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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, 2019

OR

o **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)

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 o	Accelerated filer x
Non-accelerated filer o	Smaller reporting company x
	Emerging growth company o

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 o No ☒

As of April 26, 2019, there were 41,642,603 shares of common stock, par value $0.001 per share, outstanding.

VERACYTE, INC.
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PART I. — FINANCIAL INFORMATION

Item 1. Condensed Financial Statements

VERACYTE, INC.
Condensed Balance Sheets
(In thousands of dollars, except share and per share amounts)

	March 31, 2019	December 31, 2018
	(Unaudited)	(See Note 1)
Assets		
Current assets:		
Cash and cash equivalents	$ 67,841	$ 77,995
Accounts receivable	16,615	13,168
Supplies	3,768	3,402
Prepaid expenses and other current assets	2,392	2,387
Total current assets	90,616	96,952
Property and equipment, net	8,114	8,940
Right-of-use assets - finance lease, net	735	—
Right-of-use assets - operating lease	9,630	—
Finite-lived intangible assets, net	11,733	12,000
Goodwill	1,057	1,057
Restricted cash	603	603
Other assets	1,049	1,086
Total assets	$ 123,537	$ 120,638
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 4,064	$ 2,516
Accrued liabilities	8,788	9,186
Current portion of long-term debt	—	1,357
Current portion of finance lease liability	233	—
Current portion of operating lease liability	1,244	—
Total current liabilities	14,329	13,059
Long-term debt	12,854	23,925
Deferred rent, net of current portion	—	3,899
Operating lease liability, net of current portion	12,582	—
Total liabilities	39,765	40,883
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, 2019 and December 31, 2018	—	—
Common stock, $0.001 par value; 125,000,000 shares authorized, 41,509,240 and 40,863,202 shares issued and outstanding as of March 31, 2019 and December 31, 2018, respectively	42	41
Additional paid-in capital	319,733	313,800
Accumulated deficit	(236,003)	(234,086)
Total stockholders' equity	83,772	79,755
Total liabilities and stockholders' equity	$ 123,537	$ 120,638

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

VERACYTE, INC.

Condensed Statements of Operations and Comprehensive Loss

(Unaudited)

(In thousands of dollars, except share and per share amounts)

	Three Months Ended March 31,	
	2019	**2018**
Revenue	$ 29,529	$ 20,041
Operating expenses:		
Cost of revenue	8,513	7,867
Research and development	3,435	3,675
Selling and marketing	12,477	11,543
General and administrative	6,904	5,644
Intangible asset amortization	267	267
Total operating expenses	31,596	28,996
Loss from operations	(2,067)	(8,955)
Interest expense	(303)	(448)
Other income, net	453	226
Net loss and comprehensive loss	$ (1,917)	$ (9,177)
Net loss per common share, basic and diluted	$ (0.05)	$ (0.27)
Shares used to compute net loss per common share, basic and diluted	41,168,593	34,271,254

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

VERACYTE, INC.

Condensed Statements of Stockholders' Equity

(Unaudited)

(in thousands)

	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 on exercise of stock options and vesting of restricted stock units	566	1	4,239	—	4,240
Issuance of common stock under employee stock purchase plan (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

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance at December 31, 2017	34,210	$ 34	$ 248,278	$ (211,087)	$ 37,225
Issuance of common stock on exercise of stock options and vesting of restricted stock units	44	—	108	—	108
Issuance of common stock under employee stock purchase plan (ESPP)	73	—	397		397
Tax portion of vested restricted stock units	—	—	(30)	—	(30)
Stock-based compensation expense (employee)	—	—	1,083	—	1,083
Stock-based compensation expense (non-employee)	—	—	1	—	1
Stock-based compensation expense (ESPP)	—	—	91	—	91
Legal settlement from short-swing profits, net of tax	—	—	310	—	310
Net loss and comprehensive loss	—	—	—	(9,177)	(9,177)
Balance at March 31, 2018	34,327	$ 34	$ 250,238	$ (220,264)	$ 30,008

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

VERACYTE, INC.

Condensed Statements of Cash Flows

(Unaudited)

(In thousands of dollars)

	Three Months Ended March 31,	
	2019	**2018**
Operating activities		
Net loss	$ (1,917)	$ (9,177)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	945	980
Gain on disposal of property and equipment	(16)	—
Stock-based compensation	1,759	1,175
Other income	—	(93)
Amortization of debt issuance costs	8	8
Interest on end-of-term debt obligation	64	70
Changes in operating assets and liabilities:		
Accounts receivable	(3,447)	(482)
Supplies	(366)	767
Prepaid expenses and other current assets	(11)	(239)
Right-of-use assets - operating lease and operating lease liability	(80)	—
Other assets	37	(140)
Accounts payable	1,726	(510)
Accrued liabilities and deferred rent	287	228
Net cash used in operating activities	(1,011)	(7,413)
Investing activities		
Purchases of property and equipment	(765)	(227)
Proceeds from disposal of property and equipment	16	—
Net cash used in investing activities	(749)	(227)
Financing activities		
Payment of long-term debt	(12,500)	—
Proceeds from legal settlement regarding short-swing profits	—	403
Payment of finance lease liability	(75)	(71)
Proceeds from the exercise of common stock options and employee stock purchases	4,181	569
Net cash (used in) provided by financing activities	(8,394)	901
Net decrease in cash, cash equivalents and restricted cash	(10,154)	(6,739)
Cash, cash equivalents and restricted cash at beginning of period	78,598	34,494
Cash, cash equivalents and restricted cash at end of period	$ 68,444	$ 27,755
Supplementary cash flow information of non-cash investing and financing activities:		
Operating lease liability arising from obtaining right-of-use assets - operating lease	$ 14,118	$ —
Purchases of property and equipment included in accounts payable and accrued liabilities	$ 95	$ 56
Interest paid on debt	$ 228	$ 356

Cash, Cash Equivalents and Restricted Cash:

	March 31, 2019	December 31, 2018
Cash and cash equivalents	$ 67,841	$ 77,995
Restricted cash	603	603
Total cash, cash equivalents and restricted cash	$ 68,444	$ 78,598

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

VERACYTE, INC.

Notes to Financial Statements

1. Organization and Description of Business

Veracyte, Inc. (“Veracyte” or the “Company”) is a leading genomic diagnostics company that is creating value through innovation. The Company was founded in 2008 with a mission to improve diagnostic accuracy. Today, through its innovative scientific platform, Veracyte is serving this critical medical need and expanding its offerings further along the clinical continuum of care to advance early detection of disease and inform treatment decisions. The Company utilizes its scientific platform, which uses RNA whole-transcriptome sequencing combined with machine learning, to discover and develop its products.

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 currently offers the following products in three clinical indications:

Afirma Genomic Sequencing Classifier ("GSC") and Xpression Atlas - The Company’s Afirma offering, consisting of the Afirma GSC and the Afirma Xpression Atlas, provides a comprehensive solution in thyroid nodule diagnosis and is intended to provide physicians with clinically actionable results from a single fine needle aspiration ("FNA") biopsy. The Afirma GSC is used to identify patients with benign thyroid nodules among those with indeterminate cytopathology results so that these patients can avoid unnecessary thyroid surgery. The Afirma Xpression Atlas provides genomic alteration content from the same test to help physicians decide with greater confidence on surgery strategy and treatment options for their patients.

Percepta Bronchial Genomic Classifier - The Percepta classifier improves lung cancer diagnosis by enhancing the performance of diagnostic bronchoscopies, thus identifying more patients with lung nodules who are at low risk of cancer and may avoid further, invasive procedures. 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.

Envisia Genomic Classifier - The Envisia classifier improves diagnosis of idiopathic pulmonary fibrosis ("IPF") by helping physicians better differentiate IPF from other interstitial lung diseases without the need for surgery. The test identifies the genomic pattern of usual interstitial pneumonia, 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.

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 that include extensive clinical cohorts and whole genome RNA sequencing data that it believes are important to the development of new targeted therapies, determining clinical trial eligibility and guiding treatment selection.

All of the Company's testing services are made available through its clinical reference laboratories located in South San Francisco, California and Austin, Texas.

Basis of Presentation

The Company’s 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 balance sheet as of March 31, 2019, the condensed statements of operations and comprehensive loss for the three months ended March 31, 2019 and 2018, the condensed statements of stockholders' equity for the three months ended March 31, 2019 and 2018, and the condensed statements of cash flows for the three months ended March 31, 2019 and 2018 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 and cash flows for the periods presented. The condensed balance sheet at December 31, 2018 has been derived from audited financial statements. The results for the three months ended March 31, 2019 are not necessarily indicative of the results expected for the full year or any other period.

The accompanying interim period condensed 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, 2018.

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 assets and liabilities as of the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. Significant items subject to such estimates include: revenue recognition; 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; 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

In July 2018, the Company issued and sold 5,750,000 shares of common stock in a registered public offering, including the underwriters' exercise in full of their option to purchase an additional 750,000 shares, at a price to the public of $10.25 per share. The Company's net proceeds from the offering were approximately $55.0 million, after deducting underwriting commissions and offering expenses of $3.9 million.

Concentrations of Credit Risk and Other Risks and Uncertainties

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 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. The Company generally does not perform evaluations of customers' financial condition and generally does not require collateral.

Through March 31, 2019, 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 in excess of 10% of revenue and their related revenue as a percentage of total revenue were as follows:

	Three Months Ended March 31,	
	2019	2018
Medicare	21%	29%
UnitedHealthcare	11%	13%
	32%	42%

On December 28, 2018, the Company entered into a diagnostics development agreement with Johnson & Johnson Services, Inc. ("JJSI") for which the Company recognized $3.8 million of revenue for the provision of data, which represents 12.9% of total revenue for the three months ended March 31, 2019.

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

	March 31, 2019	December 31, 2018
Medicare	14%	20%
UnitedHealthcare	12%	11%

Restricted Cash

The Company had deposits of $603,000 included in long-term assets as of March 31, 2019 and December 31, 2018, 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

The Company commenced recognizing revenue in accordance with the provisions of ASC 606, *Revenue from Contracts with Customers*, or ASC 606, starting January 1, 2018. Prior to January 1, 2018, the Company recognized revenue in accordance with the provisions of ASC 954-605, *Health Care Entities - Revenue Recognition*, or ASC 954.

Revenue from Diagnostic Services

Most of the Company's revenue is generated from the provision of diagnostic 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.

The Company adopted ASC 606 on January 1, 2018 using the modified retrospective method, which requires a cumulative catch-up adjustment as if the Company had recognized revenue under ASC 606 from January 1, 2016. Prior to January 1, 2018, the Company recognized revenue in accordance with ASC 954 and recognized revenue for tests delivered on an accrual basis when amounts that will ultimately be realized could be reasonably estimated, and on the cash basis when there was insufficient information to estimate revenue accruals. The adoption of ASC 606 did not have a material impact on the Company's statement of operations or financial position.

During the three months ended March 31, 2019, the Company changed its revenue estimates due to actual and anticipated cash collections for tests delivered in prior quarters and recognized additional revenue of $0.6 million, of which $0.4 million had been collected as of March 31, 2019. This 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.

Arrangements with Multiple-Performance Obligations

From time to time, the Company enters into arrangements for research and development and/or commercialization 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 commercialization 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 or services is transferred. 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 the 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.

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.

