stockholders' Equity |
|---|---|---|---|---|---|
| | Shares | Amount | | | |
| Balance at December 31, 2018 | 40,863 | $ 41 | $ 313,800 | $ (234,086) | $ 79,755 |
| Issuance of common stock upon exercise of stock options and vesting of restricted stock units | 566 | 1 | 4,239 | — | 4,240 |
| Issuance of common stock under ESPP | 80 | — | 491 | — | 491 |
| Tax portion of vested restricted stock units | — | — | (556) | — | (556) |
| Stock-based compensation expense (employee) | — | — | 1,598 | — | 1,598 |
| Stock-based compensation expense (non-employee) | — | — | 20 | — | 20 |
| Stock-based compensation expense (ESPP) | — | — | 141 | — | 141 |
| Net loss and comprehensive loss | — | — | — | (1,917) | (1,917) |
| Balance at March 31, 2019 | 41,509 | $ 42 | $ 319,733 | $ (236,003) | $ 83,772 |

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

**VERACYTE, INC.**

**Condensed Consolidated Statements of Cash Flows**

**(Unaudited)**

**(In thousands)**

| | Three Months Ended March 31, | |
|---|---|---|
| | **2020** | **2019** |
| **Operating activities** | | |
| Net loss | $ (11,716) | $ (1,917) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation and amortization | 1,972 | 945 |
| Gain on disposal of property and equipment | — | (16) |
| Stock-based compensation | 2,905 | 1,759 |
| Amortization of debt issuance costs | — | 8 |
| Interest on end-of-term debt obligation | 54 | 64 |
| Write-down of excess supplies | 1,088 | — |
| Noncash lease expense | 232 | 212 |
| Revaluation of acquisition-related contingent consideration | (484) | — |
| Changes in operating assets and liabilities: | | |
| Accounts receivable | 238 | (3,447) |
| Supplies | (376) | (366) |
| Prepaid expenses and other current assets | (818) | (11) |
| Operating lease liability | (331) | (292) |
| Other assets | 135 | 37 |
| Accounts payable | 5,450 | 1,726 |
| Accrued liabilities | (3,650) | 287 |
| Net cash used in operating activities | (5,301) | (1,011) |
| **Investing activities** | | |
| Purchases of property and equipment | (665) | (765) |
| Proceeds from disposal of property and equipment | — | 16 |
| Net cash used in investing activities | (665) | (749) |
| **Financing activities** | | |
| Payment of long-term debt | — | (12,500) |
| Payment of finance lease liability | — | (75) |
| Payment of taxes on vested restricted stock units | (2,304) | (556) |
| Proceeds from the exercise of common stock options and employee stock purchases | 2,085 | 4,737 |
| Net cash used in financing activities | (219) | (8,394) |
| **Net decrease in cash, cash equivalents and restricted cash** | (6,185) | (10,154) |
| **Cash, cash equivalents and restricted cash at beginning of period** | 159,920 | 78,598 |
| **Cash, cash equivalents and restricted cash at end of period** | $ 153,735 | $ 68,444 |
| **Supplementary cash flow information:** | | |
| Purchases of property and equipment included in accounts payable and accrued liability | $ 113 | $ 95 |
| Interest paid on debt | $ 1 | $ 228 |

**Cash, Cash Equivalents and Restricted Cash**:

| | March 31, 2020 | December 31, 2019 |
|---|---|---|
| Cash and cash equivalents | $ 153,132 | $ 159,317 |
| Restricted cash | 603 | 603 |
| Total cash, cash equivalents and restricted cash | $ 153,735 | $ 159,920 |

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

**VERACYTE, INC.**
**Notes to Financial Statements**
**(unaudited)**

**1. Organization and Description of Business**

Veracyte, Inc., or Veracyte, or the Company, is a global genomic diagnostics company that improves patient care by providing answers to clinical questions to inform diagnosis and treatment decisions throughout the patient journey in cancer and other diseases. The Company's growing menu of genomic tests leverage advances in genomic science and technology to change care for patients, enabling them to avoid risky, costly procedures and quicken time to appropriate treatment. With Veracyte's exclusive global access to a best-in-class diagnostics instrument platform, the Company is positioned to deliver its tests to patients worldwide through laboratories and hospitals that can perform the tests locally.

Veracyte was incorporated in the state of Delaware on August 15, 2006 as Calderome, Inc. Calderome operated as an incubator until early 2008. On March 4, 2008, the Company changed its name to Veracyte, Inc. The Company's operations are based in South San Francisco, California and Austin, Texas, and it operates in one segment.

The Company performs its genomic tests for thyroid cancer, lung cancer and idiopathic pulmonary fibrosis, or IPF, in its CLIA-certified laboratory in South San Francisco, California. In December 2019, the Company announced the exclusive global diagnostics license to the NanoString nCounter FLEX Analysis System, and the acquisition of the Prosigna breast cancer prognostic gene signature assay, which is commercially available, and the LymphMark lymphoma subtyping assay, which is in development. Both tests are designed for use on the nCounter system.

The Company offers genomic tests in four disease areas: thyroid cancer; lung cancer; IPF and breast cancer.

***Thyroid Cancer*** - ***Afirma Genomic Sequencing Classifier and Xpression Atlas.*** The Company's Afirma offerings comprise the Afirma GSC and Xpression Atlas, which help guide next steps for patients with potentially cancerous thyroid nodules. The offerings are intended to provide physicians with clinically actionable results from a single fine needle aspiration, or FNA biopsy. The Afirma GSC was developed with RNA whole-transcriptome sequencing and machine learning, and is used to identify patients with benign thyroid nodules among those with indeterminate cytopathology results in order to rule out unnecessary thyroid surgery.

The Afirma Xpression Atlas complements the Afirma GSC by providing genomic alteration content from the same FNA samples used in Afirma GSC testing to help physicians decide with greater confidence on the surgical or therapeutic pathway for their patients. The Company commercially launched the Afirma Xpression Atlas in 2018 and in April 2020 introduced an expanded version of the test, which includes significantly more genomic content.

***Lung Cancer*** - ***Percepta Genomic Sequencing Classifier.*** The Percepta classifier improves lung cancer diagnosis when diagnostic bronchoscopy results are inconclusive. This second-generation test was developed using the Company's RNA whole-transcriptome sequencing and machine learning platform and was commercially introduced in June 2019. The Percepta classifier identifies patients with lung nodules who are at low risk of cancer and may avoid further, invasive procedures as well as patients at high risk of cancer so they may obtain faster diagnosis and treatment. The test is built upon foundational "field of injury" science - through which genomic changes associated with lung cancer in current and former smokers can be identified with a simple brushing of a person's airway - without the need to sample the often hard-to-reach nodule directly.

***IPF*** - ***Envisia Genomic Classifier.*** The Envisia classifier improves diagnosis of IPF by helping physicians better differentiate IPF from other interstitial lung diseases, or ILDs, without the need for surgery. The test identifies the genomic pattern of usual interstitial pneumonia, or UIP, a hallmark of IPF, with high accuracy on patient samples that are obtained through transbronchial biopsy, a nonsurgical procedure that is commonly used in lung evaluation.

***Breast Cancer*** - ***Prosigna Breast Cancer Prognostic Gene Signature Assay.*** The Prosigna test, acquired in December 2019 through the Company's strategic transaction with NanoString, uses advanced genomic technology to inform next steps for patients with early-stage breast cancer, based on the genomic make-up of their disease. The test uses a set of 50 genes known as the PAM50 gene signature and can provide a breast cancer patient and physician with prognostic score that indicates the probability of cancer recurrence over ten years. Physicians use Prosigna to help guide therapeutic decisions so that patients receive a therapeutic intervention, such as

chemotherapy, only if clinically warranted. Patient test results outside of the United States include intrinsic breast cancer subtypes to complement the risk-of-recurrence score.

The Company’s approach also provides multiple opportunities for partnerships with biopharmaceutical companies. In developing its products, the Company has built or gained access to unique biorepositories, proprietary technology and bioinformatics that it believes are important to the development of new targeted therapies, determining clinical trial eligibility and guiding treatment selection.

The Company's testing services are performed in its clinical reference laboratories located in South San Francisco, California and Austin, Texas. The Prosigna test kits and associated products are sold to laboratories and hospitals in global markets.

***Basis of Presentation***

The Company’s condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States, or GAAP. Certain information and note disclosures normally included in financial statements prepared in accordance with GAAP have been condensed or omitted pursuant to such rules and regulations. The condensed consolidated balance sheet as of March 31, 2020, the condensed consolidated statements of operations and comprehensive loss for the three months ended March 31, 2020 and 2019, the condensed consolidated statements of stockholders' equity for the three months ended March 31, 2020 and 2019, and the condensed consolidated statements of cash flows for the three months ended March 31, 2020 and 2019 are unaudited, but include all adjustments, consisting only of normal recurring adjustments, which the Company considers necessary for a fair presentation of its financial position, operating results, stockholders' equity and cash flows for the periods presented. The condensed consolidated balance sheet at December 31, 2019 has been derived from audited financial statements. The results for the three months ended March 31, 2020 are not necessarily indicative of the results expected for the full year or any other period.

The accompanying interim period condensed consolidated financial statements and related financial information included in this Quarterly Report on Form 10-Q should be read in conjunction with the audited financial statements and notes thereto included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2019.

***Reclassifications***

Certain prior period balances have been reclassified to conform to current period presentation of the Company’s condensed consolidated financial statements and accompanying notes. Such reclassifications have no effect on previously reported results of operations, retained earnings or consolidated balance sheet totals; however, for the period ended March 31, 2019, the Company reclassified $212,000 of changes in operating assets and liabilities to noncash lease expense in the statement of cash flows.

***Use of Estimates***

The preparation of unaudited interim financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent liabilities as of the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. Items subject to such estimates include: revenue recognition; write-down of supplies; the useful lives of property and equipment; the recoverability of long-lived assets; the incremental borrowing rate for leases; the estimation of the fair value of intangible assets and contingent consideration; stock options; income tax uncertainties, including a valuation allowance for deferred tax assets; and contingencies. The Company bases these estimates on historical and anticipated results, trends, and various other assumptions that the Company believes are reasonable under the circumstances, including assumptions as to future events. These estimates form the basis for making judgments about the carrying values of assets and liabilities and recorded revenue and expenses that are not readily apparent from other sources. Actual results could differ from those estimates and assumptions.

***Issuance of Common Stock in a Public Offering***

On May 7, 2019, the Company issued and sold 6,325,000 shares of common stock in a registered public offering, including 825,000 shares issued and sold upon the underwriters’ exercise in full of their option to purchase additional shares, at a price to the public of $23.25 per share. The Company's net proceeds from the offering were approximately $137.8 million, after deducting underwriting discounts and commissions and offering expenses of $9.2 million.

**VERACYTE, INC.**
**Notes to Financial Statements**
**(unaudited)**

***Cash and Cash Equivalents***

The Company considers demand deposits in a bank, money market funds and highly liquid investments with an original maturity of 90 days or less to be cash equivalents. Cash equivalents include overnight reverse repurchase agreements which are tri-party repurchase agreements and have maturities of three months or less at the time of investment and are collateralized by U.S. treasury and agency securities of at least 102% of the principal amount. In a tri-party repurchase agreement, a third-party custodian bank functions as an independent intermediary to facilitate transfer of cash and holding the collateral on behalf of the underlying investor for the term of the agreement thereby minimizing risk and exposure to both parties. These overnight reverse repurchase agreements are included within cash equivalents due to their high liquidity and relatively low risk. There were no overnight reverse repurchase agreements at March 31, 2020.

***Concentrations of Credit Risk and Other Risks and Uncertainties***

The worldwide spread of coronavirus, or COVID-19, has created significant uncertainty in the global economy. There have been no comparable recent events that provide guidance as to the effect the spread of COVID-19 as a global pandemic may have, and, as a result, the ultimate impact of COVID-19 and the extent to which COVID-19 impacts the Company's business, results of operations and financial condition will depend on future developments, which are highly uncertain and difficult to predict. If the financial markets or the overall economy are impacted for an extended period, the Company's liquidity, revenues, supplies, goodwill and intangibles may be adversely affected

The majority of the Company's cash and cash equivalents are deposited with one major financial institution in the United States. Deposits in this institution may exceed the amount of insurance provided on such deposits. The Company has not experienced any losses on its deposits of cash and cash equivalents.

Several of the components of the Company's sample collection kit and test reagents, and its nCounter FLEX Analysis System and related test kits are obtained from single-source suppliers. If these single-source suppliers fail to satisfy the Company's requirements on a timely basis, it could suffer delays in being able to deliver its diagnostic solutions, a possible loss of revenue, or incur higher costs, any of which could adversely affect its operating results.

The Company is also subject to credit risk from its accounts receivable related to its sales. Credit risk for accounts receivable from testing revenue is incorporated in testing revenue accrual rates as the Company assesses historical collection rates and current developments to determine accrual rates and amounts the Company will ultimately collect. The Company generally does not perform evaluations of customers' financial condition for testing revenue and generally does not require collateral. The Company assesses credit risk and the amount of accounts receivable the Company will ultimately collect for product, biopharmaceutical and collaboration revenue based on collection history, current developments and credit worthiness of the customer. The estimate of credit losses is not material at March 31, 2020.

Through March 31, 2020, most of the Company's revenue has been derived from the sale of Afirma. To date, Afirma has been delivered primarily to physicians in the United States. The Company's third-party payers and other customers in excess of 10% of total revenue and their related revenue as a percentage of total revenue were as follows:

| | Three Months Ended March 31, | |
|---|---|---|
| | 2020 | 2019 |
| Medicare | 25 % | 21 % |
| Johnson and Johnson Services, Inc. | * | 13 % |
| UnitedHealthcare | 11 % | 11 % |
| | 36 % | 45 % |

*Less than 10%

**VERACYTE, INC.**
**Notes to Financial Statements**
**(unaudited)**

The Company's third-party payers and other customers in excess of 10% of accounts receivable and their related accounts receivable balance as a percentage of total accounts receivable were as follows at the following dates:

| | March 31, 2020 | December 31, 2019 |
|---|---|---|
| Johnson and Johnson Services, Inc. | * | 10 % |
| Medicare | 14 % | 15 % |

*Less than 10%

***Restricted Cash***

The Company had deposits of $603,000 included in long-term assets as of March 31, 2020 and December 31, 2019, restricted from withdrawal and held by a bank in the form of collateral for an irrevocable standby letter of credit held as security for the lease of the Company's South San Francisco facility.

***Revenue Recognition***

**Testing Revenue**

The Company recognizes testing revenue in accordance with the provisions of ASC 606, Revenue from Contracts with Customers, or ASC 606. Most of the Company's revenue is generated from the provision of testing services. These services are completed upon the delivery of test results to the prescribing physician, at which time the Company bills for the services. The Company recognizes revenue related to billings based on estimates of the amount that will ultimately be realized. In determining the amount to accrue for a delivered test, the Company considers factors such as payment history, payer coverage, whether there is a reimbursement contract between the payer and the Company, payment as a percentage of agreed upon rate (if applicable), amount paid per test and any current developments or changes that could impact reimbursement. These estimates require significant judgment by management.

For the three months ended March 31, 2019, the Company changed its testing revenue estimates due to actual and anticipated cash collections for tests delivered in 2018 or prior years and recognized additional revenue of $0.6 million, which resulted in a decrease in the Company's loss from operations of $0.6 million and a decrease in loss per share of $0.02 for the three months ended March 31, 2019. The change in testing revenue estimates for the three months ended March 31, 2020 was not material.

**Product Revenue**

The Company began recognizing product revenue in December 2019, when the Company executed an agreement with NanoString for the exclusive global license to the nCounter platform and acquisition of products for diagnostic use. More details on this agreement are in Note 4 - Business Combination.

Product revenue from instruments, consumables and in vitro diagnostic kits is recognized generally upon shipment or when the instrument is ready for use by the end customer, which is when title of the product has been transferred to the customer. This process involves identifying the contract with a customer, determining the performance obligations in the contract, determining the contract price, allocating the contract price to the distinct performance obligations in the contract, and recognizing revenue when the performance obligations have been satisfied. A performance obligation is considered distinct from other obligations in a contract when it provides a benefit to the customer either on its own or together with other resources that are readily available to the customer and is separately identified in the contract. Performance obligations are considered satisfied once the Company has transferred control of a product to the customer, meaning the customer has the ability to use and obtain the benefit of the product. The Company recognizes product revenue for satisfied performance obligations only when there are no uncertainties regarding payment terms or transfer of control. Shipping and handling costs incurred for product shipments are charged to the Company's customers and included in product revenue. Revenues are presented net of the taxes that are collected from customers and remitted to governmental authorities.

**Biopharmaceutical and Collaboration Revenue**

From time to time, the Company enters into arrangements for research and development and/or laboratory services. Such arrangements may require the Company to deliver various rights, services and/or samples, including intellectual property rights/licenses, R&D services, and/or laboratory services. The underlying terms of these arrangements generally provide for consideration to the Company in the form of nonrefundable upfront license fees, development and commercial performance milestone payments, royalty payments, and/or profit sharing.

In arrangements involving more than one performance obligation, each required performance obligation is evaluated to determine whether it qualifies as a distinct performance obligation based on whether (i) the customer can benefit from the good or service either on its own or together with other resources that are readily available and (ii) the good or service is separately identifiable from other promises in the contract. The consideration under the arrangement is then allocated to each separate distinct performance obligation based on its respective relative stand-alone selling price. The estimated selling price of each deliverable reflects the Company's best estimate of what the selling price would be if the deliverable was regularly sold by the Company on a stand-alone basis or using an adjusted market assessment approach if selling price on a stand-alone basis is not available.

The consideration allocated to each distinct performance obligation is recognized as revenue when control of the related goods is transferred or services are performed. Consideration associated with at-risk substantive performance milestones is recognized as revenue when it is probable that a significant reversal of the cumulative revenue recognized will not occur. Should there be royalties, the Company utilizes the sales and usage-based royalty exception in arrangements that resulted from the license of intellectual property, recognizing revenues generated from royalties or profit sharing as the underlying sales occur.

**Collaborative Arrangements**

The Company enters into collaborative arrangements with partners that fall under the scope of ASC Topic 808, Collaborative Arrangements, or ASC 808. While these arrangements are in the scope of ASC 808, the Company may analogize to ASC 606 for some aspects of these arrangements. The Company analogizes to ASC 606 for certain activities within the collaborative arrangement for the delivery of a good or service (i.e., a unit of account) that is part of its ongoing major or central operations.

The terms of the Company’s collaborative arrangements typically include one or more of the following: (i) up-front fees; (ii) milestone payments related to the achievement of development, regulatory, or commercial goals; and (iii) royalties on net sales of licensed products. Each of these payments may result in collaboration revenues or an offset against research and development expense.

Net sales of data or other services to our customers are classified under biopharmaceutical revenue, and all other non-customer revenue, such as milestones, are classified under collaboration revenue in our consolidated statements of operations and comprehensive loss. There was no collaboration revenue in the three months ended March 31, 2020 and 2019.

As part of the accounting for these arrangements, the Company must develop estimates and assumptions that require judgment to determine the underlying stand-alone selling price for each performance obligation which determines how the transaction price is allocated among the performance obligations. Generally, the estimation of the stand-alone selling price may include such estimates as independent evidence of market price, forecasted revenues or costs, development timelines, discount rates, and probabilities of technical and regulatory success. The Company evaluates each performance obligation to determine if they can be satisfied at a point in time or over time, and it measures the services delivered to the collaborative partner which are periodically reviewed based on the progress of the related program. The effect of any change made to an estimated input component and, therefore revenue or expense recognized, would be recorded as a change in estimate. In addition, variable consideration (e.g., milestone payments) must be evaluated to determine if it is constrained and, therefore, excluded from the transaction price.

Up-front Fees: If a license to the Company’s intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenues from the transaction price allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are bundled with other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time.

**VERACYTE, INC.**
**Notes to Financial Statements**
**(unaudited)**

Milestone Payments: At the inception of each arrangement that includes milestone payments (variable consideration), the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the Company's or the collaborative partner's control, such as non-operational developmental and regulatory approvals, are generally not considered probable of being achieved until those approvals are received. At the end of each reporting period, the Company re-evaluates the probability of achievement of milestones that are within its or the collaborative partner's control, such as operational developmental milestones and any related constraint, and if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect collaboration revenues and earnings in the period of adjustment. Revisions to the Company's estimate of the transaction price may also result in negative collaboration revenues and earnings in the period of adjustment.

***Services Agreement with Loxo Oncology***

On April 9, 2018, the Company entered into an agreement with Loxo Oncology, Inc., or Loxo, whereby the Company agreed to provide certain tissue samples and other services in exchange for agreed-upon fees. The agreement has a term of one year with an automatic renewal of one year and Loxo may terminate the agreement at any time with at least 90 days' notice. As of March 31, 2020, the agreement has not been terminated. The Company evaluated the accounting for this agreement under ASC 606 and concluded the performance obligations thereunder are the delivery of tissue samples and performance of services, both of which are distinct. For the three months ended March 31, 2019, the Company recognized revenue of $90,000 for the delivery of tissue samples. There were no deliveries of tissue samples for the three months ended March 31, 2020. The Company recognized revenue of $250,000 for the performance of services for each of the three months ended March 31, 2020 and 2019, respectively. The cost of revenue associated with revenue recognized under the agreement with Loxo is not significant. There was no deferred revenue related to this agreement at either March 31, 2020 or December 31, 2019.

***Diagnostic Development Agreement with Johnson & Johnson***

On December 28, 2018, the Company entered into a diagnostics development agreement with Johnson and Johnson Services, Inc., or JJSI, (i) to cooperate on a program to enable the Company to use JJSI samples and clinical data to develop a next generation bronchial genomic classifier diagnostic for lung cancer diagnosis, or Percepta v.2, and a nasal genomic classifier diagnostic for lung cancer and (ii) for JJSI to use Veracyte data generated in two Veracyte development programs for therapeutic purposes and for purposes of developing a companion diagnostic product used in conjunction with a JJSI therapeutic. The Company granted a license to JJSI with the right to use data and under the Company's intellectual property rights for JJSI's therapeutic purposes, including the development and commercialization of a companion diagnostic for its products, from the Percepta v.2 and Nasal programs. The license granted to JJSI is not distinct from other performance obligations as JJSI receives benefit only when other performance obligations are met.

Under the terms of the agreement, the Company will provide data from its RNA whole-transcriptome sequencing platform to JJSI in exchange for $7.0 million in payments from JJSI. The Company is also entitled to additional payments from JJSI of up to $13.0 million, conditioned upon the achievement of certain milestones relating to the development and reimbursement of the Percepta v.2 and Nasal tests. For a period of ten years commencing with the first commercial sale of the Percepta v.2 and Nasal tests, respectively, the Company will make payments to JJSI of one percent of net cash collections for Percepta v.2 and in the low-single digits of net cash collections for the Nasal test, depending on the number and timing of JJSI samples and associated clinical data the Company receives from JJSI.

The JJSI agreement is considered to be within the scope of ASC 808, as the parties are active participants and exposed to the risks and rewards of the collaborative activity. The Company evaluated the terms of the JJSI agreement and has analogized to ASC 606 for the delivery of RNA whole-transcriptome sequencing data to JJSI under the collaborative arrangement, which the Company believes is a distinct service for which JJSI meets the definition of a customer. Using the concepts of ASC 606, the Company has identified the delivery of data as its only performance obligation. The Company further determined that the transaction price under the arrangement was the $7.0 million in payments which was allocated to the obligation to deliver data. The $13.0 million in future potential payments is considered variable consideration because the Company determined that the potential payments are contingent upon

regulatory and commercialization milestones that are uncertain to occur and, as such, were not included in the transaction price, and will be recognized accordingly as each potential payment becomes probable.

The Company recognized revenue of $7.0 million and $4.0 million during 2019 for the provision of data and fulfillment of obligations relating to Percepta v.2 and Nasal program development milestones, respectively. There was no revenue for the three months ended March 31, 2020. For the three months ended March 31, 2019, the Company recognized revenue of $3.8 million for the provision of data relating to Percepta v.2, classified under biopharmaceutical revenue in the consolidated statement of operations and comprehensive loss. There was no accounts receivable from JJSI at March 31, 2020 and accounts receivable from JJSI was $2.0 million at December 31, 2019. There was no deferred revenue related to this agreement at March 31, 2020 and December 31, 2019.

***Collaboration Agreement with AstraZeneca Group***

On December 23, 2019, the Company entered into an agreement with Acerta Pharma B.V., or Acerta, a member of AstraZeneca Group whereby the Company agreed to provide genomic information that will support Acerta's development of oncology therapeutics. Acerta will pay the Company for certain development activities and pay milestones to the Company for the achievement of development milestones. For the three months ended March 31, 2020, the Company recognized $0.1 million of revenue for certain development costs activities and accounts receivable from Acerta was $0.1 million at March 31, 2020. The agreement will be accounted for in accordance with the policy on collaborative arrangements, as mentioned in this footnote.

