
**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): **May 14, 2019**

OncoCyte Corporation

(Exact name of registrant as specified in its charter)

California
(State or other jurisdiction
of incorporation)

1-37648
(Commission
File Number)

27-1041563
(IRS Employer
Identification No.)

**1010 Atlantic Avenue
Suite 102
Alameda, California 94501**
(Address of principal executive offices)

(510) 775-0515
(Registrant's telephone number, including area code)

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

<u>Title of each class</u>	<u>Trading Symbol</u>	<u>Name of each exchange on which registered</u>
Common Stock, no par value	OCX	NYSE American

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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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.

Forward-Looking Statements

Any statements that are not historical fact (including, but not limited to statements that contain words such as “may,” “will,” “believes,” “plans,” “intends,” “anticipates,” “expects,” “estimates”) should also be considered to be forward-looking statements. Additional factors that could cause actual results to differ materially from the results anticipated in these forward-looking statements are contained in OncoCyte Corporation’s Form 10-K filed with the Securities and Exchange Commission (“SEC”) under the heading “Risk Factors” and other filings that OncoCyte may make with the SEC. Undue reliance should not be placed on these forward-looking statements which speak only as of the date they are made, and the facts and assumptions underlying these statements may change. Except as required by law, OncoCyte disclaims any intent or obligation to update these forward-looking statements.

References to “OncoCyte,” “we” or “us” are references to OncoCyte Corporation.

The information in Item 2.02 and the accompanying Exhibit 99.1 shall be deemed “furnished” and not “filed” under Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liability of that section, and shall not be incorporated by reference into any filings made by OncoCyte under the Securities Act of 1933, as amended, or the Exchange Act except as may be expressly set forth by specific reference in such filing.

Section 2 - Financial Information

Item 2.02 - Results of Operations and Financial Condition

On May 14, 2019, OncoCyte issued a press release announcing its financial results for the three months ended March 31, 2019. A copy of the press release is attached as Exhibit 99.1, which, in its entirety, is incorporated herein by reference.

Item 9.01 - Financial Statements and Exhibits.

<u>Exhibit Number</u>	<u>Description</u>
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99.1	Press release dated May 14, 2019
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SIGNATURES

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.

ONCOCYTE CORPORATION

Date: May 14, 2019

By: /s/ William Annett

William Annett

President and Chief Executive Officer



ONCOCYTE PROVIDES CORPORATE UPDATE AND REPORTS FIRST QUARTER 2019 FINANCIAL RESULTS

Completes successful Analytical Validation study and initiates CLIA Validation study

On track for commercial availability of DetermaVu™ in 2H 2019

Conference Call Today at 4:30 PM EDT

ALAMEDA, Calif., May 14, 2019 — **OncoCyte Corporation (NYSE American: OCX)**, a developer of novel, non-invasive tests for the early detection of lung cancer, today reported financial and operating results for the first quarter ended March 31, 2019 and provided a corporate update.

“During the first quarter and now into the second quarter, we continued to make great strides advancing DetermaVu™ through clinical development,” commented William Annett, President and Chief Executive Officer of OncoCyte. “In addition to the previously-reported positive results of our R&D Validation study, we recently announced positive results from our Analytical Validation study of DetermaVu™. We have moved quickly into the next phase and expect to complete CLIA Laboratory Validation soon. We will then proceed to the final study before commercialization, an approximately 440 patient blinded prospective Clinical Validation study.”

“With each successful validation step, we are rapidly approaching commercial availability, which we anticipate in the second half of this year. In parallel, we have begun to develop plans to explore the utility of DetermaVu™ in other solid tumor cancer indications with the goal of making this novel technology available to as many patients as possible. We continue to believe that DetermaVu™, which leverages our proprietary Immune System Interrogation approach to detect subtle changes in immune biomarkers in response to early-stage cancer, is poised to change the paradigm in lung cancer diagnostics. We look forward to efficiently completing the remaining development steps and transitioning to a commercial-stage company.”

