ATOSSA GENETICS INC
Form 10-K
March 30, 2016

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark one)

x **Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

For the fiscal year ended December 31, 2015

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 001-35610

ATOSSA GENETICS INC.

(Exact name of registrant as specified in its charter)

Delaware	**26-4753208**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

2300 Eastlake Ave. East, Suite 200

Seattle, WA 98102

(Address of principal executive offices)

Registrant's telephone number, including area code: **(800) 351-3902**

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

Title of each class	Name of each exchange on which registered
Common Stock, $0.001 par value	The NASDAQ Capital Market

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 x

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act 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 x No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, 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 x No ¨

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K 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. Yes ¨ No x

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer or a non-accelerated filer, as defined 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 x

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

As of June 30, 2015, the last business day of the registrant’s most recently completed second fiscal quarter, the aggregate market value of the voting and non-voting common equity held by non-affiliates was $27,422,532. Shares of common stock held by each officer and director and by each person who is known to own 10% or more of the outstanding Common Stock have been excluded in that such persons may be deemed to be affiliates of the Company. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

The number of shares outstanding of the registrant's Common Stock, par value $0.001, as of March 28, 2016 was 38,823,464.

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NOTE REGARDING FORWARD-LOOKING STATEMENTS

Statements made in this report on Form 10-K that are not statements of historical information are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the ***"Securities Act"***) and Section 21E of the Securities Exchange Act of 1934, as amended (the ***" Exchange Act"***). We have made these statements in reliance on the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These statements are subject to certain risks and uncertainties, which could cause actual results to differ materially from those projected or anticipated. Although we believe our assumptions underlying our forward-looking statements are reasonable as of the date of this report we cannot assure you that the forward-looking statements set out in this report will prove to be accurate. We typically identify these forward-looking statements by the use of forward-looking words such as "expect," "potential," "continue," "may," "will," "should," "could," "would," "seek," "intend," "plan," "estimate," "an negative version of those words or other comparable words. Forward-looking statements contained in this report include, but are not limited to, statements about:

- whether we can obtain approval from the U.S. Food and Drug Administration, or FDA, and foreign regulatory bodies, to sell, market and distribute our therapeutics and devices under development;

- our ability to successfully complete clinical trials of our pharmaceutical candidates under development, including Afimoxifene Gel and our intraductal microcatheters to administer therapeutics, including the study we recently opened using fulvestrant;

- the success, cost and timing of our product and drug development activities and clinical trials;

- our ability to succeed in our lawsuit against Besins Healthcare Luxembourg SARL ("Besins") for breach of contract and other claims against them and to defend against their counterclaims;

- our ability to contract with third-party suppliers, manufacturers and service providers, including clinical research organizations, and their ability to perform adequately;

- our ability to successfully develop and commercialize new therapeutics currently in development or that we might identify in the future and in the time frames currently expected;

- our ability to successfully defend ongoing litigation, including the securities class action law suit filed against us on October 10, 2013, and other similar complaints that may be brought in the future, in a timely manner and within the coverage, scope and limits of our insurance policies;

- our ability to establish and maintain intellectual property rights covering our products;

- our expectations regarding, and our ability to satisfy, federal, state and foreign regulatory requirements;

- the accuracy of our estimates of the size and characteristics of the markets that our products and services may address;

- our expectations as to future financial performance, expense levels and capital sources;

- our ability to attract and retain key personnel; and

- our ability to raise capital.

These and other forward-looking statements made in this report are presented as of the date on which the statements are made. We have included important factors in the cautionary statements included in this report, particularly in the section titled “ITEM 1A. RISK FACTORS,” that we believe could cause actual results or events to differ materially from the anticipated results as set forth in the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any new information, future events or circumstances that may affect our business after the date of this report. Except as required by law, we do not intend to update any forward-looking statements after the date on which the statement is made, whether as a result of new information, future events or circumstances or otherwise.

CORPORATE INFORMATION

Our corporate website is located at *www.atossagenetics.com*. Information contained on, or that can be accessed through, our website is not a part of this report. We make available, free of charge through our website or upon written request, our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and other periodic SEC reports, along with amendments to all of those reports, as soon as reasonably practicable after we file the reports with the SEC.

Unless otherwise noted, the term “Atossa Genetics” refers to Atossa Genetics Inc., a Delaware corporation, the terms “Atossa,” the “Company,” “we,” “us,” and “our,” refer to the ongoing business operations of Atossa and the historic business o The National Reference Laboratory for Breast Health, Inc. (the “NRLBH”), whether conducted through Atossa Genetics or the NRLBH; however unless the context otherwise indicates, references to “we,” “our” or the “Company” as they relate to laboratory tests generally refers to activities conducted by the NRLBH. We were incorporated in Delaware in April 2009. Our principal executive offices are located at 2300 Eastlake Ave. East, Suite 200, Seattle WA 98102, and our telephone number is (800) 351-3902.

Mammary Aspiration Specimen Cytology Test (MASCT), is our registered trademark and Oxy-MASCT and our name and logo are our trademarks. ForeCYTE, FullCYTE, NextCYTE, ForeCYTE Breast Aspirator and ArgusCYTE are our service marks. This report also includes additional trademarks, trade names and service marks of third parties, which are the property of their respective owners. You are advised to read this Annual Report on Form 10-K in conjunction with other reports and documents that we file from time to time with the Securities and Exchange Commission (the “SEC”). In particular, please read our definitive proxy statement, which will be filed with the SEC in connection with our 2016 Annual Meeting of Stockholders, our Quarterly Reports on 10-Q and any Current Reports on Form 8-K that we may file from time to time. You may obtain copies of these reports after the date of this annual report from the SEC at the SEC’s Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549. In addition the SEC maintains information for electronic filers (including Atossa) at its website www.sec.gov. The public may obtain information regarding the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330.

PART I

ITEM 1. BUSINESS

Overview

We are a clinical-stage pharmaceutical company focused on the development of novel therapeutics and delivery methods for the treatment of breast cancer and other breast conditions. Our leading program uses our patented intraductal microcatheters which deliver pharmaceuticals through the breast ducts. We initiated a Phase 2 clinical study in March 2016 using our microcatheters to deliver fulvestrant as a potential treatment of ductal carcinoma in-situ, or DCIS, and breast cancer. This study is being conducted by Columbia University Medical Center Breast Cancer Programs. Our second pharmaceutical program under development is Afimoxifene Topical Gel, or AfTG, for the treatment and prevention of hyperplasia of the breast.

In addition to our clinical-stage pharmaceutical programs, we are in the process of evaluating other therapeutic candidates to treat other breast conditions, including breast cancer. Factors we are considering in evaluating potential drug candidates include, for example, the ability to obtain expedited regulatory approval, significance of unmet medical need, size of the patient population, intellectual property opportunities and the anticipated pre-clinical and clinical pathway.

Through mid-2015, we were primarily focused on the development and commercialization of our medical devices and laboratory tests. Our medical devices include the ForeCYTE Breast Aspirator and the FullCYTE Breast Aspirator. These devices are intended for the collection of nipple aspirate fluid, or NAF, for cytological testing at a laboratory. We are not, however, currently marketing and promoting our breast aspirators nor any laboratory tests as we are devoting substantially all of our resources to our pharmaceutical business. Other devices under development also include intraductal microcatheters for the potential administration of targeted pharmaceuticals, and various tools for potential use by breast surgeons.

Our laboratory tests have historically been developed and performed by The National Reference Laboratory for Breast Health, Inc., or the “NRLBH.” The NRLBH was our wholly-owned subsidiary until December 16, 2015 when, pursuant to a stock purchase agreement, we sold approximately 81% of the capital stock of the NRLBH to the NRL Investment Group, LLC. We have determined that the disposition of the lab business qualifies for reporting as a discontinued operation since the sale represents a strategic shift that will have a major effect on our operations and financial results. We have elected to recognize any subsequent gain from the earn-out payments payable to us pursuant to the stock purchase agreement as they are determined realizable.

We are now focusing our business on our pharmaceutical programs and delivery methods. Our key objectives are to advance our pharmaceutical candidates through Phase 2 trials and then evaluate further development independently or through partners and to advance one or more of our pre-clinical programs into the clinical trial stage.

Our common stock is currently quoted on The NASDAQ Capital Market under the symbol “ATOS.”

Our Clinical-Stage Programs Under Development

Delivery of Therapeutics via our Microcatheters

We believe our patented intraductal microcatheters may be useful in delivering a number of therapeutics to the ducts in the breast. Doing so is intended to provide a therapeutic directly to the breast tissue. We must obtain FDA approval of any drug delivered via our intraductal microcatheters devices which will require expensive and time-consuming studies. For example, we must complete clinical studies to demonstrate the safety and tolerability of fulvestrant using our delivery method. We may not be successful in completing these studies and obtaining FDA approval.

