OncoCyte Corp
Form 10-K
April 02, 2018

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

FORM 10-K

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2017

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from_____ to _____

Commission file number 1-37648

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

California	27-1041563
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

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

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

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

Title of each class	Name of exchange on which registered
Common Stock, no par value	NYSE American

Securities registered pursuant to Section 12(g) of the Act:
None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.
Yes No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and “emerging growth company” in Rule 12b-2 of the Exchange Act.

Large accelerated filer		Accelerated filer
Non-accelerated filer	(Do not check if a smaller reporting company)	Smaller reporting company
		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 to Section 13(a) of the Exchange Act.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act): Yes No

The approximate aggregate market value of shares of voting common stock held by non-affiliates computed by reference to the price at which shares of common stock were last sold as of June 30, 2017 was $41.4 million. Shares held by each executive officer and director and by each person who beneficially owns more than 5% of the outstanding common stock have been excluded in that such persons may under certain circumstances be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of March 20, 2018, there were outstanding 31,468,558 shares of common stock, no par value.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Proxy Statement for its 2018 Annual Meeting of Shareholders are incorporated by reference in Part III

OncoCyte Corporation
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PART I

Certain statements contained herein are forward-looking statements, within the meaning of the Private Securities Litigation Reform Act of 1995, including, but not limited to, statements pertaining to future financial and/or operating results, future growth in research, technology, clinical development, and potential opportunities for OncoCyte, along with other statements about the future expectations, beliefs, goals, plans, or prospects expressed by management constitute 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") should also be considered to be forward-looking statements. Forward-looking statements involve risks and uncertainties, including, without limitation, risks inherent in the development and/or commercialization of potential products, uncertainty in the results of clinical trials or regulatory approvals, need and ability to obtain future capital, and maintenance of intellectual property rights. Actual results may differ materially from the results anticipated in these forward-looking statements and as such should be evaluated together with the many uncertainties that affect the businesses of OncoCyte, particularly those mentioned in the cautionary statements found in OncoCyte's filings with the Securities and Exchange Commission. OncoCyte disclaims any intent or obligation to update these forward-looking statements.

References to "OncoCyte," "our" or "us" mean OncoCyte Corporation.

The description or discussion, in this Form 10-K, of any contract or agreement is a summary only and is qualified in all respects by reference to the full text of the applicable contract or agreement.

INDUSTRY AND MARKET DATA

This Annual Report (“Report”) on Form 10-K contains market data and industry forecasts that were obtained from industry publications, third party market research and publicly available information. These publications generally state that the information contained therein has been obtained from sources believed to be reliable. While we believe that the information from these publications is reliable, we have not independently verified such information.

This Report also contains estimates and other statistical data made by independent parties and by us relating to market size and growth and other data about our industry. We obtained the industry and market data in this Report from our own research as well as from industry and general publications, surveys and studies conducted by third parties, some of which may not be publicly available. Such data involves a number of assumptions and limitations and contains projections and estimates of the future performance of the industries in which we operate that are subject to a high degree of uncertainty. We caution you not to give undue weight to such projections, assumptions and estimates.

PRELIMINARY NOTE ABOUT OWNERSHIP OF OUR COMMON STOCK

As of March 20, 2018, we had 249 shareholders of record and there were 31,468,558 shares of our common stock outstanding, of which 14,674,244 shares were held by our parent BioTime, Inc. ("BioTime"). Beginning on February 17, 2017, the shares held by BioTime account for less than 50% of our total common stock outstanding. Accordingly, effective February 17, 2017, we are a no longer a consolidated subsidiary of BioTime. See Note 1 of our financial statements included elsewhere in this Report.

REVERSE STOCK SPLIT

On November 18, 2015, OncoCyte effected a 1-for-2 reverse stock split of its common stock. All references to common stock, warrants, and options to purchase common stock, and all per share data and related information, including the price at which shares of common stock have been sold or may be issued, have been retroactively adjusted, where applicable, to reflect the reverse stock split of OncoCyte common stock as if it had occurred at the beginning of the earliest period presented.

