## **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): February 25, 2019

# VERACYTE, INC.

(Exact name of registrant as specified in its charter)

DELAWARE

001-36156

20-5455398 (IRS Employer Identification

No.)

(State or other jurisdiction of incorporation)

**Commission File Number** 

94080

(Zip Code)

6000 Shoreline Court, Suite 300, South San Francisco, California

(Address of principal executive offices)

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) 0

Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12) 0

Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b)) 0

Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c)) 0

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 o

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. o

#### Item 2.02 Results of Operations and Financial Condition.

On February 25, 2019, Veracyte, Inc. issued a press release announcing its financial results for the quarter and year ended December 31, 2018. 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 <u>Press release issued by Veracyte, Inc. dated February 25, 2019.</u>

#### 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: February 25, 2019

VERACYTE, INC.

By: /s/ Keith Kennedy

Name:Keith KennedyTitle:Chief Financial Officer

(Principal Financial and Accounting Officer)



### Veracyte Announces Fourth Quarter and Full-Year 2018 Financial Results and Provides 2019 Financial Outlook

2018 Revenue Grew 28% to \$92 million

Three Commercial Products and Biopharma Collaborations to Drive Growth in 2019

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

SOUTH SAN FRANCISCO, Calif., February 25, 2019 --- Veracyte, Inc. (Nasdaq: VCYT) today announced financial results and business progress for the quarter and full year ended December 31, 2018, and provided financial guidance for 2019.

"We delivered exceptional growth in 2018 and are off to a strong start in 2019," said Bonnie Anderson, Veracyte's chairman and chief executive officer. "Our 2018 performance was driven by several factors. Our Afirma GSC and Xpression Atlas launch broadened our thyroid offering to inform both diagnosis and treatment decisions, and the first full year of Percepta classifier adoption was strong with the fourth quarter acceleration in growth positioning us for a strong 2019. Clearly, our multi-product sales strategy that is designed to give us the leverage we need to be a profitable enterprise is working."

Anderson added, "In 2018, we also entered into biopharmaceutical collaborations with Loxo Oncology and Johnson & Johnson Innovation and the Johnson & Johnson Lung Cancer Initiative that recognize the value of our novel scientific platform and can help advance our pipeline. As we look to 2019 and beyond, we believe we are well-positioned for continued success as we further increase the number of patients whose lives can be improved by our innovative tests."

#### Fourth Quarter and Full-Year 2018 Financial Results

For the three- and twelve-month periods ended December 31, 2018, compared to the prior year:

- Revenue was \$25.8 million and \$92.0 million, respectively, an increase of 31% and 28%;
- Gross Margin was 66% and 64%, respectively, an increase of 6% and 3%;
- Operating Expenses, Excluding Cost of Revenue, were \$20.1 million and \$81.2 million, respectively, an increase of 12% and 15%;
- Net Loss and Comprehensive Loss was (\$3.1) million and (\$23.0) million, respectively, an improvement of 63% and 26%;
- Basic and Diluted Net Loss Per Common Share was (\$0.08) and (\$0.62), respectively, an improvement of 67% and 32%;
- Net Cash Used in Operating Activities was \$1.2 million and \$13.5 million, respectively, an improvement of 79% and 44%;
- Cash Burn<sup>1</sup> was \$1.7 million and \$15.4 million, respectively, an improvement of 73% and 39%; and
- Cash and Cash Equivalents were \$78.0 million at December 31, 2018.

<sup>1</sup>A reconciliation of net cash used in operating activities to cash burn has been provided in the financial statement tables included in this press release. An explanation of cash burn is also included below under "Non-GAAP Financial Measures."

## 2018 Full-Year and Recent Business Highlights

## Commercial Expansion:

- Grew total genomic test volume to 9,154 tests in the fourth quarter of 2018, representing 28% growth over 2017, which resulted in full-year 2018 growth of 22% over 2017, or 31,710 tests.
- Transitioned all Afirma customers to the second-generation Afirma Genomic Sequencing Classifier (GSC) platform and launched the Afirma Xpression Atlas to provide a comprehensive solution that informs both thyroid cancer diagnosis and treatment decisions. Notably, 30% of Afirma GSC orders included Xpression Atlas in 2018, ahead of the company's expectations.
- Grew Percepta Bronchial Genomic Classifier volume to nearly 1,550 tests in its first full year of commercialization, with genomic volume accelerating 74% sequentially from the third quarter to the fourth quarter of 2018.
- Established 20 leading Early Access Program (EAP) sites across the United States for Envisia in 2018, addressing
  physician demand for patient access to the classifier which improves idiopathic pulmonary fibrosis (IPF) diagnosis and
  builds a solid foundation for the company to commercially expand it in 2019.

