

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): December 16, 2020

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))

Securities registered pursuant to Section 12(b) of the Act:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
Common Stock, par value, \$0.001 per share	VCYT	The Nasdaq Stock Market LLC

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 8.01 Other Events.

On December 16, 2020, Veracyte, Inc. (the "Company") announced new preliminary performance data for its noninvasive nasal swab test for early lung cancer detection and its Percepta Genomic Atlas for informing treatment decisions at the time of diagnosis. The data were shared during the Company's Virtual Lung Cancer R&D Day, which was held December 16, 2020. A copy of the Company's press release relating to this announcement is being furnished as Exhibit 99.1 to this Form 8-K.

Item 9.01 Financial Statements and Exhibits.

d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
<u>99.1</u>	<u>Press release issued by Veracyte, Inc. dated December 16, 2020.</u>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

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: December 16, 2020

VERACYTE, INC.

By: /s/ Jim Erlinger
Name: Jim Erlinger
Title: *Executive Vice President and General Counsel*



For Immediate Release

Veracyte Announces New Preliminary Data for Its In-Development Lung Cancer Portfolio Tests

Data on Noninvasive Nasal Swab Test and Percepta Genomic Atlas Presented Today at Virtual Lung Cancer R&D Day

SOUTH SAN FRANCISCO, Calif., December 16, 2020 --- Veracyte, Inc. (Nasdaq: VCYT) announced new preliminary performance data for its noninvasive nasal swab test for early lung cancer detection and its Percepta Genomic Atlas for informing treatment decisions at the time of diagnosis. Both tests are in development and scheduled to launch in the second half of 2021 as part of Veracyte's comprehensive portfolio of genomic tests in lung cancer. The data were shared during the company's Virtual Lung Cancer R&D Day, which was held today.

"We are excited to bring forward novel tests that we believe will address significant unmet needs throughout the patient journey in lung cancer," said Bonnie Anderson, Veracyte's chairman and chief executive officer. "The preliminary data we presented today give us further confidence that our expanding portfolio of tests will improve the lives of patients through earlier diagnosis and comprehensive genomic profiling. This progress, on the heels of our expanded collaboration with the Lung Cancer Initiative at Johnson & Johnson, underscores our deep commitment to fighting this devastating disease."

Veracyte's noninvasive nasal swab test is being developed to help physicians determine next steps for lung nodules found on CT imaging. Lung nodules identified as high risk for cancer warrant a diagnostic work-up to enable immediate treatment, while nodules identified as low risk may avoid unnecessary invasive procedures and be monitored with surveillance.

Veracyte's chief scientific officer and chief medical officer, Giulia C. Kennedy, Ph.D., shared cross-validation data for four genomic test models, which are precursors to the final test. The models were all developed using RNA whole-transcriptome sequencing data from nasal samples of patients with lung nodules, which was combined with machine learning to classify patient nodules as high or low risk for cancer. Among the four models, 44-60 percent of the truly malignant nodules were classified as high risk with a range of specificity of 90-91 percent, and 39-57 percent of the truly benign nodules were identified as low risk, with a range of sensitivity of 90-94 percent.

"We are pleased with these preliminary findings, which suggest that our final test will provide physicians much-needed clarity on which patients with lung nodules need additional diagnostic procedures and which patients may safely avoid them," said Dr. Kennedy. "We look forward to locking the final algorithm and then measuring clinical validation performance on an independent test set prior to launching the test in the second half of 2021."

Dr. Kennedy also shared preliminary data for the Percepta Genomic Atlas, which will provide comprehensive genomic profiling information on cancerous lung nodules, utilizing small samples from the biopsy used for diagnosis. The data showed that the in-development test accurately detected known gene variants in lung cancer using bronchoscopy samples, including in stage I, II and III cancers, with over 95 percent concordance to a reference next-generation sequencing assay.

"Our preliminary data gives us confidence that the Percepta Genomic Atlas will be able to accurately detect gene alterations that may allow patients to be treated with targeted therapies that are available now and that will be available in the future. Importantly, we believe it will be able to provide this critical information at the time of diagnosis, enabling earlier and more appropriate treatment," said Dr. Kennedy.

The R&D Day event also featured leading pulmonologists who discussed the challenges and opportunities in lung cancer diagnosis and treatment. A replay of the event and the presentation materials will be available on Veracyte's website at <https://investor.veracyte.com/events-presentations> for approximately 90 days.

About Lung Cancer

Lung cancer is the deadliest cancer globally, killing more than 1.75 million people worldwide each year, according to the World Health Organization. Early detection is key, with a five-year survival rate of nearly 60 percent when the cancer is found early, compared to six percent when it is found at a later stage, according to the American Lung Association. Lung nodules are typically the first sign of lung cancer. While the vast majority of lung nodules ultimately prove to be benign, physicians currently lack clear diagnostic tools to determine which patients have cancer and which do not. This can lead to unnecessary invasive biopsies, which are costly and risky, as well as to delayed diagnosis and treatment.

About Veracyte

Veracyte (Nasdaq: VCYT) is a global genomic diagnostics company that improves patient care by providing answers to clinical questions, informing diagnosis and treatment decisions throughout the patient journey in cancer and other diseases. The company's growing menu of genomic tests leverage advances in genomic science and technology, enabling patients to avoid risky, costly diagnostic procedures and quicken time to appropriate treatment. The company's tests in thyroid cancer, lung cancer, breast cancer and idiopathic pulmonary fibrosis are available to patients and its lymphoma subtyping test is in development. With Veracyte's exclusive global license to a best-in-class diagnostics instrument platform, the company is positioned to deliver its tests to patients worldwide. Veracyte is based in South San Francisco, California. For more information, please visit www.veracyte.com and follow the company on Twitter (@veracyte).

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements, including, but not limited to, our statements related to our plans, objectives, expectations (financial and otherwise) or intentions with respect to our Prosigna, Afirma, Percepta, Envisia, and nasal swab tests and products for use in diagnosing and treating diseases. Forward-looking statements can be identified by words such as: "appears," "anticipate," "intend," "plan," "expect," "believe," "should," "may," "will," "positioned," "designed" and similar references to future periods. Actual results may differ materially from those projected or suggested in any

forward-looking statements. These statements involve risks and uncertainties, which could cause actual results to differ materially from our predictions, and include, but are not limited to Veracyte's ability to develop and commercialize a nasal swab and other tests to aid in disease diagnosis, characterization and prognosis to support disease management for patients with lung nodules. Factors that may impact these forward-looking statements can be found in Item 1A – "Risk Factors" in our Annual Report on Form 10-K filed with the SEC on February 25, 2020 and in our Quarterly Report on Form 10-Q filed with the SEC on November 2, 2020. A copy of these documents can be found at the Investors section of our website at www.veracyte.com. These forward-looking statements speak only as of the date hereof and Veracyte specifically disclaims any obligation to update these forward-looking statements or reasons why actual results might differ, whether as a result of new information, future events or otherwise.

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