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. ("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. 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 and $250,000 for the performance of services. There was no deferred revenue related to this agreement at either March 31, 2019 or December 31, 2018.

Diagnostic Development Agreement with Johnson & Johnson

On December 28, 2018, the Company entered into a diagnostics development agreement with 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 ("Percepta v.2") and a nasal genomic classifier diagnostic for lung cancer ("NasaRISK") 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 NasaRISK programs. The license granted to JJSI is not distinct from other performance obligations as JJSI receives benefit only when other performance obligations are met.

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 Percepta v.2 and NasaRISK. For a period of ten years commencing with the first commercial sale of Percepta v.2 and NasaRISK, 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 NasaRISK, 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 data from its RNA whole-transcriptome sequencing platform 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.

During the three months ended March 31, 2019, the Company received $5.0 million from JJSI and recognized $3.8 million for the provision of data. The remaining $1.2 million balance is recorded as deferred revenue under accrued liabilities on the Company's condensed balance sheet as of March 31, 2019 and will be recognized as data is delivered and the related performance obligation is satisfied.

Legal Settlement

In March 2018, the Company received $0.4 million as a settlement with an institutional investor that was a beneficial owner of the Company's common stock related to the disgorgement of short-swing profits pursuant to Section 16(b) of the Securities Exchange Act of 1934, as amended. The settlement of $0.4 million was recognized as additional paid-in capital.

Recent Accounting Pronouncements

In February 2016, the FASB issued ASU No. 2016-2, *Leases (Topic 842)*. This ASU is aimed at making leasing activities more transparent and comparable, and requires substantially all leases be recognized by lessees on their balance sheet as a right-of-use asset and corresponding lease liability, including leases currently accounted for as operating leases. The ASU is effective for interim and annual periods beginning after December 15, 2018. Additionally, the FASB issued ASU No. 2018-11, *Leases (Topic 842): Targeted Improvements*, which offers an additional transition method whereby entities may apply the new leases standard at the adoption date and recognize a cumulative-effect adjustment to the opening balance of retained earnings rather than application of the new leases standard at the beginning of the earliest period presented in the financial statements. The Company elected this transition method and adopted ASC 842 on January 1, 2019 and as a result, recorded operating lease right-of-use ("ROU") assets of $9.8 million, including offsetting deferred rent of $4.3 million, along with the associated operating lease liabilities of $14.1 million. On January 1, 2019, the Company had a finance lease ROU of $0.8 million and associated finance lease liabilities

of $0.3 million for leases classified as finance leases prior to the adoption of ASC 842. The adoption of ASC 842 had an immaterial impact on the Company's condensed statement of operations and comprehensive loss, condensed statement of stockholders' equity and condensed statement of cash flows for the three-month period ended March 31, 2019. In addition, the Company elected the package of practical expedients permitted under the transition guidance within the new standard which allowed it to carry forward the historical lease classification. Additional information and disclosures required by this new standard are contained in Note 5, Commitments and Contingencies.

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 is currently evaluating the potential effect of this standard on its 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,	
	2019	2018
Shares of common stock subject to outstanding options	5,670,819	5,991,158
Employee stock purchase plan	25,672	25,693
Restricted stock units	538,759	192,806
Total common stock equivalents	6,235,250	6,209,657

3. Accrued Liabilities

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

	March 31, 2019	December 31, 2018
Accrued compensation expenses	$ 4,951	$ 6,412
Accrued other	3,837	2,774
Total accrued liabilities	$ 8,788	$ 9,186

4. 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 carrying value of the Company's debt approximates its fair value because the interest rate approximates market rates that the Company could obtain for debt with similar terms. The fair value of the Company's debt is estimated using the net present value of the payments, discounted at an interest rate that is consistent with market interest rates, which is a Level II input. 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 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 balance sheets, were $67.3 million and $76.6 million as of March 31, 2019 and December 31, 2018, respectively, and are Level I assets as described above. The deposit for the lease, included in restricted cash in the accompanying condensed balance sheets, was $603,000 as of March 31, 2019 and December 31, 2018, and is a Level I asset as described above.

5. 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, 2019 and December 31, 2018, 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 balance sheets as of March 31, 2019 and December 31, 2018.

The Company determined its operating lease liabilities for the two operating leases mentioned above using a discount rate of 7.53% based on the rate that the Company would have to pay to borrow on a collateralized basis for a similar lease an amount equal to the lease payments in a similar economic environment. Operating lease liabilities along with the associated right-of-use assets as of March 31, 2019 are disclosed in the accompanying condensed balance sheets. After the adoption of ASC 842, the Company classified its deferred rent for tenant improvements with its operating lease right-of-use assets on the condensed balance sheets.

Future minimum lease payments under non-cancelable operating leases as of March 31, 2019 are as follows (in thousands of dollars):

Year Ending December 31,		
Remainder of 2019	$	1,671
2020		2,332
2021		2,401
2022		2,472
2023		2,543
Thereafter		6,841
Total minimum lease payments	$	18,260

The Company recognizes operating lease expense on a straight-line basis over the non-cancelable lease period. Operating lease expense was $476,000 for the three months ended March 31, 2019 and 2018.

Finance Lease

The Company entered into a finance lease in December 2016 for $1.2 million of laboratory equipment which ends in December 2019. The Company paid an upfront amount of $330,000 and the present value of the total future minimum lease payments at the inception of the lease was $874,000. As of March 31, 2019, the future minimum lease payments are $238,000 for the remainder of 2019. The interest expense and related amortization of laboratory equipment are recorded in the statements of operations for

nominal amounts. After the adoption of ASC 842, this finance lease remained a finance lease and the Company did not change the discount rate to determine the lease liability nor the amortization life of the related right-of-use assets.

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 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 litigation pending that could have, either individually or in the aggregate, a material adverse effect on the Company's financial statements.

6. Debt

Loan and Security Agreement

On November 3, 2017, the Company entered into a loan and security agreement (the "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 (the "Term Loan Advance"), and a revolving line of credit of up to $10.0 million (the "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, 2019. 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. In January 2019, the Company prepaid $12.5 million of the principal amount of the Term Loan Advance. This did not trigger any prepayment premium because it was a partial, not full, repayment of the principal amount.

The Term Loan Advance bears interest at a variable rate equal to (i) the thirty-day U.S. London Interbank Offer Rate ("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 effective interest rate for the Term Loan Advance was 9.39% as of March 31, 2019.

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 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 our 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, 2019, the Company was in compliance with the loan covenants.

As of March 31, 2019, the net debt obligation for borrowings made under the Loan and Security Agreement was as follows (in thousands of dollars):

	March 31, 2019	December 31, 2018
Debt principal	$ 12,500	$ 25,000
End-of-term debt obligation	429	365
Unamortized debt issuance costs	(75)	(83)
Net debt obligation	$ 12,854	$ 25,282

Future principal and end-of-term debt obligation payments due under the Loan and Security Agreement are as follows (in thousands of dollars):

Year Ending December 31,	
2019	$ —
2020	—
2021	5,556
2022	8,132
Total	$ 13,688

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 statements of operations and comprehensive loss.

7. Stockholders' Equity

Common Stock

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

	March 31, 2019	December 31, 2018
Stock options and restricted stock units issued and outstanding	6,733,949	6,235,258
Stock options and restricted stock units available for grant under stock option plans	2,141,658	1,571,658
Common stock available for the Employee Stock Purchase Plan	229,218	309,419
Total	9,104,825	8,116,335

8. Thyroid Cytopathology Partners

The Company has an agreement with a specialized pathology practice, Thyroid Cytopathology Partners, ("TCP"), to provide testing services to the Company (the "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 includes 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 represents a variable interest entity as a result of the facility arrangement clause, but that the Company is not the primary beneficiary as it does not have the ability to direct the activities that most significantly impact TCP's economic performance, and therefore does 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.

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 and $32,000 for the three months ended March 31, 2019 and 2018, respectively, and is included in other income, net in the Company's condensed statements of operations and comprehensive loss.

9. Income Taxes

The Company did not record a provision or benefit for income taxes during the three months ended March 31, 2019 and 2018. The Company continues to maintain a full valuation allowance against its net deferred tax assets.

As of March 31, 2019, the Company had unrecognized tax benefits of $2.8 million, none of which would currently affect the Company's effective tax rate if recognized due to the Company's net deferred tax assets being fully offset by a valuation allowance. The Company does not anticipate that the amount of unrecognized tax benefits relating to tax positions existing at March 31, 2019 will significantly increase or decrease within the next 12 months. There was no interest expense or penalties related to unrecognized tax benefits recorded through March 31, 2019.

A number of years may elapse before an uncertain tax position is audited and finally resolved. While it is often difficult to predict the final outcome or the timing of resolution of any particular uncertain tax position, the Company believes that its reserves for income taxes reflect the most likely outcome. The Company adjusts these reserves, as well as the related interest, with consideration of changing facts and circumstances. Settlement of any particular position could require the use of cash.

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 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, 2018.

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; 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 estimates of the number of people covered under the TRICARE program, our belief that published clinical validation and utility study finding for the Envisia classifier can improve diagnosis and decrease the need for surgery, study results demonstrating that the Afirma GSC test has an enhanced ability to distinguish benign from cancerous Hürthle cells, our belief that variant and fusion information from the Afirma Xpression Atlas data may help guide physicians in preoperative evaluation, surgical planning and targetd therapy selections; 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, Know by Design, the Veracyte logo and the Afirma logo 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 leading genomic diagnostics company that is creating value through innovation. We were founded in 2008 with a mission to improve diagnostic accuracy. Today, through our innovative scientific platform which utilizes RNA whole-transcriptome sequencing combined with machine learning, we are serving this critical medical need and expanding our offerings further along the clinical continuum of care so that we can advance early detection of disease and inform treatment decisions at the same time as diagnosis.

We have commercialized five leading, first-to-market tests that are transforming care in large, untapped clinical areas - thyroid cancer, lung cancer and idiopathic pulmonary fibrosis, or IPF. We develop tests that answer specific clinical questions, providing patients and physicians with a clear path forward without the need for risky or costly procedures that are often unnecessary. Our RNA whole-transcriptome sequencing platform enables us to maximize the amount of genomic content that we extract from each nonsurgical patient sample. We utilize our machine learning expertise to develop genomic classifiers that provide actionable information at the time of diagnosis. At the same time, our approach enables us to provide information that can guide treatment decisions such as surgery strategy and therapy selection.

We position our tests in each clinical indication at the point where they improve diagnostic 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% to 70% of cases.

To date, we have commercialized five genomic tests that are changing disease diagnosis:

- the Afirma Genomic Sequencing Classifier, or GSC, for thyroid cancer;
- the Afirma Gene Expression Classifier, or GEC, which was the Afirma GSC’s predecessor;
- the Percepta Bronchial Genomic Classifier for lung cancer;
- the Envisia Genomic Classifier for IPF; and
- in 2018, we unveiled our Afirma® Xpression Atlas, which provides information on the most common and emerging gene alterations associated with thyroid cancer, enabling physicians to confidently tailor surgical and treatment decisions at time of diagnosis.

Collectively, we believe the tests we are currently offering address a $2 billion global market opportunity.