***Biopharmaceutical Services Agreement***

During the quarter ended March 31, 2020, the Company entered into an agreement to provide research and development services of $0.5 million for which the Company recognized $0.3 million of biopharmaceutical revenue for the three months ended March 31, 2020.

***Cost of Testing Revenue***

The components of our cost of testing services are laboratory expenses, sample collection expenses, compensation expense, license fees and royalties, depreciation and amortization, other expenses such as equipment and laboratory supplies, and allocations of facility and information technology expenses. Costs associated with performing tests are expensed as the test is processed regardless of whether and when revenue is recognized with respect to that test. Cost of testing revenue for the three months ended March 31, 2020 included $1.1 million write-down of supplies for the potential expiration of reagents due to an anticipated decline in volumes resulting from the COVID-19 pandemic.

***Cost of Product Revenue***

Cost of product revenue consists primarily of costs of purchasing instruments and consumables from third-party contract manufacturers, installation, warranty, service and packaging and delivery costs. In addition, cost of product includes royalty costs for licensed technologies included in the Company's products and labor expenses. Cost of product revenue for instruments and consumables is recognized in the period the related revenue is recognized. Shipping and handling costs incurred for product shipments are included in cost of product in the consolidated statements of operations.

***Cost of Biopharmaceutical Revenue***

Cost of biopharmaceutical revenue consists of costs of performing activities under arrangements that require the Company to perform research and development services on behalf of a customer pursuant to a biopharmaceutical service agreement.

***Recent Accounting Pronouncements***

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments-Credit Losses: Measurement of Credit Losses on Financial Instruments*. This ASU requires entities to estimate an expected lifetime credit loss on financial assets ranging from short-term trade accounts receivable to long-term financings and report credit losses using an expected losses model rather than the incurred losses model that was previously used, and establishes additional disclosures related to credit

risks. This guidance became effective for the Company beginning January 1, 2020. Based on the composition of its trade receivables, investment portfolio and other financial assets, current economic conditions and historical credit loss activity, the adoption of this standard did not have a material impact on the Company's condensed consolidated financial statements and related disclosures.

In November 2018, the FASB issued ASU No. 2018-18, *Collaborative Arrangements (Topic 808).* Under this ASU, transactions in collaborative arrangements are to be accounted for under ASC 606 if the counterparty is a customer for a good or service (or bundle of goods and services) that is a distinct unit of account. Also, entities are precluded from presenting consideration from transactions with a counterparty that is not a customer together with revenue recognized from ASC 606. This ASU is effective for all interim and annual reporting periods beginning on or after December 15, 2019, with early adoption permitted. The Company adopted this ASU in 2019 with no cumulative-effect adjustments or retrospective impact.

In August 2018 the FASB issued ASU No. 2018-15, *Intangibles—Goodwill and Other—Internal-Use Software (Subtopic 350-40): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract*. This standard clarifies the accounting for implementation costs in cloud computing arrangements. This standard became effective for the Company on January 1, 2020, and was adopted on a prospective basis with no material impact on the Company's condensed consolidated financial statements.

## 2. Net Loss Per Common Share

Basic net loss per common share is calculated by dividing net loss attributable to common stockholders by the weighted-average number of common shares outstanding during the period, without consideration of common stock equivalents. Diluted net loss per common share is computed by dividing net loss attributable to common stockholders by the weighted-average number of common share equivalents outstanding for the period determined using the treasury stock method. The following outstanding common stock equivalents have been excluded from diluted net loss per common share because their inclusion would be anti-dilutive:

| | Three Months Ended March 31, | |
|---|---|---|
| | 2020 | 2019 |
| Shares of common stock subject to outstanding options | 4,760,128 | 5,670,819 |
| Employee stock purchase plan | 19,857 | 25,672 |
| Restricted stock units | 936,524 | 538,759 |
| Total common stock equivalents | 5,716,509 | 6,235,250 |

## 3. Accrued Liabilities

Accrued liabilities consisted of the following (in thousands of dollars):

| | March 31, 2020 | December 31, 2019 |
|---|---|---|
| Accrued compensation expenses | $ 7,497 | $ 10,100 |
| Accrued other | 2,582 | 3,634 |
| Total accrued liabilities | $ 10,079 | $ 13,734 |

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**4. Business Combination**

On December 3, 2019, the Company executed an agreement with NanoString for the exclusive global diagnostics license to the nCounter FLEX Analysis System, and the acquisition of the Prosigna breast cancer prognostic gene signature assay, and the LymphMark lymphoma subtyping assay. The strategic transaction positions the Company to expand its genomic diagnostics business globally, with the ability to deliver its advanced genomic tests to physicians and their patients via hospital and clinical laboratories throughout the European Union and other parts of the world. The Company has accounted for this agreement under Accounting Standards Codification 805, Business Combinations. Pursuant to the terms of the agreement, Veracyte paid NanoString $40.0 million in cash and $10.0 million in Veracyte common stock, and may pay up to an additional $10.0 million in cash, contingent upon the commercial launch of Veracyte diagnostic tests for use on the platform. This contingency was valued at $6.1 million as of the acquisition date and as of December 31, 2019, recorded as a liability, and will be remeasured to fair value at each reporting date until the contingent consideration is settled. As of March 31, 2020, this contingency was remeasured to $5.6 million with the corresponding change included in general and administrative expense in the Company's condensed consolidated statements of operations and comprehensive loss.

Assets acquired are recorded based on valuations derived from estimated fair value assessments and assumptions used by the Company. While the Company believes that its estimates and assumptions underlying the valuations are reasonable, different estimates and assumptions could result in different valuations assigned to the individual assets acquired and the resulting amount of goodwill. The following table summarizes the fair values of assets acquired and liabilities assumed at the date of acquisition (in thousands):

| | | |
|---|---|---|
| Prosigna product technology | $ | 4,120 |
| Prosigna customer relationships | | 2,430 |
| nCounter FLEX Dx license | | 46,880 |
| LymphMark product technology | | 990 |
| Total identifiable intangible assets acquired | | 54,420 |
| Goodwill | | 1,668 |
| Net assets acquired | $ | 56,088 |

Identifiable acquisition-related intangibles included in the above table are finite-lived and are being amortized on a straight-line basis over their estimated lives, which approximates the pattern in which the economic benefits of the intangible assets are expected to be realized, as follows:

| | Estimated Useful life (In Years) |
|---|---|
| Prosigna product technology | 15 |
| Prosigna customer relationships | 5 |
| nCounter FLEX Dx license | 15 |
| LymphMark product technology | 7 |

Goodwill represents the excess of the purchase price over the fair value of the net tangible and intangible assets acquired. This acquisition includes $1.7 million of goodwill which the Company believes consists principally of the organized workforce that will help the Company execute its strategic plans in relation to the assets acquired. In accordance with ASC 350, goodwill will not be amortized but will be tested for impairment at least annually. As of March 31, 2020, goodwill is not deductible for tax purposes, however, if contingent consideration is paid at a future date, the portions of contingent consideration paid and allocated to the intangible assets for tax purposes will be tax deductible. The accounting for this acquisition is preliminary and will be finalized upon completion of the analysis of certain contracts acquired and executed as part of this acquisition along with the impact on goodwill, should there be any.

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## 5. Fair Value Measurements

The Company records its financial assets and liabilities at fair value. The carrying amounts of certain financial instruments of the Company, including cash and cash equivalents, prepaid expenses and other current assets, accounts payable and accrued liabilities, approximate fair value due to their relatively short maturities. The accounting guidance for fair value provides a framework for measuring fair value, clarifies the definition of fair value, and expands disclosures regarding fair value measurements. Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability (an exit price) in an orderly transaction between market participants at the reporting date. The accounting guidance establishes a three-tiered hierarchy, which prioritizes the inputs used in the valuation methodologies in measuring fair value as follows:

- Level I: Inputs which include quoted prices in active markets for identical assets and liabilities;

- Level II: Inputs other than Level I that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities; and

- Level III: Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The fair value of the Company’s financial assets includes money market funds, overnight reverse repurchase agreements and a deposit for the lease of the Company's South San Francisco facility. Money market funds, included in cash and cash equivalents in the accompanying condensed consolidated balance sheets, were $150.7 million and $57.6 million as of March 31, 2020 and December 31, 2019, respectively, and are Level I assets as described above. Overnight reverse repurchase agreements, included in cash and cash equivalents in the accompanying condensed consolidated balance sheets, were zero and $100.0 million as of March 31, 2020 and December 31, 2019, respectively, and are Level II assets as described above. There were no unrealized gains or losses from overnight reverse repurchase agreements at March 31, 2020 and December 31, 2019. The deposit for the lease, included in restricted cash in the accompanying condensed consolidated balance sheets, was $603,000 as of March 31, 2020 and December 31, 2019, and is a Level I asset as described above.

The contingent consideration in Note 4, Business Combination, associated with the agreement with NanoString on December 3, 2019, is a Level III financial liability. The estimation of the fair value of the contingent consideration is based on the present value of the expected payments calculated by assessing the likelihood of when the related milestones would be achieved, discounted using the Company's estimated borrowing rate. These estimates form the basis for making judgments about the carrying value of the contingent consideration that are not readily apparent from other sources. Changes to the forecasts for the achievement of the milestones and the estimates of the borrowing rate can significantly affect the estimated fair value of the contingent consideration.

## 6. Commitments and Contingencies

***Operating Leases***

The Company leases its headquarters and laboratory facilities in South San Francisco, California under a non-cancelable lease agreement for approximately 59,000 square feet. The lease began in June 2015 and ends in March 2026 and contains extension of lease term and expansion options. The Company had deposits of $603,000 included in long-term assets as of March 31, 2020 and December 31, 2019, restricted from withdrawal and held by a bank in the form of collateral for an irrevocable standby letter of credit held as security for the lease of the South San Francisco facility.

The Company also leases laboratory and office space in Austin, Texas under a lease that expires in January 2029 and includes options for expansion and early termination in 2025. The Company provided a cash security deposit for this lease of $139,000, included in other assets in the Company’s condensed consolidated balance sheets as of March 31, 2020 and December 31, 2019.

Future minimum lease payments under non-cancelable operating leases as of March 31, 2020 are as follows (in thousands of dollars):

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| **Year Ending December 31,** | | |
|---|---|---|
| Remainder of 2020 | $ | 1,760 |
| 2021 | | 2,401 |
| 2022 | | 2,472 |
| 2023 | | 2,543 |
| 2024 | | 2,614 |
| Thereafter | | 4,227 |
| Total future minimum lease payments | | 16,017 |
| Less: amount representing interest | | 3,435 |
| Present value of future lease payments | | 12,582 |
| Less: short-term lease liabilities | | 1,450 |
| Long-term lease liabilities | $ | 11,132 |

The Company recognizes operating lease expense on a straight-line basis over the non-cancelable lease period. Operating lease expense was $474,000 and $476,000 for the three months ended March 31, 2020 and 2019, respectively.

***Contingencies***

From time to time, the Company may be involved in legal proceedings arising in the ordinary course of business. The Company assesses contingencies to determine the degree of probability and range of possible loss for potential accrual in its condensed consolidated financial statements. An estimated loss contingency is accrued in the financial statements if it is probable that a liability has been incurred and the amount of the loss can be reasonably estimated. The Company believes there is no legal proceeding pending that could have, either individually or in the aggregate, a material adverse effect on the Company's condensed consolidated financial statements.

**7. Debt**

*Loan and Security Agreement*

On November 3, 2017, the Company entered into a loan and security agreement, or Loan and Security Agreement, with Silicon Valley Bank. The Loan and Security Agreement allows the Company to borrow up to $35.0 million, with a $25.0 million advance term loan, or Term Loan Advance, and a revolving line of credit of up to $10.0 million, or Revolving Line of Credit. The Term Loan Advance was advanced upon the closing of the Loan and Security Agreement and was used to pay the outstanding balance of the Company's existing long-term debt, which was canceled at that date. The Company had not drawn on the Revolving Line of Credit as of March 31, 2020. Borrowings under the Loan and Security Agreement mature on October 1, 2022. Amounts may be borrowed and repaid under the Revolving Line of Credit up until the earliest of full repayment or maturity of the Loan and Security Agreement, termination of the Loan and Security Agreement, or October 1, 2022.

The Term Loan Advance bears interest at a variable rate equal to (i) the thirty-day U.S. London Interbank Offer Rate, or LIBOR, plus (ii) 4.20%, with a minimum rate of 5.43% per annum. Principal amounts outstanding under the Revolving Line of Credit bear interest at a variable rate equal to (i) LIBOR plus (ii) 3.50%, with a minimum rate of 4.70% per annum. The average Term Loan Advance interest rate for the three months ended March 31, 2020 was 5.8%.

The Company may prepay the outstanding principal amount under the Term Loan Advance plus accrued and unpaid interest and, if the Term Loan Advance is repaid in full, a prepayment premium. The prepayment premium will be (i) $750,000 if prepayment is made prior to November 3, 2018, (ii) $500,000 if the prepayment is made after November 3, 2018 but on or before November 3, 2019, or (iii) $250,000 if the prepayment is made after November 3, 2019. In January 2019 and May 2019, the Company prepaid $12.5 million and $12.4 million, respectively, of the principal amount of the Term Loan Advance. These prepayments did not trigger any prepayment premium because they were partial, not full, repayments of the principal amount.

In addition, a final payment on the Term Loan Advance in the amount of $1.2 million is due upon the earlier of the maturity date of the Term Loan Advance or its payment in full. The Loan and Security Agreement contains customary

representations, warranties, and events of default such as a material adverse change in the Company's business, operations or financial condition, as well as affirmative and negative covenants. The negative covenants include, among other provisions, covenants that limit or restrict the Company's ability to incur liens, make investments, incur indebtedness, merge with or acquire other entities, dispose of assets, make dividends or other distributions to holders of its equity interests, engage in any new line of business, or enter into certain transactions with affiliates, in each case subject to certain exceptions. The Company's obligations under the Loan and Security Agreement are secured by substantially all of its assets (excluding intellectual property), subject to certain customary exceptions. The Loan and Security Agreement also requires the Company to achieve certain revenue levels tested quarterly on a trailing twelve-month basis. However, failure to maintain the revenue levels will not be considered a default if the sum of the Company's unrestricted cash and cash equivalents maintained with Silicon Valley Bank and amount available under the Revolving Line of Credit is at least $40.0 million. As of March 31, 2020, the Company was in compliance with the loan covenants.

The net debt obligation for borrowings made under the Loan and Security Agreement was as follows (in thousands of dollars):

| | March 31, 2020 | December 31, 2019 |
|---|---|---|
| Debt principal | $ 100 | $ 100 |
| End-of-term debt obligation | 648 | 594 |
| Net debt obligation | $ 748 | $ 694 |

Future principal and end-of-term debt obligation payments under the Loan and Security Agreement are $1.3 million and due in 2022.

The end-of-term debt obligation accretes over the term of the Loan and Security Agreement until maturity and is included in interest expense in the Company's condensed consolidated statements of operations and comprehensive loss.

**8. Stockholders' Equity**

***Common Stock***

The Company had reserved shares of common stock for issuance as follows:

| | March 31, 2020 | December 31, 2019 |
|---|---|---|
| Stock options and restricted stock units issued and outstanding | 5,988,461 | 5,562,484 |
| Stock options and restricted stock units available for grant under stock option plans | 3,200,200 | 1,954,804 |
| Common stock available for the Employee Stock Purchase Plan | 112,226 | 173,168 |
| Total | 9,300,887 | 7,690,456 |

**9. Thyroid Cytopathology Partners**

The Company has an agreement with a specialized pathology practice, Thyroid Cytopathology Partners, ("TCP"), to provide testing services to the Company, or TCP Agreement. The TCP Agreement is effective through October 31, 2022, and thereafter automatically renews every year unless either party provides notice of intent not to renew at least 12 months prior to the end of the then-current term. Under the TCP Agreement, the Company pays TCP based on a fixed price per test schedule which is reviewed periodically for changes in market pricing, and the TCP Agreement included a clause allowing TCP to sublease a portion of the Company's facility in Austin, Texas. The Company does not have an ownership interest in or provide any form of financial or other support to TCP. The Company previously concluded that TCP represented a variable interest entity as a result of the facility arrangement clause, but that the Company was not the primary beneficiary as it did not have the ability to direct the activities that most significantly impacted TCP's economic performance, and therefore did not consolidate TCP. On February 14, 2019, the TCP Agreement was amended to remove the facility clause. Accordingly, the Company believes TCP was no longer a variable interest entity as of that date.

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TCP's portion of rent and related operating expenses reimbursed to the Company for the shared space at the Austin, Texas facility was $11,000 for the three months ended March 31, 2019, and is included in other income, net in the Company's condensed consolidated statements of operations and comprehensive loss.

**10. Income Taxes**

The Company did not record a provision or benefit for income taxes during the three months ended March 31, 2020 and 2019. The Company continues to maintain a full valuation allowance against its net deferred tax assets.

On March 27, 2020, the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) was enacted in response to the COVID-19 pandemic. The Company does not expect the provisions of the legislation to have a significant impact on the effective tax rate of the Company.

## ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

*The following discussion and analysis of financial condition and results of operations should be read together with the condensed consolidated financial statements and the related notes included in Item 1 of Part I of this Quarterly Report on Form 10-Q, and with our audited financial statements and the related notes included in our Annual Report on Form 10-K for the year ended December 31, 2019.*

*This report contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. When used in this report, the words "expects," "anticipates," "intends," "estimates," "plans," "believes," "continuing," "ongoing," and similar expressions are intended to identify forward-looking statements. These are statements that relate to future events and include, but are not limited to, the factors that may impact our financial results; our expectations regarding revenue; our expectations with respect to our future research and development, general and administrative and selling and marketing expenses and our anticipated uses of our funds; the impact of the COVID-19 pandemic on our business and the U.S. and global economies; our beliefs with respect to the optimization of our processes for the analysis of ribonucleic acid, or RNA, samples; our integration of the assets acquired from NanoString Technologies, Inc.; our ability to deploy the nCounter FLEX Analysis System successfully and run our tests on this platform worldwide; our beliefs with respect to the optimization of our processes for the analysis of ribonucleic acid, or RNA, samples; our collaboration with Johnson & Johnson Services, Inc.; our belief in the importance of maintaining libraries of clinical evidence; our expectations regarding capital expenditures; our anticipated cash needs and our estimates regarding our capital requirements; the timing and success of our transition to a single platform for all of our classifiers and tests; our ability to maintain Medicare coverage for each of our tests; our need for additional financing; potential future sources of cash; our business strategy and our ability to execute our strategy; our ability to achieve and maintain reimbursement from third-party payers at acceptable levels and our expectations regarding the timing of reimbursement; the estimated size of the global markets for our tests; the estimated number of patients who receive uncertain diagnoses who are candidates for our test; the attributes and potential benefits of our tests and any future tests we may develop to patients, physicians and payers; the factors we believe drive demand for and reimbursement of our tests; our ability to sustain or increase demand for our tests; our intent to expand into other clinical areas; our ability to develop new tests, and the timeframes for development or commercialization; our ability to get our data and clinical studies accepted in peer-reviewed publications; our dependence on and the terms of our agreement with TCP, and on other strategic relationships, and the success of those relationships; our beliefs regarding our laboratory capacity; the potential for future clinical studies to contradict or undermine previously published clinical study results; the applicability of clinical results to actual outcomes; our expectations regarding our international expansion; the occurrence, timing, outcome or success of clinical trials or studies; the ability of our tests to impact treatment decisions; our beliefs regarding our competitive position; our compliance with federal, state and international regulations; the potential impact of regulation of our tests by the Food and Drug Administration, or FDA, or other regulatory bodies; the impact of new or changing policies, regulation or legislation, or of judicial decisions, on our business; the impact of seasonal fluctuations and economic conditions on our business; our belief that we have taken reasonable steps to protect our intellectual property; our belief that our intellectual property will develop and maintain our competitive position; the impact of accounting pronouncements and our critical accounting policies, judgments, estimates, models and assumptions on our financial results; and anticipated trends and challenges in our business and the markets in which we operate. We caution you that the foregoing list does not contain all of the forward-looking statements made in this report.*

*Forward-looking statements are based on our current plans and expectations and involve risks and uncertainties which could cause actual results to differ materially. These risks and uncertainties include, but are not limited to, those risks discussed in Part II, Item 1A of this report. These forward-looking statements speak only as of the date hereof. We expressly disclaim any obligation or undertaking to update any forward-looking statements contained herein to reflect any change in our expectations with regard thereto or any change in events, conditions or circumstances on which any such statement is based.*

When used in this report, all references to "Veracyte," the "company," "we," "our" and "us" refer to Veracyte, Inc.

Veracyte, Afirma, Percepta, Envisia, Prosigna, LymphMark, and Know by Design, and the Veracyte, Afirma, Percepta, Envisia and Prosigna logos are our trademarks. We also refer to trademarks of other corporations or organizations in this report.

This report contains statistical data and estimates that we obtained from industry publications and reports. These publications typically indicate that they have obtained their information from sources they believe to be reliable, but do not guarantee the accuracy and completeness of their information. Some data contained in this report is also based on our internal estimates.

**Overview**

We are a global genomic diagnostics company that improves patient care by providing answers to clinical questions to inform diagnosis and treatment decisions throughout the patient journey in cancer and other diseases. The Company's growing menu of genomic tests leverage advances in genomic science and technology to change care for patients, enabling them to avoid risky, costly procedures and quicken time to appropriate treatment. With Veracyte's exclusive global access to a best-in-class diagnostics instrument platform, the Company is positioned to deliver its tests to patients worldwide through laboratories and hospitals that can perform the tests locally.

We perform our genomic tests for thyroid cancer, lung cancer and idiopathic pulmonary fibrosis, or IPF, in our CLIA-certified laboratory in South San Francisco, California. In December 2019, we announced an exclusive global diagnostics license to the nCounter® FLEX Analysis System from NanoString Technologies, Inc., or NanoString, as well as the acquisition of the Prosigna® breast cancer prognostic gene signature assay, which is commercially available, and the LymphMark™ lymphoma subtyping assay, which is in development. Both tests are designed for use on the nCounter system. We believe this strategic transaction positions us to expand our business globally with a broad menu of advanced genomic tests that may be offered as distributed kits and performed in local laboratories worldwide. We believe our current and pipeline products address a collective $40 billion global market.

We develop our genomic tests using advanced scientific methods, such as RNA whole-transcriptome sequencing and machine learning, and then optimize the assay and classifier results for the platform on which the test will be performed. Historically, that platform has been RNA sequencing, performed in our CLIA lab. In the future, we expect this to also include the nCounter platform for international distribution of our tests.

Our classifiers are designed to improve diagnostic and prognostic clarity for cancer and other diseases. In its 2015 report, "Improving Diagnostic Errors in Medicine," the Institute of Medicine concluded that most people will experience at least one diagnostic error in their lifetime, sometimes with devastating consequences. Annually, of the hundreds of thousands of patients who are evaluated for suspected disease in our thyroid and lung indications, diagnosis can be ambiguous in 15-70% of cases. This diagnostic uncertainty can lead to additional, invasive procedures that are often unnecessary, delayed or incorrect treatment, increased healthcare costs and patient anxiety.

We position our tests to fit into the way physicians currently evaluate patients in order to facilitate adoption. We also design our tests to improve patient care and outcomes, while delivering clinical and economic utility to physicians, payers and the healthcare system in general.

We believe our powerful scientific platform provides multiple vectors to create value for patients, providers and payers, as well as stockholders, and to help advance precision medicine:

- Unique Biorepositories - When we develop new tests, we build extensive, robust biorepositories of patient-consented samples and well-curated clinical, radiological, outcome and other information from Institutional Review Board-approved clinical trials to inform our discovery efforts. Our biorepositories are designed to encompass the broad spectrum of disease that our tests may encounter when used in clinical practice, as well as the wide range of conditions associated with patients who are suspected of having a particular disease. We extract extensive genomic information from these patient samples using our RNA whole-transcriptome sequencing platform.

- Proprietary Technology and Bioinformatics - For biomarker discovery and product development, we utilize machine learning to select the genomic, clinical or other features from our biorepository that best distinguish the condition we are trying to identify. This enables us to develop high-performing genomic classifiers that can answer specific clinical questions. In addition, our bioinformatics pipelines are built to extract genomic variant content from the same assay to inform therapeutic selection.

- High-Performing Commercial Genomic Tests – With the exception of Prosigna, which competes with a first-to-market test in a highly competitive environment, our genomic tests generally serve large, untapped markets where they are changing the diagnostic and treatment paradigm for patients. We believe the nCounter platform affords us the opportunity to adapt our test menu for multiple markets globally, providing flexibility for a global distributed testing model and potentially increased efficiency in our United States-based CLIA lab. Regardless of the testing platform used for diagnosis, our RNA sequencing platform enables us to offer testing from our CLIA lab for a broad range of gene alterations, which can inform treatment decisions using the same pre-surgical patient sample that was used in diagnosis.

