VERACYTE, INC.
Form 10-Q
May 09, 2014
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2014

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.)

7000 Shoreline Court, Suite 250

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 x 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 x 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 o	Non-accelerated filer x	Smaller reporting company o

(Do not check if a
smaller reporting company)

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

As of May 1, 2014, there were 21,172,326 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

(Unaudited)

(In thousands, except share and per share amounts)

	March 31, 2014	December 31, 2013
Assets		
Current assets:		
Cash and cash equivalents	$ 64,237	$ 71,220
Accounts receivable, net of allowance of $135 and $107 as of March 31, 2014 and December 31, 2013	1,191	1,143
Supplies inventory	2,721	2,567
Prepaid expenses and other current assets	1,014	1,477
Total current assets	69,163	76,407
Property and equipment, net	3,028	2,952
Restricted cash	118	118
Other assets	145	153
Total assets	$ 72,454	$ 79,630
Liabilities and Stockholders Equity		
Current liabilities:		
Accounts payable	$ 7,214	$ 5,294
Accrued liabilities	5,267	7,594
Deferred Genzyme co-promotion fee	2,500	2,500
Current portion of long-term debt	467	
Total current liabilities	15,448	15,388
Long-term debt, net of current portion	4,467	4,899
Deferred rent, net of current portion	260	286
Deferred Genzyme co-promotion fee, net of current portion	1,989	2,614
Total liabilities	22,164	23,187
Commitments and contingencies (Note 5)		
Stockholders equity:		
Common stock, $0.001 par value; 125,000,000 shares authorized, 21,164,410 and 21,143,313 shares issued and outstanding as of March 31, 2014 and December 31, 2013, respectively	21	21

Additional paid-in capital		142,592		142,071
Preferred stock, $0.001 par value; 5,000,000 shares authorized, 0 shares issued and outstanding as of March 31, 2014 and December 31, 2013, respectively				
Accumulated deficit		(92,323)		(85,649)
Total stockholders equity		50,290		56,443
Total liabilities and stockholders equity	$	72,454	$	79,630

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

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VERACYTE, INC.

CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(Unaudited)

(In thousands, except share and per share amounts)

	Three Months Ended March 31,	
	2014	**2013**
Revenue	$ 7,476	$ 4,384
Operating expenses:		
Cost of revenue	3,607	2,773
Research and development	2,126	2,010
Selling and marketing	4,336	2,703
General and administrative	3,982	2,791
Total operating expenses	14,051	10,277
Loss from operations	(6,575)	(5,893)
Interest expense	(111)	
Other income (expense), net	12	(1,002)
Net loss and comprehensive loss	$ (6,674)	$ (6,895)
Net loss per common share, basic and diluted	$ (0.32)	$ (9.04)
Shares used to compute net loss per common share, basic and diluted	21,148,342	763,021

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

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VERACYTE, INC.

CONDENSED STATEMENTS OF CASH FLOWS

(Unaudited)

(In thousands)

	Three Months Ended March 31,	
	2014	**2013**
Operating activities		
Net loss	$ (6,674)	$ (6,895)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	264	197
Bad debt expense	28	93
Genzyme co-promotion fee amortization	(625)	(625)
Stock-based compensation	492	204
Change in value of preferred stock liability		1,002
Amortization of debt discount and issuance costs	26	
Interest on debt balloon payment	20	
Changes in operating assets and liabilities:		
Accounts receivable	(76)	12
Supplies inventory	(154)	313
Prepaid expenses and current other assets	463	(144)
Other assets	(3)	14
Accounts payable	2,045	(187)
Accrued liabilities and deferred rent	(2,563)	(603)
Net cash used in operating activities	(6,757)	(6,619)
Investing activities		
Purchases of property and equipment	(124)	(556)
Change in restricted cash		50
Net cash used in investing activities	(124)	(506)
Financing activities		
Payment of convertible preferred stock issuance costs		(52)
Commissions and issuance costs relating to the initial public offering	(129)	
Proceeds from the exercise of common stock options	27	247
Net cash provided by (used in) financing activities	(102)	195
Net decrease in cash and cash equivalents	(6,983)	(6,930)
Cash and cash equivalents at beginning of period	71,220	14,002
Cash and cash equivalents at end of period	$ 64,237	$ 7,072

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

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VERACYTE, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS

1. Organization and Summary of Significant Accounting Policies

Veracyte, Inc. (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 diagnostics company pioneering the field of molecular cytology to improve patient outcomes and lower healthcare costs. The Company specifically targets diseases that often require invasive procedures for an accurate diagnosis - diseases where many healthy patients undergo costly interventions that ultimately prove unnecessary. The Company improves the accuracy of diagnosis at an earlier stage of patient care by deriving clinically actionable genomic information from cytology samples collected in an outpatient setting. The Company s first commercial solution, the Afirma® Thyroid FNA Analysis, includes as its centerpiece the Gene Expression Classifier (GEC). The GEC helps physicians reduce the number of unnecessary surgeries by employing a proprietary 142-gene signature to preoperatively determine whether thyroid nodules previously classified by cytopathology as indeterminate can be reclassified as benign. 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 accompanying unaudited interim condensed financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (GAAP) for interim financial information. Accordingly, they do not include all of the information and notes required by GAAP for complete financial statements. The financial information for the three months ended March 31, 2014 and 2013 is unaudited but includes all adjustments (consisting of only normal recurring adjustments), which the Company considers necessary for a fair presentation of the results of operations for those periods. Interim results are not necessarily indicative of results for the full fiscal year.

The 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, 2013.

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; allowance for doubtful accounts; the useful lives of property and equipment; the recoverability of long-lived assets; the determination of fair value of the Company s common stock prior to the Company s initial public offering (IPO), stock options, preferred stock liability; income tax uncertainties, including a valuation allowance for deferred tax assets; and contingencies. The Company bases these estimates on historical and anticipated results, trends, and various other assumptions that the Company

believes are reasonable under the circumstances, including assumptions as to future events. These estimates form the basis for making judgments about the carrying values of assets and liabilities and recorded revenue and expenses that are not readily apparent from other sources. Actual results could differ from those estimates and assumptions.

Concentrations of Credit Risk and Other Risks and Uncertainties

The Company s cash and cash equivalents are deposited with one major financial institution in the United States of America. 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 solution, 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 of Afirma. The Company generally does not perform evaluations of customers financial condition and generally does not require collateral. All of the Company s accounts receivables are derived from sales of Afirma in the United States.

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Through March 31, 2014, all of the Company s revenues are derived from the sale of Afirma. The Company s solution to date has been delivered primarily to physicians in the United States. The Company s significant third-party payers and their related revenue as a percentage of total revenue are as follows:

	Three Months Ended	
	March 31, 2014	March 31, 2013
Medicare	29%	34%
United Healthcare	17%	10%
Aetna	10%	9%
Ending balance	56%	53%

Accounts receivable from Medicare amounted to 83% and 78% of accounts receivable as of March 31, 2014 and December 31, 2013. No other third-party payer represented more than 10% of the Company s accounts receivable balances for these periods.

Cash and Cash Equivalents

Cash equivalents consist of short-term, highly liquid investments with original maturities of three months or less from the date of purchase. Cash equivalents consist primarily of amounts invested in money market accounts.

Restricted Cash

Deposits of $118,000 as of March 31, 2014 and December 31, 2013, respectively, were restricted from withdrawal and held by a bank in the form of collateral for letters of credit. The balance for each respective period consists of a letter of credit totaling $118,000 held as security for the lease of the Company s office space in South San Francisco, California.

Allowance for Doubtful Accounts

The Company estimates an allowance for doubtful accounts against its individual accounts receivable based on estimates of expected reimbursement consistent with historical payment experience in relation to the amounts billed. Bad debt expense is included in general and administrative expense on the Company s statements of operations and comprehensive loss. Accounts receivable are written off against the allowance when there is other substantive evidence that the account will not be paid. If the financial condition of our customers deteriorates, resulting in an impairment of their ability to make payment, additional allowances may be required.

The balance of allowance for doubtful accounts as of March 31, 2014 and December 31, 2013, including charges to bad debt expense and write-offs, net of recoveries follows:

	Three Months Ended	
	March 31, 2014	December 31, 2013
	(In thousands)	
Beginning balance	$ 107	$ 222
Charged to expense	28	109
Write-offs, net of recoveries		(224)
Ending balance	$ 135	$ 107

Supplies Inventory

Supplies inventory consists of test reagents and other consumables used in the sample collection kits and in the GEC and are valued at the lower of cost or market value. Cost is determined using actual costs on a first-in, first-out basis.

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation and amortization. Depreciation is computed using the straight-line method over the estimated useful lives of the assets, generally between three and five years. Leasehold improvements are amortized using the straight-line method over the shorter of the estimated useful life of the asset or the term of the lease. Maintenance and repairs are charged to expense as incurred, and improvements and betterments are capitalized. When assets are retired or otherwise disposed of, the cost and accumulated depreciation are removed from the balance sheet and any resulting gain or loss is reflected in the statements of operations and comprehensive loss in the period realized.

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Internal-use Software

The Company capitalizes costs incurred in the application development stage to design and implement the software used in the tracking and reporting of laboratory activity. Costs incurred in the development of application of the software are capitalized and amortized over an estimated useful life of three years on a straight line basis. The total cost, accumulated depreciation and net book value was $507,000, $227,000 and $280,000 as of March 31, 2014, and was $482,000, $195,000 and $287,000 at December 31, 2013 and are included in property and equipment in the Company s condensed balance sheets. During the three months ended March 31, 2014 and 2013, the Company capitalized $25,000 and $99,000 of software development costs. Amortization expense totaled $32,000 and $16,000, for the three months ended March 31, 2014 and 2013, respectively.

Long-lived Assets

The Company reviews long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of the assets may not be recoverable. An impairment loss is recognized when the total of estimated future undiscounted cash flows, expected to result from the use of the asset and its eventual disposition, are less than its carrying amount. Impairment, if any, would be assessed using discounted cash flows or other appropriate measures of fair value. There were no impairments for the three months ended March 31, 2014 and 2013.

Bonus Accruals

The Company accrues for liabilities under discretionary employee and executive bonus plans. These estimated compensation liabilities are based on progress against corporate objectives approved by the Board of Directors, compensation levels of eligible individuals, and target bonus percentage levels. The Board of Directors and the Compensation Committee of the Board of Directors review and evaluate the performance against these objectives and ultimately determine what discretionary payments are made. As of March 31, 2014 and December 31, 2013, the Company accrued $262,000 and $1.1 million, respectively, for liabilities associated with these employee and executive bonus plans which are included in accrued liabilities in the Company s condensed balance sheets.