The published evidence supporting our tests demonstrates the robustness of our science and clinical studies, and we believe is key to driving adoption and reimbursement. Patients and physicians can access our full list of publications on our website. Over 38 clinical studies covering our products have been published, including two landmark clinical validation papers published in The New England Journal of Medicine for the Afirma and Percepta classifiers, respectively. 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 us to set new standards in genomic test reimbursement. Our Afirma genomic classifier is now covered by every major health plan in the United States, which collectively insure more than 275 million people for use in thyroid cancer diagnosis. Veracyte is now contracted as an in-network

service provider to health plans representing over 215 million people in the United States. Our second commercial product, the Percepta classifier, is the first genomic test to gain Medicare coverage for improved lung cancer screening and diagnosis, making it a covered benefit for nearly 60 million people.

First Quarter 2019 Financial Results

For the first quarter of 2019, as compared with the first quarter of 2018:

- *Revenue* was $29.5 million, an increase of 47%; excluding biopharmaceutical services revenue, revenue was $25.4 million, an increase of 27%;
- *Gross Margin* was 71%, an improvement of 1000 basis points or 10 percentage points;
- *Operating Expenses, Excluding Cost of Revenue*, were $23.1 million, an increase of 9%;
- *Net Loss and Comprehensive Loss* was $1.9 million, a decrease of 79%;
- *Basic and Diluted Net Loss Per Common Share* was $0.05, an improvement of 81%;
- *Net Cash Used in Operating Activities* was $1.0 million, an improvement of 86%; and
- *Cash and Cash Equivalents* were $67.8 million at March 31, 2019.

First Quarter 2019 and Recent Business Highlights

- Recognized revenue for the first time for the Envisia classifier in the first quarter of 2019.
- Grew genomic test volume to 9,162 tests in the first quarter of 2019, an increase of 33% compared with the first quarter of 2018.
- Received a final Medicare coverage determination for the Envisia classifier through the MolDX program effective April 1, 2019, making the test a covered service for nearly 60 million Medicare beneficiaries nationwide.
- Received coverage for the Afirma® Genomic Sequencing Classifier (GSC) under the U.S. Department of Defense TRICARE program for approximately 9.4 million uniformed service members, retirees and their families around the world.
- Received regulatory approval for the Envisia classifier from the New York State Department of Health, making the test available to patients in the state effective immediately.

Strengthened Library of Clinical Evidence:

- Published clinical validation and utility study findings for the Envisia classifier in *The Lancet Respiratory Medicine*, demonstrating that the test can identify more than two-thirds of patients (70% sensitivity) with the hallmark pattern of idiopathic pulmonary fibrosis (IPF), with high accuracy (88% specificity), thus improving diagnosis - without the need for surgery.
- An independent real-world study on the Afirma GSC was published in *Thyroid* showing that at Brigham and Women's Hospital use of the test identified benign thyroid nodules nearly 40% more often than the original Afirma test. This improved performance was due to the test's enhanced ability to distinguish benign from cancerous Hürthle cells, a common but hard-to-diagnose thyroid nodule subtype.
- Published a manuscript on the Afirma GSC in *BMS Systems Biology* showcasing the development of the classifier using RNA whole-transcriptome sequencing and machine learning, enabling improved diagnosis of Hürthle cell benign adenoma from carcinoma within this subtype of thyroid nodules.
- Presented Afirma Xpression Atlas data at the ENDO 2019, revealing new insights into the genomic underpinning of medullary thyroid cancer (MTC). This variant and fusion information may help guide physicians in the preoperative evaluation, surgical planning and targeted therapy selections for patients diagnosed with this rare, but aggressive, form of thyroid cancer.

Factors Affecting Our Performance

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 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.

How We Recognize Revenue

We commenced recognizing revenue in accordance with the provisions of ASC 606, *Revenue from Contracts with Customers* starting January 1, 2018. Prior to January 1, 2018, we recognized revenue in accordance with the provisions of ASC 954-605, *Health Care Entities - Revenue Recognition*.

Most of our revenue is generated from the provision of diagnostic 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.

As of December 31, 2018, 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, 2019 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.

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 list price or 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, as we did in July 2015, 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 c

lassifier 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, 2019, 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 2018 to the first quarter of 2019, we accrued between $1.0 million and $2.6 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.

Development of Additional Products

We continue to advance our product portfolio with diagnostic tests that leverage innovations in genomic science, sequencing technology and machine learning methodologies to further improve patient care. 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. In March 2018, we unveiled our Afirma Xpression Atlas, which uses the same RNA sequencing data from the platform as the Afirma GSC and enables us to extract rich genomic content - including gene expression, DNA variants and RNA fusions in over 500 genes that are associated with thyroid cancer - from thyroid FNA samples. We believe that this offering will provide clinicians with valuable genomic information that may inform surgery strategy and treatment options for patients with suspected thyroid cancer.

Together with our Afirma GSC and our tests for the BRAF v600E mutation and medullary thyroid cancer, or Malignancy Classifiers, the Afirma Xpression Atlas 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. 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 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. Additionally, we 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.

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, 2019, we 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 in excess of 10% of revenue and their related revenue as a percentage of total revenue were as follows:

	Three Months Ended March 31,	
	2019	2018
Medicare	21%	29%
UnitedHealthcare	11%	13%
	32%	42%

On December 28, 2018, we entered into a diagnostics development agreement with Johnson & Johnson Services, Inc. for which we recognized $3.8 million of revenue for the provision of data, which represents 12.9% of total revenue for the three months ended March 31, 2019.

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 quarters.

Cost of Revenue

The components of our cost of revenue 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 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.

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 2018 and the first quarter of 2019, and expect to continue doing so in the remainder of 2019. We believe a majority of our research and development expenses in and after 2019 will be predominantly in support of our pipeline products.

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, 2019, approximately 66% 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

Intangible asset amortization began in April 2015 when we launched the Percepta test. The related finite-lived intangible asset with a cost of $16.0 million, and a net book value of $11.7 million at March 31, 2019, is being amortized over 15 years, using the straight-line method.

Interest Expense

Interest expense is attributable to our borrowings under debt agreements and capital leases as well as costs associated with the pre-payment 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, 2019 and 2018 (in thousands of dollars, except percentages and genomic classifiers reported):

	Three Months Ended March 31,			
	2019	2018	Change	%
Revenue	$ 29,529	$ 20,041	$ 9,488	47%
Operating expense:				
Cost of revenue	8,513	7,867	646	8%
Research and development	3,435	3,675	(240)	(7)%
Selling and marketing	12,477	11,543	934	8%
General and administrative	6,904	5,644	1,260	22%
Intangible asset amortization	267	267	—	—%
Total operating expenses	31,596	28,996	2,600	9%
Loss from operations	(2,067)	(8,955)	6,888	(77)%
Interest expense	(303)	(448)	145	(32)%
Other income, net	453	226	227	100%
Net loss and comprehensive loss	$ (1,917)	$ (9,177)	$ 7,260	(79)%
Other Operating Data:				
Genomic classifiers reported	9,162	6,864	2,298	33%
Depreciation and amortization expense	945	980	(35)	(4)%
Stock based compensation expense	1,759	1,175	584	50%

Revenue

Revenue increased $9.5 million, or 47%, for the three months ended March 31, 2019 compared to the same period in 2018 primarily due to a 33% volume increase in genomic classifiers and an increase in the accrual rate for our Afirma genomic classifiers. In the three months ended March 31, 2019, we also recognized $4.1 million of biopharmaceutical service revenue and $0.9 million of revenue for Percepta, the volume for which is included in the number of genomic classifiers reported, compared to zero and $0.1 million in the same period in 2018, respectively. We also make adjustments, as necessary, for tests accrued in prior quarters as collections are made if the amount we expect to ultimately collect changes. The adjustment for tests accrued in prior quarters increased revenue by $0.6 million and $0.7 million for the three months ended March 31, 2019 and 2018, respectively, a net decrease of $0.1 million between the periods.

Cost of revenue

Comparison of the three months ended March 31, 2019 and 2018 is as follows (in thousands of dollars, except percentages):

	Three Months Ended March 31,			
	2019	2018	Change	%
Cost of revenue:				
Laboratory costs	$ 4,664	$ 4,167	$ 497	12%
Sample collection costs	1,095	1,014	81	8%
Compensation expense	1,460	1,149	311	27%
License fees and royalties	2	459	(457)	(100)%
Depreciation and amortization	250	200	50	25%
Other expenses	470	372	98	26%
Allocations	572	506	66	13%
Total	$ 8,513	$ 7,867	$ 646	8%

Cost of revenue increased $0.6 million, or 8%, for the three months ended March 31, 2019 compared to the same period in 2018. Reported genomic classifiers volume increased 33% and cytopathology volume was flat for the three months ended March 31, 2019 compared to the same period in 2018. The increase in laboratory costs was due primarily to the increase in reported genomic classifiers volume. The increase in compensation expense was primarily due to an average laboratory headcount increase

of 12%. The decrease in license fees and royalties was due to the completed transition to the Afirma GSC in the third quarter of 2018, for which we do not pay license fees as we did in connection with the Afirma GEC.

Research and development

Comparison of the three months ended March 31, 2019 and 2018 is as follows (in thousands of dollars, except percentages):

	Three Months Ended March 31,			
	2019	2018	Change	%
Research and development expense:				
Compensation expense	$ 2,130	$ 2,304	$ (174)	(8)%
Direct research and development expense	576	611	(35)	(6)%
Professional fees	201	208	(7)	(3)%
Depreciation and amortization	69	106	(37)	(35)%
Other expenses	158	114	44	39%
Allocations	301	332	(31)	(9)%
Total	$ 3,435	$ 3,675	$ (240)	(7)%

Research and development expense decreased $0.2 million, or 7%, for the three months ended March 31, 2019 compared to the same period in 2018. The decrease in compensation expense was primarily due to the severance costs incurred in the three months ended March 31, 2018 that were not incurred in the three months ended March 31, 2019.

Selling and marketing

Comparison of the three months ended March 31, 2019 and 2018 is as follows (in thousands of dollars, except percentages):

	Three Months Ended March 31,			
	2019	2018	Change	%
Selling and marketing expense:				
Compensation expense	$ 7,714	$ 7,862	$ (148)	(2)%
Direct marketing expense	1,587	1,138	449	39%
Professional fees	364	326	38	12%
Other expenses	2,050	1,617	433	27%
Allocations	762	600	162	27%
Total	$ 12,477	$ 11,543	$ 934	8%

Selling and marketing expense increased $0.9 million, or 8%, for the three months ended March 31, 2019 compared to the same period in 2018. Compensation expense decreased despite a 40% increase in average headcount, due to higher incentive compensation in the prior year period. The increase in direct marketing expense was due to higher trade show and general marketing spend. 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, 2019 and 2018 is as follows (in thousands of dollars, except percentages):

	Three Months Ended March 31,			
	2019	2018	Change	%
General and administrative expense:				
Compensation expense	$ 4,200	$ 3,781	$ 419	11%
Professional fees	2,281	1,399	882	63%
Occupancy expenses	623	619	4	1%
Depreciation and amortization	360	406	(46)	(11)%
Other expenses	1,075	878	197	22%
Allocations	(1,635)	(1,439)	(196)	14%
Total	$ 6,904	$ 5,644	$ 1,260	22%

General and administrative expense increased $1.3 million, or 22%, for the three months ended March 31, 2019 compared to the same period in 2018. The increase in compensation expense was mainly due to higher stock compensation expenses from the increase in our stock price, and the increase in professional fees was mainly due to higher legal expenses.

Interest expense

Interest expense decreased $145,000, or 32%, for the three months ended March 31, 2019 compared to the same period in 2018, mainly due to the prepayment of $12.5 million of the principal amount of our Term Loan in January 2019.

