OncoCyte Corp
Form DEFA14A
July 30, 2018

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

SCHEDULE 14A
(Rule 14a-101)

INFORMATION REQUIRED IN PROXY STATEMENT

SCHEDULE 14A INFORMATION

Proxy Statement Pursuant to Section 14(a) of the Securities Exchange Act of 1934

Filed by the Registrant

Filed by a Party other than the Registrant

Check the appropriate box:

Preliminary Proxy Statement
Confidential, for Use of the Commission Only (as permitted by Rule 14a-6(e)(2))
Definitive Proxy Statement
Definitive Additional Materials
Soliciting Material Pursuant to §240.14a-12

OncoCyte Corporation

(Name of Registrant as Specified in Its Charter)

(Name of Person(s) Filing Proxy Statement if other than the Registrant)

Payment of Filing Fee (Check the appropriate box):
No fee required.
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(1) Title of each class of securities to which transaction applies:

(2) Aggregate number of securities to which transaction applies:

(3) Per unit price or other underlying value of transaction computed pursuant to Exchange Act Rule 0-11 (Set forth the amount on which the filing fee is calculated and state how it was determined):

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Check box if any part of the fee is offset as provided by Exchange Act Rule 0-11(a)(2) and identify the filing for which the offsetting fee was paid previously. Identify the previous filing by registration statement number, or the form or schedule and the date of its filing.

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July 27, 2018

Dear Shareholders,

I am happy to report that since the beginning of 2018 we have seen encouraging progress in the development of DetermaVu™, our novel, non-invasive liquid biopsy test to aid in the early detection of lung cancer. While we had setbacks and delays last year related to the diagnostic testing platform we were using, our July announcement of the success of our most recent study indicates that our development plans are back on track. This latest study supports moving the test to a leading clinical diagnostic testing platform and indicates that the clinical performance of the test, utilizing an expanded panel of newly discovered genetic markers, may be better than we previously expected.

The move to a leading diagnostic testing platform is expected to resolve the inconsistent data issues we encountered during 2017 with the platform we were previously using. Working with the new diagnostic testing platform also enabled us to identify new biomarkers, and we have already filed patent applications for a group of those new markers. While the DetermaVu™ data that we reported in 2017, based on the original biomarker panel, was impressive, we believe that the addition of a select group of the newly discovered biomarkers should make DetermaVu™ a more accurate and reliable test, without the need to include clinical data such as nodule size which had been included in our earlier studies.

We now plan to use the new diagnostic testing platform to perform a prospective, blinded R&D Validation Study on approximately 250 patient sample to assess the performance of the expanded biomarker panel and a new algorithm. If successful, the R&D Validation Study will be followed by an Analytical Validation Study in the Company's CLIA laboratory. Finally, we plan to conduct a Clinical Validation Study to confirm DetermaVu's™ performance. Our goal is to complete the R&D Validation Study by the end of 2018 and the Clinical Validation Study during the first half of 2019.

The market opportunity for DetermaVu™ is significant, and based on published sources we estimate that approximately 1.4 million patients annually in the U.S. could benefit from this test. Assuming this number of patients and our currently planned pricing for DetermaVu™, the total addressable market could potentially exceed $4 billion annually. We also believe that DetermaVu™ could provide Medicare and private insurance companies with significant cost savings by eliminating the need for an invasive lung biopsy.

Despite the challenges we faced in 2017, we did achieve some significant milestones. We were successful in building out and achieving Clinical Laboratory Improvement Amendments (CLIA) certification of our commercial diagnostic testing laboratory. This means that we can now process patient samples from 48 states, and we expect to receive approval in Maryland in the near future. Since New York has its own licensing requirements, we plan on pursuing licensure there as well.

In December 2017 we presented positive data from our most recent breast cancer diagnostic test study at the 2017 San Antonio Breast Cancer Symposium. This study revealed that our novel blood based diagnostic test may allow for the non-invasive and sensitive detection of breast cancer in women who have undergone mammogram screening that shows suspicious lumps or masses. Potentially this test could differentiate women who have breast cancer from those who do not. A 19-marker model resulted in an AUC of 0.935 with a sensitivity of 90% and specificity of 82%.

We look forward to keeping you informed of our progress and thank you for your continued support as we work to achieve these objectives.

Respectfully,

William Annett
Chief Executive Officer