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.

Revenue Recognition

The Company s revenue is generated from the provision of diagnostic services using the Afirma solution. The Company s service is completed upon the delivery of test results to the prescribing physician which triggers the billing for the service. The Company recognizes revenue related to billings for Medicare and commercial carriers on an accrual basis, net of contractual adjustments, when there is a predictable pattern of collectability. These contractual adjustments represent the difference between the list price (the billing rate) and the reimbursement expected to be received from Medicare or commercial payers. Upon ultimate collection, the amount received from Medicare and commercial payers with a predictable pattern of payment is compared to previous estimates and the contractual allowance is adjusted accordingly. Until a contract has been negotiated with a commercial carrier or governmental program, the Afirma solution 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. In the absence of an agreement with the patient or other clearly enforceable legal right to demand payment directly from the patient, the related revenue is only recognized upon the earlier of payment notification, if applicable, or cash receipt.

For all services performed, the Company considers whether or not the following revenue recognition criteria are met: persuasive evidence of an arrangement exists; delivery has occurred or services have been rendered; the fee is fixed or determinable; and collectability is reasonably assured.

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Persuasive evidence of an arrangement exists and delivery is deemed to have occurred upon delivery of a patient report to the prescribing physician. The assessment of the fixed or determinable nature of the fees charged for diagnostic testing performed and the collectability of those fees require significant judgment by management. Management believes that these two criteria have been met when there is a contracted reimbursement rate and/or a predictable pattern of collectability with individual third-party payers and accordingly, recognizes revenue upon delivery of the patient report. Some patients have out-of-pocket costs for amounts not covered by their insurance carrier, and 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. Some payers may not cover the Company s GEC as ordered by the prescribing physician under their reimbursement policies. The Company pursues reimbursement from such patients on a case-by-case basis. In the absence of a contracted reimbursement rate or a predictable pattern and history of collectability, the Company believes that the fee is fixed or determinable and collectability is reasonably assured only upon receipt of third-party payer notification of payment or when cash is received and, accordingly, recognizes revenue at that time.

Cost of Revenue

Cost of revenue is expensed as incurred and includes material and service costs, including cytopathology testing services performed by a third-party pathology group, stock-based compensation expense, direct labor costs, equipment and infrastructure expenses associated with testing tissue samples, shipping charges to transport samples, and allocated overhead including rent, information technology, equipment depreciation and utilities.

Research and Development

Research and development costs are charged to operations as incurred. Research and development costs include, but are not limited to, payroll and personnel-related expenses, 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.

Income Taxes

The Company accounts for income taxes under the liability method. Under this method, deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to affect taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amounts expected to be realized.

The Company assesses all material positions taken in any income tax return, including all significant uncertain positions, in all tax years that are still subject to assessment or challenge by relevant taxing authorities. The Company s assessment of an uncertain tax position begins with the initial determination of the position s sustainability and is measured at the largest amount of benefit that is greater than 50 percent likely of being realized upon ultimate settlement. As of each balance sheet date, unresolved uncertain tax positions must be reassessed, and the Company will determine whether (i) the factors underlying the sustainability assertion have changed and (ii) the amount of the recognized tax benefit is still appropriate. The recognition and measurement of tax benefits requires significant judgment. Judgments concerning the recognition and measurement of a tax benefit may change as new information becomes available.

Stock-based Compensation

Stock-based compensation expense for equity instruments issued to employees is measured based on the grant-date fair value of the awards. The fair value of each employee stock option is estimated on the date of grant using the Black-Scholes option-pricing valuation model. The Company recognizes compensation costs on a straight-line basis for all employee stock based compensation awards that are expected to vest over the requisite service period of the awards, which is generally the awards vesting period. Forfeitures are required to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

Equity instruments issued to non-employees are valued using the Black-Scholes option-pricing valuation model and are subject to remeasurement as the underlying equity instruments vest.

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. Potentially dilutive securities consisting of convertible preferred stock and options to purchase common stock are considered to be common stock equivalents and were excluded from the calculation of diluted net loss per common share because their effect would be anti-dilutive for all periods presented.

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Recent Accounting Pronouncements

In July 2013, Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2013-11, *Presentation of an Unrecognized Tax Benefit when a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists (a consensus of the FASB Emerging Issues Task Force).* The amendments in this ASU provide guidance on the financial statements presentation of an unrecognized tax benefit when a net operating loss carryforward, a similar tax loss, or a tax credit carryforward exists. An unrecognized tax benefit should be presented in the financial statements as a reduction to a deferred tax asset for a net operating loss carryforward, a similar tax loss, or a tax credit carryforward with certain exceptions, in which case such an unrecognized tax benefit should be presented in the financial statements as a liability. The amendments in this ASU do not require new recurring disclosures and are effective for fiscal years, and interim periods within those years, beginning after December 15, 2013. The Company adopted this guidance during the first quarter of 2014 and such adoption did not have a material impact on the Company s condensed financial statements.

2. Net Loss Per Common Share

The following table presents the calculation of basic and diluted net loss per common share for the three months ended March 31, 2014 and 2013 (in thousands, except share and per share amounts):

	Three Months Ended	
	March 31, 2014	March 31, 2013
Net loss	$ (6,674)	$ (6,895)
Shares used to compute net loss per common share, basic and diluted	21,148,342	763,021
Net loss per common share, basic and diluted	$ (0.32)	$ (9.04)

The following outstanding shares of common stock equivalents have been excluded from diluted net loss per common share for the three months ended March 31, 2014 and 2013 because their inclusion would be anti-dilutive:

	Three Months Ended	
	March 31, 2014	March 31, 2013
Shares of common stock subject to outstanding options	3,166,419	2,313,107
Shares of common stock issuable upon conversion of preferred stock		13,271,122
Total shares of common stock equivalents	3,166,419	15,584,229

3. Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

	March 31, 2014	December 31, 2013
Accrued compensation expenses	$ 1,095	$ 1,962
Accrued Genzyme co-promotion fees	2,776	4,915
Accrued other	1,396	717
Accrued liabilities	$ 5,267	$ 7,594

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4. Fair Value Measurements

The Company records its financial assets and liabilities at fair value. The carrying amounts of certain financial instruments of the Company, including cash and cash equivalents, prepaid expenses and other current assets, accounts payable and accrued liabilities, approximate fair value due to their relatively short maturities. The carrying value of debt approximates its fair value because the interest rate approximates market rates that the Company could obtain for debt with similar terms. 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 following table sets forth the fair value of the Company s financial assets measured on a recurring basis, as of March 31, 2014 and December 31, 2013 (in thousands):

	As of March 31, 2014			
	Level I	Level II	Level III	Total
Financial Assets:				
Money market funds	$ 63,666	$	$	$ 63,666
Total financial assets	$ 63,666	$	$	$ 63,666

	As of December 31, 2013			
	Level I	Level II	Level III	Total
Financial Assets:				
Money market funds	$ 69,972	$	$	$ 69,972
Total financial assets	$ 69,972	$	$	$ 69,972

5. Commitments and Contingencies

Operating Leases

The Company leases its headquarters and South San Francisco laboratory facilities under a non-cancelable lease agreement that expires March 31, 2016. The Company provided security deposits in the form of irrevocable standby letters of credit secured with restricted cash deposits at the Company s primary bank. The Company deposited $118,000 in restricted cash accounts as collateral for the lease which is included in restricted cash in the Company s condensed balance sheets as of March 31, 2014 and December 31, 2013.

The Company leases laboratory space in Austin, Texas. The lease expires on July 31, 2018. The Company provided a cash security deposit of $75,000, which is included in other assets in the Company s balance sheet as of March 31, 2014 and December 31, 2013.

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Future minimum lease payments under non-cancelable operating leases as of March 31, 2014 are as follows (in thousands):

Year Ending December 31,	Amount
April through December 31, 2014	$ 712
2015	989
2016	413
2017	222
2018	130
Total minimum lease payments	$ 2,466

The Company recognizes rent expense on a straight-line basis over the non-cancelable lease period. Facilities rent expense was $213,000 and $216,000 for the three months ended March 31, 2014 and 2013, respectively.

Volume Purchase Agreement

The Company had non-cancelable purchase obligations to contract manufacturers and suppliers for approximately $196,000 at March 31, 2014, all of which is estimated to be payable before December 31, 2014.

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 financial position, results of operations or cash flows.

6. Debt

In June 2013, the Company entered into a loan and security agreement with a financial institution to fund its working capital and other general corporate needs. The agreement provided for term loans of up to $10.0 million in aggregate. The Company drew down $5.0 million in funds under the agreement in June 2013, and did not draw the remaining $5.0 million on or before the expiration date of March 31, 2014. The carrying value of the debt approximates its fair value because the interest rate approximates market rates that the Company could obtain for debt with similar terms. The Company s long-term debt obligation is a Level III liability. Level III inputs include unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the underlying asset or liability.

The Company is required to repay the outstanding principal in 30 equal installments beginning 18 months after the date of the borrowing and is due in full in June 2017. The loan bears interest at a rate of 6.06% per annum. The loan carries prepayment penalties of 2.25% and 1.5% for prepayment within one and two years, respectively, of the loan origination and 0.75% thereafter. As of March 31, 2014, the net debt obligation is

$4.9 million, consisting of the $5.0 million borrowing and the unpaid accrued balloon payment obligation net of the $100,000 discount on the note, of which $467,000 is included in current liabilities and $4.5 million is included in long-term debt in the Company s balance sheets. The obligation includes an end of term payment of $223,000, representing 4.45% of the total outstanding principal balance, which accretes over the life of the loan as interest expense. As a result of the debt discount and the end of term payment, the effective interest rate for the loan differs from the contractual rate. Total interest on the debt was $111,000 for the three months ended March 31, 2014, comprised of $76,000 of nominal interest and $35,000 in interest expense related to the amortization of the debt discount and accretion of the end of term payment.

The Company s obligations under the loan and security agreement are secured by a security interest in substantially all of its assets, excluding its intellectual property and certain other assets. The loan and security agreement contains customary conditions related to borrowing, events of default, and covenants, including covenants limiting the Company s ability to dispose of assets, undergo a change in control, merge with or acquire other entities, incur debt, incur liens, pay dividends or other distributions to holders of its capital stock, repurchase stock and make investments, in each case subject to certain exceptions. The agreement also allows the lender to call the debt in the event there is a material adverse change in the Company s business or financial condition. The loan and security agreement does not require that the Company comply with any financial covenants.

