

OncoCyte Corp  
Form 10-K  
April 01, 2019

**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, 2018

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)

<b>California</b>	<b>27-1041563</b>
(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:**

<b>Title of each class</b>	<b>Name of exchange on which registered</b>
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 every Interactive Data File required to be submitted 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 such files). Yes   No

## Edgar Filing: OncoCyte Corp - Form 10-K

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	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, 2018 was \$27.6 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 4, 2019, there were outstanding 51,972,830 shares of common stock, no par value.

### DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Proxy Statement for its 2019 Annual Meeting of Shareholders are incorporated by reference in Part III



**OncoCyte Corporation**

**Table of Contents**

	<b>Page Number</b>
<b>Part I. Financial Information</b>	
Item 1 - <u>Business</u>	4
Item 1A <u>Risk Factors</u>	24
-	
Item 1B <u>Unresolved Staff Comments</u>	40
-	
Item 2 - <u>Properties</u>	40
Item 3 - <u>Legal Proceedings</u>	40
Item 4 - <u>Mine Safety Disclosures</u>	40
<b>Part II. Other Information</b>	
Item 5 - <u>Market for Registrant’s Common Equity, Related Stockholder Matters, and Issuer Purchases of Equity Securities</u>	41
Item 6 - <u>Selected Financial Data</u>	41
Item 7 - <u>Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	42
Item 7A <u>Quantitative and Qualitative Disclosures about Market Risk</u>	48
-	
Item 8 - <u>Financial Statements and Supplementary Data</u>	50
Item 9 - <u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	75
Item 9A <u>Controls and Procedures</u>	75
-	
Item 9B <u>Other Information</u>	75
-	

<b>Part III.</b>	<b>Item 10</b>	<b><u>Directors, Executive Officers, and Corporate Governance</u></b>	<b>76</b>
	-		
	<b>Item 11</b>	<b><u>Executive Compensation</u></b>	<b>76</b>
	-		
	<b>Item 12</b>	<b><u>Security Ownership of Certain Beneficial Owners and Management, and Related Stockholder Matters</u></b>	<b>76</b>
	-		
	<b>Item 13</b>	<b><u>Certain Relationships and Related Transactions, and Director Independence</u></b>	<b>76</b>
	-		
	<b>Item 14</b>	<b><u>Principal Accounting Fees and Services</u></b>	<b>76</b>
	-		
<b>Part IV</b>	<b>Item 15</b>	<b><u>Exhibits, Financial Statement Schedules</u></b>	<b>77</b>
	-		
	<b>Item 16</b>	<b><u>Summary</u></b>	<b>79</b>
	-		
		<b><u>Signatures</u></b>	<b>80</b>

## 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 4, 2019, we had 251 shareholders of record and there were 51,972,830 shares of our common stock outstanding, of which 14,674,244 shares were held by our former parent BioTime, Inc. (“BioTime”). Beginning on February 17, 2017, the shares held by BioTime accounted for less than 50% of our total common stock outstanding. Accordingly, effective February 17, 2017, we are no longer a consolidated subsidiary of BioTime. See Note 1 of our financial statements included elsewhere in this Report.



## 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 by better meeting the needs of patients, physicians and payers. Our current focus is developing DetermaVu™, a non-invasive molecular lung cancer confirmatory diagnostic that can be administered to patients as a blood test. DetermaVu™ utilizes proprietary sets of gene expression markers to help confirm whether suspicious lung nodules detected through Low Dose Computed Tomography (“LDCT”) scans, x-rays or other imaging are likely to be benign or malignant.

Molecular diagnostics such as DetermaVu™ are assays that identify a disease by studying molecules such as proteins, DNA, and RNA in a tissue or fluid. DetermaVu™ is based on our proprietary Immune System Interrogation approach that examines the body’s immune system response to a specific disease by measuring differential RNA expression in patients with the disease versus patients without the disease. In the future, we may study whether our technology and Immune System Interrogation approach could have applications in other types of cancer or other diseases.

During January 2019 we completed an R&D Validation study of DetermaVu™ that demonstrated the accuracy of the DetermaVu™ assay in detecting lung cancer. The R&D Validation study demonstrated a sensitivity of 90% (95% CI 82%-95%) and specificity of 75% (95% CI 68%-81%) of DetermaVu™ on a prospectively collected cohort of 250 patient blood samples that were blinded to laboratory operators. Sensitivity is the percentage of malignant nodules that are correctly identified and specificity is the percentage of benign nodules correctly identified with correct identification in our study confirmed by biopsy results or serial imaging. A 95% confidence interval or “CI” suggests that there is a 95% chance that final test performance will be within the stated range. Notably, we obtained these results without including any clinical factors such as nodule size in our proprietary DetermaVu™ algorithm.

