
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): April 30, 2019

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 April 30, 2019, Veracyte, Inc. issued a press release announcing its financial results for the quarter ended March 31, 2019. 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 April 30, 2019.
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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: April 30, 2019

VERACYTE, INC.

By: /s/ Keith Kennedy

Name: Keith Kennedy

Title: *Chief Financial Officer*

(Principal Financial and Accounting Officer)



Veracyte Announces First Quarter 2019 Financial Results

Grew Revenue by 47% to \$29.5 Million

Grew Genomic Test Volume by 33% to 9,162 Tests

Company Raises 2019 Annual Revenue Guidance

Conference Call and Webcast Today at 5:00 p.m. ET

SOUTH SAN FRANCISCO, Calif., April 30, 2019 -- Veracyte, Inc. (Nasdaq: VCYT), a leading genomic diagnostics company, today announced financial results for the first quarter ended March 31, 2019 and provided an update on recent business progress.

"We delivered excellent results in the first quarter of 2019," said Bonnie Anderson, chairman and chief executive officer of Veracyte. "Product revenue and genomic volume both grew significantly in the quarter, and our biopharmaceutical service revenue exceeded our expectations. We also demonstrated financial discipline, improving our cash used in operating activities by 86%."

Anderson continued, "In addition, we received a final Medicare coverage decision for our Envisia Genomic Classifier and published clinical validation and clinical utility data in *The Lancet Respiratory Medicine*, positioning the test for commercial expansion nationwide. With this continued strong momentum, we believe we remain well-positioned for both near- and long-term growth."

First Quarter 2019 Financial Results

For the first quarter of 2019, as compared with the first quarter of 2018:

- *Revenue* was \$29.5 million, an increase of 47%; excluding biopharmaceutical services revenue, revenue was \$25.4 million, an increase of 27%;
- *Gross Margin* was 71%, an improvement of 1000 basis points or 10 percentage points;
- *Operating Expenses, Excluding Cost of Revenue*, were \$23.1 million, an increase of 9%;
- *Net Loss and Comprehensive Loss* was \$1.9 million, an improvement of 79%;
- *Basic and Diluted Net Loss Per Common Share* was \$0.05, an improvement of 81%;
- *Net Cash Used in Operating Activities* was \$1.0 million, an improvement of 86%; and
- *Cash and Cash Equivalents* were \$67.8 million at March 31, 2019.

First Quarter 2019 and Recent Business Highlights

- Recognized revenue for the first time for the Envisia classifier in the first quarter of 2019.
- Grew genomic test volume to 9,162 tests in the first quarter of 2019, an increase of 33% compared with the first quarter of 2018.
- Received a final Medicare coverage determination for the Envisia classifier through the MoIDX program effective April 1, 2019, making the test a covered service for nearly 60 million Medicare beneficiaries nationwide.

- Received coverage for the Afirma Genomic Sequencing Classifier (GSC) under the U.S. Department of Defense TRICARE program for approximately 9.4 million uniformed service members, retirees and their families around the world.
- Received regulatory approval for the Envisia classifier from the New York State Department of Health, making the test available to patients in the state effective immediately.

Strengthened Library of Clinical Evidence:

- Published clinical validation and utility study findings for the Envisia classifier in *The Lancet Respiratory Medicine*, demonstrating that the test can identify more than two-thirds of patients (70% sensitivity) with the hallmark pattern of idiopathic pulmonary fibrosis (IPF), with high accuracy (88% specificity), thus improving diagnosis - without the need for surgery.
- An independent real-world study on the Afirma GSC was published in *Thyroid* showing that at Brigham and Women's Hospital use of the test identified benign thyroid nodules nearly 40% more often than the original Afirma test. This improved performance was due to the test's enhanced ability to distinguish benign from cancerous Hürthle cells, a common but hard-to-diagnose thyroid nodule subtype.
- Published a manuscript on the Afirma GSC in *BMS Systems Biology* showcasing the development of the classifier using RNA whole-transcriptome sequencing and machine learning, enabling improved diagnosis of Hürthle cell benign adenoma from carcinoma within this subtype of thyroid nodules.
- Presented Afirma Xpression Atlas data at the ENDO 2019, revealing new insights into the genomic underpinning of medullary thyroid cancer (MTC). This variant and fusion information may help guide physicians in the preoperative evaluation, surgical planning and targeted therapy selections for patients diagnosed with this rare, but aggressive, form of thyroid cancer.

