

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2016

OR

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

For the transition period from _____ to _____

Commission file number 001-36156

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

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

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

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T

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(§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

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 Accelerated filer

Non-accelerated filer Smaller reporting company
(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 No

As of July 29, 2016, there were 27,864,442 shares of common stock, par value \$0.001 per share, outstanding.

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PART I. — FINANCIAL INFORMATION

Item 1. Condensed Financial Statements

VERACYTE, INC.

Condensed Balance Sheets

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

	June 30, 2016 (Unaudited)	December 31, 2015 (See Note 1)
Assets		
Current assets:		
Cash and cash equivalents	\$ 38,993	\$ 39,084
Accounts receivable	3,387	3,503
Supplies inventory	3,502	3,767
Prepaid expenses and other current assets	1,395	1,442
Restricted cash	120	118
Total current assets	47,397	47,914
Property and equipment, net	10,937	10,314
Finite-lived intangible assets, net	14,666	15,200
Goodwill	1,057	1,057
Restricted cash	603	603
Other assets	172	159
Total assets	\$ 74,832	\$ 75,247
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 2,705	\$ 5,085
Accrued liabilities	8,910	8,689
Deferred Genzyme co-promotion fee	227	948
Total current liabilities	11,842	14,722
Long-term debt	24,671	4,990
Deferred rent, net of current portion	4,566	4,283
Total liabilities	41,079	23,995
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.001 par value; 5,000,000 shares authorized, no shares issued and outstanding as of June 30, 2016 and December 31, 2015	—	—
Common stock, \$0.001 par value; 125,000,000 shares authorized, 27,864,285 and 27,685,291 shares issued and outstanding as of June 30, 2016 and December 31, 2015, respectively	28	28
Additional paid-in capital	203,769	199,950
Accumulated deficit	(170,044)	(148,726)
Total stockholders' equity	33,753	51,252
Total liabilities and stockholders' equity	\$ 74,832	\$ 75,247

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

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VERACYTE, INC.

Condensed Statements of Operations and Comprehensive Loss

(Unaudited)

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Revenue	\$14,675	\$ 11,908	\$28,225	\$ 23,126
Operating expenses:				
Cost of revenue	6,301	5,139	12,580	9,705
Research and development	4,267	3,103	7,728	5,890
Selling and marketing	8,263	6,937	15,329	12,557
General and administrative	6,071	5,536	12,299	11,334
Intangible asset amortization	267	267	534	267
Total operating expenses	25,169	20,982	48,470	39,753
Loss from operations	(10,494)	(9,074)	(20,245)	(16,627)
Interest expense	(785)	(90)	(1,152)	(177)
Other income, net	36	28	79	58
Net loss and comprehensive loss	\$(11,243)	\$(9,136)	\$(21,318)	\$(16,746)
Net loss per common share, basic and diluted	\$(0.40)	(0.35)	\$(0.77)	\$(0.69)
Shares used to compute net loss per common share, basic and diluted	27,859,918	26,048,934	27,838,955	24,304,022

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

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VERACYTE, INC.

Condensed Statements of Cash Flows

(Unaudited)

(In thousands of dollars)

	Six Months Ended June 30, 2016		2015	
Operating activities				
Net loss	\$ (21,318)		\$ (16,746)	
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation and amortization	1,703		996	
Bad debt expense	68		54	
Loss on disposal of property and equipment	12		—	
Genzyme co-promotion fee amortization	(721)		(949)	
Stock-based compensation	3,173		2,712	
Conversion of accrued interest to long-term debt	192		—	
Amortization and write-off of debt discount and issuance costs	119		23	
Interest on debt balloon payment and prepayment penalty	206		39	
Changes in operating assets and liabilities:				
Accounts receivable	48		(589)	
Supplies inventory	265		(279)	
Prepaid expenses and current other assets	47		(349)	
Other assets	(13)		(39)	
Accounts payable	(805)		(4,637)	
Accrued liabilities and deferred rent	712		(569)	
Net cash used in operating activities	(16,312)		(20,333)	
Investing activities	(3,587)		(852)	

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Purchases of property and equipment				
Change in restricted cash	(2)	(533)
Net cash used in investing activities	(3,589)	(1,385)
Financing activities				
Proceeds from the issuance of long-term debt, net of debt issuance costs	24,452		—	
Proceeds from the issuance of common stock in a private placement, net of costs	—		37,258	
Payment of long-term debt	(5,000)	—	
Payment of end-of-term debt obligation and prepayment penalty	(288)	—	
Proceeds from the exercise of common stock options and employee stock purchases	646		491	
Net cash provided by financing activities	19,810		37,749	
Net (decrease) increase in cash and cash equivalents	(91)	16,031	
Cash and cash equivalents at beginning of period	39,084		35,014	
Cash and cash equivalents at end of period	\$ 38,993		\$ 51,045	
Supplementary cash flow information of non-cash investing and financing activities:				
Purchases of property and equipment included in accounts payable and accrued liabilities	\$ 42		\$ 285	

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

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VERACYTE, INC.

Notes to Financial Statements

1. Organization and Description of Business

Veracyte, Inc. (“Veracyte” or the “Company”) was incorporated in the state of Delaware on August 15, 2006 as Calderome, Inc. Calderome operated as an incubator until early 2008. On March 4, 2008, the Company changed its name to Veracyte, Inc. Veracyte is a molecular diagnostics company that uses genomic technology to resolve diagnostic ambiguity. The Company targets diseases in which large numbers of patients undergo invasive and costly diagnostic procedures that could have been avoided with a more accurate diagnosis from a cytology sample taken preoperatively. By improving preoperative diagnosis, the Company helps patients avoid such unnecessary invasive procedures and surgeries while reducing healthcare costs.

