

VERACYTE, INC.  
Form 10-Q  
July 23, 2018  
Table of Contents

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 June 30, 2018

OR

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number 001-36156

---

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

---

Delaware 20-5455398  
(State or other jurisdiction of (I.R.S. Employer  
incorporation or organization) 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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

Edgar Filing: VERACYTE, INC. - Form 10-Q

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. (Check one):

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

(Do not check if a smaller reporting company) Emerging growth company

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

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

As of July 17, 2018, there were 34,533,302 shares of common stock, par value \$0.001 per share, outstanding.

---

Table of Contents

VERACYTE, INC.  
INDEX

	Page No.
<u>PART I. — FINANCIAL INFORMATION</u>	
<u>Item 1. Condensed Financial Statements (Unaudited)</u>	<u>1</u>
<u>Condensed Balance Sheets as of June 30, 2018 and December 31, 2017</u>	<u>1</u>
<u>Condensed Statements of Operations and Comprehensive Loss for the Three and Six-Month Periods Ended June 30, 2018 and 2017</u>	<u>2</u>
<u>Condensed Statements of Cash Flows for the Six-Month Periods Ended June 30, 2018 and 2017</u>	<u>3</u>
<u>Notes to Condensed Financial Statements</u>	<u>5</u>
<u>Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	<u>12</u>
<u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u>	<u>25</u>
<u>Item 4. Controls and Procedures</u>	<u>25</u>
<u>PART II. — OTHER INFORMATION</u>	
<u>Item 1A. Risk Factors</u>	<u>26</u>
<u>Item 6. Exhibits</u>	<u>49</u>
<u>SIGNATURES</u>	<u>50</u>

Table of Contents

## PART I. — FINANCIAL INFORMATION

## Item 1. Condensed Financial Statements

## VERACYTE, INC.

## Condensed Balance Sheets

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

	June 30, 2018 (Unaudited)	December 31, 2017 (See Note 1)
Assets		
Current assets:		
Cash and cash equivalents	\$ 23,758	\$ 33,891
Accounts receivable	13,006	12,716
Supplies inventory	3,049	5,324
Prepaid expenses and other current assets	1,822	1,997
Total current assets	41,635	53,928
Property and equipment, net	9,035	9,688
Finite-lived intangible assets, net	12,533	13,067
Goodwill	1,057	1,057
Restricted cash	603	603
Other assets	598	326
Total assets	\$ 65,461	\$ 78,669
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 1,962	\$ 3,853
Accrued liabilities	8,429	8,175
Total current liabilities	10,391	12,028
Long-term debt	25,103	24,938
Capital lease liability, net of current portion	156	308
Deferred rent, net of current portion	4,005	4,170
Total liabilities	39,655	41,444
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.001 par value; 5,000,000 shares authorized, no shares issued and outstanding as of June 30, 2018 and December 31, 2017	—	—
Common stock, \$0.001 par value; 125,000,000 shares authorized, 34,441,714 and 34,210,388 shares issued and outstanding as of June 30, 2018 and December 31, 2017, respectively	34	34
Additional paid-in capital	252,284	248,278
Accumulated deficit	(226,512 )	(211,087 )
Total stockholders' equity	25,806	37,225
Total liabilities and stockholders' equity	\$ 65,461	\$ 78,669

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



Table of Contents

VERACYTE, INC.

Condensed Statements of Operations and Comprehensive Loss

(Unaudited)

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

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2018	2017	2018	2017
Revenue	\$22,751	\$ 18,406	\$42,792	\$ 34,838
Operating expenses:				
Cost of revenue	8,246	6,960	16,113	13,257
Research and development	4,601	3,603	8,276	7,633
Selling and marketing	9,623	7,994	21,166	15,330
General and administrative	5,932	6,192	11,576	12,211
Intangible asset amortization	266	266	533	533
Total operating expenses	28,668	25,015	57,664	48,964
Loss from operations	(5,917 )	(6,609 )	(14,872 )	(14,126 )
Interest expense	(481 )	(808 )	(929 )	(1,608 )
Other income, net	150	119	376	219
Net loss and comprehensive loss	\$(6,248 )	\$(7,298 )	\$(15,425 )	\$(15,515 )
Net loss per common share, basic and diluted	\$(0.18 )	\$(0.22 )	\$(0.45 )	\$(0.46 )
Shares used to compute net loss per common share, basic and diluted	34,314,234	33,873,128	34,320,793	33,848,645

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

Table of Contents

VERACYTE, INC.

Condensed Statements of Cash Flows

(Unaudited)

(In thousands of dollars)

	Six Months Ended	
	June 30,	
	2018	2017
Operating activities		
Net loss	\$(15,425)	\$(15,515)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,969	1,846
Stock-based compensation	2,906	3,214
Other income	(93)	) —
Amortization of debt issuance costs	16	53
Interest on end-of-term debt obligation	149	—
Changes in operating assets and liabilities:		
Accounts receivable	(290)	) (2,271 )
Supplies inventory	2,275	158
Prepaid expenses and current other assets	98	25
Other assets	(272)	) —
Accounts payable	(1,912)	) 266
Accrued liabilities and deferred rent	67	(772 )
Net cash used in operating activities	(10,512)	) (12,996 )
Investing activities		
Purchases of property and equipment	(761)	) (728 )
Proceeds from sale of property and equipment	—	440
Net cash used in investing activities	(761)	) (288 )
Financing activities		
Proceeds from the issuance of common stock in a public offering, net of costs	—	200
Proceeds from legal settlement regarding short-swing profits	403	—
Payment of capital lease liability	(144)	) (135 )
Proceeds from the exercise of common stock options and employee stock purchases	881	463
Net cash provided by financing activities	1,140	528
Net decrease in cash, cash equivalents and restricted cash	(10,133)	) (12,756 )
Cash, cash equivalents and restricted cash at beginning of period	34,494	59,942
Cash, cash equivalents and restricted cash at end of period	\$24,361	\$47,186
Supplementary cash flow information of non-cash investing and financing activities:		
Purchases of property and equipment included in accounts payable	\$63	\$—
Interest paid on debt	\$741	\$1,540





Table of Contents

Cash, Cash Equivalents and Restricted Cash:

	June 30, December 31,	
	2018	2017
Cash and cash equivalents	\$23,758	\$ 33,891
Restricted cash	603	603
Total cash, cash equivalents and restricted cash	\$24,361	\$ 34,494

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

Table of Contents

VERACYTE, INC.

Notes to Financial Statements

1. Organization and Description of Business

Veracyte, Inc. (“Veracyte” or the “Company”) 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.

Veracyte is a genomic diagnostics company that resolves diagnostic uncertainty by combining genomic technology, clinical science and machine learning to provide diagnostic answers to physicians and patients.