7. Convertible Preferred Stock Warrant

In June 2013, in conjunction with the execution of the loan and security agreement, as discussed in Note 6, the Company issued to the lender a warrant to purchase up to 49,602 shares of Series C convertible preferred stock with an exercise price of $7.56 per share. Upon the draw down of the $5.0 million term loan, the related warrant became exercisable for 24,801 shares. The lender exercised the warrant with respect to 24,801 shares through a cashless exercise in March 2014 resulting in the issuance of 13,739 shares of the Company s common stock.

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8. Stockholders Equity

Common Stock

The Company s Restated Certificate of Incorporation authorizes the Company to issue 125,000,000 shares of common stock with a par value of $0.001 per share. The holder of each share of common stock shall have one vote for each share of stock. The common stockholders are also entitled to receive dividends whenever funds and assets are legally available and when declared by the Board of Directors, subject to the prior rights of holders of all series of convertible preferred stock outstanding. No dividends have been declared as of March 31, 2014.

As of March 31, 2014 and December 31, 2013, the Company had reserved shares of common stock for issuance as follows:

	March 31, 2014	December 31, 2013
Options issued and outstanding	3,166,419	2,359,287
Options available for grant under stock option plans	973,312	1,787,802
Common stock warrants issued and outstanding		24,801
Total	4,139,731	4,171,890

Preferred Stock

The Company s Restated Certificate of Incorporation authorizes the Company to issue 5,000,000 shares of preferred stock with a par value of $0.001 per share. No shares were issued and outstanding at March 31, 2014 or December 31, 2013.

9. Stock Incentive Plans

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

	Shares Available for Grant	Stock Options Outstanding	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value
Balance - December 31, 2013	1,787,802	2,359,287	$ 3.07	7.84	$ 26,964
Granted	(850,092)	850,092	15.05		
Canceled	35,602	(35,602)	8.06		

Exercised		(7,358)	3.69		
Balance - March 31, 2014	973,312	3,166,419	$ 6.23	8.09	$ 34,652
Options exercisable - March 31, 2014		2,104,032	$ 2.88	7.33	$ 29,984
Options vested and expected to vest - March 31, 2014		2,994,431	$ 6.04	8.03	$ 33,330

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 of $17.13 per share as of March 31, 2014.

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Outstanding and exercisable stock options at March 31, 2014 are summarized as follows:

	Options Outstanding		Options Vested and Exercisable	
Exercise Price	Number	Weighted-Average Remaining Contractual Life (in Years)	Number	Weighted-Average Remaining Contractual Life (in Years)
$0.08	177,750	3.81	177,750	3.81
$0.80	165,569	5.49	165,569	5.49
$2.36	412,009	6.43	393,803	6.43
$2.40	208,593	7.44	174,226	7.45
$2.68	650,045	7.92	601,163	7.91
$4.00	455,861	8.73	404,716	8.72
$6.04	197,875	9.22	153,055	9.22
$7.92	9,000	9.45		
$12.12	39,625	9.51	33,750	9.51
$14.34-18.24	850,092	9.90		
$0.08-18.24	3,166,419	8.09	2,104,032	7.33

The weighted average fair value of stock options granted was $10.27 and $2.71 per share for the three months ended March 31, 2014 and 2013, respectively.

The weighted average fair value of stock options vested was $2.37 and $2.07 per share for the three months ended March 31, 2014 and 2013, respectively. The aggregate estimated grant date fair value of employee options to purchase common stock vested during the three months ended March 31, 2014 and 2013 was $0.4 million and $0.6 million, respectively

The weighted average fair value of stock options exercised was $2.53 and $0.87 per share for the three months ended March 31, 2014 and 2013, respectively. The intrinsic value of stock options exercised was $0.1 million and $0.5 million for the three months ended March 31, 2014 and 2013, respectively.

Stock-based Compensation

The following table summarizes stock-based compensation expense related to stock options for the three months ended March 31, 2014 and 2013, and are included in the unaudited statements of operations and comprehensive loss as follows (in thousands):

	Three Months Ended March 31,	
	2014	2013
Cost of revenue	9	4
Research and development	107	45
Selling and marketing	93	35

General and administrative	283	120
Total	492	204

As of March 31, 2014, the Company had $9.2 million of unrecognized compensation expense related to unvested stock options, which is expected to be recognized over an estimated weighted-average period of 3.6 years.

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

	Three Months Ended March 31,	
	2014	2013
Weighted-average volatility	77.17-78.54%	80.52-81.41%
Weighted-average expected term (years)	6.08	5.0-6.08
Risk-free interest rate	1.83-1.99%	0.88-1.16%
Expected dividend yield	0%	0%

Stock-based compensation related to stock options granted to non-employees is recognized as the stock options are earned. The fair value of the stock options granted is calculated at each reporting date using the Black-Scholes option-pricing model with the following assumptions: expected life is equal to the remaining contractual term of the award as of the measurement date ranging from 8.68 years to 9.51 years as of March 31, 2014 and 8.47 years to 9.68 years as of March 31, 2013; risk free rate is based on the U.S. Treasury Constant Maturity rate with a term similar to the expected life of the option at the measurement date ranging from 2.54% to 2.66% as of March 31, 2014 and 1.55% to 1.80% as of March 31, 2013; expected dividend yield of 0%; and volatilities ranging from 76.70% to 76.87% as of March 31, 2014 and 80.27% to 80.99% as of March 31, 2013.

10. Genzyme Co-promotion Agreement

In May 2011, the Company received $100,000 from Genzyme Corporation (Genzyme) in connection with an extension of an exclusive right to negotiate a co-promotion agreement. In January 2012, the Company and Genzyme executed a co-promotion agreement for the co-exclusive rights and license to promote and market the Company s Afirma thyroid cancer solution in the United States and in 40 named countries. In exchange, the Company received a $10.0 million co-promotion fee from Genzyme in February 2012. The Company may receive an additional $3.0 million in payments, $600,000 for each country outside of the United States in which the Company obtains marketing authorization and achieves a specified level of reimbursement, for up to five countries. Under the terms of the agreement, Genzyme will receive a percentage of 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 March 2014 and thereafter. Genzyme will also spend up to $500,000 for qualifying clinical development activities in countries that require additional testing for approval. This obligation expires in July 2014. The agreement expires in January 2027 and either party may terminate the agreement at any time and with six months prior notice. The Company is amortizing the co-promotion fee over a four-year period, which is management s best estimate of the life of the agreement, in part because after that period either party may terminate the agreement without penalty. The Company incurred $2.8 million and $1.9 million in co-promotion expense in the three months ended March 31, 2014 and 2013, respectively, which is included in selling and marketing expenses the statements of operations and comprehensive loss. The Company amortized $625,000 of the $10.0 million up-front co-promotion fee in each of the three months ended March 31, 2014 and 2013, which is reflected as a reduction to selling and marketing expenses in the statements of operations and comprehensive loss. The Company s outstanding obligation to Genzyme totaled $7.7 million and $6.7 million at March 31, 2014 and December 31, 2013, respectively. Of the $7.7 million obligation at March 31, 2014, $4.9 million is included in accounts payable and $2.8 million is included in accrued liabilities in the Company s condensed balance sheets. Of the $6.7 million obligation at December 31, 2013, $1.8 million is included in accounts payable and $4.9 million is included in accrued liabilities in the Company s condensed balance sheets.

The unamortized balance of the co-promotion fee is reflected on the Company s condensed balance sheets as follows (in thousands):

	March 31, 2014	December 31, 2013
Current liabilities:		
Deferred Genzyme co-promotion fee	$ 2,500	$ 2,500
Long-term liabilities:		
Deferred Genzyme co-promotion fee, net of current portion	1,989	2,614
Total	$ 4,489	$ 5,114

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11. Thyroid Cytology 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 is effective through December 31, 2015, unless terminated earlier, and renews annually thereafter. Under the service agreement, Veracyte 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 use a portion of Veracyte 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 statements of operations and comprehensive loss. All amounts to be received from TCP will be recorded in the same period as the corresponding lease costs. The Company incurred $887,000 and $711,000 in cytopathology testing and evaluation services expenses with TCP in the three months ended March 31, 2014 and 2013, respectively. The Company s outstanding obligations to TCP for cytopathology testing services were $584,000 and $588,000 as of March 31, 2014 and December 31, 2013, respectively, and are included in accounts payable in the Company s condensed balance sheets.

Beginning in May 2013, TCP reimburses the Company for a proportionate share of the Company s rent and related operating expense costs for the leased facility. TCP s portion of rent and related operating expense costs for the shared space at the Austin, Texas facility was $20,000 for the three months ended March 31, 2014, and is included in other income in the Company s statements of operations and comprehensive loss. The Company s receivable from TCP for rent expense was $1,000 as of March 31, 2014 which is included in prepaid expenses and other current assets in the Company s balance sheet.

12. Income Taxes

The Company did not record a provision or benefit for income taxes during the three months ended March 31, 2014 and 2013, respectively. The Company continues to maintain a valuation allowance for its U.S. federal and state deferred tax assets.

On January 2, 2013, The American Taxpayer Relief Act of 2012 (ATRA), was signed into law. Under prior law, a taxpayer was entitled to a research tax credit for qualifying amounts incurred through December 31, 2011. The ATRA extends the research credit for two years for qualified research expenditures incurred through the end of 2013. The extension of the research credit is retroactive and includes amounts incurred after 2011.

At March 31, 2014, the Company had $0.8 million of unrecognized tax benefit, none of which, if recognized, would affect the effective tax rate as most of the unrecognized tax benefit is deferred tax assets currently offset by a valuation allowance.

The Company has not recognized any interest and penalties related to uncertain tax positions as part of the income tax provision.

The Company files annual income tax returns in the United States only. 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. As of March 31, 2014, changes to the Company s uncertain tax positions in the next twelve months that are reasonably possible are not expected to have a significant impact on the Company s financial position or results of operations.

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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, 2013.

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 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 expectation that our research and development, general and administrative and selling and marketing expenses will increase and our anticipated uses of those 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; our ability to achieve and maintain reimbursement from third-party payers at acceptable levels; our belief that our published evidence provides a basis for inclusion of our test in treatment guidelines; the estimated size of the global market for Afirma; the potential benefits of the Afirma solution and any future products 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 the Afirma Malignancy Classifiers and a test for interstitial lung disease, and the timeframes for development or commercial launch; our dependence on our agreements with Genzyme and TCP, and on other strategic relationships, and the success of those relationships; our beliefs regarding our laboratory capacity; the applicability of clinical results to actual outcomes; our expectations regarding our international expansion, including entering new international markets and the timing thereof; the occurrence, timing, outcome or success of clinical trials or studies; the ability of our tests to impact treatment decisions; our beliefs regarding our competitive position; our compliance with federal, state and international regulations; the potential impact of regulation of our tests by the 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 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 Afirma and any new 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 test; 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, collaborations and co-promotion arrangements; 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 or geographic 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 third parties; 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 forward-looking statements contained herein to reflect any change in our expectations with regard thereto or any change in events, conditions or circumstances on which any such statement is based.