The Company’s first commercial solution, the Afirma[®] Thyroid FNA Analysis, centers on the proprietary Afirma Gene Expression Classifier (“GEC”). The Afirma GEC helps physicians reduce the number of unnecessary surgeries by employing a proprietary 142-gene signature to preoperatively determine whether thyroid nodules previously classified by cytopathology as indeterminate can be reclassified as benign. The Afirma GEC is offered directly or as part of a comprehensive solution that also includes cytopathology. Additionally, the Afirma Malignancy Classifiers were launched in May 2014. The Company currently markets and sells Afirma in the United States and select foreign countries through a co-promotion agreement with Genzyme Corporation, a subsidiary of Sanofi, as well as selectively through other distributors internationally. On March 9, 2016, the Company gave notice of termination of the U.S. Co-Promotion Agreement, effective September 9, 2016.

In April 2015, the Company entered the lung cancer diagnostics market with the Percepta[®] Bronchial Genomic Classifier, a genomic test to resolve ambiguity in lung cancer diagnosis. The Company has a second product in pulmonology under development designed to help in the preoperative assessment of patients suspected to have idiopathic pulmonary fibrosis (“IPF”).

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

Basis of Presentation

The Company’s financial statements have been prepared in accordance with accounting principles generally accepted in the United States (“GAAP”). The financial statements include the accounts of the Company and its former wholly-owned subsidiary, which was dissolved in June 2015. For periods prior to the subsidiary dissolution, all intercompany accounts and transactions were eliminated in consolidation. Certain information and note disclosures normally included in the financial statements prepared in accordance with GAAP have been condensed or omitted pursuant to such rules and regulations. The condensed balance sheet as of June 30, 2016, the condensed statements of operations and comprehensive loss for the three and six months ended June 30, 2016 and 2015, and the condensed statements of cash flows for the six months ended June 30, 2016 and 2015 are unaudited, but include all adjustments, consisting only of normal recurring adjustments, which the Company considers necessary for a fair presentation of its financial position, operating results and cash flows for the periods presented. The condensed balance sheet at December 31, 2015 has been derived from audited financial statements. The results for the three and six months ended June 30, 2016 are not necessarily indicative of the results expected for the full year or any other period. Certain amounts have been reclassified on the condensed balance sheet at December 31, 2015 to conform with the adoption of Accounting Standards Update (“ASU”) No. 2015-3, Simplifying the Presentation of Debt Issuance Costs.

The accompanying interim period condensed financial statements and related financial information included in this Quarterly Report on Form 10-Q should be read in conjunction with the audited financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2015.

Use of Estimates

The preparation of the unaudited interim financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities as of the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. Significant items subject to such estimates include: revenue recognition; contractual allowances; the useful lives of property and equipment; the recoverability of long-lived assets; the estimation of the fair value of intangible assets; stock options; income tax uncertainties, including a valuation allowance for deferred tax assets; and contingencies. The Company

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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. Deposits in this institution may exceed the amount of insurance provided on such deposits. The Company has not experienced any losses on its deposits of cash and cash equivalents.

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

The Company is also subject to credit risk from its accounts receivable related to its sales. The Company generally does not perform evaluations of customers' financial condition and generally does not require collateral.

Through June 30, 2016, all of the Company's revenue has been derived from the sale of Afirma. To date, Afirma has been delivered primarily to physicians in the United States. The Company's third-party payers in excess of 10% of revenue and their related revenue as a percentage of total revenue were as follows:

	Three Months Ended June 30, 2016		Six Months Ended June 30, 2015	
Medicare	30%	28%	30%	26%
United Healthcare	13%	14%	12%	14%
	43%	42%	42%	40%

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

	June 30, 2016		December 31, 2015	
Medicare	42	%	31	%
United Healthcare	17	%	25	%
Aetna	14	%	23	%
Cigna	14	%	8	%

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

Restricted Cash

The Company had deposits of \$120,000 and \$118,000 as of June 30, 2016 and December 31, 2015, respectively, included in current assets. The deposit at June 30, 2016 was a pledge for corporate credit cards and the deposit at

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December 31, 2015 was restricted from withdrawal and held by a bank in the form of collateral for irrevocable standby letters of credit held as security for the lease of the Company's former headquarters and laboratory facility in South San Francisco that expired March 31, 2016. The Company also had deposits of \$603,000 included in long-term assets as of June 30, 2016 and December 31, 2015, restricted from withdrawal and held by a bank in the form of collateral for an irrevocable standby letter of credit held as security for the lease of the Company's new South San Francisco facility signed in April 2015.

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

The Company may bill the patient directly for these amounts in the form of co-payments and co-insurance in accordance with their insurance carrier and health plans. 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 contracted reimbursement coverage or the ability to estimate the amount that will ultimately be realized for the Company's services, revenue is recognized upon the earlier of receipt of third-party payer notification of payment or when cash is received.

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

	Three Months Ended June 30,				Six Months Ended June 30,			
	2016	%	2015	%	2016	%	2015	%
Revenue recognized on an accrual basis	\$9,349	64 %	\$6,587	55 %	\$17,575	62 %	\$11,973	52 %
Revenue recognized when cash is received	5,326	36 %	5,321	45 %	10,650	38 %	11,153	48 %
Total	\$14,675	100%	\$11,908	100%	\$28,225	100%	\$23,126	100%

Recent Accounting Pronouncements

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

In August 2014, FASB issued ASU No. 2014-15, Presentation of Financial Statements Going Concern - Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern. The amendments require management to assess an entity's ability to continue as a going concern by incorporating and expanding upon certain principles that are currently in U.S. auditing standards. Specifically, the amendments: (1) provide a definition of the term substantial doubt; (2) require an evaluation every reporting period including interim periods; (3) provide principles for

considering the mitigating effect of management's plans; (4) require certain disclosures when substantial doubt is alleviated as a result of consideration of management's plans; (5) require an express statement and other disclosures when substantial doubt is not alleviated; and (6) require an assessment for a period of one year after the date that the financial statements are issued (or available to be issued). ASU 2014-15 will be effective for annual periods ending after December 15, 2016 and interim periods within annual periods beginning after December 15, 2016 with early adoption permitted. ASU 2014-15 will be effective for the Company beginning with its annual report for 2016 and interim periods thereafter. The Company does not anticipate that the adoption of this ASU will have a significant impact on its financial statements.

