VERACYTE, INC.
Form 10-Q
October 29, 2018
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)
ý QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended September 30, 2018
OR
o TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to

Commission file number 001-36156

VERACYTE, INC.
(Exact name of registrant as specified in its charter)

Delaware	20-5455398
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

6000 Shoreline Court, Suite 300
South San Francisco, California 94080
(Address of principal executive offices, zip code)

(650) 243-6300
(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ý No o

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ý No o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer,"

"accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer o	Accelerated filer x
Non-accelerated filer o	Smaller reporting company x
(Do not check if a smaller reporting company)	Emerging growth company x

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. x

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).Yes o No ý

As of October 25, 2018, there were 40,538,779 shares of common stock, par value $0.001 per share, outstanding.

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PART I. — FINANCIAL INFORMATION

Item 1. Condensed Financial Statements

VERACYTE, INC.

Condensed Balance Sheets

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

	September 30, 2018 (Unaudited)	December 31, 2017 (See Note 1)
Assets		
Current assets:		
Cash and cash equivalents	$ 77,846	$ 33,891
Accounts receivable	12,262	12,716
Supplies	3,463	5,324
Prepaid expenses and other current assets	1,803	1,997
Total current assets	95,374	53,928
Property and equipment, net	8,939	9,688
Finite-lived intangible assets, net	12,267	13,067
Goodwill	1,057	1,057
Restricted cash	603	603
Other assets	837	326
Total assets	$ 119,077	$ 78,669
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,175	$ 3,853
Accrued liabilities	9,261	8,175
Total current liabilities	10,436	12,028
Long-term debt	25,192	24,938
Capital lease liability, net of current portion	79	308
Deferred rent, net of current portion	3,953	4,170
Total liabilities	39,660	41,444
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized, no shares issued and outstanding as of September 30, 2018 and December 31, 2017	—	—
Common stock, $0.001 par value; 125,000,000 shares authorized, 40,535,674 and 34,210,388 shares issued and outstanding as of September 30, 2018 and December 31, 2017, respectively	41	34
Additional paid-in capital	310,357	248,278
Accumulated deficit	(230,981)	(211,087)
Total stockholders' equity	79,417	37,225
Total liabilities and stockholders' equity	$ 119,077	$ 78,669

The accompanying notes are an integral part of these financial statements.

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VERACYTE, INC.

Condensed 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,	
	2018	2017	2018	2017
Revenue	$23,466	$17,519	$66,258	$52,357
Operating expenses:				
Cost of revenue	8,261	7,169	24,374	20,426
Research and development	3,419	3,046	11,695	10,679
Selling and marketing	10,081	7,885	31,247	23,215
General and administrative	5,742	5,520	17,318	17,731
Intangible asset amortization	267	267	800	800
Total operating expenses	27,770	23,887	85,434	72,851
Loss from operations	(4,304)	(6,368)	(19,176)	(20,494)
Interest expense	(498)	(815)	(1,427)	(2,423)
Other income, net	333	134	709	353
Net loss and comprehensive loss	$(4,469)	$(7,049)	$(19,894)	$(22,564)
Net loss per common share, basic and diluted	$(0.12)	$(0.21)	$(0.56)	$(0.67)
Shares used to compute net loss per common share, basic and diluted	38,620,036	33,946,748	35,769,623	33,881,705

The accompanying notes are an integral part of these financial statements.

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VERACYTE, INC.