We believe our ability to leverage RNA whole-transcriptome sequencing data in large biorepositories of patient-consented samples in oncology and other indications presents an opportunity for biopharmaceutical companies to enhance their research and development capabilities. In April 2018, we announced a collaboration with Loxo Oncology (now a wholly owned subsidiary of Eli Lilly and Company) to advance its development of highly selective medicines for patients with genetically defined cancers, including thyroid cancer. In December 2018, we entered into a long-term strategic collaboration with Johnson & Johnson Innovation and the Lung Cancer Initiative at Johnson & Johnson to advance the development and commercialization of novel diagnostic tests to detect lung cancer at its earliest stages, when the disease is most treatable. The collaboration builds upon foundational "field of injury" science whereby genomic changes associated with lung cancer can be identified with a simple brushing of a person's airway to develop new interventions that can save lives. Additionally, in January 2020, we announced an agreement with Acerta Pharma, the hematology research and development arm of AstraZeneca, to provide genomic information that will support its development of oncology therapeutics in lymphoma.

Our collaboration with the Lung Cancer Initiative at Johnson & Johnson has helped accelerate two of our key lung cancer programs: (i) commercialization of the Percepta GSC on our RNA whole-transcriptome sequencing platform, and (ii) development of the first non-invasive nasal swab test for early lung cancer detection. We began making the Percepta GSC available to customers in June 2019. In October 2019, we announced preliminary data for our nasal swab classifier, which demonstrated the test’s potential to identify patients at low risk of lung cancer so they can potentially avoid unnecessary procedures and those at high risk so they can receive prompt diagnosis and treatment.

The published evidence supporting our tests demonstrates the robustness of our science and clinical studies, which we believe is key to driving adoption and reimbursement. Patients and physicians can access our full list of publications on our website. Over 45 clinical studies covering our products have been published, including three landmark clinical validation papers published in *The New England Journal of Medicine* for the Afirma and Percepta classifiers, respectively, and in *The Lancet Respiratory Medicine* for the Envisia classifier. We continue to build upon our extensive library of clinical evidence.

We believe our focus on developing clinically useful tests that change patient care is enabling the company to set new standards in genomic test reimbursement. Our genomic classifiers in thyroid cancer, lung cancer and IPF, as well as the Prosigna breast cancer assay are covered by Medicare. Our Afirma classifier, for use in thyroid cancer diagnosis, is now covered by every major health plan in the United States, which collectively insure more than 275 million people. We are contracted as an in-network service provider to health plans representing over 225 million people in the United States. We believe that our in-network status with private payers will help facilitate private insurer reimbursement for our Percepta and Envisia classifiers. The Prosigna test is covered by leading private payers in the United States and is widely reimbursed by government and private payers in the countries where it is available.

We also expect to continue expanding our offerings in thyroid cancer, lung cancer, interstitial lung diseases such as IPF, breast cancer and lymphoma, as well as other indications that we believe will benefit from our technology and approach. Our product development pipelines address what we believe to be significant market opportunities for addressing clinical questions in early detection, diagnosis, staging/prognosis, therapy selection/surgery and disease monitoring across the aforementioned indications.

**Impact of COVID-19**

In December 2019, a strain of coronavirus was reported in Wuhan, China, and began to spread globally, including to the United States and Europe, in the following months. The World Health Organization has declared COVID-19 to be a pandemic and a public health emergency of international concern. The full impact of the COVID-19 outbreak is inherently uncertain at the time of this report. The COVID-19 outbreak has resulted in travel restrictions and in some cases, prohibitions of non-essential activities, disruption and shutdown of businesses and greater uncertainty in global financial markets. As COVID-19 has spread, it has significantly impacted the health and economic environment around the world and many governments have closed most public establishments, including restaurants, workplaces and schools. Our customers, third-party contract manufacturers, suppliers and collaboration partners may be affected by the closure of hospitals, doctors offices, manufacturing sites, or country borders, among other measures being put in place around the world. Consequent increases in layoffs and furloughs in the medical industry and otherwise during the shutdown are having, and will continue to have, negative impact on the demand for medical care and diagnostic tests, which affects the frequency with which tests are prescribed, and the ability of doctors and hospitals to administer such tests. Further the inability to travel and conduct face-to-face meetings can also make it more difficult to expand utilization of our products into new geographies and to drive awareness of our products. Any of these circumstances will potentially have a negative impact on our financial results and liquidity in fiscal 2020.

As for our own business, during the second half of March 2020 through the date of this filing, we experienced a significant decline in the volume of samples received resulting in a significant decline in revenue and it is currently unclear how long we will continue to experience decreased sample volumes and levels of revenue. The COVID-19 pandemic has also caused us to modify our business practices, including taking proactive steps to protect our employees and the broader community (including but not limited to curtailing or modifying employee travel, moving to full remote work wherever possible, and cancelling physical participation in meetings, events and conferences), while ensuring our ability to deliver genomic test results to physicians and their patients who need them. Given the significant challenges we face from COVID-19, we have taken actions to reduce expenses and preserve the health of our business, including our board of directors, executive team, including our Chairman and CEO, and certain other employees taking a reduction in pay until we are able to resume normal operations. We have also put approximately 60 employees on a temporary furlough with a current goal of bringing them back from furlough in the future, terminated a small number of employees, and instituted a temporary hiring freeze. We may take further actions as may be required by government authorities or that we determine are in the best interests of our employees, customers and business partners.

The extent of the impact of the COVID-19 on our future liquidity and operational performance will depend on certain developments, including the duration and spread of the outbreak, the impact on our customers' operations and the impact to our sales and renewal cycles.

**First Quarter 2020 Financial Results**

*For the first quarter of 2020, as compared with the first quarter of 2019:*

- *Total Testing and Product Revenue* was $30.4 million, an increase of 20%; including biopharmaceutical revenue, total revenue was $31.1 million, an increase of 5%;
- *Gross Margin* was 61%, which included a $1.1 million write-down of supplies;
- *Operating Expenses, Excluding Cost of Revenue*, were $31.1 million, an increase of 35%;
- *Net Loss and Comprehensive Loss* was $(11.7) million, versus $(1.9) million;
- *Basic and Diluted Net Loss Per Common Share* was $(0.24), versus $(0.05);
- *Net Cash Used in Operating Activities* was $5.3 million, versus $1.0 million; and
- *Cash and Cash Equivalents* were $153.1 million at March 31, 2020.

**First Quarter 2020 and Recent Business Highlights**

*Core Diagnostics Business:*

- Grew total genomic test volume (Afirma, Percepta and Envisia) by 15% to 10,559 tests.
- Launched “More About You,” a national campaign to help patients navigate the work-up of thyroid nodules and ask for Afirma testing by name.
- Announced that data accepted for oral presentation at the ENDO 2020 conference identified novel or rare gene fusions that are included in the newly expanded Afirma Xpression Atlas and may potentially be targeted with drugs that are approved or under development.
- Reported new data published in *npj Breast Cancer*, which suggest potential growth opportunities for the Prosigna test in global markets where the test reports intrinsic breast cancer subtypes. Additionally, data published in *Clinical Breast Cancer* suggest the Prosigna test’s ability to provide significant prognostic information beyond clinicopathologic factors in patients with invasive lobular breast cancer, a major breast cancer histopathologic subtype.

*Strategic Collaborations and Pipeline Advancement:*

- Secured an exclusive licensing and research agreement with Yale University to advance the first genomic monitoring test for idiopathic pulmonary fibrosis prognosis, complementing our Envisia classifier for improved early diagnosis of the disease. The non-invasive, blood-based test was developed for use on our nCounter diagnostic platform.
- Signed an exclusive licensing agreement with Boston University for technology that will help advance development of the first-ever, non-invasive nasal swab test for lung cancer early detection.
- Announced a multi-year collaboration with Acerta Pharma, the hematology research and development arm of AstraZeneca plc, to provide genomic information that will support the biopharmaceutical company’s development of oncology therapeutics in lymphoma.

**Factors Affecting Our Performance**

***Impact of COVID-19***

The extent of the impact of the COVID-19 outbreak on our operational and financial performance will depend on certain developments, including the duration and spread of the outbreak, impact on our customers and our sales cycles, employee or industry events, and effect on our vendors, all of which are uncertain and cannot be predicted. The COVID-19 pandemic and its adverse effects have become more prevalent in the locations where we, our customers, suppliers or third-party business partners conduct business and as a result, we have begun to experience more pronounced disruptions in our operations. We may experience constrained supply or curtailed customer demand that could materially adversely impact our business, results of operations and overall financial performance in future periods. Specifically, we may experience impact from changes in how hospital and physicians treat their patients and the frequency of their interaction with their patients, our ability to have in-person meetings with physicians and other customers and drive education and interest in our tests, and difficulties and changes to our sales, logistics, testing, customer support and other processes. As of the filing date of this Form 10-Q, the extent to which COVID-19 may impact our financial condition or results of operations or guidance is uncertain. The effect of the COVID-19 pandemic will not be fully reflected in our results of operations and overall financial performance until future periods. See Risk Factors for further discussion of the possible impact of the COVID-19 pandemic on our business.

***Reported Genomic Test Volume***

Our performance depends on the number of genomic tests that we perform and report as completed in our CLIA laboratories. Factors impacting the number of tests that we report as completed include, but are not limited to:

- the impact of COVID-19 on patients seeking to have tests performed;
- the number of samples that we receive that meet the medical indication for each test performed;
- the quantity and quality of the sample received;
- receipt of the necessary documentation, such as physician order and patient consent, required to perform, bill and collect for our tests;
- the patient's ability to pay or provide necessary insurance coverage for the tests performed;
- the time it takes us to perform our tests and report the results;
- the seasonality inherent in our business, such as the impact of work days per period, timing of industry conferences and the timing of when patient deductibles are exceeded, which also impacts the reimbursement we receive from insurers; and
- our ability to obtain prior authorization or meet other requirements instituted by payers, benefit managers, or regulators necessary to be paid for our tests.

We generate substantially all our revenue from genomic testing services, including the rendering of a cytopathology diagnosis as part of the Afirma solution. For the Afirma classifier, we do not accrue revenue for approximately 5% - 10% of the tests that we perform and report as complete due principally to insufficient RNA from which to render a result and tests performed for which we do not reasonably expect to be paid.

***Continued Adoption of and Reimbursement for our Products***

Revenue growth depends on our ability to secure coverage decisions, achieve broader reimbursement at increased levels from third-party payers, expand our base of prescribing physicians and increase our penetration in existing accounts. Because some payers consider our products experimental and investigational, we may not receive payment for tests and payments we receive may not be at acceptable levels. We expect our revenue growth to increase if more payers make a positive coverage decision and as payers enter into contracts with us, which should enhance our revenue and cash collections. To drive increased adoption of our products, we increased our sales force and marketing efforts over the last several years. Our sales team is structured to sell all of our products; we do not maintain a separate sales force for each product. If we are unable to expand the base of prescribing physicians and penetration within these accounts at an acceptable rate, or if we are not able to execute our strategy for increasing reimbursement, we may not be able to effectively increase our revenue. We expect to continue to see pressure from payers to limit the utilization of tests, generally, and we believe more payers are deploying cost containment tactics, such as pre-authorization, reduction of the payer portion of reimbursement and employing laboratory benefit managers to reduce utilization rates.

***Integrating acquired assets and advances to our collaborations***

Revenue growth, operational results and advances to our business strategy depends on our ability to integrate the assets acquired into our existing business. The integration of acquired assets may impact our revenue growth, increase the cost of operations, cause significant write-offs of intangible assets, or may require management resources that otherwise would be available for ongoing development of our existing business. The integration of assets acquired from NanoString in December

2019 may impact our revenue and operating results through integration of a sales force, development of a product supply operation and the expansion of our business internationally with a broad menu of advanced genomic tests that may be offered.

Revenue growth or reimbursement from our collaborations depends on our ability to deliver services or information and achieve milestones required from our collaborative partners. Our collaboration partners pay us for the provision of data, other services and the achievement of milestones. Under a collaboration with Johnson & Johnson in 2018, we provided data services required under this agreement for $7.0 million in 2019, however, there remains $9.0 of revenue associated with development and commercialization milestones yet to be achieved.

***How We Recognize Revenue***

**Testing Revenue**

We recognize testing revenue in accordance with the provisions of ASC 606, Revenue from Contracts with Customers. Most of our revenue is generated from the provision of diagnostic testing services. These services are completed upon the delivery of test results to the prescribing physician, at which time we bill for the services. We recognize revenue related to billings on an accrual basis based on estimates of the amount that will ultimately be realized. In determining the amount to accrue for a delivered test, we consider factors such as payment history, payer coverage, whether there is a reimbursement contract between the payer and us, payment as a percentage of agreed upon rate (if applicable), amount paid per test and any current developments or changes that could impact reimbursement. These estimates require significant judgment by management.

Prior to the adoption of ASC 606, for our testing services we recognized a portion of our revenue not at the time of delivery of test results, on an accrual-basis of accounting, but upon the ultimate payment for those services, on the cash-basis of accounting. Through December 31, 2019, cumulative amounts billed at list price for tests processed which were not recognized as revenue upon delivery of a patient report because our accrual revenue recognition criteria were not met and for which we have not collected cash or written off as uncollectible, totaled approximately $159.3 million. Of this amount, we did not collect any amounts in the three months ended March 31, 2020 and we have no expectation of future collection because we began accruing for substantially all revenue upon delivery of a patient report in the third quarter of 2016. Under ASC 606, we recognize revenue at the time we deliver test results based upon what we reasonably expect to collect and the list price of a test may not be indicative of what we ultimately expect to collect.

Generally, cash we receive is collected within 12 months of the date the test is billed. We cannot provide any assurance as to when, if ever, or to what extent any of these amounts will be collected. Notwithstanding our efforts to obtain payment for these tests, payers may deny our claims, in whole or in part, and we may never receive payment for these tests.

We bill list price regardless of contract rate, but only recognize revenue from amounts that we estimate are collectible and meet our revenue recognition criteria. Revenue may not be equal to the billed amount due to a number of factors that we consider when determining revenue accrual rates, including differences in reimbursement rates, the amounts of patient co-payments and co-insurance, the existence of secondary payers, claims denials and the amount we expect to ultimately collect. Finally, when we increase our list price, it will increase the cumulative amounts billed but may not positively impact accrued revenue. In addition, payer contracts generally include the right of offset and payers may offset payments prior to resolving disputes over tests performed.

Generally, we calculate the average reimbursement from our products from all payers, for tests that are on average a year old, since it can take a significant period of time to collect from some payers. Except in situations where we believe the rate we reasonably expect to collect to vary due to a coverage decision, contract, more recent reimbursement data or evidence to the contrary, we use an average of reimbursement for tests provided over four quarters as it reduces the effects of temporary volatility and seasonal effects. Thus, the average reimbursement per product represents the total cash collected to date against genomic classifier tests, including variants, performed during the relevant period divided by the number of these tests performed during that same period.

The average Afirma genomic classifier reimbursement rate will change over time due to a number of factors, including medical coverage decisions by payers, the effects of contracts signed with payers, changes in allowed amounts by payers, our ability to successfully win appeals for payment, and our ability to collect cash payments from third-party payers and individual patients. Historical average reimbursement is not necessarily indicative of future average reimbursement. For the three months ended March 31, 2020, we accrued, on average, between $2,800 and $2,900 for the Afirma genomic classifier tests, including variants, that met our revenue recognition standard, which was between 90% - 95% of the reported Afirma classifier test volume.

From the first quarter of 2019 to the first quarter of 2020, we accrued between $1.0 million and $2.4 million in revenue per quarter from providing cytopathology services associated with our Afirma solution.

We incur expense for tests in the period in which the test is conducted and recognize revenue for tests in the period in which our revenue recognition criteria are met.

**Product Revenue**

We began recognizing product revenue in December 2019 in accordance with the provisions of ASC 606, Revenue from Contracts with Customers, when we executed an agreement with NanoString for the exclusive worldwide license to the nCounter platform and the acquisition of products for in vitro diagnostic use.

We recognize product revenue when control of the promised goods is transferred to our customers, in an amount that reflects the consideration expected to be received in exchange for those products. This process involves identifying the contract with a customer, determining the performance obligations in the contract, determining the contract price, allocating the contract price to the distinct performance obligations in the contract, and recognizing revenue when the performance obligations have been satisfied. A performance obligation is considered distinct from other obligations in a contract when it provides a benefit to the customer either on its own or together with other resources that are readily available to the customer and is separately identified in the contract. Performance obligations are considered satisfied once we have transferred control of a product to the customer, meaning the customer has the ability to use and obtain the benefit of the product. We recognize product revenue for satisfied performance obligations only when there are no uncertainties regarding payment terms or transfer of control. Shipping and handling costs incurred for product shipments are charged to our customers and included in product revenue.

Our products consist of the Prosigna breast cancer assay, the nCounter FLEX Analysis System and related consumables. Revenues are presented net of the taxes that are collected from customers and remitted to governmental authorities.

**Biopharmaceutical and Collaboration Revenues**

From time to time, we enter into arrangements to license or provide access to our assets or services, including testing services, clinical and medical services, research and development and other services. Such arrangements may require us to deliver various rights, data, services, access and/or testing services to leading biopharmaceutical companies. The underlying terms of these arrangements generally provide for consideration paid to us in the form of nonrefundable fees, performance milestone payments, expense reimbursements and possibly royalty and/or other payments.

The terms of our collaborative arrangements typically include one or more of the following: (i) up-front fees; (ii) milestone payments related to the achievement of development, regulatory, or commercial goals; and (iii) royalties on net sales of licensed products. Each of these payments may result in collaboration revenues or an offset against research and development expense.

Arrangements with partners may fall under the scope of ASC Topic 808, Collaborative Arrangements, or ASC 808. While these arrangements are in the scope of ASC 808, we may analogize to ASC 606 for some aspects of these arrangements. We analogize to ASC 606 for certain activities within the collaborative arrangement for the delivery to a customer of a good or service (i.e., a unit of account) that is part of our ongoing major or central operations.

In arrangements involving more than one performance obligation, each required performance obligation is evaluated to determine whether it qualifies as a distinct performance obligation based on whether (i) the customer can benefit from the good or service either on its own or together with other resources that are readily available and (ii) the good or service is separately identifiable from other promises in the contract. The consideration under the arrangement is then allocated to each separate distinct performance obligation based on its respective relative stand-alone selling price. The estimated selling price of each deliverable reflects our best estimate of what the selling price would be if the deliverable was regularly sold by us on a stand-alone basis or using an adjusted market assessment approach if selling price on a stand-alone basis is not available.

The consideration allocated to each distinct performance obligation is recognized as revenue when control of the related goods is transferred or services are performed. Consideration associated with at-risk substantive performance milestones is recognized as revenue when it is probable that a significant reversal of the cumulative revenue recognized will not occur. Should there be royalties, we utilize the sales and usage-based royalty exception in arrangements that resulted from the license of intellectual property, recognizing revenues generated from royalties or profit sharing as the underlying sales occur.

Net sales of data or other services to our customers are classified under biopharmaceutical revenue, and all other non-customer revenue, such as milestones, are classified under collaboration revenue in our consolidated statements of operations and comprehensive loss. Payments made to us that are not net sales of data or other services to our customers are recorded as an offset against research and development expense in our consolidated statements of operations and comprehensive loss.

***Development of Additional Tests***

We continue to advance our portfolio of diagnostic tests that leverage innovations in genomic science, sequencing technology, machine learning and leveraging our new nCounter Analysis System to further improve patient care globally.

In May 2017, we introduced the Afirma GSC, supported by rigorous clinical validation data showing that the RNA sequencing-based test can help significantly more patients avoid unnecessary surgery in thyroid cancer diagnosis, compared to the original Afirma classifier. The Afirma GSC and Xpression Atlas, originally launched in March 2018 with an expanded version launched in April 2020, provide physicians with a comprehensive solution for thyroid nodule diagnosis. The Afirma GSC was developed with RNA whole-transcriptome sequencing and machine learning and helps identify patients with benign thyroid nodules among those with indeterminate cytopathology results in order to help patients avoid unnecessary diagnostic thyroid surgery. For those with suspected thyroid cancer, the Afirma Xpression Atlas provides physicians with genomic alteration content from the same fine needle aspiration samples that are used in Afirma GSC testing and may help physicians decide with greater confidence on the surgical or therapeutic pathway for their patients.

The expanded Afirma XA test, launched in April 2020, provides physicians with additional gene alteration content – including novel or rare NTRK, ALK, RET and BRAF fusions to further inform surgery and treatment decisions for patients with suspected or confirmed thyroid cancer. The Afirma XA utilizes RNA sequencing on the same FNA sample used for Afirma GSC testing. Compared to the original gene alteration panel, the expanded Afirma XA now reports 905 DNA variants (versus 761) and 235 RNA fusion partners (versus 130) in 593 genes (versus 511).

Together with our Afirma GSC and our tests for the BRAF v600E mutation and medullary thyroid cancer, or Malignancy Classifiers, the Afirma XA rounds out a comprehensive solution for physicians evaluating thyroid nodules. This innovation also enables us to enter into research collaborations with biopharmaceutical companies, which is intended to support their development of targeted therapies for genetically defined cancers, including thyroid cancer.

We have also expanded our ability to provide important clinical answers - without the need for surgery - into pulmonology. Our Percepta Bronchial Genomic Classifier, introduced in April 2015, is the first genomic test to receive Medicare coverage for use in lung cancer diagnosis, where it improves the performance of diagnostic bronchoscopy. In June 2019, we began making our “next-generation” Percepta Genomic Sequencing Classifier available to physicians, providing them with expanded lung cancer risk information that can further guide next steps for patients with suspicious lung nodules, as compared to the Percepta Bronchial Genomic Classifier.

Additionally, our Envisia Genomic Classifier, launched in October 2016, is the first commercial test to improve the diagnosis of IPF among patients with a suspected interstitial lung disease. In March 2019, we received final Medicare coverage for the Envisia classifier through the MolDX program, with an effective date of April 1, 2019.

We also believe our Xpression Atlas platform can be transferred to our pulmonology indications, to further improve patient care and advance precision medicine in lung cancer and IPF.

We are currently exploring opportunities to utilize the same “field of injury” technology that powers our Percepta classifier to develop a nasal swab test that can enable earlier lung cancer detection - and ultimately help reduce lung cancer deaths. In October 2019, we announced preliminary clinical data for our noninvasive nasal swab classifier - the first test of its kind. The findings show that the novel genomic test can accurately classify lung cancer risk in patients with lung nodules so that these patients can obtain the prompt diagnosis and potential treatment they need or may be monitored noninvasively.

***Timing of Our Research and Development Expenses***

We deploy state-of-the-art and costly genomic technologies in our biomarker discovery experiments, and our spending on these technologies may vary substantially from quarter to quarter. We also spend a significant amount to secure clinical samples that can be used in discovery and product development as well as clinical validation studies. The timing of these research and development activities is difficult to predict, as is the timing of sample acquisitions. If a substantial number of clinical samples are acquired in a given quarter or if a high-cost experiment is conducted in one quarter versus the next, the

timing of these expenses can affect our financial results. We conduct clinical studies to validate our new products as well as on-going clinical studies to further the published evidence to support our commercialized tests. As these studies are initiated, start-up costs for each site can be significant and concentrated in a specific quarter. Spending on research and development, for both experiments and studies, may vary significantly by quarter depending on the timing of these various expenses.

**Financial Overview**

***Revenue***

Through March 31, 2020, we had derived most of our revenue from the sale of Afirma, delivered primarily to physicians in the United States. We generally invoice third-party payers upon delivery of a patient report to the prescribing physician. As such, we take the assignment of benefits and the risk of cash collection from the third-party payer and individual patients. Third-party payers and other customers in excess of 10% of total revenue and their related revenue as a percentage of total revenue were as follows:

| | Three Months Ended March 31, | |
|---|---|---|
| | 2020 | 2019 |
| Medicare | 25 % | 21 % |
| Johnson and Johnson Services, Inc. | * | 13 % |
| UnitedHealthcare | 11 % | 11 % |
| | 36 % | 45 % |

For tests performed, we recognize the related revenue upon delivery of a patient report to the prescribing physician based on the amount that we expect to ultimately receive. In determining the amount to accrue for a delivered test, we consider factors such as payment history, payer coverage, whether there is a reimbursement contract between the payer and us, payment as a percentage of agreed upon reimbursement rate (if applicable), amount paid per test and any current development or changes that could impact reimbursement. Upon ultimate collection, the amount received is compared to previous estimates and the amount accrued is adjusted accordingly. Our ability to increase our revenue will depend on our ability to penetrate the market, obtain positive coverage policies from additional third-party payers, obtain reimbursement and/or enter into contracts with additional third-party payers for our current and new tests, and increase reimbursement rates for tests performed. Finally, should the judgments underlying our estimated reimbursement change, our accrued revenue and financial results could be negatively impacted in future periods.

