OncoCyte Corp
Form 10-K
April 02, 2018

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

FORM 10-K

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

For the fiscal year ended December 31, 2017

OR

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

For the transition period from_____ to _____

Commission file number 1-37648

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

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

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

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

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

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

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

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

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

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

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

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

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

Large accelerated filer		Accelerated filer
Non-accelerated filer	(Do not check if a smaller reporting company)	Smaller reporting company
		Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided to Section 13(a) of the Exchange Act.

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

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

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

DOCUMENTS INCORPORATED BY REFERENCE

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

OncoCyte Corporation
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PART I

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

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

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

INDUSTRY AND MARKET DATA

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

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

PRELIMINARY NOTE ABOUT OWNERSHIP OF OUR COMMON STOCK

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

REVERSE STOCK SPLIT

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

Item 1. Business

Overview

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

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

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

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

- Improve health outcomes through avoidance of unnecessary invasive procedures

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

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

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

Business Strategy

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

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

Graphic 1

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

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

·Diagnostic tests to prioritize in our development program;

·Diagnostic tests we should market ourselves;

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

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

Additional Information

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

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

·Reduced disclosure about our executive compensation arrangements;

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

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

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

DetermaVu™ Lung Cancer Diagnostic Test

Clinical Trials

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

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

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

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

Graphic 2 Wistar 2015 Study

Graphic 3 Wistar 2016 Study

DetermaVu™ R&D Validation Study

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

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

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Graphic 4 OncoCyte 2017 Results

Graphic 5

Clinical Validation Study

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

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

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

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

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

Current Standard of Care

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

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

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

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

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

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

5 Year Survival Rates by Indication
Graphic 6 1975 to 2007

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

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

·0.5 to 1% mortality and

·4-20% major complications.

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

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

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

Graphic 7 LungRADs Guidelines

Need and Market for DetermaVu™

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

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

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

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Graphic 8 Nodule Size by Prevalence

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

Market Opportunity for Lung Diagnostics

Graphic 9

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

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

Graphic 10

Graphic 11 Lung Nodule Standard of Care

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

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

Breast Cancer Diagnostic Tests

Breast Cancer Diagnostic Clinical Trials

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

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

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

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

Current Standard of Care

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

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

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

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Graphic 12 Breast Cancer Screening Protocol

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

Need and Market for a Breast Cancer Liquid Biopsy

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

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

Graphic 13 Market Opportunity for Breast Cancer Diagnostic Tests

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Bladder Cancer Diagnostic Tests

Bladder Cancer Diagnostic Test Clinical Trials

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

Current Standard of Care

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

Graphic 14 Current Bladder Diagnostic Protocol

Need and Market for a Bladder Cancer Liquid Biopsy

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

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

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Graphic 15 Bladder Diagnostic Market Opportunity

TAM numbers based on company estimates and secondary data

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

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

Future Diagnostic Development Milestones

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

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

- Finish Clinical validation of DetermaVu™;

- Launch DetermaVu™

- Start clinical utility studies of DetermaVu™;

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

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

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Achieving the commercialization and reimbursement milestones will require expanding our commercial team to include sales, marketing, market access, customer support and medical affairs. In September of 2017, we started the process of building our sales team by hiring a Vice President of Sales. We will need to build a sales force along with marketing, market access, customer support and medical affairs teams to market DetermaVu™, gain reimbursement coverage, and support the ordering of DetermaVu™ tests.

About Diagnostic Tests

Based on substantial unmet needs, large markets, and data generated thus far from patient serum (blood) or urine screening, we have focused our efforts on biomarkers associated with lung, breast and bladder cancers. The DetermaVu™ lung cancer development program is our highest priority. Our approach is based on utilizing detectable amounts of cancer-associated biomarkers in patients with early-stage disease. Our identification of certain combinations of biomarkers in lung, breast and bladder cancer as well as clinician and payer feedback on unmet need has led us to identify promising initial indications and target analytes.

The relative ease of administering a liquid biopsy diagnostic and cost savings due to the elimination of unnecessary costlier and invasive surgical biopsy procedures, we believe, 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 procedures to detect lung, breast or bladder cancer. If successful, our tests will initially reduce diagnosis uncertainty and eliminate unnecessary down-stream procedures resulting from indeterminate low dose computed tomography ("LDCT"), mammography, or cytology results.

We intend to initially develop and market a lung cancer diagnostic test in the United States before seeking regulatory approvals required to market the diagnostic test in other countries. DetermaVu™ is being developed as a blood confirmatory test for cancer biomarkers, which will be used in conjunction with LDCT for patients with indeterminate pulmonary nodules to help clinicians triage patients for follow-up procedures. DetermaVu™ will be regulated under the Clinical Laboratory Improvements Amendment ("CLIA") as a laboratory diagnostic test or "LDT". We may also develop in vitro diagnostic tests ("IVDs") 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.

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 four other states as proof of quality and good standing in order to do accept diagnostic test samples from patients in states outside of California. Five other states, Florida, Maryland, Rhode Island, Pennsylvania and New York, require out-of-state diagnostic laboratories to obtain their individual state clinical laboratory licenses or permits in order to perform diagnostic tests for patients residing in those states. We have already obtained the Pennsylvania state clinical laboratory permit and plans on obtaining the balance of the other state licenses or permits by year end.

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 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 Low Dose Computed Tomography (LDCT) for high risk patients who meet the guideline requirements. A diagnostic could be developed that could be used as an alternative to the annual LDCTs.

- Confirmatory diagnostics could be used in conjunction with a current standard of care screening procedure. For example, our lung confirmatory diagnostic would 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 procedures to determine the presence of cancer. In the case of a suspicious result, additional procedures 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;

- 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 follow-up imaging.

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Currently we are focused on diagnostics to detect early stage cancer due to the market opportunity associated with these types of diagnostics. Piper Jaffrey estimated that the domestic revenue opportunity for initial diagnosis tests is $15 billion.

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, like the recurrence risk predictor market, have both high barriers to entry and a first entrant advantage. 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. In the case of our confirmatory diagnostics, the tests 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 cancer clinicians is needed to determine whether the intended test is likely to be accepted and used by physicians in the applicable field of oncology.

Graphic 16 Types of Oncology Diagnostics

We believe that competitors that launch a "me too" product, a product that is comparable in predictive abilities with a product already on the market, will not be able to significantly erode the market share of the established product. Industry analogues of this are Genomic Health's Oncotype Dx and Veractye's Afirma diagnostic tests. Genomic Health continues to maintain 90% share for its Oncotype Dx breast test, with three competitors in the market; while Afirma appears to have about an 80% market share for its thyroid test. See Graphic 16.

Technology for Diagnostic Tests

For our liquid biopsy tests for lung, breast and bladder cancer, we used the same general strategy for the identification of mRNA, miRNA or protein biomarkers, and the development of an algorithm or gene expression classifier to interpret the differential marker expression. Our goal is to develop tests that yield a highly accurate benign call to allow clinicians to triage patients for follow-up procedures. Ultimately our research may rely on only one type of biomarker in a specific indication. In the case of lung cancer, DetermaVu™ is being developed on mRNA biomarkers only. In the case of breast cancer, our study has evolved from the use of RNA markers to an immunoassay directed to proteins only. See Graphic 17.

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Graphic 17

In the case of our lung cancer test, blood samples were collected by venipuncture into tubes and total RNA was isolated. mRNA biomarkers were identified for screening. The best performing mRNA biomarkers will be transferred to the commercial diagnostic testing platform we will use in our CLIA laboratory. The optimal combination and final panel of mRNA or miRNA biomarkers together with potential protein-based tests will be determined using bioinformatics and algorithm development strategies. The optimal algorithm will be selected that yields the best discrimination between malignant and benign. The performance of the final biomarker panel and classifier will be tested in a clinical validation study using an independent set of samples to determine performance characteristics of the test.

Biomarkers are important to the diagnosis of cancer in that their presence or absence in a specific patient sample drives the sensitivity and specificity scores of a molecular diagnostic. For example, if a specific mRNA is only seen expressed in patients with cancer, it can be used to help make a malignant call on that sample. The use of biomarkers with an algorithm can help ensure that the sensitivity score, which is a measure of correcting identifying the disease is sufficiently high to reduce false negative, ensuring that patients with the disease are correctly diagnosed. At the same time, biomarkers can be used to hone the specificity measure, which is a measure of correctly identifying patients without the disease, which reduces the number of patients who are unnecessarily referred to biopsy.

The Development Pathway

Our diagnostic tests for cancer will, in general, each go through four stages of development prior to commercialization: Research, Assay Development, R&D Validation Studies, 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 product, depending on the circumstances and requirements for that individual test system. A fifth stage, Clinical Utility Studies will also be conducted after commencement of the marketing of a diagnostic test. See Graphic 18.

Graphic 18 Diagnostic Development Stages

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1) Research: The first stage of the development of a CLIA LDT is the research stage. In the research stage of a molecular diagnostic, biological markers are analyzed to determine if specific markers are differentially expressed in certain diseases. We are developing blood and urine tests that differentiate malignant patient samples from benign patient samples by looking at differences in the amount of specific analytes expressed in whole blood or urine from cancer patients compared to patients who are cancer free. For our lung and bladder cancer tests the analytes we are looking at are specific mRNA and/or miRNA expressed in whole blood or urine; while for our breast cancer test we are looking at differentially expressing proteins. The objective of this phase of the development process is to delineate promising biomarkers, for further development and verification, before proceeding to validation work.

2) 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.

3) R&D Validation: The third stage is R&D Validation. There are three areas of studies that are undertaken during R&D Validation. These studies are carried out in our R&D laboratories.

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 urine samples from patients, the handling and storage of those samples, and the manner in which the samples are shipped to OncoCyte's 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, at which point the results will change and 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 product. In the case of the lung cancer test, 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.

Analytical Validation Studies. The last area of study in R&D Validation is Analytical Validation. The studies required for Analytical Validation have been established in the CLSI (Clinical Lab Standards Institute) Guidelines. These guidelines cover the testing for such matters as limits of quantitation, precision, reproducibility, and interfering substances. When completed, these Analytical Validation studies establish the performance characteristics of the assay system for subsequent clinical validation in the CLIA laboratory.

4) Clinical Validation: The fourth stage is Clinical Validation. This stage has two distinct sets of studies within it, that are carried out in our CLIA laboratory.

CLIA Lab Validation: In the CLIA Lab Validation Study, the 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 the CLIA lab, run by CLIA staff and on certified instrumentation, provides the same results on clinical samples as those obtained in the R&D lab.

CLIA Lab Clinical Validation. The second kind of study performed in Clinical Validation is the CLIA Lab Clinical Validation. In this study, in general, additional new clinical samples will be collected and sent blinded to the CLIA lab. The CLIA lab will perform assays on these blinded samples and the performance of the full assay system will be assessed against clinical diagnosis.

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5) Clinical Utility: The final phase of the diagnostic pathway occurs after the diagnostic test has been launched and consists of carrying out one or more Clinical Utility Studies. These studies are important for driving adoption 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.

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, 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 (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 will 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 will 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 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.

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.

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.

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 have 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.

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Manufacturing

Facilities Required

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 OncoCyte use of space for a CLIA diagnostic laboratory.

Raw Materials

The processing of our diagnostics will use commercially available reagents that are sourced by one or more manufacturers of molecular diagnostic analyzers, prep stations and reagents. An interruption in supply or quality control issues with supplies such as reagents could require us to find a different source of supply of both the reagents and the analytic equipment that we will be using in our CLIA laboratory. An interruption in supply of reagents could cause us to suspend or limit laboratory operations, and a change in analytic equipment could require us to re-establish various testing procedures, which also could disrupt our operations. We have encountered issues with reagents used in the diagnostic testing platform that we acquired for the development of our diagnostic tests, and we are evaluating alternative diagnostic testing platforms, pending a resolution of the reagent issues with the analytic platform that we initially used.

Marketing

Following clinical validation of a diagnostic test, we intend to market our diagnostic test directly to health care providers working in the areas of lung cancer and in other areas of cancer where we will be developing molecular diagnostics. These health care providers will collect blood samples or send patients to laboratories to have blood or urine 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 Alameda California 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 will ramp up sales and marketing teams over the next two to three years for our first product. Over time, we will continue to grow our sales, market access and marketing organizations to increase the awareness and utilization of our diagnostic tests and to prepare for additional diagnostic test launches. The focus of our marketing organization will be to position and promote our planned lung cancer confirmatory diagnostic to the three key stakeholders: physician, patients and payers. See Graphic 19.

Graphic 19 Commercialization Strategy

We will market DetermaVu™, primarily to pulmonologists, and secondarily to radiologists and thoracic surgeons who either do the screening for lung cancer or conduct the biopsies or serial imaging procedures. See Graphic 20.

