VERACYTE, INC.
Form 10-Q
November 03, 2016
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)
ý QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2016

OR

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

For the transition period from to

Commission file number 001-36156

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

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

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

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ý No o

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 ý No o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer o	Accelerated filer x
Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company o

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

As of October 28, 2016, there were 27,950,046 shares of common stock, par value $0.001 per share, outstanding.

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PART I. — FINANCIAL INFORMATION

Item 1. Condensed Financial Statements

VERACYTE, INC.

Condensed Balance Sheets

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

	September 30, 2016 (Unaudited)	December 31, 2015 (See Note 1)
Assets		
Current assets:		
Cash and cash equivalents	$ 31,699	$ 39,084
Accounts receivable	6,312	3,503
Supplies inventory	3,416	3,767
Prepaid expenses and other current assets	1,405	1,442
Restricted cash	120	118
Total current assets	42,952	47,914
Property and equipment, net	10,435	10,314
Finite-lived intangible assets, net	14,400	15,200
Goodwill	1,057	1,057
Restricted cash	603	603
Other assets	203	159
Total assets	$ 69,650	$ 75,247
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 3,081	$ 5,085
Accrued liabilities	7,189	8,689
Deferred Genzyme co-promotion fee	—	948
Total current liabilities	10,270	14,722
Long-term debt	24,891	4,990
Deferred rent, net of current portion	4,484	4,283
Total liabilities	39,645	23,995
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized, no shares issued and outstanding as of September 30, 2016 and December 31, 2015	—	—
Common stock, $0.001 par value; 125,000,000 shares authorized, 27,940,161 and 27,685,291 shares issued and outstanding as of September 30, 2016 and December 31, 2015, respectively	28	28
Additional paid-in capital	205,658	199,950
Accumulated deficit	(175,681)	(148,726)
Total stockholders' equity	30,005	51,252
Total liabilities and stockholders' equity	$ 69,650	$ 75,247

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

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VERACYTE, INC.

Condensed Statements of Operations and Comprehensive Loss

(Unaudited)

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Revenue	$18,603	$12,335	$46,828	$35,461
Operating expenses:				
Cost of revenue	6,367	5,618	18,947	15,322
Research and development	4,006	3,563	11,734	9,453
Selling and marketing	7,087	6,048	22,416	18,606
General and administrative	5,763	5,728	18,062	17,062
Intangible asset amortization	266	266	800	533
Total operating expenses	23,489	21,223	71,959	60,976
Loss from operations	(4,886)	(8,888)	(25,131)	(25,515)
Interest expense	(799)	(92)	(1,951)	(269)
Other income, net	48	35	127	93
Net loss and comprehensive loss	$(5,637)	$(8,945)	$(26,955)	$(25,691)
Net loss per common share, basic and diluted	$(0.20)	$(0.32)	$(0.97)	$(1.01)
Shares used to compute net loss per common share, basic and diluted	27,916,819	27,640,806	27,865,100	25,428,506

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

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VERACYTE, INC.

Condensed Statements of Cash Flows

(Unaudited)

(In thousands of dollars)

	Nine Months Ended September 30,	
	2016	2015
Operating activities		
Net loss	$ (26,955)	$ (25,691)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2,602	1,642
Bad debt expense	68	80
Loss on disposal of property and equipment	12	—
Genzyme co-promotion fee amortization	(948)	(1,423)
Stock-based compensation	4,745	4,186
Conversion of accrued interest to long-term debt	385	—
Amortization and write-off of debt discount and issuance costs	146	34
Interest on debt balloon payment and prepayment penalty	206	59
Changes in operating assets and liabilities:		
Accounts receivable	(2,877)	(550)
Supplies inventory	351	(288)
Prepaid expenses and current other assets	37	(1,878)
Other assets	(44)	(53)
Accounts payable	(387)	(1,831)
Accrued liabilities and deferred rent	(1,091)	1,578
Net cash used in operating activities	(23,750)	(24,135)
Investing activities		
	(3,760)	(1,975)

Purchases of property and equipment				
Change in restricted cash	(2	)	(533	)
Net cash used in investing activities	(3,762	)	(2,508	)
Financing activities				
Proceeds from the issuance of long-term debt, net of debt issuance costs	24,452		—	
Proceeds from the issuance of common stock in a private placement, net of costs	—		37,258	
Payment of deferred stock offering costs	—		(197	)
Payment of long-term debt	(5,000	)	—	
Payment of end-of-term debt obligation and prepayment penalty	(288	)	—	
Proceeds from the exercise of common stock options and employee stock purchases	963		684	
Net cash provided by financing activities	20,127		37,745	
Net (decrease) increase in cash and cash equivalents	(7,385	)	11,102	
Cash and cash equivalents at beginning of period	39,084		35,014	
Cash and cash equivalents at end of period	$ 31,699		$ 46,116	
Supplementary cash flow information of non-cash investing and financing activities:				
Purchases of property and equipment included in accounts payable and accrued liabilities	$ —		$ 1,173	
Unpaid deferred stock offering	—		71	

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

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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. Veracyte is a molecular diagnostics company that uses genomic technology to resolve diagnostic ambiguity. The Company targets diseases in which large numbers of patients undergo invasive and costly diagnostic procedures that could have been avoided with a more accurate diagnosis from a cytology sample. By improving diagnosis, the Company helps patients avoid such unnecessary invasive procedures and surgeries while reducing healthcare costs.

The Company's first commercial solution, the Afirma® Thyroid FNA Analysis, centers on the proprietary Afirma Gene Expression Classifier ("GEC"). The Afirma GEC helps physicians reduce the number of unnecessary surgeries by employing a proprietary 142-gene signature to determine whether thyroid nodules previously classified by cytopathology as indeterminate can be reclassified as benign. The Afirma GEC is offered directly or as part of a comprehensive solution that also includes cytopathology. Additionally, the Afirma Malignancy Classifiers were launched in May 2014. The Company currently markets and sells Afirma in the United States, in select foreign countries through a co-promotion agreement with Genzyme Corporation, a subsidiary of Sanofi, and through other distributors.

In April 2015, the Company entered the pulmonology diagnostics market with the Percepta® Bronchial Genomic Classifier, a genomic test to resolve ambiguity in lung cancer diagnosis. In October 2016, the Company introduced a second product in pulmonology, the Envisia™ Genomic Classifier, designed to help in the assessment of patients suspected to have idiopathic pulmonary fibrosis.

The Company's operations are based in South San Francisco, California and Austin, Texas, and it operates in one segment in the United States.

Basis of Presentation

The Company's financial statements have been prepared in accordance with accounting principles generally accepted in the United States ("GAAP"). The financial statements include the accounts of the Company and its former wholly-owned subsidiary, which was dissolved in June 2015. For periods prior to the subsidiary dissolution, all intercompany accounts and transactions were eliminated in consolidation. 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 September 30, 2016, the condensed statements of operations and comprehensive loss for the three and nine months ended September 30, 2016 and 2015, and the condensed statements of cash flows for the nine months ended September 30, 2016 and 2015 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, 2015 has been derived from audited financial statements. The results for the three and nine months ended September 30, 2016 are not necessarily indicative of the results expected for the full year or any other period. Certain amounts have been reclassified on the condensed balance sheet at December 31, 2015 to conform with the adoption of Accounting Standards Update ("ASU") No. 2015-3, Simplifying the Presentation of Debt Issuance Costs.

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, 2015.

Use of Estimates

The preparation of the 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

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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 September 30, 2016, 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 September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Medicare	23 %	28 %	27 %	27 %
UnitedHealthcare	11 %	11 %	12 %	13 %
	34 %	39 %	39 %	40 %

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

	September 30, 2016		December 31, 2015	
Medicare	18	%	31	%
UnitedHealthcare	9	%	25	%
Aetna	7	%	23	%

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 $120,000 and $118,000 as of September 30, 2016 and December 31, 2015, respectively, included in current assets. The deposit at September 30, 2016 was a pledge for corporate credit cards and the deposit at December 31, 2015 was restricted from withdrawal and held by a bank in the form of collateral for irrevocable

standby letters of credit held as security for the lease of the Company's former headquarters and laboratory facility in South San Francisco that expired March 31, 2016. The Company also had deposits of $603,000 included in long-term assets as of September 30, 2016 and December 31, 2015, 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 signed in April 2015.

Fair Value of Financial Instruments

The carrying amounts of certain financial instruments including cash and cash equivalents, accounts receivable, prepaid expenses and other current assets, accounts payable and accrued liabilities approximate fair value due to their relatively short maturities.

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Revenue Recognition

The Company recognizes revenue in accordance with the provision of ASC 954-605, Health Care Entities — Revenue Recognition ("ASC 954"). The Company's revenue is generated from the provision of diagnostic services. The service is completed upon the delivery of test results to the prescribing physician, at which time the Company bills for the service. The Company recognizes revenue related to billings for tests delivered on an accrual basis when amounts that will ultimately be realized can be reasonably estimated. The estimates of amounts that will ultimately be realized require significant judgment by management. Until a contract has been negotiated with a commercial payer or governmental program, the Company's tests may or may not be covered by these entities' existing reimbursement policies. In addition, patients do not enter into direct agreements with the Company that commit them to pay any portion of the cost of the tests in the event that their insurance declines to reimburse the Company.

The Company may bill the patient directly for these amounts in the form of co-payments and co-insurance in accordance with their insurance carrier and health plans. The Company pursues reimbursement from such patients on a case-by-case basis. In the absence of contracted reimbursement or the ability to reasonably estimate the amount that will ultimately be realized for the Company's services, revenue is recognized on a cash basis, i.e. upon the earlier of receipt of third-party payer notification of payment or when cash is received.

Revenue recognized on an accrual basis and cash basis for the three and nine months ended September 30, 2016 and 2015 was as follows (in thousands of dollars):

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2016	%	2015	%	2016	%	2015	%
Revenue recognized on an accrual basis	$13,903	75%	$6,985	57%	$31,478	67%	$18,957	53%
Revenue recognized on a cash basis	4,700	25%	5,350	43%	15,350	33%	16,504	47%
Total	$18,603	100%	$12,335	100%	$46,828	100%	$35,461	100%

Prior to July 1, 2016, the Company believes it did not have a consistent payment history to accrue a significant portion of its Afirma tests at the time of delivery and, as noted above, recognized revenue on a cash basis for such tests. The Company has been analyzing the amounts received for tests performed since commercialization and during the quarter ended September 30, 2016, concluded there was sufficient information to support a reasonable estimate of the amount of revenue to accrue upon test delivery for a number of payers that had been previously recognized on a cash basis. The Company considered factors such as coverage from payers, whether there is a reimbursement contract between the payer and the Company, the percentage of tests delivered for which payment is received, timeliness of payment, payment as a percentage of agreed upon rate, amount paid per test and any current developments or changes that could impact reimbursement to make an estimate of the amount to accrue upon test delivery in accordance with ASC 954. As a result, the Company recognized $3.5 million of incremental revenue during the quarter ended September 30, 2016 upon test delivery that previously would not have been recognized until notification of payment or cash was received. Tests performed prior to July 1, 2016 that did not meet the Company's accrual criteria at the time of delivery will continue to be recognized as revenue on a cash basis. However, the Company expects the amount of revenue to be recognized on a cash basis for Afirma to decline in future periods since going forward relatively fewer tests will be performed for which a reasonable estimate of revenue to accrue will not have been made at the time of delivery.

Incremental accrued revenue as a result of additional payers meeting the Company's revenue recognition criteria was $3.5 million and $4.0 million for tests delivered in the three and nine months ended September 30, 2016, respectively, and $127,000 and $692,000 for tests delivered in the three and nine months ended September 30, 2015, respectively. The incremental accrued revenue decreased the loss from operations and net loss by $3.5 million and $4.0 million for the three and nine months ended September 30, 2016, respectively, and decreased the loss per common share by $0.13

and $0.14 for the three and nine months ended September 30, 2016, respectively.

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Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board ("FASB") issued ASU No. 2014-9, Revenue from Contracts with Customers, requiring an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. The updated standard will replace most existing revenue recognition guidance in GAAP when it becomes effective and permits the use of either the retrospective or cumulative effect transition method. Adoption is permitted as early as the first quarter of 2017 and is required by the first quarter of 2018. The Company has not yet selected a transition method and is currently evaluating the potential effect of the updated standard on its financial statements.