Condensed Statements of Cash Flows

(Unaudited)

(In thousands of dollars)

	Nine Months Ended September 30,	
	2018	2017
Operating activities		
Net loss	$ (19,894)	$ (22,564)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2,950	2,839
Stock-based compensation	4,425	4,825
Other income	(93)	—
Amortization of debt issuance costs	24	79
Interest on end-of-term debt obligation	230	—
Changes in operating assets and liabilities:		
Accounts receivable	454	(2,879)
Supplies	1,861	(285)
Prepaid expenses and current other assets	61	240
Other assets	(511)	(44)
Accounts payable	(2,636)	891
Accrued liabilities and deferred rent	834	(1,201)
Net cash used in operating activities	(12,295)	(18,099)
Investing activities		
Purchases of property and equipment	(1,420)	(1,455)
Proceeds from sale of property and equipment	—	440
Net cash used in investing activities	(1,420)	(1,015)
Financing activities		
Proceeds from the issuance of common stock in a public offering, net of costs	55,039	200
	403	—

Proceeds from legal settlement regarding short-swing profits		
Payment of capital lease liability	(217)	(204)
Proceeds from the exercise of common stock options and employee stock purchases	2,445	974
Net cash provided by financing activities	57,670	970
Net increase (decrease) in cash, cash equivalents and restricted cash	43,955	(18,144)
Cash, cash equivalents and restricted cash at beginning of period	34,494	59,942
Cash, cash equivalents and restricted cash at end of period	$ 78,449	$ 41,798
Supplementary cash flow information of non-cash investing and financing activities:		
Purchases of property and equipment included in accounts payable and accrued liabilities	$ 23	$ 188
Interest paid on debt	$ 1,235	$ 2,318

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Cash, Cash Equivalents and Restricted Cash:

	September 30, 2018	December 31, 2017
Cash and cash equivalents	$ 77,846	$ 33,891
Restricted cash	603	603
Total cash, cash equivalents and restricted cash	$ 78,449	$ 34,494

The accompanying notes are an integral part of these financial statements.

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VERACYTE, INC.

Notes to Financial Statements

1. Organization and Description of Business

Veracyte, Inc. (“Veracyte” or the “Company”) was incorporated in the state of Delaware on August 15, 2006 as Calderome, Inc. Calderome operated as an incubator until early 2008. On March 4, 2008, the Company changed its name to Veracyte, Inc. The Company’s operations are based in South San Francisco, California and Austin, Texas, and it operates in one segment.

Veracyte is a genomic diagnostics company that resolves diagnostic uncertainty by combining genomic technology, clinical science and machine learning to provide diagnostic answers to physicians and patients.

Since the Company's founding in 2008, it has commercialized three products:

Afirma Thyroid FNA Analysis - Includes the next-generation Afirma Genomic Sequencing Classifier, or GSC, and its predecessor, the Afirma Gene Expression Classifier, or GEC, that is used to identify patients with benign thyroid nodules among those with indeterminate cytopathology results in order to preserve the thyroid. The Afirma classifier was developed using machine learning that is based on ensemble methods in which multiple algorithms - each playing its own role - are used to interpret large amounts of ribonucleic acid, or RNA, sequencing genomic data and obtain a better predictive performance than any single algorithm.

Percepta Bronchial Genomic Classifier - The 23-gene Percepta classifier improves lung cancer screening and diagnosis by increasing the diagnostic performance of bronchoscopies and identifying patients with lung nodules who are at low risk of cancer, without the need for more invasive procedures. The test leverages the field of injury concept and analyzes genomic changes that occur in the epithelial cells lining the airways of current or former smokers to assess a patient’s risk of having lung cancer, without the need to test the often-hard-to-reach nodule directly.

Envisia Genomic Classifier - The Envisia classifier is designed to improve physicians’ ability to differentiate idiopathic pulmonary fibrosis, or IPF, from other interstitial lung diseases, or ILD, without the need for invasive and potentially risky surgery. The Envisia classifier was developed using machine learning coupled with powerful, deep RNA sequencing to detect the presence or absence of usual interstitial pneumonia, or UIP, a classic diagnostic pattern whose presence is essential for the diagnosis of IPF.

All of the Company's testing services are made available through its clinical reference laboratories located in South San Francisco, California and Austin, Texas, both of which meet required federal and state licensing requirements.