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Graphic 20 Target Markets for DetermaVu™

The focus of our physician marketing efforts will be outreach through:

- medical conferences and symposia, for which the primary conferences are Chest, American Thoracic Society and the World Conference on Lung Cancer;
- speakers bureaus; and
- peer review journal articles

We have presented data from our clinical studies at the CHEST and the American Thoracic Society (ATS) medical conferences. At ATS in May of 2017, we had a booth, clinical symposiums focused on nodule management and the role of biomarkers, and a poster presentation of our R&D validation study. In October 2017, we presented our data at the CHEST conference, where we had a booth, a clinical symposium on nodule management and the role of biomarkers, and a presentation on additional data associated with our R&D validation study. We plan to continue to present our study data in 2018 at the ATS conference and at the Chest International Conference in San Antonio, Texas. Additionally, we may elect to present data at the World Congress on Lung Cancer in Toronto, Canada.

If we are successful in developing DetermaVu™, our marketing efforts to patients will be focused on increasing the awareness of lung cancer screening through work with advocacy groups and patient outreach. Additionally, we may develop a patient assistance program to help reduce the financial burden to patients of out of pocket expenses due to lack of insurance coverage, high co-insurance payments or high deductibles.

Market Access – Reimbursement

One of the more critical functions in a diagnostic company is market access. We have a Market Access Team that develops and implements our strategy to obtain coverage and reimbursement from public and private payers. For an oncology diagnostic, one of the most critical payers is Medicare or CMS, because oncology is a cancer that typically presents in older populations. For our lung test, Medicare may cover up to 55% of the patients for whom the test is ordered. We started the Market Access Team in mid-2016 with a team leader who has over 10 years of molecular diagnostics market access and commercial operations experience.

Obtaining medical coverage generally takes twelve to sixteen months from the time that sufficient evidence is published establishing clinical utility. Medicare, both at the local and national coverage determination levels occasionally establishes coverage prior to the completion and publication of a diagnostic's clinical utility study. As a consequence, it may be possible to obtain Medicare coverage prior to the publication of our clinical utility study. A recent example of this was CMS's national coverage determination (NDC) for NGS cancer panels for off-label use. In 2017, Noridian, the Medicare administrative contractor (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. Private payors, on the other hand, require clinical utility studies to be published before providing favorable coverage decisions.

Until a new cancer diagnostic test is accepted by third party payers for reimbursement, we will have to market the test to physicians on a patient pay basis, meaning that the patient will 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 in an amount commensurate with the cost to the patient.

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Our market access strategy is based on three components: coding, coverage and reimbursement. For product coding we will launch our diagnostic with an unlisted code and seek to get a unique CPT code later. We believe that our lung cancer confirmatory diagnostic will meet the requirements of a Multi Analyte Algorithm Assay (MAAA) in that the diagnostic that we are developing will be comprised of multiple mRNA biomarkers with a gene expression classifier.

The second focus of our reimbursement strategy will be to obtain coverage by both public and commercial payors. We will first focus on receiving a Medicare coverage decision and then focus on obtaining coverage decisions for larger commercial payors, including private health insurance plans. Medicare through the MolDX program has developed clear guidelines for the level of evidence of efficacy required to be obtained through clinical trials. Our strategy is to achieve the highest level of evidence (IA) by conducting studies for clinical utility that are randomized and prospective. Additionally, our plan is to run two clinical validation studies. We took the approach of sharing our clinical protocol designs with payors, much like many therapeutic companies share their clinical utility designs with the FDA, for feedback. See Graphic 21.

Graphic 21

We previewed our clinical protocol designs with ten payers that represent over 77 million covered lives late last year 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.

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 13 patent families owned by us with claims directed to compositions of matter and methods useful for detection of breast, bladder, colon, pancreatic, ovarian, and thyroid cancers using specific biomarkers or a panel of specific biomarkers. Patents are pending in various jurisdictions, including the United States, Europe, Australia, Canada, China, Hong Kong, Japan and Republic of Korea, with projected expiration dates ranging from 2032 to 2036. Additionally, we have one issued patent in Australia, with claims directed to a method of detecting bladder cancer; and one accepted patent application in Australia, with claims directed to a method of detecting breast cancer. The issued patent will expire in 2032.

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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 in 2036. Additionally, we have obtained from Wistar an exclusive option under which we may obtain licenses to additional issued and pending patents in the field of molecular diagnostics for lung cancer. Patents covered by the exclusive option have issued in the United States and Europe and are pending in the United States, Canada and India. Those patents are projected to expire in 2028 - 2030.

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 third parties;

- 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

- 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.

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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. After March 16, 2013 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.

Third-Party Payer 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;

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- 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.

Medicare

We expect that a substantial portion of the patients for whom we will perform diagnostic tests will have Medicare as their primary medical insurance. We cannot assure that, without Medicare reimbursement our planned tests will produce sufficient revenues to enable us to reach profitability and achieve its other commercial objectives.

Clinical diagnostic laboratory tests are generally reimbursed under the Medicare Clinical Laboratory Fee Schedule ("CLFS") and reimbursement under the Medicare program for the diagnostic tests that we will offer is based on the CLFS.

Medicare has coverage policies that can be national or regional in scope. Coverage means that the test is approved as a benefit for Medicare beneficiaries. If there is no coverage, neither we nor any other party, such as a reference laboratory, may receive reimbursement from Medicare for the service.

From time to time, Congress has revised the Medicare statute and the formulas it establishes for the clinical laboratory fee schedules or 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"), enacted April 1, 2014 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.

Prices for both CDLTs and ADLTs are established using the same methodology: the law establishes that CLFS prices will be equal to the weighted median rates paid by private payors. 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 (if the list price is greater than 130% of the weighted median private payor price, CMS will recoup the difference from the laboratory through a payment claw back). It is not known at this point if the tests we are developing will be classified as CDLTs or ADLTs. The gap-fill pricing methodology for CDLTs represents a significant short-term risk because pricing under the gap-fill methodology can vary significantly.

On January 1, 2018 the new PAMA-based CLFS 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.

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 these services would often exceed the amount receivable from the patient.

Some Medicare claims may be subject to policies issued by the Medicare Administrative Contractor ("MAC") for California. CMS relies on a network of MACs to process Medicare claims, and MACs serve as the primary operational contact between the Medicare Fee-For-Service program and approximately 1.5 million health care providers enrolled in the program. The predecessor to the current California MAC, acting on behalf of many MACs, issued a Local Coverage Determination that affects coverage, coding and billing of many molecular diagnostic tests. Under this Local Coverage Determination, the MAC took the position that it would not cover any molecular diagnostic test unless the test is expressly included in a National Coverage Determination issued by CMS, or a Local Coverage Determination, or coverage article issued by the MAC. Denial of coverage for our diagnostic tests by the current California MAC, Noridian Healthcare Solutions, or reimbursement at inadequate levels, would have a material adverse impact on our business and on market acceptance of our planned diagnostic tests.

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Private and Governmental Third Party Payers

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. Where there is no coverage policy in place, we will pursue reimbursement on a case-by-case basis. 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.

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 payor 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.

Direct Billing Laws and Other State Law Restrictions on Billing for Laboratory Services

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.

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. 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.

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Our laboratory has obtained a CLIA certificate of accreditation and is also currently licensed in California and Pennsylvania. We will be required to meet laboratory licensing and other requirements under laws of Florida, Maryland, Rhode Island, and New York if we wish to receive blood or urine samples for testing from patients in those states. To maintain our current licensing, we will be subject to regular surveys and inspections that will continue to assess our compliance with program standards.

FDA Regulation of Diagnostic Tests

Our diagnostic tests will likely 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. On October 3, 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. The FDA has indicated that it does not intend to modify its policy of enforcement restraint until the draft guidance documents are finalized.

On January 13, 2017, the FDA issued a Discussion Paper on LDTs ("Discussion Paper"), which follows the FDAs late 2016 announcement that contrary to its earlier reports, it would not issue a final guidance on its proposed oversight of LDTs and allow for further public discussion on appropriate oversight. As it did in its 2014 guidance documents, the FDA continues to advocate a risk based approach to LDT oversight and proposes focusing on new and significantly modified high and moderate risk LDTs; however, new and significantly modified LDTs in certain categories would not be expected to comply with premarket review, quality systems, and registration and listing requirements unless necessary to protect public health. These exempt categories include 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. Based on the FDA's guidance in the Discussion Paper, our DetermaVu™ products will likely not require FDA filing before launch. With respect to the postmarket 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.

Based on guidance set forth in the Discussion Paper, FDA premarket review of new and significantly modified LDTs could be phased-in over four years, 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.

Failure to comply with applicable FDA regulatory requirements may trigger a range of enforcement actions by the FDA, including warning letters, civil monetary penalties, injunctions, criminal prosecution, recall or seizure, operating restrictions, partial suspension or total shutdown of operations, and denial of or challenges to applications for clearance or approval, as well as significant adverse publicity. We cannot predict the ultimate form or impact of any such FDA guidance and the potential effect on our diagnostic test services.

We cannot provide any assurance that FDA regulation, including premarket review, will not be required in the future for our diagnostic tests, whether through additional guidance or regulations issued by the FDA, new enforcement policies adopted by the FDA or new legislation enacted by Congress. It is possible that proposed legislation discussed above or other new legislation could be enacted into law, or new regulations or guidance could be issued by the FDA.

Such new legislation may result in new or increased regulatory requirements for us to continue to offer our diagnostic tests or to develop and introduce new tests or services.

If premarket review, including approval, is required, our business could be negatively affected until such review is completed and clearance to market or approval is obtained. If we are selling any of our diagnostic tests when new FDA approval requirements are implemented, we may be required to suspend sales until we obtain premarket clearance or approval. If our diagnostic tests are allowed to remain on the market but there is uncertainty about the legal status of those tests, if we are required by the FDA to label them investigational, or if labeling claims the FDA allows us to make are limited, order levels for the use of our tests may decline and reimbursement may be adversely affected.

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. See the discussion of FDA regulation of medical devices below under In Vitro Diagnostics. If premarket review is required by the FDA, there can be no assurance that our diagnostic tests will be cleared or approved on a timely basis, if at all, nor can there any be assurance that labeling claims allowed by the FDA will be consistent with our intended claims or will be adequate to support continued adoption of and reimbursement for our tests. Compliance with FDA regulations would increase the cost of conducting our business, and subject us to heightened requirements of the FDA and penalties for failure to comply with these requirements. We may also decide voluntarily to pursue FDA premarket review of our diagnostic tests if we determine that doing so would be appropriate.

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Legislative proposals addressing oversight of genetic testing and LDTs have been introduced in previous Congresses and we expect that new legislative proposals will be introduced from time to time in the future. We cannot provide any assurance that FDA regulation, including premarket review, will not be required in the future for our tests, whether through finalization of guidance issued by the FDA, new enforcement issued by the FDA, new enforcement policies adopted by the FDA or new legislation enacted by Congress. It is possible that legislation will be enacted into law or guidance could be issue by the FDA, which may result in increased regulatory burdens for us to continue to offer our tests or to develop and introduce new tests.

We cannot predict the ultimate form of any statutes, regulations or guidance and the potential impact on our existing tests, our tests in development or materials used to perform our tests. If pre market review is required, our business could be negatively impacted until such review is completed and clearance or approval is obtained, and the FDA could require that we stop selling our tests pending pre market clearance or approval. If our tests are allowed to remain on the market but there is uncertainty about the regulatory status of our tests, if they are labeled investigational by the FDA, or if labeling claims the FDA allows us to make are more limited than the claims we currently make, orders or reimbursement may decline. The regulatory review process may involve, among other things, successfully completing additional clinical trials and submitting a pre market clearance notice or filing a pre-market application with the FDA. If pre-market review is required by the FDA, there can be assurance that our tests will be cleared or approved on a timely basis, if at all, nor can there be assurance that the labeling claims cleared or approved by the FDA will be consistent with our current claims or adequate to support continued adoption of and reimbursement for out tests. Ongoing compliance with FDA regulations would increase the costs of conduction our business and could subject us to FDA inspection and regulator requirements.

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 San Francisco Bay Area based laboratory. Such laws include 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.

We will not be permitted to perform diagnostic tests at our California CLIA laboratory if our laboratory fails to comply with California standards. 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. Any such actions could materially affect our business.

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. These states require out-of-state labs to obtain their individual state clinical laboratory licenses or permits in order to perform tests for patients residing in those states. We have already obtained the Pennsylvania state clinical laboratory permit and we plan on obtaining the licenses required by Florida, Maryland, Rhode Island, and New York by the end of 2018.

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 all regulatory requirements 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.

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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.

Submission of an application is no guarantee that the CMS or FDA will find it complete and accept it for filing. If an application is accepted for filing or licensing, following the CMS or FDA's review, the CMS or FDA may grant marketing approval, request additional information or deny the application if it determines that the application does not provide an adequate basis for approval.

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 provide individuals with a greater ability to access their health information, empowering them to take a more active role in managing their health and health care. 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.