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

Veracyte, Afirma, the Veracyte logo and the Afirma logo are our 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.

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Overview

We are a diagnostics company pioneering the field of molecular cytology focusing on genomic solutions that resolve diagnostic ambiguity and enable physicians to make more informed treatment decisions at an early stage of patient care. By improving preoperative 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, addresses a significant unmet need in thyroid nodule diagnosis. In the United States alone, physicians perform over 525,000 fine needle aspiration, or FNA, biopsies annually on thyroid nodules that are suspicious for cancer. Approximately 15% to 30% of FNAs analyzed using cytopathology alone yield inconclusive, or indeterminate, results. Prior to Afirma, the standard of care for patients with indeterminate cytopathology results was to surgically remove a portion or all of the thyroid to obtain an accurate diagnosis. The Afirma solution centers on our Gene Expression Classifier, which we refer to as the GEC. The GEC helps physicians reduce the number of unnecessary surgeries by approximately 50% by employing a proprietary 142-gene signature to preoperatively identify benign thyroid nodules among those deemed indeterminate using cytopathology. We have demonstrated the clinical utility and cost effectiveness of the GEC in multiple studies published in peer-reviewed journals and established the clinical validity of the GEC in a study published in *The New England Journal of Medicine* in 2012. We believe the GEC is the only molecular test to meet the criteria established by the National Comprehensive Cancer Network guidelines for moving patients with indeterminate thyroid nodule FNA results from diagnostic surgery to routine monitoring. Since we commercially launched Afirma in January 2011, we have received nearly 100,000 FNA samples for evaluation using Afirma and performed nearly 20,000 GECs to resolve indeterminate cytopathology results. We estimate the global potential market opportunity for Afirma to be greater than $1.3 billion and the addressable market to be approximately $800 million.

We market and sell Afirma with a sales force consisting of our own sales professionals and members of the Genzyme endocrinology sales team. In January 2012, we entered into a co-promotion agreement with Genzyme for the co-exclusive right to promote and market Afirma in the United States and in 40 countries pursuant to which we received a $10.0 million fee from Genzyme. Under the agreement, we are required to pay Genzyme a co-promotion fee that is equal to a percentage of our cash receipts from Afirma.

We increased the list price for the GEC from $4,275 to $4,875 per test in January 2014, while the list price 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. In addition, we received positive coverage decisions for the GEC from UnitedHealthcare, Aetna, Humana and Cigna all in 2013, and have also received positive coverage decisions from a number of other regional payers in 2013, and in 2014 received new positive coverage decisions from Emblem, HealthNet and Premera Blue Cross. Collectively, these payers represent over 125 million covered lives. Reimbursement rates vary by payer.

Our revenue increased $3.1 million, or 71%, from $4.4 million for the three months ended March 31, 2013 to $7.5 million for the three months ended March 31, 2014. We incurred a net loss of $6.7 million and $6.9 million for the three months ended March 31, 2014 and 2013, respectively. As of March 31, 2014, we had an accumulated deficit of $92.3 million.

Factors Affecting Our Performance

The Number of FNAs We Receive and Test

The growth in our business is tied to the number of FNAs we receive. Approximately 95% of FNAs we receive are for the Afirma solution, which consists of cytopathology, and if the cytopathology result is indeterminate, the GEC. The remaining approximate 5% of FNAs are received from centers performing cytopathology in their institution where the cytopathology result is indeterminate and we perform the GEC only. Generally 8%-12% 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 RNA from which to render a finding. 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.

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Continued Adoption of and Reimbursement for Afirma

To date only a portion of payers have reimbursed us at full list price. Revenue growth depends on our ability to achieve broader reimbursement at increased levels from third-party payers and to expand our base of prescribing physicians. To drive increased adoption of Afirma, we have increased our internal sales force in high-volume geographies domestically, and we plan to increase our marketing efforts and leverage our relationship with Genzyme to accelerate Afirma growth both in the United States and internationally. Because many payers consider the GEC experimental and investigational, we may not receive payment on many tests and payments may not be at acceptable levels compared to what we have billed. 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 collections. If we are unable to expand the base of prescribing physicians 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.

How We Recognize Revenue

A significant portion of our revenue is recognized when cash is received. Medicare and three small commercial payers are the only payers with agreed upon reimbursement rates or expected payments and a predictable history of collections, which allows us to recognize the related revenue on an accrual basis. Until we achieve a predictable pattern of collections and a consistent payment amount from a larger number of payers, we will recognize a large portion of our revenue upon the earlier of notification of payment or when cash is received. Additionally, as we commercialize new products, we will need to achieve a predictable pattern of collections and a consistent payment amount for 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 is 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 December 31, 2013, cumulative amounts billed for tests processed which were not recognized as revenue upon delivery of a patient report because our accrual revenue recognition criteria were not met and for which we have not received either notification of payment or collected cash totaled $40.9 million. Of this amount, we collected $2.7 million in the three months ended March 31, 2014.

As of March 31, 2014, cumulative amounts billed for tests processed which were not recognized as revenue upon delivery of a patient report because our accrual revenue recognition criteria were not met and for which we have not received either notification of payment or collected cash totaled $48.5 million.

These amounts are cumulative as of the date referenced and include all amounts billed in prior periods that have not yet been paid or written off as uncollectible. It is difficult to predict future revenue from tests performed but where we have not been paid. Accordingly, we cannot provide any assurance as to when, if ever, or to what extent any of these amounts will be collected. Because we are in the early stages of commercialization of Afirma, we have had limited payment and collection history. 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 any 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, the existence of secondary payers and claims denials.

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 for previously performed but unpaid Afirma tests will favorably impact our liquidity and results of operations in future periods.

Impact of Genzyme Co-promotion Agreement

The $10.0 million fee we received from Genzyme under our co-promotion agreement is being amortized over a four-year period beginning in 2012, and is recorded as a reduction of selling and marketing expenses. We amortized $0.6 million of the $10.0 million in each of the three months ended March 31, 2014 and 2013, and these offsets to expense are included in selling and marketing expense in our condensed statement of operations. The co-promotion agreement requires that we pay a certain percentage of our cash receipts to Genzyme, which percentage decreases over time. The percentage was 40% from January 2013 through February 2014, and decreased to 32% in March 2014 and will remain at this level thereafter. Our co-promotion fees were $2.8 million and $1.9 million in the three months ended March 31, 2014 and 2013, respectively, and are included in selling and marketing expense in our condensed statement of operations. As our cash collections grow, both from volume growth as well as from increased reimbursement rates and collections for Afirma, the total amount we pay to Genzyme will increase in absolute dollars although the percentage of revenue we are required to pay Genzyme has decreased over time. We believe our relationship with Genzyme will accelerate sales of Afirma. As a result, our selling and marketing expense may be higher than what we would have incurred if we alone were marketing and promoting Afirma.

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We also may receive up to an additional $3.0 million from Genzyme, consisting of $0.6 million for each of up to five countries outside of the United States in which we obtain regulatory authorization to market Afirma and achieve a specified level of reimbursement. Genzyme has also agreed to spend $0.5 million to support clinical development expenses required for entry into the international markets covered by our agreement. This obligation expires in July 2014.

Our agreement with Genzyme expires in 2027 and either party may terminate the agreement at any time without cause and with six months prior notice. If we terminate the agreement without cause between January 2014 and January 2015, we will be required to repay 40% of the $10.0 million fee we received. The percentage decreases to 30% of such fee if we were to terminate the agreement between January 2015 and January 2016. Subsequent to January 2016, we are not required to repay any portion of the fee in the event we terminate the agreement without cause.

Development of Additional Products

We rely on sales of Afirma to generate all of our revenue. Our product development pipeline includes our Afirma Malignancy Classifiers, currently in pilot stage of commercialization, which we believe will enhance our Afirma Thyroid FNA Analysis as a comprehensive way to manage thyroid nodule patients and serve our current base of prescribing physicians. We also plan to pursue development of products for additional diseases to increase and diversify our revenue. For example, we are pursuing a solution for interstitial lung disease, or ILD, that will offer an alternative to surgery by developing a genomic signature to classify samples collected through less invasive bronchoscopy techniques. Accordingly, we expect to continue to invest heavily in research and development in order to expand the capabilities of our solution and to develop additional products. Our success in developing 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 test, Afirma. 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 Collections

Our business is subject to fluctuations in FNA volume throughout the year as a result of 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 downward adjustments in its fee schedules at the beginning of the year which may negatively affect our reimbursement. Additionally, patient deductibles generally reset 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 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. The effects of these seasonal fluctuations in prior periods may have been obscured by the growth of our business.

Financial Overview

Revenue

We generate revenue from the sale of our Afirma solution. We generally invoice third-party payers upon delivery of a patient report to the prescribing physician. As such, we take the assignment of benefits and the risk of collection from the third-party payer and individual patients.

For tests performed where an agreed upon reimbursement rate and/or a predictable history of collections exists, such as in the case of Medicare, we recognize 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 collect. We determine the amount we expect to collect based on a per payer, per contract or agreement basis, after analyzing payment history. The expected amount is typically lower

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than the agreed upon reimbursement amount due to several factors, such as the amount of patient co-payments, the existence of secondary payers and claim denials. In all other situations, as we do not have sufficient history of collection and are not able to determine a predictable pattern of payment, we recognize revenue upon the earlier of receipt of third-party payer notification of payment or when cash is received. Upon ultimate collection, the amount received from Medicare and commercial payers with a predictable pattern of payment is compared to previous estimates and the contractual allowance is adjusted accordingly. Our ability to increase our revenue will depend on our ability to penetrate the market, obtain positive coverage policies from additional third-party payers, obtain reimbursement and/or enter into contracts with additional third-party payers, and increase reimbursement rates for tests performed. Finally, should we recognize revenue from payers on an accrual basis and later determine the expected payments, collectability or other judgments underlying our decision to accrue revenue or the accrued amounts 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. However, we expect that the cost per test will decrease over time due to the 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 our research and development expenses will increase in absolute dollars in future periods as we continue to invest in research and development activities related to developing additional products and evaluating various platforms. We expect that in the next 12 months the increase in research and development expenses will be for the continued development and support of Afirma and other new products and programs under development, including Afirma Malignancy Classifiers and our lung program. Specifically, we plan to increase the body of clinical and pharmacoeconomic evidence to support inclusion in additional clinical practice guidelines in order to expand our base of prescribing physicians and achieve broader reimbursement for Afirma. In our lung program, we expect to incur expenses related to the collection of prospective samples and costs associated with advancing the program into product development.