Basis of Presentation

The Company’s financial statements have been prepared in accordance with accounting principles generally accepted in the United States, or GAAP. Certain information and note disclosures normally included in financial statements prepared in accordance with GAAP have been condensed or omitted pursuant to such rules and regulations. The condensed balance sheet as of September 30, 2018, the condensed statements of operations and comprehensive loss for the three and nine months ended September 30, 2018 and 2017, and the condensed statements of cash flows for the nine months ended September 30, 2018 and 2017 are unaudited, but include all adjustments, consisting only of normal recurring adjustments, which the Company considers necessary for a fair presentation of its financial position, operating results and cash flows for the periods presented. The condensed balance sheet at December 31, 2017 has been derived from audited financial statements. The results for the three and nine months ended September 30, 2018

are not necessarily indicative of the results expected for the full year or any other period.

The accompanying interim period condensed financial statements and related financial information included in this Quarterly Report on Form 10-Q should be read in conjunction with the audited financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2017.

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Use of Estimates

The preparation of unaudited interim financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities as of the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. Significant items subject to such estimates include: revenue recognition; contractual allowances; the useful lives of property and equipment; the recoverability of long-lived assets; the estimation of the fair value of intangible assets; stock options; income tax uncertainties, including a valuation allowance for deferred tax assets; and contingencies. The Company bases these estimates on historical and anticipated results, trends, and various other assumptions that the Company believes are reasonable under the circumstances, including assumptions as to future events. These estimates form the basis for making judgments about the carrying values of assets and liabilities and recorded revenue and expenses that are not readily apparent from other sources. Actual results could differ from those estimates and assumptions.

Issuance of Common Stock in a Public Offering

In July 2018, the Company issued and sold 5,750,000 shares of common stock in a registered public offering, including the underwriters' exercise in full of their option to purchase an additional 750,000 shares, at a price to the public of $10.25 per share. The Company's net proceeds from the offering were approximately $55.0 million, after deducting underwriting commissions and offering expenses of $3.9 million.

Concentrations of Credit Risk and Other Risks and Uncertainties

The majority of the Company’s cash and cash equivalents are deposited with one major financial institution in the United States. Deposits in this institution may exceed the amount of insurance provided on such deposits. The Company has not experienced any losses on its deposits of cash and cash equivalents.

Several of the components of the Company’s sample collection kit and test reagents are obtained from single-source suppliers. If these single-source suppliers fail to satisfy the Company’s requirements on a timely basis, it could suffer delays in being able to deliver its diagnostic solutions, a possible loss of revenue, or incur higher costs, any of which could adversely affect its operating results.

The Company is also subject to credit risk from its accounts receivable related to its sales. The Company generally does not perform evaluations of customers’ financial condition and generally does not require collateral.

Through September 30, 2018, substantially all of the Company’s revenue has been derived from the sale of Afirma. To date, Afirma has been delivered primarily to physicians in the United States. The Company’s third-party payers in excess of 10% of revenue and their related revenue as a percentage of total revenue were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Medicare	29 %	26 %	28 %	26 %
UnitedHealthcare	13 %	14 %	12 %	14 %
	42 %	40 %	40 %	40 %

The Company's significant third-party payers and their related accounts receivable balance as a percentage of total accounts receivable were as follows:

	September 30, 2018		December 31, 2017	
Medicare	17	%	22	%
UnitedHealthcare	11	%	9	%

No other third-party payer represented more than 10% of the Company's accounts receivable balances as of those dates.

Restricted Cash

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The Company had deposits of $603,000 included in long-term assets as of September 30, 2018 and December 31, 2017, restricted from withdrawal and held by a bank in the form of collateral for an irrevocable standby letter of credit held as security for the lease of the Company's South San Francisco facility.

