

VERACYTE, INC.

FORM 8-K (Current report filing)

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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): May 3, 2017

VERACYTE, INC.

(Exact name of registrant as specified in its charter)

	DELAWARE	001-36156	20-5455398		
	(State or other jurisdiction of incorporation)	Commission File Number	(IRS Employer Identification No.)		
6000 Shoreline Court, Suite 300, South San Francisco California		0,	94080		
	(Address of principal executive offices)		(Zip Code)		
	Registrant's	telephone number, including area code: (650) 24	3-6300		
		N/A			
	(Former	name or former address, if changed since last repo	ort.)		
	ck the appropriate box below if the Form 8-K filing is issions:	intended to simultaneously satisfy the filing oblig	gation of the registrant under any of the following		
	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 I	ment communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))			
	Pre-commencement communications pursuant to I	e-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))			
	cate by check mark whether the registrant is an emerg	ing growth company as defined in Rule 405 of the	e Securities Act of 1933 or Rule 12b-2 of the		
Eme	erging growth company 🗵				
	n emerging growth company, indicate by check mark is sed financial accounting standards provided pursuant	•	d transition period for complying with any new or		

Item 2.02 Results of Operations and Financial Condition.

On May 3, 2017, Veracyte, Inc. issued a press release announcing its financial results for the quarter ended March 31, 2017. 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 May 3, 2017.

SIGNATURE

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: March 3, 2017

VERACYTE, INC.

By: /s/ Keith S. Kennedy

Name: Keith S. Kennedy

Title: Chief Financial Officer

(Principal Financial and Accounting Officer)

Veracyte Announces First Quarter 2017 Financial Results

SOUTH SAN FRANCISCO, Calif., May 3, 2017 ---

Revenue was \$16.4 Million, a 21% Growth Over Prior Year

Cash Burn was \$8.3 Million, a 28% Improvement Over Prior Year

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

Veracyte, Inc. (NASDAQ: VCYT) today announced financial results and business progress for the first quarter ended March 31, 2017. Revenue was \$16.4 million for the quarter, an increase of 21%, compared to \$13.6 million for the first quarter of 2016.

"We sustained strong revenue growth during the quarter and executed on key milestones driving momentum across our business," said Bonnie Anderson, Veracyte's chief executive officer and chairman. "We increased payer coverage and in-network contracts for the Afirma [®] GEC, are on track with implementation of our Quest Diagnostics agreement, and unveiled strong data from the pivotal clinical validation study for our next-generation Afirma Genomic Sequencing Classifier, which will be presented at the AACE annual meeting this week. We received final Medicare coverage and pricing for the Percepta [®] Bronchial Genomic Classifier and are poised to begin ramping test volume and revenue."

First Quarter 2017 Financial Results

For the three-month period ended March 31, 2017, as compared to the first quarter of 2016:

- Revenue was \$16.4 million, an increase of 21%;
- Operating Expenses were \$23.9 million, an increase of 3%;
- Net Loss and Comprehensive Loss was \$8.2 million, an 18% improvement;
- Cash Burn (which is defined as net cash used in operating activities and net capital expenditures) was \$8.3 million, a 28% improvement; and
- Cash and Cash Equivalents was \$51.5 million at March 31, 2017.

First Quarter 2017 and Recent Business Highlights

Commercial Growth:

- Grew Afirma Gene Expression Classifier (GEC) volume by 9% during the first quarter of 2017, compared to the first quarter of 2016.
- Executed agreement with Quest Diagnostics, which is now poised to offer the Afirma GEC to its large network of physician customers through its AmeriPath anatomic pathology business.

Reimbursement Progress:

- Announced ten new coverage policies for the Afirma GEC with Blues plans and secured coverage from the Blues Federal Employee Program. This brings the total number of covered lives for the test to nearly 230 million, including more than 75 million Blues plan members.
- Expanded the number of health plan members with in-network access to the Afirma GEC to approximately 160 million, including more than 30 million through Blues plans.
- Secured final Medicare coverage and pricing for the Percepta classifier for use in lung cancer screening and diagnosis, that is in line with our expectations and similar to the Medicare price for the Afirma GEC.

Clinical Evidence Development:

- Unveiled data from our pivotal clinical validation study demonstrating that the next-generation Afirma Genomic Sequencing Classifier achieved its endpoint of identifying 30% more benign patients than the current GEC. The new data will be shared May 4 during the American Association of Clinical Endocrinologists annual meeting in Austin, Texas.
- · A study demonstrating the cost-effectiveness of the Percepta classifier was accepted for publication in a major pulmonology journal.

2017 Outlook

Veracyte reiterates its 2017 annual revenue guidance of \$76 to \$84 million and annual cash burn of \$25 to \$27 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 4181279. 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 March 31, 2017. 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 March 31,

	2017	2016
Revenue	\$ 16,432	\$ 13,550
Operating expenses:		
Cost of revenue	6,297	6,279
Research and development	4,030	3,461
Selling and marketing	7,336	7,066
General and administrative	6,019	6,228
Intangible asset amortization	267	267
Total operating expenses	23,949	 23,301
Loss from operations	(7,517)	(9,751)
Interest expense	(800)	(367)
Other income, net	100	43
Net loss and comprehensive loss	\$ (8,217)	\$ (10,075)
Net loss per common share, basic and diluted	\$ (0.24)	\$ (0.36)
Shares used to compute net loss per common share, basic and diluted	33,823,889	 27,817,993

VERACYTE, INC. CONDENSED BALANCE SHEETS (In thousands)

	March 31, 2017	December 31, 2016
	(Unaudited)	(1)
Assets		
Current assets:		
Cash and cash equivalents	\$ 51,506	\$ 59,219
Accounts receivable	9,125	8,756
Supplies inventory	3,443	3,475
Prepaid expenses and other current assets	2,101	2,057
Restricted cash	120	120
Total current assets	66,295	73,627
Property and equipment, net	10,657	11,480
Finite-lived intangible assets, net	13,867	14,133
Goodwill	1,057	1,057
Restricted cash	603	603
Other assets	127	134
Total assets	\$ 92,606	\$ 101,034
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 2,611	\$ 2,424
Accrued liabilities	6,800	9,110
Deferred Genzyme co-promotion fee	C	0
Total current liabilities	9,411	11,534
Long-term debt	24,944	24,918
Capital lease liability, net of current portion	528	599
Deferred rent, net of current portion	4,373	4,402
Total liabilities	39,256	41,453
Total stockholders' equity	53,350	59,581
Total liabilities and stockholders' equity	\$ 92,606	\$ 101,034

(1) The condensed balance sheet at December 31, 2016 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 1, 2017.

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Source: Veracyte

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