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)

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 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

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

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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 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 a 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. 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 party 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)

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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 Development, R&D Validation studies, Analytic Validation, CLIA Laboratory Validation study, and Clinical Validation studies. The following graph illustrates the

development pathway. Although the pathway diagram shows the development process as linear, in practice certain stages of the process may be conducted concurrently rather than sequentially or portions of certain stages may overlap. This general development flow may be customized for each specific diagnostic test, depending on the circumstances and requirements for that individual test system. An additional stage, Clinical Utility studies, will also be conducted after commencement of the marketing of a diagnostic test. See Graphic 6.

Graphic 6

Diagnostic Development Stages

Research: The first stage of the development of a LDT is the research stage. In the research stage of a molecular diagnostic such as DetermaVu™, biological markers are analyzed to determine if specific markers that are differentially expressed in certain diseases are absent or present in blood samples. We are developing blood tests that differentiate malignant patient samples from benign patient samples by looking at differences in the amount of specific analytes expressed in whole blood from cancer patients compared to patients who are cancer free. For our DetermaVu™ lung cancer test, the analytes we are looking at are specific mRNA expressed in whole blood. If we elect to pursue other cancer types, we may look at other analytes including proteins or miRNA. The objective of this phase of the development process is to delineate promising biomarkers, for further development and verification, before proceeding to validation work.

Assay Development: The second stage is Assay Development. In this stage the best performing analytes (mRNA, miRNA, or protein biomarkers) are combined with all of the processes needed to create an assay system. The assay system includes the sample collection methods, sample processing and extractions, biomarker assay methods, and the mathematical “algorithm” required to provide a clinical test result for a sample. The optimal combination and weighting of biomarkers in an algorithm to be used in the final diagnostic are determined through bioinformatics which may be combined with machine learning software strategies that also reflect the biomarker contributions to and reliability within the algorithm. The end result of assay development is an assay system, including a “defined” algorithm, the performance of which has been verified on clinical samples from the targeted ‘intended use’ population. The test system, including the algorithm, can be further optimized during the R&D Validation phase.

R&D Validation: The third stage is the R&D Validation stage, which is intended to determine the best set biomarkers to use in the algorithm and the expected accuracy of the diagnostic test. These studies are carried out in our R&D laboratories and consist of two areas of study.

Assay System Reproducibility: During Assay System Reproducibility various critical aspects of diagnostic laboratory procedures are studied and tested to assure that the laboratory can produce consistent, reliable results. Multiple lots of reagents used in the laboratory are tested to determine whether lot to lot differences lead to differences in test results. Procedures for the collection of blood or other biological samples from patients, the handling and storage of those samples, and the manner in which the samples are shipped to our diagnostic testing laboratory, are studied to assure that acceptable procedures are followed and that any variations in the procedures

that can occur do not affect the diagnostic test results. Samples are studied for the stability of the biomarkers when the samples are subjected to various conditions that could be encountered throughout the total process of handling and shipping the samples, in order to define the conditions under which the clinical results for the sample will not change, since any changes will lead to a different and erroneous result being reported by the lab.

Algorithm Optimization and Lock: The Algorithm Optimization work that leads to an algorithm lock is usually customized to the needs of the specific test. In the case of DetermaVu™, we are employing a statistical method referred to as cross-validation where the algorithm is optimized on a subset of the clinical samples and then tested on the remaining untested samples. This process of optimizing the algorithm on a subset of samples and then testing on the remaining samples is repeated multiple times. Cross-validation is one of the methods for verifying the algorithm performance that leads to a ‘lock’ on the algorithm.

R&D Validation: The Algorithm obtained in Algorithm Optimization is tested to establish performance on a set of prospectively collected blood samples.

Analytical Validation. The fourth stage Analytical Validation is conducted in our CLIA laboratory and is based on the CLSI (Clinical and Laboratory Standards Institute) Guidelines. These guidelines cover testing for matters such as limits of quantitation, precision, reproducibility, and interfering substances. When completed, Analytical Validation establishes the performance characteristics of the assay system for subsequent testing in the CLIA laboratory.

CLIA Laboratory Validation: In the fifth stage CLIA Laboratory Validation, our CLIA lab will assay patient samples previously tested during the R&D Validation stage. This study is to demonstrate that the full assay system utilized in our CLIA lab, run by our CLIA staff and on the analytically validated instrumentation, provides the same results on clinical samples as those obtained in the R&D Validation stage.

Clinical Validation. The sixth stage is a Clinical Validation study, where additional new clinical samples will be assayed in a blinded manner in our CLIA lab. Our CLIA lab will perform assays on these blinded samples and the performance of the full assay system will be assessed against clinical diagnosis to show how our diagnostic test is likely to perform in clinical practice.

Clinical Utility: The final phase of the diagnostic pathway is Clinical Utility studies that occur after the diagnostic test is commercially available for use. These studies are important for driving adoption of a newly developed diagnostic test and obtaining coverage and reimbursement from payers such as Medicare, Medicaid, third party commercial insurers, health maintenance organizations (“HMOs”), and large corporations that self-insure. Clinical Utility studies analyze the improvement in patient health outcomes associated with a diagnostic test. The outcomes of these studies can also be used to understand the health economics, including the cost effectiveness, of the new diagnostic. Clinical Utility studies compare the treatment choices and outcomes of patients who received the test results versus those who did not receive the test results. The results of this phase may be published in peer review journals and are generally compiled in dossiers to share with managed care groups, including both public and commercial payers.

Types of Diagnostic Use

Cancer diagnostics may have as many as five different types of intended uses depending on whether the cancer has been diagnosed; has recurred or is in remission; and the stage of the cancer. These intended uses include:

Screening diagnostics could replace or be used as an alternative to existing screening procedures. Lung cancer screening is currently being done through the use of LDCT scans for high risk patients who meet the guideline requirements. A diagnostic could be developed that could be used as an alternative to the annual LDCT scan.

Confirmatory diagnostics could be used in conjunction with a current standard of care screening procedure. For example, our DetermaVu could be used in conjunction with LDCT to confirm a suspicious nodule by yielding a secondary or confirming suspicious versus benign result. In the case of a benign result, the patient would not need additional invasive biopsy procedures to determine the presence of cancer. In the case of a suspicious result, additional procedures, such as a biopsy, would be highly warranted.

Prognostic or risk predictors could be used by physicians to determine if a patient is at high risk of a cancer recurrence and may be a candidate for closer monitoring or for adjuvant therapies.

Diagnostics for targeted therapeutics, often referred to as companion diagnostics, could be used by physicians to help determine an optimal therapy for a specific patient. An example of this would be PDL-1 and Keytruda.

Recurrence diagnostics could be used for patients who had previously been diagnosed with cancer but are currently in remission. These diagnostics could potentially catch recurrence before cancer growth appears on a follow-up imaging.

Currently we are focused on diagnostics to detect early stage lung cancer due to the market opportunity associated with these types of diagnostics. We are presently focused on confirmatory diagnostics, which we feel will have the largest market opportunity with the greatest barriers to entry. We believe that the confirmatory diagnostic market for lung cancer, like the recurrence risk predictor market, has high barriers to entry and an absence of a strong commercial leader. See Graphic 7. The barriers to entry include:

Research and development expertise: Development of a confirmatory diagnostic necessitates developing a scoring algorithm and the detection of multiple analytes to differentiate those patients who have the disease from those who do not. DetermaVu™ is being developed to distinguish a benign nodule or mass from a suspicious nodule or mass.

Clinical relationships: Relationships with larger cancer centers are required to produce the thousands of samples needed for the full continuum of trials from proof of concept to clinical validation of the diagnostic test.

Medical community input: Key Opinion Leaders' feedback from nationally recognized thoracic and pulmonary expert clinicians is needed to determine whether the intended test is likely to be accepted and used by physicians in clinical practice.

Graphic 7:

About Our CLIA Diagnostic Laboratory

We expect that DetermaVu™ will be regulated under the Clinical Laboratory Improvements Amendment ("CLIA") as a laboratory diagnostic test or "LDT" and will not be regulated as an *in vitro* diagnostic test or IVD" that will be subject to approval by the United States Food and Drug Administration (the "FDA") and through the European Directive on *in vitro* diagnostics in the European Union. See "Government Regulation" below.

We have established a CLIA certified, California state licensed, clinical laboratory in Alameda, California. The laboratory is fully operational with state of the art equipment and staffed with experienced and highly skilled licensed clinical laboratory scientists. We have implemented a quality assurance program designed to ensure regulatory compliance and accurate, timely test results. The CLIA certification and California state license are accepted by forty-five other states as proof of quality and good standing in order to do accept diagnostic test samples from patients in states outside of California and we have obtained the Pennsylvania, Maryland, and Rhode Island state clinical laboratory permits and plan on submitting for a license from the State of New York in the next 2 years. Florida no longer requires an individual state clinical license or permit in order to perform diagnostic tests for Florida residents.

Competition

Our industry is highly competitive and characterized by rapid technological change. Key competitive factors in our industry include, among others, the ability to successfully complete clinical studies, the ability to obtain any required regulatory approval, average selling prices of competing tests, CLIA laboratory capacity and costs, intellectual property and patent rights, and sales and marketing capabilities. We are an early stage company with a limited operating history and many of our competitors have substantially more resources than we do, including financial, technical and sales resources. In addition, many of our competitors have more experience than we have in the development and commercialization of diagnostics. We are also competing with academic institutions, governmental agencies and private organizations that are conducting research in the field of diagnostics. Our competition will be determined in part by the potential indications for which our lead diagnostic test candidates are developed and ultimately marketed. Additionally, the timing of market introduction of diagnostic tests or of competitors' tests may be an important competitive factor. Accordingly, we expect that important competitive factors will be the speed with which we can complete pivotal validation and utility studies of DetermaVu™ and commercialize the test, including obtaining Medicare reimbursement approval.

Currently OncoCyte is aware of three direct competitors who are developing or have commercially available blood-based lung cancer diagnostic tests. Biodesix, Inc. product BDX-XL2 and MagArray, Inc. product Reveal are lung cancer tests based on their technologies that utilize clinical factors and blood proteins. OncoImmune, Inc. offers its Early CDT® tests for lung cancer and liver cancer using autoimmune antibodies. A fourth company has a test but it is used downstream from where the OncoCyte test will be used and so is not competitive. Veracyte has developed Percepta®, a tissue based product for indeterminate bronchoscopies.

Licensed Technology from Wistar

We have entered into a License Agreement with Wistar that entitles us to use certain patents, know-how and data belonging to Wistar.

Licenses Granted

Under the License Agreement, we have obtained an exclusive, worldwide license under certain patents, and under certain know-how and data ("Technical Information") belonging to Wistar, for use in the field of molecular diagnostics for lung cancer, including confirmatory, companion and recurrence diagnostics for any type of lung cancer with detection through whole blood, fractionated blood, plasma, serum and/or other biological samples (the "Licensed Field"). We have the right to grant sublicenses of the licensed patents and Technical Information subject to certain conditions.

Royalties, License Fees and Other Payment Obligations

We have paid Wistar an initial license fee and will pay Wistar royalties on "net sales" of licensed products," as those terms are defined in the License Agreement. The royalty rates will range from 3% to 5% depending upon the amount of cumulative net sales. The amount of royalties payable to Wistar will be reduced by the amount of any royalties that we must pay to any third parties on the sale of the licensed products, but subject to a maximum reduction of 50%. Our obligation to pay royalties to Wistar will terminate on a licensed product-by-licensed product and country-by-country basis until the later of (i) the date a valid claim of a licensed patent covering the licensed product no longer exists, or (ii) the tenth (10th) anniversary of the first commercial sale of the licensed product in each country.

We have agreed to pay Wistar a minimum annual royalty each year, which in each case will be credited against total royalties due on net sales of licensed products during the year in which the minimum royalty is paid. We will also be

obligated to pay Wistar an annual license maintenance fee in the mid-five figures.

We have agreed to pay Wistar a portion of any non-royalty sublicensing income that we may receive from the sub-licensee. Non-royalty sublicensing income will include any consideration received from a sub-licensee for granting the sublicense, but excluding royalties, the fair market value of any equity or debt securities sold to a sub-licensee, and any payments received from a sub-licensee for any related research we conduct for the sub-licensee.

We also have agreed to pay Wistar (a) milestone payments upon the occurrence of certain milestone events in the development and commercialization of a licensed product, and (b) all past or ongoing costs incurred or to be incurred by Wistar, including government fees and attorneys' fees, in the course of prosecuting the licensed patents.

Other Obligations

We have agreed to use commercially reasonable diligent efforts, directly or through sub-licensees, to develop and commercialize licensed products. We have agreed that we or a sub-licensee will commence commercial sale of a licensed product by a specified date. If sales of a licensed product do not commence by the specified date, we may purchase up to three one-year extensions of the deadline by paying Wistar a designated fee for the applicable extension. OncoCyte has agreed to purchase additional extensions.

We have agreed to indemnify Wistar and its trustees, managers, officers, agents, employees, faculty, affiliated investigators, personnel and staff, from and against certain claims and liabilities related to the License Agreement and the development, manufacture and sale of licensed products, excluding liabilities that result from or arise out of an indemnified party's gross negligence or willful misconduct.

Termination of the License Agreement

Wistar has the right to terminate the License Agreement, subject to certain notice and cure periods and *force majeure* delays in certain cases, if any of the following occur: (a) we fail to pay any amount payable to Wistar; (b) we materially breach any covenant or agreement or any continuing representation or warranty contained in the License Agreement; (c) we become subject to certain bankruptcy or insolvency events, (d) we dissolve or cease operations, (e) we or any of our affiliates or sub-licensees or affiliates of any our sub-licensees challenges the validity, patentability, scope, construction, enforceability, non-infringement, or Wistar's ownership of any issued patent comprising the licensed patents, or assists any third party in any such challenge; or (f) we fail to fulfill our product development and commercialization diligence obligations and related performance milestones.

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We have the right to terminate the License Agreement with or without cause, upon the passage of a specified period of time after giving Wistar written notice of termination.

Wistar's Retained Rights to Certain Proposed Products

Wistar has reserved the right to (i) make, use, practice and further develop the licensed patents and Technical Information for educational, research, and other internal purposes; (ii) grant to any academic, government, research or non-profit institution or organization the right to make, use and practice the licensed patents or Technical Information for non-commercial research and educational purposes; and (iii) grant licenses under the Licensed Patents or Technical Information to any party for any field, product, service or territory other than the licensed products in the Licensed Field.

In addition, if Wistar determines to develop or has developed an actual or potential licensed product that is for an application, product, sub-field or indication in the Licensed Field, but for which Wistar reasonably believes a licensed product is not being actively developed or commercialized by us or by our affiliates or sub-licensees, Wistar may give us notice of the proposed product. If we timely inform Wistar of our election to develop the proposed product, and if we successfully negotiate a development plan and milestones for the proposed product, we will be entitled to develop the proposed product as a licensed product under the License Agreement. If we do not elect to develop the proposed product or do not reach agreement with Wistar for a development plan and milestones for the proposed product, Wistar may exclude the proposed product from our license under the License Agreement and may develop the proposed product itself or grant licenses to third parties under the licensed patents and Technical Information for the development and commercialization of the proposed product.

Facilities

Under a Shared Facilities and Services Agreement (the "Shared Facilities Agreement") with BioTime, we have use of laboratory and office space at BioTime's facility in Alameda, California. BioTime has leased approximately 30,795 square feet of office and laboratory space in two buildings located in Alameda and is providing us use of space for a CLIA diagnostic laboratory.

Materials

There is a limited number of manufacturers of molecular diagnostic testing equipment and related chemical reagents necessary for the provision of our diagnostic tests. Additionally, the chemical reagents used with the diagnostic testing equipment we chose are available only from the equipment manufacturer. This situation poses a risk to us. After encountering inconsistent results using diagnostic testing equipment and reagents from one manufacturer, we switched to diagnostic testing equipment from a different manufacturer. If issues were to arise with the diagnostic testing equipment or reagents we are using causing us to acquire different diagnostic testing equipment again, we would need to conduct additional R&D Validation studies, Analytic Validation, and CLIA Laboratory Validation studies to determine whether our previous test results can be reproduced using the new equipment. If similar issues were to arise after commercialization of a diagnostic test, we could experience a disruption for a period of time in providing the diagnostic tests to patients and we would lose revenues and potentially market share as a result.

Marketing

Following the clinical validation of our DetermaVu™ diagnostic test, we intend to market our diagnostic test directly to health care providers working in the areas of pulmonary disease and lung cancer. These health care providers will collect blood samples or send patients to laboratories to have blood or other biological samples collected. These samples, also referred to as liquid biopsies, will be sent to our CLIA laboratory in California, either by the health care provider or the laboratory who drew the specimen. The sample will be run through an assay and a gene expression classifier at our laboratory to determine a binary result, either benign or suspicious. That result will be presented to the physician ordering the procedure in a standardized report.

We plan to ramp up sales and marketing teams for DetermaVu™. Over time, we plan to continue to grow our sales, market access and marketing organizations to increase the awareness and utilization of our diagnostic tests and to prepare for potential additional diagnostic test launches.

We may also explore a range of other commercialization options in order to reduce our capital needs and the risks associated with the timelines and uncertainty for attaining the Medicare and commercial reimbursement approvals that will be essential for the successful commercialization of DetermaVu™ and any other diagnostic tests that we may develop. Those alternative arrangements could include marketing arrangements with other diagnostic or pharmaceutical companies through which we might receive a royalty on sales, or through which we might form a joint venture to market DetermaVu™ or to develop and market other tests and share in net revenues.

Market Access – Reimbursement

Billing, Coverage, and Reimbursement for Diagnostic tests

Revenues from our clinical laboratory testing will be derived from several different sources. Depending on the billing arrangement, the instruction of the ordering physician, and applicable law, parties that may reimburse us for our services include:

- Third-party payers that provide coverage to the patient, such as an insurance company, a managed care organization, or a governmental payer program;
- Physicians or other authorized parties, such as hospitals or independent laboratories, that order the testing service or otherwise refer the testing services to us; or
- Patients in cases where the patient has no insurance, has insurance that partially covers the testing, or owes a co-payment, co-insurance, or deductible amount.

Until DetermaVu™, or any other new cancer diagnostic test that we may develop, is accepted by Medicare or private third party payers for reimbursement, we will have to market the test to physicians on a patient pay basis, meaning that the patient may need to pay the full cost of the test. In the absence of reimbursement by a health insurance plan or Medicare, patients who would be candidates for the use of our diagnostic tests may decline to use our tests, and physicians may be reluctant to prescribe our tests, due to the cost of the test to the patients. Because of this patient cost factor, revenues from any new cancer test that we market will experience slow growth until the test is approved for reimbursement by larger payer plans which cover many patients.

Medicare

For lung cancer diagnostics, Medicare or CMS reimbursement approval is critical. CMS relies on a network of Medicare Administrative Contractors (“MACs”) to make Local Coverage Decisions approving a diagnostic test for reimbursement. The Molecular Diagnostics Services (“MolDx”) Program was developed by Palmetto GBA (the previous MAC for California) to identify and establish coverage and reimbursement for molecular diagnostics tests. The program has developed guidelines for the level of evidence of efficacy required to be obtained through clinical trials. Palmetto, which contracted with CMS to administer the MolDx, issues Local Coverage Determinations that affect coverage, coding, and billing of many molecular diagnostic tests and the current MAC for California, Noridian Healthcare Solutions, LLC, has adopted the coverage policies from Palmetto. MACs also serve as the primary

operational contact between the Medicare Fee-For-Service program, for paying Medicare claims, and approximately 1.5 million health care providers enrolled in the program.

LDTs that have been approved for reimbursement by CMS are generally reimbursed under the Medicare Clinical Laboratory Fee Schedule ("CLFS"). From time to time, Congress has revised the Medicare statute and the formulas it establishes for the CLFS. The payment amounts under the Medicare fee schedules are important because they will determine the amount of reimbursement for a diagnostic under Medicare, and those payment amounts are also often used as a basis for payment amounts set by other governmental and private third-party payers. For example, state Medicaid programs are prohibited from paying more than the Medicare fee schedule limit for clinical laboratory services furnished to Medicaid recipients.

The Protecting Access to Medicare Act of 2014 ("PAMA"), establishes a market-based pricing methodology for laboratory test. Two categories of tests are established under PAMA: clinical diagnostic lab tests ("CDLT") and advanced diagnostic lab tests ("ADLT"). ADLTs are CDLTs furnished by a single laboratory, not sold for use by other entities, and meeting at least one of the following criteria:

Analysis of multiple biomarkers of DNA, RNA or proteins combined with a unique algorithm to yield a single patient-specific result;

Cleared or approved by the FDA; or

Meets other similar criteria established by the Secretary of Health and Human Services.

The law establishes that CLFS prices will be equal to the weighted median rates paid by private payers. However, CDLT prices are adjusted every three years whereas ADLT prices are adjusted annually. The other difference between the two types of tests is the establishment of the initial price. For CDLTs, the price paid for the first three years is established by CMS through a gap-fill methodology. For ADLTs, the price paid for the first 9 months is the test's list price and if the list price is greater than 130% of the weighted median private payer price, CMS will recoup the difference from the laboratory through a payment claw back. It is not known at this point if DetermaVu™ will be classified as a CDLT or ADLT. The gap-fill pricing methodology for CDLTs represents a significant short-term risk because pricing under the gap-fill methodology can vary significantly.

Congress has proposed on several occasions to impose a 20% coinsurance charge on patients for CDLTs reimbursed under CLFS, which would require us to bill patients for these amounts. Because of the relatively low reimbursement for many CDLTs, in the event that Congress enacts such legislation, the cost of billing and collecting for CDLTs would often exceed the amount receivable from the patient.

Medicare occasionally establishes coverage prior to the completion and publication of a clinical utility study of the diagnostic. As a consequence, it may be possible to obtain Medicare coverage prior to the completion of our DetermaVu™ clinical utility study and publication of the results. There are a number of examples of this with respect to lung cancer diagnostics. In 2017, Noridian, the (MAC for the JE jurisdiction that includes California) issued Local Coverage Decisions or LCDs for a number of diagnostics while evidence was still under development. This included Veracyte's Percepta, which received a decision in May of 2017, and Integrated Diagnostics Xypresys, which received a LCD in October of 2017.

Private Third Party Payers

In addition to seeking Medicare reimbursement approval, we will seek reimbursement approval from private payers such as health insurance companies and HMOs. Private payers generally will determine whether to approve a LDT for reimbursement based on the published results of clinical validity and clinical utility studies. Obtaining private payer medical coverage generally takes twelve to twenty-four months from the time that sufficient evidence is published establishing clinical utility. We have shown our clinical protocol designs to payers, much like many therapeutic companies share their clinical utility designs with the FDA, for feedback. We previewed our clinical protocol designs with ten payers that represent over 77 million covered lives late in 2017 and received favorable feedback on the design of our studies, the number of our studies, and the primary and secondary endpoints. From this interaction, we believe that if we are successful in meeting the endpoints of our clinical utility studies, we will receive favorable coverage decisions by some large payers.

Reimbursement rates paid by private third-party payers can vary based on whether the provider is considered to be an "in-network" provider, a participating provider, a covered provider, an "out-of-network" provider or a non-participating provider. These definitions can vary among payers. An in-network provider usually has a contract with the payer or

benefits provider. This contract governs, among other things, service-level agreements and reimbursement rates. In certain instances, an insurance company may negotiate an in-network rate for our testing. An in-network provider may have rates that are lower per test than those that are out-of-network, and that rate can vary widely. Rates vary based on the payer, the testing type and often the specifics of the patient's insurance plan. If a laboratory agrees to contract as an in-network provider, it generally expects to receive quicker payment and access to additional covered patients. However, it is likely that we will initially be considered an "out-of-network" or non-participating provider by payers who cover the vast majority of patients until we can negotiate contracts with the payers.

We cannot predict whether, or under what circumstances, payers will reimburse for patients for our tests. Full or partial denial of coverage by payers, or reimbursement at inadequate levels, would have a material adverse impact on our business and on market acceptance of our tests.

Billing and Collection

Where there is a private or governmental third-party payer coverage policy in place, we will bill the payer and the patient in accordance with the established policy. Our efforts in obtaining reimbursement based on individual claims, including pursuing appeals or reconsiderations of claims denials, could take a substantial amount of time, and bills may not be paid for many months, if at all. Furthermore, if a third-party payer denies coverage after final appeal, payment may not be received at all.

Where there is no coverage policy in place, we will pursue reimbursement on a case-by-case basis. In some cases, if not prohibited by law or regulation, we may bill physicians, hospitals and other laboratories directly for the services that they order. However, laws and regulations in certain states prohibit laboratories from billing physicians or other purchasers for testing that they order. Some states may allow laboratories to bill physicians directly but may prohibit the physician and, in some cases, other purchasers from charging more than the purchase price for the services, or may allow only for the recovery of acquisition costs, or may require disclosure of certain information on the invoice. An increase in the number of states that impose similar restrictions could adversely affect us by encouraging physicians to perform laboratory services in-house or by causing physicians to refer services to other laboratories that are not subject to the same restrictions.

Patents and Trade Secrets

We rely primarily on patents and contractual obligations with employees and third parties to protect our proprietary rights. We have sought, and intend to continue to seek, appropriate patent protection for important and strategic components of our proprietary technologies by filing patent applications in the U.S. and certain foreign countries. There can be no assurance that any of our patents will guarantee protection or market exclusivity for our diagnostic tests and diagnostic test candidates. We may also use license agreements both to access technologies developed by other companies and universities and to convey certain intellectual property rights to others. Our financial success will be dependent in part on our ability to obtain commercially valuable patent claims and to protect our intellectual property rights and to operate without infringing upon the proprietary rights of others.

Our diagnostic patent portfolio includes two patent families owned by us with claims directed to compositions of matter and methods useful for detection of breast and lung cancers using specific biomarkers or a panel of specific biomarkers. Patents are pending in the United States, with projected expiration dates ranging from 2033 to 2039.

We have also obtained an exclusive license from Wistar to certain pending patent applications in the field of molecular diagnostics for lung cancer. The pending claims are directed to compositions of matter and methods useful for detection of lung cancer using specific biomarkers or a panel of specific biomarkers, with projected expiration dates ranging from 2028 to 2039. Patents covered by the exclusive license have issued in the United States, Canada and India and are pending in the United States, Australia, Brazil. Canada, China, Europe, India, Israel, Japan, Mexico, New Zealand, Russia, Saudi Arabia, Singapore, South Korea, and the United Arab Emirates. Those patents are projected to expire in 2028 - 2029.

In addition to relying on patents, we will rely on trade secrets, know-how, and continuing technological advancement to maintain our competitive position. We have entered into intellectual property, invention, and non-disclosure agreements with our employees, and it is our practice to enter into confidentiality agreements with our consultants. There can be no assurance, however, that these measures will prevent the unauthorized disclosure or use of our trade secrets and know-how, or that others may not independently develop similar trade secrets and know-how or obtain access to our trade secrets, know-how, or proprietary technology.

General Risks Related to Obtaining and Enforcing Patent Protection

Our patents and patent applications are directed to compositions of matter, formulations, methods of use and/or methods of manufacturing. The patent positions of pharmaceutical and biotechnology companies, including ours, are generally uncertain and involve complex legal and factual questions. Our business could be negatively impacted by

any of the following:

- The claims of any patents that are issued may not provide meaningful protection, may not provide a basis for commercially viable diagnostic tests or may not provide us with any competitive advantages;
- Our patents may be challenged by competitors or other third parties and if the third parties are successful in their challenge they could use the patented inventions to compete with us;
- Others may have patents that relate to our technology or business that may prevent us from marketing our diagnostic test candidates unless we are able to obtain a license to those patents;
- Patent applications to which we have rights may not result in issued patents and the information disclosed in those applications could be used by our competitors; and
- We may not be successful in developing additional proprietary technologies that are patentable.

In addition, others may independently develop similar or alternative technologies, duplicate any of our technologies and, if patents are licensed or issued to us, design around the patented technologies licensed to or developed by us. Moreover, we could incur substantial costs in litigation if we have to defend ourselves in patent lawsuits brought by third parties or if we initiate such lawsuits.

The United States Supreme Court's decisions in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.* and *Association for Molecular Pathology v. Myriad Genetics* may limit our ability to obtain patent protection on diagnostic methods that merely recite a correlation between a naturally occurring event and a diagnostic outcome associated with that event. Our cancer diagnostic tests are based on the presence of certain genetic markers for a variety of cancers. In *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, the Supreme Court ruled that patent protection is not available for the use of a mathematical correlation of the presence of a well-known naturally occurring metabolite as a means of determining proper drug dosage. The claims in the contested patents that were the subject of that decision were directed to measuring the serum level of a drug metabolite and adjusting the dosing regimen of the drug based on the metabolite level. The Supreme Court said that a patent claim that merely claimed a correlation between the blood levels of a drug metabolite and the best dosage of the drug was not patentable subject matter because it did no more than recite a correlation that occurs in nature.

In *Association for Molecular Pathology v. Myriad Genetics,* the Supreme Court ruled that the discovery of the precise location and sequence of certain genes, mutations of which can dramatically increase the risk of breast and ovarian cancer, was not patentable. Knowledge of the gene location and sequences was used to determine the genes' typical nucleotide sequence, which, in turn, enabled the development of medical tests useful for detecting mutations in these genes in a particular patient to assess the patient's cancer risk. But the mere discovery of an important and useful gene did not render the genes patentable as a new composition of matter.

