

OncoCyte Corp
Form DEFA14A
May 05, 2016

**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

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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:

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May 4, 2016

Dear Shareholders,

2015 was a period of significant clinical progress for OncoCyte as we published strong data for each of our liquid biopsy products – tests for lung, breast and bladder cancer. Operationally, we enhanced our Board of Directors and strengthened our management team with seasoned life sciences professionals with deep scientific knowledge and extensive commercialization experience. We successfully listed our shares on the NYSE MKT, enabling us to reach out to a broader base of shareholders and giving us greater flexibility in accessing capital markets as we execute our commercial strategy in 2016 and beyond.

OncoCyte is well positioned to benefit from the current shift in the standard of care in diagnostics away from traditional methods, like imaging and tissue biopsies, towards more accurate and/or less invasive liquid biopsies. OncoCyte's diagnostic tests are being developed to address the large unmet medical need for early, accurate and non-invasive diagnosis in multiple cancers, including our initial targets of lung, breast and bladder cancer. Millions of diagnostic tests for cancer are performed each year in the U.S. Early detection can provide patients with better outcomes, doctors with more reliable treatment options and the healthcare system with lower costs. We have tests for three different kinds of cancer under development, each of which presents a significant and unique market opportunity. We are currently concentrating our efforts on commercializing our blood-based confirmatory lung cancer diagnostic.

Lung cancer is a national health priority because it leads to the largest number of annual deaths of any cancer. Unfortunately most lung cancer gets diagnosed at Stage 3 or Stage 4 when it is too late for successful treatment. In order to increase detection of lung cancer at an earlier stage the U.S. Preventative Services Taskforce recently recommended that high-risk individuals get annual scans. There are an estimated 10 million high-risk patients in the U.S. that require annual testing. Approximately 25% of all screenings are recommended for further testing, such as biopsy, which increases patient risk and healthcare payer expense. Unfortunately, today's standard of care has a high false positive rate resulting in 96% of these follow-up procedures being unnecessary - there clearly needs to be a safer and more reliable approach. Our lung cancer diagnostic is being designed to improve patient outcomes and reduce costs to the healthcare system through the early and accurate detection of cancer.

We continue to progress towards commercializing our lung cancer confirmatory diagnostic. In 2015, we presented positive interim clinical results from a trial that we sponsored at the Wistar Institute, an international biomedical research leader in cancer, immunology and infectious diseases. Wistar recently replicated the same high level of observed sensitivity and specificity in a much larger clinical trial with over 600 patients. We now need to independently validate these results in our laboratory. If we are successful in this analytical validation study, our next goal will be to obtain CLIA certification for our laboratory and build out our commercial capabilities for a product launch in the first half of 2017.

Along with our lung cancer diagnostic, we also have a robust pipeline of both confirmatory and screening products for breast and bladder cancer. Our blood-based, confirmatory test for breast cancer is in the research and development phase. If our efforts are successful, we plan to begin commercialization in 2018. OncoCyte's breast cancer diagnostic is being developed to confirm indeterminate mammograms early in the treatment process to avoid unnecessary traditional biopsies. We believe this test addresses a potential patient population of approximately 2 million American women who receive tissue biopsies each year. Furthermore, if we are successful in developing our breast cancer screening test, which will be used upstream in the treatment spectrum, we believe the market potential is the 38 million patients who receive mammograms annually in the US.

Using similar technology to our lung cancer test, our third product is a urine-based diagnostic for bladder cancer. Bladder cancer has the highest lifetime treatment costs per patient of all cancers due to the high recurrence rate and ongoing invasive monitoring requirements. In 2015, we presented an interim clinical study data for the non-invasive detection of bladder cancer at the American Association for Cancer Research (AACR) which demonstrated a high level of sensitivity and specificity in the detection of the most common type of bladder cancer, urothelial carcinoma. We will be discussing the continued development of this product at this year's American Society of Clinical Oncology (ASCO) Annual Meeting where our bladder cancer abstract was selected for presentation in a poster session.

With each of our three tests, OncoCyte is in the vanguard as the standard of care moves from traditional imaging and tissue biopsy to less invasive, safer and more reliable liquid biopsies. By addressing the concerns and needs of providers, patients and payers, OncoCyte is well positioned to execute its commercial strategy and build value for its shareholders.

We are continuing to execute on our business plan and look forward to providing updates on corporate developments as we work to develop our lung, breast and bladder tests.

Thank you for your continued support.

Respectfully,

William Annett
Chief Executive Officer

Alfred D. Kingsley
Chairman of the Board of Directors