

**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 1, 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 94080**

(Address of principal executive offices) (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))

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**Item 8.01 Other Events.**

On November 1, 2016, Veracyte, Inc. announced that it has commenced an underwritten public offering of its common stock. A copy of the press release is attached hereto as Exhibit 99.1 and incorporated by reference herein.

Veracyte, Inc. has updated its disclosures, including the addition of certain risk factors. The updated disclosures are filed herewith as Exhibit 99.2 and are incorporated herein by reference.

**Item 9.01 Financial Statements and Exhibits.**

- (d) Exhibits
- 99.1 Press release issued by Veracyte, Inc. dated November 1, 2016.
- 99.2 Disclosures.

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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: November 1, 2016

VERACYTE, INC.

By /s/ Shelly D. Guyer  
Name: Shelly D. Guyer  
Title: Chief Financial Officer  
(Principal Financial and Accounting Officer)

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EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release issued by Veracyte, Inc. dated November 1, 2016.
99.2	Disclosures.

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## Veracyte Announces Proposed Public Offering of Common Stock

SOUTH SAN FRANCISCO, Calif., November 1, 2016 — Veracyte, Inc. (NASDAQ: VCYT) today announced that it has commenced an underwritten public offering of its common stock. All of the shares are being offered by Veracyte. In addition, Veracyte expects to grant the underwriters a 30-day option to purchase additional shares of its common stock at the public offering price, less underwriting discounts and commissions. The offering is subject to market and other conditions, and there can be no assurance as to whether or when the offering may be completed, or as to the actual size or terms of the offering.

Veracyte intends to use the net proceeds from the offering for working capital and other general corporate purposes. Veracyte may also use a portion of the net proceeds from the offering to acquire or invest in complementary businesses, technologies or other assets, although it has no present commitments or agreements to do so.

Leerink Partners LLC is acting as the sole book-running manager for the offering and BTIG, LLC is acting as lead manager.

The shares will be issued pursuant to a shelf registration statement previously filed with and subsequently declared effective by the Securities and Exchange Commission (SEC). A preliminary prospectus supplement and accompanying prospectus relating to the offering will be filed with the SEC and will be available on the SEC's website. A copy of the preliminary prospectus supplement and accompanying prospectus relating to the offering, when available, may be obtained by contacting Leerink Partners LLC, Attention: Syndicate Department, One Federal Street, 37th Floor, Boston, MA, 02110, by email at [syndicate@leerink.com](mailto:syndicate@leerink.com), or by telephone at (800) 808-7525, ext. 6142.

This press release does not and shall not constitute an offer to sell or the solicitation of an offer to buy any securities, nor shall there be any sale of these securities in any state or other jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state or other jurisdiction. Any offer, if at all, will be made only by means of a prospectus, including a prospectus supplement, forming a part of the effective registration statement.

### 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. 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. In October 2016, Veracyte launched its second pulmonology product, the Envisia™ Genomic Classifier, to improve diagnosis of interstitial lung diseases, including idiopathic pulmonary fibrosis.

### 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 relating to Veracyte's expectations regarding the completion, timing and size of the proposed public offering, its

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expectations with respect to granting the underwriters a 30-day option to purchase additional shares, and its intentions with respect to the use of net proceeds from the proposed offering. 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, those relating to related to completion of the public offering on the anticipated terms or at all, market conditions, the satisfaction of conditions to closing of the proposed offering, our ability to increase usage of and reimbursement for Afirma and to obtain reimbursement for 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 of commercialization; our ability to successfully achieve adoption of and reimbursement for our Percepta Bronchial Genomic Classifier; 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; our inclusion in clinical practice guidelines; the continued application of clinical guidelines to our products; our ability to compete; 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.

Source: Veracyte

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### Media:

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### Investors:

Pam Lord



## Overview

We are a molecular diagnostics company that focuses on genomic solutions that resolve diagnostic ambiguity, thus enabling physicians to make more informed treatment decisions at an early stage in patient care. By improving diagnostic accuracy, we aim to help patients avoid unnecessary invasive procedures while reducing healthcare costs. Our first commercial solution, the Afirma Thyroid FNA Analysis, or Afirma, centers on the proprietary Afirma Gene Expression Classifier, or GEC, which is becoming a new standard of care in thyroid cancer diagnosis. The Afirma GEC helps physicians reduce the number of unnecessary surgeries by approximately 50% by employing a proprietary 142-gene signature to identify benign thyroid nodules among those deemed indeterminate by cytopathology alone. An additional 25 genes are used to differentiate uncommon neoplasm subtypes. We established the Afirma GEC's clinical validity in a study published in *The New England Journal of Medicine* in 2012 and have demonstrated the test's clinical utility, cost effectiveness and analytical validity in over 20 studies published in peer-reviewed journals. The Afirma GEC is recommended in leading practice guidelines and is covered as a medically necessary test by payers for 185 million lives in the United States, including through Medicare and many commercial insurance plans. As of September 30, 2016, we had 155 million lives under contract. Since the commercial launch of Afirma in January 2011 through September 30, 2016, we have received 290,000 fine needle aspiration, or FNA, samples for evaluation using Afirma and performed over 65,000 GECs to resolve indeterminate cytopathology results. We estimate the addressable thyroid nodule diagnostic market opportunity today is approximately \$500 million per year in the United States, and we believe that there is an estimated \$300 million additional market opportunity for the Afirma GEC internationally.

