

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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Industry	Biotechnology & Medical Research
Sector	Healthcare
Fiscal Year	12/31

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): July 31, 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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 or Rule 12b-2 of the Securities Exchange Act of 1934.

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02 Results of Operations and Financial Condition.

On July 31, 2017, Veracyte, Inc. issued a press release announcing its financial results for the quarter ended June 30, 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 July 31, 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: July 31, 2017

VERACYTE, INC.

By: /s/ Keith S. Kennedy

Name: Keith S. Kennedy

Title: *Chief Financial Officer*

(Principal Financial and Accounting Officer)



Veracyte Announces Second Quarter 2017 Financial Results

*Reports 25% Revenue Growth, to \$18.4 Million, and
37% Improvement in Loss from Operations Over Prior Year
Conference Call and Webcast Today at 4:30 p.m. ET*

SOUTH SAN FRANCISCO, Calif., July 31, 2017 -- Veracyte, Inc. (NASDAQ: VCYT) today announced financial results for the second quarter ended June 30, 2017 and provided an update on recent business progress. For the second quarter of 2017, revenue was \$18.4 million, an increase of 25%, compared to \$14.7 million for the second quarter of 2016.

"Our strong results for the quarter underscore our ability to execute against our plans," said Bonnie Anderson, Veracyte's chairman and chief executive officer. "We achieved key milestones during the quarter, including establishing coverage for the Afirma classifier by all major insurance plans; launching the next-generation version of the classifier, with improved performance; and significantly extending our market reach to physicians. In addition, we have laid the foundation to reach our commercialization goals for the Percepta Bronchial Genomic Classifier in lung cancer diagnosis. We are thrilled with this progress and believe that we are poised to accelerate growth in the second half of the year."

Second Quarter 2017 Financial Results

For the second quarter of 2017, as compared to the second quarter of 2016:

- *Revenue* increased 25%, to \$18.4 million;
- *Operating Expenses* declined 1%, to \$25.0 million;
- *Net Loss and Comprehensive Loss* improved 35% to \$7.3 million;
- *Cash Burn* (which is defined as net cash used in operating activities and net capital expenditures) improved 41%, to \$5.0 million; and
- *Cash and Cash Equivalents* was \$46.5 million at June 30, 2017.

Second Quarter 2017 and Recent Business Highlights

Commercial Achievements:

- Grew Afirma genomic classifier volume by 11% in the second quarter of 2017, compared to the second quarter of 2016;
- Initiated the transition to the next-generation Afirma Genomic Sequencing Classifier (GSC), which can save an estimated 70% of benign patients from unnecessary thyroid surgery to rule out thyroid cancer;
- Initiated access to the Afirma genomic classifier through Quest/AmeriPath division's extensive network of service providers; and
- Accepted our first commercial orders for the Percepta genomic classifier, which aids in the screening and diagnosis of lung cancer.

Reimbursement Progress:

- Received Anthem and additional Blues coverage for our Afirma classifier, which is now one of the few genomic assays to attain coverage by virtually all health plans in the U.S.; and
- Signed five new contracts through Regence Blue Cross and Blue Cross of Kansas, bringing the total contracted lives for our Afirma classifier to approximately 163 million.

Clinical Evidence Development:

- Delivered podium presentation at the World Congress on Thyroid Cancer of pivotal clinical validation data for the next-generation Afirma GSC;
- Published a clinical utility study in the Journal of Thoracic Oncology, demonstrating that adoption of the Percepta classifier in lung cancer screening and diagnosis can meaningfully reduce invasive procedures and associated costs, and is cost-effective across a range of assumptions;
- Presented pivotal clinical validation data for the Envisia Genomic Classifier at the American Thoracic Society 2017 International Conference, demonstrating the classifier's unique ability to identify patients likely to have idiopathic pulmonary fibrosis (IPF), using a non-invasive sample; and
- Initiated the CATALYST study to evaluate the clinical utility of the Envisia classifier in the diagnosis of IPF .

2017 Financial 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 call may be accessed as follows:

Veracyte Second Quarter 2017 Conference Call **4:30 p.m. ET Today**

Website: <http://investor.veracyte.com>

Dial-in number (U.S.): (855) 541-0980

International number: (970) 315-0440

Conference ID: 44718214

The webcast replay will be available on the company's website approximately two hours following completion of the call.