Since the Company's founding in 2008, it has commercialized three products:

**Afirma Thyroid FNA Analysis** - Includes the next-generation Afirma Genomic Sequencing Classifier, or GSC, and its predecessor, the Afirma Gene Expression Classifier, or GEC that is used to identify patients with benign thyroid nodules among those with indeterminate cytopathology results in order to preserve the thyroid. The Afirma classifier was developed using machine learning that is based on ensemble methods in which multiple algorithms - each playing its own role - are used to interpret large amounts of ribonucleic acid, or RNA, sequencing genomic data and obtain a better predictive performance than any single algorithm.

**Percepta Bronchial Genomic Classifier** - The 23-gene Percepta classifier improves lung cancer screening and diagnosis by increasing the diagnostic performance of bronchoscopies and identifying patients with lung nodules who are at low risk of cancer, without the need for more invasive procedures. The test leverages the field of injury concept and analyzes genomic changes that occur in the epithelial cells lining the airways of current or former smokers to assess a patient’s risk of having lung cancer, without the need to test the often-hard-to-reach nodule directly.

**Envisia Genomic Classifier** - The Envisia classifier is designed to improve physicians’ ability to differentiate idiopathic pulmonary fibrosis, or IPF, from other interstitial lung diseases, or ILD, without the need for invasive and potentially risky surgery. The Envisia classifier uses machine learning coupled with powerful, deep RNA sequencing to detect the presence or absence of usual interstitial pneumonia, or UIP, a classic diagnostic pattern whose presence is essential for the diagnosis of IPF.

All of the Company's testing services are made available through its clinical reference laboratories located in South San Francisco, California and Austin, Texas, which are each certified under the Clinical Laboratory Improvement Amendments of 1988.

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 June 30, 2018, the condensed statements of operations and comprehensive loss for the three and six months ended June 30, 2018 and 2017, and the condensed statements of cash flows for the six months ended June 30, 2018 and 2017 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, 2017 has been derived from

Edgar Filing: VERACYTE, INC. - Form 10-Q

audited financial statements. The results for the three and six months ended June 30, 2018 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, 2017.

Table of Contents

## 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; contractual allowances; the useful lives of property and equipment; the recoverability of long-lived assets; 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.

## 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 June 30, 2018, substantially all 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 June 30, 2018		Six Months Ended June 30, 2017	
Medicare	28%	26%	28%	26%
UnitedHealthcare	12%	15%	12%	14%
	40%	41%	40%	40%

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

	June 30, 2018		December 31, 2017	
Medicare	16%		22%	
UnitedHealthcare	10%		9%	

No other third-party payer represented more than 10% of the Company's accounts receivable balances as of those dates.

#### Restricted Cash

The Company had deposits of \$603,000 included in long-term assets as of June 30, 2018 and December 31, 2017, 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

6

---

## Table of Contents

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 to December 31, 2017, or the Catch-Up Period. 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. There was sufficient payment history for the Company to substantially accrue all revenue upon delivery of test results starting July 1, 2016 and the Company continued to recognize revenue upon cash receipt for unaccrued tests that were delivered prior to July 1, 2016. There was no revenue recognized on the cash basis for the three and six months ended June 30, 2018 and revenue on the cash basis for the three and six months ended June 30, 2017 was \$795,000 and \$2.1 million, respectively.

As noted above, on July 1, 2016 the Company began recognizing revenue from substantially all its tests on the accrual basis of accounting at an amount equal to management's best estimate of the cash to ultimately be collected. For tests delivered prior to July 1, 2016, substantially all the related cash had been collected by December 31, 2017. Thus, at January 1, 2018, the cumulative impact of adopting ASC 606 was not material and no adjustment was recorded.

During the first half of 2018, cash collections for certain tests delivered in 2017 came in at rates higher than originally accrued. As a result, the Company changed its estimate of the amounts to be recognized for these tests and recognized an additional \$0.5 million and \$1.2 million of revenue for the three and six months ended June 30, 2018, respectively. These changes in estimates resulted in decreases in loss from operations of \$0.5 million and \$1.2 million and decreases in loss per share of approximately \$0.02 and \$0.04 for the three and six months ended June 30, 2018, respectively.

### Biopharmaceutical Services

On April 9, 2018, the Company entered into an agreement with a biopharmaceutical company whereby the Company agreed to provide certain tissue samples and other services in exchange for agreed-upon fees. During the quarter ended June 30, 2018, the Company recognized \$450,000 of revenue upon delivery of tissue samples and the Company received \$500,000 for other services, which will be recognized ratably during the quarters ended September 30 and December 31, 2018 as the services are performed. Thereafter, the Company expects to receive approximately \$250,000 per quarter as services are performed and may also recognize revenue related to the delivery of additional tissue samples as long as the agreement is not terminated. The agreement has a term of one year with an automatic renewal of one year and the biopharmaceutical company 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.

#### 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 will be effective

7

---

Table of Contents

for interim and annual periods beginning after December 15, 2018. Entities are required to use a modified retrospective approach for leases that exist or are entered into after the beginning of the earliest comparative period in the financial statements. Full retrospective application is prohibited and early adoption is permitted. The Company expects to adopt this standard beginning in 2019. The Company does not expect that this standard will have a material impact on its results of operations or cash flows, but that it will have a material impact on the Company's assets and liabilities. The Company is currently in the process of quantifying the impact of adopting this ASU.

## 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		Six Months Ended	
	June 30,		June 30,	
	2018	2017	2018	2017
Shares of common stock subject to outstanding options	6,209,143	6,436,953	6,100,753	6,039,791
Employee stock purchase plan	42,531	41,044	34,137	35,229
Restricted stock units	450,505	70,000	322,367	54,834
Total common stock equivalents	6,702,179	6,547,997	6,457,257	6,129,854

## 3. Accrued Liabilities

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

	June 30, December 31,	
	2018	2017
Accrued compensation expenses	\$ 5,052	\$ 5,293
Accrued other	3,377	2,882
Total accrued liabilities	\$ 8,429	\$ 8,175

## 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.

Table of Contents

The fair value of the Company's financial assets include 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 \$23.2 million and \$33.1 million as of June 30, 2018 and December 31, 2017, 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 June 30, 2018 and December 31, 2017, 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. In February 2017, the Company relinquished certain expansion rights for a nominal fee. The Company had deposits of \$603,000 included in long-term assets as of June 30, 2018 and December 31, 2017, 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 related cash security deposit of \$139,000 as of June 30, 2018 and December 31, 2017 is included in other assets in the Company's condensed balance sheets.

Future minimum lease payments under non-cancelable operating leases as of June 30, 2018 are as follows (in thousands of dollars):

Year Ending December 31,	
Remainder of 2018	\$ 1,030
2019	2,227
2020	2,332
2021	2,401
2022	2,472
Thereafter	9,384
Total minimum lease payments	\$ 19,846

The Company recognizes rent expense on a straight-line basis over the non-cancelable lease period. Rent expense was \$476,000 and \$455,000 for the three months ended June 30, 2018 and 2017, respectively, and \$953,000 and \$912,000 for the six months ended June 30, 2018 and 2017, respectively.