### **Biopharmaceutical Collaborations**

- Executed a long-term strategic collaboration with Johnson & Johnson, LLC and Johnson & Johnson's Lung Cancer Initiative to advance diagnostics, including a nasal swab test, for early lung cancer detection. Veracyte estimates the combined monetary and non-monetary value of the collaboration to be more than \$50 million. The company believes this collaboration expands its addressable lung cancer diagnostic market to a more than \$30 billion global opportunity.
- Entered into a research collaboration with Loxo Oncology, through which Loxo has access to data from Veracyte's Afirma Xpression Atlas platform to help in its development of therapies for patients with genetically defined cancers, including thyroid cancer.

## Reimbursement Progress:

- Received draft Medicare coverage for the Envisia Genomic Classifier through the MoIDX program, with a final positive coverage decision expected in early 2019.
- Achieved in-network status as a service provider with the last of the major commercial health plans, which Veracyte believes will facilitate coverage and reimbursement for its Percepta and Envisia classifiers.

## Evidence Development:

- Afirma Published clinical validation data for the Afirma GSC in JAMA Surgery, demonstrating the next-generation test's ability to help approximately 70% of patients with indeterminate thyroid nodules avoid unnecessary surgery. Presented 12 Afirma studies at three endocrinology conferences, including real-world data showing that the Afirma GSC is helping even more patients avoid unnecessary surgery than is suggested by the clinical validation study findings.
- **Percepta** Presented early, interim results at the 2018 CHEST Annual Meeting from the ongoing registry clinical utility study showing the test changed clinical decision-making and reduced invasive procedures at every evaluation time point up to 12 months post-testing.
- Envisia Published a study quantifying and qualifying the challenges in obtaining timely, accurate diagnosis of IPF and other interstitial lung diseases, thus underscoring the clinical need for the

Envisia classifier. Presented data at a leading pulmonology conference demonstrating the test's ability to improve the diagnosis of IPF without the need for surgery.

## Financing and Debt Facility:

- In July 2018, Veracyte issued and sold 5,750,000 shares of common stock in a registered public offering, including the underwriters' exercise in full of their option to purchase an additional 750,000 shares, at a price to the public of \$10.25 per share. Net proceeds from the offering were approximately \$55.0 million.
- In January 2019, the company used \$12.5 million of cash and cash equivalents to reduce its principal debt balance from \$25.0 million to \$12.5 million.

## 2019 Outlook

Veracyte is guiding to full-year 2019 revenue in the range of \$113 million to \$117 million and full-year 2019 net cash used in operating activities in the range of \$4 million to \$6 million.

### **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/az9uzsk7. 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 approximately two hours following the completion of the call.

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.:	5498321

### **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 three genomic tests, which are transforming the diagnosis of thyroid cancer, lung cancer and idiopathic pulmonary fibrosis. Veracyte is based 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, our beliefs regarding momentum in our business and potential drivers of future growth, 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 receive Medicare reimbursement and expand commercialization of our Percepta and Envisia Genomic Classifiers, our expectations regarding our strategic collaboration with Johnson & Johnson, and our ability to drive revenue growth across our endocrinology and pulmonology franchises. Forwardlooking 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; our ability to successfully commercialize our Afirma classifier; the performance and acceptance of our 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 and Percepta classifiers and to obtain adequate reimbursement for our Envisia classifier, 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 guarterly 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 continue our momentum and growth; 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 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.

### **Non-GAAP Financial Measures**

To supplement our consolidated financial statements prepared in accordance with generally accepted accounting principles in the United States (GAAP), we monitor and consider cash burn, which is a non-GAAP financial measure. This non-GAAP financial measure is not based on any standardized methodology prescribed by GAAP and is not necessarily comparable to similarly-titled measures presented by other companies. We define cash burn as net cash used in operating activities plus net capital expenditures, such as net purchases of property and equipment. We believe cash burn to be a liquidity measure that provides useful information to management and investors about the amount of cash consumed by the operations of the business, including our purchases of property and equipment. A limitation of using this non-GAAP measure is that cash burn does not represent the total change in cash and cash equivalents for the period because it excludes cash provided by or used for other investing and financing activities in the statements of cash flows in our financial statements in our Annual Report on Form 10-K and by presenting cash flows from investing and financing activities in our reconciliation of cash burn. In addition, it is important to note that other companies, including companies in our industry, may not use cash burn, may calculate cash burn in a different manner than we do, or may use other financial measures to evaluate their performance, all of which could reduce the usefulness of cash burn as a comparative measure.

Because of these limitations, cash burn should not be considered in isolation from, or as a substitute for, financial information prepared in accordance with GAAP. Investors are encouraged to review the reconciliation of cash burn to net cash used in operating activities provided in the tables below.