Other income, net

Other income, net, increased $227,000 for the three months ended March 31, 2019 compared to the same period in 2018 primarily due to higher interest income from our money market investments following our public offering of common stock in July 2018.

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Liquidity and Capital Resources

From inception through March 31, 2019, 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, 2019, we had a net loss of $1.9 million, and as of March 31, 2019, we had an accumulated deficit of $236.0 million. We expect to incur additional losses in 2019 and potentially in future years.

We believe our existing cash and cash equivalents of $67.8 million as of March 31, 2019, 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, 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, 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 July 30, 2018, we issued and sold 5,750,000 shares of common stock in a registered public offering, including shares issued and sold upon the underwriters' exercise in full of their option to purchase an additional 750,000 shares, at a price to the public of $10.25 per share. Our net proceeds from the offering were approximately $55.0 million, after deducting underwriting discounts and commissions and estimated offering expenses of $3.9 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 effective interest rate was 9.39% as of March 31, 2019.

We may prepay the outstanding principal amount under the Term Loan plus accrued and unpaid interest and, if the Term Loan 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 in the amount of $1.2 million is due upon the earlier of the maturity date of the Term Loan or its payment in full. In January 2019, we prepaid $12.5 million of the principal amount of the Term Loan and did not incur any prepayment premium as we did not repay the Term Loan in full. This prepayment covers scheduled principal payments from November 2019 to April 2021.

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, 2019, the principal balance outstanding was $12.5 million and we were in compliance with 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, 2019 and 2018 (in thousands of dollars):

	Three Months Ended March 31,	
	2019	2018
Cash used in operating activities	$ (1,011)	$ (7,413)
Cash used in investing activities	(749)	(227)
Cash (used in) provided by financing activities	(8,394)	901

Cash Flows from Operating Activities

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 used in operating activities for the three months ended March 31, 2018 was $7.4 million. The net loss of $9.3 million includes non-cash charges of $1.2 million of stock-based compensation expense and $1.0 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 of $0.4 million was primarily due to an increase in accounts receivable of $0.5 million, a decrease in accounts payable of $0.5 million, and an increase in prepaid expenses and other assets of $0.4 million, partially offset by a decrease in supplies inventory of $0.8 million and an increase in accrued liabilities of $0.3 million, which included a commission accrual partially offset by the payment of annual bonuses.

Cash Flows from Investing Activities

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 used in investing activities for the three months ended March 31, 2018 was $0.2 million for the acquisition of property and equipment.

Cash Flows from Financing Activities

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.

Cash provided by financing activities for the three months ended March 31, 2018 was $0.9 million, consisting of $0.6 million in proceeds from the purchase of stock under our ESPP, and exercise of options to purchase our common stock and $0.4 million in proceeds from a legal settlement, partially offset by capital lease payments of $0.1 million during the period.

Contractual Obligations

Regarding our Loan and Security Agreement, in January 2019, the Company prepaid $12.5 million of the principal amount of the Term Loan Advance. As of March 31, 2019, future principal and end-of-term debt obligation payments due under the Loan and Security Agreement are $5.6 million in 2021 and $8.1 million in 2022. There were no other material changes during the interim period in the contractual obligations presented in our Form 10-K for the year ended December 31, 2018 filed with the Securities and Exchange Commission on February 25, 2019.

Off-balance Sheet Arrangements

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

Recent Accounting Pronouncements

In February 2016, the FASB issued ASU No. 2016-2, *Leases (Topic 842)*. This ASU is aimed at making leasing activities more transparent and comparable, and requires substantially all leases be recognized by lessees on their balance sheet as a right-of-use asset and corresponding lease liability, including leases currently accounted for as operating leases. The ASU is effective for interim and annual periods beginning after December 15, 2018. Additionally, the FASB issued ASU No. 2018-11, *Leases (Topic 842): Targeted Improvements*, which offers an additional transition method whereby entities may apply the new leases standard at the adoption date and recognize a cumulative-effect adjustment to the opening balance of retained earnings rather than application of the new leases standard at the beginning of the earliest period presented in the financial statements. We elected this transition method and adopted ASC 842 on January 1, 2019 and as a result, we recorded operating lease right-of-use ("ROU") assets of $9.8 million, including offsetting deferred rent of $4.3 million, along with the associated operating lease liabilities of $14.1 million. On January 1, 2019, we had a finance lease ROU of $0.8 million and associated finance lease liabilities of $0.3 million for leases we classified as finance leases prior to the adoption of ASC 842. The adoption of ASC 842 had an immaterial impact on our condensed statement of operations and comprehensive loss, condensed statement of stockholders' equity and condensed statement of cash flows for the three-month period ended March 31, 2019. In addition, we elected the package of practical expedients permitted under the transition guidance within the new standard which allowed us to carry forward the historical lease classification. Additional information and disclosures required by this new standard are contained in Note 5, Commitments and Contingencies, in Part I of this Quarterly Report on Form 10-Q.

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 are currently evaluating the potential effect of this standard on our 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 $67.8 million as of March 31, 2019 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, 2019 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, 2019, we had a net loss of $1.9 million and as of March 31, 2019, we had an accumulated deficit of $236.0 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 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.

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, but revenue from Envisia has not been significant to date. 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 and Envisia 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 21% and 11%, respectively, of our revenue for the three months ended March 31, 2019, compared with 29% and 13%, respectively, for the three months ended March 31, 2018. 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 March 2019, with an effective date of April 1, 2019.

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 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. This payment rate will be effective through December 31, 2020. The next data reporting period will be in 2020 for final payments made between January 1 and June 30, 2019. The volume-weighted median of these private payer rates will set the Medicare payment rate for the Afirma classifier from January 1, 2021 through December 31, 2023. There can be no assurance that the rate will not decrease from $3,600 during this or a subsequent reporting cycle under PAMA.

We submit claims to Medicare for Percepta using an unlisted code and were paid at the rate of $3,220 in 2018 under the MolDX program. A specific CPT code assigned to Percepta may be required to go through the national payment determination process, and there can be no assurance that the Medicare payment rate the test receives through this process will not be lower than the current payment rate for Percepta. There can also be no assurance that the Medicare payment rate for Percepta will not be reduced when it is set based on volume-weighted median of private payer rates after the next reporting period under PAMA.

If there is a decrease in the Medicare payment rate for our tests, our revenue from Medicare will decrease and the payment rates for some of our commercial payers may also decrease if they tie their allowable rates to the Medicare rate. 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 rate 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 many payers for the Afirma, Percepta or Envisia 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 as well as 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 rate for our tests, the payment rates for some of our commercial payers may also decrease if they tie their allowable rates to the Medicare rate. 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.

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. Because our diagnostic 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 classifiers 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.

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.

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 personal 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. As discussed in our Annual Report on Form 10-K for the year ended December 31, 2018 in the section titled "Business-Regulation-Clinical Laboratory Improvement Act of 1988, or CLIA," following a routine July 2018 survey of our Austin laboratory location, in September 2018, CMS determined that because we only collected and processed patient specimens and TCP, rather than us, performed the patient testing from the Austin laboratory, we did not require a CLIA certificate for the laboratory. As a result, CMS inactivated our Austin laboratory's CLIA number effective July 2018. While CMS recently reinstated our CLIA number effective as of February 2019, we reversed $0.6 million in previously recognized revenue associated with claims for cytopathology diagnostic services furnished after the date of the July 2018 survey and prior to the reinstatement date. 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, 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 and Percepta 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.

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. 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. 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 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.

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 Thyroid Cytopathology Partners, or TCP, to provide cytopathology professional diagnoses on thyroid fine needle aspiration, or 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.

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. Effective January 1, 2013, the ACA included a 2.3% excise tax on the sale of certain medical devices sold outside of the retail setting. Although a moratorium has been imposed on this excise tax for 2016 through 2019, the excise tax is scheduled to be restored in 2020.

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 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. The next data reporting period will be in 2020 for final payments made between January 1 and June 30, 2019. The volume weighted median of these private payer rates will set the Medicare payment rate for the Afirma classifier from January 1, 2021 through December 31, 2023. There can be no assurance that the payment rate for Afirma 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.

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 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. While we believe the impact of these revisions are favorable to us, we cannot predict with certainty the impact on our business. CMS may change this regulatory policy in the future, which 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 our tests, 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, 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.” 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 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 current tests 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.

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.

With the Percepta and Envisia tests, we believe our primary competition 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 Oncimmune Holdings PLC. We also anticipate facing potential competition from companies offering or developing approaches for assessing malignancy risk in patients with lung nodules using alternative samples, such as blood, urine or sputum, including Biodesix, Inc. and Guardant Health, Inc. However, such "liquid biopsies" are often used earlier in the diagnostic paradigm — for instance, to screen for cancer — or to gauge risk of recurrence or response to treatment.

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, 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, 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. 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.

If our internal sales force is not successful, 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.

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.

We may acquire businesses or assets, form joint ventures or make investments in other companies or technologies that could harm our operating results, dilute our stockholders' ownership, increase our debt or cause us to incur significant expense.

We have previously acquired companies and we may pursue additional acquisitions of complementary businesses or assets, as well as technology licensing arrangements as part of our business strategy. We also may pursue strategic alliances that leverage our core technology and industry experience to expand our offerings or distribution, or make investments in other companies. To date, we have limited experience with respect to acquisitions and the formation of strategic alliances and joint ventures. We may not be able to integrate acquisitions successfully into our existing business, and we could assume unknown or contingent liabilities. In addition, we may not realize the expected benefits of an acquisition or investment. Any 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 may choose 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.

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, or EKRA, 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, 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.

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 and Envisia tests, as well as tests we may develop 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.

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. 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.

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 are scheduled to go into effect on January 1, 2020. The CCPA will, among other things, require covered companies to provide disclosures to California consumers concerning the collection and sale of personal information, and will give 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. We have 25 issued patents that expire between 2029 and 2032 related to methods used in the Afirma diagnostic platform, in addition to 17 pending U.S. utility patent applications, one U.S. provisional patent application, and one PCT application. Some of these U.S. utility patent applications have pending foreign counterparts. We also exclusively licensed intellectual property, including rights to five issued patents that will expire between 2030 and 2035, and three pending U.S. utility patent applications in the thyroid space that would expire between 2030 and 2033 once issued, related to methods that are used in the Afirma diagnostic test, some of which have foreign counterparts. In the lung diagnostic space, we have exclusively licensed intellectual property rights to 12 pending patent applications and eight issued patents. Patents issuing from the licensed portfolio will expire between 2024 and 2028. In addition, we own a pending PCT patent application, a pending U.S. utility patent application, a U.S. provisional patent application, and pending foreign counterpart patent applications in Australia, Canada, China, Europe, Japan, and South Korea related to our Percepta test. We also own one U.S. patent application and one counterpart European patent application related to another lung disease, and three pending U.S. patent applications, one granted patent abroad and ten patent applications abroad related to Envisia. Any patents granted from our current lung cancer patent applications will expire no earlier than 2035 and those from the interstitial lung disease patent applications will expire no earlier than 2034. 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, 2018, we had net operating loss, or NOL, carryforwards of approximately $210.7 million, $56.1 million and $36.6 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.

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 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 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 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 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 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 ceased being an emerging growth company on December 31, 2018, and are now required to include an attestation report on the effectiveness of our internal control over financial reporting annually of our independent registered public accounting firm. 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.

