

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 2, 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 2.02 Results of Operations and Financial Condition.

On November 2, 2020, Veracyte, Inc. issued a press release announcing its financial results for the quarter ended September 30, 2020. 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

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release issued by Veracyte, Inc. dated November 2, 2020.
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: November 2, 2020

VERACYTE, INC.

By: /s/ Keith Kennedy
Name: Keith Kennedy
Title: *Chief Operating Officer and Chief Financial Officer
(Principal Financial Officer)*



For Immediate Release

Veracyte Announces Third Quarter 2020 Financial Results

Revenue of \$31.1 Million; Product and Testing Revenue Increased 79% Over Second Quarter of 2020

Achieved Key Reimbursement Milestones

Conference Call and Webcast Today at 4:30 p.m. ET

SOUTH SAN FRANCISCO, Calif., November 2, 2020-- Veracyte, Inc. (Nasdaq: VCYT) today announced financial results for the third quarter ended September 30, 2020 and provided an update on recent business progress. For the third quarter of 2020, revenue was \$31.1 million, compared to \$20.7 million in the second quarter of 2020 and \$31.0 million in the third quarter of 2019. Product and testing revenue was \$30.3 million, an increase of 79% over the second quarter of 2020 and 13% over the third quarter of 2019.

“We are pleased with the strong rebound in our business during the third quarter, with revenue returning to pre-pandemic levels, led by our Afirma franchise,” said Bonnie Anderson, Veracyte’s chairman and chief executive officer. “We also achieved important reimbursement and clinical-evidence milestones for our tests, which we believe will help further drive adoption and revenue growth. We also remain on track to launch four new clinical products in 2021. Moreover, we believe we are well-positioned in the near- and long-term with our tests that help patients avoid unnecessary invasive diagnostic procedures and accelerate access to appropriate treatment.”

Third Quarter 2020 Financial Results

For the third quarter of 2020:

- *Total Revenue* was \$31.1 million, comprising \$30.3 million in testing and product revenue and \$0.8 million in biopharmaceutical partnership revenue;
 - *Gross Margin* was 67%;
 - *Operating Expenses, Excluding Cost of Revenue*, were \$24.8 million;
 - *Net Loss and Comprehensive Loss* was \$4.1 million;
 - *Basic and Diluted Net Loss Per Common Share* was \$0.08;
 - *Net Cash Used in Operating Activities* was \$1.8 million; and
 - *Cash and Cash Equivalents* were \$345.1 million at September 30, 2020.
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For the nine-month period ended September 30, 2020:

- Total Revenue was \$82.9 million, comprising \$77.6 million in testing and product revenue and \$5.3 million in biopharmaceutical partnership revenue;
- Gross Margin was 64%;
- Operating Expenses, Excluding Cost of Revenue, were \$80.0 million;
- Net Loss and Comprehensive Loss was \$26.9 million;
- Basic and Diluted Net Loss Per Common Share was \$0.52; and
- Net Cash Used in Operating Activities was \$12.0 million.

Third Quarter 2020 and Recent Business Highlights

Commercial Growth and Reimbursement Expansion:

- Grew reported genomic testing volume (Afirma, Percepta and Envisia) to 10,242, an increase of 90% over the second quarter of 2020 and 3% over the third quarter of 2019.
- Generated \$7.0 million in year-to-date 2020 revenue from our Prosigna breast cancer test, achieving our pre-pandemic, full-year 2020 revenue goal.
- Received Advanced Diagnostic Laboratory Test (ADLT) status and new Medicare pricing for the Envisia classifier, beginning October 1, 2020, positioning the test for expanded revenue growth.
- Received new CPT codes and preliminary national Medicare pricing for the Afirma Medullary Thyroid Carcinoma (MTC) classifier and the Xpression Atlas, providing a pathway for increased reimbursement.
- Obtained coverage for the Prosigna breast cancer test from the Federal Joint Committee (G-BA) in Germany, our third largest European market.