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

In November 2015, the FASB issued ASU 2015-17, Balance Sheet Classification of Deferred Taxes. The ASU requires that deferred tax assets and liabilities be classified as noncurrent in the statement of financial position, thereby simplifying the current guidance that requires an entity to separate deferred assets and liabilities into current and noncurrent amounts. This ASU will be effective for the Company beginning in the first quarter of 2018 though early adoption is permitted. The Company early-adopted this ASU as of December 31, 2015 and the impact of adoption on its statement of financial position was not material.

In February 2016, the FASB issued ASU No. 2016-2, Leases. This ASU is aimed at making leasing activities more transparent and comparable, and requires substantially all leases be recognized by lessees on their balance sheet as a right-of-use asset and corresponding lease liability, including leases currently accounted for as operating leases. The ASU will be effective for interim and annual periods beginning after December 15, 2018. Early adoption is permitted. The Company is currently evaluating the potential effect of the updated standard on its financial statements.

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

2. Net Loss Per Common Share

The following outstanding common stock equivalents have been excluded from diluted net loss per common share because their inclusion would be anti-dilutive:

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2016	2015	2016	2015
Shares of common stock subject to outstanding options	5,320,885	4,270,882	4,890,309	3,940,304
Employee stock purchase plan	47,435	—	36,942	—
Total common stock equivalents	5,368,320	4,270,882	4,927,251	3,940,304

3. Accrued Liabilities

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

	June 30, December 31,	
	2016	2015
Accrued compensation expenses	\$ 4,471	\$ 4,212
Accrued Genzyme co-promotion fees	2,179	2,089
Accrued other	2,260	2,388
Total accrued liabilities	\$ 8,910	\$ 8,689

4. Fair Value Measurements

The Company recognizes its financial assets and liabilities at fair value. The carrying amounts of certain financial instruments of the Company, including cash and cash equivalents, prepaid expenses and other current assets, accounts payable and accrued liabilities, approximate fair value due to their relatively short maturities. The carrying value of the Company's debt approximates its fair value because the interest rate approximates market rates that the Company could obtain for debt with similar terms. The estimated fair value of the Company's debt is estimated using the net present value of the payments, discounted at an interest rate that is consistent with market interest rates, which is a Level 2 input. The accounting guidance for

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fair value provides a framework for measuring fair value, clarifies the definition of fair value, and expands disclosures regarding fair value measurements. Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability (an exit price) in an orderly transaction between market participants at the reporting date. The accounting guidance establishes a three-tiered hierarchy, which prioritizes the inputs used in the valuation methodologies in measuring fair value as follows:

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

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

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

The fair value of the Company's financial assets, which consist only of money market funds, was \$37.6 million and \$37.5 million as of June 30, 2016 and December 31, 2015, respectively, and are Level I assets as described above.

5. Commitments and Contingencies

Operating Leases

The Company leases its headquarters and South San Francisco, California laboratory facilities under a non-cancelable lease agreement for approximately 59,000 square feet. The lease began in June 2015 and ends in March 2026 and contains extension of lease term and expansion options. The Company had deposits of \$603,000 included in long-term assets as of June 30, 2016, restricted from withdrawal and held by a bank in the form of collateral for an irrevocable standby letter of credit held as security for the lease of the South San Francisco facility.

The Company also leases laboratory and office space in Austin, Texas. 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 condensed balance sheets as of June 30, 2016 and December 31, 2015.

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

Year Ending December 31,	
2016	\$1,047
2017	2,143
2018	2,102
2019	2,026
2020	2,082
Thereafter	11,956
Total minimum lease payments	\$21,356

The Company recognizes rent expense on a straight-line basis over the non-cancelable lease period. Facilities rent expense was \$457,000 and \$352,000 for the three months ended June 30, 2016 and 2015, respectively, and \$1.1 million and \$565,000 for the six months ended June 30, 2016 and 2015, respectively.

Supplies Purchase Commitments

The Company had non-cancelable purchase commitments with two suppliers to purchase a minimum quantity of supplies for approximately \$1.1 million at June 30, 2016.

Debt Obligations

See Note 6, Debt.

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Contingencies

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

6. Debt

Credit Agreement

In March 2016, the Company entered into a credit agreement (the "Credit Agreement") with Visium Healthcare Partners, LP ("Visium"). Under the Credit Agreement, two term loans are available to the Company with an aggregate principal amount of up to \$40.0 million. The Company drew down the initial \$25.0 million term loan (the "Initial Term Loan") on March 30, 2016, of which \$5.0 million was used to pay the outstanding balance of the Company's existing long-term debt, which was cancelled at that date. On or prior to June 30, 2017, the Company may request the second term loan of up to \$15.0 million (the "Second Term Loan" and together with the Initial Term Loan, the "Term Loans"). The Term Loans mature on March 31, 2022.

The Term Loans bear interest at a fixed rate of 12.0% per annum, payable quarterly at the end of each March, June, September and December. No principal payments will be due during an interest-only period, commencing on the funding date for the Initial Term Loan (the "Initial Borrowing Date") and continuing through and including March 31, 2020. The Company is obligated to repay the outstanding principal amounts under the Term Loans in eight equal installments during the final two years under the Credit Agreement. For any quarterly interest payment through and including the 16th interest payment date after the Initial Borrowing Date, so long as no event of default has occurred and is then continuing, the Company may elect to pay interest in cash on the outstanding principal amounts of the Term Loans at a fixed rate of 9.0%, with the remaining 3.0% of the 12.0% interest paid-in-kind by adding such paid-in-kind interest to the outstanding principal amounts of the Term Loans. The Company elected to pay interest in-kind for the quarter ended June 30, 2016 and has recorded \$192,000 of paid-in-kind interest through June 30, 2016.