In August 2014, FASB issued ASU No. 2014-15, Presentation of Financial Statements Going Concern - Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern. The amendments require management to assess an entity's ability to continue as a going concern by incorporating and expanding upon certain principles that are currently in U.S. auditing standards. Specifically, the amendments: (1) provide a definition of the term substantial doubt; (2) require an evaluation every reporting period including interim periods; (3) provide principles for considering the mitigating effect of management's plans; (4) require certain disclosures when substantial doubt is alleviated as a result of consideration of management's plans; (5) require an express statement and other disclosures when substantial doubt is not alleviated; and (6) require an assessment for a period of one year after the date that the financial statements are issued (or available to be issued). ASU 2014-15 will be effective for annual periods ending after December 15, 2016 and interim periods within annual periods beginning after December 15, 2016 with early adoption permitted. ASU 2014-15 will be effective for the Company beginning with its annual report for 2016 and interim periods thereafter. The Company does not anticipate that the adoption of this ASU will have a significant impact on its financial statements.

In April 2015, the FASB issued ASU No. 2015-3, Simplifying the Presentation of Debt Issuance Costs, to require debt issuance costs to be presented as an offset against debt outstanding. The update does not change current guidance on the recognition and measurement of debt issuance costs. The ASU is effective for interim and annual periods beginning after December 15, 2015. Adoption of the ASU is retrospective to each prior period presented. The Company has adopted this ASU and the retrospective adjustment of the prior period presentation was not material.

In November 2015, the FASB issued ASU 2015-17, Balance Sheet Classification of Deferred Taxes. The ASU requires that deferred tax assets and liabilities be classified as noncurrent in the statement of financial position, thereby simplifying the guidance that required an entity to separate deferred assets and liabilities into current and noncurrent amounts, and was effective for the Company beginning in the first quarter of 2016. The Company early-adopted this ASU as of December 31, 2015 and the impact of adoption on its statement of financial position was not material.

In February 2016, the FASB issued ASU No. 2016-2, Leases. 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-us 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. Early adoption is permitted. The Company is currently evaluating the potential effect of the updated standard on its financial statements.

In March 2016, the FASB issued ASU 2016-9, Compensation - Stock Compensation, related to the tax effects of share-based awards. The ASU requires that all the tax effects of share-based awards be recorded through the income statement, thereby simplifying the current guidance that requires excess tax benefits and certain excess tax deficiencies to be recorded in equity. The ASU will be effective for interim and annual periods beginning after December 15, 2016. The Company does not anticipate that the adoption of this ASU will have a significant impact on

its financial statements.

2. Net Loss Per Common Share

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

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	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Shares of common stock subject to outstanding options	5,312,081	4,241,020	5,031,926	4,041,644
Employee stock purchase plan	29,435	8,730	34,262	2,942
Total common stock equivalents	5,341,516	4,249,750	5,066,188	4,044,586

3. Accrued Liabilities

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

	September 30, 2016	December 31, 2015
Accrued compensation expenses	$ 4,970	$ 4,212
Accrued Genzyme co-promotion fees	—	2,089
Accrued other	2,219	2,388
Total accrued liabilities	$ 7,189	$ 8,689

4. Fair Value Measurements

The Company recognizes 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 estimated 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.

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

The fair value of the Company's financial assets, which consist only of money market funds, was $29.4 million and $37.5 million as of September 30, 2016 and December 31, 2015, respectively, and are Level I assets as described above.

5. Commitments and Contingencies

Operating Leases

The Company leases its headquarters and laboratory facilities in South San Francisco, California under a non-cancelable lease agreement for approximately 59,000 square feet. The lease began in June 2015 and ends in March 2026 and contains extension of lease term and expansion options. The Company had deposits of $603,000 included in long-term assets as of September 30, 2016 and December 31, 2015, 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 on July 31, 2018. The Company provided a cash security deposit of $75,000 upon entering into this lease, which is included in other assets in the Company’s condensed balance sheets as of September 30, 2016 and December 31, 2015.

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Future minimum lease payments under non-cancelable operating leases as of September 30, 2016 are as follows (in thousands of dollars):

Year Ending December 31,	
2016	$523
2017	2,143
2018	2,102
2019	2,026
2020	2,082
Thereafter	11,956
Total minimum lease payments	$20,832

The Company recognizes rent expense on a straight-line basis over the non-cancelable lease period. Rent expense was $457,000 and $687,000 for the three months ended September 30, 2016 and 2015, respectively, and $1.5 million and $1.3 million for the nine months ended September 30, 2016 and 2015, respectively.

Supplies Purchase Commitments

The Company had non-cancelable purchase commitments with five suppliers to purchase a minimum quantity of supplies for approximately $1.5 million at September 30, 2016.

Contingencies

From time to time, the Company may be involved in legal proceedings arising in the ordinary course of business. The Company believes there is no litigation pending that could have, individually or in the aggregate, a material adverse effect on the Company's financial position, results of operations or cash flows.

6. Debt

Credit Agreement

In March 2016, the Company entered into a credit agreement (the "Credit Agreement") with Visium Healthcare Partners, LP ("Visium"). Under the Credit Agreement, two term loans are 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 (the "Initial Term Loan") on March 30, 2016, of which $5.0 million was used to pay the outstanding balance of the Company's existing long-term debt, which was cancelled at that date. On or prior to June 30, 2017, the Company may request the second term loan of up to $15.0 million (the "Second Term Loan" and together with the Initial Term Loan, the "Term Loans"). The Term Loans mature on March 31, 2022.

The Term Loans bear interest at a fixed rate of 12.0% per annum, payable quarterly at the end of each March, June, September and December. No principal payments will be due during an interest-only period, commencing on the funding date for the Initial Term Loan (the "Initial Borrowing Date") and continuing through and including March 31, 2020. The Company is obligated to repay the outstanding principal amounts under the Term Loans in eight equal installments during the final two years under the Credit Agreement. For any quarterly interest payment through and including the 16th interest payment date after the Initial Borrowing Date, so long as no event of default has occurred and is then continuing, the Company may elect to pay interest in cash on the outstanding principal amounts of the Term Loans at a fixed rate of 9.0%, with the remaining 3.0% of the 12.0% interest paid-in-kind by adding such

paid-in-kind interest to the outstanding principal amounts of the Term Loans. The Company elected to pay interest in-kind for the quarter ended September 30, 2016 and has recorded $385,000 of paid-in-kind interest through September 30, 2016.

The Company may prepay the outstanding principal amount under the Term Loans subject to a minimum of $5.0 million of principal amount or a whole multiple of $1.0 million in excess thereof plus accrued and unpaid interest and a prepayment premium. The prepayment premium will be assessed on the principal amount repaid and will equal (i) 24.0% less the aggregate amount of all interest payments in cash, if the prepayment is made on or prior to March 31, 2018, (ii) 4.0%, if the

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prepayment is made after March 31, 2018 and on or prior to March 31, 2019, (iii) 2.0%, if the prepayment is made after March 31, 2019 and on or prior to March 31, 2020, and (iv) 1.0%, if the prepayment is made after March 31, 2020 and on or prior to March 31, 2021. After March 31, 2021 there is no prepayment premium.

The Company's obligations under the Credit Agreement are secured by a security interest in substantially all of its assets. The Credit Agreement contains customary representations, warranties and events of default, 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 material new line of business or enter into certain transactions with affiliates, in each case subject to certain exceptions. To the extent the Company forms or acquires certain subsidiaries domiciled in the United States, those subsidiaries are required to be guarantors of the Company's obligations under the Credit Agreement. As of September 30, 2016, the Company was in compliance with the loan covenants.

Concurrent with entering into the Credit Agreement, the Company entered into an agreement with Visium pursuant to which, for a period of one year following the Initial Borrowing Date, Visium has the right to participate in certain future equity financings of the Company in an amount of up to $5.0 million with no preferential terms.

As of September 30, 2016, the net debt obligation for borrowings made under the Credit Agreement was as follows (in thousands of dollars):

	September 30, 2016
Debt principal	$ 25,385
Unamortized deferred debt issuance costs	(494)
Net debt obligation	$ 24,891

Future principal payments under the Credit Agreement are as follows (in thousands of dollars):

Year Ending December 31,	
2020	$9,519
Thereafter	15,866
Total	$25,385

Loan and Security Agreement

In June 2013, the Company entered into a loan and security agreement as subsequently amended ("2013 Loan Agreement") with a financial institution that provided for borrowings of up to $10.0 million in aggregate. Borrowings under the 2013 Loan Agreement totaled $5.0 million, which was outstanding at January 1, 2015 and into 2016 until such amount was repaid upon the Company entering into the Credit Agreement discussed above.

Interest Expense

Interest expense was as follows (in thousands of dollars):

	Three Months Ended September 30,	Nine Months Ended September 30,

	2016	2015	2016	2015
Nominal interest	$ 772	$ 64	$ 1,600	$ 189
Amortization and write-off of debt discount and debt issuance costs	27	7	145	20
Prepayment penalty	—	—	50	—
End-of-term payment interest	—	21	156	60
Total	$ 799	$ 92	$ 1,951	$ 269

7. Stockholders’ Equity

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Common Stock

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

	September 30, 2016	December 31, 2015
Options issued and outstanding	5,287,887	4,179,521
Options available for grant under stock option plans	950,486	1,058,359
Common stock available for the Employee Stock Purchase Plan	609,053	750,000
Total	6,847,426	5,987,880

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8. Stock Incentive Plans

The following table summarizes activity under the Company's stock option plans (aggregate intrinsic value in thousands of dollars):

	Shares Available for Grant	Stock Options Outstanding	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value
Balance—December 31, 2015	1,058,359	4,179,521	$8.03	7.50	$6,511
Additional options authorized	1,107,411	—			
Granted	(1,440,350)	1,440,350	6.15		
Canceled	225,066	(218,061)	10.42		
Exercised	—	(113,923)	2.50		
Balance—September 30, 2016	950,486	5,287,887	$7.54	7.63	$8,640
Options vested and exercisable—September 30, 2016		2,568,269	$7.15	6.34	$6,206
Options vested and expected to vest—September 30, 2016		5,059,400	$7.54	7.56	$8,421

The aggregate intrinsic value was calculated as the difference between the exercise price of the options to purchase common stock and the fair market value of the Company's common stock, which was $7.61 per share as of September 30, 2016.

The weighted average fair value of options to purchase common stock granted was $3.29 and $5.23 for the nine months ended September 30, 2016 and 2015, respectively.

The intrinsic value of stock options exercised was $386,000 and $1.6 million for the nine months ended September 30, 2016 and 2015, respectively.

Stock-based Compensation

The following table summarizes stock-based compensation expense related to stock options and the Company's employee stock purchase plan ("ESPP") for the three and nine months ended September 30, 2016 and 2015 (in thousands of dollars):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Cost of revenue	$31	$32	$94	$64
Research and development	342	296	982	891
Selling and marketing	396	353	1,199	943
General and administrative	803	793	2,470	2,288
Total stock-based compensation expense	$1,572	$1,474	$4,745	$4,186

As of September 30, 2016, the Company had $10.5 million of unrecognized compensation expense related to unvested stock options, which is expected to be recognized over an estimated weighted-average period of 2.55 years.

The estimated grant-date fair value of employee stock options was calculated using the Black-Scholes option-pricing model, based on the following assumptions:

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	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Weighted-average volatility	52.68 – 52.90%	52.56 – 53.76%	52.68 – 56.36%	52.56 – 68.82%
Weighted-average expected term (years)	6.08	6.08	5.50 – 6.23	5.50 – 6.08
Risk-free interest rate	1.16 – 1.37%	1.57 – 1.92%	1.16 – 1.77%	1.55 – 2.03%
Expected dividend yield	—	—	—	—

There were no stock options granted to non-employees during the nine months ended September 30, 2016 and 2015.

The estimated grant date fair value of shares granted under the Company's ESPP was calculated using the Black-Scholes option-pricing model, based on the following assumptions:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Weighted-average volatility	46.38 – 62.85%	53.57 – 58.10%	46.38 – 75.72%	53.57 – 58.10%
Weighted-average expected term (years)	0.50 – 1.00	0.50 – 1.00	0.50 – 1.00	0.50 – 1.00
Risk-free interest rate	0.40 – 0.50%	0.17 – 0.33%	0.40 – 0.50%	0.17 – 0.33%
Expected dividend yield	—	—	—	—

9. Genzyme Co-Promotion Agreement

In January 2012, the Company and Genzyme Corporation (“Genzyme”) executed a co-promotion agreement for the co-exclusive rights and license to promote and market the Company’s Afirma thyroid diagnostic solution in the United States and in 40 named countries. In exchange, the Company received a $10.0 million upfront co-promotion fee from Genzyme in February 2012. Under the terms of the agreement, Genzyme receives a percentage of U.S. cash receipts that the Company has received related to Afirma as co-promotion fees. The percentage was 50% in 2012, 40% from January 2013 through February 2014, and 32% beginning in February 2014.

