

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **November 5, 2015**

VERACYTE, INC.

(Exact name of registrant as specified in its charter)

DELAWARE

(State or other jurisdiction of
incorporation)

001-36156

Commission File Number

20-5455398

(IRS Employer Identification
No.)

7000 Shoreline Court, Suite 250, South San Francisco, California

(Address of principal executive offices)

94080

(Zip Code)

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

N/A

(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 2.02 Results of Operations and Financial Condition.

On November 5, 2015, Veracyte, Inc. issued a press release announcing its financial results for the quarter ended September 30, 2015. The full text of the press release is furnished as Exhibit 99.1 to this report.

The information in this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act"), or otherwise subject to the liability of that section, and shall not be incorporated by reference into any registration statement or other document filed under the Securities Act of 1933 or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release issued by Veracyte, Inc. dated November 5, 2015.

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 hereunto duly authorized.

Dated: November 5, 2015

VERACYTE, INC.

By /s/ **Shelly D. Guyer**
Name: Shelly D. Guyer
Title: Chief Financial Officer

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INDEX TO EXHIBITS

Exhibit No.	Description
<u>99.1</u>	Press Release issued by Veracyte, Inc. dated November 5, 2015.



For Immediate Release

Veracyte Announces Third Quarter 2015 Financial Results

Revenue Grew 25% and Afirma® GEC Test Volume Increased 46%, Compared to Third Quarter 2014

Conference Call and Webcast Today at 5:15 p.m. ET

SOUTH SAN FRANCISCO, Calif., November 5, 2015 — Veracyte, Inc. (NASDAQ: VCYT) today announced financial results for the third quarter ended September 30, 2015 and provided an update on recent business progress. Revenue for the third quarter of 2015 was \$12.3 million, an increase of 25%, compared to \$9.8 million for the third quarter of 2014. Afirma Gene Expression Classifier (GEC) test volume grew to 5,034 tests, an increase of 46%, compared to the same period in 2014.

“We experienced robust growth in our Afirma business, driven in part by increased private payer coverage, new in-network contracts, and test performance that is unmatched in its ability to help patients avoid unnecessary surgery,” said Bonnie Anderson, Veracyte’s president and chief executive officer. “To support current and future revenue growth, we continued to amass significant data in all of our programs including extensive long-term clinical utility evidence for Afirma GEC, which positions us well for further payer coverage decisions and contracts. We also made great progress in securing additional early adopters for the Percepta™ Bronchial Genomic Classifier and presented initial clinical utility data to support reimbursement of the test.”

Third Quarter 2015 Financial Results

- Operating expenses for the third quarter of 2015 were \$21.2 million, compared to \$17.6 million for the comparable period in 2014. Operating expenses included cost of revenue of \$5.6 million for the third quarter of 2015, compared to \$4.2 million for the same period in 2014.
- Net loss for the third quarter of 2015 was \$8.9 million, or \$0.32 per common share, versus a net loss of \$7.9 million, or \$0.37 per common share, for the same period in 2014.
- Cash and cash equivalents as of September 30, 2015 totaled \$46.1 million.

Third Quarter and Recent Business Highlights

- Veracyte reached nearly 155 million lives under coverage for the Afirma GEC and expanded its Blues plan coverage to over 20 million lives. Blue Cross Blue Shield of Massachusetts issued a positive coverage policy, effective in October, and Veracyte entered into an in-network contract with Blue Cross Blue Shield of Louisiana in August.
- New guidelines from the American Thyroid Association include a recommendation that the Afirma GEC may be used in lieu of diagnostic surgery to rule out cancer in patients with indeterminate thyroid nodules, based on the test’s validated performance of 92 percent sensitivity and greater than 94 percent negative predictive value.
- Two peer-reviewed journals published long-term clinical utility studies showing the durability of a benign Afirma GEC result.
- Two additional studies were presented at the 2015 International Thyroid Congress, demonstrating the Afirma GEC’s long-term clinical utility in safely reducing unnecessary thyroid surgeries. One of these was a Veracyte-sponsored study led by HealthCore, a wholly-owned subsidiary of Anthem, Inc.
- New clinical utility data for the Percepta Bronchial Genomic Classifier were presented at the CHEST 2015 Annual Meeting, suggesting the test’s ability to reduce unnecessary invasive procedures among lung nodule patients by 41%.
- Four abstracts have been accepted for presentation at the Pulmonary Fibrosis Foundation’s upcoming PFF Summit 2015. These include the PFF’s “INTENSITY” study — supported by Veracyte, which helps define the clinical value that the ILD test will deliver.

2015 Financial Outlook

Veracyte reiterates its 2015 annual revenue guidance of \$48 million to \$53 million, as well as its forecast to achieve annual Afirma GEC test volume in the range of 19,000 to 21,000.

Conference Call and Webcast Details

Veracyte will host a conference call and webcast today at 5:15 p.m. Eastern Time to discuss the company’s financial results and provide a general business update. The live webcast and subsequent replay may be accessed by visiting Veracyte’s website at <http://investor.veracyte.com>. Alternatively, please call (855) 541-0980 (U.S.) or (970) 315-0440 (international) to listen to the live conference call. The conference ID number is 62948488. The webcast replay will be available on the company’s website approximately two hours following completion of the call.