Selling and Marketing

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, up-front co-promotion fees paid to Genzyme, net of amortization, are included in selling and marketing expenses. We expect our selling and marketing expenses to increase over the next 12 months primarily driven by the co-promotion fees to Genzyme, which fees increase as cash receipts from Afirma

increase (test volume is increasing at a greater rate than the contractual rate reduction), the costs of hiring additional internal sales and marketing personnel associated with further penetrating the domestic market and selectively launching in international markets, and marketing and education expenses to drive market penetration and reimbursement.

General and Administrative

General and administrative expenses include executive, finance and accounting, human resources, 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, and allocated overhead including rent, information technology, equipment depreciation and utilities. We expect to incur additional expenses over the next 12 months as a result of operating as a public company, including expenses related to compliance with the rules and regulations of the Securities and Exchange Commission and The NASDAQ Stock Market, additional insurance expenses, investor relations activities and other administrative and professional services. We also expect our general and administration expenses will increase in absolute dollars over the next 12 months as we expand our billing group to support anticipated increased demand for our tests, we hire more personnel in accounting and finance, and we incur increasing expenses related to the documentation of our internal controls in connection with Section 404 of the Sarbanes-Oxley Act.

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Interest Income

Interest income is from interest on our cash equivalents.

Interest Expense

Interest expense is attributable to our borrowings under the loan agreement entered into in June 2013.

Other Income (Expense), Net

Other income (expense), net is related primarily to the change in value of the preferred stock liability associated with our obligation to issue additional shares of Series C convertible preferred stock. In November 2012, we entered into a tranched Series C convertible preferred stock purchase agreement. In connection with the initial closing, we agreed to issue to the purchasers, and the purchasers agreed to purchase, additional shares of the Series C convertible preferred stock within a specified timeframe. We determined that the liability to issue additional Series C convertible preferred stock at a future date was a freestanding instrument that should be accounted for as a liability. Accordingly, we recorded a liability related to this instrument at the time of the initial close in November 2012, and we remeasured the liability at each reporting period with the corresponding gain or loss from the adjustment recorded as other income (expense), net through the issuance of the final Series C tranche in June 2013.

Critical Accounting Polices and Estimates

Our management s discussion and analysis of our financial condition and results of operations is based on our unaudited 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

Our revenue is generated from the provision of diagnostic services using the Afirma solution. Our service is completed upon the delivery of test results to the prescribing physician which triggers the billing for the service. We recognize revenue related to billings for Medicare and commercial payers on an accrual basis, net of contractual adjustments, when there is a predictable pattern of collectability. These contractual adjustments represent the difference between the list price (the billing rate) and either the reimbursement rate set by Medicare or the expected payment amounts by commercial payers. Upon ultimate collection, the amount received from Medicare and commercial payers with a predictable pattern of payment is compared to previous estimates and the contractual allowance is adjusted accordingly. Until a contract has been negotiated with a commercial carrier or governmental program, the Afirma solution may or may not be covered 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. In the absence of an agreement or other clearly enforceable legal right to demand payment, when test services are provided to patients with non-contracted insurance carriers or no insurance, the related revenue is only recognized upon the earlier of payment notification, if applicable, or cash receipt.

For all services performed, we consider whether or not the following revenue recognition criteria are met: persuasive evidence of an arrangement exists; delivery has occurred or services have been rendered; the fee is fixed or determinable; and collectability is reasonably assured.

Persuasive evidence of an arrangement exists and delivery is deemed to have occurred upon delivery of a patient report to the prescribing physician. The assessment of the fixed or determinable nature of the fees charged for testing performed and the collectability of those fees require significant judgment by management. Management believes that these two criteria have been met when there is a contracted reimbursement rate and/or a predictable pattern of collectability with individual third-party payers and

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accordingly, we recognize revenue upon delivery of the patient report. Some patients have out-of-pocket costs for amounts not covered by their insurance carrier, and 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. Some payers may not cover the GEC as ordered by the prescribing physician under their reimbursement policies. We pursue reimbursement from such patients on a case-by-case basis. In the absence of contracted reimbursement coverage or a predictable pattern and history of collectability, we believe that the fee is fixed or determinable and collectability is reasonably assured only upon receipt of third-party payer notification of payment or when cash is received and accordingly, recognize revenue at that time.

Allowance for Doubtful Accounts

We estimate an allowance for doubtful accounts against our individual accounts receivable based on estimates of expected payment consistent with historical payment experience. Our allowance for doubtful accounts is evaluated on a regular basis and adjusted when trends or significant events indicate that a change in estimate is appropriate. Historically, the amounts of uncollectible individual accounts receivable that have been written off have been consistent with management s expectations. Accounts receivable are written off against the allowance when the appeals process is exhausted or when there is other substantive evidence that the account will not be paid. If the financial conditions of our customers were to deteriorate resulting in an impairment of their ability to make payments, additional allowances may be required.

Derivative Liability

We account for derivative financial instruments as either equity or liabilities based upon the characteristics and provisions of each instrument. We recorded the preferred stock liability incurred in connection with our Series C convertible preferred stock and the preferred stock warrant liability related to the issuance of a warrant for Series C convertible preferred stock, each as a derivative financial instrument liability at their fair value on the date of issuance, and we remeasured them on each subsequent balance sheet date. The changes in fair value were recognized as a gain or loss from the adjustment to other income (expense), net in the statements of operations and comprehensive loss. We estimated the fair value of this liability using option-pricing models that include assumptions for future financings, expected volatility, expected life, yield and risk-free interest rate. The preferred stock liability was extinguished in 2013 and the warrant to purchase Series C convertible preferred stock was converted into a warrant to purchase our common stock as of the close of our initial public offering and was exercised through a cashless exercise in March 2014.

Deferred Tax Assets

We file U.S. federal income tax returns and tax returns in California, Texas and other states. To date, we have not been audited by the Internal Revenue Service or any state income tax authority.

As of December 31, 2013, our gross deferred tax assets were $32.8 million. The deferred tax assets were primarily comprised of federal and state tax net operating loss and tax credit carryforwards. Utilization of the net operating loss and tax credit carryforwards may be subject to annual limitation due to historical or future ownership percentage change rules provided by the Internal Revenue Code of 1986, and similar state provisions. The annual limitation may result in the expiration of certain net operating loss and tax credit carryforwards before their utilization.

We are required to reduce our deferred tax assets by a valuation allowance if it is more likely than not that some or all of our deferred tax assets will not be realized. We must use judgment in assessing the potential need for a valuation allowance, which requires an evaluation of both negative and positive evidence. The weight given to the potential effect of negative and positive evidence should be commensurate with the extent to which it can be objectively verified. In determining the need for and amount of our valuation allowance, if any, we assess the likelihood that we will be able to recover our deferred tax assets using historical levels of income, estimates of future income and tax planning strategies. As a result of historical cumulative losses and, based on all available evidence, we believe it is more likely than not that our recorded net deferred tax assets will not be realized. Accordingly, we recorded a valuation allowance against all of our net deferred tax assets at December 31, 2013 and March 31, 2014. We will continue to maintain a full valuation allowance on our deferred tax assets until there is sufficient evidence to support the reversal of all or some portion of this allowance.

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 valuation 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.

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Results of Operations

Comparison of the Three Months Ended March 31, 2014 and 2013

	Three Months Ended March 31,			
	2014	2013	Dollar Change	% Change
	(In thousands)			
Revenue	$ 7,476	$ 4,384	$ 3,092	71%
Operating expenses:				
Cost of revenue	3,607	2,773	834	30%
Research and development	2,126	2,010	116	6%
Selling and marketing	4,336	2,703	1,633	60%
General and administrative	3,982	2,791	1,191	43%
Total operating expenses	14,051	10,277	3,774	37%
Loss from operations	(6,575)	(5,893)	(682)	12%
Interest expense	(111)		(111)	N/A
Other income (expense), net	12	(1,002)	1,014	101%
Net loss	$ (6,674)	$ (6,895)	$ 221	3%
FNAs	14,373	10,757	3,616	34%

Revenue

Revenue increased $3.1 million, or 71%, for the three months ended March 31, 2014 compared to the same period in 2013, primarily as a result of a $2.4 million increase in commercial revenue from increased reimbursement and collections and a $0.7 million increase in Medicare revenue as a result of increased Afirma adoption.

Cost of revenue

Cost of revenue increased $0.8 million, or 30%, for the three months ended March 31, 2014 compared to the same period in 2013. This increase was primarily due to a $0.8 million, or 32%, increase in variable costs that are directly related to the increase in the number of FNAs received, offset in part by continuing refinements in our testing process and economies of scale related to the increase in FNAs. FNAs received increased by 3,616, or 34%, from 10,757 in the three months ended March 31, 2013 to 14,373 in the three months ended March 31, 2014.

Research and development

Research and development expense increased $0.1 million, or 6%, for the three months ended March 31, 2014 compared to the same period in 2013. This increase was primarily due to a $0.2 million increase in personnel expenses related to an increase in headcount, offset by a $0.1 decrease in direct research and development laboratory supplies expense.

Selling and marketing

Selling and marketing expense increased $1.6 million, or 60%, for the three months ended March 31, 2014 compared to the same period in 2013. This increase was primarily due to a $0.9 million increase in net expense recognized under our co-promotion agreement with Genzyme, partially offset by amortization of the deferred fee, a $0.5 million increase in personnel expenses related to an increase in headcount, and a $0.2 million increase in other selling and marketing expenses.

General and administrative

General and administrative expense increased $1.2 million, or 43%, for the three months ended March 31, 2014 compared to the same period in 2013. This increase was primarily due to higher costs associated with operating as a public company, including a $0.3 million increase in personnel expenses and a related increase in headcount, a $0.6 million increase in professional fees, $0.2 million increase in stock-based compensation expense, and $0.1 million increase in insurance expenses.

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Interest expense

Interest expense increased $0.1 million for the three months ended March 31, 2014 compared to the same period in 2013. Interest expense of $0.1 million for the three months ended March 31, 2014 is interest incurred on the June 2013 drawdown of $5.0 million under our loan and security agreement. We did not have any debt in the same period in 2013.