## Capital Lease

The Company entered into a capital lease in December 2016 for \$1.2 million of laboratory equipment. The Company paid an upfront amount of \$330,000 and the present value of the total future minimum lease payments was \$874,000. As of June 30, 2018, the annual future minimum lease payments are \$159,000 and \$317,000 for the remainder of 2018 and 2019, respectively.

## Contingencies

From time to time, the Company may be involved in legal proceedings arising in the ordinary course of business. The Company assesses contingencies to determine the degree of probability and range of possible loss for potential accrual

in its 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, or the Loan and Security Agreement, with

9

---

Table of Contents

Silicon Valley Bank. The Loan and Security Agreement allows the Company to borrow up to \$35.0 million, with a \$25.0 million 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 June 30, 2018. Borrowings under the Loan and Security Agreement mature on October 1, 2022. Amounts may be borrowed and repaid under the Revolving Line of Credit up until the earliest of full repayment or maturity of the Loan and Security Agreement, termination of the Loan and Security Agreement, or October 1, 2022.

The Term Loan Advance bears interest at a variable rate equal to (i) the thirty-day U.S. London Interbank Offer Rate, or LIBOR plus (ii) 4.20%, with a minimum rate of 5.34% 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 was 7.9% for the six months ended June 30, 2018.

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 June 30, 2018, the Company was in compliance with the loan covenants.

As of June 30, 2018, the net debt obligation for borrowings made under the Loan and Security Agreement was as follows (in thousands of dollars):

	June 30, 2018	December 31, 2017
Debt principal	\$25,000	\$25,000
End-of-term debt obligation	202	53
Unamortized debt issuance costs	(99 )	(115 )
Net debt obligation	\$25,103	\$24,938

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	\$1,389
----------------------------------	---------

Edgar Filing: VERACYTE, INC. - Form 10-Q

2020	8,333
2021	8,333
2022	8,132
Total	\$26,187

Credit Agreement

10

---

Table of Contents

In March 2016, the Company entered into a credit agreement, or the Credit Agreement, with Visium Healthcare Partners, LP. Under the Credit Agreement, two term loans were available to the Company with an aggregate principal amount of up to \$40.0 million. The Company drew down the initial \$25.0 million term loan, or the Term Loan, on March 30, 2016.

As noted above, upon entering into the Loan and Security Agreement, the Credit Agreement was paid in full and terminated on November 3, 2017, wherein all commitments were terminated, all liens were released and all outstanding principal, interest and fees accrued thereunder were repaid in the aggregate amount of \$27.3 million, including a prepayment premium of \$1.5 million.

## 7. Stockholders' Equity

## Common Stock

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

	June 30, 2018	December 31, 2017
Stock options and restricted stock units issued and outstanding	6,761,730	6,061,081
Stock options and restricted stock units available for grant under stock option plans	1,643,164	1,133,907
Common stock available for the Employee Stock Purchase Plan	382,929	456,002
Total	8,787,823	7,650,990

## 8. Thyroid Cytopathology Partners

In 2010, the Company entered into an arrangement with Pathology Resource Consultants, P.A., or PRC, to set up and manage a specialized pathology practice to provide testing services to the Company. There was no direct monetary compensation from the Company to PRC as a result of this arrangement. The Company's service agreement was with the specialized pathology practice, Thyroid Cytopathology Partners, or TCP, which was managed by PRC and was effective through December 31, 2015, and thereafter automatically renewed every year unless either party provided notice of intent not to renew at least 12 months prior to the end of the then-current term. Under the service agreement, the Company paid TCP based on a fixed price per test schedule, which was reviewed periodically for changes in market pricing. Subsequent to December 2012, an amendment to the service agreement allowed 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.

On October 16, 2017, the Company amended and restated its service agreement with TCP. The 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. In connection with amending and restating the TCP agreement, the Company's arrangement with PRC was simultaneously assigned by PRC to TCP and immediately terminated, and the Company agreed to pay PRC a total of \$1.8 million over eight quarterly installments in exchange for TCP reducing the price per test it charges the Company during the term of the amended TCP agreement. Payments are amortized over the term of the agreement.

The Company has concluded that TCP represents a variable interest entity and 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. Therefore, the Company does not consolidate TCP. All amounts paid to TCP under the service agreement are expensed as incurred and included in cost of revenue in the accompanying statements of operations and comprehensive loss.

The Company incurred \$1.0 million and \$1.2 million for the three months ended June 30, 2018 and 2017, respectively, and \$1.9 million and \$2.4 million for the six months ended June 30, 2018 and 2017, respectively, in cytopathology testing and evaluation services expenses with TCP, which are included in cost of revenues in the Company's condensed statements of operations and comprehensive loss. The Company's outstanding obligations to TCP for cytopathology testing services were \$297,000 and \$308,000 as of June 30, 2018 and December 31, 2017, respectively, and are included in accounts payable on the accompanying condensed balance sheets.

TCP reimburses the Company for its proportionate share of the Company's rent and related operating expenses for the leased facility. TCP's portion of rent and related operating expenses for the shared space at the Austin, Texas facility was \$32,000 and \$27,000 for the three months ended June 30, 2018 and 2017, respectively, and \$64,000 and \$52,000 for the six months ended

Table of Contents

June 30, 2018 and 2017, 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 and six months ended June 30, 2018 and 2017. The Company continues to maintain a full valuation allowance against its net deferred tax assets.

As of June 30, 2018, the Company had unrecognized tax benefits of \$2.5 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 June 30, 2018 will significantly increase or decrease within the next 12 months. There was no interest expense or penalties related to unrecognized tax benefits recorded through June 30, 2018.

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, in light of changing facts and circumstances. Settlement of any particular position could require the use of cash.

On December 22, 2017, the U.S. government enacted comprehensive tax legislation referred to as the Tax Cuts and Jobs Act (the "Tax Act"). The Tax Act significantly revises the future ongoing U.S. corporate income tax by, among other things, lowering the U.S. corporate income tax rates and implementing a territorial tax system. The corporate tax rate was reduced from 35% to 21% for tax years beginning after December 31, 2017 and certain provisions exist on which to allow accelerated expensing of equipment for a portion of 2017 and for future years. These changes primarily impacted the value of the Company's deferred tax assets with a corresponding offset to valuation allowance, both of which were recognized in the year ended December 31, 2017.

The Tax Act also limits the amount of net operating losses that can be used to reduce taxable income to 80% for net operating losses generated for periods beginning after December 31, 2017. Existing net operating losses, arising in years on or before December 31, 2017 are not affected by the Tax Act. The Company has completed a preliminary assessment of the accounting for the income tax effects of the Tax Act, as it relates to its current structure, including provisions that are effective for tax years beginning in 2018. The Company's preliminary assessment is subject to revisions to any additional guidance issued by the U.S. Treasury Department, Internal Revenue Service, FASB, and other standard-setting and regulatory bodies. Adjustments may materially impact the Company's provision for income taxes and the assessment of the accounting for the tax effects of the Tax Act will not extend beyond one year from the enactment date.