Also, in *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, the Federal Circuit ruled that a method for detecting a paternally inherited nucleic acid of fetal origin performed on a maternal serum or plasma sample from a pregnant female was not patent eligible subject matter under the framework set forth in *Mayo Collaborative Services v. Prometheus Laboratories, Inc*. The court examined the elements of the claim to determine whether the claim contained an inventive concept sufficient to transform the claimed naturally occurring phenomenon into a patent eligible application and found that the method steps did not support patentability because they used conventional amplification and detection techniques. Although the claims can be distinguished from the claims at issue in *Mayo Collaborative Services v. Prometheus Laboratories, Inc*., the court was bound by the language of the Supreme Court decision to hold Sequenom's claims unpatentable.

While the cases discussed above are instructive, the United States Patent and Trademark Office (the "USPTO") has issued interim guidelines in light of the Supreme Court decisions indicating that process claims having a natural principle as a limiting step will be evaluated to determine if the claim includes additional steps that practically apply the natural principle such that the claim amounts to significantly more than the natural principle itself. Because the diagnostic tests that we are developing combine an innovative methodology with newly discovered compositions of matter, we are hopeful that this Supreme Court decision will not preclude the availability of patent protection for our diagnostic tests.

The USPTO has also issued a Subject Matter Eligibility Update to provide further guidance in determining subject matter eligibility. The Subject Matter Eligibility Update includes new Subject Matter Eligibility Examples for the Life

Sciences. These examples provide favorable exemplary subject matter eligibility analysis of hypothetical claims covering diagnostic tests and claims drawn from case law. This update from the USPTO does not change our opinion on our ability to obtain meaningful patent protection.

There is a risk that any patent applications that we file and any patents that we hold or later obtain could be challenged by third parties and declared invalid or infringing of third party claims. A patent interference proceeding may be instituted with the USPTO when more than one person files a patent application covering the same technology, or if someone wishes to challenge the validity of an issued patent filed before March 16, 2013. At the completion of the interference proceeding, the USPTO will determine which competing applicant is entitled to the patent, or whether an issued patent is valid. Patent interference proceedings are complex, highly contested legal proceedings, and the USPTO's decision is subject to appeal. This means that if an interference proceeding arises with respect to any of our patent applications, we may experience significant expenses and delay in obtaining a patent, and if the outcome of the proceeding is unfavorable to us, the patent could be issued to a competitor rather than to us. In addition to interference proceedings, the USPTO can reexamine issued patents at the request of a third party seeking to have the patent invalidated. Currently an inter partes review proceeding will allow third parties to challenge the validity of an issued patent where there is a reasonable likelihood of invalidity. This means that patents owned or licensed by us may be subject to re-examination and may be lost if the outcome of the re-examination is unfavorable to us.

Post Grant Review under the America Invents Act makes available opposition-like proceedings in the United States. As with the USPTO interference proceedings, Post Grant Review proceedings will be very expensive to contest and can result in significant delays in obtaining patent protection or can result in a denial of a patent application. Also, a derivation proceeding may be instituted by the USPTO or an inventor alleging that a patent or application was derived from the work of another inventor.

Oppositions to the issuance of patents may be filed under European patent law and the patent laws of certain other countries. As with the USPTO interference proceedings, these foreign proceedings can be very expensive to contest and can result in significant delays in obtaining a patent or can result in a denial of a patent application.

The enforcement of patent rights often requires litigation against third party infringers, and such litigation can be costly to pursue. Even if we succeed in having new patents issued or in defending any challenge to issued patents, there is no assurance that our patents will be comprehensive enough to provide us with meaningful patent protection against our competitors.

In addition to patents, we rely on trade secrets, know-how, and continuing technological advancement to maintain our competitive position. The molecular diagnostics that we are developing use gene expression classifiers or algorithms, which are mathematical models that weight the biomarkers to produce a score. We will treat the mathematical models as trade secrets. We have entered into intellectual property, invention, and non-disclosure agreements with our employees, and it is our practice to enter into confidentiality agreements with our consultants. There can be no assurance, however, that these measures will prevent the unauthorized disclosure or use of our trade secrets and know-how, or that others may not independently develop similar trade secrets and know-how or obtain access to our trade secrets, know-how, or proprietary technology.

Government Regulation

CLIA--Clinical Laboratory Improvement Amendments of 1988 and State Regulation

As a provider of laboratory testing on human specimens for the purpose of disease diagnosis, prevention, or treatment, we are required to hold certain federal, state, and local licenses, certifications and permits to conduct our business. In 1988, Congress enacted CLIA, which established quality standards for all laboratories that provide testing services to ensure the accuracy, reliability and timeliness of patient test results regardless of where the test is performed.

Under CLIA, a laboratory is defined as any facility that performs laboratory testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention or treatment of disease, or the impairment of, or assessment of health of human beings. Because we meet this definition, CLIA requires that we hold a certificate applicable to the complexity of the categories of testing we perform and that we comply with certain standards. Laboratories performing high complexity testing are required to meet more stringent requirements than laboratories performing less complex tests. CLIA regulations require clinical laboratories like our laboratory to comply with various operational, personnel, facilities administration, quality, and proficiency testing requirements intended to ensure that testing services are accurate, reliable and timely. CLIA certification is a prerequisite for reimbursement eligibility for services provided to state and federal health care program beneficiaries. CLIA is user-fee funded. Therefore, all costs of administering the program must be covered by the regulated facilities, including certification and survey costs.

FDA Regulation of Diagnostic Tests

We believe our diagnostic tests will be classified as LDTs and consequently be governed under the CLIA regulations, as administered by CMS, as well as by applicable state laws.

Historically, the FDA has exercised enforcement restraint with respect to most LDTs and has not required laboratories that offer LDTs to comply with FDA requirements for medical devices, such as registration, device listing, quality systems regulations, premarket clearance or premarket approval, and post-market controls.

In recent years, however, the FDA has stated it intends to end its policy of enforcement restraint and begin regulating certain LDTs as medical devices. In October 2014, the FDA issued two draft guidance documents, entitled “Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs)” and “FDA Notification and Medical Device Reporting for Laboratory Developed Tests (LDTs)”, respectively, that set forth a proposed risk-based regulatory framework that would apply varying levels of FDA oversight to LDTs.

In January 2017, the FDA issued a Discussion Paper on LDTs (“Discussion Paper”), which proposes a risk based approach to LDT oversight focusing on new and significantly modified high and moderate risk LDTs. However, low risk LDTs, LDTs for rare diseases, traditional LDTs, LDTs intended solely for public health surveillance, certain LDTs used in CLIA certified labs, and LDTs intended solely for forensic use would not be expected to comply with premarket review, quality systems, and registration and listing requirements unless necessary to protect public health. With respect to the post-market surveillance of LDTs, the FDA’s Discussion Paper recommends that laboratories initially report serious adverse events for all tests except the exempted categories of tests, which include LDTs intended for public health surveillance, some stem cell/tissue/organ transplantation LDTs, and LDTs intended solely for forensic use. The Discussion Paper notes that while the report neither represents the formal position of the FDA and nor is it a final version of the LDT guidance documents published in 2014, it is hoped that its publication will continue to advance further public disclosure. The FDA has indicated that it does not intend to modify its policy of enforcement restraint until the draft guidance documents are finalized.

Based on guidance set forth in the Discussion Paper, the proposed legislation, and FDA’s comments on such legislation, FDA premarket review of new and significantly modified LDTs could be phased-in in the near future, however, to date no firm time commitments have been set. Nonetheless, the FDA may decide to regulate certain LDTs on a case-by-case basis at any time.

FDA regulations could also require, among other things, additional clinical studies and submission of a premarket notification or filing a Premarket Approval ("PMA") application with the FDA. For example, LDTs with the same intended use as a cleared or approved companion diagnostic are defined in FDA's draft guidance as "high-risk LDTs (Class III medical devices)" for which premarket review would be required. This may include the use of our LDTs for screening patients for cancer.

Since 2017, legislators have been working to advance a draft of the Diagnostic Accuracy and Innovation Act ("DAIA") to serve as a basis for creating new regulatory framework for LDTs. In August 2018, the FDA suggested changes to DAIA and addressed the need for a new regulatory framework that would require new tests to undergo FDA review to demonstrate they are analytically and clinically valid. The FDA's changes to the bill included proposals related to premarket approval, provisional approval, and a precertification program, and made explicit its authority to revoke approval, request raw data, and take corrective action against test developers in order to protect the public health. In December 2018 the FDA Commissioner and the Director of the Center for Devices and Radiological Health (CDRH) expressed significant concerns regarding disparities between some LDTs and in vitro diagnostics that have been reviewed and cleared or approved by FDA. Responding to the FDA's DAIA comments, in December 2018 legislators proposed a draft bill called the Verifying Accurate, Leading-edge IVCT Development (VALID) Act, which features a precertification program. The term IVCT refers to in vitro clinical tests, a new category that was introduced in DAIA, and comprises both test kits and lab-developed tests. As proposed, the VALID Act includes precertification proposed by the FDA, a process through which diagnostic developers could receive premarket approval or clearance for one test representative of a group of tests using the same technology and have other elements in common. Approval of that representative test would precertify other tests in the group and allow the lab to launch them without premarket review. The FDA estimates that between 40 and 50% of tests would qualify for precertification. We cannot predict whether the VALID Act as proposed, or any modified version of the VALID Act, will be enacted into law.

California State Laboratory Licensing

In addition to federal certification requirements of laboratories under CLIA, we are required to maintain licensure under California law for our laboratory in Alameda, California. The California law includes standards for the day-to-day operation of a clinical reference laboratory, including the training and skills required of personnel and quality control. In addition, California laws mandate proficiency testing, which involves testing of specimens that have been specifically prepared for the laboratory. Our diagnostic laboratory was certified by the state of California during 2017. If we do not meet the requirements of California laws, the California Department of Health Services ("DHS") may suspend, restrict or revoke our license to operate our laboratory, assess substantial civil money penalties, or impose specific corrective action plans.

Other State Laboratory Licensing

Some states require licensure of out-of-state laboratories that accept specimens from those states. Our laboratories will need to pass various state inspections in order to get licensed to provide LDTs in each of state that requires licensure. All states except five states accept federal CLIA certification and state of residence licensure as proof of quality and good standing in order to perform diagnostic tests. The five exceptions are Florida, Maryland, Rhode Island, Pennsylvania and New York. We have already obtained the Pennsylvania state clinical laboratory permit and the licenses required by Maryland and Rhode Island. Florida no longer requires an individual state clinical license or permit in order to perform diagnostic tests for Florida residents. We plan to file to obtain the license required by New York.

In Vitro Diagnostics

In the future, we may elect to develop IVDs, which are regulated by the FDA as medical devices. Medical devices marketed in the United States are subject to the regulatory controls under CLIA, the Federal Food, Drug, and Cosmetic Act, and regulations adopted by the FDA. Some requirements, known as premarket requirements, apply to medical devices before they are marketed, and other requirements, known as post-market requirements, apply to medical devices after they are marketed.

The particular premarket requirements that must be met to market a medical device in the United States will depend on the classification of the device under FDA regulations. Medical devices are categorized into one of three classes, based on the degree of risk they present. Devices that pose the lowest risk are designated as Class I devices; devices that pose moderate risk are designated as Class II devices and are subject to general controls and special controls; and the devices that pose the highest risk are designated as Class III devices and are subject to general controls and premarket approval.

A premarket submission to the FDA will be required for some Class I devices, most Class II devices; and all Class III devices. Most Class I and some Class II devices are exempt from premarket submission requirements. Some Class I and most Class II devices may be marketed after a 510(k) premarket notification, while a more extensive PMA is required to market Class III devices.

Until regulatory requirements suggested by the FDA or required by any new legislation are phased in, our initial confirmatory diagnostics will not require FDA filing before launch. Since the tests are being developed as LDTs, the regulatory pathway that we will be following is the CLIA certification and inspection pathway.

If the new requirements are phased in or if we elect to develop IVDs, our future screenings diagnostics may require a 510(k) submission or a PMA. In a 510(k) submission, the device sponsor must demonstrate that the new device is "substantially equivalent" to a predicate device in terms of intended use, technological characteristics, and performance testing. A 510(k) requires demonstration of substantial equivalence to another device that is legally marketed in the United States. Substantial equivalence means that the new device is at least as safe and effective as the predicate. A device is substantially equivalent if, in comparison to a predicate it (a) has the same intended use as the predicate and has the same technological characteristics as the predicate; or (b) has the same intended use as the predicate, has different technological characteristics, and the information submitted to FDA does not raise new questions of safety and effectiveness, and is demonstrated to be at least as safe and effective as the legally marketed predicate device.

A claim of substantial equivalence does not mean the new and predicate devices must be identical. Substantial equivalence is established with respect to intended use, design, energy used or delivered, materials, chemical composition, manufacturing process, performance, safety, effectiveness, labeling, biocompatibility, standards, and other characteristics. A device may not be marketed in the United States until the submitter receives a letter declaring the device substantially equivalent. If the FDA determines that a device is not substantially equivalent, the applicant may resubmit another 510(k) with new data, or request a Class I or II designation through the FDA's *de novo* process that allows a new device without a valid predicate to be classified into Class I or II if it meets certain criteria, or file a reclassification petition, or submit a PMA.

A new 510(k) submission is required for changes or modifications to an existing approved device, where the modifications could significantly affect the safety or effectiveness of the device or the device is to be marketed for a new or different indication for use.

A PMA for Class III devices is the most stringent type of premarket submission. Before the FDA approves a PMA, the sponsor must provide valid scientific evidence demonstrating reasonable assurance of safety and effectiveness for the device's intended use.

Health Insurance Portability and Accountability Act

Under the Health Insurance Portability and Accountability Act ("HIPAA"), the Department of Health and Human Services ("HHS") has issued regulations to protect the privacy and security of protected health information. HIPAA also regulates standardization of data content, codes and formats used in health care transactions and standardization of

identifiers for health plans and providers. Penalties for violations of HIPAA regulations include civil and criminal penalties.

CMS and the Office of Civil Rights issued a final rule in February 2014 to amend both the HIPAA and CLIA regulations. The final rule amended the HIPAA privacy rule to remove the CLIA laboratory exceptions, and as a result, HIPAA-covered laboratories are now required to provide individuals, upon request, with access to their completed test reports. Under the 2014 rule, CLIA laboratories and CLIA-exempt laboratories may provide copies of a patient's completed test reports that, using the laboratory's authentication process, can be identified as belonging to that patient. These changes to the CLIA regulations and the HIPAA Privacy Rule are intended to provide individuals with a greater ability to access their health information. CLIA laboratories must create and maintain policies, procedures, and other documentation necessary to inform patients of the right to access laboratory test reports and how to exercise that right.

Physician Referral Prohibitions

Under a federal law directed at "self-referral," commonly known as the Stark Law, there are prohibitions, with certain exceptions, on Medicare and Medicaid payments for laboratory tests referred by physicians who personally, or through a family member, have a "financial relationship"—including an investment or ownership interest or a compensation arrangement—with the clinical laboratory performing the tests. Several Stark Law exceptions are relevant to arrangements involving clinical laboratories, including: (1) fair market value compensation for the provision of items or services; (2) payments by physicians to a laboratory for clinical laboratory services; (3) certain space and equipment rental arrangements that satisfy certain requirements, and (4) personal services arrangements that satisfy certain requirements. The laboratory cannot submit claims to the Medicare Part B program for services furnished in violation of the Stark Law, and Medicaid reimbursements may be at risk as well. Penalties for violating the Stark Law include the return of funds received for all prohibited referrals, fines, civil monetary penalties and possible exclusion from the federal health care programs. Many states have comparable laws that are not limited to Medicare and Medicaid referrals.

Corporate Practice of Medicine

A number of states, including California, do not allow business corporations to employ physicians to provide professional services. This prohibition against the "corporate practice of medicine" is aimed at preventing corporations such as us from exercising control over the medical judgments or decisions of physicians. The state licensure statutes and regulations and agency and court decisions that enumerate the specific corporate practice rules vary considerably from state to state and are enforced by both the courts and regulatory authorities, each with broad discretion. If regulatory authorities or other parties in any jurisdiction successfully assert that we are engaged in the unauthorized corporate practice of medicine, we could be required to restructure our contractual and other arrangements. In addition, violation of these laws may result in sanctions imposed against us and/or the professional through licensure proceedings, and we could be subject to civil and criminal penalties that could result in exclusion from state and federal health care programs.

Federal and State Fraud and Abuse Laws

A variety of federal and state laws prohibit fraud and abuse. These laws are interpreted broadly and enforced aggressively by various state and federal agencies, including CMS, the Department of Justice, the Office of Inspector General for HHS, and various state agencies. In addition, the Medicare and Medicaid programs increasingly use a variety of contractors to review claims data and to identify improper payments as well as fraud and abuse. These contractors include Recovery Audit Contractors, Medicaid Integrity Contractors and Zone Program Integrity Contractors. In addition, CMS conducts Comprehensive Error Rate Testing audits, the purpose of which is to detect improper Medicare payments. Any overpayments identified must be repaid unless a favorable decision is obtained on appeal. In some cases, these overpayments can be used as the basis for an extrapolation, by which the error rate is applied to a larger universe of claims, and which can result in even higher repayments.

The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting, receiving, or providing remuneration, directly or indirectly, to induce or in return for either the referral of an individual, or the furnishing, recommending, or arranging for the purchase, lease or order of any health care item or service reimbursable, in whole or in part, under a federal health care program. The definition of "remuneration" has been broadly interpreted to include anything of value, including gifts, discounts, credit arrangements, payments of cash, ownership interests and providing anything at less than its fair market value. Recognizing that the Anti- Kickback Statute is broad and may technically prohibit many innocuous or beneficial arrangements within the health care industry, the Office of Inspector General for HHS has issued a series of regulatory "safe harbors." These safe harbor regulations set forth certain requirements that, if met, will assure immunity from prosecution under the federal Anti-Kickback Statute. Although full compliance with these provisions ensures against prosecution under the federal Anti-Kickback Statute, the failure of a transaction or arrangement to fit within a specific safe harbor does not necessarily mean that the transaction or arrangement is illegal or that prosecution under the federal Anti-Kickback Statute will be pursued.

HIPAA also created new federal crimes, including health care fraud and false statements relating to health care matters. The health care fraud statute prohibits knowingly and willfully executing a scheme to defraud any health care benefit program, including private third-party payers. A violation of this statute is a felony and may result in fines, imprisonment or exclusion from federal health care programs, such as the Medicare and Medicaid programs. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for health care benefits, items or services. A violation of this statute is a felony and may result in fines, imprisonment or exclusion from federal health care programs.

Many states have laws similar to the federal laws described above, and state laws may be broader in scope and may apply regardless of payer.

Additionally, the U.S. Foreign Corrupt Practices Act ("FCPA") prohibits U.S. corporations and their representatives from offering, promising, authorizing or making payments to any foreign government official, government staff member, political party or political candidate in an attempt to obtain or retain business abroad. The scope of the FCPA includes interactions with certain healthcare professionals in many countries. Other countries have enacted similar anti-corruption laws and/or regulations.

Other Regulatory Requirements

Our laboratory will be subject to federal, state and local regulations relating to the handling and disposal of regulated medical waste, hazardous waste and biohazardous waste, including chemical, biological agents and compounds, blood samples and other human tissue. Typically, we will use outside vendors who are contractually obligated to comply with applicable laws and regulations to dispose of such waste. These vendors will be licensed or otherwise qualified to handle and dispose of such waste.

The Occupational Safety and Health Administration has established extensive requirements relating to workplace safety for health care employers, including requirements to develop and implement programs to protect workers from exposure to blood-borne pathogens by preventing or minimizing any exposure through needle stick or similar penetrating injuries.

Employees

As of December 31, 2018, we employed 12 persons on a full-time basis. Four of our full-time employees hold Ph.D. degrees in one or more fields of science.

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Item 1A. **Risk Factors**

Our business is subject to various risks, including those described below. You should consider the following risk factors, together with all of the other information included in this Report, which could materially adversely affect our proposed operations, our business prospects, and financial condition, and the value of an investment in our business. There may be other factors that are not mentioned here or of which we are not presently aware that could also affect our business operations and prospects.

Risks Related to Our Business Operations

We may experience delays in conducting the additional validation studies necessary for the commercialization of DetermaVu™, or we may encounter unanticipated results or findings.

We have successfully completed our R&D Validation study and are now conducting Analytic Validation. If we successfully complete Analytic Validation, our next step prior to commercialization of DetermaVu™ will be to conduct a CLIA Laboratory Validation study and a Clinical Validation study thereafter. Clinical Validation is the final step prior to commercial launch of a LDT, and we are targeting completion of a Clinical Validation study during the second half of 2019. If these studies are completed successfully, we plan to commercialize or to arrange for the commercialization of the test as a LDT to be run solely in our clinical laboratory in Alameda, CA. Until we perform these studies, we will not know whether we can successfully complete the development of DetermaVu™. We have limited experience conducting clinical validation and have not yet performed a clinical utility demonstration in our lab. We may not be able to successfully complete this testing for DetermaVu™ or any other test we may develop. While we plan to make DetermaVu™ commercially available in the second half of 2019, there can be no assurance that there will be no delays in the successful completion of the Clinical Validation study and commercialization of DetermaVu™, due to any number factors some of which may not be within our control. Any delays in the successful completion of the additional validation studies for DetermaVu™ could cause us to incur significant additional costs and delay the completion of development and commercial launch of DetermaVu™. We may encounter unanticipated results or finding in the studies subsequent to our R&D Validation study showing that our R&D Validation study results may not be predictive of future test results with DetermaVu™ or any other future candidate tests. We have performed only limited R&D work for any other test or for any other intended patient population outside of lung cancer, and we have conducted no R&D work outside of cancer. Our Immune System Interrogation approach, which analyzes the immune systems response to a specific disease, and our technology may not ultimately have application in any other population, and we may be unable to identify any future candidates and tests for any other cancer or any other disease population.

We do not currently have any diagnostic tests on the market and have not yet generated any revenues from operations.

We plan to complete development of DetermaVu™ and make it commercially available in the second half 2019. However, we may be unable to complete development in that timeframe or at all. Even if we complete development of DetermaVu™, our commercialization arrangements may not generate revenues in sufficient amounts to meet our operating expenses. Without diagnostic test sales or licensing fee revenues, we will not be able to operate at a profit, and we will not be able to cover our operating expenses without raising additional capital.

We have limited capital, marketing, and sales resources and no distribution resources for the commercialization of DetermaVu™.

If we are successful in completing the remaining steps of CLIA Laboratory Validation and Clinical Validation for DetermaVu™, we will need to build our own marketing and sales capability, which will require the investment of significant financial and management resources to recruit, train, and manage a sales force and build-out a health care regulatory compliance program. In the alternative, due to our limited capital resources, we may need to enter into marketing arrangements with other diagnostic companies for DetermaVu™. Under such marketing arrangements we may license marketing rights to one or more other companies or to one or more joint venture companies formed to market DetermaVu™, and we might receive only a royalty on sales of DetermaVu™ or an equity interest in a joint venture company. As a result, our revenues from the sale of DetermaVu™ may be substantially less than the amount of revenues and gross profits that we might receive if we were to market DetermaVu™ ourselves.

Sales of DetermaVu™ or any other diagnostic tests that we may develop could be adversely impacted by the reluctance of physicians to adopt the use of our tests and by the availability of competing diagnostic tests.

Physicians and hospitals may be reluctant to try a new diagnostic test due to the high degree of risk associated with the application of new technologies and diagnostic test in the field of human medicine, especially if the new test differs from the current standard of care for detecting cancer in patients. Competing tests for the initial diagnosis, reoccurrence diagnosis and optimal treatment of cancer are being manufactured and marketed by established companies and by other smaller biotechnology companies. In order to compete with other diagnostic tests, particularly any that sell at lower prices, our diagnostic tests will have to provide medically significant advantages or be more cost effective. Even if we are able to overcome physician reluctance and compete with products that are currently on the market, our competitors may succeed in developing new safer, more accurate or more cost-effective diagnostic tests that could render our diagnostic tests and technologies obsolete or noncompetitive.

If our laboratory facilities become damaged or inoperable, or we are required to vacate any facility, our ability to provide services and pursue our research and development and commercialization efforts may be jeopardized.

We do not have any clinical laboratory facilities outside of our facility in Alameda, California. Our facility and equipment could be harmed or rendered inoperable by natural or man-made disasters, including fire, flooding and power outages, which may render it difficult or impossible for us to perform our tests or provide laboratory services for some period of time. The inability to perform our tests or the backlog of tests that could develop if any of our facilities is inoperable for even a short period of time may result in the loss of customers or harm to our reputation or relationships with key researchers, collaborators, and customers, and we may be unable to regain those customers or repair our reputation in the future. Furthermore, our facilities and the equipment we use to perform our research and development work could be costly and time-consuming to repair or replace.

Additionally, a key component of our research and development process involves using biological samples and the resulting data sets and medical histories, as the basis for our diagnostic test development. In some cases, these samples are difficult to obtain. If the parts of our laboratory facilities where we store these biological samples are damaged or compromised, our ability to pursue our research and development projects, commercialization of DetermaVu™, as well as our reputation, could be jeopardized. We carry insurance for damage to our property and the disruption of our business, but this insurance may not be sufficient to cover all of our potential losses and may not continue to be available to us on acceptable terms, if at all.

Further, if our laboratory becomes inoperable we may not be able to license or transfer our proprietary technology to a third-party, with established state licensure and CLIA certification under the scope of which our diagnostic tests could be performed following validation and other required procedures, to perform the tests. Even if we find a third-party with such qualifications to perform our tests, such party may not be willing to perform the tests for us on commercially reasonable terms. Moreover, we believe our test is currently subject to enforcement discretion by the FDA because we believe the test currently qualifies as an LDT. If, however, we are required to find a third-party laboratory to conduct our testing services, we believe this would change our status and the FDA would consider such test offered through a third-party to then be a medical device subject to active FDA regulation and enforcement. In that case, we may be required to obtain premarket clearance or approval prior to offering our tests, which would be time-consuming and costly and could result in delays in our ability to sell or offer our tests.

We may not be able to produce additional cancer diagnostic tests that offer high enough sensitivity to offset the availability of minimally invasive biopsies for some types of cancer, which could impede our development and commercialization of an array of diagnostic tests beyond DetermaVu™ for lung cancer.

We believe that a significant benefit of DetermaVu™ will be the reduction of unnecessary surgical biopsies to diagnose lung cancer. While lung cancer biopsies involve an invasive surgical procedure, biopsies of some other types of cancer, including breast cancer, often can be performed using less invasive procedures that result in significantly less risk, discomfort, and cost to the patient while providing a diagnostic result that would be as accurate or more accurate than any diagnostic tests we may develop. As a result, physicians and patients may prefer to rely on a non-invasive or minimally invasive biopsy to test for certain cancers rather than use a blood test.

We have incurred operating losses since inception, and we do not know if we will attain profitability.

Since our inception in September 2009, we have incurred operating losses and negative cash flows and we expect to continue to incur losses and negative cash flows in the future. Our net losses for the years ended December 31, 2018 and 2017 were $15.8 million and $19.4 million and we had an accumulated deficit of $71.3 million as of December 31, 2018. Since inception, we have financed our operations through sales of our common stock and warrants, loans from BioTime and BioTime affiliates, warrant exercises, a bank loan and sale of BioTime common shares that we hold as marketable equity securities. Although BioTime may continue to provide administrative support to us on a reimbursable basis, we do not expect BioTime to provide future financing. There is no assurance that we will be able to obtain any additional financing that we may need, or that any such financing that may become available will be on terms that are favorable to us and our shareholders. Ultimately, our ability to generate sufficient operating revenue to earn a profit depends upon our success in developing and marketing or licensing our diagnostic tests and technology.

The research and development work we are doing is costly, time consuming, and uncertain as to its results.

We incurred research and development expenses amounting to approximately $6.5 million and $7.2 million during years ended December 31, 2018 and 2017, respectively. We are presently devoting substantially all of our efforts to the development of DetermaVu™ for the detection of lung cancer but we may expand the focus of our research and development to address additional types of cancer. If we are successful in developing a new technology or diagnostic test for additional types of cancer, refinement of the new technology or diagnostic test and definition of the practical applications and limitations of the technology or diagnostic test may take years and require the expenditure of large sums of money. There is no assurance that we will be successful in developing diagnostic tests for additional types of cancer regardless of the amount of our expenditures, even if we are able to successfully complete the development of DetermaVu™.

It is likely that we will need to issue additional equity or debt securities in order to raise additional capital needed to pay our operating expenses until such time as our revenues are sufficient to finance our operating expenses.

We plan to continue to incur substantial research and development expenses and we anticipate that we will be incurring significant sales and marketing costs as we develop and commercialize DetermaVu . Our research and development expenses may also increase if we work to develop liquid biopsy tests for additional types of cancer. The period of time for which our current cash and marketable securities will be sufficient to finance our operations will depend on the extent to which we expend funds on commercializing DetermaVu and conducting new research and development programs. We will need to raise additional capital to pay operating expenses unless we are able to generate sufficient revenues from diagnostic test sales, royalties, and license fees to meet our operating expenses.