Other income (expense), net

Other income (expense), net increased $1.0 million from net other expenses of $1.0 million for the three months ended March 31, 2013 to net other income of $12,000 for the three months ended March 31, 2014. The $12,000 of net other income in the three months ended March 31, 2014 consisted of sublease rental income and interest income, offset by debt financing costs. The $1.0 million of net other expense in the three months ended March 31, 2013 consisted of a $1.0 million increase in the fair value of the preferred stock liability in the three months ended March 31, 2013 related to our Series C convertible preferred stock. The preferred stock liability was extinguished in June 2013.

Liquidity and Capital Resources

We have incurred net losses since our inception. For the three months ended March 31, 2014, and the year ended December 31, 2013, we had a net loss of $6.7 million and $25.6 million, respectively, and we expect to incur additional losses in 2014 and in future years. As of March 31, 2014, we had an accumulated deficit of $92.3 million. To date, we have generated only limited revenue, and we may never achieve revenue sufficient to offset our expenses. As of March 31, 2014, we had $64.2 million in cash and cash equivalents. We believe our existing cash and cash equivalents as of March 31, 2014 and our revenue from the sale of Afirma will be sufficient to meet our anticipated cash requirements for at least the next 12 months.

Since inception, we have received $153.4 million in net proceeds from various sources with which 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, $10.0 million from the Genzyme co-promotion agreement, net borrowings of $4.9 million under our loan and security agreement, and $0.7 million from the exercise of stock options. As of March 31, 2014 and December 31, 2013, we had $64.2 million and $71.2 million of cash and cash equivalents, respectively.

In June 2013, we entered into a loan and security agreement with a financial institution. This agreement provides for term loans of up to an aggregate of $10.0 million. On entering into the agreement, we drew down an initial $5.0 million term loan. We opted not to draw the remaining $5.0 million and the option to do so expired on March 31, 2014. Amounts drawn under the loan and security agreement were used for working capital and general corporate purposes.

The term loan bears interest at a fixed rate equal to 6.06%. We are required to repay any outstanding principal amounts in 30 equal monthly installments beginning 18 months after the date of the borrowing. On the date of our final principal payment, we must also pay an end-of-term payment equal to 4.45% of the amount borrowed. We may, at our option, prepay the term loan borrowings by paying the lender a prepayment premium.

Our obligations under the loan and security agreement are secured by a security interest on substantially all of our assets, excluding our intellectual property and certain other assets. The loan and security agreement contains customary conditions to borrowing, events of default, and covenants, including covenants limiting our ability to dispose of assets, undergo a change in control, merge with or acquire other entities, incur debt, incur liens, pay dividends or other distributions to holders of our capital stock, repurchase stock and make investments, in each case subject to certain exceptions. The loan and security agreement does not require that we comply with any financial covenants.

In connection with the draw-down of the $5.0 million term loan under the loan and security agreement, we issued the lender a warrant to purchase 24,801 shares of our common stock upon completion of the IPO. The lender exercised the warrant through a cashless exercise in March 2014, resulting in the issuance of 13,739 shares of common stock at an exercise price of $7.56 per share.

Our primary uses of cash are to fund our operations as we continue to grow our business. We expect to continue to incur operating losses in the near term as our operating expenses will be increased to support the growth of our business. We expect that our selling and marketing, research and development, and general and administrative expenses will continue to increase as we expand our marketing efforts and internal sales force to drive increased adoption of and reimbursement for Afirma, prepare to commercialize our Afirma Malignancy Classifiers, continue our research and development efforts with respect to our lung program and further develop our product pipeline, and manage increases in billing and cash collection transactional volumes, and the costs of being a public company. Cash used to fund operating expenses is impacted by the timing of when we pay expenses, as reflected in the change in our outstanding accounts payable and accrued expenses.

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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 our business. Based on our current business plan, we believe our existing cash and cash equivalents as of March 31, 2014 and our revenue from the sale of Afirma will be sufficient to meet our anticipated cash requirements for at least the next 12 months. 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 may result. Any equity securities issued may also provide for rights, preferences or privileges senior to those of holders of our common stock. If we raise funds by issuing debt securities, these debt securities would have rights, preferences and privileges senior to those of holders of our common stock. The terms of debt securities or borrowings could impose significant restrictions on our operations. If we raise funds through collaborations and licensing arrangements, we might be required to relinquish significant rights to our technologies or products, or grant licenses on terms that are not favorable to us. The credit market and financial services industry have in the past, and may in the future, experience periods of upheaval that could impact the availability and cost of equity and debt financing. If we are not able to secure additional funding when needed, on acceptable terms, 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 product or market development programs, which could lower the economic value of those programs to us.

The following table summarizes our cash flows for the three months ended March 31, 2014 and 2013:

	Three Months Ended March 31,	
	2014	2013
	(In thousands)	
Cash used in operating activities	$ (6,757)	$ (6,619)
Cash used in investing activities	(124)	(506)
Cash provided (used) in financing activities	(102)	195

Cash Flows from Operating Activities

Cash used in operating activities for the three months ended March 31, 2014 was $6.8 million. The net loss of $6.7 million reflects non-cash charges of $0.6 million in amortization of the deferred fee received from Genzyme, offset primarily by $0.5 million of stock-based compensation expense, and $0.3 million of depreciation and amortization. The increase in net operating assets of $0.3 million was primarily due to a $0.5 million decrease in accounts payable and accrued liabilities resulting from the timing of payments, offset by a $0.2 million net decrease in supplies inventory, prepaid expenses and accounts receivable.

Cash used in operating activities for the three months ended March 31, 2013 was $6.6 million. The net loss of $6.9 million reflects non-cash charges of $1.0 million for the change in the value of the preferred stock liability, $0.6 million in amortization of the deferred fee received from Genzyme, $0.2 million of depreciation and amortization, $0.2 million of stock-based and equity-based compensation and $0.1 million of bad debt expense. The decrease in net operating assets of $0.6 million was primarily due to a $0.8 million decrease in accounts payable and accrued liabilities due to timing of payments offset by a $0.3 million decrease in supply inventory due to the increase in volume of testing performed.

Cash Flows from Investing Activities

Cash used in investing activities is primarily related to the acquisition of property and equipment was $0.1 million and $0.5 million for the three months ended March 31, 2014 and 2013, respectively. Purchases of property and equipment were primarily for laboratory equipment in 2014. Purchases of property and equipment were primarily related to research and development and laboratory equipment in 2013.

Cash Flows from Financing Activities

Cash used in financing activities for the three months ended March 31, 2014 of $0.1 million consisted of IPO related disbursements during this period, net of proceeds received from the exercise of options to purchase our common stock. Cash provided by financing activities for the three months ended March 31, 2013 consisted primarily of $0.2 million in proceeds received from the exercise of options to purchase our common stock, offset by $52,000 of costs in connection with the issuance of convertible preferred stock.

Contractual Obligations

During the three months ended March 31, 2014, there were no material changes to our contractual obligations and commitments described under Management s Discussion and Analysis of Financial Condition and Results of Operations in our Form 10-K.

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Off-balance Sheet Arrangements

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

JOBS Act Accounting Election

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

Recent Accounting Pronouncements

In July 2013, Financial Accounting Standards Board, or FASB, issued Accounting Standards Update (ASU), No. 2013-11, *Presentation of an Unrecognized Tax Benefit when a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists (a consensus of the FASB Emerging Issues Task Force).* The amendments in this ASU provide guidance on the financial statements presentation of an unrecognized tax benefit when a net operating loss carryforward, a similar tax loss, or a tax credit carryforward exists. An unrecognized tax benefit should be presented in the financial statements as a reduction to a deferred tax asset for a net operating loss carryforward, a similar tax loss, or a tax credit carryforward with certain exceptions, in which case such an unrecognized tax benefit should be presented in the financial statements as a liability. The amendments in this ASU do not require new recurring disclosures and are effective for fiscal years, and interim periods within those years, beginning after December 15, 2013. We adopted this guidance during the first quarter of 2014 and such adoption did not have a material impact on our condensed 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 $64.2 million as of March 31, 2014, which consists of bank deposits and money market funds. Such interest-bearing instruments carry a degree of risk; however, we have not been exposed to, nor do we anticipate being exposed to, material risks due to changes in interest rates. 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.

During the quarterly period covered by this Form 10-Q, there were no changes in our internal control over financial reporting 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 early-stage 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 each of the three months ended March 31, 2014 and 2013, we had a net loss of $6.7 million and $6.9 million, respectively, and we expect to incur additional losses in the future. From inception through March 31, 2014, we had an accumulated deficit of $92.3 million. To date, we have generated only limited revenue, and we may never achieve revenue sufficient to offset our expenses. Over the next several years, we expect to continue to devote substantially all of our resources to increase adoption of, and reimbursement for, Afirma, to successfully commercialize our Afirma Malignancy Classifiers which we expect to launch in the second quarter of 2014, and to develop future diagnostic solutions. 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 historical revenue has 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 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 these solutions. If we are unable to increase sales of Afirma, expand reimbursement for Afirma, successfully launch our Afirma Malignancy Classifiers, or successfully 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 Medicare, Aetna and UnitedHealthcare for a significant portion of our revenue and if one or more significant payers stop providing reimbursement or decrease the amount of reimbursement for our tests, our revenue could decline.

Reimbursement on behalf of patients covered by Medicare accounted for 29% and 34% of our revenue for the three months ended March 31, 2014 and March 31, 2013, respectively. UnitedHealthcare accounted for 17% and 10% of our revenue for the three months ended March 31, 2014 and March 31, 2013, respectively. Aetna accounted for 10% and 9% of our revenue for the three months ended March 31, 2014 and March 31, 2013, respectively. 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 on the GEC. On a five-year rotational basis, Medicare requests bids for its regional MAC services. In mid-September 2013, Noridian Administrative Services succeeded

Palmetto as the MAC for our region. We believe the transition is complete with claims being processed by Noridian using the Z code established by Palmetto at the prior negotiated pricing level. This change, or any future changes, in the MAC processing Medicare claims for the GEC could result in a change in the coverage or reimbursement rates for the GEC, or the loss of coverage. In addition, the transition to Noridian has resulted in some delays in payments made to us on behalf of Medicare patients and a slower payment cycle in general.

We do not have a contracted rate of reimbursement with Aetna, Cigna, Humana or UnitedHealthcare. 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 or delay payments for our tests, or if we are unable to successfully negotiate 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 the GEC. Reimbursement by a payer may depend on a number of factors, including a payer s determination that tests such as the GEC are:

- not experimental or investigational;
- 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 policy or enter into a contract to reimburse our test, seeking these approvals is a time-consuming and costly process.