Evidence Development:

- Prosigna:
 - Launched the PROCURE study, led by a distinguished, independent scientific committee of breast cancer experts and including input from 180 clinicians throughout Europe, intended to achieve consensus on the evidence supporting the most frequently used breast cancer genomic tests, including Prosigna.
 - Data from the TransATAC study were published in the *Journal of Clinical Oncology* elucidating the foundational molecular biology on which the Prosigna test is based and its higher likelihood of predicting long-term risk of recurrence among certain groups of women with early-stage breast cancer, compared to other breast cancer genomic tests.
- Afirma:
 - An independent study published in *Cytopathology* by UCLA researchers showed that use of the Afirma GSC further reduced unnecessary surgeries in thyroid cancer diagnosis compared to the original Afirma test.
- Pulmonology:
 - Presented three e-Posters at the American Thoracic Society 2020 Virtual Meeting featuring real-world data that reinforce previous findings suggesting that the Percepta and Envisia classifiers improve the diagnosis of lung cancer and interstitial lung diseases (ILDs).
 - Published data in the journal *CHEST* suggesting that the Percepta classifier reduces unnecessary invasive procedures following inconclusive bronchoscopy results for patients with lung nodules and that these results are durable for over one year of follow-up.
 - Presented an oral and e-Poster presentation at CHEST Annual Meeting 2020 supporting advancement of our lung cancer nasal swab classifier, along with the potential to integrate radiologic data to further augment genomics in the diagnosis of ILDs, including idiopathic pulmonary fibrosis.

Financing:

- Issued and sold 6,900,000 shares of common stock in August 2020 in a registered public offering, including the underwriters' exercise in full of their option to purchase an additional 900,000 shares, at a price to the public of \$30.00 per share. Net proceeds from the offering were approximately \$194 million.

2020 Financial Guidance

While Veracyte experienced improved business trends in the third quarter, due to the continued uncertainties with respect to the COVID-19 pandemic, the company will not be providing guidance at this time.

Conference Call and Webcast Details

Veracyte will host a conference call and webcast today at 4:30 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/mmc/p/txzuzzy8m>. 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>.

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.:

3190445

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" 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 achieve and maintain Medicare coverage for its tests; the benefits of Veracyte's tests, the applicability of clinical results to actual outcomes and the effects of the COVID-19 pandemic on Veracyte's business and performance. 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 to be 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.

Veracyte, Afirma, Percepta, Envisia, Prosigna, "Know by Design" and the Veracyte, Afirma, Percepta, Envisia and Prosigna logos are registered trademarks in the U.S. and selected countries. We have common law rights and pending trademark applications for LymphMark and "More About You."

VERACYTE, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(Unaudited)

(In thousands of dollars, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Revenue:				
Testing revenue	\$ 28,270	\$ 26,723	\$ 70,473	\$ 78,798
Product revenue	2,027	—	7,149	—
Biopharmaceutical revenue	824	2,250	5,325	7,840
Collaboration revenue	—	2,000	—	4,000
Total Revenue	<u>31,121</u>	<u>30,973</u>	<u>82,947</u>	<u>90,638</u>
Operating expenses:				
Cost of testing revenue	9,118	9,114	26,157	26,404
Cost of product revenue	1,048	—	3,539	—
Cost of biopharmaceutical revenue	204	—	572	—
Research and development	4,042	3,643	12,618	10,408
Selling and marketing	10,955	13,088	39,240	39,508
General and administrative	8,546	6,624	24,316	20,448
Intangible asset amortization	1,274	267	3,822	800
Total operating expenses	<u>35,187</u>	<u>32,736</u>	<u>110,264</u>	<u>97,568</u>
Loss from operations	(4,066)	(1,763)	(27,317)	(6,930)
Interest expense	(55)	(58)	(175)	(596)
Other income (loss), net	(3)	1,091	627	2,385
Net loss and comprehensive loss	<u>\$ (4,124)</u>	<u>\$ (730)</u>	<u>\$ (26,865)</u>	<u>\$ (5,141)</u>
Net loss per common share, basic and diluted	<u>\$ (0.08)</u>	<u>\$ (0.02)</u>	<u>\$ (0.52)</u>	<u>\$ (0.11)</u>
Shares used to compute net loss per common share, basic and diluted	<u>54,858,052</u>	<u>48,588,296</u>	<u>51,632,750</u>	<u>45,141,502</u>