We have successfully completed our R&D Validation study and we are now conducting Analytic Validation to establish the performance characteristics of the DetermaVu™ assay system. If Analytic Validation is successfully completed, we will conduct a CLIA Laboratory Validation study to demonstrate that the full DetermaVu™ assay system when utilized in our CLIA diagnostic laboratory, run by our CLIA staff on analytically validated instrumentation, provides the same results on clinical samples as those obtained in our R&D Validation study. Additional information about the stages of development of DetermaVu™ can be found below under “Development of DetermaVu™ -- The Development Pathway and Milestones.”

Our goals for DetermaVu™ are to:

Reduce unnecessary and risky biopsy procedures,  
Lower the cost of care through the avoidance of more expensive diagnostic procedures such as invasive biopsies,  
Improve the quality of life for cancer patients by reducing the anxiety associated with non-definitive diagnoses, and  
Improve health outcomes through earlier detection of lung cancer and avoidance of unnecessary invasive procedures and resulting complications.

Our strategic focus is to develop diagnostic tests that support clinicians in areas of high unmet clinical need, and in particular cancer detection. We have prioritized our efforts on DetermaVu™ and lung cancer because we believe that the early detection of lung cancer is one of the greatest unmet needs in diagnostics. Our scientific approach is to measure the immune system's response to disease and as such we believe that it may prove promising in other cancers and other disease areas.

### **Additional Information**

We were incorporated in September 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. Our website is [www.oncocyte.com](http://www.oncocyte.com). Information contained on, or that can be accessed through, our website, is not, and shall not be deemed to be, incorporated into or be considered a part of this Report.

DetermaVu™ is a trademark of OncoCyte Corporation.

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**

DetermaVu™ measures biomarkers of the immune system's response to cancer to differentiate between suspicious and likely benign lung nodules in early stage lung cancer. Specifically, DetermaVu™ has been designed for use in patients with lung nodules ranging from 5 mm to 30 mm in size detected initially in a LDCT scan or incidentally through other imaging. Clinical data points, such as lung nodule size, provide a significant amount of the diagnostic power for liquid biopsy lung cancer tests developed by other companies. In the case of the size of lung nodules, larger nodules are more frequently malignant. Since we are not using any clinical data, only biomarkers, in our DetermaVu™ algorithm, we believe DetermaVu™ has the potential to provide a significant benefit as a confirmatory diagnostic tool for aiding early lung cancer detection, by providing physicians with significant biologic information about lung nodules as small as 5 mm in size that is not currently available without the use of DetermaVu™.

### *Need and Market for DetermaVu™*

Based on substantial unmet needs, large markets, and data generated thus far from patient serum (blood) screening, we have focused our efforts on biomarkers associated with lung cancer. The DetermaVu™ lung cancer development program is our highest priority for early 2019. Our development approach is based on utilizing detectable amounts of cancer-associated biomarkers in patients with early-stage disease. We intend to initially develop and market DetermaVu™ in the United States before seeking regulatory approvals required to market the test in other countries.

We believe that the relative ease of administering a liquid biopsy diagnostic test like DetermaVu™; cost savings due to the elimination of unnecessary costly and invasive surgical biopsy procedures; and potential earlier detection of disease will make liquid biopsy diagnostic tests useful as routine tests that could be performed in men and women of any age and at any desired frequency in conjunctions with normal screening and monitoring procedures to detect lung or other cancers.

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 without reliance on an invasive biopsy if nodules are detected by a LDCT scan. The United States Preventive Services Task force (“USPSTF”) guidelines recommend LDCT scans for patients at high risk for lung cancer. LDCTs have been shown to detect lung cancer early but the annual lung cancer screening guidelines are relatively recent and are still in the process of being adopted. If successful, our tests will help physicians to reduce diagnosis uncertainty and unnecessary down-stream procedures such as biopsies resulting from indeterminate LDCT screens.