Our ability to raise additional equity or debt capital will depend not only on the successful completion of development of DetermaVu and receiving reimbursement approval from Medicare and other third-party payers, but also will depend on access to capital and conditions in the capital markets. Obtaining Medicare reimbursement approval for a diagnostic test generally takes two to three years, and investors may be reluctant to provide us with additional capital until we obtain Medicare reimbursement approval for DetermaVu . There is no assurance that we will be able to raise capital at times and in amounts needed to finance the development and commercialization of DetermaVu and general operations. Even if capital is available, it may not be available on terms that we or our shareholders would consider favorable.

Sales or other issuances of additional equity securities by us could result in the dilution of the interests of our shareholders.

If we fail to meet our obligations under license agreements, we may lose our rights to key technologies on which our business depends.

Our business will depend on certain biomarkers that have been licensed from Wistar for our lung cancer diagnostic test. The license agreement imposes obligations on us, including payment obligations and obligations to pursue development and commercialization of diagnostic tests under the licensed patents and technology. If Wistar believes that we have failed to meet our obligations under a license agreement, Wistar could seek to limit or terminate our license rights, which could lead to costly and time-consuming litigation and, potentially, a loss of the licensed rights. During the period of any such litigation our ability to carry out the development and commercialization of potential diagnostic tests, and our ability to raise any capital that we might then need, could be significantly and negatively affected. If our license rights were restricted or ultimately lost, we would not be able to continue to use the licensed biomarkers in our business.

There is a limited number of manufacturers of molecular diagnostic testing equipment and related chemical reagents necessary for the provision of our diagnostic tests.

After encountering inconsistent results using diagnostic testing equipment and reagents from one manufacturer, we switched to diagnostic testing equipment from a different manufacturer. The chemical reagents used with the diagnostic testing equipment are available only from the equipment manufacturer. If issues were to arise with the new equipment or reagents we are using causing us to acquire different diagnostic testing equipment again, we would need to conduct additional R&D Validation and analytic studies to determine whether our previous test results can be reproduced using the new equipment. As a result, we could experience delays again in developing our diagnostic tests. If similar issues were to arise after commercialization of a diagnostic test, we could experience a disruption for a period of time in providing the diagnostic tests to patients and we would lose revenues and potentially market share as a result.

If we fail to enter into and maintain successful strategic alliances for diagnostic tests that we elect to co-develop, co-market, or out-license, we may have to reduce or delay our diagnostic test development or increase our expenditures.

In order to facilitate the development, manufacture and commercialization of our diagnostic tests we may enter into strategic alliances with diagnostic, pharmaceutical, or medical device companies to advance our programs and enable us to maintain our financial and operational capacity. We will face significant competition in seeking appropriate alliances. We may not be able to negotiate alliances on acceptable terms, if at all. If we fail to create and maintain suitable alliances, we may have to limit the size or scope of, or delay, one or more of our product development or research programs, or we will have to increase our expenditures and will need to obtain additional funding, which may be unavailable or available only on unfavorable terms.

If we are able to enter into development and marketing arrangements with diagnostic, pharmaceutical or medical device companies for our diagnostic tests, we may license product development, manufacturing, and marketing rights to the pharmaceutical or medical device company or to a joint venture company formed with the pharmaceutical or medical device company. Under such arrangements we might receive only a royalty on sales of the diagnostic tests developed or an equity interest in a joint venture company that develops the diagnostic test. As a result, our revenues from the sale of those diagnostic tests may be substantially less than the amount of revenues and gross profits that we might receive if we were to develop, manufacture, and market the diagnostic tests ourselves.

We may become dependent on possible future collaborations to develop and commercialize many of our diagnostic test candidates and to provide the manufacturing, regulatory compliance, sales, marketing and distribution capabilities required for the success of our business.

We may enter into various kinds of collaborative research and development, manufacturing, and diagnostic test marketing agreements to develop and commercialize our diagnostic tests. Any future milestone payments and cost reimbursements from collaboration agreements could provide an important source of financing for our research and development programs, thereby facilitating the application of our technology to the development and commercialization of our diagnostic tests, but there are risks associated with entering into collaboration arrangements.

There is a risk that we could become dependent upon one or more collaborative arrangements for diagnostic test development or manufacturing or as a source of revenues from the sale of any diagnostic tests that may be developed by us alone or through one of the collaborative arrangements. A collaborative arrangement upon which we might depend might be terminated by our collaboration partner or they might determine not to actively pursue the development or commercialization of our diagnostic tests. A collaboration partner also may not be precluded from independently pursuing competing diagnostic tests or technologies.

There is a risk that a collaboration partner might fail to perform its obligations under the collaborative arrangements or may be slow in performing its obligations. In addition, a collaboration partner may experience financial difficulties at any time that could prevent it from having available funds to contribute to the collaboration. If a collaboration partner fails to conduct its diagnostic test development, manufacturing, commercialization, regulatory compliance, sales and marketing or distribution activities successfully and in a timely manner, or if it terminates or materially modifies its agreements with us, the development and commercialization of one or more diagnostic test candidates could be delayed, curtailed or terminated because we may not have sufficient financial resources or capabilities to continue diagnostic test development, manufacturing, and commercialization on our own.

Failure to adequately protect, or disputes relating to, trademarks, could harm our business.

We cannot be certain that the legal steps we are taking are sufficient to protect our trademark rights or that, notwithstanding legal protection, others will not infringe or misappropriate our intellectual property rights. In addition, we could come into conflict with third parties over trademark rights, which could result in disruptive and expensive litigation. Challenges to our trademarks could result in significant costs related to the prosecution or defense of the registrations of our trademarks or rebranding if we need to abandon or modify a trademark.

Our business could be adversely affected if we lose the services of the key personnel upon whom we depend.

We presently rely on a small senior management team to direct our diagnostics program and our initial commercial activities. Accordingly, the loss of the services of one or more of the members of that management team could have a material adverse effect on our business.

We have granted a security interest in substantially all of our assets to secure our obligations under a bank loan agreement.

We have entered into a Loan and Security Agreement with Silicon Valley Bank for a loan that is secured by substantially all of our assets, other than our patents and trade secrets, as collateral for the loan. If a default were to arise under the Loan and Security Agreement, the bank could foreclose on its security interest and we could lose our collateral, which could force us to discontinue our operations.

Our business and operations could suffer in the event of system failures.

Despite the implementation of security measures, our internal computer systems and those of our contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Such events could cause interruption of our operations. For example, the loss of data for our diagnostic test candidates could result in delays in our regulatory filings and development efforts and significantly increase our costs. To the extent that any disruption or security breach was to result in a loss of or damage to our data, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the development of our diagnostic test candidates could be delayed.

Security breaches and other disruptions could compromise our information and expose us to liability, and could cause our business and reputation to suffer.

In the ordinary course of business, we collect and store sensitive data, including intellectual property, our proprietary business information and that of our business partners, and personally identifiable information of patients and employees. The secure processing, maintenance, and transmission of this information is critical to our operations and business strategy. Despite our security measures, our information technology and infrastructure may be vulnerable to attacks by hackers or breached due to employee error, malfeasance, or other disruptions. Any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost, or stolen. Any such access, disclosure, theft, or other loss of information could result in legal claims or proceedings or liability under laws that protect the privacy of personal information, and could disrupt our operations and damage our reputation. Even if we do not incur an interruption of or our operations, fines, penalties, or financial liability to third parties from a security breach, we could suffer a loss of confidence in our services, which could adversely affect our business and competitive position.

Failure of our internal control over financial reporting could harm our business and financial results.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting for external purposes in accordance with accounting principles generally accepted in the U.S. Internal control over financial reporting includes maintaining records that in reasonable detail accurately and fairly reflect our transactions; providing reasonable assurance that transactions are recorded as necessary for preparation of our financial statements; providing reasonable assurance that receipts and expenditures of our assets are made in accordance with management authorization; and providing reasonable assurance that unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements would be prevented or detected on a timely basis. Because of its inherent limitations, internal control over financial reporting is not intended to provide absolute assurance that a misstatement of our financial statements would be prevented or detected. Our

growth and entry into new diagnostic tests, technologies and markets will place significant additional pressure on our system of internal control over financial reporting. Any failure to maintain an effective system of internal control over financial reporting could limit our ability to report our financial results accurately and timely or to detect and prevent fraud. Because we are an emerging growth company and a smaller reporting issuer, we are exempt from the requirement of having our internal controls over financial reporting audited by our independent registered public accountants, which means that material weaknesses or significant deficiencies in our internal controls that might be detected by an audit may not be detected and remedied.

We are presently relying in part on financial systems maintained by BioTime and upon services provided by BioTime personnel. BioTime allocates certain expenses among itself, us, and BioTime's other subsidiaries, which creates a risk that the allocations may not accurately reflect the benefit of an expenditure or use of financial or other resources by us, BioTime as our parent company, and the BioTime subsidiaries among which the allocations are made.

We may record an impairment of assets and take a charge to earnings for financial reporting purposes in the future if we discontinue the use of our original diagnostic testing platform in our CLIA lab.

Although we have changed diagnostic testing platforms for research and development purposes, we are continuing to use our original platform for clinical testing in our CLIA laboratory for certification purposes. If we discontinue that use of the original diagnostic testing platform, that equipment could be considered an impaired asset for financial reporting purposes and we would write down the value of that equipment on our condensed balance sheet and take a charge to earnings for the impaired value. We acquired the equipment through a lease, and we would remain obligated to continue to make payments under the lease even if we discontinue use of the equipment.

We may from time to time be involved in or subject to legal proceedings, and unfavorable outcomes of such legal proceedings may adversely affect our business and financial condition.

We may from time to time be involved in, subject to, or threatened with legal proceedings related to, or incidental to the conduct of, our business. Such legal proceedings can be complex, costly, and disruptive to business operations by diverting the attention and energies of management and other key personnel. For example, after the public announcement of our most recent public offering of shares of common stock, we received a letter from Chardan Capital Markets, LLC, or Chardan, claiming entitlement to certain fees pursuant to an engagement letter unrelated to the offering. We believe Chardan's claims are without merit and intend to vigorously defend against any claims that may be brought by Chardan. However, we are unable to predict the outcome of this matter, or its effect on us or our financial position. The assessment of the outcome of any legal proceeding, including our potential liability, if any, is a highly subjective process that requires judgments about future events that are not within our control. In addition, defense and settlement costs for any legal proceeding can be substantial, even with respect to claims that have no merit.

Risks Related to Our Industry

Our testing of DetermaVu™ is conducted in a single, CLIA-certified laboratory. Our operations as a clinical laboratory are subject to oversight by CMS under CLIA, as well as certain state agencies, and any failure to maintain our CLIA or applicable state permits and licenses may affect our ability to commercialize DetermaVu™.

We are subject to CLIA, a federal law regulating clinical laboratories that perform testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention or treatment of disease. Our clinical laboratory must be certified under CLIA in order for us to perform testing on human specimens. CLIA is intended to ensure the quality and reliability of clinical laboratories in the United States by mandating specific standards in the areas of personnel qualifications, administration, and participation in proficiency testing, patient test management, quality control, quality assurance and inspections. We have a current certificate under CLIA to perform routine chemistry. To renew this certificate, we are subject to survey and inspection every two years. Moreover, CLIA inspectors may make periodic inspections of our clinical laboratory outside of the renewal process.

The law also requires us to maintain a state laboratory license to conduct testing in that state. Our laboratory is located in California and must maintain a California state license. California laws establish standards for day-to-day operation of our clinical laboratory, including the training and skills required of personnel and quality control. In addition, several other states require that we hold licenses to test specimens from patients in those states. For example, Maryland is just one of several states that require out-of-state laboratories to have a state laboratory license to perform diagnostic tests on samples originating from Maryland residents. Other states may have similar requirements or may adopt similar requirements in the future. Additionally, New York is exempt from CLIA and has their own stricter clinical laboratory regulatory programs. We could be required to comply with their program in the event we accept specimens from New York. We do not have immediate plans to market our tests for commercial use in the European Union and as a result, at this time we do not believe we are subject to EU or EU member state post-market regulations related to our tests.

If we were to lose our CLIA certification or California laboratory license, whether as a result of a revocation, suspension or limitation, we would no longer be able to offer our tests, which would limit our revenue and harm our business. If we were to lose our license in other states where we are required to hold licenses, we would not be able to test specimens from those states. If we perform testing on samples originating in a state where we require a license, but do not currently have one, we could be subject to fines, sanctions, and may be denied permits or licenses in the future.

If the FDA takes the position that DetermaVu™ is not within the scope of its policy on enforcement discretion for laboratory-developed tests, or otherwise determines that it will seek to actively regulate DetermaVu™,

responding to such a regulatory position could lead to delays in commercialization, or (if encountered after commercialization) requirements to halt the commercial provision of our test until FDA marketing authorization is obtained, or enforcement action from the FDA.

Although we believe we are within the scope of the FDA's policy on enforcement discretion for laboratory-developed tests, the initial commercialization and continued commercial availability of an LDT is subject to uncertainty given the FDA's latitude in interpreting and applying its laws and policies. For example, although the FDA has historically exercised enforcement discretion over most LDTs, it does not consider tests to be subject to this enforcement discretion if they were or are designed or manufactured completely, or partly, outside of the laboratory that offers and uses them, or if they are offered "over-the-counter" (as opposed to being available to patients only when prescribed by a health care provider). Even for tests that appear to fall within FDA's previously stated policy on enforcement discretion, the FDA may decide to regulate certain LDTs on a case-by-case basis at any time.

In December 2018 the FDA Commissioner and the Director of the Center for Devices and Radiological Health (CDRH) expressed significant concerns regarding disparities between some LDTs and in vitro diagnostics that have been reviewed and cleared or approved by FDA. If the FDA were to determine that our tests are not within the policy for LDTs for any reason, including new rules, policies, or guidance, or due to new legislation such as the proposed VALID Act, our tests may become subject to FDA requirements, including pre-market review. If required, the regulatory marketing authorization process may involve, among other things, successfully completing additional clinical trials and submitting a pre-market clearance (510(k)) submission or filing a *de novo* or pre-market approval application with the FDA. If pre-market review and approval is required by the FDA, we may need to incur additional expenses or require additional time to seek it, or we may be unable to satisfy FDA standards, and our tests may not be cleared or approved on a timely basis, if at all, and the labeling claims permitted by the FDA may not be consistent with our currently planned claims or adequate to support adoption of and reimbursement for our tests. Ongoing compliance with FDA regulations would increase the cost of conducting our business, and subject us to inspection by and the regulatory requirements of the FDA, for example registration and listing, adherence to good manufacturing practices under the Quality System Regulation, and medical device reporting, and enforcement action in the event we fail to comply with these requirements. Our laboratory is operating under CLIA and is not currently operating as a device manufacturing facility following FDA's Quality System Regulation. Because these standards differ, we may face challenges establishing FDA-compliant quality systems or be unable to do so. If after commercialization under the LDT framework our tests are allowed to remain on the market but there is uncertainty about the regulatory status of our tests, including questions that may be raised if competitors object to our regulatory positioning as an LDT, we may encounter ongoing regulatory and legal challenges and related costs. Such challenges or related developments (for example if the labeling claims the FDA allows us to make are more limited than the claims we currently plan to make) may impact our commercialization efforts as orders or reimbursement may be less than anticipated. Any of these regulatory developments may cause our business to suffer.

We will also need to obtain FDA and other regulatory approvals for any IVDs that we may develop, in order to market those IVD tests.

If we decide to develop IVDs, we will need to obtain regulatory approval to market each new IVD test. This means that:

- The IVDs that we may develop cannot be sold until the CMS or the FDA, and corresponding foreign regulatory authorities approve the laboratory tests or the IVDs for medical use.
- We will have to conduct expensive and time-consuming clinical trials of new diagnostic tests. The full cost of conducting and completing clinical trials necessary to obtain FDA approval of IVD tests or for gaining reimbursement from health insurance companies, health maintenance organizations, Medicare, and other third-party payers cannot be presently determined but could exceed our financial resources.
- Data obtained from preclinical and clinical studies is susceptible to varying interpretations that could delay, limit or prevent regulatory agency approvals. Delays or denials of the regulatory approvals may be encountered as a result of changes in regulatory agency policy, regulations, or laws.
- A diagnostic test that is approved may be subject to restrictions on use.
- The FDA can withdraw approval of an FDA regulated product if problems arise.

Clinical trial failures can occur at any stage of the testing and we may experience numerous unforeseen events during, or as a result of, the clinical trial process that could delay or prevent commercialization of our current or future diagnostic tests.

Clinical trial failures or delays can occur at any stage of the trials, and may be directly or indirectly caused by a variety of factors, including but not limited to:

- Delays in securing clinical investigators or trial sites for our clinical trials;
- Delays in obtaining Institutional Review Board and other regulatory approvals to commence a clinical trial;
- Slower than anticipated rates of patient recruitment and enrollment, or failing to reach the targeted number of patients due to competition for patients from other trials;
- Limited or no availability of coverage, reimbursement and adequate payment from health maintenance organizations and other third-party payers for the use of our diagnostic test candidates in our clinical trials;

Negative or inconclusive results from clinical trials;

Approval and introduction of new diagnostic or changes in standards of practice or regulatory guidance that render our clinical trial endpoints or the targeting of our proposed indications obsolete;

Inability to monitor patients adequately during or after treatment or problems with investigator or patient compliance with the trial protocols;

Inability to replicate in large controlled studies safety and efficacy data obtained from a limited number of patients in uncontrolled trials; and

Inability or unwillingness of medical investigators to follow our clinical protocols.

If the FDA regulates LDTs such as the ones we are developing, we may be subject to a medical device manufacturer's tax.

The Affordable Care Act ("ACA") requires that medical device manufacturers pay a 2.3% excise tax on U.S. sales of certain devices. The medical device excise tax moratorium expired on December 31, 2017, but Congress extended the moratorium for an additional two years and as a result the medical device excise tax will not apply to the sale of taxable medical devices by the manufacturer, producer, or importer of the device during the period beginning on January 1, 2016 and ending on December 31, 2019. The extension of the moratorium was retroactive to January 1, 2018. None of our LDTs are anticipated to be listed with the FDA and therefore to be subject to this tax, however, if in the future our tests were to be regulated by the FDA, we could become subject to the excise tax.

In 2019, when certain provisions of the Medicare Access and CHIP Reauthorization Act of 2015 ("MACRA") are scheduled to take effect, the demand and payment for our services may be impacted.

The Medicare Access and CHIP Reauthorization Act of 2015 ("MACRA"), which was signed into law on April 16, 2015, makes substantial changes to the payment structure for physicians. This legislation, beginning in 2019, encourages physicians to enroll in alternative payment methods which incentivize physicians differently than how they are currently. We do not currently know how or if this will impact the future demand or payments for our services.

The commercial success of DetermaVu™ depends on the availability and sufficiency of third-party payer coverage and reimbursement, which may be limited or unavailable.

Our ability to successfully commercialize DetermaVu™ will depend, in significant part, on the extent to which appropriate reimbursement levels can be obtained for patients. Physicians will be hesitant to order a diagnostic test for a patient when they may be left with a large out-of-pocket fee through co-payments or co-insurance or unreimbursed balances. Third-party payers, including Medicare, Medicaid and private insurers, are increasingly challenging the prices charged for healthcare products and services. In addition, legislative proposals to reform health care or reduce government insurance programs may result in lower prices or the actual inability of prospective customers to purchase DetermaVu™. Furthermore, even if reimbursement is available, it may not be available at price levels sufficient for us to realize a positive return on our investment. We have never successfully obtained reimbursement for any test and may never be able to obtain reimbursement from any third-party payer; without such coverage and reimbursement, we may not achieve market acceptance of our test and may never be profitable.

The United States government and state legislatures have shown significant interest in implementing cost containment programs to limit the growth of government-paid healthcare costs, including price controls, restrictions on

reimbursement and coverage. Adoption of government controls and measures, and tightening of restrictive policies in jurisdictions with existing controls and measures, could exclude or limit DetermaVu™ from coverage. Even if DetermaVu™ receives coverage and reimbursement from third-party payers, such coverage policies and reimbursement rates may change at any time, might not be adequate, or less favorable coverage polices and reimbursement rates may be implemented in the future. If we are unable to obtain and maintain sufficient third-party coverage and adequate reimbursement for DetermaVu™, its commercial success may be greatly hindered and our financial condition and results of operations may be materially and adversely affected.

We may need to conduct additional studies in order to demonstrate the cost-effectiveness of DetermaVu™ to the satisfaction of our target customers and their third-party payers. Such studies might require us to commit a significant amount of management time and financial and other resources

Changes in healthcare laws and policies may have a material adverse effect on our financial condition, results of operations and cash flows.

The ACA substantially changed the way health care is financed by both governmental and private insurers, and Congressional leaders and the President have voiced their intent to amend the ACA or to repeal and replace it with new legislation, the provisions of which are not yet known. Among the ACA's key changes, the ACA reduced payment rates under the Medicare Clinical Laboratory Fee Schedule and established an Independent Payment Advisory Board to reduce the per capita rate of growth in Medicare spending if spending exceeds a target growth rate. If retained, such provisions may negatively impact payment rates for our diagnostic tests. Furthermore, effective January 1, 2013, the ACA included a 2.3% excise tax on the sale of certain medical devices sold outside of the retail setting. Although a moratorium has been imposed on this excise tax for 2016 through 2019, the excise tax is scheduled to be restored in 2020.

PAMA significantly altered the payment methodology under the Clinical Laboratory Fee Schedule that determines Medicare coverage for laboratory tests. Under PAMA, clinical laboratories are required to report test payment data for each Medicare-covered clinical diagnostic laboratory test and beginning in 2017, the Medicare payment rate for each clinical diagnostic laboratory test will be equal to the weighted median amount for the test from the most recent data collection period.

Congress has proposed on several occasions to impose a 20% coinsurance payment requirement on patients for clinical laboratory tests reimbursed under the Medicare Clinical Laboratory Fee Schedule, which would require us to bill patients for these amounts. In the event that Congress were to ever enact such legislation, the cost of billing and collecting for our tests could often exceed the amount actually received from the patient.

Medicare payments for new ADLTs are now based on the list price or charge. After the test is commercially available for three quarters, the laboratory will be required to report payment and volume information and that data will be used to set payment for the test for the following year.

If data shows that the list price was greater than 130% of the payment using established methodology (a weighted median), CMS will recoup the difference from the laboratory through a payment claw back.

Payment will be updated annually based on the weighted median of commercial payer reimbursement.

On January 1, 2018 the new PAMA-based Medicare Clinical Laboratory Fee Schedule went into effect for the first time. PAMA-based prices did not impact all lab tests equally. Some tests had price reductions while others saw price increases.

We cannot predict whether future health care initiatives will be implemented at the federal or state level, or how any future legislation or regulation may affect us. The expansion of government's role in the U.S. health care industry as a result of the ACA or the repeal or amendment of the ACA, and changes to the reimbursement amounts paid by Medicare and other payers for diagnostic tests may have a materially adverse effect on our business, financial condition, results of operations and cash flows.

Because of certain Medicare billing policies, we may not receive complete reimbursement for tests provided to Medicare patients.

Medicare has coverage policies that can be national or regional in scope. Coverage means that the test or assay is approved as a benefit for Medicare beneficiaries. If there is no coverage, neither the supplier nor any other party, such as a diagnostic laboratory, may receive reimbursement from Medicare for the service. Regional policies are directed by Medicare's regional MACs. Reimbursement for our diagnostic testing may be negatively impacted by California MAC policies.

Long payment cycles of Medicare, Medicaid and other third-party payers, or other payment delays, could hurt our cash flows and increase our need for working capital.

Medicare and Medicaid have complex billing and documentation requirements that we will have to satisfy in order to receive payment. Failure to comply with these requirements and other laws applicable to billing may result in, among other things, non-payment, refunds, exclusion from government healthcare programs, and civil or criminal liabilities, any of which may have a material adverse effect on our revenues and earnings. Similarly, the failure of private health insurers or other private third-party payers to properly process our payment claims in a timely manner could delay our receipt of payment for our diagnostic tests and services, which may have a material adverse effect on our cash flows.

Private health insurance company policies may deny coverage or limit the amount they will reimburse us for the performance of our diagnostic tests.

Patients who are not covered by Medicare will generally rely on health insurance provided by private health insurance companies. If we are considered a “non-contracted provider” by a third-party payer, that payer may not reimburse patients for diagnostic tests performed by us, or doctors within the payer’s network of covered physicians may not use our services to perform diagnostic tests for their patients. As a result, we may need to enter into contracts with health insurance companies or other private payers to provide diagnostic tests to their insured patients at specified rates of reimbursement which may be lower than the rates we might otherwise collect.

We will be required to comply with federal and state laws governing the privacy of health information, and any failure to comply with these laws could result in material criminal and civil penalties.

The HIPAA sets forth security regulations that establish administrative, physical and technical standards for maintaining the confidentiality, integrity and availability of Protected Health Information in electronic form. We also may be required to comply with state laws that are more stringent than HIPAA or that provide individuals with greater rights with respect to the privacy or security of, and access to, their health care records. The Health Information Technology for Economic and Clinical Health Act (“HITECH”) established certain health information security breach notification obligations that require covered entities to notify each individual whose “protected health information” is breached.

We may incur significant compliance costs related to HIPAA and HITECH privacy regulations and varying state privacy regulations and varying state privacy and security laws. Given the complexity of HIPAA and HITECH and their overlap with state privacy and security laws, and the fact that these laws are rapidly evolving and are subject to changing and potentially conflicting interpretation, our ability to comply with the HIPAA, HITECH and state privacy requirements is uncertain and the costs of compliance are significant. The costs of complying with any changes to the HIPAA, HITECH and state privacy restrictions may have a negative impact on our operations. Noncompliance could subject us to criminal penalties, civil sanctions and significant monetary penalties as well as reputational damage.

If we are successful in commercializing DetermaVu™ or other diagnostic tests, we will be obligated to comply with numerous additional federal and state statutes and regulations pertaining to our business, and be subject to government oversight and scrutiny for our compliance with such laws. Laboratory and health care regulatory compliance efforts are expensive and time-consuming, and failure to maintain compliance with applicable laws could result in enforcement action which could be detrimental to our business.

If we are successful in commercializing DetermaVu™ or other diagnostic tests, and particularly if payment becomes available from government or commercial payers for DetermaVu™ we will be subject to extensive and frequently changing federal and state laws governing various aspects of our business. We will be subject to ongoing compliance with laws addressing our laboratory licensure and certification at the federal and state level; advertising and promotion (including laws enforced by the Federal Trade Commission); and laws intended to prevent fraud, waste, and abuse in healthcare programs (including among others the Anti-Kickback Statute, False Claims Act, the Eliminating Kickbacks in Recovery Act (EKRA), the Stark Law, and applicable state law equivalents).

These laws and regulations are complex and are subject to interpretation by the courts and by government agencies. If one or more such agencies alleges that we may be in violation of any of these requirements, regardless of the outcome, it could damage our reputation and adversely affect important business relationships with third parties. Any action brought against us for violation of these or other laws or regulations, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. If our operations are found to be in violation of any of these laws and regulations, we may be subject to any applicable penalty associated with the violation, including civil and criminal penalties, damages and fines, and in some circumstances we could be required to refund payments received by us from payers, or even be excluded from participation in healthcare programs. Any of the foregoing consequences could seriously harm our business and our financial results.

We plan to adopt policies and procedures designed to comply with applicable laws and regulations. Developing a compliance infrastructure is costly and time-consuming, and even a well-designed and implemented compliance program cannot necessarily prevent all violations of relevant laws. We may be subject to enforcement action based on the actions or omissions of employees or contractors, including our anticipated sales force.

Risks Related to Intellectual Property

We rely on patents and trade secrets, and our financial success will depend, in part, on our ability to obtain commercially valuable patent claims, protect our intellectual property rights and operate without infringing upon the proprietary rights of others.

We rely primarily on patents and contractual obligations with employees and third parties to protect our proprietary rights. We have sought, and intend to continue to seek, appropriate patent protection for important and strategic components of our proprietary technologies by filing patent applications in the United States and certain foreign countries. We may also use license agreements both to access technologies developed by other companies and universities and to convey certain intellectual property rights to others. Our financial success will depend, in part, on our ability to obtain commercially valuable patent claims, protect our intellectual property rights and operate without infringing upon the proprietary rights of others.

With regard to our DetermaVu™, we exclusively license from Wistar two patent families with claims directed to compositions of matter and methods useful for detection of lung cancer using specific biomarkers or a panel of specific biomarkers. The first patent family has patent applications pending in the United States and certain foreign jurisdictions, including Australia, Canada, China, India, and Japan, where, if issued, such patents would expire in 2036. The second patent family has patent applications pending in the United States and certain foreign jurisdictions, including Australia, Canada, China, India, and Japan, where, if issued, such patents would expire in 2037. There is no assurance that patents pending will issue.

We may not be able to obtain patent protection for our diagnostic test if our pending U.S. patent applications are found to be directed to unpatentable subject matter.

The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. For example, recent cases have held that diagnostic methods merely reciting a correlation between a naturally occurring event and a diagnostic outcome associated with that event is not patentable subject matter. If our pending U.S. patent applications are found to be directed to unpatentable subject matter by the USPTO, or any patents issuing from our pending patent applications are invalidated based on these decisions, we may be unable to prevent competitors from using the biomarkers or other subject matter disclosed in the patent applications to develop similar diagnostic tests that would compete with our tests. Additionally, there have been recent proposals for additional changes to the patent laws of the United States and other countries that, if adopted, could impact our ability to enforce our proprietary technology. Depending on future actions by the U.S. Congress, U.S. courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

Changes to the patent laws in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our diagnostic test.