We are a smaller reporting company and may elect to comply with reduced public company reporting requirements applicable to smaller reporting companies, which could make our common stock less attractive to investors.

We are a “smaller reporting company,” meaning that we are not an investment company, an asset-backed issuer, or a majority-owned subsidiary of a parent company that is not a “smaller reporting company,” and have either: (i) a public float of less than $250 million or (ii) annual revenues of less than $100 million during the most recently completed fiscal year and (A) no public float or (B) a public float of less than $700 million. As a “smaller reporting company,” we are subject to reduced disclosure obligations in our SEC filings compared to other issuers, including with respect to disclosure obligations regarding executive compensation in our periodic reports and proxy statements. Until such time as we cease to be a “smaller reporting company,” such reduced disclosure in our SEC filings may make it harder for investors to analyze our operating results and financial prospects.
If some investors find our common stock less attractive as a result of any choices to reduce future disclosure we may make, there may be a less active trading market for our common stock and our stock price may be more volatile.

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;
- 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;
- 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
10.1†	Agreement dated as of October 16, 2017, between Thyroid Cytopathology Partners, P.A. and the Registrant, as amended
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	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema
101.CAL	XBRL Taxonomy Extension Calculation Linkbase
101.DEF	XBRL Taxonomy Extension Definition Linkbase
101.LAB	XBRL Taxonomy Extension Label Linkbase
101.PRE	XBRL Taxonomy Extension Presentation Linkbase

*	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.
†	Registrant is requesting or has previously been granted confidential treatment with respect to certain portions of this Exhibit.

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: April 30, 2019

VERACYTE, INC.

By: /s/ KEITH KENNEDY

Keith Kennedy
Chief Financial Officer
(Principal Financial and Accounting Officer)

[*] Certain identified information has been excluded from the exhibit because it is both (i) not material and (ii) would likely cause competitive harm to the registrant if publicly disclosed.

AMENDED AND RESTATED PATHOLOGY SERVICES AGREEMENT

THIS AMENDED AND RESTATED PATHOLOGY SERVICES AGREEMENT ("Agreement") is made this 14th day of February, 2019 (the "Effective Date"), by and among **VERACYTE, INC.,** a Delaware corporation ("Veracyte"), and **THYROID CYTOPATHOLOGY PARTNERS, P.A.**, a Texas professional association ("Pathologists"). Veracyte and Pathologists are sometimes referred to in this Agreement as a "**Party**" or, collectively, as the "**Parties**."

RECITALS

A. Veracyte and Pathologists entered into that certain Amended and Restated Pathology Services Agreement dated October 16, 2017 (the "Original Agreement").

B. Veracyte and Pathologists now desire to enter into this Agreement in order to amend and restate the Original Agreement in its entirety.

C. Veracyte is engaged in the business of developing and marketing diagnostic testing utilizing Veracyte's proprietary molecular assays and procuring the related anatomic and cytologic pathology. Veracyte is not licensed to practice medicine, but does require the assistance of pathologists who are licensed in states in which Veracyte does business and in states in which patients who utilize Veracyte's services reside.

D. Pathologists is a Texas professional association which is engaged in the practice of medicine and specializes in pathology.

E. Veracyte desires to retain the services of Pathologists to provide professional pathology services on the terms and conditions stated herein.

AGREEMENT

THE PARTIES AGREE AS FOLLOWS:

1. Engagement.

(a) Scope of Engagement. Veracyte hereby grants to Pathologists the exclusive right to provide cytopathologic studies of thyroid specimens referred to Veracyte for cytology testing, except as set forth in Exhibit A ("Exceptions to Exclusivity"). Unless otherwise agreed in writing, Pathologists shall have no responsibility or liability for:

(i) the processing of any pathology specimens or for the performance of any clinical laboratory tests by Veracyte or any third party; and

(ii) any services provided by third party pathologists engaged by Veracyte pursuant to Section 9(b) below.

(b) Approved Physicians. Pathologists will provide the services through individual physicians listed on Exhibit B ("Approved Physicians"). From time to time additional

physicians may be engaged by Pathologists to furnish services under this Agreement; provided, however, that each additional physician must satisfy the professional standards and qualifications set forth in this Agreement. Veracyte shall have the sole discretion to approve any such physician in writing prior to furnishing services, provided that Pathologists are not in breach of this Agreement, then such approval may not be unreasonably withheld.

(c) Geographic Limitation. Services will be provided in the Austin, Texas metropolitan area unless otherwise agreed.

(d) International Arrangements. The Parties shall meet and confer in good faith to negotiate the terms and conditions pursuant to which the Services may be provided by Pathologists for samples obtained outside of the United States by Veracyte. Veracyte may engage multiple service providers to provide the Services for patients located outside of the United States.

2. Duties and Responsibilities of Pathologists.

(a) Pathology Services. Pathologists shall provide physicians and other qualified professionals necessary to provide comprehensive professional cytology evaluation on thyroid specimens from patients referred to Veracyte. Pathology services include (collectively, the "Services"):

(i) macroscopic and microscopic examinations of thyroid cytology specimens including microscopic evaluation of cell blocks prepared on fluids from thyroid FNAs;

(ii) evaluation of thyroid FNAs;

(iii) on occasion TCP may receive requests for consultations as well as for evaluation of non-thyroid FNAs, such as salivary glands or Lymph Nodes;

(iv) interpretation of immunohistochemical stains;

(v) the reporting of these examinations and findings in accordance with Veracyte's laboratory information system and protocols;

(vi) CPT-4 coding in compliance with all applicable federal, state and local laws, rules and regulations (collectively, the "Laws") with respect to the Medicare and Medicaid programs and any other Federal health care program, as defined at 42 U.S.C. Section 1320a-7b(f) (collectively, the "Federal Health Care Programs"); and

(vii) any additional services set forth on Exhibit C.

(b) Equipment. Pathologists shall provide microscopes and computers required to perform the Services. Veracyte shall provide or bear all other facilities and equipment costs, including the cost of telecommunications, software for report generation and any additional hardware, software or computer system infrastructure required by Veracyte or needed to meet Veracyte's standards.

(c) Consultation. Pathologists shall consult with Veracyte's laboratory director, if any, as clinically appropriate and in accordance with applicable licensing, accreditation and certification standards and requirements.

(d) Business Promotion. Pathologists shall assist Veracyte, at Veracyte's expense (which expenses shall be approved in advance by Veracyte), with promotion of the business as mutually agreed upon by the Parties. Pathologists shall also participate in Veracyte's branding and marketing programs as necessary to establish a unity of purpose in providing high quality technical and professional services to Veracyte's clients, all in compliance with the Laws applicable to the provision of clinical laboratory and pathology services under this Agreement. All marketing and promotion activities (which shall not include Pathologists' physician recruiting activities) shall be conducted solely at the direction of, as approved by, and in consultation with Veracyte. Veracyte shall have sole right and authority to approve the content and placement of any and all marketing and promotional materials relating to the Services provided under this Agreement.

(e) Compliance Program. Pathologists shall participate in and abide by Veracyte's compliance program, policies and procedures, as established or adopted from time to time.

(f) Designation of Agent. Tom Traweek, M.D. shall serve as Pathologists' sole and exclusive agent for purposes of communicating with Veracyte concerning the rights of Pathologists pursuant to this Agreement. Pathologists shall be bound by all actions and agreements made by this agent. Pathologists may designate, from time to time, a new agent, pursuant to written notice to Veracyte.

(g) Physician Compensation Arrangements. Pathologists represents and warrants to Veracyte that the compensation paid or to be paid by Pathologists to any physician is and will at all times be fair market value for services and items actually provided by such physician, not taking into account the value or volume of referrals or other business generated by such physician for Veracyte. Pathologists further represent and warrant to Veracyte that Pathologists has and will at all times maintain a written agreement with each physician receiving compensation from Pathologists.

3. Qualifications of Approved Physicians.

(a) Licenses and Certifications. Pathologists shall ensure that each Approved Physician: (i) has and maintains an unrestricted license to practice medicine in one or more of the Covered States as set forth herein, (ii) is and remains board certified in pathology by the applicable medical specialty board approved by the American Board of Medical Specialties, (iii) is and remains

a participating provider in all Federal Health Care Programs, (iv) participates in continuing education as necessary to maintain licensure, professional competence and skills commensurate with the standards of the medical community, and (v) meets all other licensing, credentialing and certification standards as mutually defined and agreed to during the term of this Agreement.

(b) Covered States. Veracyte may provide specimens from the fifty United States (the "Covered States").

(c) Notification of Issues. Pathologists shall notify Veracyte in writing within two (2) business days after Pathologists becomes aware of any one or more of the following events:

(i) Any Approved Physician becomes the subject of any suit, action or other legal proceeding arising out of Pathologists' professional services;

(ii) Any Approved Physician is required to pay damages or any other amount in any malpractice action by way of judgment or settlement;

(iii) Any Approved Physician becomes the subject of any disciplinary proceeding or action before any state's medical board or similar agency responsible for professional standards or behavior;

(iv) Any Approved Physician becomes permanently incapacitated or disabled from practicing medicine;

(v) Any act of nature or any other event occurs which has a material adverse effect on any Approved Physician's ability to perform the Services;

(vi) Any Approved Physician is charged with or convicted of a felony, a misdemeanor involving fraud, dishonesty, or moral turpitude, or any crime relevant to the practice of medicine; or

(vii) Any Approved Physician is debarred, suspended, excluded or otherwise ineligible to participate in any federal or state health care program.

(d) Mandatory Removal. Pathologists shall immediately remove any Approved Physician from furnishing Services under this Agreement who:

(i) has his or her state license to practice medicine or board certification denied, suspended, restricted, terminated, revoked or relinquished for any reason, whether voluntarily or involuntarily, temporarily or permanently, regardless of the availability of civil or administrative hearing rights or judicial review with respect thereto;

(ii) is debarred, suspended, excluded or otherwise ineligible to participate in any Federal Health Care Program; or

(iii) fails to be covered by the professional liability insurance required to be maintained under this Agreement.

(e) Removal Upon Request. Upon written request by Veracyte, Pathologists shall immediately remove any Approved Physician from furnishing Services under this Agreement who:

(i) engages in conduct that, in Veracyte's good faith determination, jeopardizes or damages the reputation of Veracyte;

(ii) fails to satisfy any of the standards and qualifications set forth in this Agreement;

(iii) fails to comply with any other material terms or conditions of this Agreement after being given written notice of that failure and a reasonable opportunity to comply;

(iv) within a twelve (12) month period, has two (2) or more medical malpractice claims filed against him or her; or

(v) is charged with or convicted of a felony, a misdemeanor involving fraud, dishonesty, or moral turpitude, or any crime relevant to the practice of medicine.

4. Duties and Responsibilities of Veracyte.

(a) Laboratory. Veracyte shall be responsible for its cytology and molecular lab, its functions, quality and licensure.

(b) Slide Storage. Veracyte shall maintain and store all slides.

(c) Shipping. Veracyte shall ship specimens to Pathologists and pay for cost of return shipping to Veracyte for storage and reporting.

(d) Clinical Information. Veracyte shall provide all clinical information accompanying any specimens and a manifest of shipment contents.

(e) Software. Veracyte shall be responsible for dictation and reporting software. Veracyte shall also provide any billing or networking or other software needed.