Although breast cancers and precancerous lesions are detected at an earlier stage, and despite the use of systemically administered agents such as tamoxifen and Faslodex®, serious side effects remain a major challenge, and may lead to poor patient compliance with the drug regimens. The American Cancer Society estimates over 292,000 American women were diagnosed with breast cancer (both local and invasive) in 2015. They also estimate that over 40,000 women died in 2015 due to their disease. Providing drug directly into the ducts targeting the site of the localized cancerous lesions could reduce the need for systemic anti-cancer drugs, and potentially reducing or eliminating the systemic side effects of the drugs and morbidity in such patients, and ultimately improve patient compliance and ultimately reduce mortality.

One potential market for intraductal therapy is to take advantage of the large difference in the amount of drug that potentially gets into the breast tissue with the intraductal administration versus the intramuscular injection. One analysis suggests that the drug levels in breast tissue might be over 20,000-times higher with the intraductal route than the drug levels following systemic delivery of the same dose. This provides the potential to test a 'one and done' intraductal treatment modality instead of the monthly injections and with potentially higher tissue levels than are possible with intramuscular injection which should represent a significant cost savings to the healthcare system.

A second potential indication for intraductal therapy is in the neoadjuvant setting, meaning that the drug would be delivered before the primary treatment of surgery. High drug concentration at the site of the tumor and lack of systemic exposure and subsequent toxicity could represent treatment advances. The current neoadjuvant schedules can run for three months before surgery and the ability to shorten that by one or even two months has value for the patient and the healthcare system.

Fulvestrant Delivered Via our Microcatheters

The initial drug we are studying using our microcatheters for intraductal delivery is fulvestrant. Fulvestrant is FDA-approved for metastatic breast cancer. It is administered as a monthly injection of two shots, typically into the buttocks. In 2012 a published study documented that the single dose cost of intramuscular fulvestrant was approximately $12,000.

We own one issued patent and several pending applications directed to the treatment of breast conditions, including cancer, by the intraductal administration of therapeutics including fulvestrant.

We do not yet have FDA's input, but our preliminary analysis, subject to FDA feedback, is that the intraductal fulvestrant program could qualify for designation under the 505(b)(2) status. This would allow us to file with only clinical data and without having to perform additional, significant clinical or pre-clinical studies. So the path to market is both faster and less expensive than a standard new drug application, or NDA, program.

To support this development program, we have successfully produced microcatheters for the fulvestrant Phase 2 clinical trial. The FDA has also issued a "Safe to Proceed" letter for our first Investigational New Drug application (IND) for the Phase 2 study and the institutional review board approval has also been received.

In March 2016, we opened enrollment in the study ATOS-2015-007, which will be conducted by The Columbia University Medical Center Breast Cancer Program and is known as the “007 Trial”. The 007 Trial is a Phase 2 study in women with DCIS or invasive breast cancer slated for mastectomy or lumpectomy. This study will assess the safety, tolerability and distribution of fulvestrant when delivered directly into breast milk ducts of these patients compared to those who receive the same product intramuscularly. The first six study participants will receive the standard intramuscular fulvestrant dose of 500 mg to establish the reference drug distribution. The subsequent 24 participants will receive fulvestrant by intraductal instillation utilizing our microcatheter device. The total dose administered in this manner will not exceed 500 mg.

The primary endpoint of the clinical trial is to assess the safety, tolerability and distribution of intraductally administered fulvestrant in women with DCIS or Stage 1 or 2 invasive ductal carcinoma prior to mastectomy or lumpectomy. The secondary objective of the study is to determine if there are changes in the expression of Ki67 as well as estrogen and progesterone receptors between a pre-fulvestrant biopsy and post-fulvestrant surgical specimen. Digital breast imaging before and after drug administration in both groups will also be performed to determine the effect of fulvestrant on any lesions as well as breast density of the participant. Additional information about the study can be found at: https://clinicaltrials.gov/ct2/show/NCT02540330?term=atossa&rank=2.

Other Studies of Intraductal Administration using our Microcatheters

An October 2011 peer-reviewed paper published in Science *Translational Medicine* reported the results of a study conducted at the Johns Hopkins Medical School demonstrating the prevention of breast cancer in rats with intraductal non-systemic chemotherapy, and a proof-of-principle Phase 1 clinical trial involving 17 women with breast cancer who subsequently received surgery. An accompanying editorial commented that “intraductal treatment could be especially useful for women with premalignant lesions or those at high risk of developing breast cancer, thus drastically improving upon their other, less attractive options of breast-removal surgery or surveillance (termed ‘watch and wait’).”

In a December 2012 peer-reviewed paper published in *Cancer Prevention Research,* Dr. Susan Love and her colleagues reported the results of a Phase I clinical trial of intraductal chemotherapy drugs administered into multiple ducts within one breast in women awaiting mastectomy for treatment of invasive cancer. Thirty subjects were enrolled in this dose escalation study conducted at a single center in Beijing, China. Under local anesthetic, one of two chemotherapy drugs, carboplatin or pegylated liposomal doxorubicin (PLD), was administered into five to eight ducts at three dose levels. Pharmacokinetic analysis has shown that carboplatin was rapidly absorbed into the bloodstream, whereas PLD, though more erratic, was absorbed after a delay. Pathologic analysis showed marked effects on breast duct epithelium in ducts treated with either drug compared with untreated ducts. The investigators concluded the study showed the safety and feasibility of intraductal administration of chemotherapy drugs into multiple ducts for the purpose of breast cancer prevention and that this was an important step towards implementing of this strategy as a "chemical mastectomy," potentially eliminating the need for surgery.

Afimoxifene Topical Gel (AfTG)

Overview

We hold the worldwide exclusive rights to develop and commercialize AfTG for the potential treatment and prevention of hyperplasia of the breast. The active pharmaceutical ingredient in AfTG is Afimoxifene (4-hydroxytamoxifen), which is an active metabolite of tamoxifen. Afimoxifene is an anti-estrogen with an affinity for estrogen receptor that is up to 50 fold higher compared with that of tamoxifen. AfTG is a proprietary transdermal gel formulation of Afimoxifene protected by 10 patent families. We are evaluating AfTG for potential use in several patient populations, including but not limited to: high risk women as determined by family history, etc.; women with breast hyperplasia; and women with a biopsy showing either atypical hyperplasia or DCIS.

AfTG can be dispensed from a convenient metered-dose container. We have rights to a comprehensive preclinical pharmacology and toxicology package on AfTG and its manufacturing CMC package is expected to be sufficient to support our Phase 2 and 3 programs. A total of 16 Phase 1 and Phase 2 studies have been conducted in a variety of indications in the United States, United Kingdom, France, Poland, and Czech Republic. These studies enrolled over 450 patients total, and results were published in leading medical journals such as the Journal of Clinical Oncology (J Clin Oncol 2005;23:2980-87), Clinical Cancer Research (Clin Cancer Res 2014;20:3672-82), and Breast Cancer Research and Treatment (Breast Cancer Res Treat 2007;106:389-97).

Potential Funding by NCI

The National Cancer Institute, Division of Cancer Prevention, has indicated that a member of the Consortia for Cancer Prevention Clinical Trials Program will be conducting a study of AfTG in women with DCIS and another in women with breast density. The Consortia includes five major medical research centers: the University of Arizona, Northwestern University, Mayo Clinic Foundation, M. D. Anderson Cancer Center and the University of Wisconsin. The next step is for the academic investigator to develop a clinical protocol. The majority of the cost of the clinical trial is expected to be paid for by the NCI. This program could provide major clinical validation of AfTG by the NCI and leading breast cancer academic investigators.

Existing Data on AfTG

AfTG has been used in 16 Phase 1 and Phase 2 studies conducted in a variety of indications with over 450 patients. We are in the process of re-establishing the clinical supply of AfTG and plan to commence a Phase II clinical trial in mid-2016.

The results of previous studies show that the efficacy of oral tamoxifen in preventing cancer in the study patient populations varies from a low of about 50% to a high of almost 85%. The cancers that did occur in the patients in these studies had a common theme: none of them were estrogen receptor positive. So, the most common kind of breast cancer, estrogen positive, is almost entirely prevented by oral tamoxifen. The most common form of male breast cancer is also estrogen receptor positive, so there is potential for this currently underserved breast cancer population.

These studies demonstrate that tamoxifen is quite effective in preventing breast cancer in these patient populations. We anticipate that our studies will show that AfTG is also effective but because it is delivered topically rather than orally (as in tamoxifen) that AfTG will have a superior safety profile.

In a previous study conducted by the National Cancer Institute and academic centers in women with DCIS, oral tamoxifen or AfTG was given to women for a month and the amount of drug was measured in the breast, and in the blood: blood levels are associated with toxicity. The results show that there were similar amounts of active drug in the breast of both groups but <5% of drug in the blood with our gel compared to oral tamoxifen. The blood markers of stroke, blood clots, and uterine cancer were increased by oral tamoxifen but not AfTG. Additionally, the biomarker in the breast of blocking estrogen effect, called Ki-67, showed similar blockage of cell growth.