Our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity and is costly, time-consuming and inherently uncertain. Patent reform legislation in the United States and other countries, including the Leahy-Smith America Invents Act, or the Leahy-Smith Act, signed into law in September 2011, could increase those uncertainties and costs. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. In addition, the Leahy-Smith Act has transformed the U.S. patent system into a “first to file” system. The first-to-file provisions, however, only became effective in March 2013. Accordingly, it is not yet clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could make it more difficult to obtain patent protection for our inventions and increase the uncertainties and costs surrounding the prosecution of our or our collaboration partners’ patent applications and the enforcement or defense of our or our collaboration partners’ issued patents, all of which could harm our business, results of operations and financial condition.

Other companies or organizations may challenge our patent rights or may assert patent rights that prevent us from developing and commercializing our diagnostic test.

Any patent applications that we file and any patents that we hold or later obtain could be challenged by third parties and declared invalid or infringing of third party claims. A patent interference proceeding may be instituted with the USPTO when more than one person files a patent application covering the same technology, or if someone wishes to challenge the validity of an issued patent filed before March 16, 2013. At the completion of the interference proceeding, the USPTO will determine which competing applicant is entitled to the patent, or whether an issued patent is valid. Patent interference proceedings are complex, highly contested legal proceedings, and the USPTO's decision is subject to appeal. This means that if an interference proceeding arises with respect to any of our patent applications, we may experience significant expenses and delay in obtaining a patent, and if the outcome of the proceeding is unfavorable to us, the patent could be issued to a competitor rather than to us. In addition to interference proceedings, the USPTO can reexamine issued patents at the request of a third party seeking to have the patent invalidated. An *inter partes* review proceeding allows third parties to challenge the validity of an issued patent where there is a reasonable likelihood of invalidity. This means that patents owned or licensed by us may be subject to re-examination and may be lost if the outcome of the re-examination is unfavorable to us.

Post Grant Review under the Leahy-Smith Act makes available opposition-like proceedings in the United States. As with the USPTO interference proceedings, Post Grant Review proceedings will be very expensive to contest and can result in significant delays in obtaining patent protection or can result in a denial of a patent application. Further, a derivation proceeding may be instituted by the USPTO or an inventor alleging that a patent or application was derived from the work of another inventor.

Oppositions to the issuance of patents may be filed under European patent law and the patent laws of certain other countries. As with the USPTO interference proceedings, these foreign proceedings can be very expensive to contest and can result in significant delays in obtaining a patent or can result in a denial of a patent application.

The enforcement of patent rights often requires litigation against third party infringers, and such litigation can be costly to pursue. Even if we succeed in having new patents issued or in defending any challenge to issued patents, our patents may not be comprehensive enough to provide us with meaningful patent protection against our competitors.

If we are unable to protect the confidentiality of our trade secrets, the value of our technology could be materially adversely affected and our business would be harmed.

In addition to patents, we rely on trade secrets, know-how, and continuing technological advancement to maintain our competitive position. The molecular diagnostics that we are developing use gene expression classifiers or algorithms, which are mathematical models that weight the biomarkers to produce a score. We will treat the mathematical models as trade secrets. We have entered into intellectual property, invention, and non-disclosure agreements with our employees, and it is our practice to enter into confidentiality agreements with our consultants. These measures, however, may not prevent the unauthorized disclosure or use of our trade secrets and know-how, or that others may not independently develop similar trade secrets and know-how or obtain access to our trade secrets, know-how, or proprietary technology.

We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe our patents, trademarks, copyrights or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming and divert the time and attention of our management and scientific personnel. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents, in addition to counterclaims asserting that our patents are invalid or unenforceable, or both. In any patent infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. Even if the validity of such patents is upheld, the court may construe the patent’s claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover the invention. An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert our patents against those parties or other competitors, and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Any of these occurrences could adversely affect our competitive business position, business prospects and financial condition. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question, in which case, we could ultimately be forced to cease use of such trademarks.

Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, some of our confidential information could be compromised by disclosure during litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of shares of our common stock. Moreover, we may not have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings.

We may not be able to enforce our intellectual property rights throughout the world.

Filing, prosecuting and defending patents, if issued, on our diagnostic test candidate in all countries throughout the world would be prohibitively expensive. The requirements for patentability may differ in certain countries, particularly in developing countries. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we may obtain patent protection, but where patent enforcement is not as strong as that in the United States. These products may compete with our diagnostic test in jurisdictions where we do not have any issued or licensed patents or where any future patent claims or other intellectual property rights may not be effective or sufficient to prevent them from competing with us.

Moreover, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws. Additionally, laws of some countries outside of the United States and Europe do not afford intellectual property protection to the same extent as the laws of the United States and Europe. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries, including India, China and certain developing countries, do not favor the enforcement of patents and other intellectual property rights. This could make it difficult for us to stop the infringement of our patents or the misappropriation of our other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. Consequently, we may not be able to prevent third parties from practicing our inventions in certain countries outside the United States and Europe. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, if our ability to enforce our patents to stop infringing activities is inadequate. These products may compete with our diagnostic test, and our patents, if issued, or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and resources from other aspects of our business. Furthermore, while we intend to protect our intellectual property rights in major markets for our diagnostic test, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our diagnostic test. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate.

If we are sued for infringing intellectual property rights of third parties, such litigation could be costly and time consuming and could prevent or delay us from developing or commercializing our diagnostic test.

There is a substantial amount of intellectual property litigation in the biotechnology and pharmaceutical industries, and we may become party to, or threatened with, litigation or other adversarial proceedings regarding intellectual property rights with respect to our current or future diagnostic test, including interference proceedings before the USPTO, misappropriation claims, or other allegations. The outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance. For example, the biotechnology and pharmaceutical industries have produced a significant number of patents, and it may not always be clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we were sued for patent infringement, we would need to demonstrate that our diagnostic test or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable, and we may not be able to do this. Proving invalidity is difficult. For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents.

In addition, several of our employees have executed proprietary rights, non-disclosure and non-competition agreements, or similar agreements with their previous employers, who may allege these employees have used or disclosed intellectual property, including trade secrets or other proprietary information. Even if we are successful in these proceedings, we may incur substantial costs, and the time and attention of our management and scientific personnel could be diverted in pursuing these proceedings, which could significantly harm our business and operating results. We may also not have sufficient resources to bring these actions to a successful conclusion.

If we are found to infringe a third party’s intellectual property rights, we may have to pay monetary damages, lose valuable intellectual property rights or personnel, or be forced to cease developing, manufacturing or commercializing the infringing diagnostic test. Alternatively, we may be required to obtain a license from such third party in order to use the infringing technology and continue developing, manufacturing or marketing the infringing diagnostic test. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In addition, we could be found liable for monetary damages, including treble damages and attorneys’ fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our diagnostic test or force us to cease some of our business operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could

have a similar negative impact on our business.

Patent terms may be inadequate to protect our competitive position on our diagnostic test for an adequate amount of time.

Given the amount of time required for the development, testing and regulatory review of new diagnostic tests, patents protecting such candidates might expire before or shortly after such candidates are commercialized. We expect to seek extensions of patent terms in the United States and, if available, in other countries where we are prosecuting patents. In the United States, the Drug Price Competition and Patent Term Restoration Act of 1984 permits a patent term extension of up to five years beyond the normal expiration of the patent, which is limited to the approved indication or any additional indications approved during the period of extension. However, the applicable authorities, including the FDA and the USPTO in the United States, and any equivalent regulatory authorities in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. If this occurs, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case.

Risks Related to Our Relationship with BioTime

Until recently we were a subsidiary of BioTime, and BioTime retains a substantial stock ownership position that may allow it to assert significant influence over us.

BioTime is our largest shareholder, owns approximately 28% of our issued and outstanding shares of common stock. Its high level of ownership allows it to exert significant influence on our affairs, including with respect to the election of the members of our Board of Directors and other matters requiring shareholder approval. Two of the seven members of our Board of Directors are also directors of BioTime, and one of our directors is a former executive officer and director of BioTime. This commonality of directors means that representatives of BioTime, in part, oversee our management and participate in making business decisions on our behalf.

BioTime's voting power may allow BioTime to influence our corporate actions even if the interests of BioTime conflict with the interests of our other shareholders. This concentration of voting power could have the effect of deterring or preventing a change in control that might be beneficial to our other shareholders.

With the support of a relatively small number of other shareholders that own a substantial amount of our common stock BioTime could have the voting power to approve or disapprove any matter or corporate transaction presented to our shareholders for approval, including but not limited to:

- Any amendment of our articles of incorporation or bylaws;
- Any merger or consolidation of us with another company;
- Any recapitalization or reorganization of our capital stock;
- Any sale of assets or purchase of assets; or
- A corporate dissolution or a plan of liquidation of our business.

You may not agree with the way BioTime, or any other shareholders aligned with BioTime, vote on any of matters we submit for shareholder approval.

We presently rely on BioTime for certain services and resources.

Although we have our own CLIA certified diagnostic laboratory, our own scientific personnel, and critical management personnel, we presently rely on BioTime to provide certain management and administrative services, including patent prosecution, certain legal services, accounting, financial management, and controls over financial accounting and reporting. We have entered into the Shared Facilities Agreement with BioTime under which we have agreed to bear costs allocated to us by BioTime for the use of BioTime office and research facilities, human resources, services, and materials provided for our benefit by BioTime. We will pay BioTime 105% of its costs of providing personnel and services to us, and for any use of its facilities by us, including an allocation of general overhead based on that use. We may also share the services of some research personnel with BioTime.

If BioTime's human resources and facilities are not sufficient to serve both BioTime's needs and ours, we will have to hire additional personnel of our own, either on a full-time or part-time basis, as employees or as consultants, and the cost of doing so could be greater than the costs that would be allocated to us by BioTime. Also, any new personnel that we may need to hire may not be as familiar with our business or operations as BioTime's personnel, which means that we would incur the expense and inefficiencies related to training new employees or consultants.

Conflicts of interest may arise from our relationship with BioTime.

Our relationship with BioTime could give rise to certain conflicts of interest that could have an impact on our research and development programs, business opportunities, and operations generally.

Even if BioTime is not presently developing diagnostic tests, there is no assurance that it or its subsidiaries will not do so in the future. Even if we utilize different technologies than BioTime or its subsidiaries, we could find ourselves in competition with them for research scientists, financing and other resources, licensing, manufacturing, and distribution arrangements, and for customers if we and BioTime or a BioTime subsidiary both bring diagnostic tests to market.

BioTime may retain sufficient influence through its share ownership to deter us from engaging in research and development programs, investments, business ventures, or agreements to develop, license, or acquire diagnostic tests or technologies that would or might compete with those owned, licensed, or under development by BioTime or any of its other subsidiaries.

BioTime and its subsidiaries will engage for their own accounts in research and product development programs, investments, and business ventures, and we will not be entitled to participate or to receive an interest in those programs, investments, or business ventures. BioTime and its subsidiaries will not be obligated to present any particular research and development, investment, or business opportunity to us, even if the opportunity would be within the scope of our research and development plans or programs, business objectives, or investment policies. These opportunities may include, for example, opportunities to acquire businesses or assets, including but not limited to patents and other intellectual property that could be used by us or by BioTime or by any of BioTime's subsidiaries. Our respective boards of directors will have to determine whether their company should pursue those opportunities, taking into account relevant facts and circumstances at the time, such as the financial and other resources of their company to acquire and utilize the opportunity, and the extent to which the opportunity "fits" with the business and research and development programs of the company. However, to the extent that BioTime has sufficient voting power to elect the members of our Board of Directors, BioTime may have the ultimate say in decision making with respect to the pursuit of any opportunities that might be available to both OncoCyte and BioTime.

If we enter into any patent or technology license or sublicense, or any other agreement with BioTime or with a BioTime subsidiary, a conflict of interest could arise in determining how and when a party should enforce its rights under the agreement if the other BioTime company that is a party were to default or otherwise fail to perform any of its obligations under the agreement.

Each conflict of interest will be resolved by our respective boards of directors in keeping with their fiduciary duties and such policies as they may implement from time to time. However, the terms and conditions of agreements between us and BioTime or BioTime subsidiaries may not be negotiated on an arm's-length basis due to BioTime's ownership interest in us and due to the commonality of certain directors serving on our respective boards of directors.

Conflicts of interest with BioTime could arise from our ownership of BioTime common shares and BioTime's ownership of shares of our common stock.

One of our significant assets is 353,264 BioTime common shares that we acquired from BioTime in exchange for shares of our common stock. One of BioTime's significant assets is 14,674,244 shares of OncoCyte common stock that BioTime holds. We may sell BioTime shares to raise capital to finance our operations, and BioTime may sell its OncoCyte shares to raise capital to finance its operations. The sale of such shares by either party could have a depressing effect on the market value of the other party's common stock and the prices at which the other party can sell its own shares of common stock to raise capital to support its operations. Similarly, if we or BioTime sell shares of our own respective common stock, such sales could have a depressing effect on the market value of the common stock and the prices at which the other party can sell shares it holds in the other party.

We may coordinate any future sales of our BioTime common shares with BioTime, and BioTime may coordinate any future sales of their shares of OncoCyte common stock with us, in order to provide an orderly and controlled process for raising capital through the sale of those shares. This may include an agreement as to the number of shares to be sold, the time period or "market window" for selling shares, the use of a common securities broker-dealer, and a fair allocation of net sales based on average sales prices during any trading day on which we and BioTime sell those shares. However, we and BioTime may be unable to reach agreement from time to time with respect to coordinated sales of shares.

Risks Related to Our Common Stock

Ownership of our common stock will entail certain risks associated with the limited history of the trading of our common stock, volatility of prices for our shares, and the fact that we do not pay dividends.

The price of our stock may rise and fall rapidly.

The market price of our common stock, like that of the shares of many biotechnology companies, may be highly volatile. The price of our common stock may rise or fall rapidly as a result of a number of factors, including:

Sales or potential sales of substantial amounts of our common stock;

Results of or delays in preclinical testing or clinical trials of our diagnostic test candidates;

Announcements about us or about our competitors, including clinical trial results, regulatory approvals, new diagnostic test introductions and commercial results;

The cost of our development programs;

The success of competitive diagnostic tests or technologies;

Litigation and other developments relating to our issued patents or patent applications or other proprietary rights or those of our competitors;

Conditions in the diagnostic, pharmaceutical or biotechnology industries;

Actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;

Variations in our financial results or those of companies that are perceived to be similar to us, including the failure of our earnings to meet analysts' expectations;

General economic, industry and market conditions; and

Changes in payer coverage and or reimbursement.

Many of these factors are beyond our control. The stock markets in general, and the market for pharmaceutical and biotechnological companies in particular, have been experiencing extreme price and volume fluctuations which have affected the market price of the equity securities without regard to the operating performance of the issuing companies. Broad market fluctuations, as well as industry factors and general economic and political conditions, may adversely affect the market price of our common stock.

The implementation of a new FASB accounting standard could increase the risk that our future financial statements could be qualified by going concern uncertainty.

In August 2014, the FASB issued ASU No. 2014-15, "Presentation of Financial Statements-Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern." ASU No. 2014-15 defines management's responsibility to assess an entity's ability to continue as a going concern, and to provide related footnote disclosures. ASU No. 2014-15 is effective for us for the year ended December 31, 2016, and all annual and

interim periods thereafter. In connection with preparing financial statements for each annual and interim reporting period, ASU No. 2014-15 requires that an entity's management evaluate whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the entity's ability to continue as a going concern within one year after the date that the financial statements are issued (or within one year after the date that the financial statements are available to be issued when applicable). As a result of the implementation of ASU No. 2014-15, we will be required to have more cash, cash equivalents, and liquid investments on hand on the date we issue or file our financial statements than had been the case during prior years in order to avoid going a concern qualification in our auditor's report and in the footnotes to our financial statements. If our financial statements were to become subject to a going concern qualification or uncertainty or if we are unable to alleviate substantial doubt as part of our going concern assessment, or both, the market price of our common stock could decline.

Because we do not pay dividends, our stock may not be a suitable investment for anyone who needs to earn dividend income.

We do not pay cash dividends on our common stock. For the foreseeable future we anticipate that any earnings generated in our business will be used to finance the growth of our business and will not be paid out as dividends to our shareholders. Under a Loan and Security Agreement with Silicon Valley Bank, we have agreed not to pay dividends or to make any distributions or to redeem or repurchase any capital stock without Silicon Valley Bank's prior written consent while the Loan and Security Agreement remains in effect. This means that our stock may not be a suitable investment for anyone who needs to earn income from their investments.

Securities analysts may not initiate coverage or continue to cover our common stock, and this may have a negative impact on the market price of our shares.

The market for our common stock will depend, in part, on the research and reports that securities analysts publish about our business and our common stock. We do not have any control over these analysts. Certain securities analysts cover our shares and they could issue reports or recommendations that are unfavorable to the price of our shares, and they could downgrade a previously favorable report or recommendation, and in either case our share price could decline as a result of the report. If one or more of these analysts ceases to cover our shares or fails to publish regular reports on our business, we could lose visibility in the financial markets, which could cause our share price or trading volume to decline.

You may experience dilution of your ownership interests if we issue additional shares of common stock or preferred stock.

In the future, we may issue our authorized but previously unissued equity securities, resulting in the dilution of the ownership interests of our present shareholders. We are currently authorized to issue an aggregate of 90,000,000 shares of capital stock consisting of 85,000,000 shares of common stock and 5,000,000 "blank check" shares of preferred stock. At December 31, 2018, there were 40,664,496 shares of common stock outstanding, 4,035,339 shares of common stock reserved for exercise of warrants and 4,532,153 shares of common stock reserved for issuance upon the exercise of options under our employee stock option plans. No shares of preferred stock are presently outstanding.

We may issue additional common stock or other securities that are convertible into or exercisable for common stock in order to raise additional capital, or in connection with hiring or retaining employees, directors, or consultants, or in connection with future acquisitions of licenses to technology or diagnostic tests in connection with future business acquisitions, or for other business purposes. The future issuance of any such additional common stock or other securities may create downward pressure on the trading price of our common stock.

We may also issue preferred stock having rights, preferences, and privileges senior to the rights of our common stock with respect to dividends, rights to share in distributions of our assets if we liquidate our company, or voting rights. Any preferred stock may also be convertible into common stock on terms that would be dilutive to holders of common stock.

We are an "emerging growth company," and may elect to comply with reduced public company reporting requirements applicable to emerging growth companies, which could make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act, and we may to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies" including reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We may take advantage of these reporting exemptions until we are no longer an "emerging growth company." 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 fifth anniversary of the completion of the first sale of our common equity securities pursuant to an effective registration statement under 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 SEC.

Item 1B. Unresolved Staff Comments

None

Item 2. Properties

Under a Shared Facilities Agreement with BioTime, we have use of laboratory and office space at BioTime's facility in Alameda, California. BioTime has leased approximately 30,795 square feet of office and laboratory space in two buildings located in Alameda and will provide OncoCyte use of space sufficient for a CLIA compliant diagnostic laboratory.

Item 3. Legal Proceedings

From time to time, we may be involved in routine litigation incidental to the conduct of our business. We are not presently involved in any material litigation or proceedings.

Item 4. Mine Safety Disclosures

Not applicable

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters, and Issuer Purchases of Equity Securities

Market Information

Our common stock is traded on the NYSE American under the symbol "OCX". As of March 4, 2019, there were 51,972,830 shares of our common stock outstanding.

Holders

As of March 4, 2019, we had approximately 251 holders of record of our common stock. This number does not include shareholders whose shares of OncoCyte common stock are held in "street name" in accounts with securities broker-dealers or other financial institutions or fiduciaries.

Securities Authorized for Issuance under Equity Compensation Plans

The following table shows certain information concerning the options outstanding and available for issuance under all of our compensation plans and agreements as of December 31, 2018 (in thousands, except weighted average exercise price):

Plan Category	**Number of Shares to be Issued upon Exercise of Outstanding**	**Weighted Average Exercise Price of the Outstanding**	**Number of Shares Remaining Available for Future Issuance**

	Options, Warrants, and Rights[1]	Options, Warrants, and Rights[1]	under Equity Compensation Plans[2]
OncoCyte Stock Option Plans Approved by Shareholders	4,532	$ 2.87	4,639

(1) Includes both our Employee Stock Option Plan and 2018 Equity Incentive Plan.

(2) All shares remaining available for future issuance are under our 2018 Equity Incentive Plan.

Additional information concerning our Employee Stock Option Plan and our 2018 Equity Incentive Plan and stock options may be found in Note 7 to the Financial Statements.

Dividend Policy

We have never paid cash dividends on our capital stock and we do not anticipate paying cash dividends in the foreseeable future, but intend to retain our capital resources for reinvestment in our business. Under a Loan and Security Agreement with Silicon Valley Bank, we have agreed not to pay dividends or to make any distributions or to redeem or repurchase any capital stock without Silicon Valley Bank's prior written consent while the Loan and Security Agreement remains in effect. Any future determination to pay cash dividends will be at the discretion of our Board of Directors and will be dependent upon the repayment of the loans from Silicon Valley Bank, our financial condition, results of operations, capital requirements and other factors as our Board of Directors deems relevant.

Recent Sales of Unregistered Securities

None.

ITEM 6. SELECTED FINANCIAL DATA

We are a smaller reporting company as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended, or the Exchange Act. Accordingly, we are not required to provide the information required by this item in this Report.

ITEM 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following Management's Discussion and Analysis of Financial Condition and Results of Operations is intended to provide information necessary to understand our audited financial statements for the years ended December 31, 2018 and 2017, and highlight certain other information which, in the opinion of management, will enhance a reader's understanding of our financial condition, changes in financial condition and results of operations. These historical financial statements may not be indicative of our future performance. This Management's Discussion and Analysis of Financial Condition and Results of Operations contains a number of forward-looking statements, all of which are based on our current expectations and could be affected by the uncertainties and risks described throughout this filing, particularly in "Risk Factors."

Emerging Growth Company Status

The Jumpstart our Business Startups Act of 2012 ("JOBS Act") permits an "emerging growth company" such as OncoCyte to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies. However, we elected to comply with newly adopted or revised accounting standards when they become applicable to public companies because our financial statements were consolidated with those of BioTime, which is not an emerging growth company under the JOBS Act and is therefore not permitted to delay the adoption of new or revised accounting standards that become applicable to public companies. This election under the JOBS Act to not delay the adoption of new or revised accounting standards is irrevocable.

Management's Discussion and Analysis of Financial Condition and Results of Operations.

We were incorporated during September 2009. Our operations have included planning and launching research and diagnostic test development programs in house and with partners and pursuing patents.

The inherent uncertainties of developing new diagnostic tests for medical use make it impossible to predict the amount of time and expense that will be required to complete the development and commence commercialization of new diagnostic tests. There is no assurance that we will be successful in developing new technology or diagnostic tests, or that any technology or diagnostic tests that we may develop will be proven safe and effective in diagnosis of cancer in humans, or will be successfully commercialized.

We believe we have sufficient cash, cash equivalents, and marketable equity securities to carry out our current operations through at least twelve months from the issuance date of our financial statements included elsewhere in this

Report. We expect that our operating expenses will increase if we successfully complete the development of DetermaVu™ and begin to build a sales and marketing team, begin to expand the capacity of our CLIA lab to perform a larger volume of blood tests, and begin to explore or commence the development of additional diagnostic tests. Because of the expected time frame to apply for and receive Medicare reimbursement approval for DetermaVu™, our pre-Medicare approval revenues from commercialization of DetermaVu™ are not expected to cover our operating expenses. We will need to obtain additional financing for our operations until such time as we generate sufficient revenues from the commercialization of our diagnostic tests to cover our operating expenses. Our determination as to when we will seek new financing and the amount of financing that we will need will be based on our evaluation of the progress we make in our research and development programs, any changes to or the expansion of the scope and focus of our research, progress and results of commercializing our diagnostic tests after completion of development, progress in receiving Medicare reimbursement approval, and our projection of future costs. See “Liquidity and Capital Resources” for a discussion of our available capital resources, our need for future financing, and possible sources of capital.

Critical Accounting Policies

The preparation of financial statements in conformity with accounting principles generally accepted in the United States (“GAAP”), requires management to make estimates and assumptions that affect the reported amounts in our financial statements and related notes. Our significant accounting policies are described in Note 2 to our financial statements included elsewhere in this Report. We have identified below our critical accounting policies and estimates that we believe require the greatest amount of judgment. On an ongoing basis, we evaluate estimates which are subject to significant judgment, including those related to the going concern assessments of our financial statements, allocation of direct and indirect expenses, useful lives associated with long-lived intangible assets, machinery and equipment, loss contingencies, valuation allowances related to deferred income taxes, and assumptions used to value stock-based awards, debt or other equity instruments. Actual results could differ materially from those estimates. On an ongoing basis, we evaluate our estimates compared to historical experience and trends, which form the basis for making judgments about the carrying value of assets and liabilities. To the extent that there are material differences between our estimates and our actual results, our future financial statement presentation, financial condition, results of operations and cash flows will be affected.

We believe the assumptions and estimates associated with the following have the greatest potential impact on our financial statements.

Going concern assessment

With the implementation of FASB's standard on going concern, ASU No. 2014-15, we assess going concern uncertainty in our financial statements to determine if we have sufficient cash and cash equivalents on hand and working capital, including available loans or lines of credit, if any, to operate for a period of at least one year from the date our financial statements are issued, which is referred to as the "look-forward period" as defined by ASU No. 2014-15. As part of this assessment, based on conditions that are known and reasonably knowable to us, we consider various scenarios, forecasts, projections, and estimates, and we make certain key assumptions, including the timing and nature of projected cash expenditures or programs, and our ability to delay or curtail those expenditures or programs, if necessary, among other factors. Based on this assessment, as necessary or applicable, we make certain assumptions around implementing curtailments or delays in the nature and timing of programs and expenditures to the extent we deem probable those implementations can be achieved and we have the proper authority to execute them within the look-forward period in accordance with ASU No. 2014-15.

Related party transactions - Shared Facilities and Services Agreement

As more fully described in Note 4 to our financial statements, to the extent we do not employ our own human resources for operations, BioTime, or BioTime subsidiaries provide certain employees for administrative or operational services, as necessary, for our benefit, under the Shared Facilities Agreement. Accordingly, BioTime allocates expenses such as personnel costs and related benefits incurred and paid on behalf of OncoCyte based on the amount of time that particular employees devote to our affairs. Other expenses such as legal, accounting, marketing, travel, and entertainment expenses are allocated to us to the extent that those expenses are incurred by or on behalf of OncoCyte. BioTime also allocates certain overhead expenses such as facilities, utilities, leasing, property taxes, internet and telephone expenses based on a percentage determined by management. These allocations are made based upon activity-based allocation drivers such as time spent, percentage of square feet of office or laboratory space used, and percentage of personnel devoted to our operations or management. Management evaluates the appropriateness of the percentage allocations on a periodic basis and believes that this basis for allocation is reasonable.

Accounting for warrants

We determine the accounting classification of warrants we issue, as either liability or equity classified, by first assessing whether the warrants meet liability classification in accordance with ASC 480-10, *Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity*, then in accordance with ASC 815-40, *Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock*. Under ASC 480, warrants are considered liability classified if the warrants are mandatorily redeemable, obligate us to settle the warrants or the underlying shares by paying cash or other assets, and warrants that must or may require settlement by issuing variable number of shares. If warrants do not meet the liability classification under ASC 480-10, we assess the requirements under ASC 815-40, which states that contracts that require or may require the issuer to

settle the contract for cash are liabilities recorded at fair value, irrespective of the likelihood of the transaction occurring that triggers the net cash settlement feature. If the warrants do not require liability classification under ASC 815-40, in order to conclude equity classification, we also assess whether the warrants are indexed to our common stock and whether the warrants are classified as equity under ASC 815-40 or other GAAP. After all such assessments, we conclude whether the warrants are classified as liability or equity. Liability classified warrants require fair value accounting at issuance and subsequent to initial issuance with all changes in fair value after the issuance date recorded in the statements of operations. Equity classified warrants only require fair value accounting at issuance with no changes recognized subsequent to the issuance date. We do not have any liability classified warrants as of any period presented. See Note 6 to our financial statements included elsewhere in this Report.

Stock-based compensation

We recognize compensation expense related to share-based payments in accordance with ASC 718, *Compensation - Stock Compensation* ("ASC 718"), which requires the measurement and recognition of compensation expense for share-based payment awards made to directors and employees based on estimated fair values. We estimate the fair value of employee stock-based payment awards on the grant-date and recognize the resulting fair value over the requisite service period on a straight-line basis. For stock-based awards that vest only upon the attainment of one or more performance goals, compensation cost is recognized if and when we determine that it is probable that the performance condition or conditions will be, or have been, achieved. We utilize the Black-Scholes option pricing model for determining the fair value of stock options. Our determination of fair value of share-based payment awards on the date of grant using an option-pricing model is affected by our stock price as well as assumptions regarding a number of complex and subjective variables. These variables include, but are not limited to, expected stock price volatility over the term of the awards, and actual and projected employee stock option exercise behaviors. For the years ended December 31, 2018 and 2017, we estimated the expected volatility using our own stock price volatility to the extent applicable or a combination of our stock price volatility and the stock price volatility of stock of peer companies, for a period equal to the expected term of the options. The expected term of options granted is based on our own experience and, in part, based upon the "simplified method" provided under *Staff Accounting Bulletin, Topic 14*, or SAB Topic 14, as necessary. The risk-free rate is based on the U.S. Treasury rates in effect during the corresponding period of grant. Although the fair value of employee stock options is determined in accordance with FASB guidance, the key inputs and assumptions may change as we develop our own company estimates, experience and key inputs including our expected term, and stock price volatility based on the trading history of our stock on the NYSE American. Changes in these subjective assumptions can materially affect the estimated value of equity grants and the stock-based compensation that we record in our financial statements.

