OncoCyte Corp
Form DEFA14A
May 03, 2017

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 [X]

Filed by a Party other than the Registrant [ ]

Check the appropriate box:

[ ] Preliminary Proxy Statement

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[ ] Definitive Proxy Statement

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OncoCyte Corporation

(Name of Registrant as Specified in Its Charter)

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

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(4) Date filed:

OncoCyte Corporation

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May 2, 2017

Dear Shareholders,

In the past year OncoCyte has made steady progress towards its goal of creating innovative diagnostic tests for cancer. We are excited by our success to date, and in particular by the prospective launch of our first commercial product in the second half of this year.

We believe that our novel, non-invasive liquid biopsy tests will aid in the early detection of cancer and reduce the healthcare costs and patient risks associated with unnecessary biopsies and their complications. Today the vast majority of biopsies for lung cancer and breast cancer have benign results. Our tests are designed to be administered after screening tests, such as low dose CT scans for lung cancer and mammograms for breast cancer, thereby eliminating unnecessary biopsies of benign tumors.

We are proud of our achievements over the past year, during which we:

Entered into a definitive global licensing agreement with The Wistar Institute of Anatomy and Biology, providing OncoCyte the exclusive right to commercialize the lung cancer diagnostic test that OncoCyte and Wistar have been collaboratively developing on since 2013.

Completed a market research study of 180 physicians, and a health economic outcomes study, which lead OncoCyte to believe that a successful confirmatory lung cancer test must have a sensitivity of at least 85% and a specificity of at least 30%.

Announced successful results of Wistar’s lung cancer test study of 610 subjects which was presented 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%. These results are significantly above the levels that we believe are

necessary for a commercially viable lung cancer test.

Set up a network of over 40 clinical sites across the United States to collect samples for our lung cancer studies.

Initiated a 300 patient internal R&D Validation study for the lung cancer diagnostic test to see whether we could confirm Wistar's results using our equipment to analyze samples that we collected.

Presented positive data on our other pipeline products at prestigious medical conferences – at the San Antonio Breast Cancer Symposium for our breast cancer test and at the American Society of Clinical Oncology for our bladder cancer test.

Built our R&D and commercial teams by hiring accomplished professionals with extensive experience in diagnostics.

We have continued to build momentum during 2017:

- Reported the successful results of our lung cancer R&D Validation study, which were consistent with results of Wistar's earlier study.
- Continued to build our team by adding to the CLIA laboratory a board certified Clinical Laboratory Director, a clinical supervisor and a licensed technologist.
- Ramped up the marketing and market access functions required for launch of the lung cancer diagnostic test.
- Submitted our application for Clinical Laboratory Improvement Amendments (CLIA) certification of our laboratory, which will be used for commercial operations.
- Announced that our breast cancer test development is ahead of schedule and commercial launch is being targeted for late 2018

With the successful completion of these milestones we are taking the next steps required to launch our lung cancer diagnostic test. We believe that we will receive CLIA certification late in the second quarter, and then will proceed with Clinical Validation studies to be carried out in the CLIA lab. If these studies are successful we will launch the lung test in the second half of 2017.

We are very excited about the commercial potential for our lung cancer test, and estimate that there are approximately 1.4 million patients annually in the U.S. who could benefit from it. Assuming this number of patients and our currently planned pricing, the total addressable market could potentially exceed $4 billion. Furthermore, we believe that OncoCyte is positioned to be the first company to enter this market with a highly accurate test, and that it will be several years before competitors reach the market. This first mover advantage should be significant, and we hope to use it to develop deep relationships with the key stakeholders necessary for commercial success – patients, physicians and payors. Our test should have significant benefits for each group, improving the diagnostic process for doctors, helping patients avoid risky and unnecessary biopsies, and providing payors with significant cost savings by reducing unnecessary procedures and complications.

With our lung cancer diagnostic currently on schedule and our breast cancer diagnostic test development moving forward we are pleased with OncoCyte's progress to date. Thank you for your continued support as we work to achieve these objectives.

Respectfully,

William Annett	Alfred D. Kingsley
Chief Executive Officer	Chairman of the Board of Directors