Highlights

- Successfully completed Analytical Validation and initiated CLIA Laboratory Validation study
 - Announced a late-breaking abstract and discussion session at the American Thoracic Society 2019 International Conference detailing the compelling results from the R&D Validation study, a blinded, prospective study demonstrating best-in-class performance with sensitivity of 90% and specificity of 75%
 - Completed a successful equity raise of \$37.3 million in net proceeds which provides the funding to complete the development of DetermaVu™ and initiate commercialization efforts.
 - On-track to complete remaining validation studies by mid-year and make DetermaVu™ commercially available in the second half of 2019
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Remaining Validation Pathway for DetermaVu™:

- **2Q 2019:** CLIA Laboratory Validation study – Currently underway to rerun between 100 and 120 patient blood samples previously run in the R&D Validation study to confirm that the same positive results are obtained on the analytically validated systems in OncoCyte's CLIA laboratory
- **Mid-year 2019:** Clinical Validation study – Will run approximately 440 blinded, prospectively-collected blood samples to establish DetermaVu™'s performance in an independent, blinded data set as a final confirmation of test sensitivity and specificity in OncoCyte's CLIA lab setting
- **2H 2019:** Anticipated commercial availability of DetermaVu™
- **Post-launch (2020 initiation):** Clinical Utility study – Will conduct a real world evidence study to demonstrate a net improvement in patient outcomes and cost savings for the healthcare system from the use of DetermaVu™ as a confirmatory diagnostic test for lung cancer

First Quarter 2019 Financial Highlights

At March 31, 2019, OncoCyte had cash, cash equivalents and marketable securities of \$39.9 million as compared to \$8.4 million at December 31, 2018. The balance sheet was strengthened in February 2019 with the successful equity raise of \$37.3 million in net proceeds from an underwritten public offering.

For the first quarter ended March 31, 2019, OncoCyte incurred a net loss of \$3.9 million, or \$(0.08) per share, as compared to \$3.8 million, or \$(0.12) per share, for the three months ended March 31, 2018.

Operating expenses for the three months ended March 31, 2019 were \$4.0 million, and \$3.2 million on an as-adjusted basis, as compared to \$3.9 million, or \$3.4 million on an as adjusted basis, for the same period in 2018.

The reconciliation between GAAP and non-GAAP operating expenses is provided in the financial tables included with this earnings release.

Research and development expenses for the quarter ended March 31, 2019 were \$1.3 million as compared to \$1.5 for the same period in 2018, relatively unchanged quarter over quarter, as OncoCyte continued to focus resources on the development and commercialization of DetermaVu™.

General and administrative expenses for the three months ended March 31, 2019 were \$2.4 million, as compared to \$1.7 million for the same period in 2018, an increase of \$0.7 million. This increase is primarily attributable to \$0.4 million in personnel and related expenses and \$0.3 million in stock-based compensation expense due to increased grants of equity awards.

Sales and marketing expenses for the three months ended March 31, 2019 were \$0.2 million, as compared to \$0.7 million for the same period in 2018, a decrease of \$0.5 million, primarily attributable to a decrease in marketing personnel and consultants as OncoCyte concentrated its resources on the development of DetermaVu™ rather than on marketing related activities.

Conference Call

The Company will host a conference call today, May 14, 2019, at 4:30 pm EDT / 1:30 pm PDT to discuss the results along with recent corporate developments.

The dial-in number in the U.S./Canada is 877-407-9716; for international participants, the number is 201-493-6779. For all callers, please refer to Conference ID 13689785. To access the live webcast, go to the investor relations section on the Company's website, <http://investors.oncocyte.com/events-and-presentations>.

About DetermaVu™

DetermaVu™ is being developed as an intermediate step to confirm the absence of cancer between imaging modalities (LDCTs) detecting suspicious lung nodules and downstream invasive procedures that determine if the nodules are malignant. OncoCyte estimates that a \$2 billion to \$4.7 billion annual market could develop in the U.S. for its confirmatory lung cancer liquid biopsy test, depending on the scope of physician utilization, market penetration and reimbursable pricing.