**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, 2017.

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 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; 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;

## Table of Contents

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 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 provides trustworthy and actionable answers that fundamentally improve patient care when current diagnostic test results are uncertain. Our products combine genomic technology, clinical science and machine learning to provide answers that give physicians and patients a clear path forward potentially avoiding risky, costly surgery that is often unnecessary.

The role of genomic information in medical practice is evolving rapidly and has affected the diagnosis of disease as well as treatment decisions. Over the past decade, molecular diagnostic tests that analyze genomic material from tissue samples have emerged as an important complement to evaluations performed by pathologists. Information at the molecular level enables one to understand and identify more fully the makeup and specific subtype of disease to improve diagnosis. In many cases, the genomic information derived from these samples can help guide treatment decisions as part of the standard of care.

We deploy machine learning algorithms, which leverage comprehensive ribonucleic acid, or RNA, expression data, to develop tests for the improvement of diagnostic clarity for cancer and other diseases. In our thyroid and lung indications, diagnosis can be ambiguous in 15-70% of patients undergoing diagnostic evaluation depending on the indication. Our tests provide clarity of diagnosis that can in turn guide treatment decisions in 40-70% of those cases, eliminating costly, risky surgeries and other unnecessary medical procedures, improving the lives of patients and

saving the healthcare system money.

Since our founding in 2008, we have commercialized three genomic classifiers that we believe are transforming diagnostics: the next-generation Afirma Genomic Sequencing Classifier, or GSC, and its predecessor, the Afirma Gene Expression Classifier, or GEC, for thyroid cancer; the Percepta Bronchial Genomic Classifier for lung cancer; and the Envisia Genomic Classifier for idiopathic pulmonary fibrosis, or IPF. Collectively, we believe these three tests address a \$2 billion global market opportunity.

The published evidence supporting our tests demonstrates the robustness of our science and clinical studies. Patients and physicians can access our full list of publications on our website. Over 30 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 also expect to continue expanding our offerings in thyroid cancer, lung cancer and interstitial lung diseases such as IPF, as well as other indications that we believe will benefit from our technology and approach.

13

---

Table of Contents

We believe our focus on developing clinically useful tests that change patient care is enabling the company to set new standards in genomic test reimbursement. Our Afirma genomic classifier is now covered by every major health plan in the United States, covering more than 275 million people, for use in thyroid cancer diagnosis. It is available as an in-network, contracted offering to more than 210 million people nationwide through their insurers. 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 Medicare enrollees.

Second Quarter 2018 Financial Results

For the three-month period ended June 30, 2018, as compared to the second quarter of 2017:

Revenue was \$22.8 million, an increase of 24%;  
Genomic Test Volume was 7,686, an increase of 18%;  
Gross Margin was 64%, an increase of 2%;  
Operating Expenses, Excluding Cost of Revenue were \$20.4 million, an increase of 13%;  
Net Loss and Comprehensive Loss was (\$6.2) million, an improvement of 14%;  
Basic and Diluted Net Loss Per Common Share was (\$0.18), an improvement of 18%;  
Cash Burn<sup>(1)</sup> was \$3.6 million, an improvement of 28%; and  
Cash and Cash Equivalents was \$23.8 million at June 30, 2018.

For the six-month period ended June 30, 2018, as compared to the prior year period of 2017:

Revenue was \$42.8 million, an increase of 23%;  
Genomic Test Volume was 14,550, an increase of 18%;  
Gross Margin was unchanged at 62%;  
Operating Expenses, Excluding Cost of Revenue were \$41.6 million, an increase of 16%;  
Net Loss and Comprehensive Loss was (\$15.4) million, an improvement of 1%;  
Basic and Diluted Net Loss Per Common Share was (\$0.45), an improvement of 2%; and  
Cash Burn<sup>(1)</sup> was \$11.3 million, an improvement of 15%.

(1) A reconciliation of net cash used in operating activities to cash burn has been provided below.

To supplement our financial statements prepared in accordance with U. S. GAAP, we monitor and consider cash burn, which is a non-U.S. GAAP financial measure. This non-U.S. GAAP financial measure is not based on any standardized methodology prescribed by U.S. GAAP and is not necessarily comparable to similarly-titled measures presented by other companies. We define cash burn as net cash used in operating activities plus net capital expenditures, such as net purchases of property and equipment. We believe cash burn to be a liquidity measure that provides useful information to management and investors about the amount of cash consumed by the operations of the business, including our purchases of property and equipment. A limitation of using this non-U.S. GAAP measure is that cash burn does not represent the total change in cash, cash equivalents and restricted cash for the period because it excludes cash provided by or used for other investing and financing activities. We account for this limitation by providing information about our capital expenditures and other investing and financing activities in the statements of cash flows in our financial statements and by presenting cash flows from investing and financing activities in our reconciliation of cash burn. In addition, it is important to note that other companies, including companies in our industry, may not use cash burn, may calculate cash burn in a different manner than we do or may use other financial measures to evaluate their performance, all of which could reduce the usefulness of cash burn as a comparative measure.

Because of these limitations, cash burn should not be considered in isolation from, or as a substitute for, financial information prepared in accordance with U.S. GAAP. The reconciliation of cash burn to net cash used in operating activities is provided in the tables below (in thousands of dollars):

14

---

Table of Contents

	Three Months	
	Ended June 30,	
	2018	2017
Net cash used in operating activities	\$(3,099)	\$(4,910)
Plus purchases of property and equipment	(534 )	(113 )
Cash burn	\$(3,633)	\$(5,023)
Net cash used in investing activities	\$(534 )	\$(113 )
Net cash provided by (used in) financing activities	\$239	\$(20 )

  

	Six Months Ended	
	June 30,	
	2018	2017
Net cash used in operating activities	\$(10,512)	\$(12,996)
Plus purchases of property and equipment	(761 )	(728 )
Less proceeds from the sale of property and equipment	\$—	\$440
Cash burn	\$(11,273)	\$(13,284)
Net cash used in investing activities	\$(761 )	\$(288 )
Net cash provided by financing activities	\$1,140	\$528

## Second Quarter 2018 and Recent Business Highlights

## Commercial Growth:

- Tripled Percepta revenue for the second quarter of 2018, compared to the first quarter, with the number of physicians ordering the Percepta classifier increasing by over 50 percent during this period.
- Received regulatory approval from the New York State Department of Health, enabling us to now move 100% of Afirma classifier testing to the Genomic Sequencing Classifier (GSC).
- Commercially launched the Afirma Xpression Atlas, providing RNA sequencing-based insights to inform surgery and treatment decisions in patients with suspected thyroid cancer.
- Booked our first biopharmaceutical service revenue of \$0.5 million based on the Afirma Xpression Atlas platform.
- Launched the Envisia Early Access Program to select sites across the United States in response to physician demand, further preparing for commercial expansion in 2019.