Revenue Recognition

The Company commenced recognizing revenue in accordance with the provisions of ASC 606, Revenue from Contracts with Customers, or ASC 606, starting January 1, 2018. Prior to January 1, 2018, the Company recognized revenue in accordance with the provisions of ASC 954-605, Health Care Entities - Revenue Recognition, or ASC 954.

Revenue from Diagnostic Services

Most of the Company's revenue is generated from the provision of diagnostic services. These services are completed upon the delivery of test results to the prescribing physician, at which time the Company bills for the services. The Company recognizes revenue related to billings based on estimates of the amount that will ultimately be realized. In determining the amount to accrue for a delivered test, the Company considers factors such as payment history, payer coverage, whether there is a reimbursement contract between the payer and the Company, payment as a percentage of agreed upon rate (if applicable), amount paid per test and any current developments or changes that could impact reimbursement. These estimates require significant judgment by management.

The Company adopted ASC 606 on January 1, 2018 using the modified retrospective method, which requires a cumulative catch-up adjustment as if the Company had recognized revenue under ASC 606 from January 1, 2016 to December 31, 2017. Prior to January 1, 2018, the Company recognized revenue in accordance with ASC 954 and recognized revenue for tests delivered on an accrual basis when amounts that will ultimately be realized could be reasonably estimated, and on the cash basis when there was insufficient information to estimate revenue accruals. There was sufficient payment history for the Company to substantially accrue all revenue upon delivery of test results starting July 1, 2016 and the Company continued to recognize revenue upon cash receipt for unaccrued tests that were delivered prior to July 1, 2016. There was no revenue recognized on the cash basis for the three and nine months ended September 30, 2018 and revenue recognized on the cash basis for the three and nine months ended September 30, 2017 was $262,000 and $2.4 million, respectively.

As noted above, on July 1, 2016 the Company began recognizing revenue from substantially all its tests on the accrual basis of accounting at an amount equal to management's best estimate of the cash to ultimately be collected. For tests delivered prior to July 1, 2016, substantially all the related cash had been collected by December 31, 2017. Thus, at January 1, 2018, the cumulative impact of adopting ASC 606 was not material and no adjustment was recorded.

During the first nine months of 2018, the Company collected cash in excess of the revenue recognized for certain tests delivered prior to July 1, 2018. As a result, the Company changed its estimate of the amounts to be recognized for these tests and recognized an additional net $0.5 million and $1.7 million of revenue for the three and nine months ended September 30, 2018, respectively. These changes in estimates resulted in decreases in loss from operations of $0.5 million and $1.7 million and decreases in loss per share of approximately $0.01 and $0.05 for the three and nine months ended September 30, 2018, respectively.

Biopharmaceutical Services

On April 9, 2018, the Company entered into an agreement with a biopharmaceutical company whereby the Company agreed to provide certain tissue samples and other services in exchange for agreed-upon fees. During the quarter ended June 30, 2018, the Company recognized $450,000 of revenue upon deliveries of tissue samples and the Company received $500,000 for other services, which will be recognized ratably during the quarters ended September 30 and

December 31, 2018 as the services are performed. Thereafter, the Company expects to receive approximately $250,000 per quarter as services are performed and may also recognize revenue related to the deliveries of additional tissue samples as long as the agreement is not terminated. The agreement has a term of one year with an automatic renewal of one year and the biopharmaceutical company may terminate the agreement at any time with at least 90 days' notice. The Company evaluated the accounting for this agreement under ASC 606 and concluded the performance obligations thereunder are the deliveries of tissue samples and performance of services, both of which are distinct. There were no deliveries of tissue samples for the three months ended September 30, 2018 and the Company recognized revenue of $450,000 for the deliveries of tissue samples for the nine months ended September 30, 2018. The Company recognized service revenue of $250,000 for the three and nine months ended September 30, 2018.

Legal Settlement

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In March 2018, the Company received $0.4 million as a settlement with an institutional investor that was a beneficial owner of the Company's common stock related to the disgorgement of short-swing profits pursuant to Section 16(b) of the Securities Exchange Act of 1934, as amended, or the Exchange Act. The settlement of $0.4 million was recognized as additional paid-in capital.