Accounting for BioTime Shares

We account for the BioTime shares we hold as marketable equity securities in accordance with ASC 320-10-25, *Investments – Debt and Equity Securities*, as amended by Accounting Standards Update ("ASU") 2016-01, *Financial Instruments–Overall: Recognition and Measurement of Financial Assets and Financial Liabilities*, as the shares have a readily determinable fair value quoted on the NYSE American and are held principally to meet future working capital purposes, as necessary. The securities are measured at fair value and reported as current assets on the balance sheet based on the closing trading price of the security as of the date being presented.

Beginning on January 1, 2018, with the adoption of ASU 2016-01 discussed below, these securities are now called "marketable equity securities" and unrealized holding gains and losses on these securities are reported in the statements of operations in other income and expenses, net. Prior to January 1, 2018 and the adoption of ASU 2016-01, these securities were called "available-for-sale securities" and unrealized holding gains and losses were reported in other comprehensive income or loss, net of tax, and were a component of the accumulated other comprehensive income or loss on the balance sheet. Realized gains and losses are included in other income and expenses, net, in the statements of operations.

On January 1, 2018, in accordance with the adoption of ASU 2016-01, we recorded a cumulative-effect adjustment for these available-for-sale-securities to reclassify the unrealized loss of $888,000 included in accumulated other comprehensive loss to the accumulated deficit balance.

Long-lived intangible assets

Long-lived intangible assets, primarily consisting of acquired patents, patent applications, and licenses to use certain patents are stated at acquired cost, less accumulated amortization. Amortization expense is computed using the straight-line method over the estimated useful lives of the assets over a period of 10 years.

Impairment of long-lived assets

We assess the impairment of long-lived assets, which consists primarily of long-lived intangible assets, machinery and equipment, whenever events or changes in circumstances indicate that such assets might be impaired and the carrying value may not be recoverable. If events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable and the expected undiscounted future cash flows attributable to the asset are less than the carrying amount of the asset, an impairment loss equal to the excess of the asset's carrying value over its fair value is recorded.

As part of our impairment assessment of our intangible assets, we determined that certain intangible assets, mainly comprised of patents and patent rights for therapeutic uses that we no longer plan to develop or commercialize, were impaired and, accordingly, we recorded a noncash charge of $625,000 representing the net book value of those assets as of that date, and included that charge in research and development expenses for the year ended December 31, 2018.

Income taxes

We have filed a standalone U.S. federal income tax return since our inception. For California purposes, our activity for the period from January 1, 2017 through February 16, 2017, the date immediately before BioTime owned less than 50% of our outstanding common stock, has been included in BioTime's California combined tax return. For periods beginning February 17, 2017 and thereafter, we have or will file a standalone California income tax return. The provision for state income taxes has been determined as if we had filed separate tax returns for the periods presented. Accordingly, our effective tax rate in future years could vary from our historical effective tax rates depending on our future legal structure and related tax elections. The historical deferred tax assets, including the operating losses and credit carryforwards generated by us, will remain with us. We account for income taxes in accordance with ASC 740, *Income Taxes*, which prescribes the use of the asset and liability method, whereby deferred tax asset or liability account balances are calculated at the balance sheet date using current tax laws and rates in effect. Valuation allowances are established when necessary to reduce deferred tax assets when it is more likely than not that a portion or all of the deferred tax assets will not be realized. Our judgments regarding future taxable income may change over time due to changes in market conditions, changes in tax laws, tax planning strategies or other factors. If our assumptions and consequently our estimates change in the future, the valuation allowance may be increased or decreased, which may have a material impact on our statements of operations.

The guidance also prescribes a recognition threshold and a measurement attribute for the financial statement recognition and measurement of tax positions taken or expected to be taken in a tax return. For those benefits to be recognized, a tax position must be more-likely-than-not sustainable upon examination by taxing authorities. We will recognize accrued interest and penalties, if any, related to unrecognized tax benefits as income tax expense. No amounts were accrued for the payment of interest and penalties as of the financial statements periods presented herein. We are not aware of any uncertain tax positions that could result in significant additional payments, accruals, or other material deviation for the periods presented herein. We are currently unaware of any tax issues under review.

On December 22, 2017, the United States enacted major federal tax reform legislation, Public Law No. 115-97, commonly referred to as the 2017 Tax Cuts and Jobs Act ("2017 Tax Act"), which enacted a broad range of changes to the Internal Revenue Code. Changes to taxes on corporations impacted by the 2017 Tax Act include, among others, lowering the U.S. federal tax rates to a 21 percent flat tax rate, eliminating the corporate alternative minimum tax ("AMT"), imposing additional limitations on the deductibility of interest and net operating losses, allowing any net operating loss ("NOLs") generated in tax years ending after December 31, 2017 to be carried forward indefinitely and generally repealing carrybacks, reducing the maximum deduction for NOL carryforwards arising in tax years beginning after 2017 to a percentage of the taxpayer's taxable income, and allowing for the expensing of certain capital expenditures. The 2017 Tax Act also puts into effect a number of changes impacting operations outside of the United States including, but not limited to, the imposition of a one-time tax "deemed repatriation" on accumulated offshore earnings not previously subject to U.S. tax, and shifts the U.S taxation of multinational corporations from a worldwide system of taxation to a territorial system. ASC 740 requires the effects of changes in tax rates and laws on deferred tax balances (including the effects of the one-time transition tax) to be recognized in the period in which the legislation is enacted (see Note 8 to our financial statements included elsewhere in this Report).

Research and development expenses

Research and development expenses include both direct expenses incurred by OncoCyte and indirect overhead costs allocated to us by BioTime that benefit or support our research and development functions of OncoCyte. Direct research and development expenses consist primarily of personnel costs and related benefits, including stock-based compensation, outside consultants and suppliers. Indirect research and development expenses allocated to us by BioTime under the Shared Facilities Agreement (see Note 4 to our financial statements included elsewhere in this Report), are primarily based on our headcount or space occupied, as applicable, and include laboratory supplies, laboratory expenses, rent and utilities, common area maintenance, telecommunications, property taxes and insurance. Research and development costs are expensed as incurred.

General and administrative expenses

General and administrative expenses include both direct expenses incurred by OncoCyte and indirect overhead costs allocated to us by BioTime that benefit or support our general and administrative functions. Direct general and

administrative expenses consist primarily of compensation and related benefits, including stock-based compensation, for executive and corporate personnel, and professional and consulting fees. Indirect general and administrative expenses allocated to us by BioTime under the Shared Facilities Agreement (see Note 4 to our financial statements included elsewhere in this Report) are primarily based on our headcount or space occupied, as applicable, and include costs for financial reporting and compliance, rent and utilities, common area maintenance, telecommunications, property taxes and insurance.

Sales and marketing expenses

Sales and marketing expenses consist primarily of personnel costs and related benefits, including stock-based compensation, and expenses incurred for trade shows and booths, branding and positioning, and outside consultants. Indirect sales and marketing expenses allocated by BioTime, primarily based on our headcount or space occupied, as applicable, include costs for rent and utilities, common area maintenance, telecommunications, property taxes and insurance, incurred by BioTime and allocated to us under the Shared Facilities Agreement.

Results of Operations

Comparison of the Years Ended December 31, 2018 and 2017

The following tables show our operating expenses for the years ended December 31, 2018 and 2017 (in thousands).

	Year Ended December 31,			
	2018	2017	$ Decrease	% Decrease
Research and development expenses	$6,514	$7,174	$ (660)	(9.2)%
General and administrative expenses	7,007	9,232	(2,225)	(24.1)%
Sales and marketing expenses	1,681	2,443	(762)	(31.2)%

Research and development expenses

Research and development expenses for the year ended December 31, 2018 decreased to $6.5 million from $7.2 million during 2017, a decrease of $0.7 million. This decrease in research and development expenses is primarily attributable to a $0.6 million decrease in noncash stock-based compensation expense, a $0.5 million decrease in laboratory expenses related to diagnostic tests for diseases other than lung cancer as we devoted substantially all of our research and development efforts to DetermaVu™ during 2018, and a $0.2 million decrease in personnel and related costs. The reduction in stock-based compensation expense was attributable to the decrease in the cost attributable to outstanding consultant stock options, which require mark-to-market adjustment each quarter for unvested shares, reflecting a lower market price of OncoCyte common stock during the period. These decreases were offset, in part, by a $0.5 million increase in amortization expense of intangible assets due to the noncash impairment charge recorded during the year ended December 31, 2018 related to intangible assets mainly comprised of patents and patent rights for therapeutic uses that that we no longer plan to develop or commercialize and, a $0.2 million increase in outside and consulting services related to our development of DetermaVu™.

We expect to continue to incur a significant amount of research and development expenses during the foreseeable future.

General and administrative expenses

General and administrative expenses for the year ended December 31, 2018 decreased to $7.0 million from $9.2 million during 2017, a decrease of $2.2 million. During the year ended December 31, 2017, we incurred a noncash expense of $4.1 million for the issuance of new warrants to certain investors who exercised outstanding warrants. We did not incur a similar expense during 2018, but personnel and related compensation expenses increased by $1.1 million, primarily related to the hiring of our Chief Financial Officer and our Chief Operating Officer, an increase of $0.5 million in legal, investor relations, financing and other related expenses, and we incurred an increase of $0.3 million in noncash stock-based compensation expense due to increased stock option grants, including stock options granted in connection with the hiring of the two executives noted above.

Sales and marketing expenses

Sales and marketing expenses for the year ended December 31, 2018 decreased to $1.7 million from $2.4 million during 2017. This $0.7 million decrease was primarily attributable to a $0.9 million decrease in consulting, marketing and related expenses as we concentrated our resources on the development of DetermaVu™ rather than on marketing related activities. That $0.9 decrease in expenses was offset in part by an increase of $0.2 million in noncash stock-based compensation expense.

We expect that our sales and marketing expenses will continue to increase significantly as we build a sales force for the commercialization of any cancer diagnostic tests that we successfully develop. Our sales and marketing efforts, and the amount of related expenses that we will incur, in the near term will largely depend upon the outcome of our clinical validation study of DetermaVu™, and the amount of capital, if any, that we are able to raise to finance development and commercialization of that test. Our current cash resources will require us to limit our initial sales and marketing efforts unless and until we are able to raise additional capital. Our future expenditures on sales and marketing will also depend on the amount of revenue that those efforts are likely to generate. Because physicians are more likely to prescribe a test for their patients if the cost is covered by Medicare or health insurance, demand for our diagnostic tests and our expenditures on sales and marketing are likely to increase if our diagnostic tests qualify for reimbursement by Medicare and private health insurance companies.

Other income and expenses, net

Other income and expenses, net, is primarily comprised of interest expense, net, incurred from our capital lease obligations, loan payable to the Silicon Valley Bank, and unrealized and realized gains and losses on BioTime and AgeX Therapeutics, Inc. (“AgeX”) marketable equity securities we hold.

In 2017, we sold 266,442 shares of BioTime common stock for net proceeds of $934,000 and recognized a $309,000 loss from the sale of those shares included in other income and expenses, net. The proceeds were used to pay down amounts owed to BioTime and affiliates. We did not sell any shares of BioTime common stock during the year ended December 31, 2018.

Income taxes

As of December 31, 2018, we have net operating loss carryforwards of approximately $59.0 million for U.S. federal income tax purposes and $28.0 million for state income tax purposes. Federal net operating losses generated on or prior to December 31, 2017, expire in varying amounts between 2030 and 2037, while federal net operating losses generated after December 31, 2017, carryforward indefinitely. The state net operating losses expire in varying amounts between 2029 and 2037. We also have capital loss carryforwards for federal and state income tax purposes of $1.3 million each, which expire between 2020 and 2023.

As of December 31, 2018, we have research and development credit carryforwards for federal and state purposes of $1.2 million each. The federal credits will expire between 2030 and 2038, while the state credits have no expiration.

On November 28, 2018, BioTime distributed shares of AgeX common stock to its shareholders, including to OncoCyte, on a pro-rata basis as a dividend-in-kind. As part of the distribution of AgeX common stock, we received 35,326 shares of AgeX common stock, resulting in a taxable gain $0.1 million. We have sufficient current year losses from operations to offset the entire taxable gain, resulting in no income taxes due.

A valuation allowance is provided when it is more likely than not that some portion of the deferred tax assets will not be realized. We established a full valuation allowance for all periods presented due to the uncertainty of realizing future tax benefits from our net operating loss carryforwards and other deferred tax assets. Accordingly, due to losses incurred for all periods presented, we did not record any provision or benefit for income taxes.

Liquidity and Capital Resources

Since inception, we have financed our operations through the sale of our common stock and warrants, warrant exercises, a bank loan, and sales of BioTime common shares that we hold as marketable equity securities. BioTime also provided OncoCyte with the use of BioTime facilities and services under the Shared Facilities Agreement as described in Note 4 to the financial statements. We have incurred operating losses and negative cash flows since inception and had an accumulated deficit of $71.3 million at December 31, 2018. We expect to continue to incur operating losses and negative cash flows for the near future.

At December 31, 2018, we had $8.0 million of cash and cash equivalents and held shares of BioTime and AgeX common stock as marketable equity securities valued at $0.4 million. During February 2019 we raised an additional $37.4 million of net proceeds, after the payment of underwriting fees and estimated offering expenses, through a public offering and sale of 10,733,334 shares of our common stock. We believe that our current cash, cash equivalents and marketable equity securities is sufficient to carry out our current operations through at least twelve months from the issuance date of the financial statements included in this Report.

On February 21, 2017, OncoCyte entered into a Loan and Security Agreement (the “Loan Agreement”) with Silicon Valley Bank (the “Bank”) pursuant to which OncoCyte borrowed $2.0 million on March 23, 2017. Payments of interest only on the principal balance were due monthly from the draw date through October 31, 2017, and, beginning on November 1, 2017, monthly payments of principal of approximately $67,000 plus interest are due and payable. The outstanding principal balance of the loan bears interest at a stated floating annual interest rate equal to the greater of (i) three-quarters of one percent (0.75%) above the prime rate or (ii) four and one-quarter percent (4.25%). As of December 31, 2018, the latest published prime rate plus 0.75% was 6.25% per annum.

The outstanding principal amount plus accrued interest will be due and payable to the Bank at maturity on April 1, 2020. At maturity, OncoCyte will also pay the Bank an additional final payment fee of 5.8% of the original principal borrowed. OncoCyte accrued the $116,000 final payment fee included in the loan payable as a deferred financing cost on March 23, 2017.

OncoCyte may prepay in full the outstanding principal balance at any time, subject to a prepayment fee equal to 1.0% of the outstanding principal balance. Any amounts borrowed and repaid may not be reborrowed. As of December 31, 2018, no amounts are available to be borrowed under this Loan Agreement.

The outstanding principal amount of the loan, with interest accrued, the final payment fee, and the prepayment fee may become due and payable prior to the applicable maturity date if an “Event of Default” as defined in the Loan Agreement occurs and is not cured within any applicable cure period. Upon the occurrence and during the continuance of an Event of Default, all obligations due to the Bank will bear interest at a rate per annum which is 5% above the then applicable interest rate. An Event of Default includes, among other events, failure to pay interest and principal when due, material adverse changes, which include a material adverse change in OncoCyte’s business, operations, or condition (financial or otherwise), failure to provide the bank with timely financial statements and copies of filings with the SEC, as required, legal judgments or pending or threatened legal actions of $50,000 or more, insolvency, and delisting from the NYSE American. OncoCyte’s obligations under the Loan Agreement are collateralized by substantially all of its assets other than intellectual property such as patents and trade secrets that OncoCyte owns. Accordingly, if an Event of Default were to occur and not be cured, the Bank could foreclose on its security interest in the collateral. OncoCyte was in compliance with the Loan Agreement as of the filing date of this Report.

We presently plan to build our own integrated marketing and sales force and to add new equipment and personnel to our CLIA lab to commercialize DetermaVu™ after development is completed, which will result in an increase in our operating expenses. We will also incur additional operating expenses as we explore or commence the development of additional diagnostic tests after the development of DetermaVu™ is completed. We do not expect to generate significant revenues from marketing DetermaVu™ until we receive Medicare reimbursement approval for that diagnostic test. We may also explore a range of other commercialization options in order to reduce our capital needs and expenditures and the risks associated the timelines and uncertainty for attaining the Medicare reimbursement approvals that will be essential for the successful commercialization of DetermaVu™ and any other diagnostic tests that we may develop. Those alternative arrangements could include marketing arrangements with other diagnostic companies through which we might receive a royalty on sales, or through which we might form a joint venture to market DetermaVu™ and share in net revenue

We will need to continue to raise additional capital to finance our operations, including the development of our cancer diagnostic tests, until such time as we are able to complete development and commercialize one or more diagnostic tests and generate sufficient revenues to cover our operating expenses. Delays in the development of DetermaVu™ or other diagnostic tests could prevent us from raising sufficient additional capital to finance the completion of development and commercial launch of those tests. Even if we are successful in completing the development of DetermaVu™ or other diagnostic tests, investors may be reluctant to provide us with capital until our tests are approved for reimbursement by Medicare. The unavailability or inadequacy of financing or revenues to meet future capital needs could force us to modify, curtail, delay, or suspend some or all aspects of our planned operations. Sales of additional equity securities could result in the dilution of the interests of our shareholders. We cannot assure that adequate financing will be available on favorable terms, if at all.

Cash used in operations

During the years ended December 31, 2018 and 2017, our research and development expenses were $6.5 million and $7.2 million, our general and administrative expenses were $7.0 million and $9.2 million, and our sales and marketing expenses were $1.7 million and $2.4 million, respectively. Net loss for the years ended December 31, 2018 and 2017 amounted to $15.8 million and $19.4 million, respectively. Net cash used in operating activities during these periods amounted to $11.6 million and $13.4 million, respectively. The amount by which our net loss exceeded net cash used in our operating activities during 2018 is primarily due to the following noncash items: $1.5 million of stock-based compensation; a $0.6 million impairment charge recorded for our intangible assets; $0.6 million in depreciation and amortization expenses; and $0.4 million in unrealized loss on marketable equity securities. Changes in working capital were approximately $1.0 million as a source of cash.

Cash used in investing activities

During the year ended December 31, 2018, cash used for investing activities was insignificant.

Cash provided by financing activities

During the year ended December 31, 2018, cash provided by financing activities was $12.1 million. We received $9.9 million in net cash proceeds from the sale of 7,936,508 shares of our common stock in a private offering. We also received an additional $3.3 million in net proceeds from the sale of 1,256,118 shares of common stock and warrants in an offering registered under the Securities Act as disclosed in Note 6 to our financial statements included elsewhere in this Report. These cash inflows were offset by $1.2 million used to pay the loan payable and capital lease obligations.

Contractual obligations

As of December 31, 2018, our contractual obligations for the next five years and thereafter were as follows (in thousands):

	Principal Payments Due by Period				
	Total	**Less Than 1 Year**	1-3 Years	4-5 Years	**After 5 Years**
Contractual Obligations [1]					
Shared Facilities Agreement [2]	$2,101	2,101	-	-	-
Capital lease [3]	$620	420	200	-	-
Loan payable [4]	$1,229	843	386	-	-

(1) This table does not include payments to key employees that could arise if their employment is involuntary terminated or if their employment is terminated following a change in control of OncoCyte.

(2) Under the Shared Facilities Agreement, we reimburse BioTime for 105% of their cost of providing us with the use of a portion of their leased office and laboratory facility, use of laboratory and office equipment and supplies, utilities, and personnel. Salaries and related expenses for accounting services and office and laboratory use and building maintenance are allocated based on a fixed percentage evaluated by BioTime management and us on a periodic basis and adjusted based on the level of activity, if warranted. The amount shown in the table is for shared services incurred prior to December 31, 2016, and was paid off in February 2019. See Note 10 to our financial statements included elsewhere in this Report.

(3) Includes certain capital leases for lab equipment.

(4) Loan payable amounts include principal and interest.

Off-Balance Sheet Arrangements

As of December 31, 2018, we did not have any off-balance sheet arrangements, as defined in Item 303(a)(4)(ii) of SEC Regulation S-K.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

Under SEC rules and regulations, as a smaller reporting company, we are not required to provide the information required by this item.

Report of Independent Registered Public Accounting Firm

Stockholders and Board of Directors

OncoCyte Corporation

Alameda, California

Opinion on the Financial Statements

We have audited the accompanying balance sheets of OncoCyte Corporation (the "Company") as of December 31, 2018 and 2017, the related statements of operations, comprehensive loss, stockholders' equity, and cash flows for each of the two years in the period ended December 31, 2018, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2018**,** in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ OUM & CO. LLP

San Francisco, California

April 1, 2019

We have served as the Company's auditor since 2015.

Item 8. Financial Statements and Supplementary Data

ONCOCYTE CORPORATION

BALANCE SHEETS

(*In thousands*)

	December 31,	
	2018	2017
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$8,034	$7,600
Marketable equity securities	428	760
Prepaid expenses and other current assets	180	168
Total current assets	8,642	8,528
NONCURRENT ASSETS		
Intangible assets, net	-	746
Machinery and equipment, net	614	822
Deposits and other noncurrent assets	262	120
TOTAL ASSETS	$9,518	$10,216
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Amount due to BioTime and affiliates	$2,101	$2,099
Accounts payable	166	175
Accrued expenses and other current liabilities	2,109	1,042
Loan payable, current	800	800
Capital lease liability, current	385	338
Total current liabilities	5,561	4,454
NONCURRENT LIABILITIES		
Loan payable, net of deferred financing costs, noncurrent	347	1,070
Capital lease liability, noncurrent	187	289
TOTAL LIABILITIES	6,095	5,813
Commitments and contingencies (Note 9)		
STOCKHOLDERS' EQUITY		
Preferred stock, no par value, 5,000 shares authorized; none issued and outstanding	-	-
Common stock, no par value, 85,000 shares authorized; 40,664 and 31,452 shares issued and outstanding at December 31, 2018 and 2017, respectively	74,742	59,968
Accumulated other comprehensive loss	-	(888)

Accumulated deficit	(71,319)	(54,677)
Total stockholders' equity	3,423	4,403
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$9,518	$10,216

The accompanying notes are an integral part of these financial statements.

ONCOCYTE CORPORATION

STATEMENTS OF OPERATIONS

(In thousands, except per share data)

	Year Ended December 31,	
	2018	2017
OPERATING EXPENSES		
Research and development	$6,514	$7,174
General and administrative	7,007	9,232
Sales and marketing	1,681	2,443
Total operating expenses	15,202	18,849
Loss from operations	(15,202)	(18,849)
OTHER EXPENSES, NET		
Interest expense, net	(216)	(217)
Unrealized loss on marketable equity securities	(427)	-
Other income (expense), net	91	(309)
Total other expenses, net	(552)	(526)
NET LOSS	$(15,754)	$(19,375)
Basic and diluted net loss per share	$(0.42)	$(0.64)
Weighted average shares outstanding: basic and diluted	37,850	30,195

The accompanying notes are an integral part of these financial statements.

ONCOCYTE CORPORATION

STATEMENTS OF COMPREHENSIVE LOSS

(In thousands)

	Year Ended December 31,	
	2018	2017
NET LOSS	$(15,754)	$(19,375)
Other comprehensive loss, net of tax:		
Realized loss on sale of available-for-sale securities	-	293
Unrealized loss on available-for-sale securities	-	(527)
COMPREHENSIVE LOSS	$(15,754)	$(19,609)

The accompanying notes are an integral part of these financial statements.

ONCOCYTE CORPORATION

STATEMENTS OF STOCKHOLDERS' EQUITY

(In thousands)

	Common Stock		Accumulated Other Comprehensive	Accumulated	Total Shareholders'
	Shares	**Amount**	Loss	Deficit	**Equity**
BALANCE AT DECEMBER 31, 2016	28,737	$45,818	$(654)	$(35,302)	$9,862
Net loss	-	-	-	(19,375)	(19,375)
Unrealized loss on BioTime shares held as available-for-sale securities	-	-	(527)	-	(527)
Stock-based compensation	-	1,630	-	-	1,630
Issuance of common stock upon exercise of 2016 warrants	2,392	7,774	-	-	7,774
Exercise of stock options	323	610	-	-	610
Issuance of warrants for inducement to exercise 2016 warrants	-	4,074	-	-	4,074
Issuance of warrants to Silicon Valley Bank	-	62	-	-	62
Transfer of realized loss on sale of BioTime shares	-	-	293	-	293
BALANCE AT DECEMBER 31, 2017	31,452	59,968	(888)	(54,677)	4,403
Net loss	-	-	-	(15,754)	(15,754)
Cumulative-effect adjustment for adoption of ASU 2016-01 on January 1, 2018	-	-	888	(888)	-
Stock-based compensation	-	1,479	-	-	1,479
Sale of common shares and warrants	9,192	13,592	-	-	13,592
Financing costs paid to issue common shares and warrants	-	(355)	-	-	(355)
Exercise of stock options	20	58	-	-	58
BALANCE AT DECEMBER 31, 2018	40,664	$74,742	$-	$(71,319)	$3,423

The accompanying notes are an integral part of these financial statements.

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ONCOCYTE CORPORATION

STATEMENTS OF CASH FLOWS

(In thousands)

	Year Ended December 31	
	2018	2017
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$(15,754)	$(19,375)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	438	338
Amortization of intangible assets	121	242
Amortization of prepaid maintenance	18	-
Impairment charge for intangible assets	625	-
Stock-based compensation	1,479	1,630
Loss on sale of BioTime shares	-	309
Dividend income from AgeX Therapeutics common stock received as a dividend-in-kind	(96)	-
Unrealized loss on marketable equity securities	427	-
Warrants issued to certain shareholders as inducement to exercise of warrants	-	4,074
Amortization of debt issuance costs	77	83
Other	23	-
Changes in operating assets and liabilities:		
Amount due to BioTime and affiliates	2	(753)
Prepaid expenses and other current assets	(11)	115
Accounts payable and accrued liabilities;	1,002	(48)
Net cash used in operating activities	(11,649)	(13,385)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Net proceeds from sale of BioTime shares	-	934
Purchase of equipment	(31)	(91)
Net cash provided by (used in) investing activities	(31)	843
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from exercise of stock options	58	610
Proceeds from exercise of warrants	-	7,774
Proceeds from sale of common shares	10,000	-
Financing costs to issue common shares	(65)	-
Proceeds from sale of common shares and warrants	3,592	-
Financing costs to issue common shares and warrants	(290)	-
Proceeds from issuance of loan payable, net of financing costs	-	1,982
Repayment of loan payable	(800)	(133)
Repayment of capital lease obligation	(381)	(265)
Net cash provided by financing activities	12,114	9,968

NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	434	(2,574)
CASH AND CASH EQUIVALENTS:		
At beginning of the year	7,600	10,174
At end of the year	$8,034	$7,600
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION		
Cash paid for interest	$142	$130
SUPPLEMENTAL SCHEDULE OF NONCASH FINANCING AND INVESTING ACTIVITIES		
Equipment purchased under capital leases	$209	$381
Debt issuance costs	-	196

The accompanying notes are an integral part of these financial statements.

ONCOCYTE CORPORATION

NOTES TO FINANCIAL STATEMENTS

1. Organization, Description of the Business and Liquidity

OncoCyte Corporation ("OncoCyte") is a developer of novel, non-invasive blood-based tests for the early detection of cancer. It is focused on developing molecular cancer diagnostics utilizing a discovery platform that focuses on identifying genetic markers that are differentially expressed in certain types of cancers. OncoCyte is currently devoting substantially all of its efforts on developing its lung cancer diagnostic test DetermaVu™.

OncoCyte was incorporated in 2009 in the state of California and was formerly a majority-owned subsidiary of BioTime, Inc. ("BioTime"), a publicly traded, clinical-stage, biotechnology company targeting degenerative diseases, primarily in the fields of ophthalmology, cell therapy for acute spinal cord injury and cancer immunotherapy. Beginning on February 17, 2017, OncoCyte ceased to be a subsidiary of BioTime for financial reporting purposes when BioTime's percentage ownership of outstanding OncoCyte common stock declined below 50% as a result of the issuance of additional OncoCyte common stock to certain investors who exercised OncoCyte stock purchase warrants (see Note 6).

Liquidity

For all periods presented, OncoCyte generated no revenues. Since inception, OncoCyte has financed its operations through the sale of common stock and warrants, warrant exercises, a bank loan, and sales of BioTime common shares that OncoCyte holds as marketable equity securities. BioTime also provided OncoCyte with the use of BioTime facilities and services under a Shared Facilities and Services Agreement as described in Note 4 (the "Shared Facilities Agreement"). OncoCyte has incurred operating losses and negative cash flows since inception and had an accumulated deficit of $71.3 million as of December 31, 2018. OncoCyte expects to continue to incur operating losses and negative cash flows for the near future.

At December 31, 2018, OncoCyte had $8.0 million of cash and cash equivalents and held BioTime and AgeX Therapeutics, Inc. ("AgeX") common stock as marketable equity securities valued at $0.4 million. During February 2019 OncoCyte raised an additional $37.4 million in net proceeds, after the payment of underwriting fees and estimated offering expenses, through a public offering and sale of 10,733,334 shares of its common stock (see Note 10). OncoCyte believes that its current cash, cash equivalents and marketable equity securities is sufficient to carry out current operations through at least twelve months from the issuance date of the financial statements included herein.