Item 1. Business

Overview

Our mission is to develop highly accurate, easy to administer, non-invasive molecular diagnostic tests to improve the standard of care for cancer diagnosis to better meet the needs of patients, physicians and payers. Our initial focus will be confirmatory diagnostics, utilizing novel liquid biopsy technology, for use in conjunction with imaging to confirm initial suspicious imaging results such as lung nodules and breast lesions within certain oncology indications. Our lead product is DetermaVu™, which we are developing as a confirmatory diagnostic test for lung cancer.

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Our initial liquid biopsy diagnostic tests, such as DetermaVu™, will be confirmatory diagnostics and are being developed to reduce false positive results associated with current diagnostic protocols. These new diagnostic tests are intended to:

- Reduce unnecessary and sometimes risky procedures, as well as lower the cost of care through the avoidance of more expensive diagnostic procedures, including invasive biopsies;

- Improve the quality of life for cancer patients by reducing the anxiety associated with non-definitive diagnoses; and

- Improve health outcomes through avoidance of unnecessary invasive procedures

Our strategic focus is to develop diagnostic tests in areas of high unmet need and our initial work has been devoted to developing tests to detect lung cancer, breast cancer, and bladder cancer. We have prioritized our efforts on DetermaVu™ because we believe that lung cancer has one of the greatest unmet needs and because timing is opportune due to the focus on lung cancer screening awareness.

In addition, we may develop screening diagnostics as potential replacements for screening imaging protocols that do not meet the needs of patients, health care providers or payers. For some indications, we may also pursue the probability of recurrence of a specific cancer through the development of prognostics; or companion diagnostics that help a physician determine which therapy is the optimal treatment for the patient.

We were incorporated in 2009 in the state of California. Our principal executive offices are located at 1010 Atlantic Avenue, Suite 102, Alameda, California 94501. Our telephone number is (510) 775-0515.

Business Strategy

Our strategy is to identify medical indications where current diagnostic technology is not meeting the needs of patients, physicians, or payers due to poor early detection and/or a large number of false positives. Those indications are characterized by a current standard of care requiring patients to endure unnecessary, costly and risky additional confirmatory procedures. By focusing on what we believe to be the biggest unmet needs with manageable technological hurdles and potentially rapid times to market, we believe our strategy is an efficient and risk-balanced use of capital and human resources.

Unmet need for confirmatory diagnostics, as we see it, can be defined from the physician and payer perspective as low five year survival rates and as low specificity or high numbers of false positive test results. Oncology indications that fit these parameters include lung and breast cancer, as can be seen in the following graphic. Additionally, our strategy is to focus on indications where competition is low, a specialty sales force can be leveraged rather than those that require a large primary care sales force. See Graphic 1.

Graphic 1

In order to address this unmet need, we are developing blood and urine based liquid biopsy molecular cancer diagnostics utilizing a discovery platform that focuses on identifying genetic markers expressed in specific types of cancer. The diagnostic markers we have discovered thus far may address unmet needs in cancer diagnostic indications that have a strong potential to generate short- to mid-term revenues. Our approach is based on focusing on unmet medical needs, large market sizes and ease of use of the product.

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Our current development strategy for cancer diagnostic tests is to develop, evaluate and validate specific diagnostics using methods of detecting proteins, messenger RNA ("mRNA") or micro RNA ("miRNA"). We believe that this approach, which is often referred to as a biomarker or analyte agnostic approach, allows us to have a broader look into the genetic markers that differentially express in cancer. Differential expression means that we are looking for proteins, mRNA or miRNA that are present in bodily fluids more often or less often when the patient has a specific type of cancer present in their body as compared to patients with no cancer. These elements in the bodily fluids are referred to as biomarkers. Our development strategy will be matched to our market planning strategy to determine which:

·Diagnostic tests to prioritize in our development program;

·Diagnostic tests we should market ourselves;

·Diagnostic tests we should co-market through an alliance with one or more other companies; and

·Diagnostic tests we should out-license to third parties for development and/or commercialization.

