OncoCyte Corp
Form 8-K
March 06, 2017

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): March 6, 2017

OncoCyte Corporation
(Exact name of registrant as specified in its charter)

California	1-37648	27-1041563
(State or other jurisdiction of incorporation)	(Commission File Number)	(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)

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))

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

Section 7 - Regulation FD

Item 7.01 - Regulation FD Disclosure

On March 6, 2017, OncoCyte issued the press release attached to this report as Exhibit 99.1. The content of this Item 7.01 and 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 filing 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.

Item 8.01 - Other Events

OncoCyte has successfully completed a 300 blood sample study of the mRNA biomarker-based lung cancer diagnostic test that it is developing, and has locked the prediction algorithm of the test. The study confirmed an earlier study of the same biomarkers by The Wistar Institute of Anatomy and Biology, the results of which were reported at the CHEST 2016 Annual Meeting in October 2016. The Area Under the Curve (AUC) in Wistar’s study was 0.82 with a sensitivity of 90% and specificity of 62%. OncoCyte’s study results were consistent with Wistar’s and are well above the levels that OncoCyte believes are necessary for a commercially successful test based on its own market research. The AUC of a test is a measure that combines sensitivity and specificity to express its total accuracy, with 1.0 being perfect accuracy and 0.50 being a random result. Sensitivity and specificity are statistical measures of test performance, with sensitivity measuring the percentage of malignant nodules that are identified correctly by the test and specificity measuring the percentage of benign nodules correctly identified.

OncoCyte’s study utilized Wistar’s biomarker panel, which has been exclusively licensed to OncoCyte. The study developed and tested OncoCyte’s proprietary algorithm using approximately 300 blood samples collected from patients at 26 sites across the United States. OncoCyte developed its algorithm by combining data from the top mRNA biomarkers with clinical data such as nodule size. The samples were collected from patients with nodules ranging in size from five to thirty millimeters, the size range presenting the greatest diagnostic challenge to clinicians. For patients with these size nodules physicians must weigh the risk of cancer against the risks posted by invasive biopsies to confirm whether the nodules are malignant or benign.

Based on the study results, OncoCyte will begin ramping-up its commercial capabilities in anticipation of the potential commercial launch of the test. OncoCyte will initiate a clinical validation phase for the diagnostic. During this phase, OncoCyte will also continue to carry out analytical validation studies to refine its operational stage laboratory processes, and will apply for certification of its CLIA diagnostic testing lab. Upon CLIA certification, OncoCyte will conduct a small CLIA lab validation study to demonstrate that the full assay system utilized in the CLIA lab provides the same results on clinical samples as those obtained in the R&D lab. OncoCyte will then begin a clinical validation

study on a new set of at least 300 blinded prospectively collected blood samples to confirm whether the sensitivity and specificity of the test remain within commercial parameters in a CLIA operational setting. Assuming successful completion of these steps, OncoCyte anticipates launching the test commercially in the second half of 2017.

Item 9.01 Financial Statements and Exhibits

Exhibit Number	Description
99.1	Press Release dated March 6, 2017

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: March 6, 2017 By: /s/ Russell Skibsted
Russell Skibsted
Chief Financial Officer