Summary of our Rights to AfTG

These AfTG rights were granted to us pursuant to a May 14, 2015, Intellectual Property License Agreement with Besins Healthcare Luxembourg SARL. The agreement requires that we pay a royalty of 8% to 9% of net sales for the first 15 years of commercialization. We have the non-exclusive right to also develop AfTG for breast cancer and other breast diseases, which would require the payment of the following milestone payments for these additional indications: (i) $5,000,000 for the exclusive right to review, access, and reference a Besins investigational new drug application (IND) for each additional indication, and (ii) $20,000,000 when we commence a Phase 3 clinical trial for each additional indication.

Besins has a limited right of first refusal to commercialize AfTG on a country-by-country basis in countries where Besins has a marketing presence.

The agreement automatically expires on a country-by-country basis fifteen years after the first commercial sale of AfTG in the particular country. The agreement may be terminated (i) by either party upon a material breach of the agreement that is not cured by the breaching party, (ii) by mutual agreement of the parties, (iii) by Atossa at its discretion if it elects to stop developing or commercializing AfTG, (iv) by Besins on a country-by-country basis or indication-by-indication basis if we fail to commercialize or commence commercial sales within a specified time, or (v) by Besins if we fail to accomplish any aspect of the development plan within six months of target date set forth in the development plan. The development plan covers an 18-month period and is required to be updated by us every six months during the term of the agreement.

Besins has informed us that they plan to develop AfTG for the reduction of breast density, which we believe is within the scope of our exclusive rights under the License Agreement. We have informed Besins that its efforts to develop AfTG for breast density would infringe our exclusive rights under the License Agreement, including our exclusive rights to develop AfTG for treatment and prevention of hyperplasia of the breast, and would constitute a breach of the License Agreement by Besins.

On January 28, 2016, we filed a complaint in the United States District Court for the District of Delaware captioned *Atossa Genetics Inc. v. Besins Healthcare Luxembourg SARL.* The complaint asserts claims for breach of contract, breach of the implied covenant of good faith and fair dealing, and for declaratory relief against Besins. On March 7, 2016, Besins responded to our complaint by denying our claims and asserting counterclaims against us for breach of contract, fraud, and negligent misrepresentation and declaratory relief. We believe that these counterclaims are without merit and we plan to defend our self vigorously; however, failure by us to obtain a favorable resolution of the counterclaims could have a material adverse effect on our business, results of operations and financial condition.

Next steps with AfTG

We have engaged AAIPharma/Cambridge Major Laboratories to manufacture Afimoxifene, the API in AfTG. They are an experienced pharmaceutical manufacturer with a good FDA track record and we are confident will be able to produce the cGMP quantities in a timely manner to support our study plans.

Although we have received written FDA guidance pertaining to our AfTG development program, all work is on hold pending resolution of our dispute with Besins.

Our Pre-Clinical Programs Under Development

In addition to our clinical-stage pharmaceutical programs, we are in the process of evaluating other therapeutic candidates to treat breast conditions, including breast cancer. Factors we are considering in evaluating potential drug candidates include, for example, the ability to obtain expedited regulatory approval, significance of unmet medical need, size of the patient population, intellectual property opportunities and the anticipated pre-clinical and clinical pathway.

NRLBH and our Laboratory Tests

The NRLBH, located in Seattle, Washington, is certified under CLIA and ISO 15189:2012 and is certified by the College of American Pathologists. We believe the NRLBH is one of fewer than ten laboratories in the United States to hold the ISO 15189:2012 certification and it was the first commercial lab in the country to offer enhanced pharmacogenomics testing based on the Luminex xTAG platform. Historically, substantially all of our revenue has been generated by the NRLBH from its pharmacogenomics test services.

Through December 16, 2015, our laboratory tests consisted of NAF cytology tests, pharmacogenomics tests and various tests under development including our NextCYTE Breast Cancer Test. These tests were developed by the NRLBH, and in the case of the NAF cytology and pharmacogenomics tests, were also marketed and sold by the NRLBH. The NRLBH generally owned the equipment and supplies necessary to develop the tests and to perform the tests and generally contracted directly with third parties for necessary supplies and services to develop and conduct the tests. Significant assets and contracts of the NRLBH as of December 16, 2015 included, for example, the following:

Affymetrix - GeneChip System 3000Dx v.2 and related GeneChip Human Genome U133 Plus 2.0 arrays for a total purchase obligation of $647,700 with a minimum purchase of ten 30-pack arrays per contract year, and a two year service contract for $51,600 to cover maintenance of the instrument. On September 29, 2015, we entered into a new agreement with Affymetrix to purchase the instrument for $129,000 and all of the prior purchase commitments under the initial Affymetrix agreement were terminated.

Tissue Specimens for NextCYTE Test - On September 1, 2014, we entered into a three year agreement with TME Research LLC which requires TME to provide 100 tissue specimens in connection with the development of the NextCYTE test. Fees payable to TME under the agreement includes $99,600 up front, $31,500 upon supplying the first 25 specimens and $31,500 at the time of final delivery of all specimens. The agreement is terminable with 60 days prior written notice or immediately upon a material breach. As of December 31, 2015, the Company has paid $131,000 in set-up fees, which were recorded as R&D expenses in 2014 and $41,000 in 2015 for additional R&D spending on NextCYTE.

On June 10, 2013, we entered into an irrevocable license and service agreement with A5 Genetics KFT, Corporation, pursuant to which we received the world-wide (other than the EU) exclusive license to the software used in the NextCYTE test. We have the right to prosecute patents related to this software, two of which we have filed in the United States. The patent applications have been assigned to us. We paid a one-time fee of $100,000 to A5 Genetics in 2013 and in March 2014 we completed software validation and paid an additional $100,000 to A5 Genetics. We are obligated to pay up to an additional $1.2 million to A5 Genetics upon commercial launch of the NextCYTE test and receiving FDA approval. We must also pay a royalty of $50 and a service fee of $65 for each NextCYTE test performed. The NextCYTE test is still in the validation stage and no royalty or service fees have been paid as of December 31, 2015. The agreement was terminated on February 23, 2016 with no further milestones due to A5 Genetics.

The Affymetrix machine and GeneChips were included with the NRLBH assets at the time of the transaction with the NRL.

We are not currently developing the NextCYTE Breast Cancer test nor any other tests as we are devoting substantially all of our resources to the development of our pharmaceutical programs.

On December 16, 2015, we announced the sale of approximately 81% of the capital stock of the NRLBH to the NRL Investment Group, LLC, for an initial payment of $50,000 and potential future earn-out payments based on 6% of gross revenue of the NRLBH beginning in December 2016, up to a maximum earn-out of $10,000,000. We retained 19% ownership through preferred stock which we have the right to sell after four years at the greater of $4,000,000 or fair market value. We have elected to recognize the subsequent gains from the earn-out payments as they are determined realizable.

As of the date of this report, we are no longer involved in the management and operations of the NRLBH as we are devoting substantially all of our resources towards the development of our pharmaceutical programs. The disposition of the NRLBH business qualifies for reporting as a discontinued operation since the sale represents a strategic shift that will have a major effect on our operations and financial results. Financial results of the NRLBH are presented separately as discontinued operations for both years presented.

Our Medical Devices

The ForeCYTE Breast Aspirator is a medical device which consists of a reusable hand-held pump for the collection of NAF, single-use patient kits that include two NAF sample collection tools per kit, and shipment boxes for the transportation of NAF samples to any testing laboratory for cytological analysis. The FullCYTE Breast Aspirator is FDA-cleared and is simpler in design as it contains four parts in a fully disposable, single-use aspirator. This device operates slightly differently than the ForeCYTE Breast Aspirator in that the NAF sample is captured via capillary tubes prior to being sent to any lab for analysis. We have also developed a universal transport kit to assist with the packaging and transport of NAF samples to a laboratory. NAF cytology testing is an Laboratory Developed Test (LDT) consisting of receiving and accessioning the two NAF samples from each patient, preparing routine and immunohistochemistry, or IHC, in the case of NAF collected with the current ForeCYTE or FullCYTE device, staining of slides from the NAF samples, and generating a report of the findings. The NAF is analyzed by microscopy for cytological abnormalities and by a patent-pending IHC staining technique for five biomarkers of hyperplasia and a sample integrity marker. The NAF cytology test on samples collected with the ForeCYTE device also involves one biomarker of sample integrity and has been validated to CLIA standards. However, we are not currently commercializing our breast aspirator devices nor any NAF cytology tests.