In November 2014, the Company signed an Amended and Restated U.S. Co-Promotion Agreement (“Amended Agreement”) with Genzyme. Under the Amended Agreement, the co-promotion fees Genzyme receives as a percentage of U.S. cash receipts were reduced from 32% to 15% beginning January 1, 2015. Through August 11, 2014, the Company amortized the $10.0 million upfront co-promotion fee straight-line over a four-year period, which was management’s best estimate of the life of the agreement, in part because after that period either party could have terminated the agreement without penalty. Effective August 12, 2014, the Company extended the amortization period from January 2016 to June 2016, the modified earliest period either party could terminate the agreement without penalty. The Company accounted for the change in accounting estimate prospectively. The agreement was terminable by either party with six months prior notice, however, under the Amended Agreement, neither party could terminate the agreement for convenience prior to June 30, 2016. The agreement with Genzyme was to expire in 2027. On March 9, 2016, the Company gave Genzyme notice of termination of the Amended Agreement effective September 9, 2016 and the amortization of the upfront co-promotion fee was further extended to that date. The extension of the amortization period has no impact on our 2016 financial statements on an annual basis.

In February 2015, the Company entered into an Ex-U.S. Co-promotion Agreement with Genzyme for the promotion of the Afirma GEC test with exclusivity in five countries outside the United States initially and in other countries agreed to from time to time. The agreement commenced on January 1, 2015 and continues until December 31, 2019, with extension of the agreement possible upon agreement of the parties. Country-specific terms have been established under this agreement for Brazil and Singapore and a right of first negotiation has been established for Canada, the Netherlands and Italy. The Company pays Genzyme 25% of net revenue from the sale of the Afirma GEC test in Brazil and Singapore over a five-year period commencing January 1, 2015. These payments have been immaterial for all periods presented. Beginning in the fourth year of the agreement, if the Company terminates the agreement for convenience, the Company may be required to pay a termination fee contingent on the number of GEC billable results generated during the 12 months immediately prior to the notice of termination.

The Company incurred $1.8 million and $1.8 million in co-promotion expense, excluding the amortization of the upfront co-promotion fee, for the three months ended September 30, 2016 and 2015, respectively, and $6.1 million and $5.2

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million in co-promotion expense for the nine months ended September 30, 2016 and 2015, respectively, which is included in selling and marketing expenses in the condensed statements of operations and comprehensive loss. The Company had no outstanding obligations to Genzyme as of September 30, 2016, compared to $2.1 million as of December 31, 2015 which was included in accrued liabilities on the Company's condensed balance sheet.

The Company amortized $227,000 and $474,000 of the $10.0 million upfront co-promotion fee in the three months ended September 30, 2016 and 2015, respectively, and $948,000 and $1.4 million in the nine months ended September 30, 2016 and 2015, respectively, which is reflected as a reduction to selling and marketing expenses in the condensed statements of operations and comprehensive loss.

10. Thyroid Cytopathology Partners

In 2010, the Company entered into an arrangement with Pathology Resource Consultants, P.A. ("PRC") to set up and manage a specialized pathology practice to provide testing services to the Company. There is no direct monetary compensation from the Company to PRC as a result of this arrangement. The Company's service agreement is with the specialized pathology practice, Thyroid Cytopathology Partners, ("TCP"), and was effective through December 31, 2015, and thereafter automatically renews every year unless either party provides notice of intent not to renew at least 12 months prior to the end of the then-current term. Under the service agreement, the Company pays TCP based on a fixed price per test schedule, which is reviewed periodically for changes in market pricing. Subsequent to December 2012, an amendment to the service agreement allows TCP to sublease a portion of the Company's facility in Austin, Texas. The Company does not have an ownership interest in or provide any form of financial or other support to TCP.

The Company 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 condensed statements of operations and comprehensive loss. The Company incurred $1.3 million and $1.2 million for the three months ended September 30, 2016 and 2015, respectively, and $3.8 million and $3.5 million for the nine months ended September 30, 2016 and 2015, respectively, in cytopathology testing and evaluation services expenses with TCP. The Company's outstanding obligations to TCP for cytopathology testing services were $870,000 and $820,000 as of September 30, 2016 and December 31, 2015, respectively, and are included in accounts payable on the Company's condensed balance sheets.

TCP reimburses the Company for a proportionate share of the Company's rent and related operating expenses for the leased facility. TCP's portion of rent and related operating expense for the subleased space at the Austin, Texas facility was $24,000 and $23,000 for the three months ended September 30, 2016 and 2015, respectively, and $70,000 and $67,000 for the nine months ended September 30, 2016 and 2015, respectively, and is included in other income, net in the Company's condensed statements of operations and comprehensive loss.

11. Income Taxes

The Company did not record a provision or benefit for income taxes during the three and nine months ended September 30, 2016 and 2015. The Company continues to maintain a full valuation allowance against its net deferred tax assets.

As of September 30, 2016, the Company had unrecognized tax benefits of $2.1 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 September 30, 2016 will significantly increase or decrease within the next 12 months. There was no interest expense or penalties related to unrecognized tax benefits recorded through

September 30, 2016.

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.

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12. Subsequent Event

On November 1, 2016, the Company entered into an underwriting agreement relating to a public offering of 5 million shares of its common stock at a public offering price of $6.00 per share. The underwriters exercised their option to purchase up to 750,000 additional shares of its common stock at the public offering price, less underwriting discounts and commissions. Gross proceeds to the Company would be approximately $34.3 million upon closing. The closing is subject to customary closing conditions. The Company intends to use the net proceeds from the public offering for working capital and other general corporate purposes. The Company may also use a portion of the net proceeds from the offering to acquire or invest in complementary businesses, technologies or other assets, although it has no present commitments or agreements to do so.

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, 2015.

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 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; the potential market for our tests; our ability to achieve and maintain reimbursement from third-party payers at acceptable levels; 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, including tests for interstitial lung disease, and the timeframes for development or commercialization; our ability to get our data and clinical studies accepted in peer-reviewed publications; our dependence on and the terms of our agreement with Thyroid Cytopathology Partners, 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; 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 ability to compete with potential competitors; our compliance with federal, state and international regulations; the potential impact of regulation of our tests by the FDA or other regulatory bodies; the impact of new or changing policies, regulation or legislation, or of judicial decisions, on our business; our ability to comply with the requirements of being a public company; the impact of seasonal fluctuations and economic conditions on our business; our belief that we have taken reasonable steps to protect our intellectual property; 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.

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, as well as risks and uncertainties related to: our limited operating history and history of losses since inception; our ability to increase usage of and reimbursement for the Afirma GEC,

Percepta, Envisia and any other tests we may develop; our dependence on a limited number of payers for a significant portion of our revenue; the complexity, time and expense associated with billing and collecting for our tests; current and future laws, regulations and judicial decisions applicable to our business, including potential regulation by the FDA or by regulatory bodies outside of the United States; changes in legislation related to the U.S. healthcare system; our dependence on strategic relationships and collaborations; our ability to successfully transition away from our former co-promotion agreement with Genzyme; our ability to achieve sales penetration in complex commercial accounts; unanticipated delays in research and development efforts; our ability to develop and commercialize new products and the timing of commercialization; our ability to successfully enter new product markets; our ability to conduct clinical studies and the outcomes of such clinical studies; the applicability of clinical results to actual outcomes; trends and challenges in our business; our ability to compete against other companies, products and technologies; our ability to protect our intellectual property; and our ability to obtain capital when needed. These forward-looking statements speak only as of the date hereof. We expressly disclaim any obligation or undertaking to update any

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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,” “we,” “our” and “us” refer to Veracyte, Inc.

Veracyte, Afirma, Percepta, Envisia, the Veracyte logo and the Afirma logo are our trademarks or registered 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 molecular diagnostics company that focuses on genomic solutions that resolve diagnostic ambiguity, thus enabling physicians to make more informed treatment decisions at an early stage in patient care. By improving diagnostic accuracy, we aim to help patients avoid unnecessary invasive procedures while reducing healthcare costs. Our first commercial solution, the Afirma Thyroid FNA Analysis, or Afirma, centers on the proprietary Afirma Gene Expression Classifier, or GEC, which is becoming a new standard of care in thyroid cancer diagnosis. The Afirma GEC helps physicians reduce the number of unnecessary surgeries by approximately 50% by employing a proprietary 142-gene signature to identify benign thyroid nodules among those deemed indeterminate by cytopathology alone. An additional 25 genes are used to differentiate uncommon neoplasm subtypes. We established the Afirma GEC’s clinical validity in a study published in The New England Journal of Medicine in 2012 and have demonstrated the test’s clinical utility, cost effectiveness and analytical validity in over 20 studies published in peer-reviewed journals. Since the commercial launch of Afirma in January 2011 through September 30, 2016, we have received 290,000 fine needle aspiration, or FNA, samples for evaluation using Afirma and performed over 65,000 GECs to resolve indeterminate cytopathology results.

In April 2015, we accelerated our entry into pulmonology with the launch of the Percepta Bronchial Genomic Classifier, which we obtained through our acquisition of Allegro Diagnostics Corp., or Allegro, in September 2014. The Percepta classifier is designed to improve lung cancer screening and diagnosis by helping to reduce unnecessary, invasive, risky and costly procedures in patients with suspicious lung nodules and lesions, typically found on CT scans. The 23-gene classifier identifies patients with lung nodules who are at low or very low risk of cancer following an inconclusive bronchoscopy result, making it possible to monitor these patients with CT scans in lieu of invasive diagnostic procedures. Clinical validation data from two prospective, multicenter studies, AEGIS I and II, were published in July 2015 in The New England Journal of Medicine. In February 2016, the first clinical utility study for the Percepta classifier was published in CHEST, the official journal of the American College of Chest Physicians, suggesting that use of the Percepta test could reduce unnecessary surgeries and other invasive procedures by as much as 50% in the evaluated patient population. Also in February 2016, analytical verification data for the Percepta classifier were published online in BMC Cancer, establishing the quality and reproducibility of our testing processes. As of September 2016, three Medicare Administrative Contractors have issued draft local coverage policies that, if finalized, would cover Percepta for Medicare-eligible patients in those regions. As of September 2016, more than 40 thought-leading academic and other institutions around the country are offering Percepta to their patients during this initial stage of commercialization.

In October 2016, we announced the launch of our third commercial test, the Envisia Genomic Classifier, which is also in pulmonology. This test is designed to enable improved diagnosis of idiopathic pulmonary fibrosis, or IPF, among patients presenting with a suspected interstitial lung disease, or ILD, without the need for surgery. The 190-gene

classifier uses machine learning coupled with powerful, deep ribonucleic acid, or RNA, sequencing to detect the presence or absence of usual interstitial pneumonia, or UIP, a classic diagnostic pattern that is essential for the diagnosis of IPF. In an independent test set, the Envisia classifier demonstrated high specificity (88%) and sensitivity (67%) for UIP on patient samples obtained through less-invasive bronchoscopy. The test's results showed high concordance with review of surgical samples by surgical pathology. Our initial focus for the Envisia classifier is on building the clinical evidence needed to secure coverage and reimbursement from Medicare and private payers.

Factors Affecting Our Performance

The Number of FNAs We Receive and Test

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The growth in our business is tied to the number of FNAs we receive and the number of GECs performed. Approximately 85% of FNAs we receive are for the Afirma solution, which consists of services related to rendering a cytopathology diagnosis, and if the cytopathology result is indeterminate, the GEC is performed. The remaining approximate 15% of FNAs are received from customers performing cytopathology and when the cytopathology result is indeterminate, the FNA is sent to us for the GEC only. The rate at which adoption occurs in these two settings will cause these two percentages to fluctuate over time. Less than 1% of the FNA samples we receive for cytopathology have insufficient cellular material from which to render a cytopathology diagnosis. We only bill the technical component, including slide preparation, for these tests. For results that are benign or suspicious/malignant by cytopathology, we bill for these services when we issue the report to the physician. If the cytopathology result is indeterminate, defined as atypia/follicular lesions of undetermined significance (AUS/FLUS) or suspicious for FN/HCN, we perform the GEC. Historically, approximately 14%-17% of samples we have received for the Afirma solution have yielded indeterminate results by cytopathology. Approximately 5%-10% of the samples for GEC testing have insufficient ribonucleic acid, or RNA, from which to render a result. The GEC can be reported as Benign, Suspicious or No Result. We bill for the GEC Benign and GEC Suspicious results only. After the GEC is completed, we issue the cytopathology report for the indeterminate results as well as the GEC report, and then bill for both of these tests. We incur costs of collecting and shipping the FNAs and a portion of the costs of performing tests where we cannot ultimately issue a patient report. Because we cannot bill for all samples received, the number of FNAs received does not directly correlate to the total number of patient reports issued and the amount billed.