About Veracyte

Veracyte (NASDAQ: VCYT) is pioneering the field of molecular cytology, offering genomic solutions that resolve diagnostic ambiguity and enable physicians to make more informed treatment decisions at an early stage in patient care. By improving preoperative diagnostic accuracy, the company aims to help patients avoid unnecessary invasive procedures while reducing healthcare costs. Veracyte’s Afirma Thyroid FNA Analysis centers on the proprietary Afirma Gene Expression Classifier (GEC) and is becoming a new standard of care in thyroid nodule assessment. The Afirma test is recommended in leading practice guidelines and is covered for nearly 155 million lives in the United States, including through Medicare and many commercial insurance plans. Veracyte is expanding its molecular cytology franchise to other clinical areas, beginning with difficult-to-diagnose lung diseases. In April 2015, the company launched the Percepta Bronchial Genomic Classifier, a test to evaluate patients with lung nodules that are suspicious for cancer. Veracyte is

Cautionary Note Regarding Forward-Looking Statements

This press release contains “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements can be identified by words such as: “anticipate,” “intend,” “plan,” “expect,” “believe,” “should,” “may,” “will” and similar references to future periods. Examples of forward-looking statements include, among others, statements we make regarding our beliefs regarding the drivers of adoption of Afirma, our expectations with respect to the success of our entry into the pulmonology market, our expectations regarding full-year 2015 guidance and forecast for annual GEC test volume, and the value and potential of our technology and research and development pipeline. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based only on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, anticipated events and trends, the economy and other future conditions. Forward-looking statements involve risks and uncertainties, which could cause actual results to differ materially, and reported results should not be considered as an indication of future performance. These risks and uncertainties include, but are not limited to: our limited operating history and history of losses; our ability to increase usage of and reimbursement for Afirma and to obtain reimbursement for any future products we may develop or sell; our ability to successfully achieve adoption of and reimbursement for our Percepta Bronchial Genomic Classifier; our ability to continue our momentum and growth; our dependence on a few payers for a significant portion of our revenue; the complexity, time and expense associated with billing and collecting from payers for our test; laws and regulations applicable to our business, including potential regulation by the Food and Drug Administration or other regulatory bodies; our dependence on strategic relationships and our ability to successfully convert new accounts resulting from such relationships; our ability to develop and commercialize new products and the timing of commercialization; our ability to achieve sales penetration in complex commercial accounts; the occurrence and outcome of clinical studies; our ability to show clinical value of our lung products; the timing and publication of study results; the applicability of clinical results to actual outcomes; our inclusion in clinical practice guidelines; the continued application of clinical guidelines to our products; our ability to compete; our ability to expand into international markets and achieve adoption of our tests in such markets; our ability to obtain capital when needed; and other risks set forth in the company’s filings with the Securities and Exchange Commission, including the risks set forth in the company’s Quarterly Report on Form 10-Q for the quarter ended June 30, 2015. These forward-looking statements speak only as of the date hereof and Veracyte specifically disclaims any obligation to update these forward-looking statements.

Veracyte, Afirma, Percepta, the Veracyte logo, and the Afirma logo are trademarks or registered trademarks of Veracyte, Inc.

VERACYTE, INC.
CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(Unaudited)
(in thousands, except share and per share amounts)

	<u>Three Months Ended Sept. 30,</u>		<u>Nine Months Ended Sept 30,</u>	
	2015	2014	2015	2014
Revenue	\$ 12,335	\$ 9,838	\$ 35,461	\$ 25,991
Operating expenses:				
Cost of revenue	5,618	4,168	15,322	11,741
Research and development	3,563	2,233	9,453	6,602
Selling and marketing	6,048	5,533	18,606	14,970
General and administrative	5,728	5,715	17,062	13,625
Intangible asset amortization	266	—	533	—
Total operating expenses	<u>21,223</u>	<u>17,649</u>	<u>60,976</u>	<u>46,938</u>
Loss from operations	(8,888)	(7,811)	(25,515)	(20,947)
Interest expense	(92)	(114)	(269)	(338)
Other income, net	35	23	93	54
Net loss and comprehensive loss	<u>\$ (8,945)</u>	<u>\$ (7,902)</u>	<u>\$ (25,691)</u>	<u>\$ (21,231)</u>
Net loss per common share, basic and diluted	<u>\$ (0.32)</u>	<u>\$ (0.37)</u>	<u>\$ (1.01)</u>	<u>\$ (0.99)</u>
Shares used to compute net loss per common share, basic and diluted	<u>27,640,806</u>	<u>21,648,660</u>	<u>25,428,506</u>	<u>21,346,565</u>

VERACYTE, INC.
CONDENSED BALANCE SHEETS
(In thousands, except share and per share amounts)

	<u>September 30,</u>	<u>December 31,</u>
	2015	2014
	(unaudited)	(1)
Assets		
Current assets:		
Cash and cash equivalents	\$ 46,116	\$ 35,014
Accounts receivable, net	3,520	3,050
Supplies inventory	3,984	3,696

Prepaid expenses and other current assets	3,371	1,218
Deferred tax asset	222	300
Restricted cash	118	70
Total current assets	57,331	43,348
Property and equipment, net	6,200	4,161
Finite-lived intangible assets, net	15,467	—
Indefinite-lived intangible assets: in-process research and development	—	16,000
Goodwill	1,057	1,057
Restricted cash	603	118
Other assets	195	155
Total assets	<u>\$ 80,853</u>	<u>\$ 64,839</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 6,644	\$ 7,397
Accrued liabilities	7,365	7,851
Deferred Genzyme co-promotion fee	1,423	1,897
Total current liabilities	15,432	17,145
Long-term debt	5,002	4,923
Deferred tax liability	222	300
Deferred rent, net of current portion	2,386	149
Deferred Genzyme co-promotion fee, net of current portion	—	948
Total liabilities	23,042	23,465
Total stockholders' equity	57,811	41,374
Total liabilities and stockholders' equity	<u>\$ 80,853</u>	<u>\$ 64,839</u>

(1) The condensed balance sheet at December 31, 2014 has been derived from the audited financial statements at that date included in the Company's Form 10-K filed with the Securities and Exchange Commission dated March 25, 2015.

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Source: Veracyte

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