(f) Managed Care Contracting. Except as otherwise provided in Section 9, below, Veracyte shall be responsible for all managed care contracting.

(g) Payment. Veracyte shall pay Pathologists in a timely manner as provided in the Agreement.

5. Practice of Medicine. Pathologists and Veracyte acknowledge that Veracyte is

neither authorized nor qualified to engage in any activity which may be construed or deemed to constitute the practice of medicine. Accordingly, Veracyte shall not engage in the practice of medicine nor seek to provide the Services to be provided by Pathologists under this Agreement through its own physician employees or contractors. To the extent that any act or service required of, or reserved to, Veracyte in this Agreement is construed or deemed to constitute the practice of medicine, the performance of such act or service by Veracyte shall be deemed waived or unenforceable, unless this Agreement can be amended to comply with the law, in which case the Parties shall make such amendment.

6. Term. This Agreement shall become effective on the Effective Date, and shall continue until October 31, 2022 (the "Expiration Date"), unless terminated earlier as provided herein. The Agreement shall automatically renew for successive one (1) year terms unless either Party gives written notice of its intention not to renew this Agreement at least twelve (12) months prior to the end of the then current term.

7. Termination.

(a) Termination by Pathologists. Pathologists shall have the right to terminate this Agreement immediately upon the occurrence of the following:

(i) The insolvency of Veracyte;

(ii) The suspension, revocation, termination or other restriction on Veracyte's laboratory license;

(iii) Failure of Veracyte to pay any undisputed amounts due hereunder within sixty (60) days after the receipt of written notice; or

(iv) Breach of the Agreement by Veracyte and its failure to cure such breach within sixty (60) days after the delivery of written notice thereof.

(b) Termination by Veracyte. Veracyte shall have the right to terminate this Agreement immediately upon the occurrence of any of the following:

(i) The insolvency of Pathologists;

(ii) The suspension or termination of Pathologists from any Federal Health Care Program;

(iii) Breach of the agreement by Pathologists and its failure to cure such breach within sixty (60) days after the delivery of written notice thereof; or

(iv) There is a "Substantial Change" in Pathologists, which Substantial Change has not received written approval, or subsequent ratification by Veracyte, whose approval or ratification shall not be unreasonably withheld. For purposes of this section,

"Substantial Change" means the turnover ratio for Approved Physicians exceeds thirty percent (30%) in any two-year period, whether due to retirement, withdrawal, termination, suspension or otherwise.

8. Compensation, Billing and Collection.

(a) Right to Bill. Except as otherwise provided in Section 9 below:

(i) Veracyte shall have the sole and exclusive right to bill and collect for any and all Services rendered by Pathologists pursuant to this Agreement and shall have the sole and exclusive right, title and interest in and to accounts receivable with respect to such pathology services.

(ii) Pathologists shall seek and obtain compensation for the performance of the Services only from Veracyte. Pathologists shall not bill, assess or charge any fee, assessment or charge of any type against any patient or any other person or entity for Services rendered by Pathologists pursuant to this Agreement. Pathologists shall promptly deliver to Veracyte any and all compensation, in whatever form, that is received by Pathologists for Services rendered by Pathologists pursuant to this Agreement.

(b) Pathologists' Fee. Veracyte shall pay Pathologists for each specimen according to the fee schedule attached hereto as Exhibit E. Pathologists shall be paid within sixty (60) days after the end of the calendar month in which Pathologists complete the Services. Veracyte may bill patients and/or their third party payors, and payment to Pathologists is not contingent upon Veracyte's receipt of payment.

(c) Assignment of Claims. Pathologists hereby assigns (or reassigns, as the case may be) to Veracyte all claims, demands and rights of Pathologists for payment for any and all Services rendered by Pathologists pursuant to this Agreement. Pathologists shall take such action and execute such documents as may be reasonably necessary or appropriate to effectuate the assignment (or reassignment, as the case may be) to Veracyte of all claims, demands and rights of Pathologists for payment for any and all Services rendered by Pathologists pursuant to this Agreement.

(d) Expense Reimbursements.

(i) Veracyte shall reimburse Pathologists for all reasonable and necessary business expenses incurred by Pathologists in connection with the performance of the Services, including shipping, postage, transcription fees, external consults performed at Veracyte's request, etc.; provided that: (l) Pathologists have obtained prior written approval of Veracyte to incur expenses greater than Five Hundred Dollars ($500), (2) the expenses are directly related to the performance of the Services under this Agreement, (3) the expenses meet the requirements for reimbursement under Veracyte policies, and (4) Pathologists submit receipts to Veracyte within sixty (60) days of incurring the expenses. Receipts submitted to Veracyte after sixty (60) days may or may not be paid at the sole discretion of Veracyte.

(ii) Veracyte shall reimburse Pathologists for reasonable and necessary expenses incurred by Pathologists in connection with all sales and marketing activities to promote or represent Veracyte; provided that such sales and marketing activities and expenses are approved in advance by Veracyte.

(iii) Pathologists shall assume all financial responsibility for the costs incurred for licensing all Approved Physicians, including, without limitation, any patient compensation fund contribution requirements required by any applicable state law.

9. Third Party Payor Arrangements.

(a) Cooperation. Pathologists shall reasonably cooperate with Veracyte at Veracyte's expense in the billing and collection of fees with respect to Services rendered by Pathologists pursuant this Agreement. Without limiting the generality of the foregoing, Pathologists shall reasonably cooperate with Veracyte: (i) in providing information to permit Veracyte to complete such claim forms with respect to Services rendered by Pathologists pursuant to this Agreement as may be required by insurance carriers, health care service plans, governmental agencies, or other third party payors; and (ii) in all reasonable respects necessary to facilitate Veracyte's entry into or maintenance of any third party payor arrangements for the provision of services under Federal Health Care Programs or any other public or private health care programs, including insurance programs, self-funded employer health programs, health care service plans and preferred provider organizations.

(b) Enrollment as provider. If Veracyte is not permitted to participate in any third-party payor arrangement that includes the Services, Veracyte may request Pathologists to:

(i) Enroll as a provider, separate from Veracyte, in any third party payor arrangement designated by Veracyte, with respect to services provided pursuant to this Agreement;

(ii) Enter into an express contractual agreement with said third party payor, or with any intermediate organization, including any independent practice association, as required to effect Pathologists' enrollment as a provider; and/or

(iii) Enter into an express contractual agreement with Veracyte regarding global billing, capitation or other payment arrangements that cover Veracyte services and pathology services, as necessary to implement the third party payor arrangement.

Notwithstanding any other provision in this Agreement, upon Pathologists' failure for any reason to take any of the steps above within ten (10) business days after receipt of a written request, Veracyte may engage an additional service provider to provide the Services for patients covered by the third-party payor in question.

10. Insurance.

(a) Insurance. Pathologists shall at its own expense maintain professional errors and omissions insurance with policy limits of at least One Million Dollars ($1,000,000) per claim and Three Million Dollars ($3,000,000) annual aggregate for each Approved Physician. Veracyte shall at its own expense maintain professional malpractice insurance for its laboratory operations with policy limits of at least Three Million Dollars ($3,000,000).

(b) Waiver of Subrogation. Whenever (a) any loss, cost, damage or expense resulting from professional malpractice is incurred by either Party and (b) such Party is then covered (or is required under this Agreement to be covered) in whole or in part by insurance with respect to such loss, cost, damage or expense, then the Party so insured hereby releases the other Party from any liability it may have on account of such loss, cost, damage or expense to the extent of any amount recovered by reason of such insurance, and waives any right of subrogation which might otherwise exist on account thereof, provided that such release of liability and waiver of the right to subrogation shall not be operative in any case where the effect thereof is to invalidate such insurance coverage or increase the cost thereof. The Parties shall use their respective best efforts to obtain such a release and waiver of subrogation from their respective insurance carriers and shall obtain any special endorsements, if required by their insurer, to evidence compliance with the aforementioned waiver. The releases granted herein shall include releases of claims caused by negligence.

11. Indemnity.

(a) Indemnity by Pathologists. Pathologists shall indemnify and defend Veracyte from and against any claims arising out of (i) the breach of this Agreement by Pathologists, and/or (ii) from Pathologists' professional errors or omissions.

(b) Indemnity by Veracyte. Veracyte shall indemnify and defend Pathologists against any claims arising out of (i) the breach of this Agreement by Veracyte, (ii) the preparation of any pathology specimens by Veracyte, and/or (iii) the operation of the cytology or molecular laboratories, and/or (iv) the wrongful disclosure of any patient protected health information by Veracyte or as a result of any defects in any software or computer system provided or maintained by Veracyte.

12. Cooperation between the Parties.

(a) General Duty to Cooperate. The Parties: (1) shall interact professionally, positively and respectfully with each other and with all of their respective employees and contractors; (2) shall not in any way intentionally disparage or otherwise communicate to third parties negative facts, statements or opinions regarding the other and their respective Board members, partners, employees or business; and (3) shall at all times perform the Services in a manner that is in the best interests of Veracyte and in the best interests and safety of patients. Pathologists agree to reasonably cooperate with Veracyte in: any pending or future government or payor investigation; any litigation, arbitration or other dispute resolution involving Veracyte; and any internal investigation Veracyte may conduct. Veracyte shall reimburse Pathologists for all expenses reasonably incurred by

Pathologists in compliance with this Section 12(a), except that Veracyte shall not pay Pathologists for Pathologists' expenses in any dispute resolution where Pathologists are a co-defendant in an action brought by a third party.

(b) Claim Resolution. The Parties recognize that, during the term of this Agreement and for a period thereafter, certain risk management issues, legal issues, claims or actions may arise that involve or could potentially involve the Parties and their respective employees and agents. The Parties further recognize the importance of cooperating with each other in good faith when such issues, claims or actions arise, to the extent such cooperation does not violate any applicable laws, cause the breach of any duties created by any policies of insurance or programs of self-insurance, or otherwise compromise the confidentiality of communications or information regarding the issues, claims or actions. As such, the Parties hereby agree to cooperate in good faith, using their best efforts, to address such risk management and claims handling issues in a manner that strongly encourages full cooperation between the Parties.

13. Noncompetition/Nonsolicitation.

(a) Noncompetition. During the term of this Agreement, Pathologists shall not, without first obtaining the prior written consent of Veracyte, provide cytopathologic studies of thyroid specimens. Pathologists shall ensure that each of the physicians that are providing the Services under this Agreement shall not provide a service that is similar to the Services to any third party.

(b) Nonsolicitation of Employees. Each Party agrees that during the term of the Agreement and for two (2) years after the termination for any reason, it will not solicit the employment of any employee or contractor of the other Party. Furthermore, Veracyte may not directly or indirectly employ, engage or use the services of any physician who Veracyte required that Pathologists remove from providing Services hereunder. Notwithstanding the foregoing, if Pathologists fail to provide the Services under this Agreement, Veracyte may deliver notice to Pathologists describing such failure and if Pathologists do not cure such failure within thirty (30)

days after receipt of such notice, Veracyte shall have the right to enter into agreements directly with the physicians that have provided the Services under this Agreement.