New laws governing privacy may also be adopted in the future. We will take steps to comply with all current health information privacy requirements of which we are aware and with which we must comply. However, we can provide no assurance that we will remain in compliance with diverse privacy requirements in all of the jurisdictions in which we do business. The current requirements may periodically change and could have an effect on our business operations if compliance becomes substantially more costly than under current requirements. Failure to comply with privacy requirements could result in civil or criminal penalties, which could have a materially adverse effect on our business.

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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. For further discussion of the impact of federal and state health care fraud and abuse laws and regulations on our business, see the section entitled "Risk Factors."

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 payor.

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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, 2017, we employed 16 persons on a full-time basis. Four of our full-time employees hold Ph.D. degrees in one or more fields of science.

Item1A. 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 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 flow and we expect to continue to incur losses and negative cash flows in the future. Our net losses for the years ended December 31, 2017 and 2016 were approximately $19.4 million and $11.2 million and we had an accumulated deficit of approximately $54.7 million and $35.3 million as of December 31, 2017 and 2016, respectively. 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 available-for-sale securities. Although BioTime may continue to provide administrative support to us on a reimbursable basis, there is no assurance that BioTime will 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.

We are experiencing a delay in conducting our clinical validation study of DetermaVu™.

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

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

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We do not yet know the extent to which a resolution of the issue that has caused the delay in the clinical validation study will result in additional costs to us. In addition to a loss of productivity during the period of the delay, we could incur additional quality control costs and the cost of acquiring new diagnostic testing platform equipment and reagents and training our staff in the use of the new platform. Delays in the successful completion of the clinical validation study and commercialization of DetermaVu™ could prevent us from raising, when needed, sufficient additional capital to finance the completion of development and commercial launch of DetermaVu™ or the other cancer diagnostic tests that we are developing.

If we were to determine to change diagnostic testing platforms and abandon the use of our current platform for research and development purposes and for clinical testing in our CLIA laboratory, our current diagnostic testing platform equipment could be considered an impaired asset for financial reporting purposes and we would write down the value of that equipment on our 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 will spend a substantial amount of our capital on research and development but we might not succeed in developing diagnostic tests and technologies that are useful in medicine.

- We are attempting to develop new medical diagnostic tests and technologies. The main focus of our business is on diagnostic tests for cancer. Our diagnostic tests are being developed through the use of blood and urine samples obtained in prospective and retrospective clinical trials involving humans, but none of our diagnostic tests have been used in medicine to diagnose cancer. Our technologies many not prove to be sufficiently efficacious to use in the diagnosis of cancer.

- Some of our research could also have applications in new cancer therapeutics. None of our experimental therapeutic technologies have been applied in human medicine and have only been used in laboratory studies in vitro.

- The experimentation we are doing is costly, time consuming, and uncertain as to its results. We incurred research and development expenses amounting to approximately $7.2 million and $5.7 million during years ended December 31, 2017 and 2016, respectively. Since 2011, most of our research has been devoted to the development of our lead diagnostic tests to detect lung cancer, breast cancer, and bladder cancer.

- If we are successful in developing a new technology or diagnostic test, 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.

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

- We need to successfully develop and market or license the diagnostic tests that we are developing in order to earn 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.

- Should we be able to successfully develop and market our diagnostic tests we may not be able to receive reimbursement for them from payers, such as health insurance companies, health maintenance organizations and Medicare, or any reimbursement that we receive may be lower than we anticipate.

Sales of any 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.

  - Currently there are two diagnostic tests for lung cancer and multiple diagnostic tests for bladder cancer on the market. There is one diagnostic product for breast cancer that has been approved in Europe. 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.

- There also is a risk that our competitors may succeed in developing safer, more accurate or more cost effective diagnostic tests that could render our diagnostic tests and technologies obsolete or noncompetitive.

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We may not be able to produce a high enough sensitivity to offset the availability of minimally invasive biopsies for breast cancer and this could result in an impediment to the commercialization of our planned breast cancer confirmatory test.

Very high sensitivity may be needed for our breast confirmatory test because unlike lung cancer biopsies that involve an invasive surgical procedure, breast cancer biopsies often can be performed using minimally invasive procedures that result in significantly less risk, discomfort, and cost to the patient while providing a diagnostic result that is as accurate or more accurate than our diagnostic test. As a result, physicians and patients may prefer to rely on a biopsy of a breast lesion, which may have a higher sensitivity to confirm the presence of breast cancer rather than use the blood tests that we are developing.

We will need to issue additional equity or debt securities in order to raise additional capital needed to pay 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 our diagnostic test candidates. We will need to raise additional capital to pay operating expenses until we are able to generate sufficient revenues from diagnostic test sales, royalties, and license fees, and we will need to sell additional equity or debt securities to meet those capital needs.

- Our ability to raise additional equity or debt capital will depend not only on progress made in developing our diagnostic tests, but also will depend on access to capital and conditions in the capital markets. 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 our diagnostic tests and general operations. Even if capital is available, it may not be available on terms that we or our shareholders would consider favorable.

- Sales 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 several critical technologies that have 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 patents and technology in our business.

We have limited marketing and sales resources and no distribution resources for the commercialization of any diagnostic tests that we might successfully develop.

If we are successful in developing marketable diagnostic tests, 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.

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 do not or 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.

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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 commercial activities, including marketing, market access, and sales. 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 will be 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.

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.

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.

Risks Related to Our Industry

We face certain risks arising from regulatory, legal, and economic factors that affect our business and the business of other companies engaged in the development and marketing of diagnostic tests for human diseases. Because we are a

small company without revenues and with limited capital resources, we may be less able to bear the financial impact of these risks than larger companies that have substantial income and available capital.

We may need to obtain regulatory approval of our diagnostic test candidates and laboratory facilities.

We will need to maintain certification for our diagnostic laboratory under CLIA, and under the laws and regulations of California, and in certain other states that require their own certification if we wish to receive blood or urine samples for testing from patients in those states. If we do not meet the CLIA or specific state requirements and regulations our laboratory certification may be suspended, restricted, or revoked, and we may incur substantial civil money penalties or be subject to specific corrective action plans. Any such actions could materially affect our business.

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. The need to obtain regulatory approval to market a new diagnostic test means that:

- The diagnostic tests 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.

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- We will have to obtain a CLIA certificate of registration license for our laboratory for the manufacture and use of diagnostic tests and as part of the submission, our laboratory will be inspected.

- In addition to meeting federal regulatory requirements, each state has its own laboratory certification and inspection requirements for a CLIA laboratory that must be met in order to sell diagnostic tests in the state.

- 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 CLIA certification of a new laboratory diagnostic test 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 current 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.

- CLIA licensed laboratories can lose their licenses if problems arise during a periodic inspection.

The FDA may impose additional regulations for laboratory developed tests such as the ones we are developing.

The FDA issued two draft guidance documents and a discussion paper that set forth a proposed risk-based regulatory framework that would apply varying levels of FDA oversight to LDTs such as those we are developing. If the FDA implements the regulatory measures set forth in these documents:

- We may be required to obtain pre-market clearance or approval before selling our diagnostic tests;

- As a result of required FDA pre-market review, our tests may not be cleared or approved on a timely basis, if at all;

- FDA labeling requirements may limit our claims about our diagnostic tests, which may have a negative effect on orders from physicians;

- The regulatory approval process may involve, among other things, successfully completing additional clinical trials and making a 510(k) submission, or filing a pre-market approval application with the FDA; and,

- If regulatory actions affect any of the reagents we obtain from suppliers and use in conducting our tests, our business could be adversely affected in the form of increased costs of testing or delays, limits or prohibitions on the purchase of reagents necessary to perform our testing.

If the FDA regulates LDTs such as the ones we are developing and requires that we seek pre-market approval, there is no assurance that we will be able to comply with FDA requirements.

It may take two years or more to conduct the clinical studies and trials necessary to obtain pre-market approval from the FDA. Even if our clinical trials are completed as planned, we cannot be certain that the results will support our test claims or that the FDA will agree with our conclusions regarding our test results. Success in early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the later trials will replicate the results of prior clinical trials and studies. If we are required to conduct pre-market clinical trials, delays in the commencement

or completion of clinical testing could significantly increase our test development costs and delay commercialization. Many of the factors that may cause or lead to a delay in the commencement or completion of clinical trials may also ultimately lead to delay or denial of regulatory clearance or approval. The clinical trial process may fail to demonstrate that our tests are effective for the proposed indicated uses, which could cause us to abandon a test candidate and may delay development of other tests.

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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 Jan. 1, 2016 and ending on Dec. 31, 2019. The extension of the moratorium was retroactive to Jan. 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.

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.

We will depend on Medicare and a limited number of private payers for a significant portion of our revenues, and our revenues could decline if these payers fail to provide timely and adequate payment for our diagnostic tests.

We expect that a substantial portion of the patients for whom we will perform diagnostic tests will have Medicare as their primary medical insurance. Even if our planned tests are otherwise successful, without Medicare reimbursement we might not be able to generate sufficient revenues to enable us to reach profitability and achieve our other commercial objectives. It generally takes two to three years to obtain Medicare coverage and other third party reimbursement approvals for a new LDT and there can be no assurance we will obtain such approvals for any of the cancer diagnostics that we are developing. Until a new cancer diagnostic test is accepted by third party payers for reimbursement, we will have to market the test to physicians on a patient pay basis. In the absence of reimbursement by Medicare, patients who would be candidates for the use of our diagnostic tests and who rely on Medicare coverage 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 in an amount commensurate with the cost to the patient.

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Medicare and other third-party payers may change their coverage policies or cancel future contracts with us at any time; review and adjust the rate of reimbursement; or stop paying for our tests altogether, which would reduce our total revenues. Payers have increased their efforts to control the cost, utilization, and delivery of health care services, and have undertaken measures to reduce payment rates for and decrease utilization of clinical laboratory testing. Because of the cost-trimming trends, any third-party payers that will cover and provide reimbursement for our diagnostic tests may suspend, revoke or discontinue coverage at any time, or may reduce the reimbursement rates payable to us. Any such action could have a negative impact on our revenues, which may have a material adverse effect on our financial condition, results of operations and cash flows.

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.

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Long payment cycles of Medicare, Medicaid and/or other third-party payors, 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.

We are subject to federal and state healthcare fraud and abuse laws and regulations and could face substantial penalties if we are unable to fully comply with such laws.

We are subject to health care fraud and abuse regulation and enforcement by both the federal government and the states in which we conduct our business. These health care laws and regulations include the following:

·The federal Anti-Kickback Statute;

·The federal physician self-referral prohibition, commonly known as the Stark Law;

·The federal false claims and civil monetary penalties laws;

· The federal Physician Payment Sunshine Act requirements under the ACA; and

· State law equivalents of each of the federal laws enumerated above.

Any action brought against us for violation of these 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, among others, administrative, civil and criminal penalties, damages and fines, and/or exclusion from participation in Medicare, Medicaid programs, including the California Medical Assistance Program (Medi-Cal—the California Medicaid program) or other state or federal health care programs. Additionally, we could be required to refund payments received by us, and we could be required to curtail or cease our operations.

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Risks Related to Intellectual Property

If we are unable to obtain and enforce patents and to protect our trade secrets, others could use our technology to compete with us, which could limit opportunities for us to generate revenues by licensing our technology and selling diagnostic tests.

- Our success will depend in part on our ability to obtain and enforce patents and maintain trade secrets in the United States and in other countries. If we are unsuccessful in obtaining and enforcing patents, our competitors could use our technology and create diagnostic tests that compete with our diagnostic tests, without paying license fees or royalties to us.

- The preparation, filing, and prosecution of patent applications can be costly and time consuming. Our limited financial resources may not permit us to pursue patent protection of all of our technology and diagnostic tests throughout the world.

- Even if we are able to obtain issued patents covering our technology or diagnostic tests, we may have to incur substantial legal fees and other expenses to enforce our patent rights in order to protect our technology and diagnostic tests from infringing uses. We may not have the financial resources to finance the litigation required to preserve our patent and trade secret rights.

- The Supreme Court decisions in Mayo Collaborative Services v. Prometheus Laboratories, Inc. and Association for Molecular Pathology v. Myriad Genetics may adversely impact our ability to obtain patent protection for some or all of our diagnostic tests, which use certain gene markers to indicate the presence of certain cancers. The claims in the contested patents that were the subject of the Supreme Court decision in Mayo Collaborative Services v. Prometheus Laboratories, Inc. 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 mathematical 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. The holdings 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.

There is no certainty that our pending or future patent applications will result in the issuance of patents.

We have filed patent applications for technology that we have developed, and we may obtain licenses for patent applications covering genes that we or our partners have discovered, that we believe will be useful in producing new diagnostic tests. We may also file additional new patent applications in the future seeking patent protection for new technology or diagnostics tests or products that we develop ourselves or jointly with others. However, there is no assurance that any of our licensed patent applications, or any patent applications that we have filed or that we may file in the future in the United States or abroad, will result in the issuance of patents.