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

The Company's obligations under the Credit Agreement are secured by a security interest in substantially all of its assets. The Credit Agreement contains customary representations, warranties and events of default, as well as affirmative and negative covenants. The negative covenants include, among other provisions, covenants that limit or restrict the Company's ability to incur liens, make investments, incur indebtedness, merge with or acquire other entities, dispose of assets, make dividends or other distributions to holders of its equity interests, engage in any material new line of business or enter into certain transactions with affiliates, in each case subject to certain exceptions. To the extent the Company forms or acquires certain subsidiaries domiciled in the United States, those subsidiaries are required to be guarantors of the Company's obligations under the Credit Agreement. As of June 30, 2016, the Company was in compliance with the loan covenants.

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

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

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	June 30, 2016
Debt principal	\$25,192
Unamortized deferred debt issuance costs (521)	
Net debt obligation	\$24,671

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

Year Ending December 31,	
2020	\$9,447
Thereafter	15,745
Total	\$25,192

Loan and Security Agreement

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

Interest Expense

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Nominal interest	\$758	\$ 63	\$828	\$125
Amortization and write-off of debt discount and debt issuance costs	27	7	118	13
Prepayment penalty	—	—	50	—
End-of-term payment interest	—	20	156	39
Total	\$785	\$ 90	\$1,152	\$177

7. Stockholders' Equity

Common Stock

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

	June 30, 2016	December 31, 2015
Options issued and outstanding	5,362,144	4,179,521
Options available for grant under stock option plans	876,886	1,058,359
Common stock available for the Employee Stock Purchase Plan	684,272	750,000
Total	6,923,302	5,987,880

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8. Stock Incentive Plans

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

	Shares Available for Grant	Stock Options Outstanding	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value
Balance—December 31, 2015	1,058,359	4,179,521	\$8.03	7.50	\$6,511
Additional options authorized	1,107,411	—			
Granted	(1,420,050)	1,420,050	6.17		
Canceled	131,166	(124,161)	10.80		
Exercised	—	(113,266)	2.50		
Balance—June 30, 2016	876,886	5,362,144	\$7.59	7.89	\$2,861
Options vested and exercisable—June 30, 2016		2,381,926	\$6.97	6.49	\$2,791
Options vested and expected to vest—June 30, 2016		5,056,829	\$7.59	7.81	\$2,855

The aggregate intrinsic value was calculated as the difference between the exercise price of the options to purchase common stock and the fair market value of the Company's common stock, which was \$5.03 per share as of June 30, 2016.

The weighted average fair value of options to purchase common stock granted was \$3.30 and \$5.36 for the six months ended June 30, 2016 and 2015, respectively.

The weighted-average fair value of stock options exercised was \$1.69 and \$2.12 per option for the six months ended June 30, 2016 and 2015, respectively. The intrinsic value of stock options exercised was \$383,000 and \$1.2 million for the six months ended June 30, 2016 and 2015, respectively.

Stock-based Compensation

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Cost of revenue	\$33	\$15	\$63	\$32
Research and development	340	342	640	595
Selling and marketing	395	321	803	590
General and administrative	909	811	1,667	1,495
Total stock-based compensation expense	\$1,677	\$1,489	\$3,173	\$2,712

As of June 30, 2016, the Company had \$12.0 million of unrecognized compensation expense related to unvested stock options, which is expected to be recognized over an estimated weighted-average period of 2.74 years.

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

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	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Weighted-average volatility	55.88 – 56.29%	59.10 – 65.28%	55.88 – 56.36%	59.10 – 68.82%
Weighted-average expected term (years)	5.50 – 6.08	5.50 – 6.08	5.50 – 6.23	5.50 – 6.08
Risk-free interest rate	1.24 – 1.37%	1.58 – 2.03%	1.24 – 1.77%	1.55 – 2.03%
Expected dividend yield	—	—	—	—

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

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

	Three and Six Months Ended June 30, 2016
Weighted-average volatility	67.71 – 75.72%
Weighted-average expected term (years)	0.49 – 1.00
Risk-free interest rate	0.47%
Expected dividend yield	—

9. Genzyme Co-Promotion Agreement

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

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

In February 2015, the Company entered into an Ex-U.S. Co-promotion Agreement with Genzyme for the promotion of the Afirma GEC test with exclusivity in five countries outside the United States initially and in other countries agreed to from time to time. The agreement commenced on January 1, 2015 and continues until December 31, 2019, with extension of the agreement possible upon agreement of the parties. Country-specific terms have been established

under this agreement for Brazil and Singapore and a right of first negotiation has been established for Canada, the Netherlands and Italy. The Company pays Genzyme 25% of net revenue from the sale of the Afirma GEC test in Brazil and Singapore over a five-year period commencing January 1, 2015. Beginning in the fourth year of the agreement, if the Company terminates the agreement for convenience, the Company may be required to pay a termination fee contingent on the number of GEC billable results generated.

The Company incurred \$2.1 million and \$1.7 million in co-promotion expense, excluding the amortization of the up-front co-promotion fee, for the three months ended June 30, 2016 and 2015, respectively, and \$4.2 million and \$3.4 million in co-promotion expense for the six months ended June 30, 2016 and 2015, respectively, which is included in selling and marketing expenses in the condensed statements of operations and comprehensive loss. The Company's outstanding obligations

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to Genzyme totaled \$2.2 million as of June 30, 2016 and \$2.1 million as of December 31, 2015, and are included in accrued liabilities on the Company's condensed balance sheets.

The Company amortized \$290,000 and \$475,000 of the \$10.0 million up-front co-promotion fee in the three months ended June 30, 2016 and 2015, respectively, and \$721,000 and \$949,000 in the six months ended June 30, 2016 and 2015, respectively, which is reflected as a reduction to selling and marketing expenses in the condensed statements of operations and comprehensive loss.