## Evidence Development:

- Published clinical validation data for the Afirma GSC in JAMA Surgery, demonstrating the next-generation test's ability to help approximately 70% of patients with indeterminate thyroid nodules avoid unnecessary surgery.
- Strong performance and clinical utility data for our two flagship products, the Afirma GSC and the Percepta classifier, were shared in five presentations at major endocrinology and pulmonology conferences.

## Scientific Innovation:

- Assembled over 2,000 patient samples to advance our field-of-injury research to fuel development of a nasal swab test for early detection of lung 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;

15

---

## Table of Contents

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. Revenue from Percepta has not been significant through June 30, 2018.

### 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 or 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 over the last several years, along with increasing our marketing efforts. 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 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 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 June 30, 2018 and December 31, 2017, 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 material amounts in the six months ended June 30, 2018.

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.

Revenue may not be equal to the billed amount due to a number of factors that we consider when determining revenue accrual rates, including differences in reimbursement rates, the amounts of patient co-payments and co-insurance, the existence of secondary payers, claims denials and the amount we expect to ultimately collect. Finally, when we increase our list price, as we did in July 2015, it will increase the cumulative amounts billed. 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 Afirma genomic classifier reimbursement 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 Afirma genomic classifier represents the total cash collected

## Table of Contents

to date against Afirma genomic classifier tests, including variants, performed during the relevant period divided by the number of these tests performed during that same period.

The average Afirma genomic classifier reimbursement rate will change over time due to a number of factors, including medical coverage decisions by payers, the effects of contracts signed with payers, changes in allowed amounts by payers, our ability to successfully win appeals for payment, and our ability to collect cash payments from third-party payers and individual patients. Historical average reimbursement is not necessarily indicative of future average reimbursement. For the three months ended June 30, 2018, on average we accrued between \$2,700 and \$2,800 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 second quarter of 2017 to the second quarter of 2018, we accrued between \$1.7 million and \$2.5 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 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 test. In March 2018, we unveiled our Afirma Xpression Atlas, which uses the same RNA sequencing 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 (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 collaboration 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 diagnostic performance of bronchoscopy. Additionally, our Envisia Genomic Classifier launched in October 2016 and is the first commercial test to improve the diagnosis of idiopathic pulmonary fibrosis among patients with a suspected interstitial lung disease.

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 idiopathic pulmonary fibrosis.

## 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

17

---

Table of Contents

Through June 30, 2018, we derived substantially all 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 June 30, 2018	Three Months Ended June 30, 2017	Six Months Ended June 30, 2018	Six Months Ended June 30, 2017
Medicare	28%	26%	28%	26%
UnitedHealthcare	12%	15%	12%	14%
	40%	41%	40%	40%

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 rate (if applicable), amount paid per test and any current developments 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 do 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 2017 and the first half of 2018, and expect to continue doing so in the remainder of 2018.

#### 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 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.

Table of Contents

## 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 six months ended June 30, 2018, approximately 66% of the 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 finite-lived intangible asset with a cost of \$16.0 million 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 received from payers and from our cash equivalents.

## Results of Operations

Comparison of the Three and Six Months Ended June 30, 2018 and 2017 (In Thousands of Dollars, Except Percentages and Genomic Classifiers Reported)

	Three Months Ended June 30,				Six Months Ended June 30,			
	2018	2017	Change	%	2018	2017	Change	%
Revenue	\$22,751	\$18,406	\$4,345	24%	\$42,792	\$34,838	\$7,954	23%
Operating expense:								
Cost of revenue	8,246	6,960	1,286	18%	16,113	13,257	2,856	22%
Research and development	4,601	3,603	998	28%	8,276	7,633	643	8%
Selling and marketing	9,623	7,994	1,629	20%	21,166	15,330	5,836	38%
General and administrative	5,932	6,192	(260)	(4)%	11,576	12,211	(635)	(5)%
Intangible asset amortization	266	266	—	—%	533	533	—	—%
Total operating expenses	28,668	25,015	3,653	15%	57,664	48,964	8,700	18%
Loss from operations	(5,917)	(6,609)	692	(10)%	(14,872)	(14,126)	(746)	5%
Interest expense	(481)	(808)	327	(40)%	(929)	(1,608)	679	(42)%
Other income (expense), net	150	119	31	26%	376	219	157	72%
Net loss and comprehensive loss	\$(6,248)	\$(7,298)	\$1,050	(14)%	\$(15,425)	\$(15,515)	\$90	(1)%
Other Operating Data:								
Genomic classifiers reported	7,686	6,506	1,180	18%	14,550	12,340	2,210	18%

## Revenue

Edgar Filing: VERACYTE, INC. - Form 10-Q

Revenue increased \$4.3 million, or 24%, for the three months ended June 30, 2018 compared to the same period in 2017 primarily due to an 18% volume increase in genomic classifiers and an increase in the accrual rate for our Afirma genomic classifiers. In the three months ended June 30, 2018, we also recognized \$0.5 million of biopharmaceutical service revenue and \$0.4 million of revenue for Percepta, the volume for which is included in the number of genomic classifiers reported. 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

Table of Contents

adjustment for tests accrued in prior quarters increased revenue by \$0.5 million and \$1.0 million for the three months ended June 30, 2018 and 2017, respectively, a net decrease of \$0.5 million between the periods.

Revenue increased \$8.0 million, or 23%, for the six months ended June 30, 2018 compared to the same period in 2017 primarily due to an 18% volume increase in genomic classifiers and an increase in the accrual rate for our Afirma genomic classifiers. In the six months ended June 30, 2018, we also recognized \$0.6 million of revenue for Percepta, the volume for which is included in the number of genomic classifiers reported, and \$0.5 million of biopharmaceutical service revenue. 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 \$1.2 million and \$1.0 million for the six months ended June 30, 2018 and 2017, respectively, a net increase of \$0.2 million between the periods.