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

	September 30, 2020	December 31, 2019
	(Unaudited)	(See Note 1)
Assets		
Current assets:		
Cash and cash equivalents	\$ 345,080	\$ 159,317
Accounts receivable	17,629	19,329
Supplies	4,456	6,806
Prepaid expenses and other current assets	3,150	2,235
Total current assets	<u>370,315</u>	<u>187,687</u>
Property and equipment, net	8,914	8,933
Right-of-use assets - operating lease	8,094	8,808
Finite-lived intangible assets, net	61,197	65,019
Goodwill	2,725	2,725
Restricted cash	603	603
Other assets	2,303	1,437
Total assets	<u>\$ 454,151</u>	<u>\$ 275,212</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 1,932	\$ 2,328
Accrued liabilities	10,445	13,734
Current portion of operating lease liability	1,542	1,407
Total current liabilities	<u>13,919</u>	<u>17,469</u>
Long-term debt	756	694
Acquisition-related contingent consideration	6,420	6,088
Operating lease liability, net of current portion	10,331	11,506
Total liabilities	<u>31,426</u>	<u>35,757</u>
Total stockholders' equity	<u>422,725</u>	<u>239,455</u>
Total liabilities and stockholders' equity	<u>\$ 454,151</u>	<u>\$ 275,212</u>

(1) The condensed balance sheet at December 31, 2019 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 25, 2020.

VERACYTE, INC.
CONDENSED CONSOLIDATED STATEMENT OF CASH FLOWS
(Unaudited)
(in thousands of dollars)

	Nine Months Ended September 30,	
	2020	2019
Operating activities		
Net loss	\$ (26,865)	\$ (5,141)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	5,919	2,836
Gain on disposal of property and equipment	—	(23)
Stock-based compensation	9,354	6,965
Amortization of debt issuance costs	—	83
Interest on end-of-term debt obligation	162	174
Write-down of excess supplies	1,088	—
Noncash lease expense	714	810
Revaluation of acquisition-related contingent consideration	332	—
Effect of foreign currency on operations	(17)	—
Changes in operating assets and liabilities:		
Accounts receivable	1,742	(10,445)
Supplies	1,262	(3,206)
Prepaid expenses and other current assets	(923)	185
Other assets	134	(142)
Operating lease liability	(1,040)	(881)
Accounts payable	(534)	2,505
Accrued liabilities	(3,300)	1,258
Net cash used in operating activities	<u>(11,972)</u>	<u>(5,022)</u>
Investing activities		
Purchases of property and equipment	(1,949)	(1,656)
Purchase of equity securities	(1,000)	—
Proceeds from disposal of property and equipment	—	23
Net cash used in investing activities	<u>(2,949)</u>	<u>(1,633)</u>
Financing activities		
Proceeds from the issuance of common stock in a public offering, net	193,831	137,848
Payment of long-term debt	(100)	(24,900)
Payment of finance lease liability	—	(229)
Payment of taxes on vested restricted stock units	(3,161)	(810)
Proceeds from the exercise of common stock options and employee stock purchases	10,114	12,413
Net cash provided by financing activities	<u>200,684</u>	<u>124,322</u>
Net increase in cash, cash equivalents and restricted cash	185,763	117,667
Cash, cash equivalents and restricted cash at beginning of period	159,920	78,598
Cash, cash equivalents and restricted cash at end of period	<u>\$ 345,683</u>	<u>\$ 196,265</u>
Supplementary cash flow information:		
Purchases of property and equipment included in accounts payable and accrued liability	\$ 355	\$ 821
Interest paid on debt	\$ 3	\$ 330

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

	September 30, 2020	December 31, 2019
Cash and cash equivalents	\$ 345,080	\$ 159,317
Restricted cash	603	603
Total cash, cash equivalents and restricted cash	<u>\$ 345,683</u>	<u>\$ 159,920</u>

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Investor and Media Contact:

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