We do not have a contracted rate of reimbursement with most payers. 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.

We expect to continue to focus substantial resources on increasing adoption of and coverage and reimbursement for Afirma. We believe it may 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 test. In addition, the planned launch of our Afirma Malignancy Classifiers in the second quarter of 2014 and any other new products we may develop in the future may require that we expend substantial time and resources in order to obtain reimbursement. Our failure to establish broad adoption of and reimbursement for our products, 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 Afirma.

If we are unable to create or maintain demand for Afirma 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 Afirma through published papers, presentations at scientific conferences 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 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 several current guidelines and historical practice have typically led to such procedures. Moreover, our diagnostic services are performed at our 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. Finally, as we commercially launch the Afirma Malignancy Classifiers, should we experience difficulties in the introduction, this may impact physicians view of the Afirma solution and cause them to stop ordering our services. 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 that are different than those in the United States, we may face challenges with the adoption of Afirma outside the United States.

The success of our relationship with Genzyme to co-promote Afirma may have a significant effect on our business.

We sell Afirma in the United States through our internal sales team and through our co-promotion agreement with Genzyme Corporation. We are also working with Genzyme to begin selling Afirma in certain countries outside of the United States. Under the agreement, we are required to pay Genzyme a co-promotion fee that is equal to a percentage of our cash receipts from Afirma. The percentage was 40% and decreased to 32% in March 2014 and will remain at this level thereafter. Our agreement with Genzyme expires in 2027 and either party may terminate the agreement at any time without cause and with six months prior notice. If we were to terminate the agreement without cause prior to January 2015, we would be required to repay 40% of the $10.0 million fee we received from Genzyme. Such percentage would be reduced to 30% of such fee if we were to terminate the agreement between January 2015 and January 2016. We have also granted Genzyme a right of first offer to co-promote any future thyroid cancer product that we commercialize. If Genzyme does not commit the necessary resources to market and sell Afirma to the level of our expectations, or if they terminate the agreement, we may not realize the benefits of this relationship, and our ability to generate revenue in the future may be harmed. If our agreement with Genzyme were terminated, we would have to hire additional sales personnel to support the growth of Afirma and any other thyroid product we agree to co-promote with Genzyme. Any such termination may also delay our entry into international markets.

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Because we do not recognize a significant portion of our revenue on an accrual basis, our quarterly operating results are likely to fluctuate.

We currently recognize the majority of our revenue upon the earlier of receipt of third-party payer notification of payment or when cash is received. We have little visibility as to when we will receive payment for our diagnostic test, and we must appeal negative payment decisions, which delays collections. These factors will likely result in fluctuations in our quarterly revenue. 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. Finally, should we recognize revenue from payers on an accrual basis and later determine the expected payments, collectability or other judgments underlying our decision to accrue revenue or the accrued amounts change, our financial results could be negatively impacted in future quarters.

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

We rely on sole suppliers, such as NuGEN Technologies, Inc. and Affymetrix, Inc., for critical supply of reagents, equipment, chips and other materials that we use to perform the GEC. We also purchase components used in our Afirma 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 GEC and for our collection kits, if the materials do not meet our quality specifications, or if we cannot obtain acceptable substitute materials, an interruption in test processing could occur and we may not be able to deliver patient reports. Any such interruption may significantly affect our future revenue, cause us to incur higher costs, and harm our customer relations 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.

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 is effective until December 2015 and thereafter automatically renews every year unless either party provides notice of intent not to renew at least twelve 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 are unable to agree on commercial terms and our relationship with TCP were to terminate, our business would be harmed until we are 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 tests until a replacement was fully integrated with our test processing operations.

If we are unable to support demand for Afirma or any of our future products or solutions, our business could suffer.

As demand for Afirma grows, and as we commercialize new products such as our Afirma Malignancy Classifiers, 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 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.

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 like Afirma are regulated 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 FDA regulation, although reagents, instruments, software or components provided by third parties and used to perform LDTs may be subject to regulation. Although the FDA has never defined what qualifies as an LDT, we believe that Afirma is an LDT. As a result, we believe Afirma should not be subject to regulation in accordance with the FDA s current policy of exercising enforcement discretion regarding LDTs.

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From time to time, the FDA has indicated that it was revisiting its current policy of enforcement discretion and planned to issue guidance that, when finalized, would adopt a risk-based framework that would increase FDA oversight of LDTs. In July 2010, the FDA convened a public meeting to discuss such a risk-based framework. Legislative proposals addressing oversight of LDTs were introduced in the previous two Congresses and we expect that new legislative proposals will be introduced from time to time. We cannot provide any assurance that FDA regulation, including premarket review, will not be required in the future for our tests, whether through additional guidance or regulations issued by the FDA, new enforcement policies adopted by the FDA or new legislation enacted by Congress. It is possible that legislation will be enacted into law, regulations could be promulgated or guidance could be issued by the FDA which may result in increased regulatory burdens for us to continue to offer our tests or to develop and introduce new tests. We cannot predict the timing or content of future legislation enacted, regulations promulgated or guidance issued regarding LDTs, or how it would affect our business.

If FDA premarket review, including approval, is required for Afirma or any of our future tests we may develop, or we decide to voluntarily pursue FDA approval, we may be forced to stop selling our tests or we may be allowed to keep selling our tests while we work to obtain FDA approval. Our business would be negatively affected until such review is completed and clearance to market or approval is obtained. The regulatory process may involve, among other things, successfully completing additional clinical studies and submitting premarket notification or filing a premarket approval application with the FDA. If premarket review is required by the FDA or if we decide to voluntarily pursue FDA premarket review of our tests, there can be no assurance that Afirma or any tests we may develop in the future will be cleared or approved on a timely basis, if at all, nor can there be assurance that labeling claims will be consistent with our current claims or adequate to support continued adoption of and reimbursement for our tests. If our tests are allowed to remain on the market but there is uncertainty in the marketplace about our tests, if we are required by the FDA to label them investigational, or if labeling claims the FDA allows us to make are limited, orders may decline and reimbursement may be adversely affected. Ongoing compliance with FDA regulations would increase the cost of conducting our business, and subject us to heightened regulation by the FDA and penalties for failure to comply with these requirements.

Some of the materials we use for Afirma are labeled for research use only. In June 2011, the FDA issued draft guidance regarding Commercially Distributed In Vitro Diagnostic Products Labeled for Research Use Only or Investigational Use Only. To date, the FDA has not issued final research-use only guidance. We cannot predict the ultimate timing or form of any such guidance or regulation and or the potential effect on Afirma, our tests in development or the materials used to perform our tests. While we qualify all materials used in our tests according to CLIA regulations, we cannot be certain that the FDA would not promulgate rules or issue guidance documents that could affect our ability to purchase materials necessary for the performance of our tests. Should any of the reagents, instruments, software or components obtained by us from suppliers and used in conducting our tests be affected by future regulatory actions, our business could be adversely affected by those actions, including increasing the cost of testing or delaying, limiting or prohibiting the purchase of reagents, instruments, software or components necessary to perform testing.

In addition, our sample collection container is classified as a Class I medical device and is listed with the FDA. If the FDA was to determine that it is a Class II medical device, we would be required to file a 510(k) application and obtain FDA clearance to use the container, which could be time consuming and expensive.

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 a new, 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. Additionally, growth may require us to expand and move our operations. This could disrupt our business, will require investment of resources, and may cause employee retention issues depending upon the location. 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.

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

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 solution 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 Afirma and the reimbursement rates of payers;
- compliance with complex federal and state regulations related to billing Medicare;
- disputes among payers as to which party is responsible for payment;
- differences in coverage and in information and billing requirements among payers; ;
- the effect of patient co-payments or co-insurance;
- incorrect or missing billing information; and
- the resources required to manage the billing and claims appeals process.

As we introduce new tests, such as the Afirma Malignancy Classifiers, 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. These billing complexities, and the related uncertainty in obtaining payment for our diagnostic solution, 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. If claims for Afirma are not submitted to payers on a timely basis, 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, which would have an adverse effect on our revenue and our business.

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, primarily through our co-promotion agreement with Genzyme, 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 solution 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;

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- 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, its books and records provisions or its anti-bribery provisions.

Any of these factors could significantly harm our future international expansion and operations and, consequently, our revenue and results of operations.

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

Our principal competition for Afirma comes from traditional methods used by physicians to diagnose thyroid cancer. 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 educate physicians about the benefits of Afirma to change clinical practice.

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 announced their intention to enter 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. We also face competition from Asuragen Inc. and other companies, as well as academic institutions that measure mutational markers such as BRAF and KRAS to identify nodules that are malignant instead of benign. In the future, we may also face competition from companies developing new products or technologies.

In addition, competitors may develop their own versions of our solution 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 solution 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 solution, or offer solutions at prices designed to promote market penetration, which could force us to lower the list price of our solution 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.

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 have enhancements to our current Afirma offering and other diagnostic solutions under development that will require 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 are in the process of developing a product for interstitial lung disease and other potential products. Our product for interstitial lung disease may not be fully developed and introduced as planned in 2016. In order to develop and commercialize diagnostic products, we need to:

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- 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.

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.

As part of our business strategy, we may pursue acquisitions of complementary businesses or assets, as well as technology licensing arrangements. 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 not acquired other companies and have limited experience with respect to the formation of strategic alliances and joint ventures. If we make any acquisitions, we may not be able to integrate these acquisitions successfully into our existing business, and we could assume unknown or contingent liabilities. Any future acquisitions 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 an acquired company or business also may require management resources that otherwise would be available for ongoing development of our existing business. We may not identify or complete these transactions in a timely manner, on a cost-effective basis, or at all, and we may not realize the anticipated benefits of any acquisition, technology license, strategic alliance, joint venture or investment.

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

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

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

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If we fail to comply with federal, state and foreign laboratory 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 standards in the areas of personnel qualifications, administration, and participation in proficiency testing, patient test management and quality assurance. CLIA certification is also required in order for us to be eligible to bill state and federal healthcare programs, as well as many private third-party payers, for Afirma. To renew these certifications, we are subject to survey and inspection every two years. Moreover, CLIA inspectors may make random inspections of our clinical reference laboratories. If we relocate either of our facilities, we would be required to undergo certification at our new facility in order to offer our tests.

We are also required to maintain state licenses to conduct testing in our laboratories. California law requires that we maintain a license and establishes standards for the day-to-day operation of our clinical reference laboratory in South San Francisco, including the training and skills required of personnel and quality control matters. In addition, both of our clinical reference laboratories are required to be licensed on a test-specific basis by New York State. 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. Several other states require that we hold licenses to test samples from patients in those states. Other states may have similar requirements or may adopt similar requirements in the future. If we were to lose our CLIA certificate or California license for our South San Francisco laboratory, whether as a result of revocation, suspension or limitation, we would no longer be able to perform 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.