## Cost of revenue

Comparison of the three and six months ended June 30, 2018 and 2017 is as follows (in thousands of dollars, except percentages):

	Three Months Ended June 30,				Six Months Ended June 30,			
	2018	2017	Change	%	2018	2017	Change	%
Cost of revenue:								
Laboratory costs	\$4,817	\$3,491	\$1,326	38%	\$8,984	\$6,608	\$2,376	36 %
Sample collection costs	1,070	864	206	24%	2,084	1,673	411	25 %
Compensation expense	1,035	944	91	10%	2,184	1,816	368	20 %
License fees and royalties	282	793	(511 )	(64)%	740	1,511	(771 )	(51)%
Depreciation and amortization	190	134	56	42%	755	536	219	41 %
Other expenses	383	292	91	31%	390	251	139	55 %
Allocations	469	442	27	6%	976	862	114	13 %
Total	\$8,246	\$6,960	\$1,286	18%	\$16,113	\$13,257	\$2,856	22 %

Cost of revenue increased \$1.3 million or 18%, for the three months ended June 30, 2018 compared to the same period in 2017. Reported genomic classifiers volume increased 18% and cytopathology volume declined 3%. Commencing in the second half of 2017, we began transitioning customers to our next-generation Afirma GSC, while running dual platforms to support the transition from its predecessor, the Afirma GEC. As a result, we have experienced higher costs per test to support running dual platforms in our laboratory. We recently received final state regulatory approvals for the transition and expect to be substantially complete with the transition to the Afirma GSC by September 30, 2018. The increase in laboratory costs is due principally to the transition to the Afirma GSC. The increase in sample collection costs is primarily related to the increase in the overall volume of samples received, including the recent launch of our Percepta Bronchial Genomic Classifier. Compensation expense increased due to an average laboratory headcount increase of 10%. The decrease in license fees and royalties is due to the continued transition to the Afirma GSC, for which we do not pay license fees like we do for the Afirma GEC. In total, we expect any savings from license fees to be used to pay laboratory costs for our GSC test. The increase in other expenses is primarily due to equipment maintenance costs and laboratory supplies.

Cost of revenue increased \$2.9 million or 22%, for the six months ended June 30, 2018 compared to the same period in 2017. Reported genomic classifiers volume increased 18% and cytopathology volume declined 3%. Commencing in the second half of 2017, we began transitioning customers to our next-generation Afirma GSC, while running dual platforms to support the transition from its predecessor, the Afirma GEC. As a result, we have experienced higher costs per test to support running dual platforms in our laboratory. We recently received final state regulatory approvals for the transition and expect to be to substantially complete with the transition to the Afirma GSC by September 30,



2018. The increase in laboratory costs is due principally to the transition to the Afirma GSC. The increase in sample collection costs is primarily related to the increase in the overall volume of samples received, including the recent launch of our Percepta Bronchial Genomic Classifier. Compensation expense increased due to an average laboratory headcount increase of 11%. The decrease in license fees and royalties is due to the continued transition to the Afirma GSC, for which we do not pay license fees like we do for the Afirma GEC. In total, we expect any savings from license fees to be used to pay laboratory costs for our GSC test. The increase in other expenses is primarily due to equipment maintenance costs and laboratory supplies.

Research and development

20

---

Table of Contents

Comparison of the three and six months ended June 30, 2018 and 2017 is as follows (in thousands of dollars, except percentages):

	Three Months Ended June 30,				Six Months Ended June 30,			
	2018	2017	Change	%	2018	2017	Change	%
Research and development expense:								
Compensation expense	\$2,013	\$2,129	\$(116)	(5)%	\$4,317	\$4,349	\$(32)	(1)%
Direct research and development expense	1,780	576	1,204	209%	2,391	1,574	817	52%
Professional fees	264	266	(2)	(1)%	471	465	6	1%
Depreciation and amortization	111	122	(11)	(9)%	217	235	(18)	(8)%
Other expenses	130	173	(43)	(25)%	244	326	(82)	(25)%
Allocations	303	337	(34)	(10)%	636	684	(48)	(7)%
Total	\$4,601	\$3,603	\$998	28%	\$8,276	\$7,633	\$643	8%

Research and development expense increased \$1.0 million, or 28%, for the three months ended June 30, 2018 compared to the same period in 2017, primarily attributable to one-time sequencing costs associated with research and development projects. The decrease in compensation expense was primarily due to a 10% decrease in the average headcount. The increase in direct research and development expense was due materials and supplies purchased for research and development experiments.

Research and development expense increased \$643,000 or 8%, for the six months ended June 30, 2018 compared to the same period in 2017, primarily attributable to one-time sequencing costs associated with research and development projects. Compensation expense decreased slightly, primarily due to an 8% decrease in average headcount, partially offset by severance costs. The increase in direct research and development expense was due to materials and supplies purchased for research and development experiments.

## Selling and marketing

Comparison of the three and six months ended June 30, 2018 and 2017 is as follows (in thousands of dollars, except percentages):

	Three Months Ended June 30,				Six Months Ended June 30,			
	2018	2017	Change	%	2018	2017	Change	%
Selling and marketing expense:								
Compensation expense	\$5,517	\$4,480	\$1,037	23%	\$13,378	\$8,735	\$4,643	53%
Direct marketing expense	1,512	1,658	(146)	(9)%	2,651	3,046	(395)	(13)%
Genzyme co-promotion expense, net	—	—	—		—	3	(3)	(100)%
Professional fees	314	326	(12)	(4)%	640	556	84	15%
Other expenses	1,707	1,060	647	61%	3,323	2,081	1,242	60%
Allocations	573	470	103	22%	1,174	909	265	29%
Total	\$9,623	\$7,994	\$1,629	20%	\$21,166	\$15,330	\$5,836	38%

Selling and marketing expense increased \$1.6 million, or 20%, for the three months ended June 30, 2018 compared to the same period in 2017, principally due to a 35% increase in average headcount, increased incentive compensation and to a lesser extent, increased travel and entertainment expense classified under other expenses. The decrease in direct marketing expense was primarily due to lower trade show costs, partially offset by higher speaker fees.

Selling and marketing expense increased \$5.8 million, or 38%, for the six months ended June 30, 2018 compared to the same period in 2017, principally due to a 33% increase in average headcount, increased incentive compensation and to a lesser

Table of Contents

extent, increased travel and entertainment expense classified under other expenses. The decrease in direct marketing expense was primarily due to a corporate rebranding initiative in the three months ended March 31, 2017 and lower trade show costs, partially offset by higher speaker fees.

## General and administrative

Comparison of the three and six months ended June 30, 2018 and 2017 is as follows (in thousands of dollars, except percentages):

	Three Months Ended June 30,				Six Months Ended June 30,			
	2018	2017	Change	%	2018	2017	Change	%
General and administrative expense:								
Compensation expense	\$3,879	\$4,008	\$(129)	(3)%	\$7,659	\$7,988	\$(329)	(4)%
Professional fees	1,564	1,613	(49)	(3)%	2,963	3,101	(138)	(4)%
Occupancy costs	596	529	67	13%	1,215	1,048	167	16%
Depreciation and amortization	420	422	(2)	—%	827	826	1	—%
Other expenses	819	869	(50)	(6)%	1,697	1,703	(6)	—%
Allocations	(1,346)	(1,249)	(97)	8%	(2,785)	(2,455)	(330)	13%
Total	\$5,932	\$6,192	\$(260)	(4)%	\$11,576	\$12,211	\$(635)	(5)%

General and administrative expense decreased \$260,000, or 4%, for the three months ended June 30, 2018 compared to the same period in 2017. The decrease in compensation expense was due to a 4% decrease in average headcount for the three months ended June 30, 2018 as compared to the same period in 2017. The increase in occupancy costs was due to higher maintenance charges.