Updated 2019 Financial Outlook

Veracyte is increasing its 2019 annual revenue guidance to a range of \$117 million to \$121 million from its prior guidance range of \$113 million to \$117 million. The company continues to expect full-year 2019 net cash used in operating activities to be in the range of \$4 million to \$6 million and to achieve operating cash flow breakeven before the end of this year.

Conference Call and Webcast Details

Veracyte will host a conference call and webcast today at 5:00 p.m. Eastern Time to discuss the company's financial results and provide a general business update. The conference call will be webcast live from the company's website and will be available via the following link <https://edge.media-server.com/m6/p/jsjh76tc>.

The webcast should be accessed 10 minutes prior to the conference call start time. A replay of the webcast will be available for one year following the conclusion of the live broadcast and will be accessible on the company's website at <https://investor.veracyte.com/events-presentations>.

The conference call can be accessed as follows:

U.S./Canada participant dial-in number (toll-free):	(855) 541-0980
International participant dial-in number:	(970) 315-0440
Conference I.D.:	9289499

About Veracyte

Veracyte (Nasdaq: VCYT) is a leading genomic diagnostics company that improves patient care by providing trustworthy and actionable answers to challenging clinical questions. The company's products uniquely combine advanced genomic technology, clinical science and machine learning to provide answers that give physicians and patients a clear path forward, informing both diagnosis and treatment decisions without the need for costly, risky surgeries that are often unnecessary. Since its founding in 2008, Veracyte has commercialized five genomic tests, which are transforming the diagnosis of thyroid cancer, lung cancer and idiopathic pulmonary fibrosis. Veracyte is b

ased in South San Francisco, California. For more information, please visit www.veracyte.com and follow the company on Twitter (@veracyte).

Veracyte, Afirma, Percepta, Envisia and the Veracyte logo are trademarks of Veracyte, Inc.

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 belief that we have a strong foundation in place to drive revenue growth and achieve operating cash flow breakeven before the end of 2019, our beliefs regarding momentum in our business and potential drivers of future growth, our first quarter 2019 performance and our expectations regarding full-year 2019 revenue and net cash used in operating activities, the success of our Afirma Xpression Atlas platform, our expectations regarding our ability to expand commercialization of our Percepta and Envisia Genomic Classifiers, our expectations regarding our strategic collaboration with Johnson & Johnson, our ability to drive revenue growth across our endocrinology and pulmonology franchises, our estimates of the number of people covered under the TRICARE program, our belief that published clinical validation and utility study finding for the Envisia classifier can improve diagnosis and decrease the need for surgery, study results demonstrating that the Afirma GSC test has an enhanced ability to distinguish benign from cancerous Hürthle cells, our belief that variant and fusion information from the Afirma Xpression Atlas data may help guide physicians in preoperative evaluation, surgical planning and targeted therapy selections. 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 history of losses since inception; the commercialization, performance and acceptance of our Afirma, Percepta and Envisia classifiers; our dependence on a few payers for reimbursements and payments of our tests and a significant portion of our revenue; the complexity, time and expense associated with billing and collecting from payers for our classifiers; our ability to increase usage of and reimbursement for the Afirma, Percepta and Envisia classifiers, as well as any future products we may develop or sell; our dependence on physicians and patients who decide whether to order and use our tests; the fluctuation of our quarterly operating results; our ability to comply with federal and state licensing requirements and other laws and regulations applicable to our business, including potential regulation by the Food and Drug Administration or other regulatory bodies; our dependence on supplies for equipment and other materials used for our tests; 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 attract and retain key personnel; 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 potential for future clinical studies to contradict or undermine previously published clinical 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 Annual Report on Form 10-K for the year ended December 31, 2018. These forward-looking statements speak only as of the date hereof and Veracyte specifically disclaims any obligation to update these forward-looking statements.