DetermaVu™ has the potential to dramatically reduce U.S. healthcare costs by billions of dollars each year by eliminating unnecessary biopsies, which, according to a recent Medicare study, cost on average \$14,634 each. In addition, DetermaVu™ can provide great benefit to patients by avoiding invasive biopsies and the complications that arise in up to 24% of those procedures, and deaths that occur in up to 1% of cases.

DetermaVu™ is a trademark of OncoCyte Corporation.

About OncoCyte Corporation

OncoCyte is focused on the development and commercialization of novel, non-invasive blood ("liquid biopsy") diagnostic tests for the early detection of lung cancer. Early detection of cancer can improve health outcomes, reduce the cost of care, and improve patients' quality of life. Liquid biopsy diagnostic tests like those OncoCyte is developing may reduce the need for costlier and riskier diagnostic procedures such as invasive biopsy procedures. OncoCyte is focusing its efforts on the development of DetermaVu™ as a non-invasive confirmatory diagnostic test for lung cancer. DetermaVu™ is being developed using proprietary sets of genetic molecular markers that differentially express in lung cancer. OncoCyte also plans to conduct research to identify additional molecular markers, acquire or license markers and related technology, and develop cancer tests based on those markers.

OncoCyte Forward Looking Statements

Any statements that are not historical fact (including, but not limited to statements that contain words such as “will,” “believes,” “plans,” “anticipates,” “expects,” “estimates” and similar expressions) are forward-looking statements. These statements include those pertaining to the implementation and results of research, development, clinical trials and studies, commercialization plans, future financial and/or operating results, and future opportunities for OncoCyte, along with other statements about the future expectations, beliefs, goals, plans, or prospects expressed by management. Forward-looking statements involve risks and uncertainties, including, without limitation, risks inherent in the development and/or commercialization of potential diagnostic tests or products, uncertainty in the results of clinical trials or regulatory approvals, the capacity of our third-party supplied blood sample analytic system to provide consistent and precise analytic results on a commercial scale, the need and ability to obtain future capital, and maintenance of intellectual property rights, and the need to obtain third party reimbursement for patients’ use of any diagnostic tests we commercialize. Actual results may differ materially from the results anticipated in these forward-looking statements and accordingly as such statements should be evaluated together with the many uncertainties that affect the business of OncoCyte, particularly those mentioned in the “Risk Factors” and other cautionary statements found in OncoCyte’s Securities and Exchange Commission filings. OncoCyte disclaims any intent or obligation to update these forward-looking statements, except as required by law.

Investor Contacts

Bob Yedid
LifeSci Advisors, LLC
646-597-6989
bob@lifesciadvisors.com

ONCOCYTE CORPORATION
CONDENSED BALANCE SHEETS
(IN THOUSANDS)

	<u>March 31, 2019</u> <u>(Unaudited)</u>	<u>December 31, 2018</u>
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	\$ 39,257	\$ 8,034
Marketable equity securities	606	428
Prepaid expenses and other current assets	1,130	180
Total current assets	<u>40,993</u>	<u>8,642</u>
NONCURRENT ASSETS		
Machinery and equipment, net	486	614
Deposits and other noncurrent assets	198	262
TOTAL ASSETS	<u>\$ 41,677</u>	<u>\$ 9,518</u>
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES		
Amount due to BioTime and affiliates	\$ -	\$ 2,101
Accounts payable	136	166
Accrued expenses and other current liabilities	1,957	2,109
Loan payable, current	800	800
Financing lease liability, current	304	385
Total current liabilities	<u>3,197</u>	<u>5,561</u>
NONCURRENT LIABILITIES		
Loan payable, net of deferred financing costs, noncurrent	159	347
Financing lease liability, noncurrent	134	187
TOTAL LIABILITIES	<u>3,490</u>	<u>6,095</u>
SHAREHOLDERS' EQUITY		
Preferred stock, no par value, 5,000 shares authorized; none issued and outstanding	-	-
Common stock, no par value, 85,000 shares authorized; 51,973 and 40,664 shares issued and outstanding at March 31, 2019 and December 31, 2018, respectively	113,370	74,742
Accumulated other comprehensive loss	-	-
Accumulated deficit	(75,183)	(71,319)
Total shareholders' equity	<u>38,187</u>	<u>3,423</u>
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	<u>\$ 41,677</u>	<u>\$ 9,518</u>