In 2012 we acquired from Acueity Healthcare various medical devices consisting primarily of tools to assist breast surgeons. Our breast aspirator devices, universal transport kit and devices acquired from Acueity are not currently being marketed and sold as we are devoting substantially all of our resources to the development of our pharmaceutical programs.

Our patented intraductal microcatheter devices are being developed for the targeted delivered of potential pharmaceuticals, as described above.

Our Capital Resources

We have not yet established an ongoing source of revenue sufficient to cover our operating costs and allow us to continue as a going concern. Our ability to continue as a going concern is dependent on obtaining adequate capital to fund operating losses until we become profitable. We plan to obtain additional capital resources by selling our equity securities and borrowing from stockholders or others when needed. However, we cannot assure you that we will be successful in accomplishing any of these plans and, if we are unable to obtain adequate capital, we could be forced to cease operations. Since inception, substantially all of our revenue has been from sales of our breast aspirator devices and from laboratory testing performed by the NRLBH. We have shifted our business strategies to focus on our pharmaceutical programs, and as a result, we sold 81% of the ownership of the NRLBH and are not currently marketing and promoting our devices nor the NRLBH testing services. We do not anticipate any revenue until our pharmaceutical programs are developed, including receiving all necessary regulatory approvals, and until we successfully commercialize these programs.

As of December 31, 2015, we had cash and cash equivalents of $3,715,895. Our capital raising activity from January 2014 through the date of filing this report consists of the following:

2014:

On January 29, 2014, we completed a public offering of approximately 5.8 million units at the price of $2.40 per unit, with each unit consisting of one share of common stock and a five year warrant to purchase 0.20 of a share of common stock, for gross proceeds of approximately $14.0 million. The warrants are exercisable at $3.00 per share and are callable by us if and when the trading price of our common stock is $6.00 per share over a defined period and subject to a daily volume minimum.

2015:

During the first quarter of 2015, we sold a total of 2,653,199 shares of common stock to Aspire Capital under the stock purchase agreement dated November 8, 2013 with aggregate gross proceeds to us of $4,292,349. That agreement has been terminated.

On May 26, 2015, we entered into a new common stock purchase agreement with Aspire Capital Fund, LLC, which provides that, upon the terms and subject to the conditions and limitations set forth therein, Aspire Capital is committed to purchase up to an aggregate of $25.0 million of shares of our common stock over the 30-month term of the purchase agreement. Concurrently with entering into the purchase agreement, we also entered into a registration rights agreement with Aspire Capital, in which we agreed to file one or more registration statements, as permissible and necessary to register under the Securities Act of 1933, registering the sale of the shares of our common stock that have been and may be issued to Aspire Capital under the purchase agreement. In consideration for entering into the purchase agreement, concurrently with the execution of the purchase agreement, we issued to Aspire Capital 375,000 shares of our common stock.

In June 2015, we sold 1,454,003 shares of common stock at the purchase price of $1.15 per share and pre-funded warrants to purchase 3,610,997 shares of common stock (the “Pre-Funded Warrants”) at a purchase price of $1.14 per share for total gross proceeds of $5.8 million (the “2015 Offering”). Each Pre-Funded Warrant was exercisable for $0.01 per share, subject to adjustments from time to time and certain limits on each holder’s beneficial ownership of common stock of the Company. As of December 31, 2015, all Pre-Funded Warrants had been exercised and none remain outstanding.

On November 11, 2015, we terminated the May 26, 2015 agreement with Aspire and entered into a new common stock purchase which provides that, upon the terms and subject to the conditions and limitations set forth therein, Aspire Capital is committed to purchase up to an aggregate of $25.0 million of our shares of Common Stock over the approximately 30-month term of the Purchase Agreement. Concurrently with entering into the Purchase Agreement, we also entered into a registration rights agreement with Aspire Capital in which we agreed to register 6,086,207 shares of our common stock.

On December 17, 2015, the conditions necessary for purchases to commence under the November 11, 2015 agreement were satisfied. On any trading day on which the closing sale price of our common stock exceeds $0.10, we have the right, in our sole discretion, to present Aspire Capital with a purchase notice, directing Aspire Capital (as principal) to purchase up to 150,000 shares of our common stock per trading day, provided that the aggregate price of such purchase shall not exceed $500,000 per trading day, up to $25.0 million of our Common Stock in the aggregate at a per share price calculated by reference to the prevailing market price of our common stock.

In addition, on any date on which we submit a purchase notice for 150,000 shares to Aspire Capital and the closing sale price of our stock is equal to or greater than $0.50 per share of Common Stock, we also have the right, in our sole discretion, to present Aspire Capital with a volume-weighted average price purchase notice (each, a “VWAP Purchase Notice”) directing Aspire Capital to purchase an amount of stock equal to up to 30% of the aggregate shares of our Common Stock traded on the NASDAQ on the next trading day (the “VWAP Purchase Date”), subject to a maximum number of shares we may determine (the “VWAP Purchase Share Volume Maximum”) and a minimum trading price (the “VWAP Minimum Price Threshold”). The purchase price per share pursuant to such VWAP Purchase Notice (the “VWAP Purchase Price”) is calculated by reference to the prevailing market price of our Common Stock.

The Purchase Agreement provides that we and Aspire Capital shall not affect any sales under the Purchase Agreement on any purchase date where the closing sale price of our Common Stock is less than $0.10 per share (the "Floor Price"). This Floor Price and the respective prices and share numbers in the preceding paragraphs shall be appropriately adjusted for any reorganization, recapitalization, non-cash dividend, stock split, reverse stock split or other similar transaction. There are no trading volume requirements or restrictions under the purchase agreement, and we will control the timing and amount of any sales of our common stock to Aspire Capital. Aspire Capital has no right to require any sales by us, but is obligated to make purchases from us as we direct in accordance with the purchase agreement. There are no limitations on use of proceeds, financial or business covenants, and restrictions on future fundings, rights of first refusal, participation rights, penalties or liquidated damages in the purchase agreement. Aspire Capital may not assign its rights or obligations under the purchase agreement. The purchase agreement may be terminated by us at any time, at our discretion, without any penalty or cost to us.

The issuance of the all shares to Aspire Capital under the purchase agreement is exempt from registration under the Securities Act, pursuant to the exemption for transactions by an issuer not involving any public offering under Section 4(a)(2) of the Securities Act and Rule 506 of Regulation D promulgated thereunder.

2016:

In 2016 through the date of filing this report, we have sold 6,086,207 shares of common stock to Aspire under the November 11, 2015 agreement with them for aggregate gross proceeds to us of $2,153,583. As a result, no shares are available for sale under this agreement.

Research and Development

Our pharmaceutical programs are in the research and development phase. In 2014 and 2015, we incurred significant research and development expenses to develop our medical devices and laboratory tests. Research and development costs are generally expensed as incurred. Our research and development expenses consist of costs incurred for internal and external research and development. These costs are also comprised of costs incurred to develop new technology and carry out clinical studies and includes salaries and benefits. Research and development expenses for the years ended December 31, 2015 and 2014 were $2,359,593 and $1,110,329, respectively.

Intellectual Property

As of December 31, 2015, and based on a recent periodic review of our patent estate, we own 147 issued patents (45 in the United States and approximately 102 in foreign countries), and 22 pending patent applications (10 in the United States, and 12 pending international applications) directed to our products, services, and technologies. Our patent estate consists primarily of the following:

	United States			Foreign/PCT		
Description	**Issued** (1)	Expiration	**Pending** (1)	**Issued** (1)	Expiration	Pending
ForeCYTE Breast Aspirator Program	7	2016 – 2031	4	12	2016 – 2031	8
FullCYTE Microcatheters & FullCYTE Breast Aspirators Program	20	2019 – 2031	5	53	2019 – 2031	4
NextCYTE Test Program	0	2031	1	0	2031	1
Intraductal Treatment Program	12	2030	3	47	2030	1
Carbohydrate Biomarkers Program	2	2022	0	3	2022	0
Acueity Tools	12	2015 – 2024	0	2	2015 – 2024	0

(1) The total number of patents issued or pending, as applicable, in the respective descriptive columns exceed the totals because some patents and applications contain more than one type of claim directed to methods, kits, compositions, devices and/or technology and the patent counts disclosed herein are subject to change.

Atossa, Atossa Genetics (stylized), MASCT and ArgusCYTE are our registered trademarks. We have pending allowed applications with the United States Patent and Trademark Office for registration of the use of the marks FullCYTE and NextCYTE.

Manufacturing, Distribution, and Associated Operations

Our manufacturing strategy utilizes third party contractors for the procurement and manufacture, as applicable, of raw materials, active pharmaceutical ingredients and finished drug products, as well as for storage, and distribution of our products and associated supply chain operations. As our business continues to expand, we expect that our manufacturing, distribution, and related operational requirements will correspondingly increase. Each third party contractor will always undergo a formal qualification process by Atossa subject matter experts prior to signing any service agreement and initiating any manufacturing work.