***Cost of Revenue***

The components of our cost of testing revenue are laboratory expenses, kit costs, sample collection expenses, compensation expense, license fees and royalties, depreciation and amortization, other expenses such as equipment and laboratory supplies, and allocations of facility and information technology expenses. Costs associated with performing tests are recorded as the test is processed regardless of whether and when revenue is recognized with respect to that test. As a result, our cost of revenue as a percentage of revenue may vary significantly from period to period because we may not recognize all revenue in the period in which the associated costs are incurred. We expect cost of revenue in absolute dollars to increase as the number of tests we perform increases. However, we expect that the cost per test will decrease over time due to leveraging fixed costs, efficiencies we may gain as test volume increases and from automation, process efficiencies and other cost reductions. As we introduce new tests, initially our cost of revenue will be high as we expect to run suboptimal batch sizes, run quality control batches, test batches, registry samples and generally incur costs that may suppress or reduce gross margins. This will disproportionately increase our aggregate cost of revenue until we achieve efficiencies in processing these new tests.

Our cost of product revenue consists primarily of costs of purchasing instruments and consumables from third-party contract manufacturers, installation, warranty, service and packaging and delivery costs. In addition, cost of product includes royalty costs for licensed technologies included in our products and labor expenses. As our Prosigna kits are sold in various configurations with different number of tests, our product cost per test will vary based on the specific kit configuration purchased by customers.

Our cost of biopharmaceutical revenue are the costs of performing activities under arrangements that require us to perform research and development services on behalf of a customer pursuant to a biopharmaceutical service agreement, and is mainly comprised of compensation expense and pass through costs.

***Research and Development***

Research and development expenses include expenses incurred to develop our technology, collect clinical samples and conduct clinical studies to develop and support our products and pipeline. These expenses consist of compensation expenses, direct research and development expenses such as prototype materials, laboratory supplies and costs associated with setting up and conducting clinical studies at domestic and international sites, professional fees, depreciation and amortization, other miscellaneous expenses and allocation of facility and information technology expenses. We expense all research and development costs in the periods in which they are incurred. We expect to incur significant research and development expenses as we continue to invest in research and development activities related to developing additional products and evaluating various platforms. We incurred research and development expenses on ongoing evidence development for our Afirma, Percepta and Envisia classifiers in 2019. We incurred a majority of our research and development expenses in the three months ended March 31, 2020 in support of our pipeline products, and expect this to continue in the remainder of 2020 and beyond.

***Selling and Marketing***

Selling and marketing expenses consist of compensation expenses, direct marketing expenses, professional fees, other expenses such as travel and communications costs and allocation of facility and information technology expenses. We have expanded our internal sales force as we invest in our multi-product sales strategy to assign a single point of contact to successfully develop and implement relationships with our customers and increased our marketing spending. We have also incurred increased selling and marketing expense as a result of investments in our lung product portfolio and believe total selling and marketing expenses will continue to increase as we launch and promote our new tests.

***General and Administrative***

General and administrative expenses include compensation expenses for executive officers and administrative, billing and client service personnel, professional fees for legal and audit services, occupancy costs, depreciation and amortization, and other expenses such as information technology and miscellaneous expenses offset by allocation of facility and information technology expenses to other functions. For the three months ended March 31, 2020, approximately 68% of the average headcount classified as general and administrative encompass our billing and customer care teams. We expect general and administrative expenses to continue to increase as we build our general and administration infrastructure and to stabilize thereafter.

***Intangible Asset Amortization***

Our finite-lived intangible assets, acquired in business combinations, are being amortized over 5 to 15 years, using the straight-line method. Amortization expense is expected to be approximately $5.1 million per year through 2024 and decrease thereafter.

***Interest Expense***

Interest expense is attributable to our borrowings under debt agreements and capital leases as well as costs associated with the prepayment of debt.

***Other Income, Net***

Other income, net consists primarily of sublease rental income and interest income from our cash held in interest bearing accounts.

**Results of Operations**

Comparison of the three months ended March 31, 2020 and 2019 (in thousands of dollars, except percentages and genomic classifiers reported):

| | Three Months Ended March 31, | | | |
|---|---|---|---|---|
| | 2020 | 2019 | Change | % |
| Revenue: | | | | |
| Testing revenue | $ 26,991 | $ 25,389 | $ 1,602 | 6% |
| Product revenue | 3,409 | — | 3,409 | NM |
| Biopharmaceutical revenue | 722 | 4,140 | (3,418) | (83)% |
| Total revenue | 31,122 | 29,529 | 1,593 | 5% |
| Operating expense: | | | | |
| Cost of testing revenue | 10,568 | 8,513 | 2,055 | 24% |
| Cost of product revenue | 1,559 | — | 1,559 | NM |
| Cost of biopharmaceutical revenue | 116 | — | 116 | NM |
| Research and development | 4,407 | 3,435 | 972 | 28% |
| Selling and marketing | 17,584 | 12,477 | 5,107 | 41% |
| General and administrative | 7,813 | 6,904 | 909 | 13% |
| Intangible asset amortization | 1,275 | 267 | 1,008 | 378% |
| Total operating expenses | 43,322 | 31,596 | 11,726 | 37% |
| Loss from operations | (12,200) | (2,067) | (10,133) | 490% |
| Interest expense | (55) | (303) | 248 | (82)% |
| Other income, net | 539 | 453 | 86 | 19% |
| Net loss and comprehensive loss | $ (11,716) | $ (1,917) | $ (9,799) | 511% |
| **Other Operating Data:** | | | | |
| Genomic classifiers reported | 10,559 | 9,162 | 1,397 | 15% |
| Depreciation and amortization expense | 1,972 | 945 | 1,027 | 109% |
| Stock-based compensation expense | 2,905 | 1,759 | 1,146 | 65% |

*Revenue*

During the second half of March 2020, we experienced a significant decline in the volume of samples received resulting in a significant decline in revenue due to COVID-19. In spite of this, revenue increased $1.6 million, or 5%, for the three months ended March 31, 2020 compared to the same period in 2019. This was primarily due to $3.4 million of sales of Prosigna, a product that we acquired the rights to from NanoString in December 2019, and a $1.6 million increase in testing revenue from a 15% increase in our Afirma, Percepta, and Envisia genomic classifiers reported. We also make adjustments, as necessary, for testing revenue accrued in prior periods as collections are made if the amount we expect to collect changes. The adjustment for testing revenue accrued in prior periods decreased revenue by $0.1 million and increased revenue by $0.6 million for the three months ended March 31, 2020 and 2019, respectively, a net decrease of $0.7 million between the periods. Biopharmaceutical revenue decreased $3.4 million, mainly due to the performance of data sequencing services for Johnson & Johnson in the prior year period that did not recur in the three months ended March 31, 2020.

*Cost of revenue*

Comparison of the three months ended March 31, 2020 and 2019 is as follows (in thousands of dollars, except percentages):

| | Three Months Ended March 31, | | | |
|---|---|---|---|---|
| | 2020 | 2019 | Change | % |
| Cost of testing revenue: | | | | |
| Laboratory costs | $ 6,220 | $ 4,664 | $ 1,556 | 33% |
| Sample collection costs | 1,221 | 1,095 | 126 | 12% |
| Compensation expense | 1,815 | 1,460 | 355 | 24% |
| License fees and royalties | 14 | 2 | 12 | 600% |
| Depreciation and amortization | 253 | 250 | 3 | 1% |
| Other expenses | 434 | 470 | (36) | (8)% |
| Allocations | 611 | 572 | 39 | 7% |
| Total | $ 10,568 | $ 8,513 | $ 2,055 | 24% |
| | | | | |
| Cost of product revenue: | | | | |
| Product costs | $ 1,220 | $ — | $ 1,220 | NM |
| License fees and royalties | 339 | — | 339 | NM |
| Total | $ 1,559 | $ — | $ 1,559 | NM |
| | | | | |
| Cost of biopharmaceutical revenue: | | | | |
| Compensation expense | $ 39 | $ — | $ 39 | NM |
| Other expenses | 77 | — | 77 | NM |
| Total | $ 116 | $ — | $ 116 | NM |

Cost of testing revenue increased $2.1 million, or 24%, for the three months ended March 31, 2020 compared to the same period in 2019. The increase in laboratory costs was due to a $1.1 million write-down of supplies for the potential expiration of reagents due to an anticipated decline in volumes resulting from the COVID-19 pandemic. The increase in sample collection costs primarily relates to a 15% increase in the volume of genomic classifiers reported. The increase in compensation expense primarily relates to an average laboratory headcount increase of 16%.

Cost of product revenue is related to sales of Prosigna.

Cost of biopharmaceutical revenue includes labor costs incurred by our employees working on biopharmaceutical customer projects and pass-through expenses incurred on these projects. Biopharmaceutical revenue recognized in the prior year period was mainly for the sale of sequencing data and had no related costs.

*Research and development*

Comparison of the three months ended March 31, 2020 and 2019 is as follows (in thousands of dollars, except percentages):

| | Three Months Ended March 31, | | | |
|---|---|---|---|---|
| | 2020 | 2019 | Change | % |
| Research and development expense: | | | | |
| Compensation expense | $ 2,870 | $ 2,130 | $ 740 | 35% |
| Direct research and development expense | 941 | 576 | 365 | 63% |
| Professional fees | 125 | 201 | (76) | (38)% |
| Depreciation and amortization | 78 | 69 | 9 | 13% |
| Other expenses | 78 | 158 | (80) | (51)% |
| Allocations | 315 | 301 | 14 | 5% |
| Total | $ 4,407 | $ 3,435 | $ 972 | 28% |

Research and development expense increased $1.0 million, or 28%, for the three months ended March 31, 2020 compared to the same period in 2019. The increase in compensation expense was primarily due to an 18% increase in average headcount and higher stock-based compensation expense from the increase in our stock price over the last two years. The increase in direct research and development expense was mainly due to an increase in clinical trial activity for our pipeline products.

*Selling and marketing*

Comparison of the three months ended March 31, 2020 and 2019 is as follows (in thousands of dollars, except percentages):

| | Three Months Ended March 31, | | | |
|---|---|---|---|---|
| | 2020 | 2019 | Change | % |
| Selling and marketing expense: | | | | |
| Compensation expense | $ 12,515 | $ 7,714 | $ 4,801 | 62% |
| Direct marketing expense | 1,152 | 1,587 | (435) | (27)% |
| Professional fees | 325 | 364 | (39) | (11)% |
| Other expenses | 2,597 | 2,050 | 547 | 27% |
| Allocations | 995 | 762 | 233 | 31% |
| Total | $ 17,584 | $ 12,477 | $ 5,107 | 41% |

Selling and marketing expense increased $5.1 million, or 41%, for the three months ended March 31, 2020 compared to the same period in 2019. The increase in compensation expense was primarily due to an average headcount increase of 60%, higher incentive compensation and higher stock-based compensation expense. The decrease in direct marketing expense was due to lower general marketing expenditures. The increase in other expenses was primarily due to travel and entertainment expenses related to the increase in headcount, as was the increase in allocations.

*General and administrative*

Comparison of the three months ended March 31, 2020 and 2019 is as follows (in thousands of dollars, except percentages):

| | Three Months Ended March 31, | | | |
|---|---|---|---|---|
| | 2020 | 2019 | Change | % |
| General and administrative expense: | | | | |
| Compensation expense | $ 4,988 | $ 4,200 | $ 788 | 19% |
| Professional fees | 2,951 | 2,281 | 670 | 29% |
| Occupancy expenses | 665 | 623 | 42 | 7% |
| Depreciation and amortization | 367 | 360 | 7 | 2% |
| Other expenses | 764 | 1,075 | (311) | (29)% |
| Allocations | (1,922) | (1,635) | (287) | 18% |
| Total | $ 7,813 | $ 6,904 | $ 909 | 13% |

General and administrative expense increased $1.6 million, or 24%, for the three months ended March 31, 2020 compared to the same period in 2019. The increase in compensation expense was primarily due to higher stock-based compensation expense from the increase in our stock price over the last two years. The increase in professional fees was primarily accounting and legal-related. The decrease in other expenses was primarily due to the revaluation of the contingent consideration for the NanoString transaction.

*Interest expense*

Interest expense decreased $248,000, or 82%, for the three months ended March 31, 2020 compared to the same period in 2019, mainly due to the prepayments of $12.5 million and $12.4 million of the principal amount of our Term Loan Advance in January 2019 and May 2019, respectively. The average Term Loan Advance interest rate was 5.80% and 6.68% for the three months ended March 31, 2020 and 2019, respectively.

*Other income, net*

Other income, net, increased $86,000 for the three months ended March 31, 2020 compared to the same period in 2019 primarily due to higher interest income from our cash and cash equivalents, which had higher balances in 2020, partially offset by lower interest rates.

**Liquidity and Capital Resources**

From inception through March 31, 2020, we have been financed primarily through net proceeds from the sale of our equity securities and borrowings under our credit facilities. We have incurred net losses since our inception. For the three months ended March 31, 2020, we had a net loss of $11.7 million, and as of March 31, 2020, we had an accumulated deficit of $258.4 million. We expect to incur additional losses for the remainder of 2020 and potentially in future years.

We believe our existing cash and cash equivalents of $153.1 million as of March 31, 2020, our available revolving line of credit, and our revenue during the next 12 months will be sufficient to meet our anticipated cash requirements for at least the next 12 months. We expect that our near- and longer-term liquidity requirements will continue to consist of costs to run our laboratories, research and development expenses, selling and marketing expenses, general and administrative expenses, working capital, costs to service our Loan and Security Agreement (See Note 7 to our unaudited condensed consolidated financial statements included in this Quarterly Report on Form 10-Q for more information about our Loan and Security Agreement), capital expenditures and general corporate expenses associated with the growth of our business. However, we may also use cash to acquire or invest in complementary businesses, technologies, services or products that would change our cash requirements. If we are not able to generate revenue to finance our cash requirements, including due to the impacts of the COVID-19 pandemic, we will need to finance future cash needs primarily through public or private equity offerings, debt financings, borrowings or strategic collaborations or licensing arrangements. If we raise funds by issuing equity securities, dilution to stockholders could result. Any equity securities issued also may provide for rights, preferences or privileges senior to those of holders of our common stock. The terms of debt securities issued or borrowings could impose significant restrictions on our operations. The incurrence of additional indebtedness or the issuance of certain equity securities could result in increased fixed

payment obligations and could also result in restrictive covenants, such as limitations on our ability to incur additional debt or issue additional equity, limitations on our ability to acquire or license intellectual property rights, restrictions on our cash pursuant to the terms of our Loan and Security Agreement and other operating restrictions that could adversely affect our ability to conduct our business. Our Loan and Security Agreement imposes restrictions on our operations, increases our fixed payment obligations and has restrictive covenants. In addition, the issuance of additional equity securities by us, or the possibility of such issuance, may cause the market price of our common stock to decline. In the event that we enter into collaborations or licensing arrangements to raise capital, we may be required to accept unfavorable terms. These agreements may require that we relinquish or license to a third-party on unfavorable terms our rights to technologies or product candidates that we otherwise would seek to develop or commercialize ourselves, or reserve certain opportunities for future potential arrangements when we might be able to achieve more favorable terms. If we are not able to secure additional funding when needed, we may have to delay, reduce the scope of or eliminate one or more research and development programs or selling and marketing initiatives, or forgo potential acquisitions or investments. In addition, we may have to work with a partner on one or more of our products or development programs, which could lower the economic value of those programs to us.

***Public Offering of Common Stock***

On May 7, 2019, we issued and sold 6,325,000 shares of common stock in a registered public offering, including 825,000 shares issued and sold upon the underwriters' exercise in full of their option to purchase additional shares, at a price to the public of $23.25 per share. Our net proceeds from the offering were approximately $137.8 million, after deducting underwriting discounts and commissions and offering expenses of $9.2 million.

***Loan and Security Agreement***

On November 3, 2017, we entered into the Loan and Security Agreement with Silicon Valley Bank. The Loan and Security Agreement allows us to borrow up to $35.0 million, with a $25.0 million term loan, or Term Loan, and a revolving line of credit of up to $10.0 million, or the Revolving Line of Credit, subject to, with respect to the Revolving Line of Credit, a borrowing base of 85% of eligible accounts receivable. The Term Loan was advanced upon the closing of the Loan and Security Agreement. Borrowings under the Loan and Security Agreement mature in October 2022. The Term Loan bears interest at a variable rate equal to (i) the thirty-day U.S. London Interbank Offer Rate, or LIBOR, plus (ii) 4.20%, with a minimum rate of 5.43% per annum. Principal amounts outstanding under the Revolving Line of Credit bear interest at a variable rate equal to (i) LIBOR plus (ii) 3.50%, with a minimum rate of 4.70% per annum. We are also required to pay an annual facility fee on the Revolving Line of Credit of $25,000. The average Term Loan Advance interest rate for the three months ended March 31, 2020 was 5.8%.

We may prepay the outstanding principal amount under the Term Loan Advance plus accrued and unpaid interest and, if the Term Loan Advance is repaid in full, a prepayment premium. The prepayment premium will equal (i) $750,000, if the prepayment is made on or before November 3, 2018, (ii) $500,000, if the prepayment is made after November 3, 2018 and on or prior to November 3, 2019 and (iii) $250,000, if the prepayment is made after November 3, 2019. In addition, a final payment on the Term Loan Advance in the amount of $1.2 million is due upon the earlier of the maturity date of the Term Loan Advance or its payment in full. In January 2019 and May 2019, we prepaid $12.5 million and $12.4 million of the principal amount of the Term Loan Advance, respectively, and did not incur any prepayment premium as we did not repay the Term Loan Advance in full. These prepayments cover scheduled principal payments from November 2019 to September 2022.

The Loan and Security Agreement contains customary representations, warranties, and events of default such as a material adverse change in our business, operations or financial conditions, as well as affirmative and negative covenants. The negative covenants include, among other provisions, covenants that limit or restrict our ability to incur liens, make investments, incur indebtedness, merge with or acquire other entities, dispose of assets, make dividends or other distributions to holders of our equity interests, engage in any new line of business, or enter into certain transactions with affiliates, in each case subject to certain exceptions. As of March 31, 2020, the principal balance outstanding was $0.1 million and we were in compliance with our debt covenants.

The Loan and Security Agreement also requires us to comply with certain financial covenants, including achieving certain revenue levels tested quarterly on a trailing twelve-month basis. However, failure to maintain the revenue levels will not be considered a default if the sum of our unrestricted cash and cash equivalents maintained with Silicon Valley Bank and amount available under the Revolving Line of Credit is at least $40.0 million.

Our obligations under the Loan and Security Agreement are secured by substantially all of our assets (excluding intellectual property), subject to certain customary exceptions.

***Cash Flows***

The following table summarizes our cash flows for the three months ended March 31, 2020 and 2019 (in thousands of dollars):

| | Three Months Ended March 31, | |
|---|---|---|
| | 2020 | 2019 |
| Cash used in operating activities | $ (5,301) | $ (1,011) |
| Cash used in investing activities | (665) | (749) |
| Cash provided by financing activities | (219) | (8,394) |

*Cash Flows from Operating Activities*

Cash used in operating activities for the three months ended March 31, 2020 was $5.3 million. The net loss of $11.7 million includes non-cash charges of $2.9 million of stock-based compensation expense, $2.0 million of depreciation and amortization, which includes $1.3 million of intangible asset amortization, a $1.1 million write-down of supplies, and a $0.5 million credit for the revaluation of the contingent consideration related to the NanoString transaction. Cash provided as a result of changes in operating assets and liabilities was $0.9 million, primarily comprised of an increase in accounts payable of $5.5 million, partially offset by a decrease in accrued liabilities of $3.7 million and increase in prepaid expense and other current assets of $0.8 million.

Cash used in operating activities for the three months ended March 31, 2019 was $1.0 million. The net loss of $1.9 million includes non-cash charges of $1.8 million of stock-based compensation expense and $0.9 million of depreciation and amortization, which includes $0.3 million of intangible asset amortization. Cash used as a result of changes in operating assets and liabilities was $1.8 million, comprised of an increase in accounts receivable of $3.4 million and increase in supplies of $0.4 million, partially offset by increases in accounts payable and accrued liabilities of $1.7 million and $0.3 million, respectively.

*Cash Flows from Investing Activities*

Cash used in investing activities for the three months ended March 31, 2020 was $0.7 million for the acquisition of property and equipment.

Cash used in investing activities for the three months ended March 31, 2019 was $0.7 million for the acquisition of property and equipment, net of proceeds from the disposal of property and equipment.

*Cash Flows from Financing Activities*

Cash used in financing activities for the three months ended March 31, 2020 was $0.2 million, consisting of $2.3 million in tax payments related to the vesting of restricted stock units granted to employees, partially offset by $2.1 million in proceeds from the exercise of options to purchase our common stock and purchase of stock under our Employee Stock Purchase Plan, or ESPP, during the period.

Cash used in financing activities for the three months ended March 31, 2019 was $8.4 million, consisting of $12.5 million of loan principal repayments and finance lease payments of $0.1 million, partially offset by $4.2 million in proceeds from the exercise of options to purchase our common stock and purchase of stock under our Employee Stock Purchase Plan, or ESPP, during the period.

**Contractual Obligations**

In January 2019 and May 2019, we prepaid $12.5 million and $12.4 million of the principal amount of the Term Loan Advance, respectively, under our Loan and Security Agreement. As of March 31, 2020, future principal and end-of-term debt obligation payments due under the Loan and Security Agreement are limited to $1.3 million in 2022. There were no material changes during the interim period in the contractual obligations presented in our Form 10-K for the year ended December 31, 2019 filed with the Securities and Exchange Commission on February 25, 2020.

**Off-balance Sheet Arrangements**

We have not entered into any off-balance sheet arrangements.

**Recent Accounting Pronouncements**

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments-Credit Losses: Measurement of Credit Losses on Financial Instruments*. This ASU requires entities to estimate an expected lifetime credit loss on financial assets ranging from short-term trade accounts receivable to long-term financings and report credit losses using an expected losses model rather than the incurred losses model that was previously used, and establishes additional disclosures related to credit risks. This guidance became effective for us beginning January 1, 2020. Based on the composition of our trade receivables, investment portfolio and other financial assets, current economic conditions and historical credit loss activity, the adoption of this standard did not have a material impact on our condensed consolidated financial statements and related disclosures.

In November 2018, the FASB issued ASU No. 2018-18, *Collaborative Arrangements (Topic 808).* Under this ASU, transactions in collaborative arrangements are to be accounted for under ASC 606 if the counterparty is a customer for a good or service (or bundle of goods and services) that is a distinct unit of account. Also, entities are precluded from presenting consideration from transactions with a counterparty that is not a customer together with revenue recognized from ASC 606. This ASU is effective for all interim and annual reporting periods beginning on or after December 15, 2019, with early adoption permitted. We adopted this ASU in 2019 with no cumulative-effect adjustments or retrospective impact.

In August 2018 the FASB issued ASU No. 2018-15, *Intangibles—Goodwill and Other—Internal-Use Software (Subtopic 350-40): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract*. This standard clarifies the accounting for implementation costs in cloud computing arrangements. This standard became effective for us on January 1, 2020, and was adopted on a prospective basis with no material impact on our condensed consolidated financial statements.

## ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to market risks in the ordinary course of our business. These risks primarily relate to interest rates. We had cash and cash equivalents of $153.1 million as of March 31, 2020 which include bank deposits and money market funds. Such interest-bearing instruments carry a degree of risk; however, a hypothetical 10% change in interest rates during any of the periods presented would not have had a material impact on our unaudited interim condensed financial statements. Under our Loan and Security Agreement, we pay interest on any outstanding balances under this agreement based on a variable market rate. A significant change in these market rates may adversely affect our operating results.

## ITEM 4. CONTROLS AND PROCEDURES

### (a) Evaluation of Disclosure Controls and Procedures

We maintain "disclosure controls and procedures," as such term is defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, or Exchange Act, that are designed to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, management recognized that disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the disclosure controls and procedures are met. Our disclosure controls and procedures have been designed to meet reasonable assurance standards. Additionally, in designing disclosure controls and procedures, our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible disclosure controls and procedures. The design of any disclosure controls and procedures also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions.

Based on their evaluation as of the end of the period covered by this Quarterly Report on Form 10-Q, our Chief Executive Officer and Chief Financial Officer have concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

### (b) Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as such term is defined in Rule 13a-15(f) under the Exchange Act) identified in connection with the evaluation identified above that occurred during the three months ended March 31, 2020 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## PART II. — OTHER INFORMATION

### ITEM 1A. RISK FACTORS

**Risks Related to Our Business**

***We have a history of losses, and we expect to incur net losses for the foreseeable future and may never achieve or sustain profitability.***

We have incurred net losses since our inception. For the three months ended March 31, 2020, we had a net loss of $11.7 million and as of March 31, 2020, we had an accumulated deficit of $258.4 million. We expect to incur additional losses in the future, and we may never achieve revenue sufficient to offset our expenses. Over the next couple of years, we expect to continue to devote substantially all of our resources to increase adoption of, and reimbursement for our Afirma, Percepta and Envisia classifiers and Prosigna test, and the development of additional tests. We may never achieve or sustain profitability, and our failure to achieve and sustain profitability in the future could cause the market price of our common stock to decline.