Continued Adoption of and Reimbursement for Afirma

To date, only a small number of payers have reimbursed us for Afirma at list price. Revenue growth depends on both our ability to achieve broader reimbursement at increased levels from third-party payers and to expand our base of prescribing physicians and increase our penetration in existing accounts. Because some payers consider the GEC 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 will increase as more payers make a positive coverage decision and as payers enter into contracts with us, which should enhance our accrued revenue and cash collections. To drive increased adoption of Afirma, we increased our sales force over the last several years, along with increasing our marketing efforts. We have hired institutional channel managers to focus on the institutional segment, where accounts generally send us FNAs for the GEC only, and account managers, dedicated to serving existing accounts, thereby freeing up our product specialists to focus on transacting new business. 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 increased the list price billed for the GEC from $4,875 to $6,400 per test in July 2015, while the list price billed for routine cytopathology remained at $490 per test. We obtained Medicare coverage for the GEC effective in January 2012 and contracted reimbursement at an agreed upon rate of $3,200. We have entered into contracts establishing in-network allowable rates for both our GEC and cytopathology tests with payers including United Healthcare, Aetna and Cigna, as well as several Blue Cross Blue Shield plans, among others. We have also received positive coverage determinations from numerous other commercial payers and, as of September 2016, the GEC is covered by payers representing 185 million lives. We now have 155 million lives under contract. Payers that have agreed to pay for Afirma under contract are also counted as covered lives. Contracted and reimbursement rates vary by payer.

On March 1, 2015, a separate CPT code, or Current Procedural Terminology code, for the Afirma GEC was issued. On September 30, 2016, the Centers for Medicare & Medicaid Services, or CMS, released the final 2017 gapfill rate for Afirma GEC of $2,864, a reduction from our current rate of $3,200. We have filed a reconsideration request with CMS because we believe the data that we provided to the MACs support a higher rate based on the gapfill criteria. Medicare represents approximately 20% of our GEC volume.

Our average reimbursement per GEC was approximately $2,200 for the quarter ended September 30, 2016 as compared with approximately $2,300 for the same period in 2015. The average GEC 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.

We calculate the average GEC reimbursement from all payers, whether they are on an accrual or a cash basis, for tests that are on average a year old, since it can take a significant period of time to collect from some payers. We use an average of reimbursement for tests provided over two quarters as it reduces the effects of temporary volatility and seasonal effects. Thus the average reimbursement per GEC represents the total cash collected to date against GEC tests performed during the relevant period divided by the number of GEC tests performed during that same period.

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How We Recognize Revenue

We recognize revenue on an accrual basis when we are able to make a reasonable estimate of reimbursement at the time delivery is complete. In the first period in which revenue is accrued for a particular payer or test, there generally is a one-time increase in revenue. Until we have contracts with payers or can reasonably estimate the amount that will ultimately be received, we recognize the related revenue upon the earlier of notification of payment or when cash is received. Additionally, as we commercialize new products, we will need to be able to make a reasonable estimate of the amount that will ultimately be received from each payer for each new product offering prior to being able to recognize the related revenue on an accrual basis. Because the timing and amount of cash payments received from payers as well as one-time increases in revenue from newly accrued payers are difficult to predict, we expect that our revenue will fluctuate significantly in any given quarter. In addition, even if we begin to accrue larger amounts of revenue related to Afirma, when we introduce new products, we do not expect we will be able to recognize revenue from new products on an accrual basis for some period of time. This may result in continued fluctuations in our revenue.

As of September 30, 2016 and December 31, 2015, cumulative amounts billed since 2011 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 had not received notification of payment, collected cash or written off as uncollectible, totaled approximately $163.1 million and $134.3 million, respectively. Of the $134.3 million, we recognized revenue of approximately $1.3 million and $6.7 million in the three and nine months ended September 30, 2016, respectively, when cash was received.

Generally, the majority of 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 revenue from previously performed but unpaid tests. Revenue from these tests, if any, may not be equal to the billed amount due to a number of factors, including differences in reimbursement rates, the amounts of patient co-payments and co-insurance, the existence of secondary payers and claims denials. Finally, when we increase our list price, as we did in July 2015, it will increase the cumulative amounts billed.

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. Accordingly, any revenue that we recognize as a result of cash collection in respect of previously performed but unpaid tests will favorably impact our liquidity and results of operations in the period of payment receipt.

Impact of Genzyme Co-promotion Agreement

We signed a Co-Promotion Agreement with Genzyme in January 2012 to market the Afirma solution in the United States. The agreement required that we pay a certain percentage of our cash receipts from the sale of the Afirma solution to Genzyme, which percentage decreased over time, from 50% in 2012 to 40% from January 2013 through February 2014, and 32% beginning in February 2014. We received a $10.0 million upfront co-promotion fee from Genzyme under the Co-Promotion Agreement, which we amortized over the estimated useful life based on the provisions of the agreement as a reduction to selling and marketing expenses.

In November 2014, we signed an Amended and Restated U.S. Co-Promotion Agreement, or Amended Agreement, with Genzyme which reduced the co-promotion fees Genzyme received as a percentage of U.S. cash receipts from the sale of the Afirma solution from 32% to 15% beginning January 1, 2015. On March 9, 2016, we gave Genzyme notice of termination of the Amended Agreement effective September 9, 2016 and the amortization of the upfront

co-promotion fee was extended to that date. The final payments of $4.0 million under the Amended Agreement were made in September 2016.

In February 2015, we entered into an Ex-U.S. Co-Promotion Agreement, or Ex-U.S. Agreement, with Genzyme for the promotion of the Afirma GEC with exclusivity in five countries outside the United States initially and in other countries agreed to from time to time. The agreement commenced on January 1, 2015 and continues until December 31, 2019, with extension of the agreement possible upon agreement of the parties. Country-specific terms have been established under this agreement for Brazil and Singapore and a right of first negotiation has been established for Canada, the Netherlands and Italy. We pay Genzyme 25% of net revenue from the sale of the Afirma GEC in Brazil and Singapore over a five-year period. Beginning in the fourth year of the agreement, if we terminate the agreement for convenience, we may be required to pay a termination fee contingent on the number of GEC billable results generated during the 12 months immediately prior to the notice of termination.

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We amortized $227,000 and $948,000 of the $10.0 million upfront co-promotion fee in the three and nine months ended September 30, 2016, respectively, compared to $474,000 and $1.4 million in the same periods in 2015. The upfront co-promotion fee was fully amortized as of September 30, 2016. Our co-promotion fees payable to Genzyme, excluding the amortization of the upfront co-promotion fee, were $1.8 million and $6.1 million in the three and nine months ended September 30, 2016, respectively, compared to $1.8 million and $5.2 million in the same periods in 2015, and are included in selling and marketing expenses in our condensed consolidated statements of operations and comprehensive loss.

Development of Additional Products

We currently rely on sales of Afirma to generate all of our revenue. In May 2014, we commercially launched our Afirma Malignancy Classifiers, which we believe enhances our Afirma Thyroid FNA Analysis as a comprehensive way to manage thyroid nodule patients and serve our current base of prescribing physicians. We are also pursuing development or acquisition of products for additional diseases to increase and diversify our revenue. In September 2014 we acquired Allegro and with it, the Percepta Bronchial Genomic Classifier, a molecular diagnostic lung cancer test designed to help physicians determine which patients with lung nodules who have had an inconclusive bronchoscopy result are at low risk for cancer and can thus be safely monitored with CT scans, rather than undergoing invasive procedures. We launched the Percepta test in April 2015. Additionally, we introduced in October 2016 a solution for interstitial lung disease, our Envisia Genomic Classifier, that will offer an alternative to surgery by developing a genomic signature to classify samples collected through less invasive bronchoscopy techniques. We expect to continue to invest heavily in research and development in order to expand the capabilities of our solutions and to develop additional products. Our success in developing or acquiring new products will be important in our efforts to grow our business by expanding the potential market for our products and diversifying our sources of revenue.

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.

Historical Seasonal Fluctuations in FNA Volume and Cash Collections

Our business is subject to fluctuations in the number of FNA samples received for both cytopathology and GEC testing throughout the year as a result of a number of factors, including physician practices being closed for holidays or endocrinology and thyroid-related industry meetings which are widely attended by our prescribing physicians. Like other companies in our field, vacations by physicians and patients tend to negatively affect our volumes more during the summer months and during the end of year holidays compared to other times of the year. Additionally, we may receive fewer FNAs in the winter months due to severe weather if patients are not able to visit their doctor’s office. Our reimbursed rates and cash collections are also subject to seasonality. Medicare normally makes adjustments in its fee schedules at the beginning of the year which may affect our reimbursement. Additionally, some plans reset their

deductibles at the beginning of each year which means that patients early in the year are responsible for a greater portion of the cost of our tests, and we have lower cash collection rates from individuals than from third-party payers. Later in the year, particularly in the fourth quarter, we experience improved payment results as third-party payers tend to clear pending claims toward year end. This trend historically has increased our cash collections in the fourth quarter. As we accrue more revenue in the future, this will have less of an impact on our revenue in the fourth quarter but will still impact our cash position. The effects of these seasonal fluctuations in prior periods may have been obscured by the growth of our business.

Financial Overview

Revenue

Through September 30, 2016, all of our revenue has been derived from the sale of Afirma. To date, Afirma has been delivered primarily to physicians in the United States. We generally invoice third-party payers upon delivery of a patient report

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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 September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Medicare	23%	28%	27%	27%
UnitedHealthcare	11%	11%	12%	13%
	34%	39%	39%	40%

For tests performed where we can reasonably estimate the amount we will ultimately receive at the time delivery is complete, such as in the case of Medicare and certain other payers, we recognize the related revenue upon delivery of a patient report to the prescribing physician based on the established billing rate less contractual and other adjustments to arrive at the amount that we expect to ultimately receive. We determine the amount we expect to ultimately receive based on a per payer, per contract or agreement basis. Upon ultimate collection, the amount received where reimbursement was estimated is compared to previous estimates and the amount accrued is adjusted accordingly. In other situations, where we cannot reasonably estimate the amount that will be ultimately received, we recognize revenue upon the earlier of receipt of third-party payer notification of payment or when cash is received. Incremental accrued revenue as a result of additional payers meeting our revenue recognition criteria was $3.5 million and $4.0 million for tests delivered in the three and nine months ended September 30, 2016, respectively, and $127,000 and $692,000 for tests delivered in the three and nine months ended September 30, 2015, respectively. The incremental accrued revenue decreased the loss from operations and net loss by $3.5 million and $4.0 million for the three and nine months ended September 30, 2016, respectively, and decreased the loss per common share by $0.13 and $0.14 for the three and nine months ended September 30, 2016, respectively. 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 we recognize revenue on an accrual basis and later determine the judgments underlying estimated reimbursement change, our financial results could be negatively impacted in future quarters.

Cost of Revenue

The components of our cost of revenue are materials and service costs, including cytopathology testing services, stock-based compensation expense, direct labor costs, equipment and infrastructure expenses associated with testing samples, shipping charges to transport samples, and allocated overhead including rent, information technology, equipment depreciation and utilities. 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 and from the higher costs of our new facility. 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 and will increase disproportionately our aggregate cost of revenue until we achieve efficiencies in processing these new tests.

Research and Development

Research and development expenses include costs incurred to develop our technology, collect clinical samples and conduct clinical studies to develop and support our products. These costs consist of personnel costs, including stock-based compensation expense, prototype materials, laboratory supplies, consulting costs, costs associated with setting up and conducting clinical studies at domestic and international sites, and allocated overhead including rent, information technology, equipment depreciation and utilities. 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 have been incurring research and development expenses in 2016 for the development and launch of Envisia and for the continued development and support of the Afirma and Percepta tests. Specifically, we plan to: increase the body of clinical evidence to support Afirma; incur research and development expenses associated with clinical utility studies to support the commercialization of Percepta; and incur expenses associated with analytical verification and clinical utility studies for Envisia.

Selling and Marketing

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Selling and marketing expenses consist of personnel costs, including stock-based compensation expense, direct marketing expenses, consulting costs, and allocated overhead including rent, information technology, equipment depreciation and utilities. In addition, co-promotion fees paid to Genzyme, net of amortization of the upfront fee received, are included in selling and marketing expenses. In November 2014, we amended the co-promotion agreement with Genzyme and our personnel and marketing costs increased as we took on more sales and marketing responsibilities related to Afirma, but these increases are offset by the lower rate we are required to pay Genzyme under the Amended Agreement beginning in January 2015. On March 9, 2016, we gave Genzyme notice of termination of the Amended Agreement effective September 9, 2016. Consequently, in 2016, we have further expanded our internal sales force and increased our marketing spending as we transitioned out of the relationship. We expect that these costs will be offset by the elimination of the co-promotion fee, beginning in mid-September 2016. We have incurred increased selling and marketing expense as a result of investments in our lung product portfolio. We believe total selling and marketing expenses will continue to increase as we launch and promote our new tests.