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,	
	2019	2018
Revenue	\$ 29,529	\$ 20,041
Operating expenses:		
Cost of revenue	8,513	7,867
Research and development	3,435	3,675
Selling and marketing	12,477	11,543
General and administrative	6,904	5,644
Intangible asset amortization	267	267
Total operating expenses	<u>31,596</u>	<u>28,996</u>
Loss from operations	(2,067)	(8,955)
Interest expense	(303)	(448)
Other income, net	453	226
Net loss and comprehensive loss	<u>\$ (1,917)</u>	<u>\$ (9,177)</u>
Net loss per common share, basic and diluted	<u>\$ (0.05)</u>	<u>\$ (0.27)</u>
Shares used to compute net loss per common share, basic and diluted	<u>41,168,593</u>	<u>34,271,254</u>

VERACYTE, INC.
CONDENSED BALANCE SHEETS
(In thousands)

	March 31, 2019	December 31, 2018
	(Unaudited)	(1)
Assets		
Current assets:		
Cash and cash equivalents	\$ 67,841	\$ 77,995
Accounts receivable	16,615	13,168
Supplies	3,768	3,402
Prepaid expenses and other current assets	2,392	2,387
Total current assets	<u>90,616</u>	<u>96,952</u>
Property and equipment, net	8,114	8,940
Right-of-use assets - finance lease, net	735	—
Right-of-use assets - operating lease	9,630	—
Finite-lived intangible assets, net	11,733	12,000
Goodwill	1,057	1,057
Restricted cash	603	603
Other assets	1,049	1,086
Total assets	<u>\$ 123,537</u>	<u>\$ 120,638</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 4,064	\$ 2,516
Accrued liabilities	8,788	9,186
Current portion of long-term debt	—	1,357
Current portion of finance lease liability	233	—
Current portion of operating lease liability	1,244	—
Total current liabilities	<u>14,329</u>	<u>13,059</u>
Long-term debt	12,854	23,925
Deferred rent, net of current portion	—	3,899
Operating lease liability, net of current portion	12,582	—
Total liabilities	<u>39,765</u>	<u>40,883</u>
Total stockholders' equity	83,772	79,755
Total liabilities and stockholders' equity	<u>\$ 123,537</u>	<u>\$ 120,638</u>

(1) The condensed balance sheet at December 31, 2018 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 February 25, 2019.

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

	Three Months Ended March 31,	
	2019	2018
Operating activities		
Net loss	\$ (1,917)	\$ (9,177)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	945	980
Gain on disposal of property and equipment	(16)	—
Stock-based compensation	1,759	1,175
Other income	—	(93)
Amortization of debt issuance costs	8	8
Interest on end-of-term debt obligation	64	70
Changes in operating assets and liabilities:		
Accounts receivable	(3,447)	(482)
Supplies	(366)	767
Prepaid expenses and other current assets	(11)	(239)
Right-of-use assets - operating lease and operating lease liability	(80)	—
Other assets	37	(140)
Accounts payable	1,726	(510)
Accrued liabilities and deferred rent	287	228
Net cash used in operating activities	<u>(1,011)</u>	<u>(7,413)</u>
Investing activities		
Purchases of property and equipment	(765)	(227)
Proceeds from disposal of property and equipment	16	—
Net cash used in investing activities	<u>(749)</u>	<u>(227)</u>
Financing activities		
Payment of long-term debt	(12,500)	—
Proceeds from legal settlement regarding short-swing profits	—	403
Payment of finance lease liability	(75)	(71)
Proceeds from the exercise of common stock options and employee stock purchases	4,181	569
Net cash (used in) provided by financing activities	<u>(8,394)</u>	<u>901</u>
Net decrease in cash, cash equivalents and restricted cash	<u>(10,154)</u>	<u>(6,739)</u>
Cash, cash equivalents and restricted cash at beginning of period	78,598	34,494
Cash, cash equivalents and restricted cash at end of period	<u>\$ 68,444</u>	<u>\$ 27,755</u>
Supplementary cash flow information of non-cash investing and financing activities:		
Operating lease liability arising from obtaining right-of-use assets - operating lease	\$ 14,118	\$ —
Purchases of property and equipment included in accounts payable and accrued liabilities	\$ 95	\$ 56
Interest paid on debt	\$ 228	\$ 356

CASH, CASH EQUIVALENTS AND RESTRICTED CASH
(Unaudited)
(In thousands of dollars)

	<u>March 31, 2019</u>	<u>December 31, 2018</u>
Cash and cash equivalents	\$ 67,841	\$ 77,995
Restricted cash	603	603
Total cash, cash equivalents and restricted cash	<u>\$ 68,444</u>	<u>\$ 78,598</u>

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Investor & Media Contact:

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