10. Thyroid Cytopathology Partners

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

The Company has concluded that TCP represents a variable interest entity and that the Company is not the primary beneficiary as it does not have the ability to direct the activities that most significantly impact TCP's economic performance. Therefore, the Company does not consolidate TCP. All amounts paid to TCP under the service agreement are expensed as incurred and included in cost of revenue in the condensed statements of operations and comprehensive loss. The Company incurred \$1.3 million and \$1.2 million for the three months ended June 30, 2016 and 2015, respectively, and \$2.6 million and \$2.3 million for the six months ended June 30, 2016 and 2015, respectively, in cytopathology testing and evaluation services expenses with TCP. The Company's outstanding obligations to TCP for cytopathology testing services were \$867,000 and \$820,000 as of June 30, 2016 and December 31, 2015, respectively, and are included in accounts payable on the Company's condensed balance sheets.

TCP reimburses the Company for a proportionate share of the Company's rent and related operating expenses for the leased facility. TCP's portion of rent and related operating expense for the subleased space at the Austin, Texas facility was \$23,000 and \$22,000 for the three months ended June 30, 2016 and 2015, respectively, and \$46,000 and \$45,000 for the six months ended June 30, 2016 and 2015, respectively, and is included in other income, net in the Company's condensed statements of operations and comprehensive loss.

11. Income Taxes

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

As of June 30, 2016, the Company had unrecognized tax benefits of \$2.0 million, none of which would currently affect the Company's effective tax rate if recognized due to the Company's net deferred tax assets being fully offset by a valuation allowance. The Company does not anticipate that the amount of unrecognized tax benefits relating to tax positions existing at June 30, 2016 will significantly increase or decrease within the next 12 months. There was no interest expense or penalties related to unrecognized tax benefits recorded through June 30, 2016.

A number of years may elapse before an uncertain tax position is audited and finally resolved. While it is often difficult to predict the final outcome or the timing of resolution of any particular uncertain tax position, the Company

believes that its reserves for income taxes reflect the most likely outcome. The Company adjusts these reserves, as well as the related interest, in light of changing facts and circumstances. Settlement of any particular position could require the use of cash.

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

The following discussion and analysis of financial condition and results of operations should be read together with the condensed financial statements and the related notes included in Item 1 of Part I of this Quarterly Report on Form 10-Q, and with our audited financial statements and the related notes included in our Annual Report on Form 10-K for the year ended December 31, 2015.

This report contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. When used in this report, the words "expects," "anticipates," "intends," "estimates," "plans," "believes," "continuing," "ongoing," and similar expressions are intended to identify forward-looking statements. These are statements that relate to future events and include, but are not limited to, the factors that may impact our financial results; our expectations regarding revenue; our expectations with respect to our future research and development, general and administrative and selling and marketing expenses and our anticipated uses of our funds; our expectations regarding capital expenditures; our anticipated cash needs and our estimates regarding our capital requirements; our need for additional financing; potential future sources of cash; our business strategy and our ability to execute our strategy; our ability to achieve and maintain reimbursement from third-party payers at acceptable levels; the potential benefits of our tests and any future tests we may develop to patients, physicians and payers; the factors we believe drive demand for and reimbursement of our tests; our ability to sustain or increase demand for our tests; our intent to expand into other clinical areas; our ability to develop new tests, including tests for interstitial lung disease, and the timeframes for development or commercialization; our ability to get our data and clinical studies accepted in peer-reviewed publications; our dependence on and the terms of our agreements with Genzyme and Thyroid Cytopathology Partners, and on other strategic relationships, and the success of those relationships; our beliefs regarding our laboratory capacity; the applicability of clinical results to actual outcomes; the occurrence, timing, outcome or success of clinical trials or studies; the ability of our tests to impact treatment decisions; our beliefs regarding our competitive position; our ability to compete with potential competitors; our compliance with federal, state and international regulations; the potential impact of regulation of our tests by the FDA or other regulatory bodies; the impact of new or changing policies, regulation or legislation, or of judicial decisions, on our business; our ability to comply with the requirements of being a public company; the impact of seasonal fluctuations and economic conditions on our business; our belief that we have taken reasonable steps to protect our intellectual property; the impact of accounting pronouncements and our critical accounting policies, judgments, estimates, models and assumptions on our financial results; and anticipated trends and challenges in our business and the markets in which we operate.

Forward-looking statements are based on our current plans and expectations and involve risks and uncertainties which could cause actual results to differ materially. These risks and uncertainties include, but are not limited to, those risks discussed in Part II, Item 1A of this report, as well as risks and uncertainties related to: our limited operating history and history of losses since inception; our ability to increase usage of and reimbursement for the Afirma GEC, Percepta and any other tests we may develop; our dependence on a limited number of payers for a significant portion of our revenue; the complexity, time and expense associated with billing and collecting for our 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; our ability to successfully transition away from our co-promotion agreement with Genzyme; unanticipated delays in research and development efforts; our ability to develop and commercialize new products and the timing of commercialization; our ability to successfully enter new product markets; our ability to conduct clinical studies and the outcomes of such clinical studies; the applicability of clinical results to actual outcomes; trends and challenges in our business; our ability to compete against other companies, products and technologies; our ability to protect our intellectual property; and our ability to obtain capital when needed. These forward-looking statements speak only as of the date hereof. We expressly disclaim any obligation or undertaking to update any forward-looking statements contained herein to reflect

any change in our expectations with regard thereto or any change in events, conditions or circumstances on which any such statement is based.

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

Veracyte, Afirma, Percepta, Envisia, the Veracyte logo and the Afirma logo are our trademarks or registered trademarks. We also refer to trademarks of other corporations or organizations in this report.

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

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Overview

We are a molecular diagnostics company that focuses on genomic solutions that resolve diagnostic ambiguity, thus enabling physicians to make more informed treatment decisions at an early stage in patient care. By improving 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, centers on the proprietary Afirma Gene Expression Classifier, or GEC, which is becoming a new standard of care in thyroid nodule assessment. The Afirma 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 by cytopathology alone. An additional 25 genes are used to differentiate uncommon neoplasm subtypes. We have demonstrated the clinical utility and cost effectiveness of the Afirma GEC in multiple studies published in peer-reviewed journals and established the test's clinical validity in a study published in *The New England Journal of Medicine* in 2012. The comprehensive Afirma offering also includes cytopathology testing and the Afirma Malignancy Classifiers, launched in May 2014. Since we commercially launched Afirma in January 2011 through June 30, 2016, we have received 270,000 fine needle aspiration, or FNA, samples for evaluation using Afirma and performed over 60,000 GECs to resolve indeterminate cytopathology results.