Indeterminate results may occur in two ways: from LDCT screening of high risk lung cancer patients; and from incidental scans of patients performed for other reasons, such as x-rays for broken ribs. DetermaVu™, may be used to help clinicians manage pulmonary nodules that are detected through either route. We expect that DetermaVu™ would be used for patients with indeterminate lung nodules in the 5 mm to 30 mm range to help clinicians triage patients for follow-up procedures such as biopsies, if DetermaVu™ indicates a high likelihood that a malignancy is present.

USPSTF guidelines suggest that up to 6.8 million Americans who fit the criteria of 30 pack-year smokers may benefit from annual lung cancer screens. Actual potential patient population estimates will vary over time. In addition to the nodules that will be detected through lung cancer screening, it has been estimated in a published study that there are more than 4.8 million chest scans yearly in the United States and approximately a third of those patients have lung nodules. See Graphic 1.

Graphic 1:

### **DetermaVu™ Market Opportunity**

Research has shown that although nodule size is a strong predictor of malignancy, it is not always accurate. Overall, nodules that are sent to biopsy have a malignancy rate of between 1.7% for nodules 7 mm to 10 mm and 41% for nodules greater than 30 mm, meaning that for every cancer that is found in a biopsy there are many false positives (see percent cancer in graphic 1). At the same time, even smaller nodules, in the 5 mm to 7 mm size range, may be cancer that could remain undiagnosed if a biopsy is not performed. This would suggest that the number of biopsies performed each year could be significantly reduced by a molecular diagnostic that could classify nodules as probably benign or probably malignant, because it helps clinicians better manage patients with lung nodules in a wide range of sizes. See Graphic 2.

Graphic 2

### **Nodule Size by Prevalence**

NLST investigators NEJM 2013 (numbers do not add to 100% due to missing data)

### ***Current Standard of Care***

The current standard of care for diagnosing lung cancer in high risk patients is LDCT scanning. 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 18.6% of people are still alive five years after a lung cancer diagnosis. Due to that low survival rate lung cancer is projected to kill 154,000 Americans in 2018 according to information from the the American Cancer Society. See Graphic 3.

Graphic 3

### **5 Year Survival Rates**

#### **Three Largest Cancer Types**

**1975 to 2010**

The lung cancer survival rate has not increased as fast as the survival rate for other cancers in the last 30 years. The low probability of surviving lung cancer is driven by the late diagnosis – with more than half of all patients diagnosed after the point that the cancer has spread. The poor survival rate 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 (NLST). However, the vast majority of the patients with suspicious nodules assessed in the NLST (96%) did not have cancer.

In addition to the nodules that will be detected through lung cancer screening, it has been estimated in a published study that there were more than 4.8 million chest scans yearly in the United States and approximately a third of those patients had lung nodules. Patients whose nodules are detected through screening present a diagnostic challenge to clinicians, especially patients with nodules in the intermediate range of 5 millimeters to 30 millimeters. Many of those patients will end up being referred for risky downstream procedures including bronchoscopies, needle biopsies and surgery.

These invasive procedures have been shown, in a study published in 2013, to result in morbidity and mortality including:

0.5 to 1% mortality and

4-20% major complications (CHEST 2013; 143(5)(Suppl):e93S-120S)

A more recent study published in 2019 found higher rates of adverse events associated with lung cancer screening. This study focused on community practices and may be more reflective of the overall healthcare market than other studies that only looked at patients enrolled in clinical trials. The overall complication rate for this analysis was 22% for patients 55 to 65 years of age, and 24% for Medicare eligible patients. JAMA Intern Med. 2019;179(3):324-332

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 recommended; 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 mm, are often recommended for more invasive procedures, such as bronchoscopic biopsy, needle biopsy, open biopsy or video assisted thoracoscopic surgery. See Graphic 4.



We are developing DetermaVu™ to provide physicians with a non-invasive blood test that could be used to determine whether nodules are more likely to be benign or malignant regardless of size, so that uncertainty as to the presence of cancer before biopsy and the number of unnecessary biopsies can be reduced. Many studies have shown that physicians often elect not to follow LungRADS guidelines for the evaluation of lung nodules and may biopsy nodules smaller than 8 mm in size to avoid the risk of allowing cancer to go undiagnosed at an earlier stage. OncoCyte sponsored marketing research conducted in 2016 found that in a sample of 180 physicians approximately one out of four nodules in the range of 5 mm to 7 mm were biopsied. Guidelines would suggest a serial LDCT follow-up scan rather than a biopsy for nodules in that size range based on the lower incidence of cancer associated with nodules in that size range. The incidence of biopsy increased with nodule size, as would be expected, to slightly more than one out of two for 8 mm to 10 mm nodules and approximately three out of four for 10 mm and larger nodules.