Recent Accounting Pronouncements

In February 2016, the FASB issued ASU No. 2016-2, Leases (Topic 842). This ASU is aimed at making leasing activities more transparent and comparable, and requires substantially all leases be recognized by lessees on their balance sheet as a right-of-use asset and corresponding lease liability, including leases currently accounted for as operating leases. The ASU will be effective for interim and annual periods beginning after December 15, 2018. Additionally, the FASB issued ASU, No. 2018-11, Leases (Topic 842): Targeted Improvements, which offers an additional transition method whereby entities may apply the new leases standard at the adoption date and recognize a cumulative-effect adjustment to the opening balance of retained earnings rather than application of the new leases standard at the beginning of the earliest period presented in the financial statements. The Company expects to adopt this standard beginning in 2019 and does not expect that this standard will have a material impact on its results of operations or cash flows, but that it will have a material impact on the Company’s assets and liabilities. The Company has accumulated a list of its leases and is currently in the process of quantifying the impact of adopting this ASU.

In June 2018, the FASB issued ASU No. 2018-07, Compensation - Stock Compensation (Topic 718): Improvements to Nonemployee Share Based Payment Accounting. Under this ASU, the accounting for share - based payments to nonemployees and employees will be substantially aligned, primarily by permitting the measurement of nonemployee awards to be fixed at the grant date. This ASU is effective for all interim and annual reporting periods beginning on or after December 15, 2018, with early adoption permitted. The Company does not expect the adoption to have a material impact to the condensed consolidated financial statements.

2. Net Loss Per Common Share

Basic net loss per common share is calculated by dividing net loss attributable to common stockholders by the weighted-average number of common shares outstanding during the period, without consideration of common stock equivalents. Diluted net loss per common share is computed by dividing net loss attributable to common stockholders by the weighted-average number of common share equivalents outstanding for the period determined using the treasury stock method. The following outstanding common stock equivalents have been excluded from diluted net loss per common share because their inclusion would be anti-dilutive:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Shares of common stock subject to outstanding options	5,995,401	6,322,215	6,065,250	6,134,966
Employee stock purchase plan	27,117	25,481	32,513	31,944
Restricted stock units	445,598	70,000	363,896	59,945
Total common stock equivalents	6,468,116	6,417,696	6,461,659	6,226,855

3. Accrued Liabilities

Accrued liabilities consisted of the following (in thousands of dollars):

	September 30, 2018	December 31, 2017
Accrued compensation expenses	$ 6,409	$ 5,293
Accrued other	2,852	2,882
Total accrued liabilities	$ 9,261	$ 8,175

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4. Fair Value Measurements

The Company records its financial assets and liabilities at fair value. The carrying amounts of certain financial instruments of the Company, including cash and cash equivalents, prepaid expenses and other current assets, accounts payable and accrued liabilities, approximate fair value due to their relatively short maturities. The carrying value of the Company’s debt approximates its fair value because the interest rate approximates market rates that the Company could obtain for debt with similar terms. The fair value of the Company’s debt is estimated using the net present value of the payments, discounted at an interest rate that is consistent with market interest rates, which is a Level II input. The accounting guidance for fair value provides a framework for measuring fair value, clarifies the definition of fair value, and expands disclosures regarding fair value measurements. Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability (an exit price) in an orderly transaction between market participants at the reporting date. The accounting guidance establishes a three-tiered hierarchy, which prioritizes the inputs used in the valuation methodologies in measuring fair value as follows:

- Level I: Inputs which include quoted prices in active markets for identical assets and liabilities;

- Level II: Inputs other than Level I that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities; and

- Level III: Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The fair value of the Company’s financial assets include money market funds and a deposit for the lease of the Company's South San Francisco facility. Money market funds, included in cash and cash equivalent