***The outbreak of COVID-19 could have an adverse effect on our business, results of operations and financial condition.***

COVID-19 has caused significant volatility in financial markets and has raised the prospect of an extended global recession. Public health problems resulting from COVID-19 and precautionary measures instituted by governments and businesses to mitigate its spread, including travel restrictions and quarantines, could contribute to a general slowdown in the global economy, adversely impact patients, physicians, customers, suppliers, third-party contract manufacturers, and collaboration partners, and disrupt our operations. Changes in our operations in response to COVID-19 or employee illnesses resulting from the pandemic may result in inefficiencies or delays, including in sales and product development efforts and additional costs related to business continuity initiatives, that cannot be fully mitigated through succession planning, employees working remotely or teleconferencing technologies. In addition, during the second half of March 2020 through the date of this filing, we experienced a significant decline in the volume of samples received resulting in a significant decline in revenue and it is currently unclear how long we will continue to experience decreased sample volumes and levels of revenue.

COVID-19 and related governmental reactions have had, and may continue to have a negative impact on our business, liquidity, results of operations, and stock price due to the occurrence of some or all of the following events or circumstances among others:

- We may not be able to manage our business effectively due to key employees becoming ill, working from home inefficiently and being unable to travel to our facilities.
- We and our customers, suppliers, third-party contract manufacturers, and collaboration partners may be prevented from operating worksites, including manufacturing facilities, due to employee illness or reluctance to appear at work and “stay-at-home” regulations.
- Interruptions in manufacturing (including the sourcing of reagents) and shipment of our products.
- Reduced patient demand for, or provider capacity to deliver, diagnostic testing and elective procedures generally.
- Disruptions of the operations of our third-party contract manufacturers and suppliers, which could impact our ability to purchase components at efficient prices and in sufficient amounts.
- We may need to raise capital, and if we raise capital by issuing equity securities, our common stock may be diluted.
- The market price of our common stock may drop or remain volatile.
- We may incur significant employee health care costs under our insurance programs.

The extent of the impact of COVID-19 on our business and financial results will depend largely on future developments, including the duration of the spread of the outbreak, the impact on capital and financial markets and the related impact on the financial circumstances of patients, physicians, suppliers, third-party contract manufacturers, and collaboration partners, all of which are highly uncertain and cannot be predicted. This situation is changing rapidly, and additional impacts may arise that we are not aware of at this time.

***Our financial results currently depend mainly on sales of our Afirma tests, and we will need to generate sufficient revenue from this and other diagnostic solutions to grow our business.***

Most of our revenue to date has been derived from the sale of our Afirma tests, which are used in the diagnosis of thyroid cancer. Over the next few years, we expect to continue to derive a substantial portion of our revenue from sales of our

Afirma tests. In the third quarter of 2017, we began recognizing revenue from the sale of our Percepta test, used in the diagnosis of lung cancer. We also launched our Envisia test to help improve the diagnosis of interstitial lung disease, specifically IPF, and began recognizing revenue from Envisia in the second quarter of 2019. In December 2019, we acquired the rights to the Prosigna test from NanoString Technologies, Inc. and commenced marketing and selling Prosigna test kits to U.S. and international customers. Once genomic tests are clinically validated and commercially available for patient testing, we must continue to develop and publish evidence that our tests are informing clinical decisions in order for them to receive positive coverage decisions by payers. Without coverage policies, our tests may not be reimbursed and we will not be able to recognize revenue. We cannot guarantee that tests we commercialize will gain and maintain positive coverage decisions and therefore, we may never realize revenue from tests we commercialize. In addition, we are in various stages of research and development for other diagnostic solutions that we may offer, but there can be no assurance that we will be able to identify other diseases that can be effectively addressed or, if we are able to identify such diseases, whether or when we will be able to successfully commercialize solutions for these diseases and obtain the evidence and coverage decisions from payers. If we are unable to increase sales and expand reimbursement for our Afirma, Percepta, Envisia and Prosigna tests, or develop and commercialize other solutions, our revenue and our ability to achieve and sustain profitability would be impaired, and the market price of our common stock could decline.

***We depend on a few payers for a significant portion of our revenue and if one or more significant payers stops providing reimbursement or decreases the amount of reimbursement for our tests, our revenue could decline.***

Revenue for tests performed on patients covered by Medicare and UnitedHealthcare was 24% and 11%, respectively, of our revenue for the three months ended March 31, 2020, compared with 28% and 12%, respectively, for the three months ended March 31, 2019. The percentage of our revenue derived from significant payers is expected to fluctuate from period to period as our revenue fluctuates, as additional payers provide reimbursement for our tests or if one or more payers were to stop reimbursing for our tests or change their reimbursed amounts. Effective January 2012, Palmetto GBA, the regional Medicare Administrative Contractor, or MAC, that handled claims processing for Medicare services over our jurisdiction at that time, issued coverage and payment determinations for our Afirma Classifiers now covered by Noridian Healthcare Solutions, the current MAC for our jurisdiction, through the Molecular Diagnostics Services Program, or MolDX program, administered by Palmetto GBA, under a Local Coverage Determination, or LCD.

Noridian Healthcare Solutions issued an LCD for Percepta effective for services performed on or after May 2017. This coverage policy requires us to establish and maintain a Certification and Training Registry program and make Percepta available only to certain Medicare patients through physicians who participate in this program. Failure by us or physicians to comply with the requirements of the Certification and Training Registry program could lead to loss of Medicare coverage for Percepta, which could have an adverse effect on our revenue.

We submitted the dossier of clinical evidence needed to obtain Medicare coverage for the Envisia Genomic Classifier through the MolDX technical assessment process in 2018, and received final Medicare coverage for the classifier in the first quarter of 2019, with an effective date of April 1, 2019.

An LCD was issued for Prosigna by Palmetto GBA in August 2015, which has been in effect since October 1, 2015.

On a five-year rotational basis, Medicare requests bids for its regional MAC services. Any future changes in the MAC processing or coding for Medicare claims for the Afirma, Percepta or Envisia classifiers, or for Prosigna, could result in a change in the coverage or reimbursement rates for such products, or the loss of coverage, and could also result in increased difficulties in obtaining and maintaining coverage for future products.

On March 1, 2015, an American Medical Association Current Procedural Terminology code, or CPT code, 81545 for the Afirma GEC was issued. On January 1, 2018, the Medicare Clinical Laboratory Fee Schedule payment rate for the Afirma classifier increased from $3,220 to $3,600. This rate is based on the volume-weighted median of private payer rates based on final payments made between January 1 and June 30, 2016, which we reported to the Centers for Medicare & Medicaid Services, or CMS, in 2017 as required under the Protecting Access to Medicare Act of 2014, or PAMA. In December 2019, through the Further Consolidated Appropriations Act of 2020, Congress delayed the next data reporting period from 2020 to 2021 for final payments made between January 1 and June 30, 2019, extending the applicability of the payment rates based on 2017 reporting by one year through December 31, 2021. Afirma will continue to be paid at $3,600 through that date. The volume-weighted median of private payer rates for final payments made from January through June 2019 (and now reported January through March 2021) will set the Medicare payment rate for the Afirma classifier from January 1, 2022 through December 31, 2024. There can be no assurance that the Afirma or Prosigna rates will not decrease during this or a subsequent reporting cycle under PAMA.

We submit claims to Medicare for Percepta and Envisia using unlisted codes under the MolDX program. Specific CPT codes assigned to Percepta and Envisia may be required to go through the national payment determination process, and there can be no assurance that the Medicare payment rates the tests receive through this process will not be lower than their current rates. There can also be no assurance that the Medicare payment rates for the tests will not be reduced when they are set based on the volume-weighted medians of private payer rates when we are required to report those rates under PAMA.

Moreover, federal Medicare funding and state budgets are limited and have been placed under tremendous strain in recent years, which is likely to be further exacerbated as a result in reduced tax receipts and greater deficit spending as a result of the COVID-19 pandemic. Such budgetary pressures may force Medicare or state agencies to reduce payment rates or change coverage policies. If there is a decrease in the Medicare or other payers' payment rates for our tests, our revenue from Medicare and such payers will decrease and the payment rates for some of our commercial payers may also decrease if they tie their allowable rates to the Medicare rates. These changes could have an adverse effect on our business, financial condition and results of operations.

Although we have entered into contracts with certain third-party payers that establish in-network allowable rates of reimbursement for our Afirma tests, payers may suspend or discontinue reimbursement at any time, may require or increase co-payments from patients, or may reduce the reimbursement rates paid to us. Reductions in private payer amounts could decrease the Medicare payment rates for our tests under PAMA. In addition, private payers have begun requiring prior authorization for molecular diagnostic tests. Potential reductions in reimbursement rates or increases in the difficulty of achieving payment could have a negative effect on our revenue.

***If payers do not provide reimbursement, rescind or modify their reimbursement policies, delay payments for our tests, recoup past payments, or if we are unable to successfully negotiate additional reimbursement contracts, our commercial success could be compromised.***

Physicians might not order our tests unless payers reimburse a substantial portion of the test price. There is significant uncertainty concerning third-party reimbursement of any test incorporating new technology, including our tests. Reimbursement by a payer may depend on a number of factors, including a payer's determination that these tests are:

- not experimental or investigational;
- pre-authorized and appropriate for the specific patient;
- cost-effective;
- supported by peer-reviewed publications; and
- included in clinical practice guidelines.

Since each payer makes its own decision as to whether to establish a coverage policy or enter into a contract to reimburse our tests, seeking these approvals is a time-consuming and costly process.

We do not have a contracted rate of reimbursement with some payers for our tests. Without a contracted rate for reimbursement, our claims are often denied upon submission, and we must appeal the claims. The appeals process is time consuming and expensive, and may not result in payment. In cases where there is no contracted rate for reimbursement, there is typically a greater patient co-insurance or co-payment requirement which may result in further delay or decreased likelihood of collection. Payers may attempt to recoup prior payments after review, sometimes after significant time has passed, which would impact future revenue.

We expect to continue to focus substantial resources on increasing adoption, coverage and reimbursement for the Afirma, Percepta, and Envisia classifiers, Prosigna and any other future tests we may develop. We believe it will take several years to achieve coverage and contracted reimbursement with a majority of third-party payers. However, we cannot predict whether, under what circumstances, or at what payment levels payers will reimburse for our tests. Also, payer consolidation is underway and creates uncertainty as to whether coverage and contracts with existing payers will remain in effect. Finally, if there is a decrease in the Medicare payment rates for our tests, the payment rates for some of our commercial payers may also decrease if they tie their allowable rates to the Medicare rates. Reductions in private payer amounts could decrease the Medicare payment rates for our tests under PAMA. Our failure to establish broad adoption of and reimbursement for our tests, or our inability to maintain existing reimbursement from payers, will negatively impact our ability to generate revenue and achieve profitability, as well as our future prospects and our business.

***We may experience limits on our revenue if physicians decide not to order our tests.***

If we are unable to create or maintain demand for our tests in sufficient volume, we may not become profitable. To generate demand, we will need to continue to educate physicians about the benefits and cost-effectiveness of our tests through published papers, presentations at scientific conferences, marketing campaigns and one-on-one education by our sales force. In addition, our ability to obtain and maintain adequate reimbursement from third-party payers will be critical to generating revenue. Moreover, many patients have been deferring elective procedures and medical visits as a result of the COVID-19 pandemic, and we have experienced, and may continue to experience, a significant reduction in patient demand or physician recommendations, which has and may continue to adversely affect our business.

The Afirma genomic classifier is included in most physician practice guidelines in the United States for the assessment of patients with thyroid nodules. However, historical practice recommended a full or partial thyroidectomy in cases where cytopathology results were indeterminate to confirm a diagnosis. Our lung products are not yet integrated into practice guidelines and physicians may be reluctant to order tests that are not recommended in these guidelines. The Prosigna test is included in practice guidelines in the United States and internationally but faces competition from other products. Because our Afirma, Percepta and Envisia testing services are performed by our certified laboratory under the Clinical Laboratory Improvement Amendments of 1988, or CLIA, rather than by the local laboratory or pathology practice, pathologists may be reluctant to support our testing services as well. Guidelines that include our tests currently may subsequently be revised to recommend another testing protocol, and these changes may result in physicians deciding not to use our tests. Lack of guideline inclusion could limit the adoption of our tests and our ability to generate revenue and achieve profitability. To the extent international markets have existing practices and standards of care that are different than those in the United States, we may face challenges with the adoption of our tests in international markets.

***We may experience limits on our revenue if patients decide not to use our tests.***

Some patients may decide not to use our tests because of price, all or part of which may be payable directly by the patient if the patient's insurer denies reimbursement in full or in part. There is a growing trend among insurers to shift more of the cost of healthcare to patients in the form of higher co-payments or premiums, and this trend is accelerating which puts patients in the position of having to pay more for our tests. We expect to continue to see pressure from payers to limit the utilization of tests, generally, and we believe more payers are deploying costs containment tactics, such as pre-authorization and employing laboratory benefit managers to reduce utilization rates. Implementation of provisions of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, collectively the ACA, has also resulted in increases in premiums and reductions in coverage for some patients. In addition, Congressional efforts to repeal the ACA could result in an increase in uninsured patients. These events may result in patients delaying or forgoing medical checkups or treatment due to their inability to pay for our tests, which could have an adverse effect on our revenue. Many patients have been deferring elective procedures and medical visits as a result of the COVID-19 pandemic, and we have experienced, and may continue to experience, a significant reduction in patient demand, which has and may continue to adversely affect our business.

***If we fail to comply with federal and state licensing requirements, we could lose the ability to perform our tests or experience disruptions to our business.***

We are subject to CLIA, a federal law that regulates clinical laboratories that perform testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention or treatment of disease. CLIA regulations mandate specific personnel qualifications, facilities administration, quality systems, inspections, and proficiency testing. CLIA certification is also required for us to be eligible to bill state and federal healthcare programs, as well as many private third-party payers. To renew these certifications, we are subject to survey and inspection every two years. Moreover, CLIA inspectors may make random inspections of our clinical reference laboratories. If we in the future fail to maintain CLIA certificates in our South San Francisco or Austin, Texas laboratory locations we would be unable to bill for services provided by state and federal healthcare programs, as well as many private third-party payers, which may have an adverse effect on our business, financial condition and results of operations.

We are also required to maintain state licenses to conduct testing in our laboratories. California, New York, and Texas, among other states' laws, require that we maintain a license and comply with state regulation as a clinical laboratory. Other states may have similar requirements or may adopt similar requirements in the future. In addition, both of our clinical laboratories are required to be licensed on a test-specific basis by New York State. We have received approval for the Afirma, Percepta and Envisia tests. We will be required to obtain approval for other tests we may offer in the future. If we were to lose our CLIA certificate or California license for our South San Francisco laboratory, whether as a result of revocation, suspension

or limitation, we would no longer be able to perform our molecular tests, which would eliminate our primary source of revenue and harm our business. If we fail to meet the state licensing requirements for our Austin laboratory, we would need to move the receipt and storage of FNAs, as well as the slide preparation for cytopathology, to South San Francisco, which could result in a delay in processing tests during that transition and increased costs. If we were to lose our licenses issued by New York or by other states where we are required to hold licenses, we would not be able to test specimens from those states. New tests we may develop may be subject to new approvals by regulatory bodies such as New York State, and we may not be able to offer our new tests until such approvals are received.

***If we are not successful in integrating the assets acquired from NanoString or if our general strategy of seeking growth through such acquisitions and collaborations is not successful, our prospects and financial condition will suffer.***

We have recently acquired assets, such as the nCounter FLEX Analysis System and Prosigna in December 2019, and we may pursue additional acquisitions of complementary businesses or assets as part of our business strategy. To date, we have limited experience with respect to acquisitions and the formation of strategic alliances and joint ventures. There can be no assurance that we will successfully integrate the assets acquired from NanoString successfully into our existing business, or that our exclusive worldwide license to the nCounter system for in vitro diagnostic use will allow us to expand our international reach as anticipated. This and any future acquisitions made by us also could result in significant write-offs or the incurrence of debt and contingent liabilities, any of which could harm our operating results. Integration of acquired companies or businesses we may acquire in the future also may require management resources that otherwise would be available for ongoing development of our existing business. We may not identify or complete these transactions in a timely manner, on a cost-effective basis, or at all, and we may not realize the anticipated benefits of any acquisition, technology license, strategic alliance, joint venture or investment.

To finance any acquisitions or investments, we have previously and may choose in the future to issue shares of our stock as consideration, which would dilute the ownership of our stockholders. If the price of our common stock is low or volatile, we may not be able to acquire other companies for stock. Alternatively, it may be necessary for us to raise additional funds for these activities through public or private financings. Additional funds may not be available on terms that are favorable to us, or at all. If these funds are raised through the sale of equity or convertible debt securities, dilution to our stockholders could result. Our Loan and Security Agreement with Silicon Valley Bank contains covenants that could limit our ability to sell debt securities or obtain additional debt financing arrangements, which could affect our ability to finance acquisitions or investments other than through the issuance of stock.

***If we are not successful in advancing our collaborations with Johnson & Johnson and others, or if our general strategy of seeking growth through such collaborations is not successful, our prospects and financial condition will suffer.***

We have previously entered into technology licensing and collaboration arrangements, such as our collaboration with Johnson & Johnson in December 2018 and with Acerta Pharma, the hematology research and development arm of AstraZeneca, in December 2019, reflecting important elements of our business strategy. We also may pursue additional strategic alliances that leverage our core technology and industry experience to expand our offerings or distribution, or make investments in other companies. However, we have limited experience with respect to the formation of strategic alliances and joint ventures. There can be no assurance that we will successfully identify or complete these transactions in a timely manner, on a cost-effective basis, or at all, and we may not realize the anticipated benefits of any technology license, strategic alliance, joint venture or investment.

***We rely on sole suppliers for some of the reagents, equipment, chips and other materials used to perform our tests, and we may not be able to find replacements or transition to alternative suppliers.***

We rely on sole suppliers for critical supply of reagents, equipment, chips and other materials that we use to perform our tests and for the manufacture of the nCounter FLEX Dx systems and Prosigna test kits sold to customers. We also purchase components used in our collection kits from sole-source suppliers. Some of these items are unique to these suppliers and vendors. In addition, we utilize a sole source to assemble and distribute our sample collection kits. We rely on NanoString for the supply of the nCounter FLEX Dx System and Prosigna test kits. While we have developed alternate sourcing strategies for these materials and vendors, we cannot be certain whether these strategies will be effective or the alternative sources will be available when we need them. If these suppliers can no longer provide us with the materials we need to perform the tests and for our collection kits, if the materials do not meet our quality specifications or are otherwise unusable, if we cannot obtain acceptable substitute materials, or if we elect to change suppliers, an interruption in test processing or system and test kit deliveries could occur, we may not be able to deliver patient reports and we may incur higher one-time switching costs. Any such interruption may significantly affect our future revenue, cause us to incur higher costs, and harm our customer

relationships and reputation. In addition, in order to mitigate these risks, we maintain inventories of these supplies at higher levels than would be the case if multiple sources of supplies were available. If our test volume decreases or we switch suppliers, we may hold excess supplies with expiration dates that occur before use which would adversely affect our losses and cash flow position. As we introduce any new test, we may experience supply issues as we ramp test volume. Moreover, the COVID-19 pandemic has disrupted supply chains globally, and could adversely affect our ability to source essential reagents, equipment, chips and other materials in a timely manner or at all.

***We depend on a specialized cytopathology practice to perform the cytopathology component of our Afirma test, and our ability to perform our diagnostic solution would be harmed if we were required to secure a replacement.***

We rely on TCP to provide cytopathology professional diagnoses on thyroid FNA samples pursuant to a pathology services agreement. Pursuant to this agreement, as amended, TCP has the exclusive right to provide our cytopathology diagnoses on FNA samples at a fixed price per test. Until February 2019, TCP also previously subleased a portion of our facility in Austin, Texas. Our agreement with TCP is effective through October 31, 2022, and thereafter automatically renews every year unless either party provides notice of intent not to renew at least 12 months prior to the end of the then-current term.

If TCP were not able to support our current test volume or future increases in test volume or to provide the quality of services we require, or if we were unable to agree on commercial terms and our relationship with TCP were to terminate, our business would be harmed until we were able to secure the services of another cytopathology provider. There can be no assurance that we would be successful in finding a replacement that would be able to conduct cytopathology diagnoses at the same volume or with the same high-quality results as TCP. Locating another suitable cytopathology provider could be time consuming and would result in delays in processing Afirma tests until a replacement was fully integrated with our test processing operations.

***Due to how we recognize revenue, our quarterly operating results are likely to fluctuate.***

We recognize test revenue upon delivery of the patient report to the prescribing physician based on the amount we expect to ultimately realize. We determine the amount we expect to ultimately realize based on payer reimbursement history, contracts, and coverage. Upon ultimate collection, the amount received is compared to the estimates and the amount accrued is adjusted accordingly. We cannot be certain as to when we will receive payment for our diagnostic tests, and we must appeal negative payment decisions, which delays collections. Should judgments underlying estimated reimbursement change or were incorrect at the time we accrued such revenue, our financial results could be negatively impacted in future quarters. As a result, comparing our operating results on a period-to-period basis may not be meaningful. You should not rely on our past results as an indication of our future performance. In addition, these fluctuations in revenue may make it difficult for us, for research analysts and for investors to accurately forecast our revenue and operating results. If our revenue or operating results fall below expectations, the price of our common stock would likely decline.

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

In addition to the need to scale our testing capacity, future growth, including our transition to a multi-product company with international operations, will impose significant added responsibilities on management, including the need to identify, recruit, train and integrate additional employees with the necessary skills to support the growing complexities of our business. Rapid and significant growth may place strain on our administrative, financial and operational infrastructure. Our ability to manage our business and growth will require us to continue to improve our operational, financial and management controls, reporting systems and procedures. We have implemented an internally-developed data warehouse, which is critical to our ability to track our diagnostic services and patient reports delivered to physicians, as well as to support our financial reporting systems. The time and resources required to optimize these systems is uncertain, and failure to complete optimization in a timely and efficient manner could adversely affect our operations. If we are unable to manage our growth effectively, it may be difficult for us to execute our business strategy and our business could be harmed.

***If we are unable to support demand for our commercial tests, our business could suffer.***

As demand for our tests grows, we will need to continue to scale our testing capacity and processing technology, expand customer service, billing and systems processes and enhance our internal quality assurance program. We will also need additional certified laboratory scientists and other scientific and technical personnel to process higher volumes of our tests. We cannot assure you that any increases in scale, related improvements and quality assurance will be successfully implemented or that appropriate personnel will be available. Failure to implement necessary procedures, transition to new processes or hire the necessary personnel could result in higher costs of processing tests, quality control issues or inability to meet demand. There can be no assurance that we will be able to perform our testing on a timely basis at a level consistent with demand, or that our efforts to scale our operations will not negatively affect the quality of test results. If we encounter difficulty meeting market demand or quality standards, our reputation could be harmed and our future prospects and our business could suffer.

***Changes in healthcare policy, including legislation reforming the U.S. healthcare system, may have a material adverse effect on our financial condition and operations.***

The ACA, enacted in March 2010, made changes that significantly affected the pharmaceutical and medical device industries and clinical laboratories. Along with the now-repealed 2.3% excise tax on the sale of certain medical devices sold outside of the retail setting, other significant measures contained in the ACA include, for example, coordination and promotion of research on comparative clinical effectiveness of different technologies and procedures, initiatives to revise Medicare payment methodologies, such as bundling of payments across the continuum of care by providers and physicians, and initiatives to promote quality indicators in payment methodologies. The ACA also includes significant new fraud and abuse measures, including required disclosures of financial arrangements with physician customers, lower thresholds for violations and increasing potential penalties for such violations.

In the beginning of 2017, the U.S. Congress and the Administration took actions to repeal the ACA and indicated an intent to replace it with another act and efforts to repeal or amend the ACA are ongoing. We cannot predict if, or when, the ACA will be repealed or amended, and cannot predict the impact that an amendment or repeal of the ACA will have on our business.

In addition to the ACA, various healthcare reform proposals have also periodically emerged from federal and state governments. For example, in February 2012, Congress passed the Middle Class Tax Relief and Job Creation Act of 2012, which in part reset the clinical laboratory payment rates on the Medicare Clinical Laboratory Fee Schedule, or CLFS, by 2% in 2013. In addition, under the Budget Control Act of 2011, which is effective for dates of service on or after April 1, 2013, Medicare payments, including payments to clinical laboratories, are subject to a reduction of 2% due to the automatic expense reductions (sequester) until fiscal year 2024. Reductions resulting from the Congressional sequester are applied to total claims payment made; however, they do not currently result in a rebasing of the negotiated or established Medicare or Medicaid reimbursement rates.