General and Administrative

General and administrative expenses include those from executive, finance and accounting, human resources, legal, billing and client services, and quality and regulatory functions. These expenses include personnel costs, including stock-based compensation expense, audit and legal expenses, consulting costs, costs associated with being a public company, and allocated overhead including rent, information technology, equipment depreciation and utilities. We expect these expenses to continue to grow in 2016 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 our loan and security agreement and the credit agreement that replaced it.

Other Income (Expense), Net

Other income (expense), net consists primarily of sublease rental income and interest income received from payers and from our cash equivalents.

Critical Accounting Polices and Estimates

Our management’s discussion and analysis of our financial condition and results of operations is based on our unaudited interim condensed financial statements, which have been prepared in accordance with United States generally accepted accounting principles, or U.S. GAAP. The preparation of the financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenue generated and expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions and any such differences may be

material. We believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

Revenue Recognition

We recognize revenue in accordance with the provisions of Accounting Standards Codification ("ASC") 954-605, Health Care Entities — Revenue Recognition. Our revenue is generated from the provision of diagnostic services. The service is completed upon the delivery of test results to the prescribing physician, at which time we bill for the service. We recognize revenue related to billings for tests delivered on an accrual basis when amounts that will ultimately be realized can be reasonably estimated. The estimates of amounts that will ultimately be realized require significant judgment by management. Until a contract has been negotiated with a commercial payer or governmental program, our tests may or may not be covered

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by these entities' existing reimbursement policies. In addition, patients do not enter into direct agreements with us that commit them to pay any portion of the cost of the tests in the event that their insurance declines to reimburse us.

We may bill the patient directly for these amounts in the form of co-payments and co-insurance in accordance with their insurance carrier and health plans. We pursue reimbursement from such patients on a case-by-case basis. In the absence of contracted reimbursement coverage or the ability to reasonably estimate the amount that will ultimately be realized for our services, revenue is recognized on a cash basis i.e. upon the earlier of receipt of third-party payer notification of payment or when cash is received.

We use judgment in determining if we are able to make a reasonable estimate of what will be ultimately realized. We also use judgment in estimating the amounts we expect to collect by payer. Our judgments will continue to evolve in the future as we continue to gain payment experience.

Finite-lived Intangible Assets

Finite-lived intangible assets relates to intangible assets reclassified from indefinite-lived intangible assets, following the launch of Percepta in April 2015. We amortize finite-lived intangible assets using the straight-line method, over their estimated useful life. The estimated useful life of 15 years was used for the intangible asset related to Percepta based on management's estimate of product life, product life of other diagnostic tests and patent life. We test this finite-lived intangible asset for impairment when events or circumstances indicate a reduction in the fair value below its carrying amount. There was no impairment for the nine months ended September 30, 2016.

Stock-based Compensation

We recognize stock-based compensation cost for only those shares underlying stock options that we expect to vest on a straight-line basis over the requisite service period of the award. We estimate the fair value of stock options using a Black-Scholes option-pricing model, which requires the input of highly subjective assumptions, including the option's expected term and stock price volatility. In addition, judgment is also required in estimating the number of stock-based awards that are expected to be forfeited. Forfeitures are estimated based on historical experience at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. The assumptions used in calculating the fair value of share-based payment awards represent management's best estimates, but these estimates involve inherent uncertainties and the application of management's judgment. As a result, if factors change and we use different assumptions, our stock-based compensation expense could be materially different in the future.

Results of Operations

Comparison of the Three and Nine Months Ended September 30, 2016 and 2015 (In Thousands of Dollars, Except Percentages and GECs reported)

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	Three Months Ended September 30,				Nine Months Ended September 30,			
	2016	2015	Change	%	2016	2015	Change	%
Revenue	$18,603	$12,335	$6,268	51%	$46,828	$35,461	$11,367	32%
Operating expense:								
Cost of revenue	6,367	5,618	749	13%	18,947	15,322	3,625	24%
Research and development	4,006	3,563	443	12%	11,734	9,453	2,281	24%
Selling and marketing	7,087	6,048	1,039	17%	22,416	18,606	3,810	20%
General and administrative	5,763	5,728	35	1%	18,062	17,062	1,000	6%
Intangible asset amortization	266	266	—	—%	800	533	267	50%
Total operating expenses	23,489	21,223	2,266	11%	71,959	60,976	10,983	18%
Loss from operations	(4,886)	(8,888)	4,002	(45)%	(25,131)	(25,515)	384	(2)%
Interest expense	(799)	(92)	(707)	768%	(1,951)	(269)	(1,682)	625%
Other income (expense), net	48	35	13	37%	127	93	34	37%
Net loss and comprehensive loss	$(5,637)	$(8,945)	$3,308	(37)%	$(26,955)	$(25,691)	$(1,264)	5%
Other Operating Data:								
GECs reported	5,740	5,034	706	14%	16,924	13,812	3,112	23%

We incurred a net loss of $5.6 million and $27.0 million for the three and nine months ended September 30, 2016 compared to a net loss of $8.9 million and $25.7 million in the same periods in 2015. As of September 30, 2016, we had an accumulated deficit of $175.7 million.

Revenue

Revenue increased $6.3 million, or 51%, for the three months ended September 30, 2016 compared to the same period in 2015. The increase was primarily due to additional payers meeting our revenue recognition criteria for accrual and increased adoption of Afirma and the resultant increase in tests delivered, especially the proportion of GEC tests reported. Revenue recognized when cash is received has decreased because payers who were previously recognized on a cash basis have met our revenue recognition criteria and are recognized on an accrual basis.

Revenue increased $11.4 million, or 32%, for the nine months ended September 30, 2016 compared to the same period in 2015. The increase was primarily due to additional payers meeting our revenue recognition criteria for accrual and increased adoption of Afirma and the resultant increase in tests delivered, especially the proportion of GEC tests reported. Revenue recognized when cash is received has decreased because payers who were previously recognized on a cash basis have met our revenue recognition criteria and are recognized on an accrual basis.

Revenue recognized on an accrual basis and cash basis for the three and nine months ended September 30, 2016 and 2015 was as follows (in thousands of dollars):

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2016	%	2015	%	2016	%	2015	%
Revenue recognized on an accrual basis	$13,903	75%	$6,985	57%	$31,478	67%	$18,957	53%
Revenue recognized on a cash basis	4,700	25%	5,350	43%	15,350	33%	16,504	47%
Total	$18,603	100%	$12,335	100%	$46,828	100%	$35,461	100%

Prior to July 1, 2016, we believe we did not have a consistent payment history to accrue a significant portion of our Afirma tests at the time of delivery and recognized revenue on a cash basis for such tests. We have been analyzing the amounts received for tests performed since commercialization and during the quarter ended September 30, 2016, concluded there was sufficient information to support a reasonable estimate of the amount of revenue to accrue upon

test delivery for a number of payers that had been previously recognized on a cash basis. We considered factors such as coverage from payers, whether there is a reimbursement contract between the payer and us, the percentage of tests delivered for which payment is received, timeliness of payment, payment as a percentage of agreed upon rate, amount paid per test and any current developments or changes that could impact reimbursement to make an estimate of the amount to accrue upon test delivery in accordance with ASC 954. As a result, we recognized $3.5 million of incremental revenue during the quarter ended September 30, 2016 upon

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test delivery that previously would not have been recognized until notification of payment or cash was received. Tests performed prior to July 1, 2016 that did not meet our accrual criteria at the time of delivery will continue to be recognized as revenue on a cash basis. However, we expect the amount of revenue to be recognized on a cash basis for Afirma to decline in future periods since going forward relatively fewer tests will be performed for which a reasonable estimate of revenue to accrue will not have been made at the time of delivery.

Cost of revenue

Comparison of the three and nine months ended September 30, 2016 and 2015 is as follows (in thousands of dollars, except percentages):

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2016	2015	Change	%	2016	2015	Change	%
Cost of revenue:								
Reagents, chips, consumables and related	$2,459	$2,008	$ 451	22%	$7,063	$5,210	$1,853	36%
Cytopathology fees and related costs	1,489	1,395	94	7%	4,477	3,978	499	13%
Sample collection	824	834	(10)	(1)%	2,617	2,256	361	16%
Direct labor	792	685	107	16%	2,361	1,790	571	32%
Other	803	696	107	15%	2,429	2,088	341	16%
Total	$6,367	$5,618	$ 749	13%	$18,947	$15,322	$3,625	24%

Cost of revenue increased $749,000, or 13%, for the three months ended September 30, 2016 compared to the same period in 2015. Given our corporate focus on GEC growth and the adoption of the Afirma test, GEC tests increased by 14% and cytopathology tests increased by 5%. The increase in reagents, chips, consumables and related costs is associated primarily with increased GEC test volume and commission expense to a supplier corresponding to the $3.5 million of incremental revenue for the quarter ended September 30, 2016. The increase in cytopathology fees is related to the volume increase in FNA samples processed. The increase in direct labor is associated with an average lab headcount increase of 14%, the increase in sample volume, and the mix shift to relatively more GECs versus cytopathology tests as more labor hours are incurred on the GEC tests compared to the cytopathology tests and at a higher average employee cost. Other costs are primarily indirect costs, such as facilities allocation, depreciation and equipment maintenance, which increased as a result of increased allocable costs, mainly due to our move into a larger facility in the first quarter of 2016.

Cost of revenue increased $3.6 million, or 24%, for the nine months ended September 30, 2016 compared to the same period in 2015. Given our corporate focus on GEC growth and the adoption of the Afirma test, GEC tests increased by 23% and cytopathology tests increased by 10%. The increase in reagents, chips, consumables and related costs is associated primarily with increased GEC test volume and commission expense to a supplier corresponding to the $3.5 million of incremental revenue for the quarter ended September 30, 2016. The increase in cytopathology fees is related to the volume increase in FNA samples processed. The increase in sample collection costs is primarily related to increased volume of samples. The increase in direct labor is associated with an average lab headcount increase of 22%, the increase in sample volume, and the mix shift to relatively more GECs versus cytopathology tests as more labor hours are incurred on the GEC tests compared to the cytopathology tests and at a higher average employee cost. Other costs are primarily indirect costs, such as facilities allocation, depreciation and equipment maintenance, which increased as a result of increased allocable costs, mainly due to our move into a larger facility.

Research and development

Comparison of the three and nine months ended September 30, 2016 and 2015 is as follows (in thousands of dollars, except percentages):

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	Three Months Ended September 30,				Nine Months Ended September 30,			
	2016	2015	Change	%	2016	2015	Change	%
Research and development expense:								
Personnel-related expense	$1,829	$1,553	$ 276	18%	$5,239	$4,470	$769	17%
Stock-based compensation expense	342	296	46	16%	982	890	92	10%
Direct R&D expense	1,074	999	75	8%	3,295	2,328	967	42%
Other expense	761	715	46	6%	2,218	1,765	453	26%
Total	$4,006	$3,563	$ 443	12%	$11,734	$9,453	$2,281	24%

Research and development expense increased $443,000, or 12%, for the three months ended September 30, 2016 compared to the same period in 2015. The increase in personnel-related expense was primarily due to an 8% increase in average headcount including an increase in senior level positions, and increased accrued bonuses as a result of increased bonus targets and performance. The increase in stock-based compensation expense reflects option grants to new and existing employees. The increase in direct R&D expense was primarily due to materials purchased for research and development experiments. Other expense increased primarily as a result of increased information technology and facilities expenses that were related to research and development activities.

Research and development expense increased $2.3 million, or 24%, for the nine months ended September 30, 2016 compared to the same period in 2015. The increase in personnel-related expense was primarily due to a 6% increase in average headcount including an increase in senior level positions, and increased accrued bonuses as a result of increased bonus targets and performance. The increase in stock-based compensation expense reflects option grants to new and existing employees. The increase in direct R&D expense was primarily due to materials purchased for research and development experiments. Other expense increased primarily as a result of increased information technology and facilities expenses that were related to research and development activities.