In April 2015, we accelerated our entry into pulmonology with the launch of the Percepta Bronchial Genomic Classifier, which we obtained through our acquisition of Allegro Diagnostics Corp. in September 2014. The Percepta classifier is designed to improve lung cancer screening and diagnosis by helping to reduce unnecessary, invasive, risky and costly procedures in patients with suspicious lung nodules and lesions, typically found on CT scans. The 23-gene classifier identifies patients with lung nodules who are at low or very low risk of cancer following an inconclusive bronchoscopy result, making it possible to monitor these patients with CT scans in lieu of invasive diagnostic procedures. Clinical validation data from two prospective, multicenter studies, AEGIS I and II, were published in July 2015 in *The New England Journal of Medicine*. In February 2016, the first clinical utility study for the Percepta classifier was published in *CHEST*, the official journal of the American College of Chest Physicians, suggesting that use of the Percepta test could reduce unnecessary surgeries and other invasive procedures by as much as 50% in the evaluated patient population. Also in February 2016, analytical verification data for the Percepta classifier were published online in *BMC Cancer*, establishing the quality and reproducibility of our testing processes. As of September 2016, three Medicare Administrative Contractors have issued draft local coverage policies that, if finalized, would cover Percepta for Medicare-eligible patients in those regions. As of September 2016, more than 40 thought-leading academic and other institutions around the country are offering Percepta to their patients during this initial stage of commercialization. We estimate the U.S. market opportunity for Percepta to be \$425 million to \$525 million today and expect the market to increase in size as lung cancer screening expands. The European market opportunity for Percepta is estimated to be \$220 million.

In October 2016, we announced the launch of our third commercial test, the Envisia Genomic Classifier, which is also in pulmonology. This test is designed to enable improved diagnosis of idiopathic pulmonary fibrosis, or IPF, among patients presenting with a suspected interstitial lung disease, or ILD, without the need for surgery. The 190-gene classifier uses machine learning coupled with powerful, deep RNA sequencing to detect the presence or absence of usual interstitial pneumonia, or UIP, a classic diagnostic pattern that is essential for the diagnosis of IPF. In an independent test set, the Envisia classifier demonstrated high specificity (88%) and sensitivity (67%) for UIP on patient samples obtained through less-invasive bronchoscopy. The test's results showed high concordance with review of surgical

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samples by surgical pathology. Our initial focus for the Envisia classifier is on building the clinical evidence needed to secure coverage and reimbursement from Medicare and private payers. We estimate the addressable market for our Envisia test to be over \$500 million in the United States and Europe.

### Additional Risks Related to Our Business

***Our ability to use our net operating loss carryforwards may be limited and may result in increased future tax liability to us.***

We have incurred net losses since our inception and may never achieve profitability. To the extent that we continue to generate taxable losses, unused losses will carry forward to offset future taxable income, if any, until such unused losses expire. We may be unable to use these losses to offset income before those unused losses expire. Generally, a change of more than 50% in the ownership of a corporation's stock, by value, over a three-year period constitutes an ownership change for U.S. federal income tax purposes. An ownership change may limit a company's ability to use its net operating loss carryforwards attributable to the period prior to such change. In the event we have undergone an ownership change under Section 382 of the Internal Revenue Code, if we earn net taxable income, our ability to use our pre-change net operating loss carryforwards to offset U.S. federal taxable income may become subject to limitations, which could potentially result in increased future tax liability to us.

***Our financial results depend solely on sales of Afirma, and we will need to generate sufficient revenue from this and other diagnostic solutions to grow our business.***

All of our revenues have been derived from the sale of Afirma, which we commercially launched in January 2011. For the foreseeable future, we expect to derive substantially all of our revenue from sales of Afirma. We launched our first product in pulmonology for lung cancer, Percepta, in April 2015, and our commercialization efforts may not be successful. We also launched Envisia for improved diagnosis of Idiopathic Pulmonary Fibrosis in October 2016, and our commercialization efforts for Envisia may not be successful. In addition, we are in various stages of research and development for other diagnostic solutions that we may offer, but there can be no assurance that we will be able to identify other diseases that can be effectively addressed with our molecular cytology platform or, if we are able to identify such diseases, whether or when we will be able to successfully commercialize solutions for these diseases. If we are unable to increase sales and expand reimbursement for Afirma, or successfully commercialize and obtain coverage and reimbursement for Percepta and Envisia and develop and commercialize other solutions, our revenue and our ability to achieve and sustain profitability would be impaired, and the market price of our common stock could decline.

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