Integral to our manufacturing strategy is our quality control and quality assurance program, which includes standard operating procedures and specifications with the goal that our compounds are manufactured in accordance with current Good Manufacturing Practices (cGMP), and other applicable global regulations. The cGMP compliance includes strict adherences to regulations for quality control, quality assurance, and commercialized products must have acquired FDA, EMA, and any other applicable regulatory approval. In this regard, we expect to rely on our contract manufacturers to produce sufficient quantities of our products in accordance with cGMPs for use in clinical trials and ultimately commercial distribution.

We believe our operational strategy of utilizing qualified contractors and suppliers in the foregoing manner allows us to direct our financial and managerial resources to development and commercialization activities, rather than to the establishment and maintenance of a manufacturing and distribution infrastructure.

Government Regulation

Drug Regulations

We are subject to extensive regulation by the FDA and other federal, state, and local regulatory agencies. The Federal Food, Drug, and Cosmetic Act, or the FDCA, and its implementing regulations set forth, among other things, requirements for the testing, development, manufacture, quality control, safety, effectiveness, approval, labeling, storage, record keeping, reporting, distribution, import, export, advertising and promotion of our products. Our

activities in other countries will be subject to regulation that is similar in nature and scope as that imposed in the U.S., although there can be important differences. Additionally, some significant aspects of regulation in the E.U. are addressed in a centralized way through the EMA and the European Commission, but country-specific regulation by the competent authorities of the E.U. member states remains essential in many respects.

U.S. Regulations

In the U.S., the FDA regulates drugs under the FDCA and its implementing regulations, through review and approval of NDAs. NDAs require extensive studies and submission of a large amount of data by the applicant.

Drug Development

Preclinical Testing: Before testing any compound in human subjects in the U.S., a company must generate extensive preclinical data. Preclinical testing generally includes laboratory evaluation of product chemistry and formulation, as well as toxicological and pharmacological studies in several animal species to assess the quality and safety of the product. Animal studies must be performed in compliance with the FDA's Good Laboratory Practice regulations and the U.S. Department of Agriculture's Animal Welfare Act.

IND Application: In most cases, human clinical trials in the U.S. cannot commence until an Investigational New Drug Application (IND) is submitted to the FDA for review and a "Safe to Proceed" letter has been provided to the sponsor. The sponsor must prepare a dossier of information that includes the results of preclinical studies; detailed drug manufacturing information and results; and proposed clinical studies, design and development strategy. The FDA then evaluates if there is an adequate basis for testing the drug in an initial (human) clinical study. Unless the FDA raises concerns, the IND application becomes effective 30 days following its receipt by the FDA at which time written notification is provided. Once human clinical trials have commenced, the sponsor is obligated to report serious side effects to the FDA. The FDA may suspend a clinical trial by placing it on "clinical hold" if the FDA has concerns about the safety of the product being tested, subject risks, investigator actions, related product information or for other reasons.

Clinical Trials: Clinical trials involve the administration of the drug to healthy human volunteers or to patients, under the supervision of a qualified investigator according to vetted and approved protocol.

The conduct of clinical trials is subject to extensive regulation, including compliance with the FDA's bioresearch monitoring regulations and Good Clinical Practice, or GCP, requirements, which establish standards for conducting, recording data from and reporting the results of, clinical trials, and are intended to assure that the data and reported results are credible and accurate, and that the rights, safety, and well-being of study participants are protected. Clinical trials must be conducted under protocols that detail the study objectives, parameters for monitoring safety, and the efficacy criteria, if any, to be evaluated. Each protocol is reviewed by the FDA as part of the IND application. In addition, each clinical trial must be reviewed, approved, and conducted under the auspices of an institutional review board, or IRB, at the institution conducting the clinical trial. Companies sponsoring the clinical trials, investigators, and IRBs also must comply with regulations and guidelines for obtaining informed consent from the study subjects, complying with the protocol and investigational plan, adequately monitoring the clinical trial and timely reporting adverse events. Foreign studies conducted under an IND application must meet the same requirements that apply to studies being conducted in the U.S. Data from a foreign study not conducted under an IND application may be submitted in support of an NDA if the study was conducted in accordance with GCP and the FDA is able to validate the data.

A study sponsor is required to submit certain details about active clinical trials and clinical trial results to the National Institutes of Health for public posting on http://clinicaltrials.gov. Human clinical trials typically are conducted in three sequential phases, although the phases may overlap with one another:

- Phase 1 clinical trials include the initial administration of the investigational drug to humans, typically to a small group of healthy human subjects, but occasionally to a group of patients with the targeted disease or disorder. Phase 1 clinical trials generally are intended to determine the metabolism and pharmacologic actions of the drug, the side effects associated with increasing doses, and, if possible, to gain early evidence of effectiveness.

- Phase 2 clinical trials generally are controlled studies that involve a relatively small sample of the intended patient population, and are designed to develop data regarding the product's effectiveness, to determine dose response and the optimal dose range and to gather additional information relating to safety and potential adverse effects.

- Phase 3 clinical trials are conducted after preliminary evidence of effectiveness has been obtained, and are intended to gather the additional information about safety and effectiveness necessary to evaluate the drug's overall risk-benefit profile, and to provide a basis for physician labeling. Generally, Phase 3 clinical development programs consist of expanded, large-scale studies of patients with the target disease or disorder to obtain statistical evidence of the efficacy and safety of the drug, or the safety, purity, and potency of a biological product, at the proposed dosing regimen.

The sponsoring company, the FDA or the IRB may suspend or terminate a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk. Further, success in early-stage clinical trials does not assure success in later-stage clinical trials. Data obtained from clinical activities are not always conclusive and may be subject to alternative interpretations that could delay, limit or prevent regulatory approval.

There are regulatory pathways that can accelerate the speed with which a product can be developed, including a Special Protocol Assessment (SPA), Break-through therapy designation, etc. The designations are obtained from the FDA on a case-by-case basis and do not guarantee the ultimate approval of a product for commercialization.

Drug Approval

Assuming successful completion of the required clinical testing, the results of the preclinical studies and of the clinical trials, together with other detailed information, including information on the manufacture and composition of the investigational product, are submitted to the FDA in the form of an NDA (New Drug Application) requesting approval to market the product for one or more indications. The testing and approval process requires substantial time, effort and financial resources. Submission of an NDA requires payment of a substantial review user fee to the FDA. The FDA will review the application and may deem it to be inadequate to support commercial marketing, and there can be no assurance that any product approval will be granted on a timely basis, if at all. The FDA may also seek the advice of an advisory committee, typically a panel of clinicians practicing in the field for which the product is intended, for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendations of the advisory committee.

The FDA has various programs, including breakthrough therapy, fast track, priority review and accelerated approval that are intended to expedite or simplify the process for reviewing drugs and/or provide for approval on the basis of surrogate endpoints. Generally, drugs that may be eligible for one or more of these programs are those for serious or life-threatening conditions, those with the potential to address unmet medical needs and those that provide meaningful benefit over existing treatments. We cannot be sure that any of our drugs will qualify for any of these programs, or that, if a drug does qualify, the review time will be reduced or the product will be approved.

Before approving a NDA, the FDA usually inspects the clinical sites with the greatest accrual to confirm the veracity of the clinical data, execution of the clinical study and protection of patient safety. The FDA will inspect the facility or the facilities where the product is manufactured, tested and distributed. Approval is not granted if these inspections raise concerns about the execution of the clinical studies or there is a lack of cGMP compliance. If the FDA evaluates the NDA and determines the clinical trial execution and manufacturing facilities as acceptable, the FDA may issue an approval letter If the NDA is not approved, the FDA issues a complete response letter which is only issued for applications that are not approved The approval letter authorizes commercial marketing of the drug for specific indications. As a condition of approval, the FDA may require post-marketing testing and surveillance to monitor the product’s safety or efficacy, or impose other post-approval commitment conditions.

In some circumstances, post-marketing testing may include post-approval clinical trials, sometimes referred to as Phase 4 clinical trials, which are used primarily to gain additional experience from the treatment of patients in the intended population, particularly for long-term safety follow-up. In addition, the FDA may require a Risk Evaluation and Mitigation Strategy, or REMS, to ensure that the benefits outweigh the risks. A REMS can include medication guides, physician communication plans and elements to assure safe use, such as restricted distribution methods, patient registries or other risk mitigation tools.

After approval, certain changes to the approved product, such as adding new indications, making certain manufacturing changes or making certain additional labeling claims, are subject to further FDA review and approval. Obtaining approval for a new indication generally requires that additional clinical trials be conducted.