Additional Information

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012. We will remain an "emerging growth company" until the earliest of (i) the last day of the fiscal year in which we have total annual gross revenues of $1.0 billion or more; (ii) the last day of our fiscal year following the fifth anniversary of the first sale of our common equity securities pursuant to an effective registration statement under the Securities Act of 1933, as amended (the "Securities Act"); (iii) the date on which we have issued more than $1.0 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the Securities and Exchange Commission, or the SEC. We refer to the Jumpstart Our Business Startups Act of 2012 herein as the "JOBS Act," and references herein to "emerging growth company" shall have the meaning associated with it in the JOBS Act.

As an emerging growth company, we may take advantage of specified reduced disclosure and other requirements that are otherwise applicable, in general, to public companies that are not emerging growth companies. These provisions include:

·Reduced disclosure about our executive compensation arrangements;

·No non-binding shareholder advisory votes on executive compensation or golden parachute arrangements; and

·Exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting.

We may take advantage of these exemptions for up to five years or such earlier time that we are no longer an emerging growth company.

DetermaVu™ Lung Cancer Diagnostic Test

Clinical Trials

To develop DetermaVu™ we tested blood samples from patients who were at risk for lung cancer, based on having positive or suspicious results from Low Dose Computed Tomography or LDCT screening, and who had undergone biopsies to determine the pathology results or who had undergone a series of imaging procedures (LDCT or PETscans) to determine if the nodule is continuing to grow. We then assessed gene expression patterns in those blood

samples to determine whether gene expression can distinguish between patients who likely have lung cancer and those who likely do not. Additionally, we will test blood samples from patients who used alternative screening procedures such as chest x-rays and who were referred for biopsies in order to validate our test on both screened patients with nodules and patients who had their nodules incidentally detected.

Our clinical trials began through work we sponsored at The Wistar Institute of Anatomy and Biology ("Wistar"). Wistar investigators and OncoCyte have assessed gene expression patterns in blood cells of patients with imaging detected nodules to differentiate malignant lung nodules from patients with non-malignant lung nodules. Initial analysis of patient data from this study was completed during the first quarter of 2015.

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The Wistar study results presented in 2015 included both nodules and non-nodules and is the first proof of concept for both our confirmatory and screening lung cancer diagnostic. A larger proof of concept study conducted by Wistar validated Wistar's earlier results with comparable findings. This larger analysis of 610 patients showed that the biomarkers alone had an AUC or ROC score of 0.82, resulting in a sensitivity of 90% and a specificity of 62%. These results suggest that a diagnostic comprised of biomarkers and a classifier could help clinicians manage treatment of patients with intermediate size nodules in way that would both improve health outcomes by potentially avoiding morbidity and mortality associated with lung biopsies as well as decreasing the overall costs of lung cancer detection. See Graphic 2 and Graphic 3.

Graphic 2 Wistar 2015 Study

Graphic 3 Wistar 2016 Study

DetermaVu™ R&D Validation Study

As an independent validation of Wistar's work, we developed our own algorithm using a subset of the biomarkers identified at Wistar, and combining data from the top mRNA biomarkers with clinical data such as nodule size. We used this new algorithm in an R&D validation study of DetermaVu™ in which we tested 299 blood samples collected from patients at 26 sites across the United States. 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. Our R&D validation study was able to surpass the results of the Wistar study with consistent findings of sensitivity of 97% (confidence interval of 90-98%) and specificity of 73% (confidence interval of 65-79%) compared to Wistar's 2015 results that showed a sensitivity of 76% and a specificity of 88%. See Graphic 2. Sensitivity refers to the probability of detecting the presence of the disease accurately; while specificity refers to the probability of accurately predicting not having the disease. The OncoCyte and Wistar preliminary lung cancer test had a false positive rate of only 12%. In comparison, National Lung Screening Test results reported in the New England Journal of Medicine (August 2011) showed that LDCTs have a very high false positive rate of approximately 96%. Under Lung RADS, most nodules over 10 mms are sent to biopsy even through the probability of malignancy is less than 12%.

Using a methodology referred to as violin plots, Dr. Anil Vachani a pulmonologist at the University of Pennsylvania demonstrated that DetermaVu™ was more accurate in calling a benign versus malignant sample than nodule size, which is used in the standard of care Lung RADS and the Veterans Administration model, a probability model used by some clinicians to estimate the probability of malignancy. See Graphic 5 violin plot is a graphic tool that allows the viewer to see the clustering effect of the test. In the case of a binary call of malignant versus benign, clustering can be desirable. Clustering for our lung cancer test, which is designated as the "classifier" in Graphic 4, shows low scores for most of the benign samples suggesting high specificity, and high scores for the malignant samples suggesting high sensitivity; while the scores for nodule size and the VA model are more spread out suggesting that nodule size and the model are less accurate than our test.