The process of applying for and obtaining patents can be expensive and slow.

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The preparation and filing of patent applications, and the maintenance of patents that are issued, may require substantial time and money.

- 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. 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.

- 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.

- Post Grant Review under the America Invents Act enables 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.

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- Oppositions to the issuance of patents may be filed under European patent law and the patent laws of certain other countries. As with 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.

Our patents may not protect our diagnostic tests from competition.

- We might not be able to obtain any patents beyond the bladder cancer marker patent and lung cancer marker patents that have been issued by the USPTO, and any patents that we do obtain might not be comprehensive enough to provide us with meaningful patent protection.

- There will always be a risk that our competitors might be able to successfully challenge the validity or enforceability of any patent issued or licensed or licensed to us.

- In addition to interference proceedings, the USPTO can reexamine issued patents at the request of a third party. Our patents may be subject to inter partes review (replacing the reexamination proceeding), a proceeding in which a third party can challenge the validity of one of our patents to have the patent invalidated. This means that patents owned or licensed by us may be subject to reexamination and may be lost if the outcome of the reexamination is unfavorable to us.

We may be subject to patent infringement claims that could be costly to defend, which may limit our ability to use disputed technologies, and which could prevent us from pursuing research and development or commercialization of some of our diagnostic tests, require us to pay licensing fees to have freedom to operate and/or result in monetary damages or other liability for us.

The success of our business depends significantly on our ability to operate without infringing patents and other proprietary rights of others. If the technology that we use infringes a patent held by others, we could be sued for monetary damages by the patent holder or its licensee, or we could be prevented from continuing research, development, and commercialization of diagnostic tests that rely on that technology, unless we are able to obtain a license to use the patent. The cost and availability of a license to a patent cannot be predicted, and the likelihood of obtaining a license at an acceptable cost would be lower if the patent holder or any of its licensees is using the patent to develop or market a diagnostic test with which our diagnostic test would compete. If we were unable to obtain a necessary license, we would need to develop or obtain rights to alternative technologies, which could prove costly and could cause delays in diagnostic test development, or we could be forced to discontinue the development or marketing of any diagnostic tests that were developed using the technology covered by the patent.

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.

Although BioTime now owns less than 50% (approximately 47%) of our issued and outstanding shares of common stock, it still holds a sufficient number of shares to elect at least a minority, and potentially a majority, depending on how other shareholders vote, of the members of our Board of Directors and to influence our management. Two of the seven members of our Board of Directors are also officers or directors of BioTime and one of our directors is our Chief Executive Officer. This commonality of directors means that representatives of BioTime and our management are participating in making business decisions on our behalf.

BioTime's voting power may allow BioTime to cause corporate actions to be taken 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 only a small number of other shareholders 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;

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- Any sale of assets or purchase of assets; or

- A corporate dissolution or a plan of liquidation of our business.

We presently rely on BioTime for certain services and resources.

Although we have our own CLIA certified diagnostic laboratory, our own scientific personnel, and many 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 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 which company should pursue those opportunities, taking into account relevant facts and circumstances at the time, such as the financial and other resources of the companies available to acquire and utilize the opportunity, and the best "fit" between the opportunity and the business and research and development programs of the companies. 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 allocation of opportunities.

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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.

One of our significant assets is 353,264 BioTime common shares that we acquired from BioTime in exchange for shares of our common stock. We may sell the BioTime shares from time to time, or pledge the shares as collateral for loans, to raise capital to finance our operations. Because a sale of those shares could have a depressing effect on the market value of BioTime common shares, BioTime will have a continuing interest in the number of shares we sell, the prices at which we sell the shares, and the time and manner in which the shares are sold. Further, we may need or find it desirable to sell BioTime common shares at the same time as BioTime, or BioTime subsidiaries that hold BioTime common shares, also desire to sell some of their BioTime common shares. Concurrent sales of BioTime common shares by us, BioTime, or BioTime subsidiaries cold have a depressing effect on the market price of the BioTime common shares, lower the price at which we and they are able to sell BioTime common shares, and result in lower net proceeds from the sales. We plan to coordinate any future sales of our BioTime common shares with BioTime and its subsidiaries in order to provide an orderly and controlled process for raising capital through the sale of BioTime shares. This will 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 they sell BioTime shares.

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- 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 patent and technology licenses and other agreements between us and BioTime or BioTime subsidiaries will 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.

Risks Related to Our Dependence on Third Parties

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

We have been developing our lung cancer diagnostic test using diagnostic testing equipment and reagents from one manufacturer. However, we have encountered inconsistent results using that equipment, which we believe was caused by issues with the chemical reagents that are required for use with that particular manufacturer's equipment. The chemical reagents are available only from that equipment manufacturer. We are evaluating alternative analytic platforms from other manufacturers to determine which, if any, could replace the initial diagnostic testing platform that we have been using. If we need to acquire different diagnostic testing equipment, we will 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 are experiencing delays 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.

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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.

Risks Pertaining 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.

Because we are engaged in the development of medical diagnostic tests, 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.

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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.

BioTime will also be impacted by ASU No. 2014-15 in much the same manner us. If the consolidated financial statements BioTime were to become subject to a going concern qualification or uncertainty, the market price of their common stock could decline, resulting in a loss or decline in value of the BioTime shares we own as available for sale securities.

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 to 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. Four 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 55,000,000 shares of capital stock consisting of 50,000,000 shares of common stock and 5,000,000 "blank check" shares of

preferred stock. At March 20, 2018, there were 31,468,558 shares of common stock outstanding, 2,779,221 shares of common stock reserved for exercise of warrants and 3,373,287 shares of common stock reserved for issuance upon the exercise of options under our employee stock option plan. 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 or consultants, or in connection with future acquisitions of licenses to technology or rights to acquire 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.

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We will incur costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives.

As a public reporting company, we will continue to incur significant legal, accounting and other expenses. The Sarbanes-Oxley Act of 2002 and rules subsequently implemented by the SEC, have imposed various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will entail significant legal and financial compliance costs and will make some activities more time consuming and costly. For example, we expect that these rules and regulations may make it difficult and expensive for us to obtain director and officer liability insurance, and we may be required to accept low policy limits and coverage.

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, and to our knowledge no such litigation or proceedings are contemplated.

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

Our common stock has been traded on the NYSE American under the symbol "OCX" since January 4, 2016. The following table sets forth the range of high and low closing prices for our common shares for the fiscal year ended December 31, 2017, as reported by the NYSE American:

Quarter Ended	High	Low
March 31, 2016	$10.11	$2.62
June 30, 2016	$6.07	$3.37
September 30, 2016	$5.32	$3.25
December 31, 2016	$7.70	$3.95
March 31, 2017	$7.00	$4.70
June 30, 2017	$7.35	$4.95
September 30, 2017	$7.55	$3.60

December 31, 2017 $7.40 $3.90

As of March 20, 2018, we had 249 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.

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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, 2017 (in thousands, except weighted average exercise price):

Plan Category	Number of Shares to be Issued upon Exercise of Outstanding Options, Warrants, and Rights	Weighted Average Exercise Price of the Outstanding Options, Warrants, and Rights	Number of Shares Remaining Available for Future Issuance under Equity Compensation Plans
OncoCyte Stock Option Plans Approved by Shareholders	3,390	$3.25	1,384

Additional information concerning our Employee Stock Option Plan and the 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 to repurchase any capital stock without Silicon Valley Bank's prior written consent. 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.

Performance Measurement Comparison [(1)]

The following graph compares total stockholder returns of OncoCyte for the last twelve months beginning December 31, 2015 to two indices: the NYSE Amex Market Value – U.S. Companies ("Amex Market Value") and the NYSE Arca Biotechnology Index. The total return for our common shares and for each index assumes the reinvestment of dividends, although we have never declared dividends on OncoCyte common shares, and is based on the returns of the component companies weighted according to their capitalizations as of the end of each quarterly period. The Amex Market Value tracks the aggregate price performance of equity securities of U.S. companies listed therein. The NYSE Arca Biotechnology Index represents biotechnology companies, trading on NYSE American under the Standard Industrial Classification ("SIC") Code Nos. 283 (Drugs) and 382 (Laboratory Apparatus and Analytical, Optical) main categories (2834: Pharmaceutical Preparations; 2835: Diagnostic Substances; 2836: Biological Products; 3826: Laboratory Analytical Instruments; and 3829: Measuring & Controlling Devices). OncoCyte common stock trades on the NYSE American and is a component of the NYSE Amex Market Value – US Companies.

Comparison of Twenty-Four Month Cumulative Total Return on Investment

		12/31/2015	3/31/2016	6/30/2016	9/30/2016	12/31/2016	3/31/2017	6/30/2017	9/30/2017	12/31/2017
OncoCyte Corporation	Return %		-26.24	-22.78	41.57	39.88	-15.60	-12.61	45.19	-38.41
	Cum $	100.00	73.76	56.96	80.64	112.80	95.20	83.20	120.80	74.40
AMEX Market Value Index (US Companies)	Return %		-0.87	5.86	5.81	1.27	3.92	2.18	0.10	3.48

	Cum $	100.00	99.13	104.94	111.04	112.45	116.85	119.40	119.53	123.68
NYSE Arca Biotechnology Index	Return %		-22.37	2.31	11.50	-8.70	16.03	8.32	8.96	0.53
	Cum $	100.00	77.63	79.42	88.55	80.85	93.81	101.62	110.73	111.33

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OncoCyte Corporation, the Amex Market Value and NYSE Arca Biotechnology Index [2]

(1) This Section is not "soliciting material," is not deemed "filed" with the SEC and is not to be incorporated by reference in any filing of OncoCyte under the Securities Act of 1933, or the Securities Exchange Act of 1934, whether made before or after the date hereof and irrespective of any general incorporation language in any such filing.

(2) Shows the cumulative total return on investment assuming an investment of $100 in each of OncoCyte, the Amex Market Value and the NYSE Arca Biotechnology Index on December 31, 2015. The cumulative total return on OncoCyte common shares has been computed based on a price of $9.00 per share, the price at which OncoCyte's common shares closed on January 4, 2016, OncoCyte's first day of "regular way" trading on NYSE American.

Item 6. Selected Financial Data (in thousands, except per share data)

	Year Ended December 31,		
	2017	2016	2015
OPERATING EXPENSES			
Research and development	$7,174	$5,677	$4,527
General and administrative	9,232	4,265	3,867
Sales and marketing	2,443	1,198	324
Total operating expenses	18,849	11,140	8,718
Loss from operations	(18,849)	(11,140)	(8,718)
OTHER EXPENSES, NET			
Loss on sale of available-for-sale securities and other expenses, net	(309)	-	-
Interest expense, net	(217)	(28)	(19)
Other income, net	-	-	2
Total other expenses, net	(526)	(28)	(17)
NET LOSS	$(19,375)	$(11,168)	$(8,735)
Basic and diluted net loss per share	$(0.64)	$(0.42)	$(0.42)
Weighted average shares outstanding: basic and diluted	30,195	26,529	21,009

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	December 31,	
	2017	2016
Balance Sheet Data (in thousands):		
Cash and cash equivalents	$7,600	$10,174
BioTime shares held as available-for-sale securities, at fair value	760	2,237
Intangible assets, net	746	988
Total assets	10,216	14,447
Total liabilities	5,813	4,585
Total stockholders' equity	$4,403	$9,862

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, 2017, 2016 and 2015, 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, pursuing patents, and conducting clinical trials.

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 working capital 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 will need to obtain additional financing in order to commercialize any diagnostic tests that we develop and to continue our operations, including additional capital equipment purchases for our diagnostic laboratory and adding personnel required in 2018 and beyond to perform any laboratory diagnostic tests that we develop. 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, 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, 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. 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.

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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 new standard on going concern, ASU No. 2014-15, beginning with the year ended December 31, 2016 and all annual and interim periods thereafter, 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 or are available to be 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, 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 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 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.

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Stock-based compensation

We have adopted accounting standards governing share-based payments, which require the measurement and recognition of compensation expense for all share-based payment awards made to directors and employees, including employee stock options, based on estimated fair values. We utilize the Black-Scholes-Merton option pricing model. 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. Because our common stock had no public trading history prior to December 31, 2015, for the year ended December 31, 2015, we estimated the expected volatility of the awards from the historical volatility of selected public companies within the biotechnology industry with comparable characteristics to us, including similarity in size, lines of business, market capitalization, revenue and financial leverage. For the years ended December 31, 2017 and 2016, 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 upon the "simplified method" provided under Staff Accounting Bulletin, Topic 14, or SAB Topic 14, including, in part, based on our own experience. 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 available-for-sale equity securities in accordance with ASC 320-10-25, Investments – Debt and Equity Securities, as the shares have a readily determinable fair value quoted on the NYSE American and are held principally for future working capital purposes, as necessary. These shares 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. Unrealized holding gains and losses are excluded from the statements of operations and reported in equity as part of other comprehensive income or loss, net of income taxes, until realized. As discussed in Note 2 to our financial statements included elsewhere in this Report, on February 17, 2017, BioTime deconsolidated our financial statements from its consolidated financial statements. Due to this deconsolidation, and based on BioTime no longer having "control" over OncoCyte under GAAP, any realized gains and losses we generate from the sale of BioTime shares after February 17, 2017 are included in our statements of operations. Prior to February 17, 2017, any realized gains and losses for shares sold were reclassified out of accumulated other comprehensive income or loss and included in equity, as an increase or decrease to common stock equity consistent with, and pursuant to, ASC 805-50 Business Combinations ("ASC 805"), transactions between entities under common control. See Note 2 under the section Recent Accounting Pronouncements for additional disclosures.