OncoCyte will need to raise additional capital to finance its operations, including the development of its cancer diagnostic tests, until such time as it is able to complete development and commercialize one or more diagnostic tests and generate sufficient revenues to cover its operating expenses. Presently, OncoCyte is devoting substantially all of its research and development resources to the completion of the development of DetermaVu™. OncoCyte may also explore a range of other commercialization options in order to reduce capital needs and the risks associated with the timelines and uncertainty for attaining the Medicare and commercial reimbursement approvals that will be essential for the successful commercialization of DetermaVu™ and any other diagnostic tests that OncoCyte may develop. Those alternative arrangements could include marketing arrangements with other diagnostic companies through which OncoCyte might receive a royalty on sales, or through which it might form a joint venture to market DetermaVu™ and share in net revenues.

Delays in the development of DetermaVu™ could prevent OncoCyte from raising sufficient additional capital to finance the completion of development and commercial launch of DetermaVu™ or other cancer diagnostic tests. Even if OncoCyte is successful in completing the development of DetermaVu™, investors may be reluctant to provide OncoCyte with capital until DetermaVu™ is approved for reimbursement by Medicare. The unavailability or inadequacy of financing or revenues to meet future capital needs could force OncoCyte to modify, curtail, delay, or suspend some or all aspects of planned operations. Sales of additional equity securities could result in the dilution of the interests of its shareholders. OncoCyte cannot assure that adequate financing will be available on favorable terms, if at all.

2. Summary of Significant Accounting Policies

Basis of presentation

The financial statements presented herein have been prepared on a separate, stand-alone basis. The financial statements are presented in accordance with U.S. generally accepted accounting principles (“GAAP”). Prior to February 17, 2017, BioTime consolidated the results of OncoCyte into BioTime’s consolidated results based on BioTime’s ability to control OncoCyte’s operating and financial decisions and policies through its majority ownership of OncoCyte common stock. BioTime owned 51.1% of the outstanding common stock of OncoCyte at December 31, 2016. Beginning on February 17, 2017, BioTime’s percentage ownership of the outstanding OncoCyte common stock declined below 50%, resulting in a loss of “control” of OncoCyte under GAAP and, as a result, BioTime deconsolidated OncoCyte’s financial statements from BioTime’s consolidated financial statements. As a result of this deconsolidation, OncoCyte is no longer considered a subsidiary of BioTime under GAAP with effect from February 17, 2017. OncoCyte remains an affiliate of BioTime based on BioTime’s retained share ownership in OncoCyte, which is sufficient to allow BioTime to exert significant influence over the operations and management of OncoCyte.

To the extent OncoCyte does not have its own employees or human resources for its operations, BioTime or BioTime subsidiaries provide certain employees for administrative or operational services, as necessary, for the benefit of OncoCyte (see Note 4). Accordingly, BioTime allocates expenses such as salaries and payroll related expenses incurred and paid on behalf of OncoCyte based on the amount of time that particular employees devote to OncoCyte affairs. Other expenses such as legal, accounting, human resources, marketing, travel, and entertainment expenses are allocated to OncoCyte to the extent that those expenses are incurred by or on behalf of OncoCyte. BioTime also allocates certain overhead expenses such as facilities rent and utilities, property taxes, insurance, internet and telephone expenses based on a percentage determined by management. These allocations are made based upon activity-based allocation drivers such as time spent, percentage of square feet of office or laboratory space used, and percentage of personnel devoted to OncoCyte's operations or management. Management evaluates the appropriateness of the percentage allocations on a periodic basis and believes that this basis for allocation is reasonable.

Use of estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. On an ongoing basis, management evaluates estimates which are subject to significant judgment, including those related to the going concern assessments of OncoCyte financial statements, allocation of direct and indirect expenses, useful lives associated with long-lived intangible assets, equipment and furniture, loss contingencies, valuation allowances related to deferred income taxes, and assumptions used to value stock-based awards, debt or other equity instruments. Actual results could differ materially from those estimates.

Going concern assessment

With the implementation of FASB's standard on going concern, Accounting Standard Update, or ASU No. 2014-15, OncoCyte assesses going concern uncertainty in its financial statements to determine if it has sufficient cash, cash equivalents and working capital on hand, including marketable equity securities, and any available borrowings on loans, to operate for a period of at least one year from the date the financial statements are issued, which is referred to as the "look-forward period" as defined by ASU No. 2014-15. As part of this assessment, based on conditions that are known and reasonably knowable to OncoCyte, it will consider various scenarios, forecasts, projections, estimates and will make certain key assumptions, including the timing and nature of projected cash expenditures or programs, and its ability to delay or curtail expenditures or programs, if necessary, among other factors. Based on this assessment, as necessary or applicable, OncoCyte makes certain assumptions around implementing curtailments or delays in the nature and timing of programs and expenditures to the extent OncoCyte deems probable those implementations can be achieved and it has the proper authority to execute them within the look-forward period in accordance with ASU No. 2014-15.

Fair value measurements

OncoCyte accounts for fair value measurements in accordance with Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 820, *Fair Value Measurements* ("ASC 820"). ASC 820 establishes a single authoritative definition of fair value, sets out a framework for measuring fair value and expands on required disclosures about fair value measurement. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. ASC 820 describes a fair value hierarchy based on three levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value, which are the following:

Level 1 – Quoted prices in active markets for identical assets and liabilities.

Level 2 – Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted market prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 – Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

In determining fair value, OncoCyte utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible, and also considers counterparty credit risk in its assessment of fair value. For the periods presented, OncoCyte has no financial assets or liabilities recorded at fair value on a recurring basis, except for cash and cash equivalents consisting of money market funds and marketable equity securities of BioTime and AgeX common stock held by OncoCyte described below. These assets are measured at fair value using the period-end quoted market prices as a Level 1 input.

The carrying amounts of cash equivalents, prepaid expenses and other current assets, amounts due to BioTime and other affiliates, accounts payable, accrued expenses and other current liabilities approximate fair values because of the short-term nature of these items.

The carrying amount of the Loan Payable to Silicon Valley Bank approximates fair value because the loan bears interest at a floating market rate (see Note 5).

Cash and cash equivalents

Cash equivalents typically consisted of highly liquid investments, with maturities of three months or less when purchased. At December 31, 2018 and 2017, OncoCyte's cash balances totaled $8.0 million and $7.6 million, respectively.

Financial instruments that potentially subject OncoCyte to credit risk consist principally of cash and cash equivalents. OncoCyte maintains cash and cash equivalent balances at financial institutions in excess of amounts insured by United States government agencies. OncoCyte places its cash and cash equivalents with high credit quality financial institutions.

Accounting for BioTime and AgeX shares of common stock

OncoCyte accounts for the BioTime shares it holds, including the AgeX shares of common stock received as a dividend-in-kind on November 28, 2018, as marketable equity securities in accordance with ASC 320-10-25, *Investments – Debt and Equity Securities*, as amended by Accounting Standards Update ("ASU") 2016-01, *Financial Instruments–Overall: Recognition and Measurement of Financial Assets and Financial Liabilities*, as the shares have a readily determinable fair value quoted on the NYSE American and are held principally to meet future working capital purposes, as necessary. The securities are measured at fair value and reported as current assets on the balance sheet based on the closing trading price of the security as of the date being presented.

Beginning on January 1, 2018, with the adoption of ASU 2016-01 discussed below, these securities are now called "marketable equity securities" and unrealized holding gains and losses on these securities are reported in the statements of operations in other income and expenses, net. Prior to January 1, 2018 and the adoption of ASU 2016-01, the BioTime shares held were called "available-for-sale securities" and unrealized holding gains and losses were reported in other comprehensive income or loss, net of tax, and were a component of the accumulated other comprehensive income or loss on the balance sheet. Realized gains and losses are included in other income and expenses, net, in the statements of operations.

On January 1, 2018, in accordance with the adoption of ASU 2016-01, OncoCyte recorded a cumulative-effect adjustment for the BioTime shares as available-for-sale-securities to reclassify the unrealized loss of $888,000 included in accumulated other comprehensive loss to the accumulated deficit balance.

On November 28, 2018, BioTime distributed shares of AgeX common stock owned by BioTime to holders of BioTime common shares, on a pro rata basis, in the ratio of one share of AgeX common stock for every ten BioTime common shares owned. As a shareholder of BioTime common stock, OncoCyte received 35,326 shares of AgeX common stock as its pro rata share and recorded a $96,000 dividend in other income and expenses for the year ended December 31, 2018.

For the year ended December 31, 2018, OncoCyte recorded an unrealized loss of $427,000, included in other income and expenses, net, due to the decrease in fair market value of the BioTime shares from January 1, 2018 to December 31, 2018, and the decrease in the fair market value of the AgeX shares from November 28, 2018 to December 31, 2018.

In 2017, OncoCyte sold 266,442 shares of BioTime common stock for net proceeds of $934,000 and recognized a $309,000 loss from the sale of the BioTime shares included in other income and expenses, net. The proceeds were used to pay down amounts owed to BioTime and affiliates (see Note 4). OncoCyte did not sell any shares of BioTime stock during the year ended December 31, 2018.

As of December 31, 2018, OncoCyte held 353,264 and 35,326 shares of common stock of BioTime and AgeX, respectively, as marketable equity securities with a combined fair market value of $428,000. Any proceeds from the sale of BioTime shares may be used by OncoCyte to pay amounts owed to BioTime and its affiliates or for working capital purposes (see Notes 4 and 10).

Long-lived intangible assets

Long-lived intangible assets, primarily consisting of acquired patents, patent applications, and licenses to use certain patents are stated at acquired cost, less accumulated amortization (see Note 3). Amortization expense is computed using the straight-line method over the estimated useful lives of the assets over a period of 10 years.

Machinery and equipment

Machinery and equipment are stated at cost, less accumulated depreciation. Depreciation is computed using the straight-line method over the estimated useful lives of the assets, generally over a period of 3 to 10 years. For equipment purchased under capital leases, OncoCyte depreciates the equipment based on the shorter of the useful life of the equipment or the term of the lease, ranging from 3 to 5 years, depending on the nature and classification of the capital lease. Maintenance and repairs are expensed as incurred whereas significant renewals and betterments are capitalized. When assets are retired or otherwise disposed of, the cost and the related accumulated depreciation are removed from the respective accounts and any resulting gain or loss is reflected in OncoCyte’s results of operations.

Impairment of long-lived assets

OncoCyte assesses the impairment of long-lived assets, which consist primarily of long-lived intangible assets, machinery and equipment, whenever events or changes in circumstances indicate that such assets might be impaired and the carrying value may not be recoverable. If events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable and the expected undiscounted future cash flows attributable to the asset are less than the carrying amount of the asset, an impairment loss equal to the excess of the asset’s carrying value over its fair value is recorded. As part of OncoCyte’s impairment assessment of its intangible assets, OncoCyte determined that certain intangible assets, mainly comprised of patents and patent rights for therapeutic uses that OncoCyte no longer plans to develop or commercialize, were impaired as of June 30, 2018 and, accordingly, OncoCyte recorded a noncash charge of $625,000 representing the net book value of those assets as of that date, and included that charge in research and development expenses for the year ended December 31, 2018.

Accounting for warrants

OncoCyte determines the accounting classification of warrants it issues, as either liability or equity classified, by first assessing whether the warrants meet liability classification in accordance with ASC 480-10, *Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity*, then in accordance with ASC 815-40, *Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock*. Under ASC 480, warrants are considered liability classified if the warrants are mandatorily redeemable, obligate OncoCyte to settle the warrants or the underlying shares by paying cash or other assets, or warrants that must or may require settlement by issuing variable number of shares. If warrants do not meet liability classification under ASC 480-10, OncoCyte assesses the requirements under ASC 815-40, which states that contracts that require or may require the issuer to settle the contract for cash are liabilities recorded at fair value, irrespective of the likelihood of the transaction occurring that triggers the net cash settlement feature. If the warrants do not require liability classification under ASC 815-40, and in order to conclude equity classification, OncoCyte also assesses whether the warrants are indexed to its common stock and whether the warrants are classified as equity under ASC 815-40 or other applicable GAAP. After all relevant assessments, OncoCyte concludes whether the warrants are classified as liability or equity. Liability classified warrants require fair value accounting at issuance and subsequent to initial issuance with all changes in fair value after the issuance date recorded in the statements of operations. Equity classified warrants only require fair value accounting at issuance with no changes recognized subsequent to the issuance date. OncoCyte does not have any liability classified warrants as of any period presented (see Note 6).

Income taxes

OncoCyte has filed a standalone U.S. federal income tax return since its inception. For California purposes, OncoCyte activity for 2016 and for the period from January 1, 2017 through February 16, 2017, the date immediately before BioTime owned less than 50% of OncoCyte outstanding common stock, was included in BioTime's California combined tax return. For periods beginning on February 17, 2017 and thereafter, OncoCyte filed or will file a standalone California income tax return. The provision for state income taxes has been determined as if OncoCyte had filed separate tax returns for the periods presented. Accordingly, the effective tax rate of OncoCyte in future years could vary from its historical effective tax rates depending on the future legal structure of OncoCyte and related tax elections. The historical deferred tax assets, including the operating losses and credit carryforwards generated by OncoCyte, will remain with OncoCyte. OncoCyte accounts for income taxes in accordance with ASC 740, *Income Taxes*, which prescribes the use of the asset and liability method, whereby deferred tax asset or liability account balances are calculated at the balance sheet date using current tax laws and rates in effect. Valuation allowances are established when necessary to reduce deferred tax assets when it is more likely than not that a portion or all of the deferred tax assets will not be realized. OncoCyte's judgments regarding future taxable income may change over time due to changes in market conditions, changes in tax laws, tax planning strategies or other factors. If OncoCyte's assumptions and consequently its estimates change in the future, the valuation allowance may be increased or decreased, which may have a material impact on OncoCyte's statements of operations.

The guidance also prescribes a recognition threshold and a measurement attribute for the financial statement recognition and measurement of tax positions taken or expected to be taken in a tax return. For those benefits to be recognized, a tax position must be more-likely-than-not sustainable upon examination by taxing authorities. OncoCyte will recognize accrued interest and penalties related to unrecognized tax benefits as income tax expense. No amounts were accrued for the payment of interest and penalties as of December 31, 2018 and 2017. OncoCyte is not aware of any uncertain tax positions that could result in significant additional payments, accruals, or other material deviation for the years ended December 31, 2018 and 2017. OncoCyte is currently unaware of any tax issues under review.

On December 22, 2017, the United States enacted major federal tax reform legislation, Public Law No. 115-97, commonly referred to as the 2017 Tax Cuts and Jobs Act ("2017 Tax Act"), which enacted a broad range of changes to the Internal Revenue Code. Changes to taxes on corporations impacted by the 2017 Tax Act include, but are not limited to, lowering the U.S. federal tax rates to a 21% flat tax rate, eliminating the corporate alternative minimum tax ("AMT"), imposing additional limitations on the deductibility of interest and net operating losses, allowing any net operating loss ("NOLs") generated in tax years ending after December 31, 2017 to be carried forward indefinitely and generally repealing carrybacks, reducing the maximum deduction for NOL carryforwards arising in tax years beginning after 2017 to a percentage of the taxpayer's taxable income, and allowing for additional expensing of certain capital expenditures. The 2017 Tax Act also puts into effect a number of changes impacting operations outside of the United States including, but not limited to, the imposition of a one-time tax "deemed repatriation" on accumulated offshore earnings not previously subject to U.S. tax, and shifts the U.S taxation of multinational corporations from a worldwide system of taxation to a territorial system. ASC 740 requires the effects of changes in tax rates and laws on deferred tax balances (including the effects of the one-time transition tax) to be recognized in the period in which the legislation is enacted (see Note 8).

On December 22, 2017, the SEC staff issued Staff Accounting Bulletin No. 118 ("SAB 118") to provide guidance for companies that are not able to complete their accounting for the income tax effects of the 2017 Tax Act in the period of enactment. SAB 118 allows OncoCyte to record provisional amounts during a measurement period not to extend beyond one year of the enactment date (see Note 8). OncoCyte applied the guidance in SAB 118 when accounting for the enactment-date effects of the 2017 Tax Act during the years ended December 31, 2018 and 2017. As of December 31, 2018, OncoCyte completed its accounting for all the enactment-date income tax effects of the 2017 Tax Act.

Research and development expenses

Research and development expenses include both direct expenses incurred by OncoCyte and indirect overhead costs allocated by BioTime that benefit or support OncoCyte's research and development functions. Direct research and development expenses consist primarily of personnel costs and related benefits, including stock-based compensation, outside consultants and suppliers. Indirect research and development expenses allocated by BioTime to OncoCyte under the Shared Facilities Agreement (see Note 4), are primarily based on headcount or space occupied, as applicable, and include laboratory supplies, laboratory expenses, rent and utilities, common area maintenance, telecommunications, property taxes and insurance. Research and development costs are expensed as incurred.

General and administrative expenses

General and administrative expenses include both direct expenses incurred by OncoCyte and indirect overhead costs allocated by BioTime that benefit or support OncoCyte's general and administrative functions. Direct general and administrative expenses consist primarily of compensation and related benefits, including stock-based compensation, for executive and corporate personnel, and professional and consulting fees. Indirect general and administrative expenses allocated by BioTime to OncoCyte under the Shared Facilities Agreement (see Note 4) are primarily based on headcount or space occupied, as applicable, and include costs for financial reporting and compliance, rent and utilities, common area maintenance, telecommunications, property taxes and insurance.

Sales and marketing expenses

Sales and marketing expenses consist primarily of personnel costs and related benefits, including stock-based compensation, trade shows and booths, branding and positioning, and outside consultants. Indirect sales and marketing expenses allocated by BioTime, primarily based on OncoCyte's headcount or space occupied, as applicable, include costs for rent and utilities, common area maintenance, telecommunications, property taxes and insurance, incurred by BioTime and allocated to us under the Shared Facilities Agreement.

Stock-based compensation

OncoCyte recognizes compensation expense related to employee option grants and restricted stock grants, if any, in accordance with FASB ASC 718, *Compensation – Stock Compensation* ("ASC 718").

In March 2016, the FASB issued ASU 2016-09, *Compensation - Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting,* which simplifies several aspects of the accounting for share-based payment transactions, including the income tax consequences, forfeitures, classification of awards as either equity or liabilities, and classification on the statement of cash flows. OncoCyte adopted ASU 2016-09 beginning on January 1, 2017.

In connection with the adoption of ASU 2016-09, OncoCyte changed its accounting policies including how it accounts for excess tax benefits and deficiencies, if any, and forfeitures, as applicable. All excess tax benefits and tax deficiencies from stock-based compensation awards accounted for under ASC 718 are recognized as income tax benefit or expense, respectively, in the statements of operations. Prior to the adoption of ASU 2016-09, OncoCyte recognized excess tax benefits, if any, in additional paid-in capital only if the tax deduction reduced cash income taxes payable and, excess tax deficiencies were recognized either as an offset to accumulated excess tax benefits, if any, on OncoCyte's statements of operations. An excess income tax benefit arises when the tax deduction of a share-based award for income tax purposes exceeds the compensation cost recognized for financial reporting purposes and, a tax deficiency arises when the compensation cost exceeds the tax deduction. Because OncoCyte has a full valuation allowance for all periods presented (see Note 8) and an insignificant number of stock option exercises during the current quarter, there was no impact to OncoCyte statements of operations for any excess tax benefits or deficiencies, as any excess benefit or deficiency would be offset by the change in the valuation allowance.

Forfeitures are accounted for as they occur instead of based on the number of awards that were expected to vest. Based on the nature and timing of OncoCyte's grants, straight line expense attribution of stock-based compensation for the entire award and the relatively low forfeiture rate on OncoCyte's experience, the impact of the adoption of ASU 2016-09 pertaining to forfeitures was not significant to OncoCyte's financial statements.

OncoCyte estimates the fair value of employee stock-based payment awards on the grant-date and recognizes the resulting fair value over the requisite service period. For stock-based awards that vest only upon the attainment of one or more performance goals set by OncoCyte at the time of the grant, compensation cost is recognized if and when OncoCyte determines that it is probable that the performance condition or conditions will be, or have been, achieved. OncoCyte uses the Black-Scholes option pricing model for estimating the fair value of options granted under OncoCyte's equity plans. The fair value of each restricted stock grant, if any, is determined based on the value of the common stock granted or sold. OncoCyte has elected to treat stock-based payment awards with graded vesting schedules and time-based service conditions as a single award and recognizes stock-based compensation on a straight-line basis over the requisite service period.

Compensation expense for non-employee stock-based awards is recognized in accordance with ASC 718 and FASB ASC 505-50, *Equity-Based Payments to Non-Employees*. Stock option awards issued to non-employees, principally consultants and employees of BioTime or employees of BioTime subsidiaries who perform services for OncoCyte, are accounted for at fair value using the Black-Scholes option pricing model. Management believes that the fair value of the stock options can more reliably be measured than the fair value of services received. OncoCyte records compensation expense based on the then-current fair values of the stock options at each financial reporting date. Compensation expense recorded during the service period is adjusted in subsequent periods for changes in the fair value of the stock options until the earlier of the date at which the non-employee's performance is complete or a performance commitment is reached, which is generally when the stock option award vests. Compensation expense for non-employee grants is recorded on a straight-line basis in the statements of operations (see *Recent Accounting Pronouncements* section below).

The Black-Scholes option pricing model requires OncoCyte to make certain assumptions including the expected option term, the expected volatility, the risk-free interest rate and the dividend yield (see Note 7).

The expected term of employee stock options represents the weighted-average period that the stock options are expected to remain outstanding. OncoCyte estimates the expected term of options granted based on its own experience and, in part, based on upon the "simplified method" provided under *Staff Accounting Bulletin, Topic 14*, or SAB Topic 14, as necessary. For the years ended December 31, 2018 and 2017, OncoCyte estimated the expected volatility using its own stock price volatility to the extent applicable or a combination of its stock price volatility and the stock price volatility of stock of peer companies, for a period equal to the expected term of the options. The risk-free interest rate assumption is based upon observed interest rates on the United States government securities appropriate for the expected term of OncoCyte's stock options. The dividend yield assumption is based on OncoCyte's history and expectation of dividend payouts. OncoCyte has never declared or paid any cash dividends on its common stock, and OncoCyte does not anticipate paying any cash dividends in the foreseeable future.

Net loss per common share

Basic net loss per common share is computed by dividing net loss by the weighted-average number of shares of common stock outstanding for the period. Diluted net loss per share reflects the weighted-average number of shares of common stock outstanding plus the potential effect of dilutive securities or contracts which are exercisable to common stock, such as stock options and warrants (using the treasury stock method) and shares issuable in future periods, except in cases where the effect would be anti-dilutive. Because OncoCyte reported net losses for all periods presented, all potentially dilutive common stock are antidilutive for those periods.

The following common stock equivalents were excluded from the computation of diluted net loss per common share of common stock for the years ended December 31, 2018 and 2017 because including them would have been antidilutive (in thousands):

	Year Ended December 31,	
	2018	2017
Stock options	3,578	1,125
Warrants	4,035	2,779

Segments

OncoCyte's executive management team, as a group, represents the entity's chief operating decision makers. To date, OncoCyte's executive management team has viewed OncoCyte's operations as one segment that includes, the research and development of diagnostic tests for the detection of cancer. As a result, the financial information disclosed materially represents all of the financial information related to OncoCyte's sole operating segment.

Recent accounting pronouncements

The following accounting standards, which are not yet effective, are presently being evaluated by OncoCyte to determine the impact that they might have on its financial statements.

In June 2018, the FASB issued ASU 2018-07, *Compensation - Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting*, which simplifies the accounting for non-employee share-based payment transactions. The new standard expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from non-employees. ASU 2018-07 is effective for fiscal years beginning after December 15, 2018 (including interim periods within that fiscal year), with early adoption permitted. As OncoCyte does not have a significant number of nonemployee share-based awards, OncoCyte does not believe that the application of the new standard will have a material impact on its financial statements when it is adopted on January 1, 2019.

In February 2016, the FASB issued ASU 2016-02, *"Leases (Topic 842)",* which requires lessees to recognize assets and liabilities for leases with lease terms greater than twelve months in the statement of financial position. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. ASU 2016-02 also requires improved disclosures to help users of financial statements better understand the amount, timing and uncertainty of cash flows arising from leases. The update is effective for fiscal years beginning after December 15, 2018, including interim reporting periods within that reporting period. Early adoption is permitted. In July 2018, the FASB issued ASU 2018-10 and ASU 2018-11. ASU 2018-10 provides certain areas for improvement in ASU 2016-02 and ASU 2018-11 provides an additional optional transition method by allowing entities to initially apply the new lease standard at the adoption date and recognize a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. OncoCyte is completing its assessment of the impact the adoption of ASU 2016-02 will have on its financial statements, but because OncoCyte does not have significant operating leases that would meet the scope of ASU 2016-02, OncoCyte does not expect the adoption of ASU 2016-02 on January 1, 2019, including the use of the optional transition method allowed by ASU 2018-11, will have a material impact to its financial statements.

3. Selected Balance Sheet Components

Accrued expenses and other current liabilities

At December 31, 2018 and 2017, accrued expenses and other current liabilities were comprised of the following (in thousands):

	2018	2017
Accrued compensation	$1,303	$636
Accrued vendors and other expenses	806	406
Accrued expenses and other current liabilities	$2,109	$1,042

Intangible assets, net

In 2011, OncoCyte, through its then parent, BioTime, acquired substantially all of the assets of Cell Targeting, Inc., a company that was engaged in cancer therapy. The assets acquired consist primarily of patents, patent applications, and licenses to use certain patents. OncoCyte amortizes intangible assets over their useful lives estimated to be 10 years at the date of the acquisition.

At December 31, 2018 and 2017, intangible assets were comprised of the following (in thousands):

	2018[(1)]	2017
Intangible assets	$ 625	$2,419
Accumulated amortization	(625)	(1,673)
Intangible assets, net	$ -	$746

(1) As part of OncoCyte's impairment assessment of certain intangible assets, OncoCyte determined that those assets were impaired as of June 30, 2018 and, accordingly, OncoCyte recorded a noncash charge of $625,000 representing the net book value of those assets as of that date, and included that charge in research and development expenses for the year ended December 31, 2018. The impairment was primarily due to OncoCyte's decision to discontinue any further utilization of the underlying patents, patent applications and licenses since those assets are for therapeutic use and not for diagnostic use, as OncoCyte continues to devote all of its research and development resources and commercialization efforts to cancer diagnostic tests. Research and development expenses for the year ended December 31, 2018 include $121,000 in amortization expense related to those

intangible assets recorded prior to the impairment charge. For the year ended December 31, 2017, research and development expenses include $242,000 of amortization of intangible assets.

Machinery and equipment, net

At December 31, 2018 and 2017, machinery and equipment were comprised of the following (in thousands):

	2018	2017
Machinery and equipment	$1,562	$1,479
Accumulated depreciation	(948)	(657)
Machinery and equipment, net	$614	$822

Depreciation expense amounted to approximately $438,000 and $338,000 for the years ended December 31, 2018 and 2017, respectively. During the year ended December 31, 2018, OncoCyte wrote off $150,000 in fully depreciated machinery and equipment with a corresponding adjustment to accumulated depreciation. During the years ended December 31, 2018 and 2017, OncoCyte entered into capital leases for laboratory equipment totaling $209,000 and $381,000, respectively (see Note 9).

4. Related Party Transactions

Shared Facilities and Service Agreement

On October 8, 2009, OncoCyte and BioTime executed the Shared Facilities Agreement. Under the terms of the Shared Facilities Agreement, BioTime will allow OncoCyte to use BioTime's premises and equipment located in Alameda, California for the purpose of conducting business. BioTime provides accounting, billing, bookkeeping, payroll, treasury, payment of accounts payable, and other similar administrative services to OncoCyte. BioTime may also provide the services of attorneys, accountants, and other professionals who may also provide professional services to BioTime and its other subsidiaries. BioTime may also provide OncoCyte with the services of BioTime laboratory and research personnel, including BioTime employees and contractors, for the performance of research and development work for OncoCyte at the premises.

BioTime charges OncoCyte a Use Fee for services received and usage of facilities, equipment, and supplies. For each billing period, BioTime prorates and allocates costs incurred, as applicable, to OncoCyte. Such costs include services of Bio Time employees, equipment, insurance, lease, professional, software, supplies and utilities. Allocation depends on key cost drivers including actual documented use, square footage of facilities used, time spent, costs incurred by or for OncoCyte, or upon proportionate usage by BioTime and OncoCyte, as reasonably estimated by BioTime (collectively "Use Fees"). BioTime charges OncoCyte a 5% markup on such allocated costs as permitted by the Shared

Facilities Agreement.

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The Use Fee is determined and invoiced to OncoCyte on a regular basis, generally monthly or quarterly. If the Shared Facilities Agreement terminates prior to the last day of a billing period, the Use Fee will be determined for the number of days in the billing period elapsed prior to the termination of the Shared Facilities Agreement. Each invoice will be payable in full by OncoCyte within 30 days after receipt. Any invoice, or portion thereof, not paid in full when due will bear interest at the rate of 15% per annum until paid, unless the failure to make a payment is due to any inaction or delay in making a payment by BioTime employees from OncoCyte funds available for such purpose, rather than from the unavailability of sufficient funds legally available for payment or from an act, omission, or delay by any employee or agent of OncoCyte. Through December 31, 2018 BioTime has not charged OncoCyte any interest.