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Graphic 4 OncoCyte 2017 Results

Graphic 5

Clinical Validation Study

After completing our R&D validation study, we proceeded with work to commence a clinical validation study of DetermaVu™. We collected our own patient blood samples to conduct the clinical validation study to assure that the samples were geographically diverse, from different types of care centers, and represented a cross-section of the high-risk patient population with nodules. The patients selected for sample collection have lung nodules of 5 to 30 millimeters in size, which is the size range of nodules in patients for which the DetermaVu™ is intended.

During the process of running initial samples for our clinical validation study in November 2017, inconsistent analytic results were observed by our technical team. We determined that this was caused by a variance in the lots of consumables used in the analytic system that analyzes blood samples for the genetic markers that may indicate whether lung nodules found in patients are benign or suspicious. We engaged with the system manufacturer to more completely understand the issues that have delayed the DetermaVu™ clinical validation study.

Over the past few months, we reviewed a number of diagnostic testing platforms and during that analysis, we conducted studies that enabled us to discover new, not previously identified biomarkers, for which we have filed patent applications. Many of the new biomarkers were detected on multiple molecular diagnostic testing platforms, providing confidence in the results. In addition, many of the new biomarkers have fold changes greater than what we had seen in our earlier biomarkers. Fold change is a measure describing how much a biomarker changes between the average benign sample level and the average malignant sample level. For example, an average benign sample biomarker level of 100 and an average malignant biomarker level of 300 corresponds to a fold change of 3 or in common terms, a three-fold increase. The larger fold changes of these new biomarkers could make the biomarker more detectable using DetermaVu™ with standard molecular diagnostic laboratory testing platforms and therefore more operationally efficient and consistent.

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These new biomarkers also potentially may enhance the lung cancer signal identified by DetermaVu™ and as such we have incorporated certain of these biomarkers into a revised algorithm. This revised algorithm was tested on approximately 60 patient blood samples and resulted in accuracy as measured by AUC data equivalent or superior to our previously reported results, although the error bar or potential range of results from this small sample set is wide and the results must be confirmed in a larger sample set.

We are continuing to evaluate alternative diagnostic testing platforms by doing a follow-on study utilizing a larger set of clinical samples. We expect to complete the process of choosing the commercial diagnostic testing platform during the second quarter of 2018. After concluding this process, data will be available to determine which platform delivers the most accurate, consistent and robust test results while maintaining a reasonable cost of goods. If the results indicate that the chosen platform can produce consistent result in our CLIA lab, we plan to complete product development on the selected platform by carrying out an R&D validation study followed by an analytical validation study, and if those studies are successfully completed, we plan to conduct a clinical validation study. Clinical validation is the final step prior to commercial launch of a diagnostic test, and we are targeting completion of a clinical validation study by the latter part of 2018. We have collected all the samples necessary for carrying out these studies. If these studies are completed successfully, we plan to commercialize DetermaVu™. Until we perform these studies, we will not know whether we can successfully complete the development of DetermaVu™ and commence commercialization of the test.

Current Standard of Care

The current standard of care for diagnosing lung cancer in high risk patients is LDCT scanning. The United States Preventive Services Task force ("USPSTF") guidelines recommend annual LDCTs for patients at high risk for lung cancer. The USPSTF was created in 1984 as an independent, volunteer panel of national experts in prevention and evidence-based medicine. The USPSTF works to improve the health of all Americans by making evidence-based recommendations about clinical preventive services such as screenings, counseling services, and preventive medications.

The guidelines, released in December of 2013, recommend annual LDCT scans for all Americans aged 55 to 80 years old who have a 30 pack-year smoking history and currently smoke or have quit within the past 15 years. A 30 pack-year smoking history is defined as the number of cigarette packs smoked per day times the number of years smoked. A 30 pack-year patient would include the following types of patients:

·Person who has smoked a pack a day (20 cigarettes) for 30 years;

·Person who has smoked 15 cigarettes a day for 40 years; or

·Person who has smoked 40 cigarettes a day for 15 years.