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 consist primarily of long-lived intangible assets, equipment and furniture, 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. To date, there have been no such impairment losses.

Income taxes

We have filed a standalone U.S. federal income tax return since our inception. For California purposes, our activity for 2015, 2016 and 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 or will be included in BioTime's California combined tax return. For periods beginning February 17, 2017 and thereafter, we 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.

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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, 2017 and 2016

The following tables show our operating expenses for the years ended December 31, 2017 and 2016 (in thousands).

	Year Ended December 31,		$	%
	2017	2016	Increase	Increase
Research and development expenses	$ 7,174	$ 5,677	$ 1,497	26.4 %
General and administrative expenses	9,232	4,265	4,967	116.5 %
Sales and marketing expenses	2,443	1,198	1,245	103.9 %

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Research and development expenses

Research and development expenses for the year ended December 31, 2017 increased to $7.2 million from $5.7 million during 2016. This $1.5 million increase in research and development expenses is primarily due to the certification and maintenance costs related to the CLIA laboratory and the cost of DetermaVu™ program. The increase includes $0.8 million in outside laboratory and clinical trial expenses, $0.7 million in personnel and benefits costs, which includes $0.4 million in stock-based compensation expense, and $0.4 million in research and development allocated amounts charged to us by BioTime for facilities and other services provided to us.

We expect to continue to incur a significant amount of research and development expenses.

General and administrative expenses

General and administrative expenses for the year ended December 31, 2017 increased to $9.2 million from $4.3 million during 2016. The $5.0 million increase in general and administrative expenses during 2017 is primarily attributable to $4.1 million in noncash expense for the issuance of additional warrants to certain investors who exercised stock purchase warrants that we issued during 2016, $0.4 million in legal-patent related expenses, $0.3 million in personnel cost and related benefits, including stock-based compensation expense, and $0.2 million in insurance expense.

Sales and marketing expenses

Sales and marketing expenses for the year ended December 31, 2017 increased to $2.4 million from $1.2 million during 2016, as we prepared for the commercial launch of our lung cancer diagnostic test, DetermaVu™. The increase in sales and marketing expenses during 2017 is attributable to increases of $0.6 million in salaries and payroll related expenses, $0.2 million in sales and marketing expenses amounts charged to us by BioTime for facilities and services provided to us, $0.2 million in consulting expenses and $0.1 million in stock-based compensation expenses.

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.

Comparison of the Years Ended December 31, 2016 and 2015

The following tables show our operating expenses for the years ended December 31, 2016 and 2015 (in thousands).

	Year Ended December 31,		$	%
	2016	2015	Increase	Increase
Research and development expenses	$ 5,677	$ 4,527	$+1,150	+ 25.4 %
General and administrative expenses	4,265	3,867	+398	+10.3 %
Sales and marketing expenses	1,198	324	+874	+269.8 %

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Research and development expenses

The following table shows the approximate amounts and percentages of our total research and development expenses of $5.7 million and $4.5 million allocated to our primary research and development projects during the years ended December 31, 2016 and 2015, respectively (in thousands).

	Amount [1]		Percent	
Program	2016	2015	2016	2015
General	$1,649	$1,687	29.1%	37.3%
Lung Cancer Confirmatory Diagnostic	2,940	763	51.8%	16.8%
Bladder Cancer Confirmatory Diagnostic	376	895	6.6 %	19.8%
Breast Cancer Confirmatory Diagnostic	375	1,105	6.6 %	24.4%
CLIA Lab	337	77	5.9 %	1.7 %
Total	$5,677	$4,527	100 %	100 %

(1) Amount also includes certain general research and development expenses, such as laboratory supplies, laboratory expenses, rent allocated, and insurance allocated to research and development expenses, incurred directly by BioTime on behalf of OncoCyte and allocated to OncoCyte under the Shared Facilities Agreement.

Research and development expenses for the year ended December 31, 2016 increased to $5.7 million from $4.5 million during 2015. Overall the increase in research and development expenses is due to increased staffing and costs of clinical trials as part of the development of our cancer diagnostic tests. The increases in research and development expenses during 2016 are primarily attributable to increases of $0.4 million in laboratory expenses, $0.3 million in salaries and payroll related expenses, $0.2 million in business development expenses, and $0.2 million in clinical trials expenses, principally focused on the lung cancer confirmatory diagnostic test.

We expect to continue to incur a significant amount of research and development expenses.

General and administrative and sales and marketing expenses

General and administrative and sales and marketing expenses for the year ended December 31, 2016 increased to $5.5 million from $4.2 million during 2015. The increase in general and administrative expenses during 2016 is primarily attributable to increases of $0.6 million in general consulting expenses, $0.5 million in salaries and payroll related expenses, $0.2 million in marketing research expenses, $0.2 million in general and administrative expenses allocated to us by BioTime, and $0.4 million in other general administrative costs including legal fees and SEC filing fees. These increases were in part offset by a decrease in stock-based compensation expense of $0.8 million due to fewer stock option grants made in 2016 as compared to 2015 and certain modifications of stock option grants to an executive in 2015 that resulted in higher expense in 2015. Stock-based compensation was also lower in 2016 due to OncoCyte not granting stock options to employees of BioTime in 2016, whereas options were granted during 2015 and prior years to certain BioTime employees who provided services to us 2015 and prior years, which are treated as nonemployee grants and generally result in higher stock-based compensation expense in OncoCyte's financial statements.

Income taxes

As of December 31, 2017, we had net operating loss carryforwards of approximately $47.8 million for U.S. federal income tax purposes and $15.6 million for state income tax purposes, which expire generally between 2029 and 2037. In addition, as of December 31, 2017, we had research and development credit carryforwards for federal and state tax

purposes of $1.0 million and $1.1 million, respectively. The federal credits expire between 2030 and 2037, while the state credits have no expiration. Due to our losses incurred for all periods presented, we did not record any provision or benefit for income taxes.

During 2017, we sold 266,442 BioTime common shares in at-the-market transactions which resulted in a taxable loss of approximately $301,000. No BioTime common shares were sold in 2016. During 2015, we sold 259,712 BioTime common shares in at-the-market transactions which resulted in a taxable loss of approximately $397,000.

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 its net operating loss carryforwards and other deferred tax assets.

Liquidity and Capital Resources

At December 31, 2017, we had $7.6 million of cash and cash equivalents and held BioTime common shares as available-for-sale securities valued at $0.8 million. Since inception, we have financed our operations through the sale of our common stock and warrants to our shareholders, loans from BioTime and BioTime affiliated entities, the sale of BioTime common shares, a bank loan, and exercises of our warrants.

On March 28, 2018, we entered into a securities purchase agreement with two accredited investors. The agreement provides for the private placement of 7,936,508 shares of our common stock for $1.26 per share, for total gross proceeds of $10.0 million before deducting offering expenses. Of this amount, we have received $8.0 million in gross proceeds from the sale of 6,349,206 shares of common stock, and one of the investors irrevocably committed in the agreement to pay to us an additional $2.0 million on or prior to April 30, 2018 for the purchase of an additional 1,587,302 shares of common stock (see Note 10 to our financial statements included elsewhere in this Report).

Based on cash, cash equivalents and available-for-sale securities currently on hand, including the $8.0 million in gross proceeds from the private placement completed on March 28, 2018, and the $2.0 million irrevocably committed to us on or prior to April 30, 2018 (see Note 10 to our financial statements included elsewhere in this Report), we believe we have sufficient cash, cash equivalents, available-for-sale securities and working capital to carry out our current operations through at least twelve months from the issuance date of the financial statements included herein, but will need to raise additional capital if we determine to devote more resources to the development or initial commercialization efforts for our lung cancer test during that time frame.

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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, 2017, the latest published prime rate plus 0.75% was 5.25% 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 2.0% of the outstanding principal balance if prepaid after February 21, 2018 but not later than February 21, 2019, or 1.0% of the outstanding principal balance if prepaid after February 21, 2019. Any amounts borrowed and repaid may not be reborrowed. As of December 31, 2017, 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 Securities and Exchange Commission, 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.

OncoCyte plans to continue to invest significant resources in research and development in the field of molecular cancer diagnostics. OncoCyte expects to continue to incur operating losses and negative cash flows. If results of OncoCyte's research and development efforts, including the results of validation studies of its lung cancer test, DetermaVu™, are successful to the point where OncoCyte believes that a commercial product can be launched successfully, additional capital will be required to develop a sales and marketing team to market DetermaVu™ and to hire additional administrative personnel for patient billing and reimbursement procedures. OncoCyte will also need to raise additional capital in subsequent years to develop and launch additional diagnostic tests, for working capital, and for other expenses, until such time as it is able to generate sufficient revenues from the commercialization of its diagnostic tests to finance its operations. Delays in the development or commercialization of DetermaVu™ could prevent OncoCyte from raising, when needed, sufficient additional capital to finance the completion of development and commercial launch of DetermaVu™ or the other cancer diagnostic tests that OncoCyte is developing. 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 its 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.

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Cash used in operations

During the years ended December 31, 2017 and 2016, our research and development expenses were $7.2 million and $5.7 million, our general and administrative expenses were $9.2 million and $4.3 million, and our sales and marketing expenses were $2.4 million and $1.2 million, respectively. Net loss for the years ended December 31, 2017 and 2016 amounted to $19.4 million and $11.2 million, respectively. Net cash used in operating activities during these periods amounted to $13.4 million and $7.5 million, respectively. The amount by which our net loss exceeded net cash used in our operations during 2017 is primarily due to the following noncash items: a $4.1 million noncash charge related to warrants issued to certain investors as an inducement to exercise previously issued warrants; $1.6 million of stock-based compensation; $580,000 in depreciation and amortization expenses; and a $309,000 loss on sales of BioTime shares held as available-for-sale securities. Changes in working capital amounted to an approximate $686,000 of additional use of cash.

Cash used in investing activities

During the years ended December 31, 2017 and 2016, $91,000 and $106,000 in cash payments were made for purchase of machinery and equipment, respectively, and $934,000 in net cash proceeds were received from the sale of 266,442 shares of BioTime common stock we held as available-for-sale securities. We used these proceeds to pay down amounts owed to BioTime and affiliates. Under the provisions of the Loan Agreement discussed in Note 5 of the notes to financial statements, after October 26, 2017, we can use any proceeds from sale of BioTime shares to pay amounts owed to BioTime and its affiliates or for working capital purposes.

Cash provided by financing activities

During the year ended December 31, 2017, cash provided by financing activities was $10.0 million. During this period, certain investors exercised 2,392,000 warrants at an exercise price of $3.25 per warrant, providing us with total exercise proceeds of $7.8 million. We also received $610,000 in proceeds from exercise of stock options and we borrowed $2.0 million from a bank. These cash inflows were offset by $265,000 used to pay down capital lease obligations and $133,000 in payments due on the bank loan.

Contractual obligations

As of December 31, 2017, our contractual obligations for the next five years and thereafter were as follows (in thousands):

	Principal Payments Due by Period				
		Less Than			After
Contractual Obligations [1]	Total	1 Year	1-3 Years	4-5 Years	5 Years
Shared Facilities Agreement [2]	$ 2,099	2,099	-	-	-
Capital lease [3]	$ 690	383	307	-	-
Loan payable [4]	$ 2,097	876	1,221	-	-

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

(2) Under the Shared Facilities Agreement, we reimburse BioTime for a portion of the rent and other expenses of leasing our office and laboratory facility, and for BioTime's cost of providing us with the use of laboratory and office equipment and supplies, utilities, and personnel. Salaries and related expenses for accounting services 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.

(3) Includes certain capital leases for lab equipment.

(4) Loan payable amounts include principal and interest.

Off-Balance Sheet Arrangements

As of December 31, 2017, 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

Foreign Currency Exchange Risk

We are not presently exposed in a significant degree to foreign exchange currency risks because we are not conducting international business at this time, and we do not engage in foreign currency hedging activities. If we engage in international transactions, we will need to translate foreign currencies into U.S. dollars for reporting purposes, and currency fluctuations could have an impact on our financial results.

