

**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): **March 10, 2016**

**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.)

**6000 Shoreline Court, Suite 300, 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 March 10, 2016, Veracyte, Inc. issued a press release announcing its financial results for the quarter and the year ended December 31, 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 March 10, 2016.

**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.

Date: March 10, 2016

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

INDEX TO EXHIBITS

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release issued by Veracyte, Inc. dated March 10, 2016.



For Immediate Release

**Veracyte Announces Fourth Quarter and Full-Year 2015 Financial Results,  
Provides 2016 Financial Outlook**

*30% Growth in Revenue, 38% Increase in Afirma® GEC Volume for 2015*

*Increased Covered Lives for Afirma to 180 Million, In-Network Contracted Lives to 130 Million*

*Concluding U.S. Co-promotion with Sanofi Genzyme to Retain Full Value of Afirma*

*Conference Call and Webcast Today at 4:30 p.m. ET*

SOUTH SAN FRANCISCO, Calif., March 10, 2016 — Veracyte, Inc. (NASDAQ: VCYT) today announced financial results and business progress for the quarter and full year ended December 31, 2015, and provided financial guidance for 2016.

“We had an excellent year in 2015, driving the growth of our Afirma Gene Expression Classifier (GEC), gaining payer coverage and reimbursement, and advancing our pulmonology program,” said Bonnie Anderson, president and chief executive officer of Veracyte. “We are firmly establishing Afirma as a new standard of care that helps patients avoid unnecessary surgery in thyroid cancer diagnosis. We are also creating a growing body of long-term clinical utility evidence and are well-positioned to further drive market penetration for our test.

“We also believe that the substantial clinical data now supporting our Percepta® Bronchial Genomic Classifier to improve diagnosis of lung nodules that are potentially cancerous will strengthen reimbursement and commercialization efforts for the new test. Additionally, we are advancing our pipeline with clinical studies underway to support the launch of our test to help diagnose idiopathic pulmonary fibrosis, or IPF, without the need for surgery. We are targeting launch of our IPF product during the fourth quarter of 2016.”

**Fourth Quarter and Full-Year 2015 Financial Results**

- Revenue was \$14.0 million for the fourth quarter of 2015, an increase of 15%, compared to \$12.2 million in the fourth quarter of 2014. Excluding a one-time revenue pick-up and cash receipts in the fourth quarter of 2014, the revenue increase was 23% for the fourth quarter of 2015, compared to the same quarter of the prior year. 2015 revenue was \$49.5 million, an increase of 30%, compared to 2014 revenue of \$38.2 million.
- Afirma GEC test volume grew to 5,609 during the fourth quarter of 2015, an increase of 38%, compared to the same period in 2014. Total GECs performed for 2015 also increased by 38% to 19,421, compared to 14,061 GEC tests for 2014.

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- Operating expense for the fourth quarter of 2015 was \$22.0 million, compared to \$20.3 million for the comparable period in 2014. Operating expense for 2015 was \$83.0 million compared to operating expense of \$67.2 million for 2014.
  - Net loss for the fourth quarter of 2015 was \$8.0 million, or \$0.29 per common share, compared to a net loss of \$8.1 million, or \$0.36 per common share, for the same period in 2014. Net loss for 2015 was \$33.7 million, or \$1.30 per common share, compared to a net loss of \$29.4 million, or \$1.36 per common share, for 2014.
  - Cash and cash equivalents as of December 31, 2015 totaled \$39.1 million.