In April 2015, we accelerated our entry into pulmonology, our second clinical area, with the launch of the Percepta Bronchial Genomic Classifier, which we obtained through our acquisition of Allegro Diagnostics Corp., or Allegro, in September 2014. The Percepta classifier is designed to improve the diagnosis of lung cancer, thus helping to reduce unnecessary invasive, risky and costly procedures in patients with suspicious lung nodules and lesions that were initially found on CT scans. Clinical validation data from two multicenter, prospective studies — AEGIS I and II — were published in July 2015 in *The New England Journal of Medicine*. Our initial focus is on building our library of clinical evidence, including clinical utility, for the Percepta classifier, while we work to secure reimbursement coverage for the test from Medicare and private payers. In February 2016, the first clinical utility study for the Percepta classifier was published in *CHEST*, the official journal of the American College of Chest Physicians. As of June 2016, more than 40 thought-leading academic and other institutions around the country are offering Percepta to their patients during this initial stage of commercialization.

Our second pulmonology product, which we plan to introduce in the fourth quarter of 2016, Envisia™ Genomic Classifier, is designed to assess the likelihood of idiopathic pulmonary fibrosis, or IPF, among patients presenting with a suspected interstitial lung disease, or ILD, without the need for surgery.

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 and the number of GECs performed. Approximately 86% of FNAs we receive are for the Afirma solution, which consists of services related to rendering a cytopathology diagnosis, and if the cytopathology result is indeterminate, the GEC is performed. The remaining approximate 14% of FNAs are received from customers performing cytopathology and when the cytopathology result is indeterminate, the FNA is sent to us for the GEC only. The rate at which adoption occurs in these two settings will cause these two percentages to fluctuate over time. Less than 1% of the FNA samples we receive for cytopathology have insufficient cellular material from which to render a cytopathology diagnosis. We only bill the technical component, including slide preparation, for these tests. For results that are benign or suspicious/malignant by cytopathology, we bill for these services when we issue the report to the physician. If the cytopathology result is indeterminate, defined as atypia/follicular lesions of undetermined significance (AUS/FLUS) or suspicious for FN/HCN, we perform the GEC. Historically, approximately 14%-17% of samples we have received for the Afirma

solution have yielded indeterminate results by cytopathology. Approximately 5%-10% of the samples for GEC testing have insufficient ribonucleic acid, or RNA, from which to render a result. The GEC can be reported as Benign, Suspicious or No Result. We bill for the GEC Benign and GEC Suspicious results only. After the GEC is completed, we issue the cytopathology report for the indeterminate results as well as the GEC report, and then bill for both of these tests. We incur costs of collecting and shipping the FNAs and a portion of the costs of performing tests where we cannot ultimately issue a patient report. Because we cannot bill for all samples received, the number of FNAs received does not directly correlate to the total number of patient reports issued and the amount billed.

Continued Adoption of and Reimbursement for Afirma

To date, only a small number of payers have reimbursed us for Afirma at list price. Revenue growth depends on both our ability to achieve broader reimbursement at increased levels from third-party payers and to expand our base of prescribing physicians and increase our penetration in existing accounts. Because some payers consider the GEC experimental and

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investigational, we may not receive payment for tests and payments we receive may not be at acceptable levels. We expect our revenue growth will increase as more payers make a positive coverage decision and as payers enter into contracts with us, which should enhance our accrued revenue and cash collections. To drive increased adoption of Afirma, we increased our sales force over the last several years, along with increasing our marketing efforts. We have hired institutional channel managers to focus on the institutional segment, where accounts generally send us FNAs for the GEC only, and account managers, dedicated to serving existing accounts, thereby freeing up our product specialists to focus on bringing in new business. If we are unable to expand the base of prescribing physicians and penetration within these accounts at an acceptable rate, or if we are not able to execute our strategy for increasing reimbursement, we may not be able to effectively increase our revenue.

We increased the list price billed for the GEC from \$4,875 to \$6,400 per test in July 2015, while the list price billed for routine cytopathology remained at \$490 per test. We obtained Medicare coverage for the GEC effective in January 2012 and contracted reimbursement at an agreed upon rate of \$3,200. We have entered into contracts establishing in-network allowable rates for both our GEC and cytopathology tests with payers including United Healthcare, Aetna and Cigna, as well as several Blue Cross Blue Shield plans, among others. We have also received positive coverage determinations from numerous other commercial payers and, as of June 2016, the GEC is covered by payers representing 180 million lives. We now have over 140 million lives under contract. Payers that have agreed to pay for Afirma under contract are also counted as covered lives. Contracted and reimbursement rates vary by payer.

On March 1, 2015, a separate CPT code, or Current Procedural Terminology code, for the Afirma GEC was issued. In November 2015, the Centers for Medicare & Medicaid Services, or CMS, issued a final determination to establish a national limitation amount for this new CPT code under the gapfill process through the regional Medicare administrative contractors, or MACs for 2017. This maintained our 2016 rate at \$3,200. On June 10, 2016, CMS released a preliminary 2017 gapfill rate for Afirma GEC of \$2,240. This preliminary rate is open to public comment for 60 days. We intend to appeal the proposed reduction. The GEC rate will be finalized later this year and be effective January 1, 2017 and remain in effect for 2017. Medicare represents approximately 20% of our GEC volume.