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Credit Risk

Under our Loan Agreement with Silicon Valley Bank, we are required to hold our cash in (a) marketable direct obligations issued or unconditionally guaranteed by the United States or any agency or any state thereof having maturities of not more than one year from the date of acquisition; (b) commercial paper maturing no more than one (1) year after its creation and having the highest rating from either Standard & Poor's Ratings Group or Moody's Investors Service, Inc.; (c) certificates of deposit issued by the Bank and maturing no more than one (1) year after issue, or deposit accounts with other banks. Deposits with banks may temporarily exceed the amount of insurance provided on such deposits. We will monitor the cash balances in the accounts and adjust the cash balances as appropriate, and as permitted by the Loan Agreement, but if the amount of a deposit at any time exceeds the federally insured amount at a bank, the uninsured portion of the deposit could be lost, in whole or in part, if the bank were to fail.

Interest Rate Risk

We hold our funds in investments permitted by the Loan Agreement. The primary objective of our investments will be to preserve principal and liquidity while earning a return on our invested capital, without incurring significant risks. Our future investment income is not guaranteed and may fall short of expectations due to changes in prevailing interest rates. If we sell any investment security prior to its maturity date, we may suffer a loss in principal if the market value of the security declines below our acquisition cost.

Available for sale securities at fair value

We hold 353,264 BioTime common shares at fair value as available-for-sale securities. Those shares are subject to changes in market value. BioTime common shares trade on the NYSE American under the ticker "BTX". As of December 31, 2017, the 52-week high/low stock price per share range for BioTime was $3.73 to $2.15.

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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, 2017 and 2016, the related statements of operations, comprehensive loss, stockholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2017, 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, 2017 and 2016, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2017, 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 2, 2018
We have served as the Company's auditor since 2015.

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Item 8. Financial Statements and Supplementary Data

ONCOCYTE CORPORATION
BALANCE SHEETS
(In thousands)

	December 31, 2017	2016
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$7,600	$10,174
BioTime shares held as available-for-sale securities, at fair value	760	2,237
Prepaid expenses and other current assets	168	285
Total current assets	8,528	12,696
NONCURRENT ASSETS		
Intangible assets, net	746	988
Equipment and furniture, net	822	688
Deposits	120	75
TOTAL ASSETS	$10,216	$14,447
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Amount due to BioTime and affiliates	$2,099	$2,854
Accounts payable	175	422
Accrued expenses and other current liabilities	1,042	797
Loan payable, current	800	-
Capital lease liability, current	338	202
Total current liabilities	4,454	4,275
LONG-TERM LIABILITIES		
Loan payable, net of deferred financing costs, noncurrent	1,070	-
Capital lease liability, noncurrent	289	310
TOTAL LIABILITIES	5,813	4,585
Commitments and contingencies (see Note 9)		
STOCKHOLDERS' EQUITY		
Preferred stock, no par value, 5,000 shares authorized; none issued and outstanding	-	-
Common stock, no par value, 50,000 shares authorized; 31,452 and 28,737 shares issued and outstanding at December 31, 2017 and 2016, respectively	59,968	45,818
Accumulated other comprehensive loss on available-for-sale securities	(888)	(654)
Accumulated deficit	(54,677)	(35,302)
Total stockholders' equity	4,403	9,862
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$10,216	$14,447

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

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ONCOCYTE CORPORATION
STATEMENTS OF OPERATIONS
(In thousands, except per share data)

	Year Ended December 31,		
	2017	2016	2015
OPERATING EXPENSES			
Research and development	$7,174	$5,677	$4,527
General and administrative	9,232	4,265	3,867
Sales and marketing	2,443	1,198	324
Total operating expenses	18,849	11,140	8,718
Loss from operations	(18,849)	(11,140)	(8,718)
OTHER EXPENSES, NET			
Loss on sale of available-for-sale securities and other expenses, net	(309)	-	-
Interest expense, net	(217)	(28)	(19)
Other income, net	-	-	2
Total other expenses, net	(526)	(28)	(17)
NET LOSS	$(19,375)	$(11,168)	$(8,735)
Basic and diluted net loss per share	$(0.64)	$(0.42)	$(0.42)
Weighted average shares outstanding: basic and diluted	30,195	26,529	21,009

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

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ONCOCYTE CORPORATION
STATEMENTS OF COMPREHENSIVE LOSS
(In thousands)

	Year Ended December 31,		
	2017	2016	2015
NET LOSS	$(19,375)	$(11,168)	$(8,735)
Other comprehensive loss, net of tax:			
Realized loss on sale of available-for-sale securities	293	-	397
Unrealized gain (loss) on available-for-sale securities	(527)	(304)	75
COMPREHENSIVE LOSS	$(19,609)	$(11,472)	$(8,263)

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

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ONCOCYTE CORPORATION
STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)
(In thousands)

	Common Stock		Accumulated Other Comprehensive	Accumulated	Total Shareholders' Equity
	Shares	Amount	Loss	Deficit	(Deficit)
BALANCE AT DECEMBER 31, 2014	18,200	$15,147	$ (822)	$ (15,399)	$ (1,074)
Net loss	-	-	-	(8,735)	(8,735)
Unrealized gain on BioTime shares held as available-for-sale securities	-	-	75	-	75
Stock-based compensation	-	1,815	-	-	1,815
Common stock issued to BioTime for extinguishment of debt	1,500	3,300	-	-	3,300
Common stock issued to investors for cash	1,500	3,300	-	-	3,300
Common stock issued to BioTime upon conversion of BioTime convertible note payable and accrued interest	1,508	3,318	-	-	3,318
Common stock issued to BioTime for cash	2,711	8,349	-	-	8,349
Exercise of stock options	3	4	-	-	4
Fair value of contingently issuable warrant	-	65	-	-	65
OncoCyte common stock received as a dividend in kind from BioTime	(31)	-	-	-	-
Transfer of realized loss into equity from sale of BioTime shares	-	(397)	397	-	-
BALANCE AT DECEMBER 31, 2015	25,391	34,901	(350)	(24,134)	10,417
Net loss	-	-	-	(11,168)	(11,168)
Unrealized loss on BioTime shares held as available-for-sale securities	-	-	(304)	-	(304)
Stock-based compensation	-	922	-	-	922
Proceeds from issuance of common stock and warrants, net of discounts and financing costs	3,246	9,777	-	-	9,777
Exercise of stock options	100	218	-	-	218
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

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		
	2017	2016	2015
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss	$(19,375)	$(11,168)	$(8,735)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation expense	338	145	41
Amortization of intangible assets	242	242	242
Stock-based compensation	1,630	922	1,815
Loss on sale of available-for-sale securities, including selling commissions	309	-	-
Warrants issued to certain shareholders as inducement to exercise of warrants	4,074	-	-
Contingently issuable warrant expense to investors	-	-	65
Amortization of debt issuance costs and interest expense	83	-	18
Changes in operating assets and liabilities:			
Amount due to BioTime and affiliates	(753)	2,007	1,557
Prepaid expenses and other current assets	115	101	(274)
Accounts payable and accrued liabilities	(48)	229	1,042
Net cash used in operating activities	(13,385)	(7,522)	(4,229)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Net proceeds from sale of available-for-sale securities	934	-	815
Purchase of equipment	(91)	(106)	(500)
Security deposit	-	(75)	-
Net cash provided by (used in) investing activities	843	(181)	315
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from exercise of options	610	218	4
Proceeds from exercise of warrants	7,774	-	-
Proceeds from sale of common stock	-	-	11,649
Proceeds from sale of common stock and warrants	-	10,550	-
Financing costs related to sale of common stock and warrants	-	(773)	-
Proceeds from issuance of loan payable, net of financing costs	1,982	-	-
Repayment of loan payable	(133)	-	-
Repayment of capital lease obligation	(265)	(114)	-
Net cash provided by financing activities	9,968	9,881	11,653
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(2,574)	2,178	7,739
CASH AND CASH EQUIVALENTS:			
At beginning of the year	10,174	7,996	257
At end of the year	$7,600	$10,174	$7,996
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION			
Cash paid for interest	$130	$29	$-
SUPPLEMENTAL SCHEDULE OF NONCASH FINANCING AND INVESTING ACTIVITIES			
Equipment purchased under capital leases	$381	$626	$-

Debt issuance costs	196	-	-
Common stock issued to BioTime for extinguishment of debt	-	-	3,300
Common stock issued to BioTime upon conversion of convertible note payable and accrued interest	-	-	3,318
Realized loss on sale of BioTime shares	-	-	397

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

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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 efforts have focused on developing diagnostic tests for use in detecting lung, bladder, and breast cancers. During 2017, OncoCyte devoted substantially all of its efforts on developing its lung cancer diagnostic test DetermaVu™.

OncoCyte was incorporated in 2009 in the state of California and at December 31, 2016 was a majority-owned subsidiary of BioTime, Inc. ("BioTime"), a publicly traded, clinical-stage, biotechnology company targeting degenerative diseases primarily in the fields of ophthalmology, aesthetics and cell/drug delivery. 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 its common stock and warrants, warrant exercises, a bank loan (see Note 5), and sales of BioTime common shares that OncoCyte holds as available-for-sale securities. BioTime has also provided OncoCyte with the use of BioTime facilities and services under a Shared Facilities and Services Agreement as described in Note 4. OncoCyte has incurred operating losses and negative cash flows since inception, and had an accumulated deficit of $54.7 million and $35.3 million as December 31, 2017 and 2016, respectively.

At December 31, 2017, OncoCyte had $7.6 million of cash and cash equivalents and held BioTime common shares as available-for-sale securities valued at $0.8 million. Based on cash, cash equivalents and available-for-sale securities currently on hand, including the $8.0 million in gross proceeds from the private placement completed on March 28, 2018, and the $2.0 million irrevocably committed to OncoCyte on or prior to April 30, 2018 (see Note 10), OncoCyte believes it has sufficient cash, cash equivalents, available-for-sale securities and working capital to carry out its current operations through at least twelve months from the issuance date of the financial statements included herein, but will need to raise additional capital if it determines to devote more resources to the development or initial commercialization efforts for its lung cancer test during that time frame.

OncoCyte plans to continue to invest significant resources in research and development in the field of molecular cancer diagnostics. OncoCyte expects to continue to incur operating losses and negative cash flows. If results of OncoCyte's research and development efforts, including the results of validation studies of its lung cancer test, DetermaVu™, are successful to the point where OncoCyte believes that a commercial product can be launched successfully, additional capital will be required to develop a sales and marketing team to market DetermaVu™ and to hire additional administrative personnel for patient billing and reimbursement procedures. OncoCyte will also need to raise additional capital in subsequent years to develop and launch additional diagnostic tests, for working capital, and for other expenses, until such time as it is able to generate sufficient revenues from the commercialization of its diagnostic tests to finance its operations. Delays in the development or commercialization of DetermaVu™ could prevent OncoCyte from raising, when needed, sufficient additional capital to finance the completion of development and commercial launch of DetermaVu™ or the other cancer diagnostic tests that OncoCyte is developing. 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 its 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.

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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.

As further discussed in Notes 4 and 7, OncoCyte granted stock options to employees of BioTime, or employees of other BioTime subsidiaries who performed services for OncoCyte, and OncoCyte recorded stock-based compensation expense in the accompanying statements of operations for the services performed in the periods presented.

Reverse stock split

On November 18, 2015, OncoCyte effected a one-for-two reverse stock split of its common stock. All share, per-share and related information including the price at which shares of common stock have been sold or may be issued, including shares issuable upon the exercise of stock options or convertible debt, have been retroactively adjusted, in these financial statements and accompanying footnotes, where applicable, to reflect the impact of the reverse stock split.

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 new standard on going concern, Accounting Standard Update, or ASU No. 2014-15, beginning with year ended December 31, 2016 and all annual and interim periods thereafter, OncoCyte assesses going concern uncertainty in its financial statements to determine if it has sufficient cash on hand and working capital, including any available borrowings on loans, to operate for a period of at least one year from the date the financial statements are issued or available to be 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:

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- 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 the available-for-sale securities of BioTime 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, 2017 and 2016, OncoCyte's cash balances totaled $7.6 million and $10.2 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 shares

OncoCyte accounts for the BioTime shares it holds as available-for-sale equity securities in accordance with ASC 320-10-25, Investments – Debt and Equity Securities, as the shares have a readily determinable fair value quoted on the NYSE American and are held principally for future working capital purposes, as necessary. These shares 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. Unrealized holding gains and losses are excluded from the statements of operations and reported in equity as part of other comprehensive income or loss, net of income taxes, until realized. As discussed in Note 1, on February 17, 2017, BioTime deconsolidated OncoCyte’s financial statements from its consolidated financial statements. Due to this deconsolidation, and based on BioTime no longer having "control" over OncoCyte under GAAP, any realized gains and losses OncoCyte generates from the sale of BioTime shares after February 17, 2017 are included in the statements of operations. Prior to February 17, 2017, any realized gains and losses for shares sold were reclassified out of accumulated other comprehensive income or loss and included in equity, as an increase or decrease to common stock equity consistent with, and pursuant to, ASC 805-50 Business Combinations ("ASC 805"), transactions between entities under common control. See section Recent Accounting Pronouncements included herein.