In addition to the Use Fees, OncoCyte will reimburse BioTime for any out of pocket costs incurred by BioTime for the purchase of office supplies, laboratory supplies, and other goods and materials and services for the account or use of OncoCyte, provided that invoices documenting such costs are delivered to OncoCyte with each invoice for the Use Fee. BioTime has no obligation to purchase or acquire any office supplies or other goods and materials or any services for OncoCyte, and if any such supplies, goods, materials or services are obtained for OncoCyte, BioTime may arrange for the suppliers thereof to invoice OncoCyte directly.

The Shared Facilities Agreement will remain in effect, unless either party gives the other party written notice stating that the Shared Facilities Agreement will terminate on December 31 of that year, or unless the agreement otherwise is terminated under another provision of the agreement.

In the aggregate, BioTime charged Use Fees to OncoCyte as follows (in thousands):

	Year Ended December 31,	
	2018	2017
Research and development	$882	$1,085
General and administrative	375	268
Sales and marketing	310	213
Total use fees	$1,567	$1,566

As of December 31, 2018 and 2017, OncoCyte had $2.1 million outstanding and payable to BioTime and affiliates included in current liabilities in connection with the costs incurred under the Shared Facilities Agreement. Since these amounts are due and payable in 30 days of being invoiced, the payables are classified as current liabilities for all periods presented (see Note 10).

The minimum fixed payments due under the Shared Facilities Agreement are approximately $131,000 per month.

Financing Transactions

As further discussed in Note 6, in March 2018, OncoCyte sold shares to two investors who beneficially owned more than 5% of OncoCyte's outstanding common stock. The shares were sold under a securities purchase agreement that contains certain registration rights. OncoCyte agreed to register the shares sold to the investors for resale under the Securities Act of 1933, as amended (the "Securities Act"), not later than 60 days after the closing of the sale of the shares. OncoCyte also agreed to pay liquidated damages calculated in the manner provided in the securities purchase agreement if OncoCyte did not file the registration statement in a timely manner. Because the registration statement was not filed as required by the securities purchase agreement, during the year ended December 31, 2018, OncoCyte accrued $300,000 on account of liquidated damages owed.

5. Loan Payable to Silicon Valley Bank

On February 21, 2017, OncoCyte entered into a Loan and Security Agreement (the "Loan Agreement") with Silicon Valley Bank (the "Bank") pursuant to which OncoCyte borrowed $2.0 million on March 23, 2017. Payments of interest only on the principal balance were due monthly from the draw date through October 31, 2017, and, beginning on November 1, 2017, monthly payments of principal of approximately $67,000 plus interest are due and payable. The outstanding principal balance of the loan bears interest at a stated floating annual interest rate equal to the greater of (i) three-quarters of one percent (0.75%) above the prime rate or (ii) four and one-quarter percent (4.25%). As of December 31, 2018, the latest published prime rate plus 0.75% was 6.25% per annum.

The outstanding principal amount plus accrued interest will be due and payable to the Bank at maturity on April 1, 2020. At maturity, OncoCyte will also pay the Bank an additional final payment fee of 5.8% of the original principal borrowed. OncoCyte accrued the $116,000 final payment fee included in the loan payable as a deferred financing cost on March 23, 2017 draw date.

OncoCyte may prepay in full the outstanding principal balance at any time, subject to a prepayment fee equal to 1.0% of the outstanding principal balance if prepaid after February 21, 2019. Any amounts borrowed and repaid may not be reborrowed. There are no amounts available to be borrowed on the Loan Agreement.

The outstanding principal amount of the loan, with interest accrued, the final payment fee, and the prepayment fee may become due and payable prior to the applicable maturity date if an "Event of Default" as defined in the Loan Agreement occurs and is not cured within any applicable cure period. Upon the occurrence and during the continuance of an Event of Default, all obligations due to the Bank will bear interest at a rate per annum which is 5% above the then applicable interest rate. An Event of Default includes, among other events, failure to pay interest and principal when due, material adverse changes, which include a material adverse change in OncoCyte's business, operations, or condition (financial or otherwise), failure to provide the bank with timely financial statements and copies of filings

with the Securities and Exchange Commission (the “SEC”), as required, legal judgments or pending or threatened legal actions of $50,000 or more, insolvency, and delisting from the NYSE American. OncoCyte’s obligations under the Loan Agreement are collateralized by substantially all of its assets other than intellectual property such as patents and trade secrets that OncoCyte owns. Accordingly, if an Event of Default were to occur and not be cured, the Bank could foreclose on its security interest in the collateral. OncoCyte was in compliance with the Loan Agreement as of the filing date of this Report.

Bank Warrants

On February 21, 2017 and in conjunction with the $2.0 million becoming available under the Loan Agreement, OncoCyte issued common stock purchase warrants to the Bank (the "Bank Warrants") entitling the Bank to purchase shares of OncoCyte common stock in tranches related to the loan tranches under the Loan Agreement. In conjunction with the availability of the loan, the Bank was issued warrants to purchase 8,247 shares of OncoCyte common stock at an exercise price of $4.85 per share, through February 21, 2027. On March 23, 2017, in conjunction with borrowing $2.0 million, the Bank was issued warrants to purchase an additional 7,321 shares at an exercise price of $5.46 per share, through March 23, 2027. The Bank may elect to exercise the Bank Warrants on a "cashless exercise" basis and receive a number of shares determined by multiplying the number of shares for which the applicable tranche is being exercised by (A) the excess of the fair market value of the common stock over the applicable exercise price, divided by (B) the fair market value of the common stock. The fair market value of the common stock will be the last closing or sale price on a national securities exchange, interdealer quotation system, or over-the-counter market.

The Bank Warrants are classified as equity since, among other factors, they are not mandatorily redeemable, cannot be settled in cash or other assets and require settlement by issuing a fixed number of shares of common stock of OncoCyte. OncoCyte determined the fair value of the Bank Warrants using the Black-Scholes option pricing model to be approximately $62,000, which was recorded as a deferred financing cost against the loan payable balance. Aggregate deferred financing costs of $196,000, recorded against the loan payable balance, are amortized to interest expense over the term of the loan using the effective interest method. As of December 31, 2018, unamortized deferred financing costs were $36,000.

Future Cash Payments of Loan Payable

As of December 31, 2018, principal and interest payments due on the loan payable in each of the next two years are as follows (in thousands):

Year Ending December 31,	Loan Payments
2019	$ 843
2020	386
Total payments of principal and interest	1,229
Less: amounts representing interest	(46)
Total payments of principal before deferred financing costs	1,183
Less: deferred financing costs	(36)
Total loan payable, net of deferred financing costs	$ 1,147

6. Shareholders' Equity

Preferred Stock

OncoCyte is authorized to issue up to 5,000,000 shares of no par value preferred stock. As of December 31, 2018, no preferred shares were issued or outstanding.

Common Stock

OncoCyte has up to 85,000,000 shares of no par value common stock authorized. The holders of OncoCyte's common stock are entitled to receive ratably dividends when, as, and if declared by the Board of Directors out of funds legally available. Upon liquidation, dissolution, or winding up, the holders of OncoCyte common stock are entitled to receive ratably the net assets available after the payment of all debts and other liabilities and subject to the prior rights of OncoCyte outstanding preferred shares, if any.

The holders of common stock are entitled to one vote for each share held on all matters submitted to a vote of OncoCyte stockholders. The holders of common stock have no preemptive, subscription, or redemption rights. The outstanding shares of common stock are fully paid and non-assessable.

On March 28, 2018, OncoCyte entered into a securities purchase agreement with two accredited investors. The agreement provides for the private placement of 7,936,508 shares of OncoCyte's common stock for $1.26 per share, for total gross proceeds of $10.0 million before deducting offering expenses, $8.0 million of which was received in March 2018 and $2.0 million in May 2018. The agreement contains certain registration rights. The investors were Broadwood Partners, L.P. and George Karfunkel, who beneficially owned more than 5% of OncoCyte's outstanding common stock (see Note 4).

On July 31, 2018, OncoCyte raised approximately $3.3 million in net proceeds from the sale of 1,256,118 shares of its common stock and warrants, after offering expenses (the “July 2018 Offering”). The shares of common stock and warrants were sold in “Units” at a purchase price of $2.86 per Unit, with each Unit consisting of one share of common stock and one warrant to purchase one share of its common stock (“July 2018 Offering Warrants”). The Units of common stock and warrants were sold in a registered direct offering. OncoCyte’s Chief Executive Officer, the Chief Financial Officer, the Senior Vice President of Research and Development, and certain members of OncoCyte’s Board of Directors purchased Units in the July 2018 Offering on the same terms as other investors.

As of December 31, 2018 and 2017, OncoCyte had 40,664,496 and 31,451,558 issued and outstanding shares of common stock, respectively (see Note 10).

July 2018 Offering Warrants

Each July 2018 Offering Warrant has an initial exercise price of $3.00 per share, will become exercisable six months after the date of issuance and will expire five years from the date it becomes exercisable. Subject to limited exceptions, a holder of the warrants will not have the right to exercise any portion of such securities if the holder, together with its affiliates, would beneficially own in excess of 4.99% of the number of shares of OncoCyte’s common stock outstanding immediately after the exercise.

The July 2018 Offering Warrants are not mandatorily redeemable, cannot be settled in cash or other assets and require settlement by issuing a fixed number of shares of common stock of OncoCyte. The July 2018 Offering Warrants may be exercised on a net “cashless exercise” basis, meaning that the value of a portion of warrant shares may be used to pay the exercise price (rather than payment in cash), if a registration statement for the July 2018 Offering Warrants and underlying shares of common stock is not effective under the Securities Act of 1933, as amended (the “Securities Act”) or a prospectus in the registration statement is not available for the issuance of shares upon the exercise of the July 2018 Offering Warrants. The exercise price and the number of warrant shares will be adjusted to account for certain transactions, including stock splits, dividends paid in common stock, combinations or reverse splits of common stock, or reclassifications of common stock.

Under certain provisions of the July 2018 Offering Warrants, in the event of a Fundamental Transaction, as defined in the July 2018 Offering Warrants, OncoCyte will use reasonable best efforts for the acquirer, or any successor entity other than OncoCyte, to assume the July 2018 Offering Warrants. If the acquirer does not assume the OncoCyte July 2018 Offering Warrants, and provided that the Fundamental Transaction is not within OncoCyte’s control, including not approved by OncoCyte’s Board of Directors, then the holders of the July 2018 Offering Warrants shall solely be entitled to receive, at a defined Black Scholes value, the same type or form of consideration, and in the same proportion, that is being offered and paid to all the holders of OncoCyte common stock in connection with the Fundamental Transaction.

OncoCyte considered the guidance in ASC 815-40, which states that contracts that require or may require the issuer to settle the contract for cash are liabilities recorded at fair value, irrespective of the likelihood of the transaction occurring that triggers the net cash settlement feature. This liability classification guidance also applies to financial instruments that may require cash or other form of settlement for transactions outside of the company's control and, in which the form of consideration to the warrant holder may not be the same as to all other shareholders in connection with the transaction. However, if a transaction is not within the company's control but the holder of the financial instrument can solely receive the same type or form of consideration as is being offered to all the shareholders in the transaction, then equity classification of the financial instrument is not precluded, if all other applicable equity classification criteria are met.

Based on the above guidance, OncoCyte has met all the equity classification criteria for the July 2018 Offering Warrants and has classified those warrants as equity.

Issuance of Common Stock and Warrants

On August 29, 2016, OncoCyte sold an aggregate of 3,246,153 immediately separable units, with each unit consisting of one share of OncoCyte common stock and one warrant to purchase one share of OncoCyte common stock (the "2016 Warrants"), at a price of $3.25 per unit (the "Offering"). The sales were made pursuant to the terms and conditions of certain Purchase Agreements between OncoCyte and the purchasers in the Offering. OncoCyte received $9.8 million in net proceeds after discounts, commissions and expenses from the Offering.

2016 Warrants and New Warrants

The 2016 Warrants have an exercise price of $3.25 per Warrant Share, and may be exercised until the close of business on October 16, 2021. The 2016 Warrants may be exercised on a net "cashless exercise" basis, meaning that the value of a portion of Warrant Shares may be used to pay the exercise price (rather than payment in cash), in certain circumstances. The exercise price and the number of Warrant Shares will be adjusted to account for certain transactions, including stock splits, dividends paid in common stock, combinations or reverse splits of common stock, or reclassifications of common stock.

Under certain provisions of the 2016 Warrants, in the event of a Fundamental Transaction, as defined in the 2016 Warrants, OncoCyte will use reasonable best efforts for the acquirer, or any successor entity other than OncoCyte, to assume the 2016 Warrants. If the acquirer does not assume the OncoCyte 2016 Warrant obligations, then the acquirer shall pay the holders of 2016 Warrants an amount equal to the aggregate value equal to the Black Scholes Value, as defined in the 2016 Warrants. The payment of the Black Scholes Value shall be made in cash or such other consideration as the acquirer paid to the other OncoCyte shareholders in the Fundamental Transaction.

OncoCyte is not required to net cash settle the 2016 Warrants under any circumstance. OncoCyte considered the guidance in ASC 815-40, which states that contracts that require or may require the issuer to settle the contract for cash are liabilities recorded at fair value, irrespective of the likelihood of the transaction occurring that triggers the net cash settlement feature. Since solely an acquirer, and not OncoCyte itself, may be required to net cash settle the 2016 Warrants in the event of a Fundamental Transaction, the 2016 Warrants are classified as equity.

On February 17, 2017, certain OncoCyte investors exercised 2016 Warrants to acquire 625,000 shares of common stock at an exercise price of $3.25 per warrant for total exercise cash proceeds of $2.0 million (the “Warrant exercise”). In order to induce the investors to complete the Warrant exercise and, in conjunction with the Warrant exercise, OncoCyte issued new warrants to those investors (the “New Warrants”). Certain investors received New Warrants to purchase 200,000 shares of common stock at an exercise price of $5.50 per share and one investor received New Warrants to purchase 212,500 shares of common stock at an exercise of $3.25 per share. The New Warrants are exercisable at any time for five years from February 17, 2017.

The New Warrants are classified as equity as their terms are consistent with the 2016 Warrants. For financial reporting purposes, the issuance of the New Warrants was treated as an inducement offer to certain shareholders to exercise their 2016 Warrants. Accordingly, the fair value of the New Warrants, determined using the Black-Scholes option pricing model, approximating $1.1 million was recognized by OncoCyte as a noncash charge to shareholder expense included in general and administrative expenses and a corresponding increase to equity on February 17, 2017, the issuance date.

On July 21, 2017, OncoCyte entered into three forms of Warrant Exercise Agreements (each, an “Exercise Agreement”) with certain holders of the 2016 Warrants providing for the cash exercise of their 2016 Warrants and the issuance of new warrants (the “July 2017 Warrants”) to them.

Pursuant to one form of Exercise Agreement, two investors exercised 2016 Warrants to purchase 226,923 shares of OncoCyte’s common stock at the exercise price of $3.25 per share, and OncoCyte issued to them July 2017 Warrants expiring five years from the date of issue, to purchase 226,923 shares of common stock at an exercise price of $5.50 per share.

Pursuant to a second form of Exercise Agreement, one investor exercised 2016 Warrants to purchase 540,000 shares of common stock at the exercise price of $3.25 per share, and OncoCyte issued to the investor a July 2017 Warrant, expiring five years from the date of issue, to purchase 270,000 shares of common stock at an exercise price of $3.25 per share. In this alternative form of Exercise Agreement, OncoCyte also agreed to use commercially reasonable efforts to file with the SEC a registration statement covering the resale of the shares of common stock issuable upon exercise of the July 2017 Warrant and to keep it continuously effective for up to five years, subject to conditions set forth in the Exercise Agreement.

Pursuant to a third form of Exercise Agreement, one investor exercised 2016 Warrants to purchase 1,000,000 shares of common stock at the exercise price of $3.25 per share, and OncoCyte issued to the investor (i) a July 2017 Warrant, expiring two years from the date of issue, to purchase 500,000 shares of common stock at an exercise price of $5.50 per share, and (ii) a July 2017 Warrant, expiring two years from the date of issue, to purchase 500,000 shares of common stock at an exercise price of $3.25 per share. In this alternative form of Exercise Agreement, OncoCyte also agreed to use commercially reasonable efforts to file with the SEC a registration statement covering the resale of the shares of common stock issuable upon exercise of the July 2017 Warrant and to keep it continuously effective for up to five years, subject to conditions set forth in the Exercise Agreement.

In the aggregate, upon the exercise of 2016 Warrants under the Exercise Agreements, OncoCyte received gross proceeds of approximately $5.74 million and issued July 2017 Warrants to purchase 1,496,923 shares of common stock at a weighted average price of $4.34 per share.

The July 2017 Warrants are classified as equity as their terms are consistent with the 2016 Warrants. For financial reporting purposes, the issuance of the July 2017 Warrants is treated as an inducement offer to certain investors to exercise their 2016 Warrants. Accordingly, the fair value of the July 2017 Warrants, determined to be approximately $3.0 million using the Black-Scholes option pricing model, was recorded as a noncash charge to shareholder expense included in general and administrative expenses, and a corresponding increase was recorded to equity on July 21, 2017, the issuance date.

As of December 31, 2018, OncoCyte has an aggregate of 4,035,339 warrants issued and outstanding at exercise prices ranging from $3.00 and $5.50 per warrant.

Stock Option Exercises

During the years ended December 31, 2018 and 2017, 20,312 and 323,019 shares of common stock were issued upon the exercise of stock options, from which OncoCyte received $58,000 and $610,000 in cash proceeds, respectively.

7. Stock-Based Compensation

Stock Option Plan

OncoCyte had a 2010 Stock Option Plan (the "2010 Plan") under which 5,200,000 shares of common stock were authorized for the grant of stock options or the sale of restricted stock.

On August 27, 2018, OncoCyte shareholders approved a new Equity Incentive Plan (the "2018 Incentive Plan") to replace the 2010 Plan. In adopting the 2018 Incentive Plan, OncoCyte terminated the 2010 Plan and will not grant any additional stock options or sell any stock under restricted stock purchase agreements under the 2010 Plan; however, stock options issued under the 2010 Plan will continue in effect in accordance with their terms and the terms of the 2010 Plan until the exercise or expiration of the individual options.

The 2018 Incentive Plan reserved 5,000,000 shares of common stock for the grant of stock options or the sale of restricted stock ("Restricted Stock") or for the settlement of hypothetical units issued with reference to common stock ("Restricted Stock Units"). OncoCyte may also grant stock appreciation rights ("SARs") under the 2018 Incentive Plan. The 2018 Incentive Plan also permits OncoCyte to issue such other securities as its Board of Directors (the "Board") or the Compensation Committee (the "Committee") administering the 2018 Incentive Plan may determine. Awards of stock options, Restricted Stock, SARs, and Restricted Stock Units ("Awards") may be granted under the 2018 Incentive Plan to OncoCyte employees, directors, and consultants.

Awards may vest and thereby become exercisable or have restrictions on forfeiture lapse on the date of grant or in periodic installments or upon the attainment of performance goals, or upon the occurrence of specified events. Awards may not vest, in whole or in part, earlier than one year from the date of grant. Vesting of an Award after the date of

grant may be accelerated only in the limited circumstances specified in the 2018 Incentive Plan. In the case of the acceleration of vesting of any performance-based Award, acceleration of vesting shall be limited to actual performance achieved, pro rata achievement of the performance goal(s) on the basis for the elapsed portion of the performance period, or a combination of actual and pro rata achievement of performance goals.

No person shall be granted, during any one year period, options to purchase, or SARs with respect to, more than 1,000,000 shares in the aggregate, or any Awards of Restricted Stock or Restricted Stock Units with respect to more than 500,000 shares in the aggregate. If an Award is to be settled in cash, the number of shares on which the Award is based shall not count toward the individual share limit.

No Awards may be granted under the 2018 Incentive Plan more than ten years after the date upon which the 2018 Incentive Plan was adopted by the Board, and no options or SARS granted under the 2018 Incentive Plan may be exercised after the expiration of ten years from the date of grant.

Stock Options

Options granted under the 2018 Incentive Plan may be either “incentive stock options” within the meaning of Section 422(b) of the Internal Revenue Code of 1986, as amended (the “Code”), or “non-qualified” stock options that do not qualify incentive stock options. Incentive stock options may be granted only to OncoCyte employees and employees of subsidiaries. The exercise price of stock options granted under the 2018 Incentive Plan must be equal to the fair market of OncoCyte common stock on the date the option is granted. In the case of an optionee who, at the time of grant, owns more than 10% of the combined voting power of all classes of OncoCyte stock, the exercise price of any incentive stock option must be at least 110% of the fair market value of the common stock on the grant date, and the term of the option may be no longer than five years. The aggregate fair market value of common stock (determined as of the grant date of the option) with respect to which incentive stock options become exercisable for the first time by an optionee in any calendar year may not exceed $100,000.

The exercise price of an option may be payable in cash or in common stock having a fair market value equal to the exercise price, or in a combination of cash and common stock, or other legal consideration for the issuance of stock as the Board or Committee may approve.

Generally, options will be exercisable only while the optionee remains an employee, director or consultant, or during a specific period thereafter, but in the case of the termination of an employee, director, or consultant's services due to death or disability, the period for exercising a vested option shall be extended to the earlier of 12 months after termination or the expiration date of the option.

Restricted Stock and Restricted Stock Units

In lieu of granting options, OncoCyte may enter into purchase agreements with employees under which they may purchase or otherwise acquire Restricted Stock or Restricted Stock Units subject to such vesting, transfer, and repurchase terms, and other restrictions. The price at which Restricted Stock may be issued or sold will be not less than 100% of fair market value. Employees or consultants, but not executive officers or directors, who purchase Restricted Stock may be permitted to pay for their shares by delivering a promissory note or an installment payment agreement that may be secured by a pledge of their Restricted Stock. Restricted Stock may also be issued for services actually performed by the recipient prior to the issuance of the Restricted Stock. Unvested Restricted Stock for which OncoCyte has not received payment may be forfeited, or OncoCyte may have the right to repurchase unvested shares upon the occurrence of specified events, such as termination of employment.

Subject to the restrictions set with respect to the particular Award, a recipient of Restricted Stock generally shall have the rights and privileges of a shareholder, including the right to vote the Restricted Stock and the right to receive dividends; provided that, any cash dividends and stock dividends with respect to the Restricted Stock shall be withheld for the recipient's account, and interest may be credited on the amount of the cash dividends withheld. The cash dividends or stock dividends so withheld and attributable to any particular share of Restricted Stock (and earnings thereon, if applicable) shall be distributed to the recipient in cash or, at the discretion of the Board or Committee, in shares of common stock having a fair market value equal to the amount of such dividends, if applicable, upon the release of restrictions on the Restricted Stock and, if the Restricted Stock is forfeited, the recipient shall have no right to the dividends.

The terms and conditions of a grant of Restricted Stock Units shall be determined by the Board or Committee. No shares of common stock shall be issued at the time a Restricted Stock Unit is granted. A recipient of Restricted Stock Units shall have no voting rights with respect to the Restricted Stock Units. Upon the expiration of the restrictions applicable to a Restricted Stock Unit, OncoCyte will either issue to the recipient, without charge, one share of common stock per Restricted Stock Unit or cash in an amount equal to the fair market value of one share of common stock.

At the discretion of the Board or Committee, each Restricted Stock Unit (representing one share of common stock) may be credited with cash and stock dividends paid in respect of one share ("Dividend Equivalents"). Dividend Equivalents shall be withheld for the recipient's account, and interest may be credited on the amount of cash Dividend Equivalents withheld. Dividend Equivalents credited to a recipient's account and attributable to any particular

Restricted Stock Unit (and earnings thereon, if applicable) shall be distributed in cash or in shares of common stock having a fair market value equal to the amount of the Dividend Equivalents and earnings, if applicable, upon settlement of the Restricted Stock Unit. If a Restricted Stock Unit is forfeited, the recipient shall have no right to the related Dividend Equivalents.

SARs

An SAR is the right to receive, upon exercise, an amount payable in cash or shares, or a combination of shares and cash, equal to the number of shares subject to the SAR that is being exercised, multiplied by the excess of (a) the fair market value of a common share on the date the SAR is exercised, over (b) the exercise price specified in the SAR Award agreement. SARs may be granted either as free standing SARs or in tandem with options. No SAR may be exercised later than 10 years after the date of grant.

The exercise price of an SAR shall not be less than 100% of the fair market value of one share of common stock on the date of grant. An SAR granted in conjunction with an option shall have the same exercise price as the related option, shall be transferable only upon the same terms and conditions as the related option, and shall be exercisable only to the same extent as the related option; provided, however, that the SAR by its terms shall be exercisable only when the fair market value per share exceeds the exercise price per share of the SAR or related option. Upon any exercise of an SAR granted in tandem with an option, the number of shares for which the related option shall be exercisable shall be reduced by the number of shares for which the SAR has been exercised. The number of shares for which an SAR issued in tandem with an option shall be exercisable shall be reduced by the number of shares for which the related option has been exercised.

Options Granted

A summary of OncoCyte stock option activity under the 2010 Plan and related information follows (in thousands except weighted average exercise price):

Options	Shares Available for Grant	Number of Options Outstanding	Weighted Average Exercise Price
Balance at January 1, 2017	880	3,017	$ 2.52
Increase in pool	1,200	-	
Options granted	(896)	896	5.17
Options exercised	-	(323)	1.89
Options forfeited, cancelled or expired	200	(200)	3.11
Balance at December 31, 2017	1,384	3,390	3.25
Options granted	(1,446)	1,446	2.39
Options exercised	-	(20)	2.84
Options forfeited, cancelled or expired	138	(645)	3.96
Termination of the 2010 Plan	(76)	-	-
Balance at December 31, 2018	-	4,171	$ 2.92
Exercisable at December 31, 2018		2,348	$ 2.82

Of the stock options granted under the 2010 Plan during the year ended December 31, 2018, OncoCyte granted 1,318,948 stock options to employees and consultants, with exercise prices ranging from $2.30 per share to $3.15 per share, that will vest in increments upon the attainment of specified performance conditions related to the development of DetermaVu™ and obtaining Medicare reimbursement coverage for that test (“Performance-Based Options”). As of December 31, 2018, there were 1,066,800 Performance-Based Options outstanding and none of the performance conditions required for vesting had been met, and, accordingly, no stock-based compensation expense was recorded during the year ended December 31, 2018 with regard to the Performance-Based Options.

At December 31, 2018 and 2017, OncoCyte had approximately $2.7 million and $1.6 million, respectively, of total unrecognized compensation expense related to the 2010 Plan and 2018 Incentive Plan that will be recognized over a weighted-average period of approximately 3.3 and 2.5 years, respectively.

A summary of 2018 Incentive Plan activity and related information follows (in thousands except weighted average exercise price):

Options	Shares Available for Grant	Number of Options Outstanding	Weighted Average Exercise Price
Balance at December 31, 2017	-	-	$ -
Approval of 2018 Incentive Plan	5,000	-	-
Options granted	(411)	411	2.21
Options exercised	-	-	-
Options forfeited, cancelled or expired	50	(50)	1.95
Balance at December 31, 2018	4,639	361	$ 2.21
Exercisable at December 31, 2018		-	$ -

Additional information regarding the Company's outstanding stock options and vested and exercisable stock options is summarized below:

	As of December 31, 2018 Options Outstanding		
Exercise Prices	(in thousands) Number of Shares	Weighted-Average Remaining Contractual Life (Years)	Weighted-Average Exercise Price
$1.34 - $1.95	554	2.76	$1.40
$2.01 - $2.85	2,404	7.86	2.30
$3.06 - $7.25	1,574	6.61	4.24
$1.34 - $7.25	4,532	6.80	$2.87

OncoCyte recorded stock-based compensation expense in the following categories on the accompanying statements of operations for the years ended December 31, 2018 and 2017 (in thousands):

	2018	2017
Research and development	$50	$668
General and administrative	1,154	841
Sales and marketing	275	121
Total stock-based compensation expense	$1,479	$1,630

The weighted-average estimated fair value of stock options with service-conditions granted during the years ended December 31, 2018 and 2017 was $1.46 and $3.24 per share, respectively, using the Black-Scholes option pricing model with the following weighted-average assumptions:

	2018		2017	
Expected life (in years)	5.65		6.15	
Risk-free interest rates	2.85	%	2.03	%
Volatility	75.51	%	66.01	%
Dividend yield	-	%	-	%

With the adoption of ASU 2016-09, effectively January 1, 2017, forfeitures are accounted for as they occur instead of based on the number of awards that were expected to vest.

The determination of stock-based compensation is inherently uncertain and subjective and involves the application of valuation models and assumptions requiring the use of judgment. If OncoCyte had made different assumptions, its stock-based compensation expense, and net loss for years ended December 31, 2018 and 2017, may have been significantly different.

OncoCyte does not recognize deferred income taxes for incentive stock option compensation expense and records a tax deduction only when a disqualified disposition has occurred.

8. Income Taxes

U.S. Federal Income Tax Reform

On December 22, 2017, in response to the enactment of the 2017 Tax Act (see Note 2), the SEC staff issued SAB 118 that allows OncoCyte to record provisional amounts during a measurement period not to extend beyond one year of the enactment date. OncoCyte applied the guidance in SAB 118 when accounting for the enactment-date effects of the 2017 Tax Act during the years ended December 31, 2018 and 2017. As of December 31, 2018, OncoCyte completed its accounting for all the enactment-date income tax effects of the 2017 Tax Act discussed below.