Our average reimbursement per GEC was approximately \$2,100 for the quarter ended June 30, 2016 as compared with approximately \$2,300 for the same period in 2015. The average GEC reimbursement rate will change over time due to a number of factors, including medical coverage decisions by payers, the effects of contracts signed with payers, changes in allowed amounts by payers, our ability to successfully win appeals for payment, and our ability to collect cash payments from third-party payers and individual patients. Historical average reimbursement is not necessarily indicative of future average reimbursement.

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

How We Recognize Revenue

We recognize revenue on an accrual basis when we are able to make a reasonable estimate of reimbursement at the time delivery is complete. In the first period in which revenue is accrued for a particular payer or test, there generally is a one-time increase in revenue. Until we have contracts with or can estimate the amount that will ultimately be received, we recognize the related revenue upon the earlier of notification of payment or when cash is received. Additionally, as we commercialize new products, we will need to be able to make an estimate of the amount that will ultimately be received from each payer for each new product offering prior to being able to recognize the related revenue on an accrual basis. Because the timing and amount of cash payments received from payers as well as

one-time increases in revenue from newly accrued payers 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 June 30, 2016 and December 31, 2015, cumulative amounts billed since 2011 at list price for tests processed which were not recognized as revenue upon delivery of a patient report because our accrual revenue recognition criteria were not met and for which we had not received notification of payment, collected cash or written off as uncollectible, totaled approximately \$167.1 million and \$134.3 million, respectively. Of the \$134.3 million, we recognized revenue of approximately \$1.8 million and \$5.4 million in the three and six months ended June 30, 2016, respectively, when cash was received.

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Generally, cash we receive is collected within 12 months of the date the test is billed. We cannot provide any assurance as to when, if ever, or to what extent any of these amounts will be collected. Notwithstanding our efforts to obtain payment for these tests, payers may deny our claims, in whole or in part, and we may never receive revenue from previously performed but unpaid tests. Revenue from these tests, if any, may not be equal to the billed amount due to a number of factors, including differences in reimbursement rates, the amounts of patient co-payments and co-insurance, the existence of secondary payers and claims denials. Finally, when we increase our list price, as we did in July 2015, it will increase the cumulative amounts billed.

We incur expense for tests in the period in which the test is conducted and recognize revenue for tests in the period in which our revenue recognition criteria are met. Accordingly, any revenue that we recognize as a result of cash collection in respect of previously performed but unpaid tests will favorably impact our liquidity and results of operations in future periods.

Impact of Genzyme Co-promotion Agreement

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

In November 2014, we signed an Amended and Restated U.S. Co-Promotion Agreement, or Amended Agreement, with Genzyme which reduced the co-promotion fees Genzyme receives as a percentage of U.S. cash receipts from the sale of the Afirma solution from 32% to 15% beginning January 1, 2015. Either party may terminate the agreement for convenience with six months' prior notice, however, neither party can terminate the agreement for convenience prior to June 30, 2016. On March 9, 2016, we gave Genzyme notice of termination of the Amended Agreement effective September 9, 2016 and the amortization of the upfront co-promotion fee has been extended to that date.

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

We amortized \$290,000 and \$721,000 of the \$10.0 million up-front co-promotion fee in the three and six months ended June 30, 2016, respectively, compared to \$475,000 and \$949,000 in the same periods in 2015. The balance of the unamortized up-front co-promotion fee was \$227,000 at June 30, 2016. Our co-promotion fees payable to Genzyme, excluding the amortization of the up-front co-promotion fee, were \$2.1 million and \$4.2 million in the three and six months ended June 30, 2016, respectively, compared to \$1.7 million and \$3.4 million in the same periods in 2015, and are included in selling and marketing expenses in our condensed consolidated statements of operations and comprehensive loss.

Development of Additional Products

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

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Timing of Our Research and Development Expenses

We deploy state-of-the-art and costly genomic technologies in our biomarker discovery experiments, and our spending on these technologies may vary substantially from quarter to quarter. We also spend a significant amount to secure clinical samples that can be used in discovery and product development as well as clinical validation studies. The timing of these research and development activities is difficult to predict, as is the timing of sample acquisitions. If a substantial number of clinical samples are acquired in a given quarter or if a high-cost experiment is conducted in one quarter versus the next, the timing of these expenses can affect our financial results. We conduct clinical studies to validate our new products as well as on-going clinical studies to further the published evidence to support our commercialized tests. As these studies are initiated, start-up costs for each site can be significant and concentrated in a specific quarter. Spending on research and development, for both experiments and studies, may vary significantly by quarter depending on the timing of these various expenses.

Historical Seasonal Fluctuations in FNA Volume and Cash Collections

Our business is subject to fluctuations in the number of FNA samples received for both cytopathology and GEC testing throughout the year as a result of a number of factors, including physician practices being closed for holidays or endocrinology and thyroid-related industry meetings which are widely attended by our prescribing physicians. Like other companies in our field, vacations by physicians and patients tend to negatively affect our volumes more during the summer months and during the end of year holidays compared to other times of the year. Additionally, we may receive fewer FNAs in the winter months due to severe weather if patients are not able to visit their doctor's office. Our reimbursed rates and cash collections are also subject to seasonality. Medicare normally makes adjustments in its fee schedules at the beginning of the year which may affect our reimbursement. Additionally, some plans reset their deductibles at the beginning of each year which means that patients early in the year are responsible for a greater portion of the cost of our tests, and we have lower cash collection rates from individuals than from third-party payers. Later in the year, particularly in the fourth quarter, we experience improved payment results as third-party payers tend to clear pending claims toward year end. This trend historically has increased our cash collections in the fourth quarter. As we accrue more revenue in the future, this will have less of an impact on our revenue in the fourth quarter but will still impact our cash position. The effects of these seasonal fluctuations in prior periods may have been obscured by the growth of our business.