State legislation on reimbursement applies to Medicaid reimbursement and managed Medicaid reimbursement rates within that state. Some states have passed or proposed legislation that would revise the reimbursement methodology for clinical laboratory payment rates under those Medicaid programs. For example, effective July 2015, California’s Department of Health Care Services implemented a new rate methodology for clinical laboratories and laboratory services. This methodology involves the use of a range of rates that fell between zero and 80% of the calculated California-specific Medicare rate and the calculation of a weighted average (based on units billed) of such rates.

We cannot predict whether future healthcare initiatives will be implemented at the federal or state level or in countries outside of the United States in which we may do business, or the effect any future legislation or regulation will have on us. The taxes imposed by the new federal legislation, cost reduction measures and the expansion in the role of the U.S. government in the healthcare industry may result in decreased revenue, lower reimbursement by payers for our tests or reduced medical procedure volumes, all of which may adversely affect our business, financial condition and results of operations. In addition, sales of our tests outside the United States subject our business to foreign regulatory requirements and cost-reduction measures, which may also change over time.

Ongoing calls for deficit reduction at the federal government level and reforms to programs such as the Medicare program to pay for such reductions may affect the pharmaceutical, medical device and clinical laboratory industries. Currently, clinical laboratory services are excluded from the Medicare Part B co-insurance and co-payment as preventative services. Any requirement for clinical laboratories to collect co-payments from patients may increase our costs and reduce the amount ultimately collected.

CMS bundles payments for clinical laboratory diagnostic tests together with other services performed during hospital outpatient visits under the Hospital Outpatient Prospective Payment System. CMS currently maintains an exemption for molecular pathology tests from this bundling provision. It is possible that this exemption could be removed by CMS in future rule making, which might result in lower reimbursement for tests performed in this setting.

PAMA includes a substantial new payment system for clinical laboratory tests under the CLFS. Under PAMA, laboratories that receive the majority of their Medicare revenues from payments made under the CLFS and the Physician Fee Schedule would report on triennial bases (or annually for advanced diagnostic laboratory tests, or ADLTs), private payer rates and volumes for their tests with specific CPT codes based on final payments made during a set data collection period (the first of which was January 1 through June 30, 2016). We believe that PAMA and its implementing regulations are generally favorable to us. We reported to CMS the data required under PAMA before the March 31, 2017 deadline. The new payment rate for the Afirma genomic classifier based on the volume-weighted median of private payer rates took effect January 1, 2018, increasing from $3,220 to $3,600 through December 31, 2020. In December 2019, through the Further Consolidated Appropriations Act of 2020, Congress delayed the next data reporting period from 2020 to 2021 for final payments made between January 1 and June 30, 2019, extending the applicability of the current rate for Afirma through December 31, 2021. The volume-weighted median of the private payer rates between January 1 and June 30, 2019 will now set the Medicare payment rate for the Afirma classifier from January 1, 2022 through December 31, 2024. There can be no assurance that the payment rate for Afirma or Prosigna will not decrease in the future or that the payment rates for Percepta or Envisia will not be adversely affected by the PAMA law and regulations.

We believe our Afirma genomic classifier as well as our Percepta and Envisia classifiers would be considered ADLTs under PAMA. The initial payment rate (for a period not to exceed nine months) under PAMA for a new ADLT (an ADLT for which payment has not been made under the CLFS prior to January 1, 2018) will be set at the “actual list charge” for the test as reported by the laboratory. Insofar as the actual list charge substantially exceeds private payer rates (by more than 30%), CMS will have the ability to recoup excess payments made during the initial nine-month payment period. We can determine whether to seek ADLT status for our tests, but there can be no assurance that our tests will be designated ADLTs or that the payment rates for our tests will not be adversely affected by such designation.

There have also been recent and substantial changes to the payment structure for physicians, including those passed as part of the Medicare Access and CHIP Reauthorization Act of 2015, or MACRA, which was signed into law on April 16, 2015. MACRA created the Merit-Based Incentive Payment System which, beginning in 2019, more closely aligns physician payments with composite performance on performance metrics similar to three existing incentive programs (i.e., the Physician Quality Reporting System, the Value-based modifier program and the Electronic Health Record Meaningful Use program) and incentivizes physicians to enroll in alternative payment methods. At this time, we do not know whether these changes to the physician payment systems will have any impact on orders or payments for our tests.

In December 2016, Congress passed the 21st Century Cures Act, which, among other things, revised the process for LCDs. Additionally, effective June 11, 2017, a MAC is required to, among other things, publish a summary of the evidence that it considered when developing an LCD, including a list of sources, and an explanation of the rationale that supports the MAC’s determinations. In October 2018, CMS issued additional guidance revising the requirements for the development of LCDs. We cannot predict whether these revisions will delay future LCDs and result in impeded coverage for our test products, which could have a material negative impact on revenue.

Congress is considering legislation to limit balance billing of patients who receive services from out-of-network providers (including laboratories) at in-network facilities and to set a methodology for payment of the out-of-network provider in such circumstances. This legislation, if enacted, could limit our ability to achieve payment in full for our testing services.

***Because of Medicare billing rules, we may not receive reimbursement for all tests provided to Medicare patients.***

Under previous Medicare billing rules, hospitals were required to bill for our tests when performed on Medicare beneficiaries who were hospital outpatients at the time of tissue specimen collection when these tests were ordered less than 14 days following the date of the patient's discharge.

Effective January 1, 2018, CMS revised its billing rules to allow the performing laboratory to bill Medicare directly for molecular pathology tests performed on specimens collected from hospital outpatients, even when those tests are ordered less than 14 days after the date of discharge, if certain conditions are met. We believe that our Afirma, Percepta, and Envisia classifiers, along with Prosigna, should be covered by this policy. Accordingly, we bill Medicare for these tests when we perform them on specimens collected from hospital outpatients and meet the conditions set forth in CMS's revised billing rules.

This change does not apply to tests performed on specimens collected from hospital inpatients. We will continue to bill hospitals for tests performed on specimens collected from hospital inpatients when the test was ordered less than 14 days after the date of discharge.

In the CY 2020 Hospital Outpatient Prospective Payment System Proposed Rule, CMS solicited comments on potential revisions to these billing rules that could have impacted our ability to bill Medicare directly for our Afirma, Percepta, and Envisia classifiers, as well as for Prosigna, when performed on specimens collected from hospital outpatients. Although these changes were not finalized, if CMS makes similar changes in the future, it could negatively impact our business.

In addition, we must maintain CLIA compliance and certification to sell our tests and be eligible to bill for diagnostic services provided to Medicare beneficiaries.

***If the FDA were to begin regulating those of our tests that are not currently regulated, we could incur substantial costs and delays associated with trying to obtain premarket clearance or approval.***

Clinical laboratory tests have long been subject to comprehensive regulations under CLIA, as well as by applicable state laws. Most laboratory developed tests, or LDTs, are not currently subject to regulation under the FDA's enforcement discretion policy, although reagents, instruments, software or components provided by third parties and used to perform LDTs may be subject to regulation. While the FDA maintains its authority to regulate LDTs, it has chosen to exercise its enforcement discretion not to enforce the premarket review and other applicable medical device requirements for LDTs. We believe that the Afirma, Percepta and Envisia classifiers are LDTs that fall under the FDA's enforcement discretion policy. In October 2014, the FDA issued draft guidance, entitled "Framework for Regulatory Oversight of LDTs," proposing a risk-based framework of oversight and a phased-in enforcement of premarket review requirements for most LDTs. In 2016, the FDA announced that it would not be finalizing the guidance.

In January 2017, the FDA issued a "Discussion Paper on Laboratory Developed Tests" following input it received from multiple stakeholders who had commented on its 2014 draft guidance. The FDA specifically states in its Discussion Paper that the proposals contained in the document do not represent a final version of the LDT draft guidance documents and are only designed to provide a possible approach to spark further dialogue. The suggested LDT framework could grandfather many types of LDTs without requiring new premarket review or quality management requirements. It also suggests a four-year phased implementation of the premarket review requirements for some types of tests. In a December 2018 statement, the FDA said that there is a need for “a unified approach to the regulation of in vitro clinical tests to protect patient safety, support innovation, and keep pace with the rapidly evolving technology that’s helping us find new treatments for disease.” The FDA listed key principles of an approach it would support.

In March 2017, a draft bill on the regulation of LDTs, entitled "The Diagnostics Accuracy and Innovation Act", or DAIA, was released for discussion. In December 2018, the sponsors of DAIA released a new version of the legislation called the “Verifying Accurate, Leading-edge IVCT Development Act, or VALID Act. The VALID Act proposes a risk-based approach to regulate LDTs and creates a new in vitro clinical test category, which includes LDTs, and a regulatory structure under the FDA. As proposed, the bill would create a precertification program for lower risk tests not otherwise required to go through premarket review. It would grandfather existing tests but would allow the FDA to subject otherwise grandfathered tests to premarket review under certain conditions. We cannot predict whether this draft bill will become legislation and cannot quantify the effect of this draft bill on our business.

If the FDA were to require us to seek clearance or approval for our existing tests or any of our future products for clinical use, we may not be able to obtain such approvals on a timely basis, or at all. While we believe our Afirma, Percepta and Envisia classifiers would likely qualify for the “grandfathered” tests treatment, there can be no assurance of what the FDA might ultimately require if it issued final guidance. If premarket reviews were required, our business could be negatively impacted if we were required to stop selling our products pending their clearance or approval. In addition, the launch of any new products that we develop could be delayed by the implementation of future FDA guidance. The cost of complying with premarket review requirements, including obtaining clinical data, could be significant. In addition, future regulation by the FDA could subject our business to further regulatory risks and costs. Failure to comply with applicable regulatory requirements of the FDA could result in enforcement action, including receiving untitled or warning letters, fines, injunctions, or civil or criminal penalties. Any such enforcement action would have a material adverse effect on our business, financial condition and operations. In addition, our sample collection containers are listed as Class I devices with the FDA. If the FDA were to determine that they are not Class I devices, we would be required to file 510(k) applications and obtain FDA clearance to use the containers, which could be time consuming and expensive.

Some of the materials we use for our tests and that we may use for future tests are labeled for research-use only, or RUO, or investigational-use only, or IUO. In November 2013, the FDA finalized guidance regarding the sale and use of products labeled RUO or IUO. Among other things, the guidance advises that the FDA continues to be concerned about distribution of research or investigational-use only products intended for clinical diagnostic use and that the manufacturer's objective intent for the product's intended use will be determined by examining the totality of circumstances, including advertising, instructions for clinical interpretation, presentations that describe clinical use, and specialized technical support, surrounding the distribution of the product in question. The FDA has advised that if evidence demonstrates that a product is inappropriately labeled for research or investigational-use only, the device would be considered misbranded and adulterated within the meaning of the Federal Food, Drug and Cosmetic Act. Some of the reagents, instruments, software or components obtained by us from suppliers for use in our products are currently labeled as RUO or IUO. If the FDA were to determine that any of these reagents, instruments, software or components are improperly labeled RUO or IUO and undertake enforcement actions, some of our suppliers might cease selling these reagents, instruments, software or components to us, and any failure to obtain an acceptable substitute could significantly and adversely affect our business, financial condition and results of operations, including increasing the cost of testing or delaying, limiting or prohibiting the purchase of reagents, instruments, software or components necessary to perform testing.

***Obtaining marketing authorization by the FDA and foreign regulatory authorities for our diagnostic tests will take significant time and require significant research, development and clinical study expenditures and ultimately may not succeed.***

Before we begin to label and market some of our products for use as clinical diagnostics in the United States, unless an exemption applies, we are required to obtain clearance from FDA by submitting a premarket notification under section 510(k) of the FDC Act, or 510(k), or approval from FDA by submitting a PMA. We may also be able to obtain marketing authorization through a de novo classification process rather than through a PMA if the 510(k) pathway is not available. In September 2013, Prosigna obtained FDA 510(k) clearance as a prognostic indicator for distant recurrence-free survival at ten years in post-menopausal women with Stage I/II lymph node-negative or Stage II lymph node-positive (1-3 positive nodes), hormone receptor-positive breast cancer to be treated with adjuvant endocrine therapy alone, when used in conjunction with other clinicopathological factors after they have undergone surgery in conjunction with locoregional treatment and consistent with the standard of care.

In August 2014, the FDA issued a final guidance document titled In Vitro Companion Diagnostic Devices. In the guidance, FDA defined an IVD companion diagnostic device as an in vitro diagnostic device that provides information that is essential for the safe and effective use of a corresponding therapeutic product. The use of an IVD companion diagnostic device with a therapeutic product is stipulated in the instructions for use in the labeling of both the diagnostic device and the corresponding therapeutic product, including the labeling of any generic equivalents of the therapeutic product. FDA stated that an IVD companion diagnostic should be submitted for review and approved or cleared through an appropriate device submission contemporaneously with the review and approval of the therapeutic product to facilitate concurrent review. The FDA guidance also stated that while there may be cases when a companion diagnostic could come to market through the 510(k) pathway, FDA expects that most companion diagnostics will be Class III devices. Class III devices generally require the approval of a PMA before they can be marketed. An IVD diagnostic device that is not a companion diagnostic device because it is not essential for the safe and effective use of a corresponding therapeutic product, may still be beneficial for use with a therapeutic product but may not be identified in the labeling of the therapeutic product. It is possible that revenue from a cleared or approved beneficial or complementary IVD diagnostic device may be less than revenue from a cleared or approved IVD companion diagnostic device. There is no assurance that we would be able to obtain clearance or approval for any of our diagnostic devices in development as a companion diagnostic device.

Any marketing authorization we obtain for any future device product would be subject to regulatory requirements that would affect how we are able to market and sell the device. The FDC Act and FDA regulations place considerable requirements on our products, including, but not limited to, compliance with the QSR, establishment registration and product listing with the FDA, and compliance with labeling, marketing, complaint handling, medical device reporting requirements, and reporting certain corrections and removals. Obtaining FDA clearance or approval for diagnostics can be expensive and uncertain, generally may take several months to several years, and generally requires detailed and comprehensive scientific and clinical data, as well as compliance with FDA regulations for investigational devices. In addition, we have limited experience in obtaining PMA approval from the FDA and are therefore supplementing our operational capabilities to manage the more complex processes needed to obtain and maintain PMAs. Notwithstanding the expense, these efforts may never result in FDA clearance or approval. Even if we were to obtain marketing authorization, it may not be for the uses we believe are important or commercially attractive, in which case we would not market our product for those uses.

Sales of our diagnostic products outside the United States are subject to foreign regulatory requirements governing clinical studies, vigilance reporting, marketing approval, manufacturing, regulatory inspections, product licensing, pricing and reimbursement. These regulatory requirements vary greatly from country to country. As a result, the time required to obtain approvals outside the United States may differ from that required to obtain FDA marketing authorization, and we may not be able to obtain foreign regulatory approvals on a timely basis or at all. Marketing authorization from the FDA does not ensure approval by regulatory authorities in other countries, and approval by any foreign regulatory authority does not ensure marketing authorization by regulatory authorities in other countries or by the FDA. Foreign regulatory authorities could require additional testing beyond what the FDA requires. In addition, the FDC Act imposes requirements on the export of medical devices, such as labeling requirements, and foreign governments impose requirements on the import of medical devices from the United States. Failure to comply with these regulatory requirements or to obtain required approvals, clearances, and export certifications could impair our ability to commercialize our diagnostic products outside of the United States.

***If we are unable to obtain marketing authorizations to market Prosigna in additional countries or if regulatory limitations are placed on our diagnostic kit products, our business and growth will be harmed.***

FDA cleared the Prosigna test for marketing in the United States; Prosigna also has a CE mark which permits us to market the test in the European Union; and Prosigna received marketing authorizations in selected other jurisdictions. We intend to seek regulatory authorizations for Prosigna in other jurisdictions and, potentially, for other indications.

In addition, pursuant to our collaborations with pharmaceutical companies for the development of companion diagnostic tests for use with their drugs, we are responsible for obtaining regulatory authorizations to use the companion diagnostic tests in clinical trials as well as the marketing authorizations to sell the companion diagnostic tests following completion of such trials. Some of the compensation we expect to receive pursuant to these collaborations is based on the receipt of marketing authorizations. Any failure to obtain marketing authorizations for our diagnostic kits in a particular jurisdiction may also reduce sales of our nCounter systems for clinical use in that jurisdiction, as the lack of a robust menu of available diagnostic tests would make those systems less attractive to testing laboratories.

We cannot assure investors that we will be successful in obtaining regulatory clearances, approvals, or marketing authorizations. If we do not obtain regulatory clearances, approvals, or marketing authorizations for future kit products or expand future indications for diagnostic purposes, if additional regulatory limitations are placed on our kit products or if we fail to successfully commercialize such products, the market potential for our diagnostic kit products would be constrained, and our business and growth prospects would be adversely affected.

***We are subject to ongoing and extensive regulatory requirements, and our failure to comply with these requirements could substantially harm our business.***

Certain of our products are regulated as in vitro diagnostic medical devices, including Prosigna and the nCounter FLEX Analysis System. Accordingly, we and certain of our contract manufacturers are subject to ongoing International Organization for Standardization, or ISO, obligations as well as requirements under the FDC Act and device regulations enforced by the FDA and other statutory and regulatory requirements enforced by other government authorities. These may include routine inspections by Notified Bodies, FDA, and other health authorities, of our manufacturing facilities and our records for compliance with standards such as ISO 13485 and QSR regulations, which establish extensive requirements for quality assurance and control as well as manufacturing and change control procedures, among other things. We are also subject to other regulatory obligations, such as registration of our company offices and facilities and the listing of our devices with the FDA; continued adverse event and malfunction reporting; reporting certain corrections and removals; and labeling and promotional requirements. Other regulatory bodies may also issue guidelines and regulations that could impact the development of our products, including companion diagnostic tests. For example, the European Medicines Agency, a European Union agency which is responsible for the scientific evaluation of medicines used in the European Union, recently launched an initiative to determine guidelines for the use of genomic biomarkers in the development and life-cycle of drugs. On April 5, 2017, the European Union Parliament passed Regulation (EU) 2017/746, referred to as the IVD Device Regulation, or IVDR, which increases the regulatory requirements applicable to in vitro diagnostics in the EU and would require that we re-classify and obtain approval, registration, or clearance for our existing CE-marked IVD products within a five-year grace period (by May 25, 2022).

We may also be subject to additional FDA or global regulatory authority post-marketing obligations or requirements by the FDA or global regulatory authority to change our current product classifications which would impose additional regulatory obligations on us. The promotional claims we can make for Prosigna are limited to the indications for use in the United States as cleared by FDA or outside the United States as authorized by the applicable regulatory authority. If we are not able to maintain regulatory compliance, we may not be permitted to market our medical device products and/or may be subject

to enforcement actions by the FDA or other governmental authorities such as the issuance of warning or untitled letters, fines, injunctions, and civil penalties; recall or seizure of products; operating restrictions; and criminal prosecution. In addition, we may be subject to similar regulatory regimes of foreign jurisdictions as we continue to commercialize our products in new markets outside of the United States and Europe. Adverse Notified Body, EU Competent Authority or FDA or global regulatory authority action in any of these areas could significantly increase our expenses and limit our revenue and profitability.

***If we are unable to compete successfully, we may be unable to increase or sustain our revenue or achieve profitability.***

Our principal competition for our tests comes from traditional methods used by physicians to diagnose and manage patient care decisions. For example, with our Afirma genomic classifier, practice guidelines in the United States have historically recommended that patients with indeterminate diagnoses from cytopathology results be considered for surgery to remove all or part of the thyroid to rule out cancer. This practice has been the standard of care in the United States for many years, and we need to continue to educate physicians about the benefits of the Afirma genomic classifier to change clinical practice.

We also face competition from companies and academic institutions that use next generation sequencing technology or other methods to measure mutational markers such as BRAF and KRAS, along with numerous other mutations. These organizations include Interpace Diagnostics Group, Inc., CBLPath, Inc./University of Pittsburgh Medical Center and others who are developing new products or technologies that may compete with our tests. In the future, we may also face competition from companies developing new products or technologies.

We believe our primary competition in pulmonology with our Percepta and Envisia classifiers will similarly come from traditional methods used by physicians to diagnose the related diseases. For the Percepta test, we expect competition from companies focused on lung cancer such as Oncocyte Corporation and Biodesix, Inc. We believe our principal competitor in the breast cancer diagnostics market is Exact Sciences, Inc. (having combined with Genomic Health, Inc.), which currently commands a substantial majority of the market. As we expand our portfolio of tests to address clinical questions across the clinical care continuum, we may also face competition from companies focused on screening at-risk patients for cancer or companies informing treatment decisions such as Guardant Health or GRAIL. Competition could also emerge using alternative samples, such as blood, urine or sputum. However, such “liquid biopsies” are currently being used to gauge risk of recurrence or response to treatment in patients already diagnosed with lung cancer.

In general, we also face competition from commercial laboratories, such as Laboratory Corporation of America Holdings and Sonic Healthcare USA, with strong infrastructure to support the commercialization of diagnostic services. We face potential competition from companies such as Illumina, Inc. and Thermo Fisher Scientific Inc., both of which have entered the clinical diagnostics market. Other potential competitors include companies that develop diagnostic products, such as Roche Diagnostics, a division of Roche Holding Ltd, Siemens AG and Qiagen N.V.

In addition, competitors may develop their own versions of our solutions in countries we may seek to enter where we do not have patents or where our intellectual property rights are not recognized and compete with us in those countries, including encouraging the use of their solutions by physicians in other countries.

To compete successfully, we must be able to demonstrate, among other things, that our diagnostic test results are accurate and cost effective, and we must secure a meaningful level of reimbursement for our products.

Many of our potential competitors have widespread brand recognition and substantially greater financial, technical and research and development resources, and selling and marketing capabilities than we do. Others may develop products with prices lower than ours that could be viewed by physicians and payers as functionally equivalent to our solutions, or offer solutions at prices designed to promote market penetration, which could force us to lower the list price of our solutions and affect our ability to achieve profitability. If we are unable to change clinical practice in a meaningful way or compete successfully against current and future competitors, we may be unable to increase market acceptance and sales of our products, which could prevent us from increasing our revenue or achieving profitability and could cause the market price of our common stock to decline. As we add new tests and services, we will face many of these same competitive risks for these new tests.

***The loss of members of our senior management team or our inability to attract and retain key personnel could adversely affect our business.***

Our success depends largely on the skills, experience and performance of key members of our executive management team and others in key management positions. The efforts of each of these persons together will be critical to us as we continue

to develop our technologies and test processes and focus on our growth. If we were to lose one or more of these key employees, including due to illness resulting from COVID-19, we may experience difficulties in competing effectively, developing our technologies and implementing our business strategy.

In addition, our research and development programs and commercial laboratory operations depend on our ability to attract and retain highly skilled scientists. We may not be able to attract or retain qualified scientists and technicians in the future due to the intense competition for qualified personnel among life science businesses, particularly in the San Francisco Bay Area. Our success in the development and commercialization of advanced diagnostics requires a significant medical and clinical staff to conduct studies and educate physicians and payers on the merits of our tests in order to achieve adoption and reimbursement. We are in a highly competitive industry to attract and retain this talent. Additionally, our success depends on our ability to attract and retain qualified sales people. We recently significantly expanded our sales force as we invest in our multi-product sales strategy, which includes assignment of a single contact to successfully develop and implement relationships with our customers. There can be no assurance that we will be successful in maintaining and growing our business. Additionally, as we increase our sales channels for new tests we commercialize, including the Percepta and Envisia tests, or acquire, such as Prosigna, we may have difficulties recruiting and training additional sales personnel or retaining qualified salespeople, which could cause a delay or decline in the rate of adoption of our tests. As a public company located in the San Francisco Bay Area, we also face intense competition for highly skilled finance and accounting personnel. If we are unable to attract and retain finance and accounting personnel experienced in public company financial reporting, we risk being unable to close our books and file our public documents on a timely basis. Finally, our business requires specialized capabilities in reimbursement, billing, and other areas and there may be a shortage of qualified individuals. If we are not able to attract and retain the necessary personnel to accomplish our business objectives, we may experience constraints that could adversely affect our ability to support our research and development, clinical laboratory, sales and reimbursement, billing and finance efforts. All of our employees are at will, which means that either we or the employee may terminate their employment at any time. We do not carry key man insurance for any of our employees.

***Billing for our diagnostic tests is complex, and we must dedicate substantial time and resources to the billing process to be paid.***

Billing for clinical laboratory testing services is complex, time-consuming and expensive. Depending on the billing arrangement and applicable law, we bill various payers, including Medicare, insurance companies and patients, all of which have different billing requirements. We generally bill third-party payers for our diagnostic tests and pursue reimbursement on a case-by-case basis where pricing contracts are not in place. To the extent laws or contracts require us to bill patient co-payments or co-insurance, we must also comply with these requirements. We may also face increased risk in our collection efforts, including potential write-offs of accounts receivable and long collection cycles, which could adversely affect our business, results of operations and financial condition.