ONCOCYTE CORPORATION
CONDENSED STATEMENTS OF OPERATIONS
(IN THOUSANDS, EXCEPT PER SHARE DATA)
(UNAUDITED)

	Three Months Ended March 31,	
	2019	2018
EXPENSES:		
Research and development	\$ 1,343	\$ 1,461
General and administrative	2,449	1,787
Sales and marketing	205	658
Total operating expenses	3,997	3,906
Loss from operations	(3,997)	(3,906)
OTHER INCOME (EXPENSES), NET		
Interest expense, net	(19)	(60)
Unrealized gain on marketable equity securities	178	190
Other expenses, net	(26)	(2)
Total other income, net	133	128
NET LOSS	\$ (3,864)	\$ (3,778)
Net loss per share: basic and diluted	\$ (0.08)	\$ (0.12)
Weighted average common shares outstanding: basic and diluted	46,647	31,676

ONCOCYTE CORPORATION
CONDENSED STATEMENTS OF CASH FLOWS
(IN THOUSANDS)
(UNAUDITED)

	Three Months Ended March 31,	
	2019	2018
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (3,864)	\$ (3,778)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	110	103
Amortization of intangible assets	-	61
Amortization of prepaid maintenance	9	-
Stock-based compensation	686	347
Unrealized gain on marketable equity securities	(178)	(190)
Amortization of debt issuance costs	12	22
Other	26	-
Changes in operating assets and liabilities:		
Amount due to BioTime and affiliates	(2,101)	7
Prepaid expenses and other current assets	(950)	(324)
Accounts payable and accrued liabilities	(468)	999
Net cash used in operating activities	<u>(6,718)</u>	<u>(2,753)</u>
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of equipment	(7)	(5)
Security deposit and other	54	-
Net cash provided by (used in) investing activities	<u>47</u>	<u>(5)</u>
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from exercise of options	943	51
Proceeds from sale of common shares	40,250	8,000
Financing costs to issue common shares	(2,965)	-
Repayment of loan payable	(200)	(200)
Repayment of financing lease obligations	(134)	(81)
Net cash provided by financing activities	<u>37,894</u>	<u>7,770</u>
NET INCREASE IN CASH AND CASH EQUIVALENTS	31,223	5,012
CASH AND CASH EQUIVALENTS:		
At beginning of the period	8,034	7,600
At end of the period	<u>\$ 39,257</u>	<u>\$ 12,612</u>

Non-GAAP Financial Measures

This earnings release includes operating expenses prepared in accordance with accounting principles generally accepted in the United States (GAAP), and includes certain historical non-GAAP operating expenses. In particular, OncoCyte has provided non-GAAP total operating expenses, adjusted to exclude noncash stock-based compensation and depreciation and amortization expense. Non-GAAP financial measures are not meant to be considered in isolation or as a substitute for comparable financial measures prepared in accordance with GAAP. However, OncoCyte believes the presentation of non-GAAP total operating expenses, when viewed in conjunction with our GAAP total operating expenses, is helpful in understanding OncoCyte's ongoing operating expenses and its programs.

Furthermore, management uses these non-GAAP financial measures in the aggregate to establish budgets and operational goals, to manage OncoCyte's business and to evaluate its performance and its programs.

OncoCyte Corporation

Reconciliation of Non-GAAP Financial Measure
Adjusted Operating Expenses

	Amounts In Thousands	
	For the Three Months Ended March 31,	
	2019 (unaudited)	
GAAP Operating Expenses - as reported	\$	3,997
Stock-based compensation expense		(686)
Depreciation and amortization expense		(119)
Non-GAAP Operating Expenses, as adjusted	\$	3,192