Financial Overview

Revenue

Through June 30, 2016, all of our revenue has been derived from the sale of Afirma. To date, Afirma has been delivered primarily to physicians in the United States. We generally invoice third-party payers upon delivery of a patient report to the prescribing physician. As such, we take the assignment of benefits and the risk of cash collection from the third-party payer and individual patients. Third-party payers in excess of 10% of revenue and their related revenue as a percentage of total revenue were as follows:

	Three Months Ended June 30, 2016	Six Months Ended June 30, 2015	Three Months Ended June 30, 2016	Six Months Ended June 30, 2015
Medicare	30%	28%	30%	26%
United Healthcare	13%	14%	12%	14%

43% 42% 42% 40%

For tests performed where we can estimate the amount we will ultimately receive at the time delivery is complete, such as in the case of Medicare and certain other payers, we recognize the related revenue upon delivery of a patient report to the prescribing physician based on the established billing rate less contractual and other adjustments to arrive at the amount that we expect to ultimately receive. We determine the amount we expect to ultimately receive based on a per payer, per contract or agreement basis. Upon ultimate collection, the amount received where reimbursement was estimated is compared to previous estimates and the amount accrued is adjusted accordingly. In other situations, where we cannot estimate the amount that will be ultimately received, we recognize revenue upon the earlier of receipt of third-party payer notification of payment or when cash is received. Incremental accrued revenue as a result of additional payers meeting our revenue recognition criteria was approximately \$338,000 and \$484,000 million for the three and six months ended June 30, 2016, respectively, and \$240,000 and \$565,000 for the three and six months ended June 30, 2015, respectively. Our ability to increase our revenue will depend on our ability to penetrate the market, obtain positive coverage policies from additional third-party payers, obtain

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reimbursement and/or enter into contracts with additional third-party payers, and increase reimbursement rates for tests performed. Finally, should we recognize revenue on an accrual basis and later determine the judgments underlying estimated reimbursement change, our financial results could be negatively impacted in future quarters.

Cost of Revenue

The components of our cost of revenue are materials and service costs, including cytopathology testing services, stock-based compensation expense, direct labor costs, equipment and infrastructure expenses associated with testing samples, shipping charges to transport samples, and allocated overhead including rent, information technology, equipment depreciation and utilities. Costs associated with performing tests are recorded as the test is processed regardless of whether and when revenue is recognized with respect to that test. As a result, our cost of revenue as a percentage of revenue may vary significantly from period to period because we do not recognize all revenue in the period in which the associated costs are incurred. We expect cost of revenue in absolute dollars to increase as the number of tests we perform increases and from the higher costs of our new facility. However, we expect that the cost per test will decrease over time due to leveraging fixed costs, efficiencies we may gain as test volume increases and from automation, process efficiencies and other cost reductions. As we introduce new tests, initially our cost of revenue will be high and will increase disproportionately our aggregate cost of revenue until we achieve efficiencies in processing these new tests.

Research and Development

Research and development expenses include costs incurred to develop our technology, collect clinical samples and conduct clinical studies to develop and support our products. These costs consist of personnel costs, including stock-based compensation expense, prototype materials, laboratory supplies, consulting costs, costs associated with setting up and conducting clinical studies at domestic and international sites, and allocated overhead including rent, information technology, equipment depreciation and utilities. We expense all research and development costs in the periods in which they are incurred. We expect to incur significant research and development expenses as we continue to invest in research and development activities related to developing additional products and evaluating various platforms. We are incurring research and development expenses in 2016 for the development and launch of Envisia and for the continued development and support of the Afirma and Percepta tests. Specifically, we plan to: increase the body of clinical evidence to support Afirma; incur research and development expenses associated with clinical utility studies to support the commercialization of Percepta; and incur expenses associated with development, analytical verification and clinical validation studies for Envisia.

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, co-promotion fees paid to Genzyme, net of amortization of the up-front fee received, are included in selling and marketing expenses. In November 2014, we amended the co-promotion agreement with Genzyme and our personnel and marketing costs increased as we took on more sales and marketing responsibilities related to Afirma, but these increases are offset by the lower rate we are required to pay Genzyme under the Amended Agreement beginning in January 2015. On March 9, 2016, we gave Genzyme notice of termination of the Amended Agreement effective September 9, 2016. Consequently, in 2016, we have further expanded our internal sales force and marketing spending as we transition out of the relationship. We expect that these costs will be offset by the elimination of the co-promotion fee, beginning in mid-September 2016. In 2016, we also expect to incur increased selling and marketing expense as a result of investments in our lung product portfolio. We believe total selling and marketing expenses will continue to increase as we launch and promote our new tests.

General and Administrative

General and administrative expenses include those from executive, finance and accounting, human resources, legal, billing and client services, and quality and regulatory functions. These expenses include personnel costs, including stock-based compensation expense, audit and legal expenses, consulting costs, costs associated with being a public company, and allocated overhead including rent, information technology, equipment depreciation and utilities. We expect these expenses to continue to grow in 2016 as we build our general and administration infrastructure and to stabilize thereafter.

Intangible Asset Amortization

Intangible asset amortization began in April 2015 when we launched the Percepta test. The finite-lived intangible asset with a cost of \$16.0 million is being amortized over 15 years, using the straight-line method.

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Interest Expense

Interest expense is attributable to our borrowings under our loan and security agreement and the credit agreement that replaced it.

Other Income (Expense), Net

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

Critical Accounting Policies and Estimates

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

Revenue Recognition

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

We may bill the patient directly for these amounts in the form of co-payments and co-insurance in accordance with their insurance carrier and health plans. Some payers may not cover our 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 the ability to estimate the amount that will ultimately be realized for our services, revenue is recognized upon the earlier of receipt of third-party payer notification of payment or when cash is received.

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

Finite-lived Intangible Assets

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

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Stock-based Compensation

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

Results of Operations

Comparison of the Three and Six Months Ended June 30, 2016 and 2015 (In Thousands of Dollars, Except Percentages)

	Three Months Ended June 30,				Six Months Ended June 30,			
	2016	2015	Change	%	2016	2015	Change	%
Revenue	\$14,675	\$11,908	\$2,767	23%	\$28,225	\$23,126	\$5,099	22%
Operating expense:								
Cost of revenue	6,301	5,139						