These guidelines were driven by a need to improve the standard of care for diagnosing lung cancer. Currently, the survival rate for lung cancer is very low – only 17% of people are still alive five years after a lung cancer diagnosis. These low survival rates result in one of the highest mortality rates for lung cancer, which is projected to kill 154,050 Americans in 2018 (American Cancer Society). See Graphic 6.

5 Year Survival Rates by Indication
Graphic 6 1975 to 2007

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Moreover, the lung cancer survival rate, unlike many other types of cancer, has not increased significantly in the last 30 years. The low probability of surviving lung cancer is significantly affected by the late diagnosis – with more than half of all patients diagnosed after the point that the cancer has spread. Poor survival rates for lung cancer was one of the drivers for the development of the USPSTF guidelines. Annual screening with LDCTs is projected to increase the probability of detecting lung cancer in earlier stages such as Stage I where it is treatable and where survival rates could be significantly improved. The number of Stage I patients has been projected to almost double as LDCT becomes part of the high risk patients' annual check-ups.

However, the earlier detection of lung cancer will not come without risks. LDCTs are highly sensitive imaging procedures and they result in many false positives. About one out of every four high risk patients have been shown to have a nodule detected by LDCT as was seen in the National Lung Study Trial. However, the vast majority of these patients (96%) do not have cancer; only 4% of these patients are actually found to have cancer. This results in patients being referred for risky downstream procedures including bronchoscopies, needle biopsies and surgery. These invasive procedures have been shown to result in morbidity and mortality including:

·0.5 to 1% mortality and

·4-20% major complications.

Source: Evaluation of Individuals with Pulmonary Nodules: When is it Lung Cancer? Chest 2013 May: 143 (Suppl):e83-e120.

In order to provide better guidance for physicians in managing lung nodules, the American College of Radiology developed the Lung CT Screening Reporting and Data System (LungRADS). LungRADS was developed to be a quality assurance tool designed to: standardize lung cancer screening reporting and management recommendations; reduce confusion in lung cancer screening interpretation; and facilitate outcome monitoring.

At a high level, LungRADS divides nodules for clinical management into three categories. For patients with nodules less than 5 mm, no follow-up procedures are necessary; while patients with nodules greater than 5 mm have follow-up procedures. In the case of nodules that are 5 to 7 mm, watchful waiting or serial imaging is recommended. Watchful waiting is the process where an individual is monitored through a series of follow-up scans to see if a nodule grows over time. A patient can be brought back quarterly or semi-annually to monitor if the nodule is growing. Typically, when a nodule has not grown for one to two years, the nodule is considered to be benign. Patients in the third category, with nodules over 8 mms, are often recommended for more invasive procedures, such as bronchoscopic biopsy, needle biopsy, open biopsy or video assisted thoracoscopic surgery. See Graphic 7.

Graphic 7 LungRADs Guidelines

Need and Market for DetermaVu™

Lung cancer is a primary cause of cancer-related death, in part because there is no effective diagnostic test to screen patients for lung cancer at an early stage. USPSTF guidelines, which recommend LDCT scans for patients at high risk for lung cancer, may impact up to 10 million Americans who fit the criteria of 30 pack-year smokers. Research has shown that although nodule size is a strong predictor of malignancy, it is not always accurate. Even the largest nodules, those that are greater than three centimeters, have a low malignancy rate of only 41%.

Overall, nodules that are sent to biopsy have a malignancy of between 1.7% for nodules 7 to 10 mm to 41.3% for nodules greater than 30 mm, meaning that for every cancer that is found in a biopsy, there are many false positives. In the case of smaller nodules from 7 to 10 mm, 98% of the nodules are benign; while in the case of larger nodules from

30 mms or larger 59% are benign. This would suggest that the number of biopsies performed each year could be significantly reduced by a molecular diagnostic that could help clinicians triage patients with intermediate size nodules from 8 mm to 30 mm. See Graphic 8.