**2015 and Recent Business Highlights**

- Expanded the total number of covered lives for the Afirma GEC to nearly 180 million today, including more than 45 million Blues plan members, compared to approximately 140 million total and 20 million Blues covered lives at the beginning of 2015, with new coverage from HCSC in December.
- Grew the total number of contracted lives for the Afirma GEC to nearly 130 million today from 90 million at the beginning of 2015.
- Significantly expanded the clinical utility evidence for the Afirma GEC, with more than a dozen such studies now published, including two long-term clinical outcome studies published in peer-reviewed journals, and another study, conducted by Anthem, Inc. subsidiary HealthCore, presented at a major medical conference in October.
- Concluding U.S. co-promotion agreement with Sanofi Genzyme, effective mid-September 2016, when Veracyte will assume full sales and marketing responsibility for Afirma. This will allow us to end payments to Sanofi Genzyme of 15% of all U.S. Afirma sales.
- Launched the Percepta Bronchial Genomic Classifier ahead of schedule in April, followed by strong clinical validation data published in *The New England Journal of Medicine* in July and *BMC Medical Genomics* in May, clinical utility data published in *CHEST* in February 2016 and analytical verification data published in *BMC Cancer* in February 2016.
- Presented new data for Veracyte’s IPF classifier, which was developed and cross-validated on bronchoscopy samples — the same type of patient sample that will be used upon commercialization — at the Pulmonary Fibrosis Foundation Summit in November 2015.
- Strengthened the Board with the appointments of Robert S. Epstein, M.D., M.S., and Tina S. Nova, Ph.D., and the management team with the addition of Neil M. Barth, M.D., as chief medical officer during 2015.

**2016 Financial Outlook**

Veracyte’s guidance for 2016 is to achieve Afirma GEC test volume in the range of 24,000 to 25,500, and annual 2016 revenue in the range of \$59 million to \$63 million.

## Conference Call and Webcast Details

Veracyte will host a conference call and webcast today at 4:30 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 49854042. 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 180 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 developing a second product in pulmonology, targeting interstitial lung diseases, including idiopathic pulmonary fibrosis. For more information, please visit [www.veracyte.com](http://www.veracyte.com).

## 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 2016 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 successfully transition sales and marketing of the Afirma GEC from Genzyme to our internal sales and marketing personnel; 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 September 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)

	Three Months Ended December 31,		Year Ended December 31,	
	2015	2014	2015	2014
Revenue	\$ 14,042	\$ 12,199	\$ 49,503	\$ 38,190
Operating expenses:				
Cost of revenue	6,175	4,865	21,497	16,606
Research and development	3,343	3,202	12,796	9,804
Selling and marketing	6,687	6,962	25,293	21,932
General and administrative	5,521	5,229	22,583	18,854
Intangible asset amortization	267	—	800	—
Total operating expenses	21,993	20,258	82,969	67,196
Loss from operations	(7,951)	(8,059)	(33,466)	(29,006)
Interest expense	(96)	(101)	(378)	(439)
Other income, net	34	18	140	72
Net loss and comprehensive loss	\$ (8,013)	\$ (8,142)	\$ (33,704)	\$ (29,373)
Net loss per common share, basic and diluted	\$ (0.29)	\$ (0.36)	\$ (1.30)	\$ (1.36)
Shares used to compute net loss per common share, basic and diluted	27,672,806	22,508,250	25,944,193	21,639,374

**VERACYTE, INC.**  
**CONDENSED BALANCE SHEETS**  
(In thousands)

	December 31, 2015 (Unaudited)	December 31, 2014 (1)
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 39,084	\$ 35,014
Accounts receivable, net	3,503	3,050
Supplies inventory	3,767	3,696
Prepaid expenses and other current assets	1,461	1,218
Deferred tax asset	—	300
Restricted cash	118	70
Total current assets	<u>47,933</u>	<u>43,348</u>
Property and equipment, net	10,314	4,161
Finite-lived intangible assets, net	15,200	—
Infinite-lived intangible assets: in-process research and development	—	16,000
Goodwill	1,057	1,057
Restricted cash	603	118
Other assets	178	155
Total assets	<u>\$ 75,285</u>	<u>\$ 64,839</u>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 5,085	\$ 7,397
Accrued liabilities	8,689	7,851
Deferred Genzyme co-promotion fee	948	1,897
Total current liabilities	<u>14,722</u>	<u>17,145</u>
Long-term debt	5,028	4,923
Deferred tax liability	—	300
Deferred rent, net of current portion	4,283	149
Deferred Genzyme co-promotion fee, net of current portion	—	948
Total liabilities	<u>24,033</u>	<u>23,465</u>
Total stockholders' equity	51,252	41,374
Total liabilities and stockholders' equity	<u>\$ 75,285</u>	<u>\$ 64,839</u>

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

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Source: Veracyte

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