14. Confidentiality.

(a) Confidential Information. Each Party recognizes and acknowledges that, by virtue of entering into this Agreement and performing their respective obligations hereunder, each Party may have access to certain information of the other Party that is confidential and constitutes proprietary, valuable, special and unique property of the other Party. The Parties agree that they shall not at any time, either during or subsequent to the term of this Agreement, disclose to others, use, copy or permit to be copied, without the express prior written consent of the other Party whose confidential information is so disclosed

or used, except pursuant to the performance of such Party's duties thereunder, any confidential or proprietary information of the other Party, including, but not limited to, information which concerns clients and their respective patients, costs, or methods of operation or marketing, and which is not otherwise available to the public.

(b) Disclosure of Terms of this Agreement. Except for disclosure to a Party's legal counsel, accountants or financial advisors, neither Party shall disclose the terms of this Agreement to any person who is not a party or signatory, unless disclosure thereof is required by law or otherwise authorized by this Agreement or consented to in writing by the other Party.

(c) Patient Information. Pathologists shall not disclose to any third party, except where permitted or required by law or where such disclosure is expressly approved by Veracyte in writing, any patient or medical record information regarding patients of Veracyte, and Pathologists shall comply with all federal and state laws and regulations regarding the confidentiality of such information. Pathologists acknowledge and agree that it shall be deemed to constitute a "business associate" of Veracyte as such term is defined in the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information, Technology for Economic and Clinical Health Act of 2009 (collectively, "HIPAA"). Accordingly, Pathologists shall comply with all applicable provisions of HIPAA and the regulations and rules promulgated thereto, including, without limitation, executing and delivering to Veracyte a business associate agreement in the form as attached as Exhibit G hereto.

(d) Survival. The provisions of this Section 14 shall survive expiration or other termination of this Agreement, regardless of the cause of such termination.

15. Miscellaneous Provisions.

(a) Independent Contractor. In performance of all work, duties and obligations under this Agreement, Pathologists are at all times acting and performing as independent contractors practicing the profession of medicine. Veracyte shall have no control or direction over the methods by which Pathologists perform the work and functions required by this Agreement. Pathologists have sole responsibility for the recruitment, retention and compensation of physicians providing Services under this agreement.

(b) Tradename. To the extent that Pathologists adopt a legal name, tradename and/or servicemark that is derivative of "Veracyte," use of such derivative shall be subject to Veracyte's prior written approval and subject to a revocable license granted by Veracyte, which license shall be revoked and terminate upon termination or expiration of this Agreement.

(c) Governing Law. This Agreement will be governed by the laws of the State of Texas.

(d) Assignment. No assignment of this Agreement or the rights and obligation hereunder shall be valid without the specific written consent of both Parties hereto. This is not a third party beneficiary agreement. Notwithstanding the foregoing, the Parties agree that either Party may assign this Agreement without such consent (a) to any entity which is controlled by or under common control with that Party, or (b) in connection with the transfer or sale of all or substantially all of its business or assets related to this Agreement, or in the event of its merger, consolidation, change in control or other similar transaction.

(e) Notices. All notices, requests, demands and any other communications required or permitted hereunder shall be in writing and shall be deemed to have been duly delivered in person or if sent by registered or certified first class United States mail, postage prepaid, or via electronic mail, to:

If to Veracyte:

Veracyte, Inc.
6000 Shoreline Court, Suite 300
South San Francisco, CA 94080
Attention: Bonnie Anderson
email: bonnie@veracyte.com
copy email: keith@veracyte.com

with copy to:

Fenwick & West LLP
555 California St., 12th Floor
San Francisco, CA 94104
Attention: Doug Cogen
email: dcogen@fenwick.com

If to Pathologists:

Thyroid Cytopathology Partners, P.A.
12357 A Riata Trace Parkway
Building 5, Ste 100
Austin, Texas 78727
Attention: Tom Traweek, M.D.
email: tom@thyroidcytopath.com

with copy to:

Rivas Goldstein, LLP

7035 Bee Cave Road, Suite 200
Austin, Texas 78746
Attention: Dana Thompson
email: dana@rivasgoldstein.com

Any of the undersigned may from time to time change said addresses by written notice to the other Party as provided in this Agreement.

(f) Entire Agreement. This Agreement contains the complete, full and exclusive understanding of the Parties with respect to the subject matter hereof and supersedes any and all other agreements between the Parties with respect to this subject matter, including the Original Agreement provided that all rights and obligations that accrued under the Original Agreement prior to the Effective Date shall continue in accordance with the terms of the Original Agreement.

(g) Headings. All headings are for convenience only and shall not be construed to modify the substance of this Agreement.

(h) Amendments. Any amendments, additions or supplements to this Agreement shall be effective and binding on the Parties only if in writing and signed by each Party to this Agreement.

(i) Severability. If any provision of this Agreement is found to be invalid or unenforceable, such provision shall be deemed stricken from this Agreement and the remainder of this Agreement shall remain in full force and effect. The Parties shall negotiate in good faith to amend the Agreement to replace any provision found to be invalid or unenforceable with a valid and enforceable provision which, as nearly as possible, accomplishes the original objectives of the Parties.

(j) Waivers. One or more waivers by either Party of a breach of this Agreement by the other Party shall not be construed as a waiver of further breaches of this Agreement.

(k) Inurement. This Agreement shall be binding upon and shall inure to the benefit of each of the Parties hereto, their heirs, estates, spouses, executors, administrators, partners, successors and assigns.

(l) Multiple Counterparts. This Agreement may be executed in multiple counterparts, each of which shall be deemed an original and each alone and all together shall constitute one and the same instrument.

(m) Arbitration.

(i) Any controversy or claim arising out of or relating to this Agreement shall be settled by binding arbitration in accordance with the applicable rules

of the American Arbitration Association or a successor organization (the "Arbitration Company"), or such other rules as may be agreed upon by the Parties, and judgment upon the award rendered by the arbitrators may be entered in any court having jurisdiction thereof, subject to the following terms, conditions, and exceptions:

(ii) There shall be one (1) arbitrator agreed to by the Parties from the Arbitration Company or, if the Parties cannot agree on one arbitrator, there shall be three (3) arbitrators whose selection shall be made in accordance with the procedures then existing for the selection of such arbitrators by the Arbitration Company.

(iii) The venue of any arbitration shall be Travis County, Texas, and the arbitration shall be conducted in accordance with the laws of the State of Texas.

(iv) Notwithstanding any provision of Texas law or the applicable rules of the Arbitration Company to the contrary, each Party shall have all of the rights of discovery pertaining to civil litigation as provided in Texas law. Unless the Parties otherwise agree in writing, any arbitration hereunder shall be conducted in accordance with the rules of evidence existing in the State of Texas at the time of the arbitration.

(v) Each of the Parties will share equally in the costs and expenses of

arbitration unless the arbitrators find that the position of the non-prevailing Party in such arbitration was without substantial justification, in which event the arbitrators may assess all or an unequal portion of such costs and expenses together with reasonable attorneys' fees against the non-prevailing Party, as the arbitrators deem equitable.

[signature page follows]

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be executed as of the day and year first written above.

PATHOLOGISTS VERACYTE, INC.

THYROID CYTOPATHOLOGY PARTNERS, P.A.

By: /s/ Tom Traweek By: /s/ Bonnie Anderson

Its: CEO Its: Chief Executive Officer

EXHIBIT A

EXCEPTIONS TO EXCLUSIVITY

NONE

EXHIBIT B

APPROVED PHYSICIANS

Dr. Tom Traweek Dr. Cherry Starling Dr. Kelly Gilliland Dr. Laura Been
Dr. Robert Domingo Dr. Michelle Horton Dr. Lorna Ogden Dr. Cindi Snowden Dr. Sharenda Williams Dr. Karen Nauschuetz

EXHIBIT C

ADDITIONAL PATHOLOGY SERVICES

NONE

EXHIBIT D [RESERVED]

EXHIBIT E

FEE SCHEDULE

Period	Price per Nodule
February 1, 2019 – September 30, 2019	$[*]
October 1, 2019 – October 31, 2022	$[*]

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EXHIBIT F
RESERVED

EXHIBIT G

BUSINESS ASSOCIATE AGREEMENT

This Business Associate Agreement (the "Agreement") is made by and among **VERACYTE, INC**., a California corporation (herein referred to as "Covered Entity") and **THYROID CYTOPATHOLOGY PARTNERS, P.A.**, a Texas professional association (hereinafter referred to as "Business Associate"). Covered Entity and Business Associate shall be collectively referred to herein as the "Parties".

WHEREAS, Covered Entity is entering into a business relationship with Business Associate that is memorialized in that certain Amended and Restated Pathology Services Agreement (the "Underlying Agreement") entered into as of even date herewith pursuant to which Business Associate may be considered a "business associate" of Covered Entity as defined in the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") including all pertinent regulations (45 CFR Parts 160 and 64) issued by the U.S. Department of Health and Human Services as either have been amended by Subtitle D of the Health Information Technology for Economic and Clinical Health Act (the "HITECH Act"), as Title XIII of Division A and Title IV of Division B of the American Recovery and Reinvestment Act of 2009 (Pub. L. 111-5);

WHEREAS, the nature of the prospective contractual relationship between Covered Entity and Business Associate may involve the exchange of Protected Health Information ("PHI") as that term is defined under HIPAA; and

For good and lawful consideration as set forth in the Underlying Agreement, Covered Entity and Business Associate enter into this agreement for the purpose of ensuring compliance with the requirements of HIPAA, its implementing regulations, the HITECH Act and relevant State law.

NOW THEREFORE, the premises having been considered and with acknowledgment of the mutual promises and of other good and valuable consideration herein contained, the Parties, intending to be legally bound, hereby agree as follows:

DEFINITIONS.

Individual. "Individual" shall have the same meaning as the term "individual" in 45 CFR §164.501 and shall include a person who qualifies as a personal representative in accordance with 45 CFR §164.502(g).

Breach. "Breach" shall have the same meaning as the term "breach" in § 13400 of the HITECH Act and shall include the unauthorized acquisition, access, use, or disclosure of PHI that compromises the security or privacy of such information.

Designated Record Set. "Designated Record Set" shall have the same meaning as the term "designated record set" in 45 CFR §164.501.

Privacy Rule. "Privacy Rule" shall mean the Standards for Privacy of Individually Identifiable Health Information at 45 CFR Part 160 and Part 164, Subparts A and E, as amended
by the HITECH Act and as may otherwise be amended from time to time.

Protected Health Information. "Protected Health Information" or "PHI" shall have the same meaning as the term "protected health information" in 45 CFR §164.501, limited to the information created or received by Business Associate from or on behalf of Covered Entity.

Required by Law. "Required by Law" shall have the same meaning as the term "required by law" in 45 CFR §164.501.

Secretary. "Secretary" shall mean the Secretary of the U.S. Department of Health and Human Services or his or her designee.

Security Rule. The "Security Rule" shall mean the regulations found at 45 CFR Parts 160 and 164, Subpart C, as may be amended from time to time.

Unsecured Protected Health Information. "Unsecured Protected Health Information" or "Unsecured PHI" shall mean PHI that is not secured through the use of a technology or methodology specified by the Secretary in guidance or as otherwise defined in the §13402(h) of the HITECH Act.

USE OR DISCLOSURE OF PHI BY BUSINESS ASSOCIATE.

Except as otherwise limited in this Agreement, Business Associate may use or disclose Protected Health Information to perform functions, activities, or services for, or on behalf of, Covered Entity as specified in the Underlying Agreement, provided that such use or disclosure would not violate the Privacy Rule.

Business Associate shall only use and disclose PHI if such use or disclosure complies with each applicable requirement of 45 CFR §164.504(e).

