
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): September 30, 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 September 30, 2016, Veracyte, Inc. (the Company) issued a press release on the Centers for Medicare and Medicaid Services' (CMS) 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 September 30, 2016, the CMS' final 2017 gapfill Medicare reimbursement rate for the Afirma GEC was released. The final 2017 gapfill rate for the Afirma GEC as published is \$2,864.45. The Company plans to file a reconsideration request with CMS regarding this rate.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release issued by Veracyte, Inc. dated September 30, 2016.

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: October 3, 2016

VERACYTE, INC.

By: /s/ Julie A. Brooks

Name: Julie A. Brooks

Title: *Executive Vice President, General Counsel and Secretary*



For Immediate Release

**Veracyte Releases Statement on CMS's Final 2017 Gapfill Rate
for the Afirma® Gene Expression Classifier**

SOUTH SAN FRANCISCO, Calif., September 30, 2016 -- Veracyte, Inc. (NASDAQ: VCYT), a genomic diagnostics company focused on reducing diagnostic uncertainty, today issued the statement below on the Centers for Medicare and Medicaid Services' (CMS) final 2017 "gapfill" Medicare reimbursement rate for the Afirma Gene Expression Classifier (GEC), which the agency released this afternoon. The rate is intended to be in effect for one year before new Medicare rates based on private-payer reimbursement amounts are instated on January 1, 2018.

Medicare has covered the Afirma GEC since 2012 at a rate of \$3,200. To date, the genomic test has helped an estimated more than 25,000 patients avoid unnecessary thyroid surgery and the often-resulting lifelong need for daily hormone replacement therapy. The final 2017 gapfill rate for the Afirma GEC as published is \$2,864.45, which is based on the median rate submitted by all Medicare Administrative Contractors (MACs), regardless of whether they have experience with the genomic test or not. Medicare represents approximately 20 percent of Afirma GEC test volume.

"We are pleased that the final Afirma GEC rate is higher than the preliminary rate announced by CMS in June," said Bonnie Anderson, Veracyte's president and chief executive officer. "However, we believe this new rate is still based on a flawed application of the CMS gapfill criteria. We plan to file a reconsideration request with CMS because we believe the data that we provided to the MACs support a higher rate, based on CMS's gapfill criteria. We are hopeful that CMS will override this misguided result and uphold its commitment to bring more transparency to its rate-setting processes, which is at the heart of PAMA (the Protecting Access to Medicare Act)."

Through the current gapfill process, the price of a test is determined by the median price submitted by each of the MACs. The MAC (Noridian) that currently processes Medicare claims for the Afirma GEC submitted a rate that matches the test's current rate of \$3,200; other MACs, which have no experience with the test, submitted lower rates.

Beginning January 1, 2018, through 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 rates will override any prior rates.

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 the fourth quarter of 2016, Veracyte plans to launch 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 Afirma, our expectations with respect to the success of our entry into the pulmonology market, our expectations regarding full-year 2016 guidance and forecast for annual GEC test volume, 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 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; the size of the market opportunity for our products; our ability to successfully achieve adoption of and adequate reimbursement for our products; the amount by which use of our products are 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; our inclusion in clinical practice guidelines; the continued application of clinical guidelines to our products; 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 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.

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