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Graphic 8 Nodule Size by Prevalence

OncoCyte is initially focusing on patients with indeterminate diagnoses of larger nodules over 8 millimeters, which is shown as "Initial Focus" in the graph below. See Graphic 9. These nodules are most likely to be sent for biopsies. This potential market is estimated to include between 400,000 to 600,000 patients annually based on the estimates of patients eligible for USPSTF guidelines (7 to 10 million based on USPSTF and NCI estimates) as well as the approximately 5 million patients with incidentally detected nodules (Gould MK, et al. Am J Resp Critical Care Med 2015 Nov). We intend to expand the use of our lung cancer diagnostic into smaller nodules shown as "Expanded Use" in the graph below, which targets patients with smaller nodules, who currently are put into a wait and hold pattern and can be scheduled for repeated LDCTs, raising the risk of increased radiation exposure and incurring incremental costs to determine whether the nodule is growing. This will increase the potential patient population to approximately 1.4 million patients. Finally, we may pursue work on a diagnostic that could be used as a screening diagnostic and potentially replace LDCTs for the 7-10 million patients who meet the USPSTF guidelines for high risk, which is represented as the overall lung nodule market in the following graph.

Market Opportunity for Lung Diagnostics

Graphic 9

TAM Numbers based on company estimates and secondary data: 7-10 Million screening patients (USPSTF, NCI); 4.9 Million patients with incidental nodules (Gould MK, et al. Am J Respir Crit Care Med 2015 Nov 15; 192 (10):1208-1214).

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OncoCyte estimates the revenue opportunity associated with this test is between $2.1B and $4.7B yearly with the initial use targeting the larger nodules (greater than 8 mms) and the expanded use targeting nodules greater than 5 mms. See Graphic 10.

Graphic 10

Graphic 11 Lung Nodule Standard of Care

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OncoCyte's DetermaVu™ test could eventually fit in the lung cancer screening standard of care, by being used as a way to triage patients with suspicious nodules. See Graphic 11. The test would be run and patients who receive a benign or suspicious result would either be:

·cleared with a benign result and sent home and told to come back for annual scans like a mammogram
·monitored and sent home and told to return for a follow-up scan in three to six months.

Breast Cancer Diagnostic Tests

Breast Cancer Diagnostic Clinical Trials

We have completed proof of concept study for a confirmatory test for breast cancer. Our study looked at serum samples from 100 women who had a mammogram with a result of BIRADs 3 or 4. These samples were collected over approximately two years during 2014 and 2016 and by March of 2016, we had collected over 900 patient blood samples. The 100 women whose samples were used in the analysis were all sent for biopsies and half of the patients had a pathology confirmed benign and half of them had a pathology confirmed malignant. The analysis looked at proteins that were differentially expressing in women with malignances from a large screen of 1,310 proteins.

The results of this analysis were quite promising with a 15 marker model producing a sensitivity of 90% and a specificity of 76%. The analysis was a strong proof of concept that a non-invasive blood test could help differentiate women with indeterminate mammograms into two groups – those needing to be biopsied and those for whom the finding was highly likely to be benign.

We subsequently conducted a larger follow-on liquid biopsy breast cancer diagnostic test study that showed that a blood based assay may have the ability to differentiate women who have breast cancer from those who do not. A nineteen marker model resulted in an AUC of 0.935 with a sensitivity of 90% and a specificity of 82%. This data was consistent with the data from our previous study.

We are encouraged by the results of the studies that have been done to date. However, since 2017 we have devoted substantially all of our time and resources to the development of DetermaVu™, and we plan to continue to devote our resources to lung cancer tests at least for the near term. If our financial and other resources permit, we may continue to pursue the development effort of our breast cancer test.

