

VERACYTE, INC.

FORM 8-K (Current report filing)

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Address	6000 SHORELINE COURT, SUITE 300 SOUTH SAN FRANCISCO, CA 94080
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Sector	Healthcare
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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 1, 2017

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))
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Item 2.02 Results of Operations and Financial Condition.

On March 1, 2017, Veracyte, Inc. issued a press release announcing its financial results for the quarter and the year ended December 31, 2016. 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

Exhibit No.	Description
99.1	Press release issued by Veracyte, Inc. dated March 1, 2017.

For Immediate Release

**Veracyte Announces Fourth Quarter and Full-Year 2016 Financial Results,
Provides 2017 Financial Outlook**

SOUTH SAN FRANCISCO, Calif., March 1, 2017

Revenue Grew 31%, to \$65.1 Million in 2016

Full-Year Afirma[®] GEC Volume Increased 20%, to 23,237 Tests

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

Veracyte, Inc. (NASDAQ: VCYT) today announced financial results and business progress for the quarter and full year ended December 31, 2016, and provided financial guidance for 2017.

"We delivered strong revenue growth and executed on the key milestones for our business in 2016," said Bonnie Anderson, Veracyte's chief executive officer and chairman of the board. "We also have tremendous momentum heading into 2017, underscored by several recent Blues coverage decisions for the Afirma GEC and final Medicare coverage policies for the Percepta[®] classifier. These two products will fuel our revenue growth in 2017."

Fourth Quarter and Full-Year 2016 Financial Results

- *Revenue* for the three- and twelve-month periods ended December 31, 2016 was \$18.3 million and \$65.1 million, respectively, an increase of 30% and 31% over the prior year.
- *Afirma Gene Expression Classifier (GEC) Reported Volume* for the three- and twelve-month periods ended December 31, 2016 was 6,313 and 23,237, respectively, an increase of 13% and 20% over the prior year.
- *Operating Expenses* for the three- and twelve-month periods ended December 31, 2016, were \$21.9 million and \$93.9 million, respectively, an increase of 0% and 13% over the prior year.
- *Net Loss and Comprehensive Loss* for the three- and twelve-month periods ended December 31, 2016 was (\$4.4) million and (\$31.4) million, respectively, a 45% and 7% reduction from the prior year.
- *Cash and cash equivalents* was \$59.2 million at December 31, 2016. During the twelve-month period ended December 31, 2016, the company raised \$51.1 million in capital, including \$19.2 million in net proceeds from its March 2016 debt financing and \$31.9 million in net proceeds from a public offering of common stock.
- *Cash Burn* for the three- and twelve-month periods ended December 31, 2016 (which is defined as net cash used in operating activities and purchases of property and equipment), was \$4.7 million and \$32.2 million, respectively, a 33% and 3% improvement compared to the prior year.

2016 and Recent Business Highlights

Reimbursement:

- Executed a Blues group-purchasing agreement in April 2016, accelerating Blues plan in-network contracting and overall reimbursement for the Afirma GEC thyroid cancer test. As of February 28, 2017, the company has more than 70 million Blues plan members under coverage and nearly 25 million under contract.
 - Expanded overall covered lives for the Afirma GEC by 50 million to nearly 225 million and overall contracted lives by 25 million to over 155 million as of February 28, 2017.
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- Achieved draft Medicare coverage policies for the Percepta Bronchial Genomic Classifier for use in lung cancer screening and diagnosis, leading to two final policies scheduled to become effective in March 2017.

Clinical Evidence and Commercial Expansion:

- Clinical utility and cost-effectiveness data for the Percepta classifier were presented at the American Thoracic Society and the CHEST annual meetings, further suggesting that use of the Percepta classifier changes patient care and reduces healthcare costs as intended.
- Launched the Envisia™ Genomic Classifier at the CHEST annual meeting in October 2016, in conjunction with the presentation of new data suggesting the test's ability to significantly improve the diagnosis of idiopathic pulmonary fibrosis (IPF) without the need for risky, expensive surgery.

Pipeline Advancements:

- Presented data at the American Thyroid Association meeting in September 2016, demonstrating the potential for a next-generation Afirma GEC, planned for 2017 introduction, to substantially increase the percentage of patients with benign thyroid nodules who may be able to avoid unnecessary surgery.
- Data were published in the *Journal of the National Cancer Institute* suggesting the potential for the "field of injury" technology behind Veracyte's Percepta classifier to enable lung cancer detection using a simple, non-invasive nasal swab test.

2017 Outlook

Veracyte expects to achieve the following results in 2017:

- Annual revenue in the range of \$76 to \$84 million; and
- Annual cash burn of \$25 to \$27 million, a reduction of 16 to 22% over the prior year.