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). No shares of BioTime common stock were sold in 2016. In 2015, OncoCyte sold 259,712 shares of BioTime common stock it held in at-the-market transactions for $815,000 in net cash proceeds to be used for working capital purposes. The sale resulted in a $397,000 realized loss, which is recorded as a decrease to common stock equity on the dates of sale.

As of December 31, 2017, OncoCyte held 353,264 BioTime common shares as available-for-sale securities with a fair market value of $0.8 million. 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.

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.

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Equipment and furniture

Equipment and furniture 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 lower 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, furniture 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. Through 2017, there have been no such impairment losses.

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 to be accounted for at fair value 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 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 2015, 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, has been or will be included in BioTime's California combined tax return. For periods beginning on February 17, 2017 and thereafter, OncoCyte 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, 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, 2017 and 2016. 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, 2017, 2016 and 2015. OncoCyte is currently unaware of any tax issues under review.

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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).

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).

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.

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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 now 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 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. OncoCyte uses the Black-Scholes-Merton option pricing model for estimating the fair value of options granted under OncoCyte's Stock Option Plan. 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.

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

Prior to December 31, 2015, the Board of Directors determined the fair value of the common stock at the time of the grant of options by considering a number of objective and subjective factors including contemporaneous sales of common stock to investors, valuation of comparable companies, operating and financial performance and general and industry-specific economic outlook, among other factors in accordance with applicable elements of the practice aid issued by the American Institute of Certified Public Accountants titled Valuation of Privately Held Company Equity Securities Issued As Compensation. OncoCyte common stock began to trade publicly on the NYSE American on December 31, 2015, and since that date the fair value of OncoCyte common stock underlying stock options has been determined with reference to closing prices reported on the NYSE American.

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 upon the “simplified method” provided under Staff Accounting Bulletin, Topic 14, or SAB Topic 14, including, in part, based on its own experience.

Because OncoCyte’s common stock had no public trading history prior to December 31, 2015, for the year ended December 31, 2015, OncoCyte estimated the expected volatility of the awards from the historical volatility of selected public companies within the biotechnology industry with comparable characteristics to OncoCyte, including similarity in size, lines of business, market capitalization, revenue and financial leverage. For the years ended December 31, 2017 and 2016, 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.

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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 convertible to common stock, such as stock options (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 computations of basic and diluted net loss per common share for the years ended December 31, 2017, 2016 and 2015 are as follows (in thousands, except per share amounts):

	Year Ended December 31,		
	2017	2016	2015
Net loss	$(19,375)	$(11,168)	$(8,735)
Weighted average common shares outstanding – basic and diluted	30,195	26,529	21,009
Net loss per common share – basic and diluted	$(0.64)	$(0.42)	$(0.42)

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, 2017, 2016 and 2015 because including them would have been antidilutive (in thousands):

	Year Ended December 31,		
	2017	2016	2015
Stock options	3,390	3,017	2,240
Warrants	2,779	3,246	-

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.

Reclassifications

Certain reclassifications from general and administrative expenses have been made to present sales and marketing expenses shown on the statements of operations for the years ended December 31, 2016 and 2015 to conform and be comparable to the year ended December 31, 2017 presentation. These reclassifications have been made as OncoCyte's sales and marketing expenses have increased in 2017, thus making separate presentation of those category of expenses more meaningful to the readers of this report. The reclassifications had no impact to loss from operations or net loss as reported in the statements of operations and had no impact to the statements of cash flows or to the balance sheets for any period presented.

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.

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On January 5, 2016, the FASB issued Accounting Standards Update 2016-01, Financial Instruments–Overall: Recognition and Measurement of Financial Assets and Financial Liabilities (ASU No. 2016-01). Changes to the current GAAP model primarily affects the accounting for equity investments, financial liabilities under the fair value option, and the presentation and disclosure requirements for financial instruments. In addition, the ASU No. 2016-01 clarified guidance related to the valuation allowance assessment when recognizing deferred tax assets resulting from unrealized losses on available-for-sale debt securities. The accounting for other financial instruments, such as loans, investments in debt securities, and financial liabilities is largely unchanged. The more significant amendments are to equity investments in unconsolidated entities. In accordance with ASU No. 2016-01, all equity investments in unconsolidated entities (other than those accounted for using the equity method of accounting) will generally be measured at fair value through earnings. There will no longer be an available-for-sale classification (changes in fair value reported in other comprehensive income) for equity securities with readily determinable fair values. The classification and measurement guidance will be effective for public business entities in fiscal years beginning after December 15, 2017, including interim periods within those fiscal years. ASU No. 2016-01, when adopted, could have a material impact to OncoCyte's financial statements based on the current accounting for shares of BioTime common stock OncoCyte holds as available-for-sale securities.

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 those annual periods. Early adoption is permitted. OncoCyte is currently evaluating the impact that the adoption of ASU 2016-02 will have on its financial statements.

In May 2017, the FASB issued ASU 2017-09, Compensation – Stock Compensation (Topic 718) – Scope of Modification Accounting, to clarify existing guidance and reduce diversity in practice about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting in Topic 718. ASU 2017-09 requires modification accounting to a share-based award unless all of the following are met: (1) the fair value of the modified award is the same as the fair value of the original award immediately before the original award is modified, (2) the vesting conditions of the modified award are the same as the vesting conditions of the original award immediately before the original award is modified, and (3) the classification of the modified award, as equity or liability instrument, is the same as the classification of the original award immediately before the original award is modified. ASU 2017-09 is effective for annual periods, and interim periods within those annual periods, beginning after December 15, 2017. OncoCyte currently applies the three-step test to all modifications, if any, or as they occur, and if all the conditions are not met, applies modification accounting. OncoCyte believes the adoption of ASU 2017-09 will not have a material impact on its financial statements.

3. Selected Balance Sheet Components

Accrued expenses and other current liabilities

At December 31, 2017 and 2016, accrued expenses and other current liabilities were comprised of the following (in thousands):

	2017	2016
Accrued bonuses and payroll related expenses	$636	$549
Other accrued expenses	406	248
Accrued expenses and other current liabilities	$1,042	$797

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, 2017 and 2016, intangible assets were comprised of the following (in thousands):

	2017	2016
Intangible assets	$2,419	$2,419
Accumulated amortization	(1,673)	(1,431)
Intangible assets, net	$746	$988

Amortization expense amounted to approximately $242,000 annually.

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Equipment and furniture, net

At December 31, 2017 and 2016, equipment and furniture were comprised of the following (in thousands):

	2017	2016
Equipment and furniture	$1,479	$1,007
Accumulated depreciation	(657)	(319)
Equipment and furniture, net	$822	$688

Depreciation expense amounted to approximately $338,000, $145,000 and $41,000 for the years ended December 31, 2017, 2016 and 2015, respectively. During the year ended December 31, 2017 and 2016, OncoCyte entered into capital leases for laboratory equipment totaling $381,000 and $626,000, respectively (see Note 9).

4. Related Party Transactions

Shared Facilities and Service Agreement

On October 8, 2009, OncoCyte and BioTime executed a Shared Facilities and Services Agreement ("Shared Facilities Agreement"). Under the terms of the Shared Facilities Agreement, BioTime will allow OncoCyte to use its premises and equipment located at Alameda, California for the sole purpose of conducting business. BioTime will also provide 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 will also provide OncoCyte with the services of its 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, at its discretion, has the right to charge OncoCyte a 5% markup on such allocated costs although BioTime has not elected to charge this markup since the inception of the Shared Facilities Agreement and through the end of 2015. Beginning in 2016, BioTime commenced charging the 5% markup. The allocated cost of BioTime employees and contractors who provide services is based upon records maintained of the number of hours of such personnel devoted to the performance of services.

The Use Fee is determined and invoiced to OncoCyte on a quarterly basis for each calendar quarter of each calendar year. 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, 2017 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. Furthermore, BioTime will have 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.

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In the aggregate, BioTime allocated and charged such Use Fees to OncoCyte of $268,000, $790,000 and $595,000 included in general and administrative expenses and Use Fees of $1.1 million, $691,000 and $565,000 included in research and development expenses, during the years ended December 31, 2017, 2016 and 2015, respectively. Use Fees of $213,000 in sales and marketing expenses are included in OncoCyte's statements of operations during the year ended December 31, 2017. There were no Use Fees allocated to sales and marketing expenses during 2016 and 2015.

As of December 31, 2017 and 2016, OncoCyte had $2.1 million and $2.9 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.

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

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, 2017, the latest published prime rate plus 0.75% was 5.25% 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 2.0% of the outstanding principal balance if prepaid after February 21, 2018 but not later than February 21, 2019, or 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, 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.

Under the provisions of the Loan Agreement, as consented by the Bank on October 26, 2017, any proceeds received by OncoCyte from sales of BioTime shares may be used by OncoCyte to fund its operations.

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 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.

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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, 2017, unamortized deferred financing costs were $113,000.

Future Cash Payments of Loan Payable

As of December 31, 2017, principal and interest payments due on the loan payable in each of the next three years are as follows (in thousands):

Year Ending December 31,	Loan Payments
2018	$ 876
2019	835
2020	386
Total payments of principal and interest	2,097
Less: amounts representing interest	(114)
Total payments of principal before deferred financing costs	1,983
Less: deferred financing costs	(113)
Total loan payable, net of deferred financing costs	$ 1,870

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, 2017, no preferred shares were issued or outstanding.

Common Stock

OncoCyte has up to 50,000,000 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.

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. The purchasers included certain

OncoCyte existing shareholders other than BioTime. At the close of the Offering, BioTime's percentage ownership of the outstanding common stock of OncoCyte declined to 51.2% through which BioTime retained a controlling interest in OncoCyte. OncoCyte received $9.8 million in net proceeds after discounts, commissions and expenses from the Offering. OncoCyte will use the proceeds from the Offering for funding its operations or for working capital or other general corporate purposes.

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Pursuant to the terms of the Purchase Agreements, OncoCyte agreed (i) to file a resale registration statement with the Securities and Exchange Commission, or SEC, to register for sale under the Securities Act of 1933, as amended, or the Securities Act, the shares of OncoCyte common stock sold in the Offering and the shares of OncoCyte common stock, or Warrant Shares, that may be issued if the Warrants are exercised, and (ii) to use commercially reasonable efforts to maintain the effectiveness of the resale registration statement under the Securities Act until the earlier of (a) the date that all shares of its common stock covered by the Resale Registration Statement have been sold or can be sold publicly without restriction or limitation under Rule 144 (including, without limitation, the requirement to be in compliance with Rule 144(c)(1)), or (b) August 29, 2018.

2016 Warrants and New Warrants

The 2016 Warrants have an exercise price of $3.25 per Warrant Share, and may be exercised for five years from October 17, 2016, the date the 2016 Warrants became exercisable. 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, including if the Resale Registration Statement is not effective when and as required by the Purchase Agreements. 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 Offering 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.

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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, 2017, OncoCyte has an aggregate of 2,779,221 warrants issued and outstanding at exercise prices ranging from $3.25 and $5.50 per warrant.

Stock Option Exercises

During the years ended December 31, 2017 and 2016, 323,019 and 99,496 shares of common stock were issued upon the exercise of stock options, from which OncoCyte received $610,000 and $218,000 in cash proceeds, respectively.

7. Stock-based Compensation

Stock Option Plan

OncoCyte has adopted a 2010 Stock Option Plan (the “Plan”) under which 5,200,000 shares of common stock were made available for the grant of stock options or the sale of restricted stock. The Plan also permits OncoCyte to issue such other securities as its Board of Directors or the Compensation Committee administering the Plan may determine.

No options may be granted under the Plan more than ten years after the date upon which the Plan was adopted by the Board of Directors, and no options granted under the Plan may be exercised after the expiration of ten years from the date of grant. Under the Plan, options to purchase common stock may be granted to employees, directors and certain consultants at exercise prices not less than the fair market value of common stock at date of grant, subject to certain limited exceptions for options granted in substitution of other options. Options may be fully exercisable immediately, or may be exercisable according to a schedule or conditions specified by the Board of Directors or the Compensation Committee. Generally, OncoCyte stock options have service related vesting conditions based on the continued performance of services for OncoCyte. The Plan also permits OncoCyte to award restricted stock for services rendered or to sell common stock to employees subject to vesting provisions under restricted stock agreements that provide for forfeiture of unvested shares upon the occurrence of specified events. OncoCyte may permit employees or consultants, but not officers or directors, who purchase stock under restricted stock purchase agreements, to pay for their shares by delivering a promissory note that is secured by a pledge of their shares. To date, only stock options have been issued under the Plan.