Selling and marketing

Comparison of the three and nine months ended September 30, 2016 and 2015 is as follows (in thousands of dollars, except percentages):

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2016	2015	Change	%	2016	2015	Change	%
Selling and marketing expense:								
Genzyme co-promotion expense, net	$1,590	$1,330	$260	20%	$5,103	$3,752	$1,351	36%
Personnel-related expense	3,640	2,905	735	25%	11,606	8,822	2,784	32%
Stock-based compensation expense	396	353	43	12%	1,199	943	256	27%
Direct marketing expense	671	656	15	2%	2,205	2,238	(33)	(1)%
Other expense	790	804	(14)	(2)%	2,303	2,851	(548)	(19)%
Total	$7,087	$6,048	$1,039	17%	$22,416	$18,606	$3,810	20%

Selling and marketing expense increased $1.0 million, or 17%, for the three months ended September 30, 2016 compared to the same period in 2015. The increase in Genzyme co-promotion expense, net, reflects lower amortization expense from the extension of the amortization life of the $10.0 million upfront co-promotion fee to reflect the termination of the Amended Agreement effective September 9, 2016. The increase in personnel-related expense was primarily due to a 28% increase in average headcount of our sales and marketing team in preparation for the termination of the Amended Agreement, as well as increased commissions. The increase in stock-based compensation expense reflects option grants to new and existing employees.

Selling and marketing expense increased $3.8 million, or 20%, for the nine months ended September 30, 2016 compared to the same period in 2015. The increase in Genzyme co-promotion expense, net, reflects an increase in cash collections for Afirma and lower amortization expense from the extension of the amortization life of the $10.0 million upfront co-promotion fee. The increase in personnel-related expense was primarily due to a 31% increase in average headcount of our sales and marketing team in preparation for the termination of the Amended Agreement, as well as increased commissions. The

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increase in stock-based compensation expense reflects option grants to new and existing employees. The decrease in other expense was primarily due to a reduction of consulting expenses.

General and administrative

Comparison of the three and nine months ended September 30, 2016 and 2015 is as follows (in thousands of dollars, except percentages):

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2016	2015	Change	%	2016	2015	Change	%
General and administrative expense:								
Personnel-related expense	$3,150	$2,596	$ 554	21%	$9,586	$7,811	$1,775	23%
Stock-based compensation expense	803	794	9	1%	2,470	2,289	181	8%
Professional fees expense	1,039	1,101	(62)	(6)%	3,371	3,832	(461)	(12)%
Rent and other facilities expense	537	898	(361)	(40)%	1,940	1,821	119	7%
Other expense	234	339	(105)	(31)%	695	1,309	(614)	(47)%
Total	$5,763	$5,728	$ 35	1%	$18,062	$17,062	$1,000	6%

General and administrative expense increased $35,000, or 1%, for the three months ended September 30, 2016 compared to the same period in 2015. The increase in personnel-related expense was primarily due to an 8% increase in average headcount for the three months ended September 30, 2016 as compared to the same period in 2015, and increased accrued bonuses as a result of increased bonus targets and performance. The decrease in professional fees expense was due to lower audit expenses. The decrease in rent and other facilities expense was largely due to incurring facilities expenses for the three months ended September 30, 2015 for our new South San Francisco facility, as well as our previous space, for which the lease ended in March 2016. The decrease in other expense was primarily due to consulting expenses of approximately $200,000 for the three months ended September 30, 2015 largely related to accounting services that did not recur as we hired full-time staff, partially offset by higher general administrative expenses.

General and administrative expense increased $1.0 million, or 6%, for the nine months ended September 30, 2016 compared to the same period in 2015. The increase in personnel-related expense was primarily due to a 9% increase in average headcount for the nine months ended September 30, 2016 as compared to the same period in 2015, increased accrued bonuses as a result of increased bonus targets and performance, and higher employee separation costs. The increase in stock-based compensation expense was primarily due to option grants to new and existing employees. The decrease in professional fees was primarily due to lower audit and legal expenses. The increase in rent and other facilities expense was largely due to the higher rent expenses for our new South San Francisco facility compared to our previous space. The decrease in other expense was primarily due to consulting expense of approximately $1.1 million for the nine months ended September 30, 2015 largely related to accounting services that did not recur as we hired full-time staff, partially offset by higher general administrative expenses.

Interest expense

Interest expense increased $707,000 for the three months ended September 30, 2016 compared to the same period in 2015 due to interest on the initial term loan of $25.0 million under a credit agreement entered into in March 2016.

Interest expense increased $1.7 million for the nine months ended September 30, 2016 compared to the same period in 2015 due to interest on the initial term loan of $25.0 million under a credit agreement entered into in March 2016 and due to the paying off of the loan and security agreement in March 2016, which included expenses for an end-of-term

payment, a prepayment penalty and the write-off of debt issuance costs and debt discount.

Other income (expense), net

Other income, net, increased $13,000 for the three months ended September 30, 2016 compared to the same period in 2015 primarily due to higher interest income from our money market investments.

Other income, net, increased $34,000 for the nine months ended September 30, 2016 compared to the same period in 2015 primarily due to higher interest income from our money market investments.

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Liquidity and Capital Resources

We have incurred net losses since our inception. For the nine months ended September 30, 2016, we had a net loss of $27.0 million, and we expect to incur additional losses in the remainder of 2016 and in future years. As of September 30, 2016, we had an accumulated deficit of $175.7 million. We may never achieve revenue sufficient to offset our expenses.

We believe our existing cash and cash equivalents of $31.7 million as of September 30, 2016, our available term loan and our revenue during the next 12 months will be sufficient to meet our anticipated cash requirements for at least the next 12 months.

From inception through September 30, 2016, we have received $217.8 million in net proceeds from various sources to finance our operations, including net proceeds of $78.6 million from sales of our preferred stock, net proceeds of $59.2 million from our IPO, net proceeds of $37.3 million from our sale of common stock in a private placement, $10.0 million from the Genzyme co-promotion agreement, net borrowings of $4.9 million under our loan and security agreement which was paid off in March 2016, net borrowings of $24.5 million under our credit agreement, the exercise of stock options and employee stock purchases of $2.9 million and conversion of accrued interest to long-term debt of $0.4 million.

In March 2016, we entered into a credit agreement, or Credit Agreement, with Visium Healthcare Partners, LP, or Visium. Under the Credit Agreement, two term loans are available to us with an aggregate principal amount of up to $40.0 million. We drew down the initial $25.0 million term loan, or Initial Term Loan, on March 30, 2016. On or prior to June 30, 2017, we may request the second term loan of up to $15.0 million, or the Second Term Loan. The Initial Term Loan and the Second Term Loan are referred to as Term Loans, which mature on March 31, 2022.

The Term Loans bear interest at a fixed rate of 12.0% per annum, payable quarterly at the end of each March, June, September and December. No principal payments will be due during an interest-only period, commencing on the funding date for the Initial Term Loan, or Initial Borrowing Date, and continuing through and including March 31, 2020. We are obligated to repay the outstanding principal amounts under the Term Loans in eight equal installments during the final two years under the Credit Agreement. For any quarterly interest payment through and including the 16th interest payment date after the Initial Borrowing Date, so long as no event of default has occurred and is then continuing, we may elect to pay interest in cash on the outstanding principal amounts of the Term Loans at a fixed rate of 9.0%, with the remaining 3.0% of the 12.0% interest paid-in-kind by adding such paid-in-kind interest to the outstanding principal amounts of the Term Loans. We elected to pay interest in-kind for the quarter ended September 30, 2016 and have recorded $385,000 of paid-in-kind interest through September 30, 2016.

We may prepay the outstanding principal amount under the Term Loans subject to a minimum of $5.0 million of principal amount or a whole multiple of $1.0 million in excess thereof plus accrued and unpaid interest and a prepayment premium. The prepayment premium will be assessed on the principal amount repaid and will equal (i) 24.0% less the aggregate amount of all interest payments in cash, if the prepayment is made on or prior to March 31, 2018, (ii) 4.0%, if the prepayment is made after March 31, 2018 and on or prior to March 31, 2019, (iii) 2.0%, if the prepayment is made after March 31, 2019 and on or prior to March 31, 2020, and (iv) 1.0%, if the prepayment is made after March 31, 2020 and on or prior to March 31, 2021. After March 31, 2021 there is no prepayment premium.

Our obligations under the Credit Agreement are secured by a security interest in substantially all of our assets. The Credit Agreement contains customary representations, warranties and events of default, 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 its equity interests, engage in any material new line of business or

enter into certain transactions with affiliates, in each case subject to certain exceptions. The Credit Agreement also includes financial covenants requiring minimum cash and cash equivalents balances and minimum revenues. To the extent we form or acquire certain subsidiaries domiciled in the United States, those subsidiaries are required to be guarantors of our obligations under the Credit Agreement. As of September 30, 2016, we were in compliance with the loan covenants.

In June 2013, we entered into a loan and security agreement as subsequently amended ("2013 Loan Agreement") with a financial institution that provided for borrowings of up to $10.0 million in aggregate. Borrowings under the 2013 Loan Agreement totaled $5.0 million, which was outstanding at January 1, 2015 and into 2016 until such amount was repaid upon us entering into the Credit Agreement discussed above.

We expect that our near- and longer-term liquidity requirements will continue to consist of selling and marketing expenses, research and development expenses, working capital and general corporate expenses associated with the growth of

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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 and other operating restrictions that could adversely affect our ability to conduct our business. Our current credit 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.

The following table summarizes our cash flows for the nine months ended September 30, 2016 and 2015 (in thousands of dollars):

	Nine Months Ended September 30,	
	2016	2015
Cash used in operating activities	$(23,750)	$(24,135)
Cash used in investing activities	(3,762)	(2,508)
Cash provided by financing activities	20,127	37,745

Cash Flows from Operating Activities

Cash used in operating activities for the nine months ended September 30, 2016 was $23.8 million. The net loss of $27.0 million includes non-cash charges of $0.9 million in amortization of the deferred fee received from Genzyme, offset primarily by $4.7 million of stock-based compensation expense, $2.6 million of depreciation and amortization, which includes $0.8 million of intangible asset amortization, $0.3 million in interest and prepayment penalty relating to the repayment of our borrowings under our 2013 Loan Agreement and $0.4 million from conversion of accrued interest to long-term debt. Cash used as a result of changes in operating assets and liabilities of $4.0 million is primarily due to an increase in accounts receivable of $2.9 million and a decrease in accrued liabilities and deferred rent of $1.1 million.

Cash used in operating activities for the nine months ended September 30, 2015 was $24.1 million. The net loss of $25.7 million primarily includes non-cash charges of $4.2 million of stock-based compensation expense and $1.6 million of depreciation and amortization, offset by $1.4 million in amortization of the deferred upfront fee received from Genzyme. Cash used as a result of changes in operating assets and liabilities of $3.0 million was primarily due to an increase in prepaid and other current assets of $1.9 million, a decrease in accounts payable of $1.8 million, an increase in accounts receivable of $0.6 million and an increase in supplies inventory of $0.3 million, offset

by an increase in accrued liabilities and deferred rent of $1.6 million.

Cash Flows from Investing Activities

Cash used in investing activities for the nine months ended September 30, 2016 was $3.8 million for the acquisition of property and equipment, primarily for the build out of office space and laboratory for our new South San Francisco facility.

Cash used in investing activities for the nine months ended September 30, 2015 was $2.5 million, of which $2.0 million was used for the acquisition of property and equipment. Additionally, we restricted additional cash of $0.5 million, consisting of $0.6 million in conjunction with collateral for an irrevocable standby letter of credit as security for our new

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headquarters, offset by approximately $0.1 million of cash used to pay down liabilities associated with the acquisition of Allegro.

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Cash Flows from Financing Activities

Cash provided by financing activities for the nine months ended September 30, 2016 was $20.1 million. The financing activities for the nine months ended September 30, 2016 consisted of $24.5 million of net proceeds from the draw-down of the Initial Term Loan of the Credit Agreement and $1.0 million from the exercise of options to purchase our common stock, partially offset by the payment of $5.0 million for the remaining principal balance and a $0.3 million of end-of-term payment and prepayment penalty related to our previous loan and security agreement that we repaid on March 30, 2016.

Cash provided by financing activities for the nine months ended September 30, 2015 of $37.7 million consisted of $37.3 million of net proceeds from our sale of common stock in a private placement and $0.7 million of cash received from the exercise of options to purchase our common stock, offset by $0.2 million in deferred stock offering costs.

Contractual Obligations

The following table summarizes certain contractual obligations as of September 30, 2016 (in thousands of dollars):

	Payments Due by Period				
	Remainder of 2016	Fiscal Year 2017 to 2018	Fiscal Year 2019 to 2021	Fiscal 2022 and Beyond	Total
Operating lease obligations	$523	$4,245	$6,252	$9,812	$20,832
Long-term debt obligations	—	—	22,212	3,173	25,385
Supplies purchase commitments	1,315	173	—	—	1,488
Total	$1,838	$4,418	$28,464	$12,985	$47,705

In April 2015, we signed a non-cancelable lease agreement for approximately 59,000 square feet to serve as our new South San Francisco facility. The lease began in June 2015 and expires in March 2026, and contains extension of lease term and expansion options.

