
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 22, 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

(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))
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Item 7.01 Regulation FD Disclosure.

On November 22, 2016, Veracyte, Inc. (the Company) issued a press release on the Centers for Medicare and Medicaid Services' (CMS) revised final 2017 "gapfill" Medicare reimbursement rate for the Afirma Gene Expression Classifier (GEC). The full text of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

Item 8.01 Other Events.

On November 22, 2016, the CMS' revised final 2017 gapfill Medicare reimbursement rate for the Afirma GEC was released. CMS has determined that the genomic test's current rate of \$3,200 will be maintained for 2017.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release issued by Veracyte, Inc. dated November 22, 2016.



FOR IMMEDIATE RELEASE

**Veracyte Announces that CMS Will Maintain Historic Medicare Reimbursement Rate
for the Afirma® Gene Expression Classifier in 2017**

SOUTH SAN FRANCISCO, Calif., November 22, 2016 --- Veracyte, Inc. (NASDAQ: VCYT) announced today that the Centers for Medicare and Medicaid Services (CMS) has released its revised final 2017 Medicare reimbursement rate for the company's Afirma Gene Expression Classifier (GEC). As a result of Veracyte's reconsideration request, the agency has determined the genomic test's current rate of \$3,200 will be maintained in 2017. This final rate replaces the previously released lower "gapfill" amount and will go into effect on January 1, 2017.

"We are pleased with CMS's decision to uphold the Afirma GEC Medicare reimbursement rate that the agency has been paying since 2012," said Bonnie Anderson, Veracyte's president and chief executive officer. "Moreover, with final Medicare rates in place for 2017 and market-based pricing to begin in 2018 through the Protecting Access to Medicare Act, we believe that Medicare reimbursement for the Afirma GEC will now remain stable for the foreseeable future."

The rate announced today follows Veracyte's submission to CMS of a reconsideration request expressing its concern that the previously released lower gapfill rate was not supported by CMS's own gapfill regulatory criteria. Through the gapfill process, the price of a test is determined by the median price submitted by each of CMS's Medicare Administrative Contractors (MACs).

Beginning January 1, 2018, through the Protecting Access to Medicare Act (PAMA), Medicare reimbursement for advanced genomic tests such as the Afirma GEC will be based on the median price paid by commercial payers, which Veracyte calculates as above \$3,200 for the Afirma GEC. Under PAMA, the new market-based Medicare rate will override any prior rate. Medicare represents approximately 20 percent of Afirma GEC test volume.

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 preoperative 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. The Afirma test is recommended in

leading practice guidelines and is covered for 185 million lives in the United States, including through Medicare and many commercial insurance plans. 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, which has already received draft Medicare coverage. In October 2016, Veracyte launched its second pulmonology product, the Envisia™ Genomic Classifier, to improve diagnosis of interstitial lung diseases, including idiopathic pulmonary fibrosis. For more information, please visit www.veracyte.com.

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 adoption of our products, 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 2016 revenue guidance and forecast for annual GEC test volume, our expectation that Medicare reimbursement for the Afirma GEC will remain stable, 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 Envisia test; 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; our ability to successfully launch our Envisia test and achieve adoption of our Percepta and Envisia tests; 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 September 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.

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Source: Veracyte

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