Current Standard of Care

The early detection of cancer is typically associated with improved outcomes for patients. Mammography has been widely used since the 1970s for breast cancer screening in asymptomatic women; in 2017, over 39 million screening mammograms were performed in the US alone. Current US National Cancer Institute ("NCI") guidelines recommend screening mammograms every one to two years in women 40 years and older, while the American Cancer Society and the National Comprehensive Cancer Network both recommend screening mammography every year starting at age 40. However, in November of 2009, USPSTF revised their screening recommendations increasing the age to 50 and length of time between screenings from annual to biennial. This was partially driven by the concerns around false positives. Approximately 10% of women are recalled from screening mammography for further testing and approximately 95% of those women's test results end up as false positives. Over the course of 10 years of screening, one out of every two women will experience a false positive with 7% to 17% of those women having unnecessary biopsies. (Rosenberg RD et al. Radiology 2006. Elmore JG et al. N Engl J Med 1998, Hubbard RA et al. Ann Intern Med 2011, Rosenberg RD et al. Radiology 1998, Kerlikowske K et al. JAMA 1996, Porter PL et al. J Natl Cancer Inst 1999)

At the same time, mammography screening in women aged 40 to 74 has been associated with the relative reduction in breast cancer mortality of 15% to 20%. However, the NCI estimates that approximately 20% of all breast cancers are not detected by mammography during screening. In the case of women with dense breast tissue, mammography has been shown to have poor sensitivity with only 62-69% of all cancers detected (Carney et al 2003, Pisano et al 2006) This has resulted in 27 state legislatures dictating that radiologists notify women about the difficulties of detecting breast cancer in dense breast tissue and alert them that supplemental screening may be appropriate in their case. These false negatives or missed diagnoses, together with the false positives or over diagnoses, indicate a strong unmet need for a breast cancer screening test with superior specificity and sensitivity when compared to standard screening mammography.

Additionally, guidelines recommend MRI screening for approximately 6 million women who either have a family history, a BRCA gene mutation or dense breast tissue, since mammograms have been shown to miss cases of cancer in patients that meet these profiles. See Graphic 12.

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Graphic 12 Breast Cancer Screening Protocol

OncoCyte's goal has been to develop a confirmatory diagnostic test that could be used with women who have an indeterminate mammogram result (BI-RADS 3 or 4). In the case of a mammogram BI-RADS 3 score, repeat imaging is recommended, which means that women may have to schedule another mammogram or they may be referred to a more costly MRI procedure. In the case of a mammogram BI-RADS 4 score, women are often referred for a biopsy. Our breast confirmatory diagnostic could be incorporated into breast screening protocols to confirm whether women with BI-RADS 3 or 4 scores need to undergo additional costly imaging or an invasive biopsy.

Need and Market for a Breast Cancer Liquid Biopsy

Each year approximately 5% of women have mammograms that are suspicious and many of these women are sent on to biopsies (Geller et al Radiology 222:2 2002). Currently it is estimated that about 16% or 250,000 of these biopsies will be cancerous. This is the focus of our initial research for our breast cancer confirmatory diagnostic as shown in Graphic 13. We could also expand our research efforts to include the second intended use – women who meet the guidelines for MRIs. There are over 6 million women in the U.S. for whom the guidelines recommend both a mammogram and a MRI yearly.

Additionally, we may elect to expand the use of our diagnostic in the future to meet the needs for a better breast cancer screening diagnostic, which could impact up to 38 million women each year. Research over the last 25 years has shown that large numbers of women are having unnecessary biopsies resulting in estimates of $4 billion a year being spent on false positives (Health Affairs, 34, no.4 (2015):576-583).

Graphic 13 Market Opportunity for Breast Cancer Diagnostic Tests

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Bladder Cancer Diagnostic Tests

Bladder Cancer Diagnostic Test Clinical Trials

As part of our clinical development of a urine-based bladder cancer diagnostic test, we initiated a clinical trial in January 2014 that was expanded to a multi-site trial. Preliminary findings from that trial showed a sensitivity of 90% and a specificity of 83%. Sensitivity is the probability of detecting the presence of the disease accurately. A sensitivity of 90% means that 9 out of 10 cancers were detected. Specificity is the probability of accurately predicting not having the disease. Due to marketing considerations and the limits of our resources, we have not proceeded further with our bladder cancer test development in order to focus our clinical operations on the development of our lung cancer test. See “Need and Market for a Bladder Cancer Liquid Biopsy.”