About Veracyte

Veracyte 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 classifiers, 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 our ability to execute against

our plans, our belief that we have laid the foundation to reach our commercialization goals for the Percepta classifier, our belief that we are poised to accelerate growth in the second half of 2017, our belief as to the size of our addressable markets, our expectations regarding full-year 2017 revenue and cash burn guidance, our expectations regarding reimbursement coverage and policies, and the benefits and attributes of our tests, including our next-generation Afirma GSC. 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 classifier; the performance and acceptance of our Percepta and Envisia classifiers; our ability to increase usage of and reimbursement for the Afirma classifier and to obtain adequate reimbursement for our Percepta and Envisia classifiers, 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 classifiers; 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 June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Revenue	\$ 18,406	\$ 14,675	\$ 34,838	\$ 28,225
Operating expenses:				
Cost of revenue	6,960	6,301	13,257	12,580
Research and development	3,603	4,267	7,633	7,728
Selling and marketing	7,994	8,263	15,330	15,329
General and administrative	6,192	6,071	12,211	12,299
Intangible asset amortization	266	267	533	534
Total operating expenses	25,015	25,169	48,964	48,470
Loss from operations	(6,609)	(10,494)	(14,126)	(20,245)
Interest expense	(808)	(785)	(1,608)	(1,152)
Other income, net	119	36	219	79
Net loss and comprehensive loss	\$ (7,298)	\$ (11,243)	\$ (15,515)	\$ (21,318)
Net loss per common share, basic and diluted	\$ (0.22)	\$ (0.40)	\$ (0.46)	\$ (0.77)
Shares used to compute net loss per common share, basic and diluted	33,873.128	27,859.918	33,848.645	27,838.955

VERACYTE, INC.
CONDENSED BALANCE SHEETS
(In thousands of dollars)

	<u>June 30, 2017</u>	<u>December 31, 2016</u>
	(Unaudited)	(See Note 1)
Assets		
Current assets:		
Cash and cash equivalents	\$ 46,463	\$ 59,219
Accounts receivable	11,027	8,756
Supplies inventory	3,317	3,475
Prepaid expenses and other current assets	1,933	2,057
Restricted cash	120	120
Total current assets	<u>62,860</u>	<u>73,627</u>
Property and equipment, net	10,093	11,480
Finite-lived intangible assets, net	13,600	14,133
Goodwill	1,057	1,057
Restricted cash	603	603
Other assets	134	134
Total assets	<u>\$ 88,347</u>	<u>\$ 101,034</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 2,349	\$ 2,424
Accrued liabilities	8,450	9,110
Total current liabilities	<u>10,799</u>	<u>11,534</u>
Long-term debt	24,971	24,918
Capital lease liability, net of current portion	456	599
Deferred rent, net of current portion	4,277	4,402
Total liabilities	<u>40,503</u>	<u>41,453</u>
Total stockholders' equity	47,844	59,581
Total liabilities and stockholders' equity	<u>\$ 88,347</u>	<u>\$ 101,034</u>

(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.

VERACYTE, INC.
Condensed Statements of Cash Flows
(Unaudited)
(In thousands of dollars)

	Six Months Ended June 30,	
	2017	2016
Operating activities		
Net loss	\$ (15,515)	\$ (21,318)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,846	1,703
Bad debt expense	—	68
Loss on disposal of property and equipment	—	12
Genzyme co-promotion fee amortization	—	(721)
Stock-based compensation	3,214	3,173
Conversion of accrued interest on long-term debt	—	192
Amortization and write-off of debt discount and issuance costs	53	119
Interest on debt balloon payment and prepayment penalty	—	206
Changes in operating assets and liabilities:		
Accounts receivable	(2,271)	48
Supplies inventory	158	265
Prepaid expenses and current other assets	25	47
Other assets	—	(13)
Accounts payable	266	(805)
Accrued liabilities and deferred rent	(772)	712
Net cash used in operating activities	(12,996)	(16,312)
Investing activities		
Purchases of property and equipment	(728)	(3,587)
Proceeds from sale of property and equipment	440	—
Change in restricted cash	—	(2)
Net cash used in investing activities	(288)	(3,589)
Financing activities		
Proceeds from the issuance of long-term debt, net of debt issuance costs	—	24,452
Payment of long-term debt	—	(5,000)
Payment of end-of-term debt obligation and prepayment penalty	—	(288)
Proceeds from the issuance of common stock in a public offering, net of costs	200	—
Payment of capital lease liability	(135)	—
Proceeds from the exercise of common stock options and employee stock purchases	463	646
Net cash provided by financing activities	528	19,810
Net decrease in cash and cash equivalents	(12,756)	(91)
Cash and cash equivalents at beginning of period	59,219	39,084
Cash and cash equivalents at end of period	\$ 46,463	\$ 38,993
Supplementary cash flow information of non-cash investing and financing activities:		
Purchases of property and equipment included in accounts payable and accrued liabilities	\$ —	\$ 42

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