Post-Approval Requirements

Holders of an approved NDA are required to: (i) report certain adverse reactions to the FDA; (ii) comply with certain requirements concerning advertising and promotional labeling for their products; and (iii) continue to have cGMP compliance and all aspects of product manufacturing in a "state of control." The FDA periodically inspects the sponsor's records related to safety reporting and/or manufacturing and distribution facilities; this latter effort includes assessment of compliance with cGMP. Accordingly, manufacturers must continue to expend time, money and effort in the area of production, quality control and distribution to maintain cGMP compliance. Future FDA inspections may identify compliance issues at manufacturing facilities that may disrupt production or distribution, or require substantial resources to correct. In addition, discovery of problems with a product after approval may result in restrictions on a product, manufacturer or holder of an approved NDA, including withdrawal of the product from the market.

Marketing of prescription drugs is also subject to significant regulation through federal and state agencies tasked with consumer protection and prevention of medical fraud, waste and abuse. After approval in the U.S., we must comply with FDA's regulation of drug promotion and advertising, including restrictions on off-label promotion, and we comply with federal anti-kickback statutes, limitations on gifts and payments to physicians and reporting of payments to certain third parties, among other requirements.

Failure to comply with applicable U.S. requirements may subject us to administrative or judicial sanctions, such as clinical holds, FDA refusal to approve pending NDAs or supplemental applications, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions and/or criminal prosecution.

Non-U.S. Regulation

Before our products can be marketed outside of the U.S., they are subject to regulatory approval similar to that required in the U.S., although the requirements governing the conduct of clinical trials, including additional clinical trials that may be required, product licensing, pricing and reimbursement vary widely from country to country. No action can be taken to market any product in a country until an appropriate application has been approved by the regulatory authorities in that country. The current approval process varies from country to country, and the time spent in gaining approval varies from that required for FDA approval. In certain countries, the sales price of a product must also be approved. The pricing review period often begins after market approval is granted. Even if a product is approved by a regulatory authority, satisfactory prices may not be approved for such product.

In the E.U., marketing authorizations for medicinal products can be obtained through several different procedures founded on the same basic regulatory process. The centralized procedure is mandatory for certain medicinal products, including orphan medicinal products, medicinal products derived from certain biotechnological processes, advanced therapy medicinal products and certain other new medicinal products containing a new active substance for the treatment of certain diseases. It is optional for certain other products, including medicinal products that are significant therapeutic, scientific or technical innovations, or whose authorization would be in the interest of public or animal health. The centralized procedure allows a company to submit a single application to the EMA which will provide a positive opinion regarding the application if it meets certain quality, safety, and efficacy requirements. Based on the opinion of the EMA, the European Commission takes a final decision to grant a centralized marketing authorization which is valid in all 28 E.U. Member States and three of the four European Free Trade Association states (Iceland, Liechtenstein and Norway). Cancer products are usually required to go through the centralized procedure.

Unlike the centralized authorization procedure, the decentralized marketing authorization procedure requires a separate application to, and leads to separate approval by, the competent authorities of each E.U. Member State in which the product is to be marketed. One national competent authority selected by the applicant, the Reference Member State, assesses the application for marketing authorization. Following a positive opinion by the competent

authority of the Reference Member State the competent authorities of the other E.U. Member States, Concerned Member States are subsequently required to grant marketing authorization for their territory on the basis of this assessment except where grounds of potential serious risk to public health require this authorization to be refused. The mutual recognition procedure is similarly based on the acceptance by the competent authorities of the Concerned Member States of the marketing authorization of a medicinal product by the competent authorities of other Reference Member States. The holder of a national marketing authorization granted by a Reference Member State may submit an application to the competent authority of a Concerned Member State requesting that this authority mutually recognize the marketing authorization delivered by the competent authority of the Reference Member State.

Similar to accelerated approval regulations in the U.S., conditional marketing authorizations can be granted in the E.U. by the European Commission in exceptional circumstances. A conditional marketing authorization can be granted for medicinal products where a number of criteria are fulfilled; i) although comprehensive clinical data referring to the safety and efficacy of the medicinal product have not been supplied, the benefit/risk balance of the product is positive, ii) it is likely that the applicant will be in a position to provide the comprehensive clinical data, iii) unmet medical needs will be fulfilled and iv) the benefit to public health of the immediate availability on the market of the medicinal product concerned outweighs the risk inherent in the fact that additional data are still required. A conditional marketing authorization must be renewed annually.

Even if a product receives authorization in the E.U., there can be no assurance that reimbursement for such product will be secured on a timely basis or at all. Individual countries comprising the EU member states, rather than the EU, have jurisdiction across the region over patient reimbursement or pricing matters. Therefore, we will need to expend significant effort and expense to establish and maintain reimbursement arrangements in the various countries comprising the E.U. and may never succeed in obtaining widespread reimbursement arrangements therein.

The national authorities of the individual E.U. Member States are free to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices and/or reimbursement of medicinal products for human use. Some E.U. Member States adopt policies according to which a specific price or level of reimbursement is approved for the medicinal product. Other E.U. Member States adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market, including volume-based arrangements and reference pricing mechanisms.

Health Technology Assessment, or HTA, of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures in some E.U. Member States. These E.U. Member States include the U.K, France, Germany and Sweden. The HTA process, which is governed by the national laws of these countries, is the procedure according to which the assessment of the public health impact, therapeutic impact and the economic and societal impact of use of a given medicinal product in the national healthcare systems of the individual country is conducted. The extent to which pricing and reimbursement decisions are influenced by the HTA of the specific medicinal product vary between E.U. Member States.

Post-Approval Regulation

Similarly to the U.S., both marketing authorization holders and manufacturers of medicinal products are subject to comprehensive regulatory oversight by the EMA and the competent authorities of the individual E.U. Member States both before and after grant of the manufacturing and marketing authorizations. Failure by us or by any of our third party partners, including suppliers, manufacturers and distributors to comply with E.U. laws and the related national laws of individual E.U. Member States governing the conduct of clinical trials, manufacturing approval, marketing authorization of medicinal products and marketing of such products, both before and after grant of marketing authorization, may result in administrative, civil or criminal penalties. These penalties could include delays or refusal to authorize the conduct of clinical trials or to grant marketing authorization, product withdrawals and recalls, product seizures, suspension, withdrawal or variation of the marketing authorization, total or partial suspension of production, distribution, manufacturing or clinical trials, operating restrictions, injunctions, suspension of licenses, fines and criminal penalties.

The holder of an E.U. marketing authorization for a medicinal product must also comply with E.U. pharmacovigilance legislation and its related regulations and guidelines, which entail many requirements for conducting

pharmacovigilance, or the assessment and monitoring of the safety of medicinal products. These rules can impose on central marketing authorization holders for medicinal products the obligation to conduct a labor intensive collection of data regarding the risks and benefits of marketed products and to engage in ongoing assessments of those risks and benefits, including the possible requirement to conduct additional clinical studies, which may be time consuming and expensive and could impact our profitability. Non-compliance with such obligations can lead to the variation, suspension or withdrawal of the marketing authorization for the product or imposition of financial penalties or other enforcement measures.

The manufacturing process for medicinal products in the E.U. is highly regulated and regulators may shut down manufacturing facilities that they believe do not comply with regulations. Manufacturing requires a manufacturing authorization, and the manufacturing authorization holder must comply with various requirements set out in the applicable E.U. laws, regulations and guidance, including Directive 2001/83/EC, Directive 2003/94/EC, Regulation (EC) No 726/2004 and the European Commission Guidelines for Good Manufacturing Practice. These requirements include compliance with E.U. cGMP standards when manufacturing medicinal products and active pharmaceutical ingredients, including the manufacture of active pharmaceutical ingredients outside of the E.U. with the intention to import the active pharmaceutical ingredients into the E.U. Similarly, the distribution of medicinal products into and within the E.U. is subject to compliance with the applicable E.U. laws, regulations and guidelines, including the requirement to hold appropriate authorizations for distribution granted by the competent authorities of the E.U. Member States.

We and our third party manufacturers are subject to cGMP, which are extensive regulations governing manufacturing processes, stability testing, record keeping and quality standards as defined by the EMA, the competent authorities of E.U. Member States and other regulatory authorities. The EMA reviews Periodic Safety Update Reports for medicinal products authorized in the E.U. If the EMA has concerns that the risk benefit profile of a product has varied, it can adopt an opinion advising that the existing marketing authorization for the product be suspended or varied and can advise that the marketing authorization holder be obliged to conduct post-authorization safety studies. The EMA opinion is submitted for approval by the European Commission. Failure by the marketing authorization holder to fulfill the obligations for which the approved opinion provides can undermine the on-going validity of the marketing authorization.