We expect that physicians who follow the LungRADS guidelines may initially adopt the use a confirmatory diagnostic like DetermaVu™ in their practice initially for testing patients with nodules of 8 mm or larger because those nodules are statistically more likely to be malignant than smaller nodules, but we see an opportunity for DetermaVu™ in testing patients with nodules in 5 mm to 7 mm size range as well based on the incidence of physicians electing to biopsy those nodules. Ultimately, one of our goals for DetermaVu™ is to change the current standard of care by encouraging physicians to use DetermaVu™ as a confirmatory test for guidance in making patient care recommendations, regardless of the size of the nodules detected by a LDCT or other scan. See Graphic 1 above. Patients with a result indicating the low likelihood of a malignancy would be advised to return periodically for follow-up imaging; while patients with a result indicating a higher likelihood of malignancy may be candidates for a biopsy or closer monitoring, potentially resulting in cancer detection at an earlier stage when treatment is more likely to result in a better outcome for the patient. The impact to the practice of medicine of a diagnostic like this could be that unnecessary biopsies could be minimized, so that patients with a very low risk of lung cancer would be spared the biopsy procedure and the healthcare system would be spared the cost. See Graphic 5.

Graphic 5

#### **Use of DetermaVu™ in the Lung Nodule Standard of Care**

#### **Development of DetermaVu™**

In developing DetermaVu™ we are testing blood samples from patients who were at risk for lung cancer, based on having positive or suspicious results from LDCT or other imaging scans and who have confirmed diagnoses through pathology or serial LDCT imaging. We then assess 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. We are validating DetermaVu™ on both screened patients, where nodules were found at the time of a lung cancer screening, and patients who had their nodules incidentally detected through alternative screening procedures such as chest x-ray or LDCT scans ordered for a different medical reason.

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. We have also been carrying out our own clinical trials.

During January 2019 we completed an R&D Validation study of DetermaVu™ that demonstrated the accuracy of the DetermaVu™ assay in detecting lung cancer. The R&D Validation study demonstrated a sensitivity of 90% (95% CI 82%-95%) and specificity of 75% (95% CI 68%-81%) of DetermaVu™ on a prospectively collected cohort of 250 patient blood samples that were blinded to laboratory operators. Sensitivity is the percentage of malignant nodules that are correctly identified and specificity is the percentage of benign nodules correctly identified with correct identification in our study confirmed by biopsy results or serial imaging. A 95% confidence interval or “CI” suggests that there is a 95% chance that final test performance will be within the stated range. Notably, we obtained these results without including any clinical factors such as nodule size in our proprietary DetermaVu™ algorithm.

We have successfully completed our R&D Validation study and we are now conducting Analytic Validation to establish the performance characteristics of the DetermaVu™ assay system. If Analytic Validation is successfully completed, we will conduct a CLIA Laboratory Validation study to demonstrate that the full DetermaVu™ assay system when utilized in our CLIA diagnostic laboratory, run by our CLIA staff on analytically validated instrumentation, provides the same results on clinical samples as those obtained in our R&D Validation Study.

### ***The Development Pathway and Milestones***

#### ***2019 Diagnostic Development Milestones***

During 2019 we will work to achieve the following milestones relating to the development and commercialization of DetermaVu™.

Complete CLIA Laboratory Validation study, which is progress on the date of this Report

Conduct Clinical Validation study

Commence commercialization of DetermaVu™

Prepare DetermaVu™ dossier for draft Medicare Local Coverage Decision

Prepare to commence Clinical Utility studies which we expect may take up to 3 years to complete

Achieving the commercialization and reimbursement milestones will require building a commercial team, which may include sales, marketing, market access, customer support and medical affairs personnel. We may also enter into joint venture, co-marketing, or similar arrangements with a diagnostic or pharmaceutical company that already has an established marketing force.

### ***The Stages of Development***

We expect that our diagnostic tests for cancer, including DetermaVu™, will primarily be laboratory developed tests or “LDTs” that we will conduct in our clinical or CLIA laboratory. In general, these tests will go through a series of stages of development prior to commercialization: Research, Assay Dev