General and administrative expense decreased \$635,000, or 5%, for the six months ended June 30, 2018 compared to the same period in 2017. The decrease in compensation expense was due to a 2% decrease in average headcount for the six months ended June 30, 2018 as compared to the same period in 2017. The increase in occupancy costs was due to higher maintenance charges.

## Interest expense

Interest expense decreased \$327,000 or 40% for the three months ended June 30, 2018 compared to the same period in 2017 due to a decrease in the effective interest rate to 7.9%, under the Loan and Security Agreement as of June 30, 2018, as compared to 12.3% as of June 30, 2017, under the credit agreement that was in place at that time.

Interest expense decreased \$679,000 or 42% for the six months ended June 30, 2018 compared to the same period in 2017 due to a decrease in the effective interest rate to 7.9%, under the Loan and Security Agreement as of June 30, 2018, as compared to 12.3% as of June 30, 2017, under the credit agreement that was in place at that time.

## Other income, net

Other income, net, increased \$31,000 for the three months ended June 30, 2018 compared to the same period in 2017 primarily due to higher interest income from our money market investments.

Other income, net, increased \$157,000 for the six months ended June 30, 2018 compared to the same period in 2017 primarily due to the tax benefit from the legal settlement regarding short-swing profits and higher interest income from our money market investments.

Liquidity and Capital Resources

We have incurred net losses since our inception. For the six months ended June 30, 2018, we had a net loss of \$15.4 million, and as of June 30, 2018, we had an accumulated deficit of \$226.5 million. We expect to incur additional losses in the future and may never achieve revenue sufficient to offset our expenses.

22

---

Table of Contents

We believe our existing cash and cash equivalents of \$23.8 million as of June 30, 2018, 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.

**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, 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 7.9% for the six months ended June 30, 2018.

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.

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 June 30, 2018, the principal balance outstanding was \$25.0 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

Table of Contents

property), subject to certain customary exceptions.

## Cash Flows

The following table summarizes our cash flows for the six months ended June 30, 2018 and 2017 (in thousands of dollars):

	Six Months Ended	
	June 30,	
	2018	2017
Cash used in operating activities	\$(10,512)	\$(12,996)
Cash used in investing activities	(761 )	(288 )
Cash provided by financing activities	1,140	528

## Cash Flows from Operating Activities

Cash used in operating activities for the six months ended June 30, 2018 was \$10.5 million. The net loss of \$15.4 million includes non-cash charges of \$2.9 million of stock-based compensation expense and \$2.0 million of depreciation and amortization, which includes \$0.5 million of intangible asset amortization. Cash used as a result of changes in operating assets and liabilities was flat, comprised of a decrease in supplies inventory of \$2.3 million, a decrease in prepaid expenses and other assets of \$0.1 million and an increase in accrued liabilities and deferred rent of \$0.1 million, offset by a decrease in accounts payable of \$1.9 million, an increase in accounts receivable of \$0.3 million and an increase in other assets of \$0.3 million.

Cash used in operating activities for the six months ended June 30, 2017 was \$13.0 million. The net loss of \$15.5 million includes non-cash charges of \$3.2 million of stock-based compensation expense and \$1.8 million of depreciation and amortization, which includes \$0.5 million of intangible asset amortization. Cash used as a result of changes in operating assets and liabilities of \$2.6 million was primarily due to an increase in accounts receivable of \$2.3 million, and a net decrease in accounts payable, accrued liabilities and deferred rent of \$0.5 million, primarily from the payment of annual bonuses.

## Cash Flows from Investing Activities

Cash used in investing activities for the six months ended June 30, 2018 was \$0.8 million for the acquisition of property and equipment.

Cash used in investing activities for the six months ended June 30, 2017 was \$0.7 million for the acquisition of property and equipment, partially offset by \$0.4 million of proceeds from the sale of property and equipment.

## Cash Flows from Financing Activities

Cash provided by financing activities for the six months ended June 30, 2018 was \$1.1 million, consisting of \$0.9 million in proceeds from the purchase of stock under our Employee Stock Purchase Plan, or 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.

Cash provided by financing activities for the six months ended June 30, 2017 was \$0.5 million, consisting of \$0.5 million in proceeds from the purchase of stock under our ESPP and exercise of options to purchase our common stock and \$0.2 million in cost reimbursements received related to our issuance of common stock in a public offering in the fourth quarter of 2016 offset by capital lease payments of \$0.1 million during the period.



### Contractual Obligations

There were no material changes during the interim period in the contractual obligations presented in our Form 10-K for the year ended December 31, 2017 filed with the Securities and Exchange Commission on February 27, 2018.

### Off-balance Sheet Arrangements

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

### Recent Accounting Pronouncements

## Table of Contents

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 will be effective for interim and annual periods beginning after December 15, 2018. Entities are required to use a modified retrospective approach for leases that exist or are entered into after the beginning of the earliest comparative period in the financial statements. Full retrospective application is prohibited and early adoption is permitted. We expect to adopt this standard beginning in 2019. We do not expect that this standard will have a material impact on our results of operations or cash flows, but that it will have a material impact on our assets and liabilities. We are currently in the process of quantifying the impact of adopting this ASU.

### 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 \$23.8 million as of June 30, 2018 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 June 30, 2018 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.



Table of Contents

PART II. — OTHER INFORMATION

ITEM 1A. RISK FACTORS

Risks Related to Our Business

We are an emerging growth company with 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 six months ended June 30, 2018, we had a net loss of \$15.4 million and as of June 30, 2018, we had an accumulated deficit of \$226.5 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 tests, Percepta, our lung cancer test which we launched in April 2015, Envisia, our test for idiopathic pulmonary fibrosis, or IPF, which we launched in October 2016, 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. However, revenue from Percepta has not been significant to date. We also launched our Envisia test to help improve the diagnosis of interstitial lung disease, specifically IPF, in October 2016, but have not recognized revenue from Envisia 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 and Percepta tests, or successfully obtain coverage and reimbursement for our Envisia test 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.

If we are not able to successfully transition to our next-generation Afirma GSC, our business, operating results and competitive position could be harmed.

We are in the process of transitioning our customers to our next-generation Afirma Genomic Sequencing Classifier, or GSC, that uses a new technology platform for the Afirma genomic classifier testing. There are risks associated with this transition that include, but are not limited to, operational implementation, reimbursement, and customer adoption risks. If we are unable to effectively transition to the new platform, our business, financial condition and results of operations could be adversely effected and our reputation and competitive position could be harmed.

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 28% and 12%, respectively, of our revenue for the six months ended June 30, 2018, compared with 26% and 14%, respectively, for the six months ended June 30, 2017. 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 the Afirm Gene Expression Classifier, or GEC. Afirm GSC is 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.

Table of Contents

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 have submitted the dossier of clinical evidence needed to obtain Medicare coverage for the Envisia Genomic Classifier through the MoIDX technical assessment process, but there can be no assurances that Envisia will obtain Medicare coverage in 2018 or in subsequent years.