Current Standard of Care

The current standard of care for bladder cancer diagnosis is cytology and cystoscopies. Urine cytology is a test to look for abnormal cells in a patient's urine. Urine cytology is used along with other tests and procedures to diagnose urinary tract cancers. Cystoscopy is a procedure that allows a doctor to examine the lining of the bladder and the urethra, tube that carries urine out of the body. A hollow tube called a cystoscope, equipped with a lens, is inserted into the patient's urethra and slowly advanced into the bladder. Increasingly over the years, cystoscopies have been used in conjunction with cytology which has resulted in increasing costs for the detection and surveillance of bladder cancer. See Graphic 14.

Graphic 14 Current Bladder Diagnostic Protocol

Need and Market for a Bladder Cancer Liquid Biopsy

Bladder cancer has the highest lifetime treatment costs per patient of all cancers. High prevalence, high recurrence rates and ongoing invasive monitoring requirements are the key contributors to the economic and human toll of this disease.

Urothelial carcinoma constitutes more than 90% of bladder cancers in the Americas, Europe and Asia. Although most patients with bladder cancer can be treated with organ-sparing chemotherapy, UC has a relapse rate of nearly 70% and can progress to invasive, metastatic, and lethal disease. The regular surveillance and treatment of recurrent disease from the time of diagnosis for the remainder of a patient's life makes urothelial Carcinoma the most costly malignancy on a per patient basis. The problem is amplified because the two standard methods for surveillance - microscopic assessment of urinary cytology specimens and bladder cystoscopy – possess significant limitations with respect to both performance and cost. Although urine cytology does have a very high positive predictive value and low false positive rate, it has a low negative predictive value and a high indeterminate rate. Patients who have indeterminate urine cytology results commonly undergo cystoscopy, which is painful, time consuming, costly, and unnecessary in many cases since a neoplasm is often not present. In urothelial carcinoma, as in virtually all other cancers, earlier and more accurate diagnosis, including diagnosis of disease recurrence, is generally associated with better outcomes and lower cost.

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Graphic 15 Bladder Diagnostic Market Opportunity

TAM numbers based on company estimates and secondary data

Overall markets for bladder cancer diagnostics are large and growing. Based on National Cancer Institute SEER statistics it was estimated that in 2017 there were 79,030 new cases of bladder cancer in the United States. The same source estimates that as of 2014, there were 696,440 patients with bladder cancer in the United States. Many of these patients would be monitored for recurrence using cystoscopy or urine cytology. Additionally, another 3 million patients present yearly with hematuria (blood in urine), an early symptom of bladder cancer and 500,000 patients have indeterminate cytology findings. These three patient profiles: indeterminate cytology, hematuria and surveillance, could result in a potential market opportunity of approximately 4.5 million tests yearly. See Graphic 15.

OncoCyte believes that in order to obtain coverage by insurance companies, the target market for this test will need to be primary care physicians. To market this test successfully will require a large sales force, which is not part of OncoCyte's business model. Due to this need and our limited financial and marketing resources, we are seeking to enter into an agreement with a larger company that has greater marketing resources for the marketing of our bladder cancer test. We have elected to co-develop or license out this test to another company, retaining rights to receive a royalty on sales and possibly some sales related milestone payments, or we may complete the development of the test and seek to license the test to another company. There is no assurance that we will be successful in entering into a licensing or co-marketing arrangement or that a licensee or co-marketing partner will succeed in marketing our bladder cancer diagnostic test. If we enter into a license or co-marketing agreement, our revenues from the sale of our bladder cancer diagnostic test may be substantially less than the amount of revenues and gross profits that we might receive if we were to market that diagnostic test ourselves.

Future Diagnostic Development Milestones

Over the next two years, we will continue to work to achieve the following milestones relating to the development and commercialization of our lung cancer diagnostic test:

- Complete R&D studies to the extent necessary to ready DetermaVu™ for clinical validation.

- Finish Clinical validation of DetermaVu™;

- Launch DetermaVu™

- Start clinical utility studies of DetermaVu™;

- Submit dossier to CMS for draft Medicare Local Coverage Decision for DetermaVu™; and

- Obtain a certificate of registration, a certificate of compliance and inspection for our CLIA laboratory for all 50 states by completing requirements for State of Florida, Maryland, New York, and Rhode Island.

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Achieving the commercialization and reimbursement milestones will require expanding our commercial team to include sales, marketing, market access, customer support and medical affairs. In September of 2017, we started the pro