
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 3, 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 November 3, 2016, Veracyte, Inc. issued a press release announcing its financial results for the quarter ended September 30, 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 November 3, 2016.

For Immediate Release

Veracyte Announces Third Quarter 2016 Financial Results

Grew Revenue 51%, Compared to the Third Quarter of 2015

Secured Draft Medicare Local Coverage Decisions for Percepta®

Launched Envisia™ Genomic Classifier for IPF

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

SOUTH SAN FRANCISCO, Calif., November 3, 2016 --- Veracyte, Inc. (NASDAQ: VCYT) today announced financial results for the third quarter ended September 30, 2016 and provided an update on recent business progress. For the third quarter of 2016, revenue was \$18.6 million, an increase of 51%, compared to \$12.3 million for the third quarter of 2015. Afirma® Gene Expression Classifier (GEC) volume was 5,740 tests, an increase of 14%, compared to the same period in 2015.

"We had tremendous success across our business since our second quarter call," said Bonnie Anderson, Veracyte's president and chief executive officer. "We delivered robust revenue growth in the third quarter, while experiencing Afirma GEC volume growth that aligns with the seasonal cadence of our business. We achieved a major Medicare coverage milestone for Percepta and we launched the Envisia Genomic Classifier, our third commercial product, while demonstrating a narrowing in cash burn for the quarter. We have a strong financial foundation for growth as we now target three clinical indications, which collectively comprise a more than \$2 billion annual opportunity."

Third Quarter 2016 Financial Results

- Revenue was \$18.6 million, an increase of 51%, compared to \$12.3 million for the third quarter of 2015. This includes a \$3.5 million increase due to improved predictability of payments, which allowed the company to accrue revenue that previously would have been recognized upon cash receipt.
- Operating expenses for the third quarter of 2016 were \$23.5 million, compared to \$21.2 million for the comparable period in 2015. Operating expenses included cost of revenue of \$6.4 million for the third quarter of 2016, compared to \$5.6 million for the same period in 2015.
- Net loss for the third quarter of 2016 was \$5.6 million, or \$0.20 per common share, versus a net loss of \$8.9 million, or \$0.32 per common share, for the same period in 2015.
- Cash and cash equivalents as of September 30, 2016 totaled \$31.7 million.
- Cash burn for the quarter was \$7.3 million, which includes \$4.0 million in final payments to Sanofi Genzyme under Veracyte's U.S. co-promotion agreement, which was terminated in September 2016.

Third Quarter and Recent Business Highlights

Afirma Growth and Reimbursement Progress:

- Increased the number of contracted lives by approximately 15 million, to nearly 155 million. This included executing a contract with Blue Shield of California, which brings the total number of contracted Blues plan lives to over 25 million.
- Six studies were presented by external researchers at the 86th Annual Meeting of the American Thyroid Association (ATA), which reinforce the Afirma GEC's clinical value and utility in thyroid cancer diagnosis.
- Veracyte scientists also presented data at the ATA meeting showing the potential to maintain the Afirma GEC's high sensitivity and negative predictive value, while potentially increasing the test's specificity to 70-80%. The prototype enhanced Afirma GEC combines rich RNA sequencing data and machine learning to optimize test performance.

Percepta Coverage and Commercial Expansion:

- Secured three draft Medicare local coverage decisions through the Palmetto GBA MoDx program covering over 35 million – or nearly two thirds – of the 57 million Medicare beneficiaries in the United States as part of lung cancer screening and diagnosis.
- Findings from two clinical utility studies were presented at the CHEST Annual Meeting 2016 showing that use of the Percepta classifier led to a significant reduction in surgeries or other invasive procedures in patients being evaluated for potential lung cancer.

Envisia Launch:

- Announced launch of the Envisia Genomic Classifier, which the company believes to be the first commercially available test to enable improved diagnosis of idiopathic pulmonary fibrosis without the need for invasive surgery.
- Unveiled strong clinical validation data from an independent test set during the CHEST annual meeting demonstrating the genomic test's ability to accurately identify usual interstitial pneumonia, a classic diagnostic pattern whose presence is essential to IPF diagnosis.

2016 Financial Outlook

Veracyte is increasing its 2016 annual revenue guidance to \$62.0 million to \$65.0 million (formerly \$59.0 million to \$63.0 million). Afirma GEC test volume is expected to be at the lower end of the previously guided range of 24,000 to 25,500 tests performed in 2016.

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 94530436. 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 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 185 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 2015, the company launched the Percepta® Bronchial Genomic Classifier, a test to evaluate patients with lung nodules that are suspicious for cancer, which has already received draft Medicare coverage. In October 2016, Veracyte launched its second pulmonology product, the Envisia™ Genomic Classifier, to improve diagnosis of interstitial lung diseases, including idiopathic pulmonary fibrosis. For more information, please visit 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 our products, 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 2016 revenue 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 enhance the performance of our Afirma test; the performance and acceptance of our Envisia test; 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; our ability to successfully launch our Envisia test and achieve adoption of our Percepta and Envisia tests; 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 June 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, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Revenue	\$ 18,603	\$ 12,335	\$ 46,828	\$ 35,461
Operating expenses:				
Cost of revenue	6,367	5,618	18,947	15,322
Research and development	4,006	3,563	11,734	9,453
Selling and marketing	7,087	6,048	22,416	18,606
General and administrative	5,763	5,728	18,062	17,062
Intangible asset amortization	266	266	800	533
Total operating expenses	23,489	21,223	71,959	60,976
Loss from operations	(4,886)	(8,888)	(25,131)	(25,515)
Interest expense	(799)	(92)	(1,951)	(269)
Other income, net	48	35	127	93
Net loss and comprehensive loss	\$ (5,637)	\$ (8,945)	\$ (26,955)	\$ (25,691)
Net loss per common share, basic and diluted	\$ (0.20)	\$ (0.32)	\$ (0.97)	\$ (1.01)
Shares used to compute net loss per common share, basic and diluted	27,916,819	27,640,806	27,865,100	25,428,506

VERACYTE, INC.
CONDENSED BALANCE SHEETS
(In thousands)

	September 30, 2016	December 31, 2015
	(Unaudited)	(1)
Assets		
Current assets:		
Cash and cash equivalents	\$ 31,699	\$ 39,084
Accounts receivable	6,312	3,503
Supplies inventory	3,416	3,767
Prepaid expenses and other current assets	1,405	1,442
Restricted cash	120	118
Total current assets	42,952	47,914
Property and equipment, net	10,435	10,314
Finite-lived intangible assets, net	14,400	15,200
Goodwill	1,057	1,057
Restricted cash	603	603
Other assets	203	159
Total assets	\$ 69,650	\$ 75,247
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 3,081	\$ 5,085
Accrued liabilities	7,189	8,689
Deferred Genzyme co-promotion fee	—	948
Total current liabilities	10,270	14,722
Long-term debt	24,891	4,990
Deferred rent, net of current portion	4,484	4,283
Total liabilities	39,645	23,995
Total stockholders' equity	30,005	51,252
Total liabilities and stockholders' equity	\$ 69,650	\$ 75,247

(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.

#

Source: Veracyte

Media:

Tracy Morris

650-380-4413

Tracy.Morris@Veracyte.com

Investors:

Pam Lord

Canale Communications

619-849-6003

pam@canalecomm.com