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 63407446. 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 a leading genomic diagnostics company that is fundamentally improving patient care by resolving diagnostic uncertainty with evidence that is trustworthy and actionable. The company's products uniquely combine genomic technology, clinical science and machine learning to provide answers that give physicians and patients a clear path forward without risky, costly surgery that is often unnecessary. Since its founding in 2008, Veracyte has commercialized three genomic tests, which are transforming the diagnosis of thyroid cancer, lung cancer and idiopathic pulmonary fibrosis and collectively target a \$2 billion market opportunity. Veracyte is based in South San Francisco, California. For more information, please visit www.veracyte.com and follow the company on Twitter (@veracyte).

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 our revenue growth and drive toward profitability, our belief as to the size of our addressable markets and our financial foundation for growth, our expectations with respect to the success of our entry into the pulmonology market, our expectations regarding full-year 2017 revenue and cash burn guidance, our expectations regarding reimbursement coverage and policies, the benefits of our pipeline and planned timing of future product launches, 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 enhance the performance of our Afirma test; the performance and acceptance of our Percepta and Envisia tests; our ability to increase usage of and reimbursement for Afirma and to obtain adequate reimbursement for our Percepta and Envisia tests, as well as any future products we may develop or sell; 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 tests; laws and regulations applicable to our business, including potential regulation by the Food and Drug Administration or other regulatory bodies; our ability to develop and commercialize new products and the timing and speed of commercialization; the amount by which use of our products is able to reduce invasive procedures and reduce healthcare costs; our ability to achieve sales penetration in complex commercial accounts; the occurrence and outcome of clinical studies; the timing and publication of study results; the applicability of clinical results to actual outcomes; the continued application of clinical guidelines to our products and their inclusion in such clinical practice guidelines; our ability to compete; 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, 2016. 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, Envisia, the Veracyte logo, and the Afirma logo are trademarks of Veracyte, Inc.

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

	Three Months Ended December 31,		Year Ended December 31,	
	2016	2015	2016	2015
Revenue	\$ 18,257	\$ 14,042	\$ 65,085	\$ 49,503
Operating expenses:				
Cost of revenue	6,515	6,175	25,462	21,497
Research and development	3,590	3,343	15,324	12,796
Selling and marketing	5,832	6,687	28,248	25,293
General and administrative	5,725	5,521	23,787	22,583
Intangible asset amortization	267	267	1,067	800
Total operating expenses	<u>21,929</u>	<u>21,993</u>	<u>93,888</u>	<u>82,969</u>
Loss from operations	(3,672)	(7,951)	(28,803)	(33,466)
Interest expense	(806)	(96)	(2,757)	(378)
Other income, net	75	34	202	140
Net loss and comprehensive loss	<u>\$ (4,403)</u>	<u>\$ (8,013)</u>	<u>\$ (31,358)</u>	<u>\$ (33,704)</u>
Net loss per common share, basic and diluted	<u>\$ (0.14)</u>	<u>\$ (0.29)</u>	<u>\$ (1.09)</u>	<u>\$ (1.30)</u>
Shares used to compute net loss per common share, basic and diluted	<u>31,705,603</u>	<u>27,672,806</u>	<u>28,830,472</u>	<u>25,994,193</u>

VERACYTE, INC.
CONDENSED BALANCE SHEETS
(In thousands)

	December 31, 2016	December 31, 2015
	<u>(Unaudited)</u>	<u>(1)</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 59,219	\$ 39,084
Accounts receivable	8,756	3,503
Supplies inventory	3,475	3,767
Prepaid expenses and other current assets	2,057	1,442
Restricted cash	120	118
Total current assets	<u>73,627</u>	<u>47,914</u>
Property and equipment, net	11,480	10,314
Finite-lived intangible assets, net	14,133	15,200
Goodwill	1,057	1,057
Restricted cash	603	603
Other assets	134	159
Total assets	<u><u>\$ 101,034</u></u>	<u><u>\$ 75,247</u></u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 2,424	\$ 5,085
Accrued liabilities	9,110	8,689
Deferred Genzyme co-promotion fee	—	948
Total current liabilities	<u>11,534</u>	<u>14,722</u>
Long-term debt	24,918	4,990
Capital lease liability, net of current portion	599	—
Deferred rent, net of current portion	4,402	4,283
Total liabilities	<u>41,453</u>	<u>23,995</u>
Total stockholders' equity	<u>59,581</u>	<u>51,252</u>
Total liabilities and stockholders' equity	<u><u>\$ 101,034</u></u>	<u><u>\$ 75,247</u></u>

(1) The condensed balance sheet at December 31, 2015 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 14, 2016.

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Source: Veracyte

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