Several factors make the billing process complex, including:

- differences between the list price for our tests and the reimbursement rates of payers;
- compliance with complex federal and state regulations related to billing government payers, such as Medicare and Medicaid, including requirements to have an active CLIA certificate;
- risk of government audits related to billing Medicare and other government payers;
- disputes among payers as to which party is responsible for payment;
- differences in coverage and in information and billing requirements among payers, including the need for prior authorization and/or advanced notification;
- the effect of patient co-payments or co-insurance;
- changes to billing codes used for our tests;
- incorrect or missing billing information; and
- the resources required to manage the billing and claims appeals process.

We use standard industry billing codes, known as CPT codes, to bill for cytopathology. In addition, we use the CPT code 81545 to bill for our Afirma classifier. CPT codes do not exist for our other proprietary molecular diagnostic tests. Therefore, until such time that we are assigned and are able to use a designated CPT code specific to Percepta and Envisia, we use "unlisted" codes for claim submissions, which can lead to delays in payers adjudicating our claims or denying payment altogether. Moreover, these codes can change over time. When codes change, there is a risk of an error being made in the claim adjudication process. These errors can occur with claims submission, third-party transmission or in the processing of the claim by the payer. Claim adjudication errors may result in a delay in payment processing or a reduction in the amount of the payment received. Coding changes, therefore, may have an adverse effect on our revenues. Even when we receive a designated CPT code specific to our tests, such as the 81545 code for the Afirma GEC that became effective January 1, 2016, there can be no assurance that payers will recognize these codes in a timely manner or that the process of transitioning to such a code and updating their billing systems and ours will not result in errors, delays in payments and a related increase in accounts receivable balances.

As we introduce new tests, we will need to add new codes to our billing process as well as our financial reporting systems. Failure or delays in effecting these changes in external billing and internal systems and processes could negatively affect our collection rates, revenue and cost of collecting.

Correct coding is subject to the coding policies of the American Medical Association CPT Editorial Panel, or AMA CPT. With respect to claims submitted to Medicare and Medicaid, it is also subject to coding policies developed through the National Correct Coding Initiative, or NCCI. Other payers may develop their own payer-specific coding policies. The broader coding policies of the AMA CPT, NCCI, and other payers are subject to change. For instance, the NCCI recently adopted an update to its Coding Policy Manual effective January 1, 2019, to limit instances when multiple codes may be billed for molecular pathology testing. Although the NCCI appears to have moderated this change in its updates effective January 1, 2020, such coding policy changes may negatively affect our revenues and cash flow.

Additionally, our billing activities require us to implement compliance procedures and oversight, train and monitor our employees, challenge coverage and payment denials, assist patients in appealing claims, and undertake internal audits to evaluate compliance with applicable laws and regulations as well as internal compliance policies and procedures. Payers also conduct external audits to evaluate payments, which add further complexity to the billing process. If the payer makes an overpayment determination, there is a risk that we may be required to return some portion of prior payments we have received. Additionally, the ACA established a requirement for providers and suppliers to report and return any overpayments received from government payers under the Medicare and Medicaid programs within 60 days of identification. Failure to identify and return such overpayments exposes the provider or supplier to liability under federal false claims laws. These billing complexities, and the related uncertainty in obtaining payment for our tests, could negatively affect our revenue and cash flow, our ability to achieve profitability, and the consistency and comparability of our results of operations.

***We rely on a third-party provider to transmit claims to payers, and any delay in transmitting claims could have an adverse effect on our revenue.***

While we manage the overall processing of claims, we rely on a third-party provider to transmit the actual claims to payers based on the specific payer billing format. We have previously experienced delays in claims processing when our third-party provider made changes to its invoicing system, and again when it did not submit claims to payers within the timeframe we require. Additionally, coding for diagnostic tests may change, and such changes may cause short-term billing errors that may take significant time to resolve. If claims are not submitted to payers on a timely basis or are erroneously submitted, or if we are required to switch to a different provider to handle claim submissions, we may experience delays in our ability to process these claims and receipt of payments from payers, or possibly denial of claims for lack of timely submission, which would have an adverse effect on our revenue and our business.

***If our internal sales force is less successful than anticipated, our business expansion plans could suffer and our ability to generate revenues could be diminished. In addition, we have limited history selling our molecular diagnostics tests on a direct basis and our limited history makes forecasting difficult.***

We acquired several international sales employees from NanoString, and expect to build upon this team as we offer additional tests internationally in the future. If our internal sales force is not successful, however, or new additions to our sales team fail to gain traction among our customers, we may not be able to increase market awareness and sales of our molecular diagnostic tests. If we fail to establish our molecular diagnostic tests in the marketplace, it could have a negative effect on our ability to sell subsequent molecular diagnostic tests and hinder the desired expansion of our business. We have growing, however limited, historical experience forecasting the direct sales of our molecular diagnostics products. Our ability to produce test volumes that meet customer demand is dependent upon our ability to forecast accurately and plan production capacities accordingly.

***Developing new products involves a lengthy and complex process, and we may not be able to commercialize on a timely basis, or at all, other products we are developing.***

We continually seek to develop enhancements to our current test offerings and additional diagnostic solutions that requires us to devote considerable resources to research and development. There can be no assurance that we will be able to identify other diseases that can be effectively addressed with our molecular cytology platform. In addition, if we identify such diseases, we may not be able to develop products with the diagnostic accuracy necessary to be clinically useful and commercially successful. We may face challenges obtaining sufficient numbers of samples to validate a genomic signature for a molecular diagnostic product. After launching new products, we still must complete studies that meet the clinical evidence required to obtain reimbursement. Moreover, we may experience delays in the development and introduction of new products due to the effects of the current COVID-19 outbreak.

In order to develop and commercialize diagnostic tests, we need to:

- expend significant funds to conduct substantial research and development;
- conduct successful analytical and clinical studies;
- scale our laboratory processes to accommodate new tests; and
- build the commercial infrastructure to market and sell new products.

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

- failure to identify a genomic signature in biomarker discovery;
- inability to secure sufficient numbers of samples at an acceptable cost and on an acceptable timeframe to conduct analytical and clinical studies; or
- failure of clinical validation studies to support the effectiveness of the test.

Typically, few research and development projects result in commercial products, and success in early clinical studies often is not replicated in later studies. At any point, we may abandon development of a product candidate or we may be required to expend considerable resources repeating clinical studies, which would adversely affect the timing for generating potential revenue from a new product and our ability to invest in other products in our pipeline. If a clinical validation study fails to demonstrate the prospectively-defined endpoints of the study or if we fail to sufficiently demonstrate analytical validity, we might choose to abandon the development of the product, which could harm our business. In addition, competitors may develop and commercialize competing products or technologies faster than us or at a lower cost.

***If we cannot enter into new clinical study collaborations, our product development and subsequent commercialization could be delayed.***

In the past, we have entered into clinical study collaborations, and our success in the future depends in part on our ability to enter into additional collaborations with highly regarded institutions. This can be difficult due to internal and external constraints placed on these organizations. Some organizations may limit the number of collaborations they have with any one company so as to not be perceived as biased or conflicted. Organizations may also have insufficient administrative and related infrastructure to enable collaboration with many companies at once, which can extend the time it takes to develop, negotiate and implement a collaboration. Moreover, it may take longer to obtain the samples we need which could delay our trials, publications, and product launches and reimbursement. Additionally, organizations often insist on retaining the rights to publish

the clinical data resulting from the collaboration. The publication of clinical data in peer-reviewed journals is a crucial step in commercializing and obtaining reimbursement for our diagnostic tests, and our inability to control when and if results are published may delay or limit our ability to derive sufficient revenue from them.

***If we are unable to develop products to keep pace with rapid technological, medical and scientific change, our operating results and competitive position could be harmed.***

In recent years, there have been numerous advances in technologies relating to diagnostics, particularly diagnostics that are based on genomic information. These advances require us to continuously develop our technology and to work to develop new solutions to keep pace with evolving standards of care. Our solutions could become obsolete unless we continually innovate and expand our product offerings to include new clinical applications. If we are unable to develop new products or to demonstrate the applicability of our products for other diseases, our sales could decline and our competitive position could be harmed.

***Our Loan and Security Agreement provides our lenders with a first-priority lien against substantially all of our assets, excluding our intellectual property, and contains financial covenants and other restrictions on our actions, which could limit our operational flexibility and otherwise adversely affect our financial condition.***

Our Loan and Security Agreement restricts our ability to, among other things, incur liens, make investments, incur indebtedness, merge with or acquire other entities, dispose of assets, make dividends or other distributions to holders of its equity interests, engage in any new line of business, or enter into certain transactions with affiliates, in each case subject to certain exceptions. It also requires us to achieve certain revenue levels tested quarterly on a trailing twelve-month basis. However, failure to maintain the revenue levels will not be considered a default if the sum of our unrestricted cash and cash equivalents maintained with Silicon Valley Bank and amount available under the revolving line of credit is at least $40.0 million. Our ability to comply with these and other covenants is dependent upon a number of factors, some of which are beyond our control.

Our failure to comply with the financial covenants, or the occurrence of other events specified in our Loan and Security Agreement, could result in an event of default under the Loan and Security Agreement, which would give our lenders the right to terminate their commitments to provide additional loans under the Loan and Security Agreement and to declare all borrowings outstanding, together with accrued and unpaid interest and fees, to be immediately due and payable. In addition, we have granted our lenders a first-priority lien against all of our assets, excluding our intellectual property, as collateral. Failure to comply with the covenants or other restrictions in the Loan and Security Agreement could result in a default. If the debt under our Loan and Security Agreement was to be accelerated, we may not have sufficient cash on hand or be able to sell sufficient collateral to repay it, which would have an immediate adverse effect on our business and operating results. This could potentially cause us to cease operations and result in a complete loss of your investment in our common stock.

***Complying with numerous statutes and regulations pertaining to our business is an expensive and time-consuming process, and any failure to comply could result in substantial penalties.***

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

- the Federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which established comprehensive federal standards with respect to the privacy and security of protected health information and requirements for the use of certain standardized electronic transactions, and amendments made in 2013 to HIPAA under the Health Information Technology for Economic and Clinical Health Act, or HITECH, which strengthen and expand HIPAA privacy and security compliance requirements, increase penalties for violators, extend enforcement authority to state attorneys general, and impose requirements for breach notification;

- Medicare billing and payment regulations applicable to clinical laboratories, including requirements to have an active CLIA certificate;

- the Federal Anti-kickback Statute (and state equivalents), which prohibits knowingly and willfully offering, paying, soliciting, or receiving remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing, arranging for, or recommending of an item or service that is reimbursable, in whole or in part, by a federal healthcare program;

- the Eliminating Kickbacks in Recovery Act of 2018, which prohibits the solicitation, receipt, payment or offering of any remuneration in return for referring a patient or patronage to a recovery home, clinical treatment facility, or laboratory for services covered by both government and private payers;

- the Federal Stark physician self-referral law (and state equivalents), which prohibits a physician from making a referral for certain designated health services covered by the Medicare program, including laboratory and pathology services, if the physician or an immediate family member has a financial relationship with the entity providing the designated health services, unless the financial relationship falls within an applicable exception to the prohibition;

- the Federal Civil Monetary Penalties Law, which prohibits, among other things, the offering or transfer of remuneration to a Medicare or state health care program beneficiary if the person knows or should know it is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of services reimbursable by Medicare or a state health care program, unless an exception applies;

- the Federal False Claims Act, which imposes liability on any person or entity who knowingly presents, or causes to be presented, a false, fictitious, or fraudulent claim for payment to the federal government;

- other federal and state fraud and abuse laws, such as anti-kickback laws, prohibitions on self-referral, fee-splitting restrictions, prohibitions on the provision of products at no or discounted cost to induce physician or patient adoption, and false claims acts, which may extend to services reimbursable by any third-party payer, including private insurers;

- the prohibition on reassignment of Medicare claims, which, subject to certain exceptions, precludes the reassignment of Medicare claims to any other party;

- the Protecting Access to Medicare Act of 2014, which requires us to report private payer rates and test volumes for specific CPT codes on a triennial basis and imposes penalties for failures to report, omissions, or misrepresentations;

- the rules regarding billing for diagnostic tests reimbursable by the Medicare program, which prohibit a physician or other supplier from marking up the price of the technical component or professional component of a diagnostic test ordered by the physician or other supplier and supervised or performed by a physician who does not "share a practice" with the billing physician or supplier;

- state laws that prohibit other specified practices related to billing such as billing physicians for testing that they order, waiving co-insurance, co-payments, deductibles, and other amounts owed by patients, and billing a state Medicaid program at a price that is higher than what is charged to other payers;

- the Foreign Corrupt Practices Act of 1977, and other similar laws, which apply to our international activities;

- unclaimed property (escheat) laws and regulations, which may require us to turn over to governmental authorities the property of others held by us that has been unclaimed for a specified period of time; and

- enforcing our intellectual property rights.

We have adopted policies and procedures designed to comply with applicable laws and regulations. In the ordinary course of our business, we conduct internal reviews of our compliance with these laws. Our compliance with some of these laws and regulations is also subject to governmental review. The growth of our business and sales organization and our expansion outside of the United States may increase the potential of violating these laws or our internal policies and procedures. We believe that we are in material compliance with all statutory and regulatory requirements, but there is a risk that one or more government agencies could take a contrary position.

In recent years U.S. Attorneys' Offices have increased scrutiny of the healthcare industry, as have Congress, the Department of Justice, the Department of Health and Human Services' Office of the Inspector General and the Department of Defense. These bodies have all issued subpoenas and other requests for information to conduct investigations of, and commenced civil and criminal litigation against, healthcare companies based on financial arrangements with health care providers, regulatory compliance, product promotional practices and documentation, and coding and billing practices.

Whistleblowers have filed numerous qui tam lawsuits against healthcare companies under the federal and state False Claims Acts in recent years, in part because the whistleblower can receive a portion of the government's recovery under such suits.

These laws and regulations are complex and are subject to interpretation by the courts and by government agencies. If one or more such agencies alleges that we may be in violation of any of these requirements, regardless of the outcome, it could damage our reputation and adversely affect important business relationships with third parties, including managed care organizations and other commercial third-party payers. Any action brought against us for violation of these or other laws or regulations, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. If our operations are found to be in violation of any of these laws and regulations, we may be subject to any applicable penalty associated with the violation, including civil and criminal penalties, damages and fines, we could be required to refund payments received by us, and we could be required to curtail or cease our operations. Any of the foregoing consequences could seriously harm our business and our financial results.

***If we use hazardous materials in a manner that causes contamination or injury, we could be liable for resulting damages.***

We are subject to federal, state and local laws, rules and regulations governing the use, discharge, storage, handling and disposal of biological material, chemicals and waste. We cannot eliminate the risk of accidental contamination or injury to employees or third parties from the use, storage, handling or disposal of these materials. In the event of contamination or injury, we could be held liable for any resulting damages, remediation costs and any related penalties or fines, and any liability could exceed our resources or any applicable insurance coverage we may have. The cost of compliance with these laws and regulations may become significant, and our failure to comply may result in substantial fines or other consequences, and either could negatively affect our operating results.

***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 includes international expansion in select countries, and may include developing and maintaining physician outreach and education capabilities outside of the United States, establishing agreements with laboratories, and expanding our relationships with international payers. Doing business internationally involves a number of risks, including:

- multiple, conflicting and changing laws and regulations such as tax laws, privacy laws, export and import restrictions, employment laws, regulatory requirements and other governmental approvals, permits and licenses;
- failure by us to obtain regulatory approvals where required for the use of our solutions in various countries;
- complexities associated with managing multiple payer reimbursement regimes, government payers or patient self-pay systems;
- logistics and regulations associated with shipping tissue samples, including infrastructure conditions and transportation delays;
- challenges associated with establishing laboratory partners, including proper sample collection techniques, management of supplies, sample logistics, billing and promotional activities;
- limits on our ability to penetrate international markets if we are not able to process tests locally;
- financial risks, such as longer payment cycles, difficulty in collecting from payers, the effect of local and regional financial crises, and exposure to foreign currency exchange rate fluctuations;
- natural disasters, political and economic instability, including wars, terrorism, and political unrest, outbreak of disease, including COVID-19, boycotts, curtailment of trade and other business restrictions; and
- regulatory and compliance risks that relate to maintaining accurate information and control over activities that may fall within the purview of the Foreign Corrupt Practices Act of 1977, including both its books and records provisions and 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.

***Our reliance on distributors for sales of our products outside of the United States, and on clinical laboratories for delivery of Prosigna testing services, could limit or prevent us from selling our products and impact our revenue.***

We have established distribution agreements for our nCounter FLEX Analysis System and related consumable products in certain countries where we do not sell directly. We intend to continue to grow our business internationally, and to do so we must attract additional distributors and retain existing distributors to maximize the commercial opportunity for our products. There is no guarantee that we will be successful in attracting or retaining desirable sales and distribution partners or that we will be able to enter into such arrangements on favorable terms. Distributors may not commit the necessary resources to market and sell our products to the level of our expectations or may choose to favor marketing the products of our competitors. If current or future distributors do not perform adequately, or we are unable to enter into effective arrangements with distributors in particular geographic areas, we may not realize long-term international revenue growth.

Similarly, we or our distributors have entered into agreements with clinical laboratories globally to provide Prosigna testing services. We do not provide testing services directly and, thus, we are reliant on these clinical laboratories to actively promote and sell Prosigna testing services. These clinical laboratories may take longer than anticipated to begin offering Prosigna testing services and may not commit the necessary resources to market and sell Prosigna testing services to the level of our expectations. Furthermore, we intend to contract with additional clinical laboratories to offer Prosigna testing services, including physician-owned laboratories, and we may be unsuccessful in attracting and contracting with new clinical laboratory providers. If current or future Prosigna testing service providers do not perform adequately, or we are unable to enter into contracts with additional clinical laboratories to provide Prosigna testing services, we may not be successful selling Prosigna and our future revenue prospects may be adversely affected.

***If we are sued for product liability or errors and omissions liability, we could face substantial liabilities that exceed our resources.***

The marketing, sale and use of our current or future tests could lead to product liability claims if someone were to allege that the tests failed to perform as they were designed. We may also be subject to liability for errors in the results we provide to physicians or for a misunderstanding of, or inappropriate reliance upon, the information we provide. Our Afirma classifiers are performed on FNA samples that are diagnosed as indeterminate by standard cytopathology review. We report results as benign or suspicious to the prescribing physician. Under certain circumstances, we might report a result as benign that later proves to have been malignant. This could be the result of the physician having poor nodule sampling in collecting the FNA, performing the FNA on a different nodule than the one that is malignant or failure of the classifier to perform as intended. We may also be subject to similar types of claims related to our Percepta, Envisia and Prosigna tests, as well as tests we may develop or acquire in the future. A product liability or errors and omissions liability claim could result in substantial damages and be costly and time consuming for us to defend. Although we maintain product liability and errors and omissions insurance, we cannot assure you that our insurance would fully protect us from the financial impact of defending against these types of claims or any judgments, fines or settlement costs arising out of any such claims. Any product liability or errors and omissions liability claim brought against us, with or without merit, could increase our insurance rates or prevent us from securing insurance coverage in the future. Additionally, any product liability lawsuit could cause injury to our reputation or cause us to suspend sales of our products and solutions. The occurrence of any of these events could have an adverse effect on our business and results of operations.

***Our business is subject to the risk of disruptions caused by pandemics, political events, war, terrorism, earthquakes, fire, power outages, floods, and other catastrophic events.***

War, terrorism, geopolitical uncertainties, trade restrictions, public health issues, natural disasters and other catastrophic events may cause damage or disruption to the economy and commerce on a global, regional or country-specific basis, and could disrupt supply or delivery of, or demand for, our products. For example, the recent COVID-19 outbreak, could have a negative effect on consumer confidence and spending, and other impacts, which could adversely affect our business.

***If a catastrophe strikes either of our laboratories or if either of our laboratories becomes inoperable for any other reason, we will be unable to perform our testing services and our business will be harmed.***

We perform all of the Afirma, Percepta and Envisia genomic classifier testing at our laboratory in South San Francisco, California, near major earthquake faults known for seismic activity. Our laboratory in Austin, Texas accepts and stores the majority of our Afirma FNA samples pending transfer to our California laboratory for genomic test processing. The laboratories and equipment we use to perform our tests would be costly to replace and could require substantial lead time to replace and qualify for use if they became inoperable. Either of our facilities may be harmed or rendered inoperable by natural

or man-made disasters, including earthquakes, flooding and power outages, which may render it difficult or impossible for us to perform our testing services for some period of time or to receive and store samples. The inability to perform our tests for even a short period of time may result in the loss of customers or harm our reputation, and we may be unable to regain those customers in the future. Although we maintain insurance for damage to our property and the disruption of our business, this insurance may not be sufficient to cover all of our potential losses and may not continue to be available to us on acceptable terms, if at all.

***Our inability to raise additional capital on acceptable terms in the future may limit our ability to develop and commercialize new solutions and technologies and expand our operations.***

We expect continued capital expenditures and operating losses over the next few years as we expand our infrastructure, commercial operations and research and development activities. We may seek to raise additional capital through equity offerings, debt financings, collaborations or licensing arrangements. Additional funding may not be available to us on acceptable terms, or at all. If we raise funds by issuing equity securities, dilution to our stockholders could result. Any equity securities issued also may provide for rights, preferences or privileges senior to those of holders of our common stock. The terms of debt securities issued or borrowings could impose significant restrictions on our operations. The incurrence of additional indebtedness or the issuance of certain equity securities could result in increased fixed payment obligations and could also result in restrictive covenants, such as limitations on our ability to incur additional debt or issue additional equity, limitations on our ability to acquire or license intellectual property rights, and other operating restrictions that could adversely affect our ability to conduct our business. Our Loan and Security Agreement imposes restrictions on our operations, increases our fixed payment obligations, and has restrictive covenants. In addition, the issuance of additional equity securities by us, or the possibility of such issuance, may cause the market price of our common stock to decline. In the event that we enter into collaborations or licensing arrangements to raise capital, we may be required to accept unfavorable terms. These agreements may require that we relinquish or license to a third-party on unfavorable terms our rights to technologies or product candidates that we otherwise would seek to develop or commercialize ourselves, or reserve certain opportunities for future potential arrangements when we might be able to achieve more favorable terms. The trading prices for our common stock and other biotechnology companies have been highly volatile as a result of the COVID-19 pandemic, which may reduce our ability to access capital on favorable terms or at all. In addition, a recession, depression or other sustained adverse market event resulting from the spread of COVID-19 could materially and adversely affect our business and the value of our common stock. If we are not able to secure additional funding when needed, we may have to delay, reduce the scope of or eliminate one or more research and development programs or selling and marketing initiatives. In addition, we may have to work with a partner on one or more of our products or development programs, which could lower the economic value of those programs to our company.

***Security breaches, loss of data and other disruptions to us or our third-party service providers could compromise sensitive information related to our business or prevent us from accessing critical information and expose us to liability, which could adversely affect our business and our reputation.***

In the ordinary course of our business, we and our third-party service providers collect and store sensitive data, including legally protected health information, personally identifiable information about our patients, credit card information, intellectual property, and our proprietary business and financial information. We manage and maintain our applications and data utilizing a combination of on-site systems, managed data center systems and cloud-based data center systems. We face a number of risks related to our protection of, and our service providers' protection of, this critical information, including loss of access, inappropriate disclosure and inappropriate access, as well as risks associated with our ability to identify and audit such events. System failures or outages, including any potential disruptions due to significantly increased global demand on certain cloud based systems during the COVID-19 pandemic, could compromise our ability to perform these functions in a timely manner, which could harm our ability to conduct business or delay our financial reporting. Such failures could materially adversely affect our operating results and financial condition.

The secure processing, storage, maintenance and transmission of this critical information is vital to our operations and business strategy, and we devote significant resources to protecting such information. Although we take measures to protect sensitive information from unauthorized access or disclosure, our information technology and infrastructure may be vulnerable to attacks by hackers or viruses or otherwise breached due to employee error, malfeasance or other activities. While we are not aware of any such attack or breach, if such event would occur and cause interruptions in our operations, our networks would be compromised and the information we store on those networks could be accessed by unauthorized parties, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under federal, state, and international laws that protect the privacy of personal information, such as HIPAA, and regulatory penalties. Unauthorized access, loss or dissemination could also disrupt our operations, including our ability to process tests, provide test results, bill payers or patients, process claims and appeals, provide customer assistance services, conduct research and development activities, collect, process and prepare company financial information, provide information about our tests and

other patient and physician education and outreach efforts through our website, manage the administrative aspects of our business and damage our reputation, any of which could adversely affect our business.