As discussed in Note 4, OncoCyte may grant stock options to employees of BioTime, or employees of other BioTime subsidiaries, who perform services for OncoCyte. OncoCyte records stock-based compensation expense in the accompanying statements of operations for those services performed in the periods presented.

Stock Options

Options granted under the 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. Incentive stock options may be granted only to OncoCyte employees and employees of its subsidiaries, if any. The exercise price of stock options granted under the Plan must be equal to the fair market value 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 OncoCyte 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.

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The options' exercise price 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 of Directors or Compensation Committee may approve.

Incentive stock options granted under the Plan are nontransferable except by will or the laws of descent and distribution and may be exercised only during employment or within three months after termination of such employment, subject to certain exceptions in the event of the death or disability of the optionee.

Options other than incentive stock options under the Code are also nontransferable except by will or the laws of descent and distribution, except to the extent that the Board of Directors or Committee permits the optionee to transfer an option to a family member, a trust for family members, or other persons approved by the Board of Directors or Committee in its discretion.

Generally, options will be exercisable only while the optionee remains an employee, director or consultant, or during a specific period thereafter as approved by the Board of Directors or Committee, 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.

The number of shares of common stock covered by the Plan, and the number of shares of common stock and the exercise price per share of each outstanding option, shall be proportionately adjusted for any increase or decrease in the number of issued and outstanding shares of common stock resulting from a subdivision or consolidation of shares or the payment of a stock dividend, or any other increase or decrease in the number of issued and outstanding shares of common stock effected without receipt of consideration by OncoCyte.

Options Granted

As of December 31, 2017, 1,384,198 shares were available for future grants under the Plan.

A summary of OncoCyte stock option activity under the 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
Total at January 1, 2016	1,757	2,240	$ 2.03
Options granted	(962)	962	3.58
Options exercised	-	(100)	2.19
Options forfeited, cancelled or expired	85	(85)	2.00
Total at December 31, 2016	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
Total at December 31, 2017	1,384	3,390	$ 3.25
Exercisable at December 31, 2017		1,835	$ 2.48

At December 31, 2017 and 2016, OncoCyte had approximately $1.6 million and $2.7 million, respectively, of total unrecognized compensation expense related to the Plan that will be recognized over a weighted-average period of approximately 2.5 and 2.4 years, respectively.

OncoCyte recorded stock-based compensation expense in the following categories on the accompanying statements of operations for the years ended December 31, 2017, 2016 and 2015 (in thousands):

	Year Ended December 31,		
	2017	2016	2015
Research and development	$ 668	$ 312	$ 456
General and administrative	841	610	1,359
Sales and marketing	121	-	-
Total stock-based compensation expense	$ 1,630	$ 922	$ 1,815

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The assumptions that were used to calculate the grant date fair value of OncoCyte's employee and non-employee stock option grants for the years ended December 31, 2017, 2016 and 2015 were as follows.

	Year Ended December 31,		
	2017	2016	2015
Expected life (in years)	6.15	6.21	6.83
Risk-free interest rates	2.03 %	1.46 %	1.87 %
Volatility	66.01%	64.64%	74.15%
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, 2017, 2016 and 2015, may have been significantly different.

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 is currently analyzing the 2017 Tax Act, and in certain areas, has made reasonable estimates of the effects on its financial statements and tax disclosures, including and changes to OncoCyte's existing deferred tax balances, 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, as discussed below.

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 for 2017 were re-rated from 34 percent to 21 percent pursuant to the 2017 Tax Act.

OncoCyte has filed standalone U.S. federal income tax returns since its inception. For California purposes, OncoCyte's activity for 2015 and 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 will file a separate California return for tax year 2017. 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 deferred tax assets, including the operating loss and credit carryforwards, generated by OncoCyte, will remain with OncoCyte.

The primary components of the deferred tax assets and liabilities at December 31, 2017 and 2016 were as follows (in thousands):

	2017	2016

Deferred liabilities:		
Available-for-sale securities	$-	$(761)
Total deferred tax liabilities	-	(761)
Deferred tax assets:		
Net operating loss carryforwards	11,414	11,730
Research and development credit carryforwards	2,141	1,765
Patents and fixed assets	268	179
Stock-based compensation and accrued payroll	1,260	1,041
Valuation Allowance	(15,083)	(13,954)
Total deferred tax assets	-	761
Net deferred tax asset (liability)	$-	$-

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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 U.S. federal income tax of 34% to pretax losses from operations as a result of the following:

	Year Ended December 31,		
	2017	2016	2015
Computed tax benefit at federal statutory rate	34 %	34 %	34 %
Re-rate of federal net deferred tax assets	(35)%	0 %	0 %
Permanent differences	(8)%	(1)%	(9)%
State tax benefit	3 %	2 %	15 %
Research and development credits	1 %	2 %	2 %
Other	0 %	7 %	3 %
Adjust basis for available-for-sale-securities	11 %	0 %	0 %
Change in valuation allowance	(6)%	(44)%	(45)%
	- %	- %	- %

As of December 31, 2017, OncoCyte has net operating loss carryforwards of approximately $47.8 million for U.S. federal income tax purposes and $15.6 million for state income tax purposes. Federal net operating loss carryforwards expire in varying amounts from 2030 and 2037, and state carryforwards expire from 2029 and 2037. In addition, as of December 31, 2017, OncoCyte has research and development credit carryforwards for federal and state purposes of $1.0 million and $1.1 million, respectively. The federal credits will expire between 2030 and 2037, while the state credits have no expiration.

During 2017, OncoCyte sold 266,442 BioTime common shares, in at-the-market transactions which resulted in a taxable loss of approximately $301,000. No BioTime common shares were sold in 2016. During 2015, OncoCyte sold 259,712 BioTime common shares in at-the-market transactions which resulted in a taxable loss of approximately $397,000.

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 $1.1 million and $5.1 million for the years ended December 31, 2017 and 2016, 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 net operating loss (“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 control change, 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.

OncoCyte may be subject to potential income tax examination by U.S. federal or states authorities. These potential examinations may include inquiries regarding the timing and amount of deductions, and compliance with U.S. federal and state tax laws. In general, OncoCyte is no longer subject to tax examination by major taxing authorities for years before 2013. Although the statute is closed for purposes of assessing additional income and tax in those years, the taxing authorities may still make adjustments to the net operating loss and credit carryforwards used in open years. Any potential examinations may include inquiries regarding the timing and amount of deductions, and compliance with U.S. federal and state tax laws.

9. Commitments and Contingencies

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

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Master Lease Line Agreement

On April 7, 2016, OncoCyte entered into a Master Lease Line Agreement ("Lease Agreement") 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 through April 2017. Each lease schedule OncoCyte enters into under Lease Agreement 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, 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 under the Lease Agreement ("Lease Schedule 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 was closed and has no remaining financing available.

OncoCyte has accounted for these leases as a capital lease in accordance with ASC 840, Leases, due to the net present value of the payments under the lease approximating the fair value of the equipment at inception of the lease. 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.

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. As of December 31, 2017, $820,000 under Lease Agreement No. 2 was available to OncoCyte.

Future minimum annual lease payments under Lease Schedule No.'s 1, 2, and 3 above for the years ending after December 31, 2017 are as follows (in thousands):

Year Ending December 31,	Capital Lease Payments
2018	$ 383
2019	248
2020	59
Total minimum lease payments	690
Less amounts representing interest	(63)
Present value of net minimum lease payments	$ 627

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 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 others. 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. OncoCyte is not aware of any claims likely to have a material adverse effect on its financial condition or results of operations.

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.

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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, 2017 and 2016.

10. Subsequent Events

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. Of this amount, OncoCyte has received $8.0 million in gross proceeds from the sale of 6,349,206 shares of common stock, and one of the investors irrevocably committed in the agreement to pay to OncoCyte an additional $2.0 million on or prior to April 30, 2018 for the purchase of an additional 1,587,302 shares of common stock. The agreement contains certain registration rights. The investors are existing security holders of OncoCyte, including Broadwood Partners, L.P., which beneficially owns more than 5% of OncoCyte's outstanding common stock.

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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 period covered by this Annual Report on Form 10-K 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, 2017, 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

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PART III

Item 10. Directors, Executive Officers, and Corporate Governance

The name, age, and background of each of our directors are contained under the caption “Election of Directors” in our Proxy Statement for our 2018 Annual Meeting of Shareholders, and are incorporated herein by reference. Information about our executive officers, committees of the Board of Directors, and compensation of directors is reported under the caption “Corporate Governance” in our Proxy Statement for our 2018 Annual Meeting of Shareholders, and is incorporated herein by reference.

We have a written Code of Ethics that applies to our principal executive officer, our principal financial officer and accounting officer, our other executive officers, and our directors. The purpose of the Code of Ethics is 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 Securities and Exchange Commission 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 is reported under the caption “Compliance with Section 16(a) of the Securities Exchange Act of 1934” in our Proxy Statement for our 2018 Annual Meeting of Shareholders, and is incorporated herein by reference.

Item 11. Executive Compensation

Information on compensation of our executive officers is reported under the caption “Executive Compensation” in our Proxy Statement for our 2018 Annual Meeting of Shareholders, and 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, is contained under the caption “Principal Shareholders” in our Proxy Statement for our 2018 Annual Meeting of Shareholders, and 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; and director independence is reported under the caption “Election of Directors” in our Proxy Statement for our 2018 Annual Meeting of Shareholders, and 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 is reported under the caption “Ratification of the Selection of Our Independent Auditors” in our Proxy Statement for our 2018 Annual Meeting of Shareholders, and is incorporated herein by reference.

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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 (Deficit)
Statements of Cash Flows

Exhibit Numbers	Exhibit Description
3.1	Articles of Incorporation with all amendments (1)
3.2	By-Laws, as amended (1)
4.1	Specimen of Common Stock Certificate (1)
4.2	Form of August 2016 Warrant (5)
4.3	Form of 2017 Warrant, Exercise Price $3.25 (7)
4.4	Form of 2017 Warrant, Exercise Price $5.50 (7)
4.5	Silicon Valley Bank Warrant (7)
4.6	Form of July 2017 Warrant, Exercise Price $5.50; five-year term (10)
4.7	Form of July 2017 Warrant, Exercise Price $3.25, five-year term (10)
4.8	Form of July 2017 Warrant, Exercise Price $3.25, two-year term (10)
4.9	Form of July 2017 Warrant, Exercise Price $5.50, two-year term (10)
10.1	Shared Facilities Agreement, dated October 8, 2009 between OncoCyte Corporation and BioTime, Inc. (1)
10.2	Form of Director/Consultant Option Agreement
10.3	Form of Employee Incentive Stock Option Agreement (1)
10.4	Employment Agreement, dated June 15, 2015, between OncoCyte Corporation and William Annett (1)
10.5	Employment Agreement, dated August 1, 2015, between OncoCyte Corporation and Kristine Mechem (1)
10.6	Registration Rights Agreement dated October 15, 2009 (1)

10.7	Amendment of Registration Rights Agreement, dated August 23, 2011 (1)
10.8	Second Amendment of Registration Rights Agreement, dated May 8, 2015 (1)

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10.9	Third Amendment to Registration Rights Agreement, dated November 16, 2015 (2)
10.10	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) (3)
10.11	First Amendment to License Agreement, dated January 25, 2016, between OncoCyte Corporation and The Wistar Institute of Anatomy and Biology (3)
10.12	Second Amendment to License Agreement, dated January 25, 2016, between OncoCyte Corporation and The Wistar Institute of Anatomy and Biology (4)
10.13	Form of OncoCyte Corporation Securities Purchase Agreement (5)
10.14	Alternate Form of OncoCyte Corporation Securities Purchase Agreement (5)
10.15	Employment Agreement, dated November 1, 2016, between OncoCyte Corporation and Lyndal Hesterberg (7)
10.16	Form of Warrant Exercise Agreement (6)
10.17	Form of Alternate Warrant Exercise Agreement (6)
10.18	Loan and Security Agreement, dated February 21, 2017, between OncoCyte Corporation and Silicon Valley Bank (7)
10.19	Employment Termination and Release Agreement, dated February 27, 2017, between OncoCyte Corporation and Karen Chapman (8)
10.20	2017 Amendment to 2010 Stock Option Plan (9)
10.21	Form of July 2017 Warrant Exercise Agreement (July 2017 Warrant for 100% of shares received on exercise of Original Warrant, at $5.50 exercise price with five-year term) (10)
10.22	Form of July 2017 Warrant Exercise Agreement (July 2017 Warrant for 50% of shares received on exercise of Original Warrant, at $3.25 exercise price with five-year term) (10)
10.23	Form of July 2017 Warrant Exercise Agreement (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) (10)
10.24	Employment Agreement, dated November 15, 2017, between OncoCyte Corporation and Mitchell Levine*
10.25	Employment Agreement, dated August 31, 2017, between OncoCyte Corporation and Michael Vicari*
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*