In November 2012, we entered into a non-cancelable lease agreement commencing February 2013 for our laboratory and office space in Austin, Texas. The lease expires in July 2018.

Off-balance Sheet Arrangements

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

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, No. 2014-09, Revenue from Contracts with Customers, requiring an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. The updated standard will replace most existing revenue recognition guidance in GAAP when it becomes effective and permits the use of either the retrospective or cumulative effect transition method. Adoption is permitted as early as the first quarter of 2017 and is required by the first quarter of 2018. We have not yet selected a transition method and are currently evaluating the potential effect of the updated standard on our financial statements.

In August 2014, FASB issued Accounting Standards Update No. 2014-15, Presentation of Financial Statements Going Concern - Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern. The amendments require management to assess an entity's ability to continue as a going concern by incorporating and expanding upon certain principles that are currently in U.S. auditing standards. Specifically, the amendments: (1) provide a definition of the term substantial doubt; (2) require an evaluation every reporting period including interim periods; (3) provide principles for considering the mitigating effect of management's plans; (4) require certain disclosures when substantial doubt is alleviated as a result of consideration of management's plans; (5) require an express statement and other disclosures when substantial doubt is not alleviated; and (6) require an assessment for a period of one year after the date that the financial statements are issued (or available to be issued). ASU 2014-15 will be effective for annual periods ending after December 15, 2016 and interim periods within annual periods beginning after December 15, 2016 with early adoption permitted. ASU 2014-15 will be effective for us beginning with our annual report for 2016 and interim periods thereafter. We do not anticipate that the adoption of this ASU will have a significant impact on our financial statements.

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In April 2015, the FASB issued ASU No. 2015-03, Simplifying the Presentation of Debt Issuance Costs, to require debt issuance costs to be presented as an offset against debt outstanding. The update does not change current guidance on the recognition and measurement of debt issuance costs. The ASU is effective for interim and annual periods beginning after December 15, 2015. Adoption of the ASU is retrospective to each prior period presented. We have adopted this ASU and the retrospective adjustment of the prior period presentation was not material.

In November 2015, the FASB issued ASU 2015-17, Balance Sheet Classification of Deferred Taxes. The ASU requires that deferred tax assets and liabilities be classified as noncurrent in the statement of financial position, thereby simplifying the guidance that required an entity to separate deferred assets and liabilities into current and noncurrent amounts, and was effective for us beginning in the first quarter of 2016. We early-adopted this ASU as of December 31, 2015 and the impact of adoption on our statement of financial position was not material.

In February 2016, the FASB issued ASU No. 2016-2, Leases. 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-us 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. Early adoption is permitted. We are currently evaluating the potential effect of the updated standard on our financial statements.

In March 2016, the FASB issued ASU 2016-09, Compensation - Stock Compensation, related to the tax effects of share-based awards. This ASU requires that all the tax effects of share-based awards be recorded through the income statement, thereby simplifying the current guidance that requires excess tax benefits and certain excess tax deficiencies to be recorded in equity. The ASU will be effective for interim and annual periods beginning after December 15, 2016. We do not anticipate that the adoption of this ASU will have a significant impact on our financial statements.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to market risks in the ordinary course of our business. These risks primarily relate to interest rates. We had cash and cash equivalents of $31.7 million as of September 30, 2016 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.

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 quarter ended

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September 30, 2016 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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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 nine months ended September 30, 2016, we had a net loss of $27.0 million and we expect to incur additional losses for the remainder of 2016 and in future years. As of September 30, 2016, we had an accumulated deficit of $175.7 million. 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, Afirma, our lung cancer test, Percepta, 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 depend solely on sales of Afirma, and we will need to generate sufficient revenue from this and other diagnostic solutions to grow our business.

All of our revenues have been derived from the sale of Afirma, which we commercially launched in January 2011. For the foreseeable future, we expect to derive substantially all of our revenue from sales of Afirma. We launched our first product in pulmonology for lung cancer, Percepta, in April 2015, and our commercialization efforts may not be successful. We also launched Envisia for improved diagnosis of IPF in October 2016, and our commercialization efforts for Envisia may not be successful. 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 with our molecular cytology platform or, if we are able to identify such diseases, whether or when we will be able to successfully commercialize solutions for these diseases. If we are unable to increase sales and expand reimbursement for Afirma, or successfully commercialize and obtain coverage and reimbursement for Percepta and Envisia and develop and commercialize other solutions, our revenue and our ability to achieve and sustain profitability would be impaired, and the market price of our common stock could decline.

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

Revenue for tests performed on patients covered by Medicare and UnitedHealthcare was 27% and 12%, respectively, of our revenue for the nine months ended September 30, 2016, compared with 27% and 13%, respectively, in the nine months ended September 30, 2015. The percentage of our revenue derived from significant payers is expected to fluctuate from period to period as our revenue increases, 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 with jurisdiction at that time, issued coverage and payment determinations for the Afirma Gene Expression Classifier, or GEC. 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 GEC could result in a change in the coverage or reimbursement rates for such products, or the loss of coverage. On March 1, 2015, a separate CPT code, or Current Procedural Terminology code, for the Afirma GEC was issued. On September 30, 2016, CMS released the final 2017 gapfill rate for the Afirma GEC of $2,864, a reduction from our current rate of $3,200. We have filed a reconsideration request with CMS because we believe the data that we provided to the MACs

support a higher rate based on the gapfill criteria, but there can be no assurance that our request for reconsideration will be successful. We do not yet know whether the gapfill process for GEC will impact the 2017 Medicare payment rate. A decrease in the current Medicare payment rate for our tests will decrease our revenue from Medicare and may also decrease the payment rates for some of our commercial payers if they tie their allowable rates to Medicare, which may have an adverse effect on our business, financial condition and results of operations.

Although we have entered into contracts with certain third-party payers which 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. Any such actions could have a negative effect on our revenue.

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

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

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

We do not have a contracted rate of reimbursement with many payers for Afirma, and we do not have any contracted reimbursement with respect to Percepta or Envisia. 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 not a 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 GEC, Afirma Malignancy Classifiers, launched in May 2014, Percepta, launched in April 2015, and Envisia, launched in October 2016, 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, commercial payers may tie their allowable rates to Medicare rates, and should Medicare reduce their rates as they did with Afirma in September 2016, we may be negatively impacted. 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.

Several existing guidelines and historical practices in the United States regarding indeterminate thyroid nodule fine needle aspiration, or FNA, results recommend a full or partial surgical thyroidectomy in most cases. Accordingly, physicians may be reluctant to order a diagnostic solution that may suggest surgery is unnecessary where some current guidelines and historical practice have typically led to such procedures. Moreover, our diagnostic services often are performed at a specialized clinical reference laboratory rather than by a pathologist in a local laboratory, so pathologists may be reluctant to support our services. In addition, guidelines for the diagnosis and treatment of thyroid nodules may subsequently be revised to recommend another type of treatment protocol, and these changes may result in medical practitioners deciding not to use Afirma. These facts may make physicians reluctant to convert to using or continuing to use Afirma, which could limit our ability to generate revenue and our ability to achieve profitability. To the extent international markets have existing practices and standards of care which are different than those in the United States, we may face challenges with the adoption of Afirma outside the United States. We will face similar challenges with our other tests.

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

For tests performed where we have an agreed upon reimbursement rate or we are able to reasonably estimate the amount that will ultimately be realized at the time delivery of a patient report is complete, such as in the case of Medicare and certain other payers, we recognize the related revenue upon delivery of a patient report to the prescribing physician based on the established billing rate less contractual and other adjustments to arrive at the amount that we expect to realize. We determine the amount we expect to realize based on a per payer, per contract or agreement basis. In the first period in which revenue is accrued for a particular payer, there generally is a one-time increase in revenue. Upon ultimate collection, the amount received from Medicare and other payers where reimbursement was estimated is compared to previous estimates and the amount accrued is adjusted accordingly. In situations where we cannot reasonably estimate the amount that will ultimately be collected, we recognize revenue upon the earlier of receipt of third-party notification of payment or when cash is received. We have little visibility as to when we will receive payment for our diagnostic tests, and we must appeal negative payment decisions, which delays collections. We may receive a large number of past payments from a payer all at once, which might cause a one-time increase in revenue. These factors have and will likely continue to result in fluctuations in our quarterly revenue. Should we recognize revenue from payers on an accrual basis and later determine the 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, research analysts and 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 Afirma, 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, P.A., or TCP, to provide cytopathology professional diagnoses on thyroid 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 was effective through

December 31, 2015 and automatically renews every year thereafter 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.

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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 Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, collectively the ACA, enacted in March 2010, makes changes that are expected to significantly affect the pharmaceutical and medical device industries and clinical laboratories. Effective January 1, 2013, the ACA includes 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 and 2017, the excise tax is scheduled to be restored in 2018.

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 addition, the ACA establishes an Independent Payment Advisory Board, or IPAB, to reduce the per capita rate of growth in Medicare spending. The IPAB has broad discretion to propose policies to reduce expenditures, which may have a negative effect on payment rates for services. The IPAB proposals may affect payments for clinical laboratory services beginning in 2016 and for hospital services beginning in 2020. We are monitoring the effect of the ACA to determine the trends and changes that may be necessitated by the legislation, any of which may potentially affect our business.

In addition to the ACA, the effect of which on our business cannot presently be fully quantified, various healthcare reform proposals have also 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 resets 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. We cannot predict whether future healthcare initiatives will be implemented at the federal or state level or in countries outside of the United States in which we may do business, or the effect any future legislation or regulation will have on us. The taxes imposed by the new

federal legislation, cost reduction measures and the expansion in the role of the U.S. government in the healthcare industry may result in decreased revenue, lower reimbursement by payers for our tests or reduced medical procedure volumes, all of which may adversely affect our business, financial condition and results of operations. In addition, sales of our tests outside the United States subject our business to foreign regulatory requirements and cost-reduction measures, which may also change over time.

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

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CMS announced plans to bundle payments for clinical laboratory diagnostic tests together with other services performed during hospital outpatient visits under the Hospital Outpatient Prospective Payment System. For calendar year 2016, CMS maintained 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.

The Protecting Access to Medicare Act of 2014, or 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 would report initially and then on a subsequent three year basis thereafter (or annually for advanced diagnostic laboratory tests, or ADLTs), private payer payment rates and volumes for their tests. The final PAMA ruling was issued June 17, 2016 indicating that data for reporting for the new PAMA process will begin in 2017 and the new market based rates will take effect January 1, 2018. CMS will use the rates and volumes reported by laboratories to develop Medicare payment rates for the tests equal to the volume-weighted median of the private payer payment rates for the tests. We believe that the final PAMA regulations are generally favorable for us. The private payer rate will be calculated based on claims whose adjudication is final and will be inclusive of patient deductible and co-insurance amounts. Additionally, we believe our Afirma GEC as well as our Percepta test, once covered, would be considered ADLTs and that we can determine when to seek ADLT status. We cannot assure you that reimbursement rates under the final regulations for tests like ours will not be adversely affected.

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

Under current Medicare billing rules, payment for our tests performed on Medicare beneficiaries who were hospital inpatients at the time the tissue samples were obtained and whose tests were ordered less than 14 days from discharge must be bundled into the payment that the hospital receives for the inpatient services provided. Medicare billing rules also require hospitals to bill for our tests when ordered for hospital outpatients less than 14 days following the date of the hospital procedure where the tissue samples were obtained. Accordingly, we are required to bill individual hospitals for tests performed on Medicare beneficiaries during these time frames. We cannot ensure that hospitals will pay us for tests performed that fall under these rules. We cannot assure you that Medicare will not change this limitation in the future.

If the FDA were to begin regulating our tests, we could incur substantial costs and delays associated with trying to obtain premarket clearance or approval.

Clinical laboratory tests have long been subject to comprehensive regulations under the Clinical Laboratory Improvement Amendments of 1988, or CLIA, as well as by applicable state laws. Most laboratory developed tests, or LDTs, are not currently subject to regulation by the U.S. Food and Drug Administration, or FDA, 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 regulate LDTs as medical devices. We believe the Afirma GEC and the Percepta and Envisia classifiers are LDTs. In October 2014, the FDA issued draft guidance, entitled "Framework for Regulatory Oversight of LDTs," proposing the phased-in enforcement of premarket review requirements for most LDTs. The framework is similar to previously issued guidance. There is no timeframe in which the FDA must issue final guidance documents. If the guidance were enacted, our tests could be required to comply with FDA regulations applicable to medical devices.