Sales and Marketing Regulations

In the E.U., the advertising and promotion of our products are subject to E.U. Member States' laws governing promotion of medicinal products, interactions with physicians, misleading and comparative advertising and unfair commercial practices. In addition, other legislation adopted by individual E.U. Member States may apply to the advertising and promotion of medicinal products. These laws require that promotional materials and advertising in relation to medicinal products comply with the product's Summary of Product Characteristics, or SmPC, as approved by the competent authorities. Promotion of a medicinal product that does not comply with the SmPC is considered to constitute off-label promotion. The off-label promotion of medicinal products is prohibited in the E.U. The applicable laws at E.U. level and in the individual E.U. Member States also prohibit the direct-to-consumer advertising of prescription-only medicinal products. Violations of the rules governing the promotion of medicinal products in the E.U. could be penalized by administrative measures, fines and imprisonment. These laws may further limit or restrict the advertising and promotion of our products to the general public and may also impose limitations on our promotional activities with health care professionals.

Anti-Corruption Legislation

Our business activities outside of the U.S. are subject to anti-bribery or anti-corruption laws, regulations, industry self-regulation codes of conduct and physicians' codes of professional conduct or rules of other countries in which we operate, including the U.K. Bribery Act of 2010.

Interactions between pharmaceutical companies and physicians are also governed by strict laws, regulations, industry self-regulation codes of conduct and physicians' codes of professional conduct developed at both E.U. level and in the individual E.U. Member States. The provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is prohibited in the E.U. Violation of these laws could result in substantial fines and imprisonment. Payments made to physicians in certain E.U. Member States also must be publicly disclosed. Moreover, agreements with physicians must often be the

subject of prior notification and approval by the physician's employer, his/her competent professional organization, and/or the competent authorities of the individual E.U. Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

Data Privacy and Protection

Data protection laws and regulations have been adopted at E.U. level with related implementing laws in individual E.U. Member States which impose significant compliance obligations. For example, the E.U. Data Protection Directive, as implemented into national laws by the E.U. Member States, imposes strict obligations and restrictions on the ability to collect, analyze and transfer personal data, including health data from clinical trials and adverse event reporting. Furthermore, there is a growth towards the public disclosure of clinical trial data in the E.U. which also adds to the complexity of processing health data from clinical trials. Such public disclosure obligations are provided in the new E.U. Clinical Trials Regulation, EMA disclosure initiatives, and voluntary commitments by industry. Data protection authorities from the different E.U. Member States may interpret the E.U. Data Protection Directive and national laws differently, which adds to the complexity of processing personal data in the E.U., and guidance on implementation and compliance practices are often updated or otherwise revised. Failing to comply with these laws could lead to government enforcement actions and significant penalties against us, and adversely impact our operating results. Apart from exceptional circumstances, the E.U. Data Protection Directive prohibits the transfer of personal data to countries outside of the European Economic Area that are not considered by the European Commission to provide an adequate level of data protection including the U.S.

United States Medical Device Regulation

The Federal Food, Drug, and Cosmetic Act, or FDCA, and the FDA's implementing regulations, govern registration and listing, manufacturing, labeling, storage, advertising and promotion, sales and distribution, and postmarket surveillance. Medical devices and their manufacturers are also subject to inspection by the FDA. The FDCA, supplemented by other federal and state laws, also provides civil and criminal penalties for violations of its provisions. We manufacture and market a medical device that is regulated by the FDA, comparable state agencies and regulatory bodies in other countries. The FDA classifies medical devices into one of three classes (Class I, II or III) based on the degree of risk the FDA determines to be associated with a device and the extent of control deemed necessary to ensure the device's safety and effectiveness. Devices requiring fewer controls because they are deemed to pose lower risk are placed in Class I or II. Class I devices are deemed to pose the least risk and are subject only to general controls applicable to all devices, such as requirements for device labeling, premarket notification, and adherence to the FDA's current Good Manufacturing Practice requirements, as reflected in its QSR. Most pathology staining kits, reagents, and routine antibody-based immunohistochemistry protocols which we intend to use initially are Class I devices. Class II devices are intermediate risk devices that are subject to general controls and may also be subject to special controls such as performance standards, product-specific guidance documents, special labeling requirements, patient registries or post-market surveillance.

The FullCYTE Breast Aspirator is a Class II device. Class III devices are those for which insufficient information exists to assure safety and effectiveness solely through general or special controls, and include life-sustaining, life-supporting, or implantable devices, and devices not "substantially equivalent" to a device that is already legally marketed. Most Class I devices, including the laboratory staining kits and reagents we use, and some Class II devices are exempted by regulation from the 510(k) clearance requirement and can be marketed without prior authorization from the FDA. Class I and Class II devices that have not been so exempted are eligible for marketing through the 510(k) clearance pathway. By contrast, devices placed in Class III generally require premarket approval, or PMA, prior to commercial marketing. To obtain 510(k) clearance for a medical device, an applicant must submit a premarket notification to the FDA demonstrating that the device is "substantially equivalent" to a predicate device legally marketed in the United States. A device is substantially equivalent if, with respect to the predicate device, it has the same intended use and (i) the same technological characteristics, or (ii) has different technological characteristics and the information submitted demonstrates that the device is as safe and effective as a legally marketed device and does not raise different questions of safety or effectiveness. A showing of substantial equivalence sometimes, but not always, requires clinical data. Generally, the 510(k) clearance process can exceed 90 days and may extend to a year or more. After a device has received 510(k) clearance for a specific intended use, any modification that could significantly affect its safety or effectiveness, such as a significant change in the design, materials, method of manufacture or intended use, will require a new 510(k) clearance or (if the device as modified is not substantially equivalent to a legally marketed predicate device) PMA approval. While the determination as to whether new authorization is needed is initially left to the manufacturer, the FDA may review this determination and evaluate the regulatory status of the modified product at any time and may require the manufacturer to cease marketing and recall the modified device until 510(k) clearance or PMA approval is obtained. The manufacturer may also be subject to significant regulatory fines or penalties.

All clinical trials must be conducted in accordance with regulations and requirements collectively known as Good Clinical Practice, or GCP. GCPs include the FDA's Investigational Device Exemption, or IDE, regulations, which describe the conduct of clinical trials with medical devices, including the recordkeeping, reporting and monitoring responsibilities of sponsors and investigators, and labeling of investigation devices. They also prohibit promotion, test marketing, or commercialization of an investigational device, and any representation that such a device is safe or effective for the purposes being investigated. GCPs also include FDA's regulations for institutional review board approval and for protection of human subjects (informed consent), as well as disclosure of financial interests by clinical investigators.

Required records and reports are subject to inspection by the FDA. The results of clinical testing may be unfavorable or, even if the intended safety and effectiveness success criteria are achieved, may not be considered sufficient for the FDA to grant approval or clearance of a product.

We expect that each of our devices under development will require clinical trials to support a 510(k) or PMA submission, as the case may be. For example, we expect that our intraductal microcatheters may be considered part of a "combination" product along with a drug and may require a PMA prior to commercialization.

The commencement or completion of clinical trials, if any, that we may sponsor, may be delayed or halted, or be inadequate to support approval of a PMA application or clearance of a premarket notification for numerous reasons, including, but not limited to, the following:

- the FDA or other regulatory authorities do not approve a clinical trial protocol or a clinical trial (or a change to a previously approved protocol or trial that requires approval), or place a clinical trial on hold;
- patients do not enroll in clinical trials or follow up at the rate expected;
- institutional review boards and third-party clinical investigators may delay or reject the Company's trial protocol or changes to its trial protocol;
- third party clinical investigators decline to participate in a trial or do not perform a trial on the Company's anticipated schedule or consistent with the clinical trial protocol, investigator agreements, Good Clinical Practices or other FDA requirements;
- third party organizations do not perform data collection and analysis in a timely or accurate manner;
- regulatory inspections of clinical trials or manufacturing facilities, which may, among other things, require the Company to undertake corrective action or suspend or terminate its clinical trials;
- changes in governmental regulations or administrative actions;
- the interim or final results of the clinical trial are inconclusive or unfavorable as to safety or effectiveness; and

- the FDA concludes that the Company's trial design is inadequate to demonstrate safety and effectiveness.

After a device is approved and placed in commercial distribution, numerous regulatory requirements apply. These include:

- establishment registration and device listing;
- the Quality System Regulations (QSR), which requires manufacturers to follow design, testing, control, documentation and other quality assurance procedures;
- labeling regulations, which prohibit the promotion of products for unapproved or "off-label" uses and impose other restrictions on labeling;
- medical device reporting regulations, which require that manufacturers report to the FDA if a device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if malfunctions were to occur; and

- corrections and removal reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA caused by the device that may present a risk to health.

The FDA enforces regulatory requirements by conducting periodic, announced and unannounced inspections and market surveillance. Inspections may include the manufacturing facilities of our subcontractors. Failure to comply with applicable regulatory requirements, including those applicable to the conduct of our clinical trials, can result in enforcement action by the FDA, which may lead to any of the following sanctions:

- warning letters or untitled letters;
- fines and civil penalties;
- unanticipated expenditures;
- delays in clearing or approving or refusal to clear or approve products;
- withdrawal or suspension of FDA clearance;
- product recall or seizure;
- orders for physician notification or device repair, replacement, or refund;
- production interruptions;
- operating restrictions; and
- criminal prosecution.