Finally, we may be subject to regulation in foreign jurisdictions as we pursue offering Afirma internationally. Other limitations, such as prohibitions on the import of tissue necessary for us to perform our tests or restrictions on the export of tissue imposed by countries outside of the United States or the import of tissue into the United States, may limit our ability to offer Afirma internationally in the future.

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 PPACA, enacted in March 2010, makes changes that are expected to significantly affect the pharmaceutical and medical device industries and clinical laboratories. Beginning in 2013, each medical device manufacturer must pay a sales tax in an amount equal to 2.3% of the price for which such manufacturer sells its medical devices that are listed with the FDA. The FDA has asserted that clinical laboratory tests such as Afirma are medical devices. However, consistent with the FDA s policy of exercising enforcement discretion for LDTs, Afirma is not currently listed as a medical device with the FDA. We cannot assure you that the tax will not be extended to services such as ours in the future if Afirma were to be regulated as a device. The PPACA also mandates a reduction in payments for clinical laboratory services paid under the Medicare Clinical Laboratory Fee Schedule, or CLFS, of 1.75% for the years 2011 through 2015 and a productivity adjustment to the CLFS which would affect our cytopathology billings.

Other significant measures contained in the PPACA 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 PPACA 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 PPACA 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 PPACA 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 PPACA, 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 lab payment rates on the Medicare CLFS by 2% in 2013. In addition, a further reduction of 2% is anticipated from implementation of the automatic expense reductions (sequester) under the Budget Control Act of 2011, which is legislated to be in effect for dates of service on or after April 1, 2013 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.

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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. Recent changes to reimbursement methodologies have not changed the payment rate for Afirma; however, 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 will 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. In particular, recommendations by the Simpson-Bowles Commission called for the combination of Medicare Part A (hospital insurance) and Part B (physician and ancillary service insurance) into a single co-insurance and co-payment structure. Currently, clinical laboratory services are excluded from the Medicare Part B co-insurance and co-payment as preventative services. Combining Parts A and B may require clinical laboratories to collect co-payments from patients which may increase our costs and reduce the amount ultimately collected.

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

Some patients may decide not to use Afirma due to its 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 PPACA 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 test, 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.

We are subject to other regulation by both the federal government and the states in which we conduct our business, including:

- Medicare billing and payment regulations applicable to clinical laboratories;
- the Federal anti-kickback law and state anti-kickback prohibitions;
- the Federal physician self-referral prohibition, commonly known as the Stark Law, and state equivalents;

- the Federal Health Insurance Portability and Accountability Act of 1996;

- the Medicare civil money penalty and exclusion requirements;

- the Federal False Claims Act civil and criminal penalties and state equivalents; and

- the Foreign Corrupt Practices Act of 1977, which applies 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. The risk of our being found in violation of these or other laws and regulations is further increased by the fact that many have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. 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.

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

The marketing, sale and use of Afirma could lead to product liability claims if someone were to allege that the GEC failed to perform as it was 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 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 products 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.

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

Our success depends largely on the skills, experience and performance of key members of our executive management team and others in key management positions. The efforts of each of these persons together will be critical to us as we continue to develop our technologies and test processes and focus on our growth. If we were to lose one or more of these key employees, we may experience difficulties in competing effectively, developing our technologies and implementing our business strategy.

In addition, our research and development programs and commercial laboratory operations depend on our ability to attract and retain highly skilled scientists, including licensed clinical laboratory scientists and biostatisticians. 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. Because it is expected that there will be a shortage of clinical laboratory scientists in coming years, it may become more difficult to hire sufficient numbers of qualified personnel. We also face competition from universities and public and private research institutions in recruiting and retaining highly qualified scientific personnel. Additionally, our success depends on our ability to attract and retain qualified salespeople. In early 2014, we significantly expanded our sales force. There can be no assurance that they will be successful in maintaining and growing the business in their territory. We may have difficulties locating and recruiting additional sales personnel in the future or retaining qualified salespeople, which could cause a delay or decline in the rate of adoption of our solution. Finally, our business requires specialized capabilities in reimbursement, billing, finance, 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.

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 GEC 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 GEC processing. The equipment we use to perform the GEC would be costly to replace and could require substantial lead time to replace and qualify for use. 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 GEC testing or the backlog of GEC tests that could develop if our California facility is inoperable 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.

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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 collaborations with many companies at once, which can extend the time it takes to develop, negotiate and implement a collaboration. 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 a diagnostic solution such as Afirma, and our inability to control when and if results are published may delay or limit our ability to derive sufficient revenue from any solution.

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.

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 have not experienced 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 the Health Insurance Portability and Accountability Act of 1996, 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 solution 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. 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.

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.

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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 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 eight pending United States utility patent applications and two patents which expire between 2030 and 2031 related to methods that are used in the Afirma diagnostic and one pending United States utility patent application relating to our lung disease product under development. 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 DNA.

In particular, the patent positions of companies engaged in the development and commercialization of genomic diagnostic tests, like Afirma, 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 genetic diagnostics tests would be considered natural laws. Accordingly, the evolving case law in the United States may adversely affect our ability to obtain patents and may facilitate third-party challenges to any owned and licensed patents. The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States, and we may encounter difficulties protecting and defending such rights in foreign jurisdictions. The legal systems of many other countries do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biotechnology, which could make it difficult for us to stop the infringement of our patents in such countries. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business.

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

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

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

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

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

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

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

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

We might not have been the first to make the inventions covered by each of our pending patent applications and we might not have been the first to file patent applications for these inventions. To determine the priority of these inventions, we may have to participate in interference proceedings, derivation proceedings, or other post-grant proceedings declared by the United States 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

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

We expect capital expenditures and operating expenses to increase 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. 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 market development programs, which could lower the economic value of those programs to our company.

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 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.

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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 will be required 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, beginning with our annual report for the year ending December 31, 2014, provide a management report on our internal controls. 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 are in the process of compiling the system and processing documentation necessary to perform the evaluation needed to comply with Section 404 of the Sarbanes-Oxley Act. We may not be able to complete our evaluation, testing and any required remediation in a timely and effective fashion. During the evaluation and testing process, if we identify one or more material weaknesses in our internal controls, 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 in the future.

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 for up to five years, 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. We cannot predict whether investors will find our common stock less attractive if we choose to rely on any of these exemptions. If some investors find our common stock less attractive as a result of any choices to reduce future disclosure we may make, there may be a less active trading market for our common stock and our stock price may be more volatile.

Risks Related to Our Common Stock

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

Prior to our initial public offering in October 2013, there was no public market for our common stock, and an active and liquid public market for our stock may not develop or be sustained. In addition, 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;

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- issuance of new securities analysts reports or changed recommendations for our stock;
- periodic 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 in the trading market for our stock for some period of time following our initial public offering, especially if the trading volume in 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 and our business. We do not control these analysts or the content and opinions 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.

Future sales of shares by existing stockholders could cause our stock price to decline.

Our stock price could decline as a result of sales of a large number of shares of our common stock in the public market or the perception that such sales could occur. On May 1, 2014, 21,172,326 shares of common stock were outstanding. Of these shares, 5,100,351 are freely tradable, without restriction, in the public market. Based on shares outstanding as of May 1, 2014, up to an additional 16,071,975 shares of common stock are eligible for sale in the public market, of which 14,825,544 shares are held by directors, executive officers and other affiliates and are subject to volume limitations under Rule 144 under the Securities Act, and other restrictions. In addition, 3,250,319 shares of common stock that are subject to outstanding options as of May 1, 2014 will become eligible for sale in the public market to the extent permitted by the provisions of various vesting agreements, Rule 144 under the Securities Act and other restrictions. We have filed a registration statement on Form S-8 under the Securities Act covering all of the shares of common stock subject to options outstanding and reserved for issuance under our stock incentive plans. This registration statement became effective immediately upon filing, and shares covered by this registration statement are eligible for sale in the public markets, subject to Rule 144 limitations applicable to affiliates and other restrictions. If these additional shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

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

As of May 1, 2014, directors and executive officers and their affiliates beneficially owned, in the aggregate, 71.5% 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 loan and security agreement restricts our ability to pay cash dividends on our common stock and we may also enter into credit agreements or other borrowing arrangements in the future that will restrict our ability to declare or pay cash dividends on our common stock. Any determination to pay dividends in the future will be at the discretion of our board of directors and will depend on our financial condition, operating results, capital requirements, general business conditions and other factors that our board of directors may deem relevant. As a result, capital appreciation, if any, of our common stock will be the sole source of gain for the foreseeable future.

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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 Sarbanes-Oxley Act of 2002)
32.2*	Certification Pursuant to 18 U.S.C. § 1350 (Section 906 of Sarbanes-Oxley Act of 2002)
#101.INS	XBRL Instance Document
#101.SCH	XBRL Taxonomy Extension Schema Document
#101.CAL	XBRL Taxonomy Extension Calculation Document
#101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
#101.LAB	XBRL Taxonomy Extension Label Linkbase Document
#101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

*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 (the Securities Act) except to the extent that the registrant specifically incorporates it by reference.

In accordance with Rule 406T of Regulation S-T, the information furnished in these exhibits will not be deemed filed for purposes of Section 18 of the Exchange Act. Such exhibits will not be deemed to be incorporated by reference into any filing under the Securities Act or the Exchange Act 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: May 9, 2014

VERACYTE, INC.

By: /s/ Shelly D. Guyer
Shelly D. Guyer
Chief Financial Officer
Principal Financial and Accounting Officer

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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 Sarbanes-Oxley Act of 2002)
32.2*	Certification Pursuant to 18 U.S.C. § 1350 (Section 906 of Sarbanes-Oxley Act of 2002)
#101.INS	XBRL Instance Document
#101.SCH	XBRL Taxonomy Extension Schema Document
#101.CAL	XBRL Taxonomy Extension Calculation Document
#101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
#101.LAB	XBRL Taxonomy Extension Label Linkbase Document
#101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

*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 (the Securities Act) except to the extent that the registrant specifically incorporates it by reference.

In accordance with Rule 406T of Regulation S-T, the information furnished in these exhibits will not be deemed filed for purposes of Section 18 of the Exchange Act. Such exhibits will not be deemed to be incorporated by reference into any filing under the Securities Act or the Exchange Act except to the extent that the registrant specifically incorporates it by reference.