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 classifier or Percepta 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 the Envisia classifier.

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 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. There can be no assurance that the rate will not decrease in the future following the next reporting period under PAMA.

We submit claims to Medicare for Percepta using an unlisted code and were paid at the rate of \$3,220 in 2017 under the MoIDX 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. Any such actions 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.

Table of Contents

We do not have a contracted rate of reimbursement with many payers for the Afirma or Percepta tests, and we do not have any contracted reimbursement with any payers with respect to the Envisia test. 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 classifiers, the Percepta classifier and the Envisia classifier 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 cost 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.

Table of Contents

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

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

We 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 supply were available. If our test volume decreases or we switch suppliers, we may hold excess inventory 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, TCP has the exclusive right to provide the cytopathology diagnoses on FNA samples at a fixed price per test. We have also agreed to allow TCP to co-locate in a portion of our facilities 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

Table of Contents

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

## Table of Contents

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 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. 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. Starting on 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. 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 are required to bill hospitals 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.

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.

Table of Contents

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 March 2017, a draft bill titled "The Diagnostics Accuracy and Innovation Act" was released for discussion. The bill 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 grandfathers existing tests and gives companies five years to augment test development pipelines to ensure new tests have the data necessary for FDA approval. 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

Table of Contents

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, Rosetta Genomics Ltd., 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 Integrated Diagnostics, Inc., Oncocyte Corporation and Oncimmune. 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. 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. 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. 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

## Table of Contents

or retaining qualified salespeople, which could cause a delay or decline in the rate of adoption of our tests. 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 doubtful accounts 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 Medicare;
- risk of government audits related to billing Medicare;
- 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 payors 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.

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

Table of Contents

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 payors 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.

Our future success will depend in part on our ability to successfully transition from our relationship with Genzyme to co-promote Afirma in the United States.

We sell Afirma in the United States through our internal sales team and, until recently, also through a co-promotion agreement with Genzyme Corporation, which we terminated effective September 9, 2016. In connection with the transition, we have hired additional sales personnel to sell our Afirma tests. If we are unsuccessful in transitioning the sales and marketing of the Afirma test from Genzyme solely to our internal sales and marketing personnel, we may experience declining test volumes and associated declines in revenue. We may not be able to market or sell the Afirma test effectively enough to maintain or increase demand for the test, or without significant additional sales and marketing efforts and expense. Our failure to do so successfully without the benefit of Genzyme's efforts could have an adverse effect on our business, financial condition and results of operations.

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

Table of Contents

- 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 acquired Allegro Diagnostics Corp. in September 2014, 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.

Table of Contents

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 lender with a first-priority liens 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.

Our loan and security agreement 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 first-priority liens 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.

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.

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 were to lose our CLIA certificate 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.

Table of Contents

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;
- 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 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;

Edgar Filing: VERACYTE, INC. - Form 10-Q

- 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;

38

---

Table of Contents

- 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;

39

---

Table of Contents

- 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, inventory management, 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 substantially all 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,

Table of Contents

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. Recent developments in Europe have created compliance uncertainty regarding the processing of personal data from Europe. For example, the General Data Protection Regulation (“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

## Table of Contents

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 22 issued patents that expire between 2029 and 2032 related to methods used in the Afirma diagnostic platform, in addition to 15 pending U.S. utility patent applications, and two U.S. provisional patent applications. Some of these U.S. utility patent applications have pending foreign counterparts. We also exclusively licensed intellectual property, including rights to four issued patents that will expire between 2030 and 2032, 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 nine 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 Patent Cooperation Treaty, or PCT, patent application, a pending U.S. utility 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 two pending U.S. patent applications, five patent applications abroad, and one PCT patent application 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.

Table of Contents

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.

Table of Contents

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 the fiscal year ended December 31, 2017, we had U.S. federal and state net operating losses, or NOLs, of approximately \$196.1 million and \$91.8 million, respectively. The federal and state NOL carryforwards will begin to expire, if not utilized, beginning in 2028. These NOL carryforwards could expire unused and be unavailable to offset future income tax liabilities. Under the newly enacted federal income tax law, 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

Table of Contents

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.

Comprehensive tax reform bills could adversely affect our business and financial condition.

The U.S. government has recently enacted comprehensive tax legislation that includes significant changes to the taxation of business entities. These changes include, among others, (i) a permanent reduction to the corporate income tax rate, (ii) a partial limitation on the deductibility of business interest expense, (iii) a shift of the U.S. taxation of multinational corporations from a tax on worldwide income to a territorial system (along with certain rules designed to prevent erosion of the U.S. income tax base) and (iv) a one-time tax on accumulated offshore earnings held in cash and illiquid assets, with the latter taxed at a lower rate.

Notwithstanding the reduction in the corporate income tax rate, the overall impact of this tax reform is uncertain, and our business and financial condition could be adversely affected. In addition, it is uncertain if and to what extent various states will conform to the newly enacted federal tax law.

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. 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.



Table of Contents

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. Our independent registered public accounting firm will be required to issue an attestation report on the effectiveness of our internal control over financial reporting when we cease being an emerging growth company on December 31, 2018. 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 an emerging growth company and may elect to comply with reduced public company reporting requirements applicable to emerging growth companies, which could make our common stock less attractive to investors.

We are an emerging growth company, as defined under the Securities Act of 1933, or the Securities Act. We will remain an emerging growth company until December 31, 2018. As an emerging growth company, we may choose to take advantage of exemptions from various reporting requirements applicable to certain other public companies,

including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirement of holding a nonbinding advisory vote on executive compensation and obtaining stockholder approval of any golden parachute payments not previously approved by our stockholders. However, we previously irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. 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.

Table of Contents

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.

Insiders have substantial control over us and will be able to influence corporate matters.

As of July 17, 2018, directors and executive officers and their affiliates beneficially owned, in the aggregate, 14% of our outstanding capital stock. As a result, these stockholders will be able to exercise significant influence over all matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions, such as a merger or other sale of our company or its assets. This concentration of ownership could limit stockholders' ability to influence corporate matters and may have the effect of delaying or preventing a third-party from acquiring control over us.

Table of Contents

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.





Table of Contents

ITEM 6. EXHIBITS

Exhibit Number	Description
<u>31.1*</u>	<u>Principal Executive Officer’s Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</u>
<u>31.2*</u>	<u>Principal Financial Officer’s Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</u>
<u>32.1**</u>	<u>Certification Pursuant to 18 U.S.C. § 1350 (Section 906 of the Sarbanes-Oxley Act of 2002)</u>
<u>32.2**</u>	<u>Certification Pursuant to 18 U.S.C. § 1350 (Section 906 of the Sarbanes-Oxley Act of 2002)</u>
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.

Table of Contents

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: July 23, 2018

VERACYTE, INC.

By: /s/ KEITH KENNEDY  
Keith Kennedy  
Chief Financial Officer  
(Principal Financial and Accounting Officer)