## 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,			
		2018 2017		2018		2017		
Revenue	\$	25,750	\$	19,596	\$	92,008	\$	71,953
Operating expenses:								
Cost of revenue		8,704		7,769		33,078		28,195
Research and development		3,125		3,202		14,820		13,881
Selling and marketing		10,066		9,045		41,313		32,260
General and administrative		6,645		5,357		23,963		23,088
Intangible asset amortization		267		267		1,067		1,067
Total operating expenses		28,807		25,640		114,241		98,491
Loss from operations		(3,057)		(6,044)		(22,233)		(26,538)
Interest expense		(536)		(2,518)		(1,963)		(4,941)
Other income, net		488		123		1,197		476
Net loss and comprehensive loss	\$	(3,105)	\$	(8,439)	\$	(22,999)	\$	(31,003)
Net loss per common share, basic and diluted	\$	(0.08)	\$	(0.24)	\$	(0.62)	\$	(0.91)
Shares used to compute net loss per common share, basic and diluted		40,731,334		34,055,524		37,020,246		33,925,617

## VERACYTE, INC. CONDENSED BALANCE SHEETS (In thousands)

	Decer	December 31, 2017			
	(U	(1)			
Assets					
Current assets:					
Cash and cash equivalents	\$	77,995	\$	33,891	
Accounts receivable		13,168		12,716	
Supplies		3,402		5,324	
Prepaid expenses and other current assets		2,387		1,997	
Total current assets		96,952		53,928	
Property and equipment, net		8,940		9,688	
Finite-lived intangible assets, net		12,000		13,067	
Goodwill		1,057		1,057	
Restricted cash		603		603	
Other assets		1,086		326	
Total assets	\$	120,638	\$	78,669	
Liabilities and Stockholders' Equity					
Current liabilities:					
Accounts payable	\$	2,516	\$	3,853	
Accrued liabilities		9,186		8,175	
Current portion of long-term debt		1,357		_	
Total current liabilities		13,059		12,028	
Long-term debt		23,925		24,938	
Capital lease liability, net of current portion		_		308	
Deferred rent, net of current portion		3,899		4,170	
Total liabilities		40,883		41,444	
Total stockholders' equity		79,755		37,225	
Total liabilities and stockholders' equity	\$	120,638	\$	78,669	

(1) The condensed balance sheet at December 31, 2017 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 27, 2018.

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

	Year Ended December 31,					
	2018			2017		
Operating activities						
Net loss	\$	(22,999)	\$	(31,003)		
Adjustments to reconcile net loss to net cash used in operating activities:						
Depreciation and amortization		3,920		3,841		
Loss on disposal of property and equipment		_		12		
Stock-based compensation		5,958		6,617		
Other income		(93)		—		
Amortization and write-off of debt discount and issuance costs		32		472		
Interest on end-of-term debt obligations and prepayment penalty		312		1,589		
Changes in operating assets and liabilities:						
Accounts receivable		(452)		(3,960)		
Supplies		1,922		(1,849)		
Prepaid expenses and current other assets		(517)		(7)		
Other assets		(760)		(192)		
Accounts payable		(1,568)		1,728		
Accrued liabilities and deferred rent		724		(1,163)		
Net cash used in operating activities		(13,521)		(23,915)		
Investing activities						
Purchases of property and equipment		(1,874)		(1,755)		
Proceeds from sale of property and equipment		—		440		
Net cash used in investing activities		(1,874)		(1,315)		
Financing activities						
Proceeds from the issuance of long-term debt, net of debt issuance costs		—		24,880		
Proceeds from the issuance of common stock in a public offering, net of costs		55,038		200		
Payment of long-term debt		—		(25,385)		
Payment of end-of-term debt obligation and prepayment penalty		—		(1,536)		
Proceeds from legal settlement regard short-swing profits		403		—		
Payment of capital lease liability		(292)		(274)		
Proceeds from the exercise of common stock options and employee stock purchases		4,350		1,897		
Net cash provided by financing activities		59,499		(218)		
Net increase (decrease) in cash, cash equivalents and restricted cash		44,104		(25,448)		
Cash, cash equivalents and restricted cash at beginning of period		34,494		59,942		
Cash, cash equivalents and restricted cash at end of period	\$	78,598	\$	34,494		
Supplementary cash flow information of non-cash investing and financing activities:						
Purchases of property and equipment included in accounts payable	\$	273	\$	42		
Cash paid for interest on debt	\$	1,547	\$	2,718		
Cash paid for tax	\$	79	\$	21		

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

	Decer	nber 31, 2018	December 31, 2017		
Cash and cash equivalents	\$	77,995	\$	33,891	
Restricted cash - long-term		603		603	
Total cash, cash equivalents and restricted cash	\$	78,598	\$	34,494	

	Three Months Ended December 31,				Year Ended December 31,				
	2018		2017		2018		2017		
Net cash used in operating activities	\$	(1,226)	\$	(5,816)	\$	(13,521)	\$	(23,915)	
Plus purchases of property and equipment		(454)		(300)		(1,874)		(1,755)	
Less proceeds from the sale of property and equipment		—		—		—		440	
Cash burn	\$	(1,680)	\$	(6,116)	\$	(15,395)	\$	(25,230)	
Net cash used in investing activities	\$	(454)	\$	(300)	\$	(1,874)	\$	(1,315)	
Net cash provided by (used in) financing activities	\$	1,829	\$	(1,188)	\$	59,499	\$	(218)	

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Veracyte Investor & Media Contact: Angie McCabe Vice President, Investor Relations & Corporate Communications 650-243-6371 angie@veracyte.com