If the FDA requires 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. If premarket review is required, our business could be negatively impacted if we are 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 the

guidance. The cost of complying with premarket review requirements, including obtaining clinical data, may 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. In November 2013, the FDA finalized guidance regarding the sale and use of products labeled for research or investigational-use only. Among other things, the guidance 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

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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 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 research or investigational-use only products. If the FDA were to undertake enforcement actions, some of our suppliers might cease selling research or investigational-use only products to us, and any failure to obtain an acceptable substitute could significantly and adversely affect our business, financial condition and results of operations, 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 test, practice guidelines in the United States have historically recommended that patients with indeterminate diagnoses from cytopathology results be considered for surgery to remove all or part of the thyroid to rule out cancer. This practice has been the standard of care in the United States for many years, and we need to continue to educate physicians about the benefits of the Afirma test 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., 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 Percepta, we expect competition from companies focused on lung cancer such as Integrated Diagnostics, Inc. 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, Quest Diagnostics Incorporated 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 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

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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 transition out of our Genzyme Corporation co-promotion agreement in the United States. There can be no assurance that we will be successful in maintaining and growing our business. As we plan to further increase our sales channels for new tests we commercialize, including Percepta, we may have difficulties locating and recruiting additional sales personnel 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.

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. In addition, rapid and significant growth may place strain on our administrative, financial and operational infrastructure. Our ability to manage our business and growth will require us to continue to improve our operational, financial and management controls, reporting systems and procedures. We have implemented an internally-developed data warehouse, which is critical to our ability to track our diagnostic services and patient reports delivered to physicians, as well as to support our financial reporting systems. The time and resources required to optimize these systems is uncertain, and failure to complete optimization in a timely and efficient manner could adversely affect our operations. The move of our laboratory facility to a new location in South San Francisco required us to notify appropriate regulatory agencies, which may result in an inspection or audit of the new facility which would disrupt our business, including the provision of Afirma GEC and Percepta test reports, and require the investment of resources. 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.

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;

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- 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.

Standard industry billing codes, known as CPT codes, that we use to bill for cytopathology do not generally exist for our proprietary molecular diagnostic tests. Therefore, until such time that we are awarded and are able to use a designated CPT code specific to our tests, we use "miscellaneous" codes for claim submissions. 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, 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 will not result in errors, delays in payments and a related increase in accounts receivable balances. The separate CPT code for the Afirma GEC test became effective January 1, 2016. There can be no assurance that we or our customers who bill will not face issues as the new code is utilized, which could have an adverse effect on our collection rates, revenue, and cost of collecting.

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 revenue and cash flow.

Additionally, our billing activities require us to implement compliance procedures and oversight, train and monitor our employees, challenge coverage and payment denials, assist patients in appealing claims, and undertake internal audits to evaluate compliance with applicable laws and regulations as well as internal compliance policies and procedures. Payers also conduct external audits to evaluate payments, which add further complexity to the billing process. If the payer makes an overpayment determination, there is a risk that we may be required to return some portion of prior payments we have received. 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 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.

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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, or the Amended Agreement. On March 9, 2016, we gave Genzyme notice of termination of the Amended Agreement effective September 9, 2016. In connection with the transition, we have hired additional sales personnel to sell our Afirma test, and we plan in the remainder of 2016 to hire additional sales personnel. If we are unsuccessful in transitioning the sales and marketing of Afirma 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 Afirma 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.

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. We launched the Percepta test in April 2015 and the Envisia test in October 2016. We still must complete studies that meet the clinical evidence required to obtain reimbursement, which studies are currently underway.

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

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

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

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

Typically, few research and development projects result in commercial products, and success in early clinical studies often is not replicated in later studies. At any point, we may abandon development of a product candidate or we may be required to expend considerable resources repeating clinical studies, which would adversely affect the timing for

generating potential revenue from a new product and our ability to invest in other products in our pipeline. If a clinical validation study fails to demonstrate the prospectively-defined endpoints of the study or if we fail to sufficiently demonstrate analytical validity, we might choose to abandon the development of the product, which could harm our business. In addition, competitors may develop and commercialize competing products or technologies faster than us or at a lower cost.

If we 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

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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.

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. 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 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 current credit agreement contains covenants that could limit our ability to acquire companies or technologies, sell debt securities or obtain additional debt financing arrangements.

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 quality standards, personnel qualifications and responsibilities, facility administration, general laboratory systems, quality assessment, quality control, pre-analytic, analytic, and post-analytic systems 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. With our recent relocation of our South San Francisco CLIA laboratory to our new building, we may be subject to additional inspections or audits by federal or state regulatory agencies to maintain our CLIA certificate. If we were to relocate our Texas facility, we might be subject to the same inspections or audits at our new facility.

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. New York law also mandates proficiency testing for laboratories licensed under New York state law, regardless of whether such laboratories are located in New York. 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 the GEC, 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.

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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. Implementation of provisions of the ACA has also resulted in increases in premiums and reductions in coverage for some 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.

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, 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 that, among other things, knowingly presents, or causes to be presented, a false 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 rules regarding billing for diagnostic tests reimbursable by the Medicare program, which prohibit a physician or other supplier from marking up the price of the technical component or professional component of a diagnostic test ordered by the physician or other supplier and supervised or performed by a physician who does not "share a practice" with the billing physician or supplier;

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

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

We have adopted policies and procedures designed to comply with these laws and regulations. In the ordinary course of our business, we conduct internal reviews of our compliance with these laws. Our compliance 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. 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.

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

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

- multiple, conflicting and changing laws and regulations such as tax laws, privacy laws, export and import restrictions, employment laws, regulatory requirements and other governmental approvals, permits and licenses;

- failure by us to obtain regulatory approvals where required for the use of our solutions in various countries;

- complexities associated with managing multiple payer reimbursement regimes, government payers or patient self-pay systems;

- logistics and regulations associated with shipping tissue samples, including infrastructure conditions and transportation delays;

- challenges associated with establishing laboratory partners, including proper sample collection techniques, 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.

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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 GEC is 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 GEC to perform as intended. We may also be subject to similar types of claims related to our Afirma Malignancy Classifiers and 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 our laboratory in South San Francisco becomes inoperable due to an earthquake or 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 GEC, Percepta and Envisia testing at our laboratory in South San Francisco, California. Our laboratory in Austin, Texas accepts and stores substantially all FNA samples pending transfer to our California laboratory for Afirma GEC 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.

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 launch 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 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.

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.

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We expect continued capital expenditures and operating losses over the next several years as we expand our infrastructure, commercial operations and research and development activities. We may seek to raise additional capital through equity offerings, debt financings, collaborations or licensing arrangements. Additional funding may not be available to us on acceptable terms, or at all. If we raise funds by issuing equity securities, dilution to our stockholders could result. Any equity securities issued also may provide for rights, preferences or privileges senior to those of holders of our common stock. The terms of debt securities issued or borrowings could impose significant restrictions on our operations. The incurrence of additional indebtedness or the issuance of certain equity securities could result in increased fixed payment obligations and could also result in restrictive covenants, such as limitations on our ability to incur additional debt or issue additional equity, limitations on our ability to acquire or license intellectual property rights, and other operating restrictions that could adversely affect our ability to conduct our business. Our current credit 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 relative 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 laws that protect the privacy of personal information, such as HIPAA, and regulatory penalties. Unauthorized access, loss or dissemination could also disrupt our operations, including our ability to process tests, provide test results, bill payers or patients, process claims and appeals, provide customer assistance services, conduct research and development activities, collect, process and prepare company financial information, provide information about our tests and other patient and physician education and outreach efforts through our website, manage the administrative aspects of our business and damage our reputation, any of which could adversely affect our business.

In addition, the interpretation and application of consumer, health-related and data protection laws in the United States, Europe and elsewhere are often uncertain, contradictory and in flux. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices. If so, this could result in government-imposed fines or orders requiring that we change our practices, which could adversely affect our business. In addition, in October 2015, the European Court of Justice invalidated a safe-harbor agreement between the United States and European Union member-states, which addressed how U.S. companies handle personal information of European customers. On May 4, 2016, the European Commission published a new Regulation and a new Directive regarding personal data privacy. The Regulation went into force on May 24, 2016 and shall apply beginning May 25, 2018. The Directive went into force on May 5, 2016 and EU member states must transpose it into their national law by May 6, 2018. As a result, we may need to modify the way we treat such information. Complying with these various laws could cause us to incur substantial costs or require us to change our business practices, systems and compliance procedures in a manner adverse to our business.

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

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

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

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

We apply for and in-license patents covering our products and technologies and uses thereof, as we deem appropriate, however we may fail to apply for patents on important products and technologies in a timely fashion or at all, or we may fail to apply for patents in potentially relevant jurisdictions. We have twelve issued patents that expire between 2029 and 2032 related to methods used in the Afirma diagnostic platform, in addition to fourteen pending U.S. utility patent applications and two pending Patent Cooperation Treaty, or PCT, patent applications. Some of these U.S. utility patent applications have pending foreign counterparts. We also exclusively licensed intellectual property, including rights to two 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 exclusively license intellectual property rights to seven pending patent applications and one issued patent in the United States and abroad. Patents issuing from the licensed portfolio will expire between 2024 and 2028. In addition, we own a PCT application and a pending U.S. application related to our Percepta test. We also own two applications related to other lung diseases, and a PCT application, a pending U.S. application, two ex-U.S. applications, and one provisional U.S. application related to Envisia. Any patents granted from our current lung cancer patent applications will expire no earlier than 2035 and those from our interstitial lung disease patent applications will expire no earlier than from 2034 to 2037. 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

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systems of many other countries do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biotechnology, which could make it difficult for us to stop the infringement of our patents in such countries. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business.

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

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

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

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

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

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

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

expensive.

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

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

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

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

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

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, during the course of this kind of litigation, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

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

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

We have incurred net losses since our inception and may never achieve profitability. 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.

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We may be unable to use these losses to offset income before those unused losses expire. Generally, a change of more than 50% in the ownership of a corporation's stock, by value, over a three-year period constitutes an ownership change for U.S. federal income tax purposes. An ownership change may limit a company's ability to use its net operating loss carryforwards attributable to the period prior to such change. 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 net operating loss carryforwards to offset U.S. federal taxable income may become subject to limitations, which could potentially result in increased future tax liability to us.

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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 Securities and Exchange Commission, or 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. Moreover, when we are no longer an emerging growth company, our independent registered public accounting firm will be required to issue an attestation report on the effectiveness of our internal control over financial reporting. 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 when we are no longer an emerging growth company, 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, although if our revenue exceeds $1 billion in any fiscal year before that time, we would cease to be an emerging growth company as of the end of that fiscal year. In

addition, if the market value of our common stock that is held by non-affiliates exceeds $700 million as of the last business day of our second fiscal quarter of any fiscal year before the end of that five-year period, we would cease to be an emerging growth company as of December 31 of that year. 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 financial statement and financial-related disclosures, 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. 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.

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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 October 28, 2016, directors and executive officers and their affiliates beneficially owned, in the aggregate, 41% 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.

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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 credit 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.

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ITEM 6. EXHIBITS

Exhibit Number	Description
31.1	Principal Executive Officer's Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Principal Financial Officer's Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1**	Certification Pursuant to 18 U.S.C. § 1350 (Section 906 of the Sarbanes-Oxley Act of 2002)
32.2**	Certification Pursuant to 18 U.S.C. § 1350 (Section 906 of the Sarbanes-Oxley Act of 2002)
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema
101.CAL	XBRL Taxonomy Extension Calculation Linkbase
101.DEF	XBRL Taxonomy Extension Definition Linkbase
101.LAB	XBRL Taxonomy Extension Label Linkbase
101.PRE	XBRL Taxonomy Extension Presentation Linkbase

** 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 Securities Exchange Act of 1934 (the "Exchange Act") or deemed to be incorporated by reference into any filing under the Exchange Act or the Securities Act of 1933 except to the extent that the registrant specifically incorporates it by reference.

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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: November 3, 2016

VERACYTE, INC.

By: /s/ SHELLY D. GUYER
Shelly D. Guyer
Chief Financial Officer
(Principal Financial and Accounting Officer)

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EXHIBIT INDEX

Exhibit Number	Description
31.1	Principal Executive Officer's Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Principal Financial Officer's Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1**	Certification Pursuant to 18 U.S.C. § 1350 (Section 906 of the Sarbanes-Oxley Act of 2002)
32.2**	Certification Pursuant to 18 U.S.C. § 1350 (Section 906 of the Sarbanes-Oxley Act of 2002)
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema
101.CAL	XBRL Taxonomy Extension Calculation Linkbase
101.DEF	XBRL Taxonomy Extension Definition Linkbase
101.LAB	XBRL Taxonomy Extension Label Linkbase
101.PRE	XBRL Taxonomy Extension Presentation Linkbase

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