DUTIES OF BUSINESS ASSOCIATE RELATIVE TO PHI.

Business Associate shall not use or disclose PHI other than as permitted or required by this Agreement or as Required by Law.

Business Associate shall be directly responsible for full compliance with the relevant requirements of the Privacy Rule to the same extent as Covered Entity.

Business Associate shall comply with the provisions of the Security Rule directing the implementation of administrative, physical and technical safeguards for electronic-PHI ("e-PHI") and the development and enforcement of related policies, procedures, and documentation standards (including but not limited to designation of a security official).

In the event of an unauthorized use or disclosure of PHI or a Breach of Unsecured PHI, Business Associate shall mitigate, to the extent practicable, any harmful effects of said disclosure that are known to it.

Business Associate agrees to ensure that any agent, including a subcontractor, to whom it provides Protected Health Information received from, or created or received by Business Associate on behalf of Covered Entity, agrees to the same restrictions and conditions that apply through this Agreement to Business Associate with respect to such information.

To the extent applicable, Business Associate shall provide access to Protected Health Information in a Designated Record Set at reasonable times, at the request of Covered Entity or, as directed by Covered Entity, to an Individual in order to meet the requirements under 45 CFR §164.524.

Business Associate will, upon receipt of written notice from Covered Entity, promptly amend or permit Covered Entity access to amend any portion of Covered Entity's PHI so that Covered Entity may meet its amendment obligations under 45 CFR §164.526.

Business Associate shall, upon request with reasonable notice, provide Covered Entity access to its premises for a review and demonstration of its internal practices and procedures for safeguarding PHI.

Business Associate agrees to document such disclosures of PHI and information related to such disclosures as would be required for a Covered Entity to respond to a request by an Individual for an accounting of disclosures of PHI in accordance with 45 C.F.R. §164.528. Should an Individual make a request to Covered Entity for an accounting of disclosures of his or her PHI pursuant to 45 C.F.R. §164.528, Business Associate agrees to promptly provide Covered Entity with information in a format and manner sufficient to respond to the Individual's request.

Business Associate shall, upon request with reasonable notice, provide Covered Entity with an accounting of uses and disclosures of PHI provided to it by Covered Entity.

Business Associate shall make its internal practices, books, records, and any other material requested by the Secretary relating to the use, disclosure, and safeguarding of PHI received from Covered Entity available to the Secretary for the purpose of determining compliance with the Privacy Rule. The aforementioned information shall be made available to the Secretary in the manner and place as designated by the Secretary or the Secretary's duly appointed delegate. Under this Agreement, Business Associate shall comply and cooperate with any request for documents or other information from the Secretary directed to Covered Entity that seeks documents or other information held by Business Associate.

Business Associate may use Protected Health Information to report violations of law to appropriate Federal and State authorities, consistent with 42 C.F.R. §164.502(j)(1).

Except as otherwise limited in this Agreement, Business Associate may disclose PHI for the proper management and administration of Business Associate, provided that disclosures are Required by Law, or Business Associate obtains reasonable assurances from the person to whom the information is disclosed that it will remain confidential and used or further disclosed only as Required by Law or for the purpose for which it was disclosed to the person, and the person notifies Business Associate of any instances of which it is aware in which the confidentiality of the information has been breached.

REPORTING.

A. Privacy Breach. Business Associate will report to Covered Entity any use or disclosure of Covered Entity's PHI that is not permitted by this Agreement or the Underlying Agreement. In addition, Business Associate will report to Covered Entity, following discovery and without reasonable delay, but in no event later than ten (10) days following discovery, any suspected or actual "Breach" of "Unsecured Protected Health Information" as these terms are defined by the HITECH Act and any implementing regulations. Business Associate shall cooperate with Covered Entity in investigating the potential or actual breach and in meeting Covered Entity's obligations under the HITECH Act and any other state or federal privacy or security breach notification laws. Any such report shall contain at a minimum the information set forth on Attachment A attached hereto and incorporated by reference. Since time is of the essence under the HITECH Act, in addition to providing the report in accordance with the notice provisions contained in Section XI below, a copy of the report shall be faxed to the Privacy Officer at (615)695-8426 or to such other person as Covered Entity shall request in writing of Business Associate.

TERM AND TERMINATION.

Term. The Term of this Agreement shall be effective as of the date the Underlying Agreement is effective, and shall terminate when all of the Protected Health Information provided by Covered Entity to Business Associate, or created or received by Business Associate on behalf of Covered Entity, is destroyed or returned to Covered Entity, or, if it is infeasible to return or destroy Protected Health Information, protections are extended to such information, in accordance with the termination provisions in this Section V.

A. Termination for Cause. Upon Covered Entity's knowledge of a material breach by Business Associate, Covered Entity shall:

Provide a reasonable opportunity for Business Associate to cure the breach or end the violation and, if Business Associate does not cure the breach or end the violation within the reasonable time specified by Covered Entity, terminate this Agreement;

Immediately terminate this Agreement if Business Associate has breached a material term of this Agreement and cure is not possible; or

If neither termination nor cure is feasible, report the violation to the Secretary. Effect of Termination.

Except as provided in paragraph C(2) of this section, upon termination of this Agreement, for any reason, Business Associate shall return or destroy (at Covered Entity's sole discretion) all Protected Health Information received from Covered Entity, or created or received by Business Associate on behalf of Covered Entity. This provision shall apply to Protected Health Information that is in the possession of subcontractors or agents of Business Associate. Business Associate shall not retain any copies of the Protected Health Information. Any information that is in electronic format shall be provided to Covered Entity at no additional charge. The format to be provided should be one that is commonly used for export (i.e., comma delimited, text file, Word, Excel or Access database) that is agreeable to Covered Entity.

In the event that Business Associate determines that returning or destroying the Protected Health Information is infeasible, Business Associate shall provide to Covered Entity written notification of the conditions that make return or destruction infeasible. After written notification that return or destruction of Protected Health Information is infeasible, Business Associate shall extend the protections of this Agreement to such Protected Health Information and limit further uses and disclosures of such Protected Health Information to those purposes that make the return or destruction infeasible, for so long as Business Associate maintains such Protected Health Information.

Should Business Associate make a disclosure of PHI in violation of this Agreement, Covered Entity shall have the right to immediately terminate any contract, other than this Agreement, then in force between the Parties, including the Underlying Agreement.

REMEDIES IN EVENT OF BREACH AND INDEMNIFICATION. Business Associate hereby recognizes that irreparable harm may result to Covered Entity, and to the business of Covered Entity, in the event of breach by Business Associate of any of the covenants and assurances contained in this Agreement. As such, in the event of breach of any of the covenants and assurances contained in Sections II, III or IV above, Covered Entity shall be entitled to enjoin and restrain Business Associate from any continued violation of Sections II, III or IV. Furthermore, Business Associate will indemnify, defend and hold harmless Covered Entity, its officers, directors, employees, agents, and assigns, from and against any and all losses, liabilities, damages, costs, and expenses (including reasonable attorneys' fees) arising out of or related to the Business Associate's breach of its obligations under this Agreement.

MODIFICATION. This Agreement may only be modified through a writing signed by the Parties. The Parties agree to take such action as is necessary to amend this Agreement from time to time as is necessary for Covered Entity to comply with the requirements of the Privacy Rule and HIPAA.

INTERPRETATION OF THIS CONTRACT IN RELATION TO OTHER CONTRACTS BETWEEN THE PARTIES. Should there be any conflict between the language of this contract and any other contract entered into between the Parties (either previous or subsequent to the date of this Agreement), the language and provisions of this Agreement shall control and prevail unless the Parties specifically refer in a subsequent written agreement to this Agreement by its title and date and specifically state that the provisions of the later written agreement shall control over this Agreement.

COMPLIANCE WITH STATE LAW. If the HIPAA Privacy or Security Rules and the law of the State in which Covered Entity is located conflict regarding the degree of protection provided for protected health information, Business Associate shall comply with the more restrictive protection requirement.

MISCELLANEOUS.

Ambiguity. Any ambiguity in this Agreement shall be resolved to permit Covered Entity

to comply with the Privacy Rule.

Notice to Covered Entity. Any notice required under this Agreement to be given Covered Entity shall be made in writing to:

Veracyte, Inc.
6000 Shoreline Court, Suite 300
South San Francisco, CA 94080
Attention: Bonnie Anderson

with copy to:

Fenwick & West LLP
555 California St., 12th Floor
San Francisco, CA 94104
Attention: Doug Cogen

Notice to Business Associate. Any notice required under this Agreement to be given Business Associate shall be made in writing to:

Thyroid Cytopathology Partners, P.A.
12357 A Riata Trace Parkway
Building 5, Ste 100
Austin, Texas 78727
Attention: Tom Traweek, M.D.

with copy to:

Rivas Goldstein, LLP
7035 Bee Cave Road, Suite 200
Austin, Texas 78746
Attention: Dana Thompson

IN WITNESS WHEREOF and acknowledging acceptance and agreement of the foregoing, the Parties affix their signatures hereto.

COVERED ENTITY: BUSINESS ASSOCIATE:

By: /s/ Bonnie Anderson By: /s/ Tom Traweek

Name: Bonnie Anderson Name: Tom Traweek

Title: Chairman & CEO Title: CEO

ATTACHMENT A

FORM OF NOTIFICATION TO COVERED ENTITY OF

BREACH OF UNSECURED PHI

This notification is made pursuant to the Business Associate Agreement between **VERACYTE, INC**., a California corporation ("Covered Entity"), and **THYROID CYTOPATHOLOGY PARTNERS, P.A.**, a Texas professional association ("Business Associate").

Business Associate hereby notifies Covered Entity that there has been an actual or potential breach of unsecured (unencrypted) protected health information (PHI) that Business Associate has used or has had access to under the terms of the Business Associate Agreement.

Description of the breach:

Date of the breach: Date breach discovered:

Number of individuals affected by the breach:

Indicate type of breach:

☐ Theft

☐ Loss

☐ Improper Disposal

☐ Unauthorized Access

☐ Hacking/IT Incident

☐ Other:

☐ Unknown

Location of Breached Information:

☐ Laptop

☐ Desktop Computer

☐ Email

☐ Portable Media/Device

☐ EMR

☐ Paper

☐ Other:

A description of the types of unsecured PHI that were involved in the breach (Demographic - full or partial name, Social Security number, date of birth, home address, account number, or disability code; Financial - billing information, credit card # or check/bank account number; Clinical - any mention of diagnosis, procedure, treatment provided, or ICD-9-CM or CPT-codes; Other):

What safeguards were in place prior to the breach: (Circle all that apply) Firewalls, packet filtering, secure browser, strong authentication, encrypted wireless, physical security (explain), logic access control, anti-virus software (list product name), intrusion detection, biometrics, etc.:

Description of what Business Associate is doing to investigate the breach, to mitigate losses, and to protect against any further breaches:

Contact information to ask questions or learn additional information:

Name:

Title:

Address:

Email Address:_____

Phone Number: _____

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, 2019;

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: April 30, 2019

/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, 2019;

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: April 30, 2019

/s/ Keith Kennedy

Keith Kennedy

Chief Financial Officer

(Principal Financial and Accounting 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, 2019, 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: April 30, 2019

/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, 2019, 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: April 30, 2019

/s/ Keith Kennedy

Keith Kennedy
Chief Financial Officer
(Principal Financial and Accounting Officer)