For the year ended December 31, 2017 OncoCyte remeasured certain deferred tax assets and liabilities based on the enacted tax rate at which they are expected to reverse in the future. The estimated tax affected amount related to the remeasurement of these balances was a reduction of OncoCyte's net deferred tax assets by $6.8 million with a corresponding decrease in the valuation allowance by the same amount, recognized as of December 31, 2017.

OncoCyte has filed standalone U.S. federal income tax returns since its inception. For California purposes, OncoCyte's activity for 2016 was included in BioTime's California Combined tax return. As a result of OncoCyte's deconsolidation from BioTime on February 17, 2017, (see Note 1), OncoCyte has filed a separate California return for tax year 2017 and will continue do so for subsequent years. The provision for state income taxes has been determined as if OncoCyte had filed separate tax returns for the periods presented. Accordingly, the effective tax rate of OncoCyte in 2018 and future years could vary from its historical effective tax rates depending on the future legal structure of OncoCyte and related tax elections. The deferred tax assets, including the operating loss and credit carryforwards, generated by OncoCyte, will remain with OncoCyte.

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. As of December 31, 2017, the federal portion of the deferred tax assets and liabilities were re-rated from 34% to 21% percent pursuant to the 2017 Tax Act. Accordingly, the federal portion of the deferred tax assets and liabilities for all periods presented are rated at 21%.

The primary components of the deferred tax assets and liabilities at December 31, 2018 and 2017 were as follows (in thousands):

	2018	2017
Deferred tax assets/(liabilities):		
Net operating loss carryforwards and capital loss carryforwards	$15,204	$11,414
Research and development credit carryforwards	2,444	2,141
Marketable equity securities	393	-
Patents and fixed assets	523	268
Stock-based and other compensation	1,326	1,260
Total	19,890	15,083
Valuation Allowance	(19,890)	(15,083)
Net deferred tax asset	$-	$-

Due to losses incurred for all periods presented, OncoCyte did not record any provision or benefit for income taxes.

Income taxes differed from the amounts computed by applying the applicable U.S. federal income tax rates indicated to pretax losses from operations as a result of the following:

	2018		2017	
Computed tax benefit at federal statutory rate	21	%	34	%
Re-rate of federal net deferred tax assets	-	%	(35	)%
Permanent differences	-	%	(8	)%
State tax benefit	10	%	3	%
Research and development credits	1	%	1	%
Other	(1	)%	-	%
Adjust basis for available-for-sale-securities	-	%	11	%
Change in valuation allowance	(31	)%	(6	)%
	-	%	-	%

As of December 31, 2018, OncoCyte had net operating loss carryforwards of approximately $59.0 million for U.S. federal income tax purposes and $28.0 million for state income tax purposes. Federal net operating losses generated on or prior to December 31, 2017 expire in varying amounts between 2030 and 2037, while federal net operating losses generated after December 31, 2017 carryforward indefinitely. The state net operating losses expire in varying amounts between 2029 and 2037. OncoCyte also has capital loss carryforwards for federal and state income tax purposes of $1.3 million each which expire between 2020 and 2023.

As of December 31, 2018, OncoCyte has research and development credit carryforwards for federal and state purposes of $1.2 million each. The federal credits will expire between 2030 and 2038, while the state credits have no expiration.

On November 28, 2018, BioTime distributed shares of AgeX common stock to its shareholders, including to OncoCyte, on a pro-rata basis as a taxable dividend-in-kind. As part of the distribution of AgeX common stock, OncoCyte received 35,326 shares of AgeX common stock, resulting in a taxable gain to OncoCyte of $0.1 million. OncoCyte has sufficient current year losses from operations to offset the entire taxable gain, resulting in no income taxes due.

A valuation allowance is provided when it is more likely than not that some portion of the deferred tax assets will not be realized. OncoCyte established a full valuation allowance for all periods presented due to the uncertainty of realizing future tax benefits from its net operating loss carryforwards and other deferred tax assets. The change in the valuation allowance was $4.8 million and $1.1 million for the years ended December 31, 2018 and 2017, respectively.

Other Income Tax Matters

Internal Revenue Code Section 382 places a limitation ("Section 382 Limitation") on the amount of taxable income that can be offset by NOL carryforwards after a change in control (generally greater than 50% change in ownership within a three-year period) of a loss corporation. California has similar rules. Generally, after a change in control, a loss corporation cannot deduct NOL carryforwards in excess of the Section 382 Limitation. Due to these "change in ownership" provisions, utilization of the NOL and tax credit carryforwards may be subject to an annual limitation regarding their utilization against taxable income in future periods.

In general, OncoCyte is no longer subject to tax examination by the Internal Revenue Service or state taxing authorities for years before 2014. Although the federal and state statutes are closed for purposes of assessing additional income tax in those prior years, the taxing authorities may still make adjustments to the NOL and credit carryforwards used in open years. Therefore, the tax statutes should be considered open as it relates to the NOL and credit carryforwards used in open years. For tax years that remain open to examination, potential examinations may include questioning of the timing and amount of deductions, the nexus of income among various tax jurisdictions and compliance with the Internal Revenue Code or state tax laws. OncoCyte's management does not expect that the total amount of unrecognized tax benefits will materially change over the next twelve months.

OncoCyte's practice is to recognize interest and penalties related to income tax matters in tax expense. As of December 31, 2018 and 2017, OncoCyte has no accrued interest and penalties.

9. Commitments and Contingencies

OncoCyte has certain commitments other than those under the Shared Facilities Agreement described in Note 4.

Master Lease Line Agreement

On April 7, 2016, OncoCyte entered into a Master Lease Line Agreement ("Lease Agreement No. 1") with an unrelated financing company for the purchase and financing of certain equipment. OncoCyte may use up to $881,000, as amended, for purchases of equipment financed under the Lease Agreement No. 1 through April 2017. Each lease schedule OncoCyte enters into under Lease Agreement No. 1 must be in minimum increments of $50,000 each with a 36-month lease term, collateralized by the equipment financed under the lease schedule. Each lease schedule requires a deposit for the first and last payment under that schedule. Monthly payments will be determined using a lease factor approximating an interest rate of 10% per annum. At the end of each lease schedule under Lease Agreement No. 1, assuming no default has occurred, OncoCyte may either return the equipment financed under the schedule for a restocking fee of 7.5% of the original cost of the equipment or purchase the equipment from the financing company at a fair value not less than 12.5% of the original cost of the equipment.

On April 7, 2016, OncoCyte entered into a lease schedule ("Lease Schedule No. 1") under the Lease Agreement No. 1 for certain equipment costing approximately $435,000 applied against the lease line, requiring payments of $14,442 per month over 36 months. In December 2016, OncoCyte entered into another lease schedule ("Lease Schedule No. 2") for certain equipment costing approximately $161,000, requiring payments of $5,342 per month over 36 months. In April 2017, OncoCyte entered into a third and final lease schedule ("Lease Schedule No. 3") for certain equipment costing approximately $285,000, requiring payments of $9,462 per month over 36 months. After this last tranche, the Lease Agreement No. 1 was closed and has no remaining financing available.

On May 11, 2017, OncoCyte entered into another Master Lease Line Agreement ("Lease Agreement No. 2") with the same finance company above and similar terms. OncoCyte may use up to $900,000 for purchases of equipment financed under Lease Agreement No. 2 through October 28, 2018.

On July 2, 2018, OncoCyte entered into a lease schedule under the Lease Agreement No. 2 for certain equipment costing approximately $209,000, requiring payments of $6,709 per month over 36 months, and a $116,000 prepaid maintenance contract for the duration of the lease of the equipment requiring 12 monthly payments of $10,238, including imputed interest. After the financing of this equipment and the prepaid maintenance contract, there was approximately $502,000 of remaining financing available under Lease Agreement No. 2 as of December 31, 2018.

OncoCyte accounts for these leases as capital leases in accordance with ASC 840, *Leases*, due to the net present value of the payments under the leases approximating the fair value of the equipment at inception of the leases. The payments under the lease schedules will be amortized to capital lease obligations and interest expense using the interest method at an imputed rate of approximately 10% per annum.

Future minimum annual lease payments under Lease Agreement No.'s 1 and 2 above for the years ending after December 31, 2018 are as follows (in thousands):

Year Ending December 31,	**Capital Lease Payments**
2019	$ 420
2020	140
2021	60
Total minimum lease payments	620
Less amounts representing interest	(48)
Present value of net minimum lease payments	$ 572

Wistar License Agreement

OncoCyte has entered into a License Agreement with The Wistar Institute of Anatomy and Biology ("Wistar") that entitles OncoCyte to use certain patents, know-how and data belonging to Wistar.

Under the License Agreement, OncoCyte has obtained an exclusive, worldwide license under certain patents, and under certain know-how and data ("Technical Information") belonging to Wistar, for use in the field of molecular diagnostics for lung cancer, including, but not limited to confirmatory, companion and recurrence diagnostics for any type of lung cancer with detection through whole blood, fractionated blood, plasma, serum and/or other biological samples. OncoCyte has the right to grant sublicenses of the licensed patents and Technical Information subject to certain conditions.

OncoCyte paid Wistar an initial license fee and will pay Wistar royalties on "net sales" of "licensed products," as such terms are defined in the License Agreement. The royalty rates will range from 3% to 5% depending upon the amount of cumulative net sales. The amount of royalties payable to Wistar will be reduced by the amount of any royalties that OncoCyte must pay to any third parties on the sale of the licensed products, but subject to a maximum reduction of 50%. The obligation to pay royalties to Wistar will terminate on a licensed product by-licensed product and country-by-country basis until the later of (i) the date a valid claim of a licensed patent covering the licensed product no longer exists, or (ii) the tenth (10th) anniversary of the first commercial sale of the licensed product in each country.

OncoCyte will pay Wistar a minimum annual royalty each year, which in each case will be credited against total royalties due during the year in which the minimum royalty is paid. OncoCyte will also be obligated to pay Wistar an annual license maintenance fee in the mid-five figures.

OncoCyte will also pay Wistar a portion of any non-royalty sublicensing income that OncoCyte may receive from any sub-licensee. Non-royalty sublicensing income will include any consideration received from a sub-licensee for granting the sublicense, but excluding royalties, the fair market value of any equity or debt securities sold to a sub-licensee, and any payments received from a sub-licensee for any related research conducted by OncoCyte for the sub-licensee.

OncoCyte also will pay Wistar (a) milestone payments upon the occurrence of certain milestone events in the development and commercialization of a licensed product, and (b) all past or ongoing costs incurred or to be incurred by Wistar, including government fees and attorneys' fees, in the course of prosecuting the licensed patents.

OncoCyte has agreed to use commercially reasonable diligent efforts, directly or through sub-licensees, to develop and commercialize licensed products. OncoCyte has agreed that it or a sub-licensee will commence commercial sale of a licensed product by a specified date. If sales of a licensed product do not commence by the specified date, OncoCyte may purchase up to three one-year extensions of the deadline by paying Wistar a designated fee for the applicable extension. OncoCyte has agreed to purchase additional extensions.

OncoCyte has agreed to indemnify Wistar and its trustees, managers, officers, agents, employees, faculty, affiliated investigators, personnel and staff from and against certain claims and liabilities related to the License Agreement and development, manufacture and sale of licensed products, excluding liabilities that result from or arise out of an indemnified party's gross negligence or willful misconduct.

Wistar has the right to terminate the License Agreement, subject to certain notice and cure periods and *force majeure* delays in certain cases, if any of the following occur: (a) OncoCyte fails to pay any amount payable to Wistar; (b) OncoCyte materially breaches any covenant or agreement or any continuing representation or warranty contained in the License Agreement; (c) OncoCyte becomes subject to certain bankruptcy or insolvency events, (d) OncoCyte dissolves or ceases operations, (e) OncoCyte or any of its affiliates or sub-licensees or affiliates of any our sub-licensees challenges the validity, patentability, scope, construction, enforceability, non-infringement, or Wistar's ownership of any issued patent comprising the licensed patents, or assists any third party in any such challenge; or (f) OncoCyte fails to fulfill its product development and commercialization diligence obligations and related performance milestones.

OncoCyte may terminate the License Agreement, with or without cause, upon the passage of a specified period of time after giving Wistar written notice of termination.

Litigation – General

OncoCyte will be subject to various claims and contingencies in the ordinary course of its business, including those related to litigation, business transactions, employee-related matters, and other matters. When OncoCyte is aware of a claim or potential claim, it assesses the likelihood of any loss or exposure. If it is probable that a loss will result and the amount of the loss can be reasonably estimated, OncoCyte will record a liability for the loss. If the loss is not probable or the amount of the loss cannot be reasonably estimated, OncoCyte discloses the claim if the likelihood of a potential loss is reasonably possible and the amount involved could be material (see Note 10).

Tax Filings

OncoCyte tax filings are subject to audit by taxing authorities in jurisdictions where it conducts business. These audits may result in assessments of additional taxes that are subsequently resolved with the authorities or potentially through the courts. Management believes OncoCyte has adequately provided for any ultimate amounts that are likely to result from these audits; however, final assessments, if any, could be significantly different than the amounts recorded in the financial statements.

Employment Contracts

OncoCyte has entered into employment contracts with certain executive officers. Under the provisions of the contracts, OncoCyte may be required to incur severance obligations for matters relating to changes in control, as defined, and involuntary terminations.

Indemnification

In the normal course of business, OncoCyte may provide indemnification of varying scope under OncoCyte's agreements with other companies or consultants, typically OncoCyte's clinical research organizations, investigators, clinical sites, suppliers and others. Pursuant to these agreements, OncoCyte will generally agree to indemnify, hold harmless, and reimburse the indemnified parties for losses and expenses suffered or incurred by the indemnified parties arising from claims of third parties in connection with the use or testing of OncoCyte's diagnostic tests. Indemnification provisions could also cover third party infringement claims with respect to patent rights, copyrights, or other intellectual property pertaining to OncoCyte's diagnostic tests. The term of these indemnification agreements will generally continue in effect after the termination or expiration of the particular research, development, services, or license agreement to which they relate. The potential future payments OncoCyte could be required to make under these indemnification agreements will generally not be subject to any specified maximum amounts. Historically, OncoCyte has not been subject to any claims or demands for indemnification. OncoCyte also maintains various liability insurance policies that limit OncoCyte's financial exposure. As a result, OncoCyte management believes that the fair value of these indemnification agreements is minimal. Accordingly, OncoCyte has not recorded any liabilities for these agreements as of December 31, 2018 and 2017.

10. Subsequent Events

During February 2019, OncoCyte sold 10,733,334 shares of its common stock, for $37.4 million of net proceeds after the payment of underwriting fees and estimated offering expenses, through an underwritten public offering.

During February 2019, OncoCyte received $0.9 million in proceeds from exercise of stock options to purchase 575,000 shares of OncoCyte common stock.

On February 15, 2019, OncoCyte paid the $2.1 million owed to BioTime for prior services provided under the Shared Facilities Agreement (see Note 4).

In February 2019, following the announcement of OncoCyte's public offering, OncoCyte received a letter from Chardan Capital Markets, LLC ("Chardan") claiming entitlement to certain fees pursuant to an engagement letter unrelated to the public offering. OncoCyte believes Chardan's claims are without merit and intends to vigorously defend all claims asserted. It is not possible at this time to assess whether the outcome of this matter will have a material adverse effect on OncoCyte's results of operations, cash flows or financial position.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

Not applicable.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

It is management's responsibility to establish and maintain adequate internal control over all financial reporting pursuant to Rule 13a-15 under the Exchange Act. Our management, including our principal executive officer and our principal financial officer, have reviewed and evaluated the effectiveness of our disclosure controls and procedures as of the end of our fourth quarter. Following this review and evaluation, management collectively determined that our disclosure controls and procedures are effective to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act (i) is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms; and (ii) is accumulated and communicated to management, including our chief executive officer and our chief financial officer, as appropriate to allow timely decisions regarding required disclosure.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the fourth quarter our fiscal year ended December 31, 2018 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting, as defined in Exchange Act Rule 13a-15(f), is a process designed by, or under the supervision of, our principal executive officer, our principal operations officer, and our principal financial officer, and effected by our Board of Directors, management, and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets;

Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and

Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2018, based on criteria established in the 2013 Internal Control - Integrated Framework issued by COSO. Based on this assessment, management believes that, as of that date, our internal control over financial reporting was effective.

Item 9B. Other Information

None

PART III

Item10. Directors, Executive Officers, and Corporate Governance

Information about each of our directors and each nominee for election as a director is contained under the caption "Election of Directors" in our Proxy Statement for our 2019 Annual Meeting of Shareholders and is incorporated herein by reference. Information about our executive officers, and committees of the Board of Directors, reported under the caption "Corporate Governance," in our Proxy Statement for our 2019 Annual Meeting of Shareholders is incorporated herein by reference.

We have a written Code of Business Conduct and Ethics ("Code of Ethics") that applies to our principal executive officer, our principal financial officer and accounting officer, our other executive officers, our other employees, and our directors. The purpose of the Code of Ethics is to deter wrongdoing and to promote (i) honest and ethical conduct, including the ethical handling of actual or apparent conflicts of interest between personal and professional relationships; (ii) full, fair, accurate, timely, and understandable disclosure in reports and documents that we file with or submit to the SEC and in our other public communications; (iii) compliance with applicable governmental rules and regulations; (iv) prompt internal reporting of violations of the Code of Ethics to an appropriate person or persons identified in the Code; and (v) accountability for adherence to the Code. A copy of our Code of Ethics has been posted on our internet website and can be found at *www.oncocyte.com*. If we amend or waive a provision of our Code of Ethics that applies to our chief executive officer or chief financial officer, we will post the amended Code of Ethics or information about the waiver on our internet website.

Information about our compliance with Section 16(a) of the Securities Exchange Act of 1934 reported under the caption "Compliance with Section 16(a) of the Securities Exchange Act of 1934" in our Proxy Statement for our 2019 Annual Meeting of Shareholders is incorporated herein by reference.

Item 11. Executive Compensation

Information about compensation of our executive officers reported under the caption "Executive Compensation," and information about compensation of directors reported under the caption "Director Compensation," in our Proxy Statement for our 2019 Annual Meeting of Shareholders is incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management, and Related Stockholder Matters

Information on the number of common shares of OncoCyte beneficially owned by each shareholder known by us to be the beneficial owner of 5% or more of our common shares, and by each director and named executive officer, and by all directors and named executive officers as a group, contained under the caption “Principal Shareholders” in our Proxy Statement for our 2019 Annual Meeting of Shareholders, is incorporated herein by reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence

Information about transactions with related persons; review, and approval or ratification of transactions with related persons reported under the caption “Principal Shareholders,” and information about director independence reported under the caption “Election of Directors,” in our Proxy Statement for our 2019 Annual Meeting of Shareholders is incorporated herein by reference.

Item 14. Principal Accounting Fees and Services

Information about our Audit Committee’s pre-approval policy for audit services, and information on our principal accounting fees and services reported under the caption “Ratification of the Selection of Our Independent Auditors” in our Proxy Statement for our 2019 Annual Meeting of Shareholders is incorporated herein by reference.

PART IV

Item 15. Exhibits, Financial Statement Schedules

(a-1) Financial Statements.

The following financial statements of OncoCyte Corporation are filed in the Form 10-K:

Balance Sheets

Statements of Operations

Statements of Comprehensive Loss

Statements of Shareholders' Equity

Statements of Cash Flows

Exhibit Numbers	**Exhibit Description**
3.1	Articles of Incorporation with all amendments (Incorporated by reference to OncoCyte Corporation's Form 8-K filed with the Securities and Exchange Commission on August 29, 2018)
3.2	By-Laws, as amended (Incorporated by reference to OncoCyte Corporation's Form 10-Q filed with the Securities and Exchange Commission on August 14, 2018.)
4.1	Specimen of Common Stock Certificate (Incorporated by reference to OncoCyte Corporation's Form 10 12(b) filed with the Securities and Exchange Commission on November 23, 2015)
4.2	Form of August 2016 Warrant (Incorporated by reference to OncoCyte Corporation's Current Report on Form 8-K filed with the Securities and Exchange Commission on August 29, 2016)
4.3	Form of 2017 Warrant, Exercise Price $3.25 (Incorporated by reference to OncoCyte Corporation's Annual Report on Form 10-K filed with the Securities and Exchange Commission on February 27, 2017)
4.4	Form of 2017 Warrant, Exercise Price $5.50 (Incorporated by reference to OncoCyte Corporation's Annual Report on Form 10-K filed with the Securities and Exchange Commission on February 27, 2017)

4.5	Silicon Valley Bank Warrant (Incorporated by reference to OncoCyte Corporation's Annual Report on Form 10-K filed with the Securities and Exchange Commission on February 27, 2017)
4.6	Form of July 2017 Warrant, Exercise Price $5.50; five-year term (Incorporated by reference to OncoCyte Corporation's Current Report on Form 8-K filed with the Securities and Exchange Commission on July 26, 2017)
4.7	Form of July 2017 Warrant, Exercise Price $3.25, five-year term (Incorporated by reference to OncoCyte Corporation's Current Report on Form 8-K filed with the Securities and Exchange Commission on July 26, 2017)
4.8	Form of July 2017 Warrant, Exercise Price $3.25, two-year term (Incorporated by reference to OncoCyte Corporation's Current Report on Form 8-K filed with the Securities and Exchange Commission on July 26, 2017)
4.9	Form of July 2017 Warrant, Exercise Price $5.50, two-year term (Incorporated by reference to OncoCyte Corporation's Current Report on Form 8-K filed with the Securities and Exchange Commission on July 26, 2017)
4.10	Form of July 2018 Warrant (Incorporated by reference to OncoCyte Corporation's Current Report on Form 8-K filed with the Securities and Exchange Commission on August 1, 2018)

10.1	Shared Facilities Agreement, dated October 8, 2009 between OncoCyte Corporation and BioTime, Inc. (Incorporated by reference to OncoCyte Corporation's Form 10 12(b) filed with the Securities and Exchange Commission on November 23, 2015)
10.2	Form of Director/Consultant Option Agreement (Incorporated by reference to OncoCyte Corporation's Form 10 12(b) filed with the Securities and Exchange Commission on November 23, 2015)
10.3	Form of Employee Incentive Stock Option Agreement (Incorporated by reference to OncoCyte Corporation's Form 10 12(b) filed with the Securities and Exchange Commission on November 23, 2015)
10.4	Employment Agreement, dated June 15, 2015, between OncoCyte Corporation and William Annett (Incorporated by reference to OncoCyte Corporation's Form 10 12(b) filed with the Securities and Exchange Commission on November 23, 2015)
10.5	Registration Rights Agreement dated October 15, 2009 (Incorporated by reference to OncoCyte Corporation's Form 10 12(b) filed with the Securities and Exchange Commission on November 23, 2015)
10.6	Amendment of Registration Rights Agreement, dated August 23, 2011 (Incorporated by reference to OncoCyte Corporation's Form 10 12(b) filed with the Securities and Exchange Commission on November 23, 2015)
10.7	Second Amendment of Registration Rights Agreement, dated May 8, 2015 (Incorporated by reference to OncoCyte Corporation's Form 10 12(b) filed with the Securities and Exchange Commission on November 23, 2015)
10.8	Third Amendment to Registration Rights Agreement, dated November 16, 2015 (Incorporated by reference to OncoCyte Corporation's Form 10 12(b) A-1 filed with the Securities and Exchange Commission on December 29, 2015)
10.9	License Agreement, dated January 22, 2016, between OncoCyte Corporation and The Wistar Institute of Anatomy and Biology (Portions of this exhibit have been omitted pursuant to a request for confidential treatment) (Incorporated by reference to OncoCyte Corporation's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 30, 2016)
10.10	First Amendment to License Agreement, dated January 25, 2016, between OncoCyte Corporation and The Wistar Institute of Anatomy and Biology (Incorporated by reference to OncoCyte Corporation's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 30, 2016)
10.11	Second Amendment to License Agreement, dated May 27, 2016, between OncoCyte Corporation and The Wistar Institute of Anatomy and Biology (Incorporated by reference to OncoCyte Corporation's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 11, 2016)
10.12	Third Amendment to the Sponsored Research Agreement, dated December 1, 2015, between OncoCyte Corporation and The Wistar Institute of Anatomy and Biology (Incorporated by reference to OncoCyte Corporation's Form 10 12(b) A-1 filed with the Securities and Exchange Commission on December 29, 2015)
10.13	Employment Agreement, dated November 1, 2016, between OncoCyte Corporation and Lyndal Hesterberg (Incorporated by reference to OncoCyte Corporation's Annual Report on Form 10-K filed with the Securities and Exchange Commission on February 27, 2017)

10.14	Form of Warrant Exercise Agreement, dated February 17, 2017 (Incorporated by reference to OncoCyte Corporation's Current Report on Form 8-K filed with the Securities and Exchange Commission on February 24, 2017)
10.15	Form of Alternate Warrant Exercise Agreement, dated February 17, 2017 (Incorporated by reference to OncoCyte Corporation's Current Report on Form 8-K filed with the Securities and Exchange Commission on February 24, 2017)
10.16	Loan and Security Agreement, dated February 21, 2017, between OncoCyte Corporation and Silicon Valley Bank (Incorporated by reference to OncoCyte Corporation's Annual Report on Form 10-K filed with the Securities and Exchange Commission on February 27, 2017)

10.17	2017 Amendment to 2010 Stock Option Plan (Incorporated by reference to Registration Statement on Form S-8, File Number 333-219109 filed with the Securities and Exchange Commission on June 30, 2017)
10.18	Form of July 2017 Warrant Exercise Agreement, dated July 21, 2017 (July 2017 Warrant for 100% of shares received on exercise of Original Warrant, at $5.50 exercise price with five-year term) (Incorporated by reference to OncoCyte Corporation's Current Report on Form 8-K filed with the Securities and Exchange Commission on July 26, 2017)
10.19	Form of July 2017 Warrant Exercise Agreement, dated July 21, 2017 (July 2017 Warrant for 50% of shares received on exercise of Original Warrant, at $3.25 exercise price with five-year term) (Incorporated by reference to OncoCyte Corporation's Current Report on Form 8-K filed with the Securities and Exchange Commission on July 26, 2017)
10.20	Form of July 2017 Warrant Exercise Agreement, dated July 21, 2017 (July 2017 Warrant for 50% of shares received on exercise of Original Warrant, at $3.25 exercise price with two-year term, and July 2017 Warrant for 50% of shares received on exercise of Original Warrant, at $5.50 exercise price with two-year term) (Incorporated by reference to OncoCyte Corporation's Current Report on Form 8-K filed with the Securities and Exchange Commission on July 26, 2017)
10.21	Employment Agreement, dated November 15, 2017, between OncoCyte Corporation and Mitchell Levine (Incorporated by reference to OncoCyte Corporation's Annual Report on Form 10-K filed with the Securities and Exchange Commission on April 2, 2018)
10.22	Securities Purchase Agreement, dated March 28, 2018 (Incorporated by reference to OncoCyte Corporation's Current Report on Form 8-K filed with the Securities and Exchange Commission on March 29, 2018)
10.23	Engagement Agreement, dated July 26, 2018, by and between OncoCyte Corporation and Chardan Capital Markets, LLC (Incorporated by reference to OncoCyte Corporation's Current Report on Form 8-K filed with the Securities and Exchange Commission on August 1, 2018)
10.24	Form of Securities Purchase Agreement dated July 26, 2018, by and among OncoCyte Corporation and the investors signatory thereto (Incorporated by reference to OncoCyte Corporation's Current Report on Form 8-K filed with the Securities and Exchange Commission on August 1, 2018)
10.25	Employment Agreement, dated August 6, 2018, between OncoCyte Corporation and Albert P. Parker (Incorporated by reference to OncoCyte Corporation's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on November 13, 2018)
10.26	Separation Agreement, dated January 22, 2019, between OncoCyte Corporation and Kristine Mechem*
23.1	Consent of OUM & Co. LLP *
31	Rule 13a-14(a)/15d-14(a) Certification *
32	Section 1350 Certification *

101	Interactive Data Files *
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema
101.CAL	XBRL Taxonomy Extension Calculation Linkbase
101.DEF	XBRL Taxonomy Extension Definition Document
101.LAB	XBRL Taxonomy Extension Label Linkbase
101.PRE	XBRL Taxonomy Extension Presentation Linkbase

Item 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized on the 1st day of April 2019.

ONCOCYTE CORPORATION

By: */s/ William Annett*
William Annett
President and Chief Executive Officer

Signature	Title	Date
/s/ William Annett WILLIAM ANNETT	President and Chief Executive Officer and Director (Principal Executive Officer)	April 1, 2019
/s/ Mitchell Levine MITCHELL LEVINE	Chief Financial Officer (Principal Financial and Accounting Officer)	April 1, 2019
/s/ Ronald Andrews Ronald Andrews	Director	April 1, 2019
/s/ Andrew Arno ANDREW ARNO	Director	April 1, 2019
/s/ Alfred D. Kingsley ALFRED D. KINGSLEY	Director	April 1, 2019
/s/ Andrew Last ANDREW LAST	Director	April 1, 2019
/s/ Aditya Mohanty ADITYA MOHANTY	Director	April 1, 2019
/s/ Cavan Redmond CAVAN REDMOND	Director	April 1, 2019