In addition, the interpretation and application of consumer, health-related and data protection laws in the United States, Europe and elsewhere are often uncertain, contradictory and in flux. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices. If so, this could result in government-imposed fines or orders requiring that we change our practices, which could adversely affect our business. In addition, we are subject to various state laws, including the California Consumer Privacy Act, or CCPA, which was enacted in California in 2018 and components of which went into effect on January 1, 2020. The CCPA, among other things, requires covered companies to provide disclosures to California consumers concerning the collection and sale of personal information, and gives such consumers the right to opt-out of certain sales of personal information. Amendments to the CCPA have been made since its enactment, and it remains unclear what, if any, further amendments will be made to this legislation or how it will be interpreted. We cannot yet predict the impact of the CCPA on our business or operations, but it may require us to modify our data processing practices and policies and to incur substantial costs and expenses in an effort to comply.

Recent developments in Europe have created compliance uncertainty regarding the processing of personal data from Europe. For example, the General Data Protection Regulation, or GDPR, which became effective in the European Union on May 25, 2018, applies to our activities conducted from an establishment in the EU or related to products and services that we offer to European Union users. The GDPR creates new compliance obligations applicable to our business, which could cause us to change our business practices, and increases financial penalties for noncompliance (including possible fines of up to 4% of global annual turnover for the preceding financial year or €20 million (whichever is higher) for the most serious infringements). As a result, we may need to modify the way we treat such information.

***If we cannot license rights to use technologies on reasonable terms, we may not be able to commercialize new products in the future.***

In the future, we may license third-party technology to develop or commercialize new products. In return for the use of a third-party's technology, we may agree to pay the licensor royalties based on sales of our solutions. Royalties are a component of cost of revenue and affect the margins on our solutions. We may also need to negotiate licenses to patents and patent applications after introducing a commercial product. Our business may suffer if we are unable to enter into the necessary licenses on acceptable terms, or at all, if any necessary licenses are subsequently terminated, if the licensors fail to abide by the terms of the license or fail to prevent infringement by third parties, or if the licensed patents or other rights are found to be invalid or unenforceable.

***If we are unable to protect our intellectual property effectively, our business would be harmed.***

We rely on patent protection as well as trademark, copyright, trade secret and other intellectual property rights protection and contractual restrictions to protect our proprietary technologies, all of which provide limited protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage. If we fail to protect our intellectual property, third parties may be able to compete more effectively against us and we may incur substantial litigation costs in our attempts to recover or restrict use of our intellectual property.

We apply for and in-license patents covering our products and technologies and uses thereof, as we deem appropriate, however we may fail to apply for patents on important products and technologies in a timely fashion or at all, or we may fail to apply for patents in potentially relevant jurisdictions. Our issued patents expire between 2029 and 2035 and are related to methods used in thyroid diagnostics, lung diagnostics, breast cancer diagnostics, and the nCounter FLEX analysis platform.

It is possible that none of our pending patent applications will result in issued patents in a timely fashion or at all, and even if patents are granted, they may not provide a basis for intellectual property protection of commercially viable products, may not provide us with any competitive advantages, or may be challenged and invalidated by third parties. It is possible that others will design around our current or future patented technologies. We may not be successful in defending any challenges made against our patents or patent applications. Any successful third-party challenge to our patents could result in the unenforceability or invalidity of such patents and increased competition to our business. The outcome of patent litigation can be uncertain and any attempt by us to enforce our patent rights against others may not be successful, or, if successful, may take substantial time and result in substantial cost, and may divert our efforts and attention from other aspects of our business.

The patent positions of life sciences companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in such companies' patents has emerged to date in the United States or elsewhere. Courts frequently render opinions in the

biotechnology field that may affect the patentability of certain inventions or discoveries, including opinions that may affect the patentability of methods for analyzing or comparing nucleic acids.

In particular, the patent positions of companies engaged in the development and commercialization of genomic diagnostic tests are particularly uncertain. Various courts, including the U.S. Supreme Court, have rendered decisions that affect the scope of patentability of certain inventions or discoveries relating to certain diagnostic tests and related methods. These decisions state, among other things, that patent claims that recite laws of nature (for example, the relationship between blood levels of certain metabolites and the likelihood that a dosage of a specific drug will be ineffective or cause harm) are not themselves patentable. What constitutes a law of nature is uncertain, and it is possible that certain aspects of genomic diagnostics tests would be considered natural laws. Accordingly, the evolving case law in the United States may adversely affect our ability to obtain patents and may facilitate third-party challenges to any owned and licensed patents.

The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States, and we may encounter difficulties protecting and defending such rights in foreign jurisdictions. The legal systems of many other countries do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biotechnology, which could make it difficult for us to stop the infringement of our patents in such countries. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business.

Changes in either the patent laws or in interpretations of patent laws in the United States or other countries may diminish the value of our intellectual property. We cannot predict the breadth of claims that may be allowed or enforced in our patents or in third-party patents. We may not develop additional proprietary products, methods and technologies that are patentable.

In addition to pursuing patents on our technology, we take steps to protect our intellectual property and proprietary technology by entering into agreements, including confidentiality agreements, non-disclosure agreements and intellectual property assignment agreements, with our employees, consultants, academic institutions, corporate partners and, when needed, our advisors. Such agreements may not be enforceable or may not provide meaningful protection for our trade secrets or other proprietary information in the event of unauthorized use or disclosure or other breaches of the agreements, and we may not be able to prevent such unauthorized disclosure. If we are required to assert our rights against such party, it could result in significant cost and distraction.

Monitoring unauthorized disclosure is difficult, and we do not know whether the steps we have taken to prevent such disclosure are, or will be, adequate. If we were to enforce a claim that a third-party had illegally obtained and was using our trade secrets, it would be expensive and time consuming, and the outcome would be unpredictable. In addition, courts outside the United States may be less willing to protect trade secrets.

We may also be subject to claims that our employees have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers, or to claims that we have improperly used or obtained such trade secrets. Litigation may be necessary to defend against these claims. If we fail in defending such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights and face increased competition to our business. A loss of key research personnel work product could hamper or prevent our ability to commercialize potential products, which could harm our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

Further, competitors could attempt to replicate some or all of the competitive advantages we derive from our development efforts, willfully infringe our intellectual property rights, design around our protected technology or develop their own competitive technologies that fall outside of our intellectual property rights. Others may independently develop similar or alternative products and technologies or replicate any of our products and technologies. If our intellectual property does not adequately protect us against competitors' products and methods, our competitive position could be adversely affected, as could our business.

We have not registered certain of our trademarks in all of our potential markets. If we apply to register these trademarks, our applications may not be allowed for registration in a timely fashion or at all, and our registered trademarks may not be maintained or enforced. In addition, opposition or cancellation proceedings may be filed against our trademark applications and registrations, and our trademarks may not survive such proceedings. If we do not secure registrations for our trademarks, we may encounter more difficulty in enforcing them against third parties than we otherwise would.

To the extent our intellectual property offers inadequate protection, or is found to be invalid or unenforceable, we would be exposed to a greater risk of direct competition. If our intellectual property does not provide adequate coverage of our competitors' products, our competitive position could be adversely affected, as could our business. Both the patent application process and the process of managing patent disputes can be time consuming and expensive.

***We may be involved in litigation related to intellectual property, which could be time-intensive and costly and may adversely affect our business, operating results or financial condition.***

We may receive notices of claims of direct or indirect infringement or misappropriation or misuse of other parties' proprietary rights from time to time. Some of these claims may lead to litigation. We cannot assure you that we will prevail in such actions, or that other actions alleging misappropriation or misuse by us of third-party trade secrets, infringement by us of third-party patents and trademarks or other rights, or the validity of our patents, trademarks or other rights, will not be asserted or prosecuted against us.

We might not have been the first to make the inventions covered by each of our pending patent applications and we might not have been the first to file patent applications for these inventions. To determine the priority of these inventions, we may have to participate in interference proceedings, derivation proceedings, or other post-grant proceedings declared by the U.S. Patent and Trademark Office that could result in substantial cost to us. No assurance can be given that other patent applications will not have priority over our patent applications. In addition, recent changes to the patent laws of the United States allow for various post-grant opposition proceedings that have not been extensively tested, and their outcome is therefore uncertain. Furthermore, if third parties bring these proceedings against our patents, we could experience significant costs and management distraction.

Litigation may be necessary for us to enforce our patent and proprietary rights or to determine the scope, coverage and validity of the proprietary rights of others. The outcome of any litigation or other proceeding is inherently uncertain and might not be favorable to us, and we might not be able to obtain licenses to technology that we require on acceptable terms or at all. Further, we could encounter delays in product introductions, or interruptions in product sales, as we develop alternative methods or products. In addition, if we resort to legal proceedings to enforce our intellectual property rights or to determine the validity, scope and coverage of the intellectual property or other proprietary rights of others, the proceedings could be burdensome and expensive, even if we were to prevail. Any litigation that may be necessary in the future could result in substantial costs and diversion of resources and could have a material adverse effect on our business, operating results or financial condition.

As we move into new markets and applications for our products, incumbent participants in such markets may assert their patents and other proprietary rights against us as a means of slowing our entry into such markets or as a means to extract substantial license and royalty payments from us. Our competitors and others may now and, in the future, have significantly larger and more mature patent portfolios than we currently have. In addition, future litigation may involve patent holding companies or other adverse patent owners who have no relevant product revenue and against whom our own patents may provide little or no deterrence or protection. Therefore, our commercial success may depend in part on our non-infringement of the patents or proprietary rights of third parties. Numerous significant intellectual property issues have been litigated, and will likely continue to be litigated, between existing and new participants in our existing and targeted markets and competitors may assert that our products infringe their intellectual property rights as part of a business strategy to impede our successful entry into or growth in those markets. Third parties may assert that we are employing their proprietary technology without authorization. In addition, our competitors and others may have patents or may in the future obtain patents and claim that making, having made, using, selling, offering to sell or importing our products infringes these patents. We could incur substantial costs and divert the attention of our management and technical personnel in defending against any of these claims. Parties making claims against us may be able to obtain injunctive or other relief, which could block our ability to develop, commercialize and sell products, and could result in the award of substantial damages against us. In the event of a successful claim of infringement against us, we may be required to pay damages and ongoing royalties, and obtain one or more licenses from third parties, or be prohibited from selling certain products. We may not be able to obtain these licenses on acceptable terms, if at all. We could incur substantial costs related to royalty payments for licenses obtained from third parties, which could negatively affect our financial results. In addition, we could encounter delays in product introductions while we attempt to develop alternative methods or products to avoid infringing third-party patents or proprietary rights. Defense of any lawsuit or failure to obtain any of these licenses could prevent us from commercializing products, and the prohibition of sale of any of our products could materially affect our business and our ability to gain market acceptance for our products.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, during the course of this kind of litigation, there could be public announcements of the results of

hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

In addition, our agreements with some of our customers, suppliers or other entities with whom we do business require us to defend or indemnify these parties to the extent they become involved in infringement claims, including the types of claims described above. We could also voluntarily agree to defend or indemnify third parties in instances where we are not obligated to do so if we determine it would be important to our business relationships. If we are required or agree to defend or indemnify third parties in connection with any infringement claims, we could incur significant costs and expenses that could adversely affect our business, operating results, or financial condition.

***Our ability to use our net operating loss carryforwards may be limited and may result in increased future tax liability to us.***

We have incurred net losses since our inception and may never achieve profitability. As of December 31, 2019, we had net operating loss, or NOL, carryforwards of approximately $236.9 million, $58.3 million and $45.2 million available to reduce future taxable income, if any, for federal, California and other state income tax purposes, respectively. The U.S. federal NOL carryforwards will begin to expire in 2026 while for state purposes, the NOL carryforwards begin to expire in 2028. These NOL carryforwards could expire unused and be unavailable to offset future income tax liabilities. Under the Tax Cuts and Jobs Acts, or Tax Act, which was enacted in December 2017, federal NOLs incurred in tax years beginning after December 31, 2017 may be carried forward indefinitely, but the deductibility of such federal NOLs is limited. It is uncertain if and to what extent various states will conform to the newly enacted federal tax law.

To the extent that we continue to generate taxable losses, unused losses will carry forward to offset future taxable income, if any, until such unused losses expire. We may be limited in the portion of NOL carryforwards that we can use in the future to offset taxable income for U.S. federal and state income tax purposes, and federal tax credits to offset federal tax liabilities. Sections 382 and 383 of Internal Revenue Code limit the use of NOLs and tax credits after a cumulative change in corporate ownership of more than 50% occurs within a three-year period. The limitation could prevent a corporation from using some or all its NOL and tax credits before they expire within their normal 20-year lifespan, as it places a formula limit of how much NOL and tax credits a loss corporation can use in a tax year. In the event we have undergone an ownership change under Section 382 of the Internal Revenue Code, if we earn net taxable income, our ability to use our pre-change NOL carryforwards to offset U.S. federal taxable income may become subject to limitations, which could potentially result in increased future tax liability to us.

On March 27, 2020, the Coronavirus Aid, Relief, and Economic Security Act, or CARES Act, was signed into law. The CARES Act changes certain provisions of the 2017 Tax Act. Under the CARES Act, NOLs arising in taxable years beginning after December 31, 2017 and before January 1, 2021 may be carried back to each of the five taxable years preceding the tax year of such loss, but NOLs arising in taxable years beginning after December 31, 2020 may not be carried back. In addition, the CARES Act eliminates the limitation on the deduction of NOLs to 80% of current year taxable income for taxable years beginning before January 1, 2021, and increases the amount of interest expense that may be deducted to 50% of adjusted taxable income for taxable years beginning in 2019 or 2020. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the Tax Act, as modified by the CARES Act, is uncertain and our business, financial conditions, results of operations and growth prospects could be materially and adversely affected. In addition, it is uncertain if and to what extent various states will conform to the Tax Act, as modified by the CARES Act. The impact of the Tax Act, as modified by the CARES Act, on holders of our common stock is also uncertain and could be adverse.

***If our goodwill or intangible assets become impaired, we may be required to record a significant charge to earnings.***

We review our goodwill and intangible assets for impairment when events or changes in circumstances indicate the carrying value may not be recoverable, such as declines in stock price, market capitalization, or cash flows and slower growth rates in our industry. Goodwill is required to be tested for impairment at least annually. If we are required to record a significant charge in our consolidated financial statements during the period in which any impairment of our goodwill or intangible assets is determined, that would negatively affect our operating results.

***Changes in financial accounting standards or practices may cause adverse, unexpected financial reporting fluctuations and affect our reported operating results.***

U.S. GAAP is subject to interpretation by the Financial Accounting Standards Board, the Securities and Exchange Commission, or the SEC, and various bodies formed to promulgate and interpret appropriate accounting principles. A change in accounting standards or practices can have a significant effect on our reported results and may even affect our reporting of transactions completed before the change is effective. New accounting pronouncements and varying interpretations of accounting pronouncements have occurred and may occur in the future. Changes to existing rules or the questioning of current practices may adversely affect our reported financial results or the way we conduct our business.

***Our condensed consolidated financial statements are subject to change and if our estimates or judgments relating to our critical accounting policies prove to be incorrect, our operating results could be adversely affected.***

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in our condensed consolidated financial statements and related notes. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, as provided in the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" in this Quarterly Report on Form 10-Q. The results of these estimates form the basis for making judgments about the carrying values of assets, liabilities, and equity, and the amount of revenue and expenses that are not readily apparent from other sources. Critical accounting policies and estimates used in preparing our condensed consolidated financial statements include those related to revenue recognition, finite-lived intangible assets, goodwill, and stock-based compensation expense. Our operating results may be adversely affected if our assumptions change or if actual circumstances differ from those in our assumptions, which could cause our operating results to fall below the expectations of securities analysts and investors, resulting in a decline in the price of our common stock.

**Risks Related to Being a Public Company**

***We will continue to incur increased costs and demands on management as a result of compliance with laws and regulations applicable to public companies, which could harm our operating results.***

As a public company, we will continue to incur significant legal, accounting, consulting and other expenses that we did not incur as a private company, including costs associated with public company reporting requirements. In addition, the Sarbanes-Oxley Act of 2002 and the Dodd-Frank Act of 2010, as well as rules implemented by the SEC, and The Nasdaq Stock Market, impose a number of requirements on public companies, including with respect to corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these compliance and disclosure obligations. Moreover, these rules and regulations have and will continue to increase our legal, accounting and financial compliance costs and make some activities more complex, time-consuming and costly. We also expect that it will continue to be expensive for us to maintain director and officer liability insurance.

***If we are unable to implement and maintain effective internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our reported financial information and the market price of our common stock may be negatively affected.***

As a public company, we are required to maintain internal control over financial reporting and to report any material weaknesses in such internal control. Section 404 of the Sarbanes-Oxley Act of 2002 requires that we evaluate and determine the effectiveness of our internal control over financial reporting and provide a management report on our internal controls on an annual basis. If we have material weaknesses in our internal control over financial reporting, we may not detect errors on a timely basis and our consolidated financial statements may be materially misstated. We have only recently compiled the systems, processes and documentation necessary to comply with Section 404 of the Sarbanes-Oxley Act. We will need to maintain and enhance these processes and controls as we grow, and we will require additional management and staff resources to do so. Additionally, even if we conclude our internal controls are effective for a given period, we may in the future identify one or more material weaknesses in our internal controls, in which case our management will be unable to conclude that our internal control over financial reporting is effective. We are now required to include an attestation report from our independent registered public accounting firm on the effectiveness of our internal control over financial reporting annually. Even if our management concludes that our internal control over financial reporting is effective, our independent registered public accounting firm may conclude that there are material weaknesses with respect to our internal controls or the level at which our internal controls are documented, designed, implemented or reviewed.

If we are unable to conclude that our internal control over financial reporting is effective, or if our auditors were to express an adverse opinion on the effectiveness of our internal control over financial reporting because we had one or more material weaknesses, investors could lose confidence in the accuracy and completeness of our financial disclosures, which could cause the price of our common stock to decline. Irrespective of compliance with Section 404, any failure of our internal control over financial reporting could have a material adverse effect on our reported operating results and harm our reputation. Internal control deficiencies could also result in a restatement of our financial results.

**Risks Related to Our Common Stock**

***Our stock price may be volatile, and you may not be able to sell shares of our common stock at or above the price you paid.***

The trading price of our common stock is likely to continue to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. These factors include:

- actual or anticipated variations in our and our competitors' results of operations
- the global macroeconomic impact of the current COVID-19 outbreak;
- announcements by us or our competitors of new products, commercial relationships or capital commitments;
- changes in reimbursement by current or potential payers, including governmental payers;
- issuance of new securities analysts' reports or changed recommendations for our stock;
- fluctuations in our revenue, due in part to the way in which we recognize revenue;
- actual or anticipated changes in regulatory oversight of our products;
- developments or disputes concerning our intellectual property or other proprietary rights;
- commencement of, or our involvement in, litigation;
- announced or completed acquisitions of businesses or technologies by us or our competitors;
- any major change in our management; and
- general economic conditions and slow or negative growth of our markets.

In addition, the stock market in general, and the market for stock of life sciences companies and other emerging growth companies in particular, has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. Broad market and industry factors may seriously affect the market price of our common stock, regardless of our actual operating performance. These fluctuations may be even more pronounced if the trading volume of our stock remains low. In addition, in the past, following periods of volatility in the overall market and the market price of a particular company's securities, securities class action litigation has often been instituted against these companies. This litigation, if instituted against us, could result in substantial costs and a diversion of our management's attention and resources.

***If securities or industry analysts issue an adverse opinion regarding our stock or do not publish research or reports about our company, our stock price and trading volume could decline.***

The trading market for our common stock will depend in part on the research and reports that equity research analysts publish about us, our business and our competitors. We do not control these analysts or the content and opinions or financial models included in their reports. Securities analysts may elect not to provide research coverage of our company, and such lack of research coverage may adversely affect the market price of our common stock. The price of our common stock could also decline if one or more equity research analysts downgrade our common stock or if those analysts issue other unfavorable commentary or cease publishing reports about us or our business. If one or more equity research analysts cease coverage of our company, we could lose visibility in the market, which in turn could cause our stock price to decline.

***Anti-takeover provisions in our charter documents and under Delaware law could discourage, delay or prevent a change in control and may affect the trading price of our common stock.***

Provisions in our restated certificate of incorporation and our amended and restated bylaws may have the effect of delaying or preventing a change of control or changes in our management. Our restated certificate of incorporation and amended and restated bylaws include provisions that:

- authorize our board of directors to issue, without further action by the stockholders, up to 5.0 million shares of undesignated preferred stock;
- require that any action to be taken by our stockholders be effected at a duly called annual or special meeting and not by written consent;
- specify that special meetings of our stockholders can be called only by our board of directors, our chairman of the board, or our chief executive officer;
- establish an advance notice procedure for stockholder approvals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to our board of directors;
- establish that our board of directors is divided into three classes, Class I, Class II and Class III, with each class serving staggered terms;
- provide that our directors may be removed only for cause;
- provide that vacancies on our board of directors may, except as otherwise required by law, be filled only by a majority of directors then in office, even if less than a quorum;
- provide that the federal district courts of the United States shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act of 1933, as amended;
- specify that no stockholder is permitted to cumulate votes at any election of directors; and
- require a super-majority of votes to amend certain of the above-mentioned provisions.

In addition, we are subject to the provisions of Section 203 of the Delaware General Corporation Law regulating corporate takeovers. Section 203 generally prohibits us from engaging in a business combination with an interested stockholder subject to certain exceptions.

***We have never paid dividends on our capital stock, and we do not anticipate paying dividends in the foreseeable future.***

We have never paid dividends on any of our capital stock and currently intend to retain any future earnings to fund the growth of our business. In addition, our Loan and Security Agreement restricts our ability to pay cash dividends on our common stock and we may also enter into credit agreements or other borrowing arrangements in the future that will restrict our ability to declare or pay cash dividends on our common stock. Any determination to pay dividends in the future will be at the discretion of our board of directors and will depend on our financial condition, operating results, capital requirements, general business conditions and other factors that our board of directors may deem relevant. As a result, capital appreciation, if any, of our common stock will be the sole source of gain for the foreseeable future.

**ITEM 6. EXHIBITS**

| Exhibit Number | Description |
|---|---|
| 3.1 | Amended and Restated Bylaws of the Registrant |
| 31.1* | Certification of Principal Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a), 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)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 |
| 32.1** | Certification of Principal Executive Officer pursuant to 18 U.S.C. § 1350 (Section 906 of the Sarbanes-Oxley Act of 2002) |
| 32.2** | Certification of Principal Financial Officer pursuant to 18 U.S.C. § 1350 (Section 906 of the Sarbanes-Oxley Act of 2002) |
| 101.INS | Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL |
| 101.SCH | Inline XBRL Taxonomy Extension Schema |
| 101.CAL | Inline XBRL Taxonomy Extension Calculation Linkbase |
| 101.DEF | Inline XBRL Taxonomy Extension Definition Linkbase |
| 101.LAB | Inline XBRL Taxonomy Extension Label Linkbase |
| 101.PRE | Inline XBRL Taxonomy Extension Presentation Linkbase |
| 104 | Cover Page Interactive Data File (embedded within the Inline XBRL and contained in Exhibit 101). |

* Filed herewith.

** In accordance with Item 601(b)(32)(ii) of Regulation S-K and SEC Release No. 34-47986, the certifications furnished in Exhibits 32.1 and 32.2 hereto are deemed to accompany this Form 10-Q and will not be deemed “filed” for purposes of Section 18 of the Exchange Act or deemed to be incorporated by reference into any filing under the Exchange Act or the Securities Act except to the extent that the registrant specifically incorporates it by reference.

**SIGNATURES**

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

Date: May 6, 2020

VERACYTE, INC.

By: /s/ MARK HO

Mark Ho
*Principal Accounting Officer*

**Exhibit 31.1**

**PRINCIPAL EXECUTIVE OFFICER'S CERTIFICATION PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Bonnie H. Anderson, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Veracyte, Inc. for the quarter ended March 31, 2020;

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

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

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

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

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

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

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

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

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

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

Date: May 6, 2020

/s/ Bonnie H. Anderson

Bonnie H. Anderson

*Chairman and Chief Executive Officer*

*(Principal Executive Officer)*

**Exhibit 31.2**

**PRINCIPAL FINANCIAL OFFICER'S CERTIFICATION PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Keith Kennedy, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Veracyte, Inc. for the quarter ended March 31, 2020;

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

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

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

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

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

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

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

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

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

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

Date: May 6, 2020

/s/ Keith Kennedy

Keith Kennedy

*Chief Operating Officer and Chief Financial Officer*

*(Principal Financial Officer)*

**Exhibit 32.1**

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

In connection with the quarterly report of Veracyte, Inc. (the "Company") on Form 10-Q for the quarter ended March 31, 2020, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned officer of the Company certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to such officer's knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 6, 2020

/s/ Bonnie H. Anderson

Bonnie H. Anderson
*Chairman and Chief Executive Officer*
*(Principal Executive Officer)*

**Exhibit 32.2**

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

In connection with the quarterly report of Veracyte, Inc. (the "Company") on Form 10-Q for the quarter ended March 31, 2020, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned officer of the Company certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to such officer's knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 6, 2020

/s/ Keith Kennedy

Keith Kennedy
*Chief Operating Officer and Chief Financial Officer*
*(Principal Financial Officer)*