We and our contract manufacturers, specification developers and suppliers are also required to manufacture our medical devices, including our intraductal microcatheters in compliance with current Good Manufacturing Practice requirements set forth in the QSR. The QSR requires a quality system for the design, manufacture, packaging, labeling, storage, installation and servicing of marketed devices, and includes extensive requirements with respect to quality management and organization, device design, buildings, equipment, purchase and handling of components,

production and process controls, packaging and labeling controls, device evaluation, distribution, installation, complaint handling, servicing and recordkeeping. The FDA enforces the QSR through periodic announced and unannounced inspections that may include the manufacturing facilities of our subcontractors. If the FDA believes we or any of our contract manufacturers or regulated suppliers is not in compliance with these requirements, it can shut down our manufacturing operations, require recall of our devices, refuse to clear or approve new marketing applications, institute legal proceedings to detain or seize products, enjoin future violations, or assess civil and criminal penalties against us or our officers or other employees. Any such action by the FDA would have a material adverse effect on our business.

Privacy and Security of Health Information and Personal Information; Standard Transactions

We are subject to state and federal laws and implementing regulations relating to the privacy and security of the medical information of the patients it treats. The principal federal legislation is part of HIPAA. Pursuant to HIPAA, the Secretary of the Department of Health and Human Services, or HHS, has issued final regulations designed to improve the efficiency and effectiveness of the healthcare system by facilitating the electronic exchange of information in certain financial and administrative transactions, while protecting the privacy and security of the patient information exchanged. These regulations also confer certain rights on patients regarding their access to and control of their medical records in the hands of healthcare providers such as us.

Four principal regulations have been issued in final form: privacy regulations, security regulations, standards for electronic transactions, and the National Provider Identifier regulations. The HIPAA privacy regulations, which fully came into effect in April 2003, establish comprehensive federal standards with respect to the uses and disclosures of an individual's personal health information, referred to in the privacy regulations as "protected health information," by health plans, healthcare providers, and healthcare clearinghouses. We are a healthcare provider within the meaning of HIPAA. The regulations establish a complex regulatory framework on a variety of subjects, including:

- the circumstances under which uses and disclosures of protected health information are permitted or required without a specific authorization by the patient, including but not limited to treatment purposes, activities to obtain payment for services, and healthcare operations activities;
- a patient's rights to access, amend, and receive an accounting of certain disclosures of protected health information;
- the content of notices of privacy practices for protected health information; and
- administrative, technical and physical safeguards required of entities that use or receive protected health information.

The federal privacy regulations, among other things, restrict our ability to use or disclose protected health information in the form of patient-identifiable laboratory data, without written patient authorization, for purposes other than payment, treatment, or healthcare operations (as defined by HIPAA) except for disclosures for various public policy purposes and other permitted purposes outlined in the privacy regulations. The privacy regulations provide for significant fines and other penalties for wrongful use or disclosure of protected health information, including potential civil and criminal fines and penalties. Although the HIPAA statute and regulations do not expressly provide for a private right of damages, we could incur damages under state laws to private parties for the wrongful use or disclosure of confidential health information or other private personal information.

We have implemented policies and practices that we believe brings us into compliance with the privacy regulations. However, the documentation and process requirements of the privacy regulations are complex and subject to interpretation. Failure to comply with the privacy regulations could subject us to sanctions or penalties, loss of business, and negative publicity.

The HIPAA privacy regulations establish a "floor" of minimum protection for patients as to their medical information and do not supersede state laws that are more stringent. Therefore, we are required to comply with both HIPAA privacy regulations and various state privacy laws. The failure to do so could subject us to regulatory actions, including significant fines or penalties, and to private actions by patients, as well as to adverse publicity and possible loss of business. In addition, federal and state laws and judicial decisions provide individuals with various rights for

violation of the privacy of their medical information by healthcare providers such as us. The final HIPAA security regulations, which establish detailed requirements for physical, administrative, and technical measures for safeguarding protected health information in electronic form, became effective on April 21, 2005. We have employed what we consider to be a reasonable and appropriate level of physical, administrative and technical safeguards for patient information. Failure to comply with the security regulations could subject us to sanctions or penalties and negative publicity.

The final HIPAA regulations for electronic transactions, referred to as the transaction standards, establish uniform standards for certain specific electronic transactions and code sets and mandatory requirements as to data form and data content to be used in connection with common electronic transactions, such as billing claims, remittance advices, enrollment, and eligibility. We have outsourced to a third party vendor the handling of our billing and collection transactions, to which the transaction standards apply. Failure of the vendor to properly conform to the requirements of the transaction standards could, in addition to possible sanctions and penalties, result in payors not processing transactions submitted on our behalf, including claims for payment.

The healthcare information of our patients includes personal information that are not of an exclusively medical nature. The consumer protection laws of a majority of states now require organizations that maintain such personal information to notify each individual if their personal information is accessed by unauthorized persons or organizations, so that the individuals can, among other things, take steps to protect themselves from identity theft. The costs of notification and the adverse publicity can both be significant. Failure to comply with these state consumer protection laws can subject a company to penalties that vary from state to state, but may include significant civil monetary penalties, as well as to private litigation and adverse publicity. California recently enacted legislation that expanded its version of a notification law to cover improper access to medical information generally, and other states may follow suit.

Federal and State Fraud and Abuse Laws

The federal healthcare Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting, or receiving remuneration to induce referrals or in return for purchasing, leasing, ordering, or arranging for the purchase, lease, or order of any healthcare item or service reimbursable under a governmental payor program. The definition of “remuneration” has been broadly interpreted to include anything of value, including gifts, discounts, the furnishing of supplies or equipment, credit arrangements, payments of cash, waivers of payments, ownership interests, opportunity to earn income, and providing anything at less than its fair market value. The Anti-Kickback Statute is broad, and it prohibits many arrangements and practices that are lawful in businesses outside of the healthcare industry. Recognizing that the Anti-Kickback Statute is broad and may technically prohibit many innocuous or beneficial arrangements within the healthcare industry, HHS has issued a series of regulatory “safe harbors.” These safe harbor regulations set forth certain provisions that, if met, will provide healthcare providers and other parties with an affirmative defense against 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.

From time to time, the Office of Inspector General, or OIG, issues alerts and other guidance on certain practices in the healthcare industry. In October 1994, the OIG issued a Special Fraud Alert on arrangements for the provision of clinical laboratory services. The Fraud Alert set forth a number of practices allegedly engaged in by some clinical laboratories and healthcare providers that raise issues under the “fraud and abuse” laws, including the Anti-Kickback Statute.

Physician Referral Prohibitions

Under a federal law directed at "self-referral," commonly known as the Stark Law, prohibitions exist, with certain exceptions, on Medicare and Medicaid payments for laboratory tests referred by physicians who personally, or through a family member, have an investment interest in, or a compensation arrangement with, the laboratory performing the tests. A person who engages in a scheme to circumvent the Stark Law's referral prohibition may be fined up to $100,000 for each such arrangement or scheme. In addition, any person who presents or causes to be presented a claim to the Medicare or Medicaid programs in violation of the Stark Law is subject to civil monetary penalties of up to $15,000 per bill submission, an assessment of up to three times the amount claimed, and possible exclusion from participation in federal governmental payor programs. Bills submitted in violation of the Stark Law may not be paid by Medicare or Medicaid, and any person collecting any amounts with respect to any such prohibited bill is obligated to refund such amounts.

Any arrangement between a laboratory and a physician's or physicians' practice that involves remuneration will prohibit the laboratory from obtaining payment for services resulting from the physicians' referrals, unless the arrangement is protected by an exception to the self-referral prohibition or a provision stating that the particular arrangement would not result in remuneration. Among other things, a laboratory's provision of any item, device, or supply to a physician would result in a Stark Law violation unless it was used only to collect, transport, process, or store specimens for the laboratory, or was used only to order tests or procedures or communicate related results. This may preclude a laboratory's provision of fax machines and computers that may be used for unrelated purposes. Most arrangements involving physicians that would violate the Anti-Kickback Statute would also violate the Stark Law. Many states also have "self-referral" and other laws that are not limited to Medicare and Medicaid referrals. These laws may prohibit arrangements which are not prohibited by the Stark Law, such as a laboratory's placement of a phlebotomist in a physician's office to collect specimens for the laboratory. Finally, recent amendments to these laws require self-disclosure of violations by providers.

We estimate that the majority of our billings for our pharmacogenomics test that we began offering in October 2014 is from Medicare billings.

Referrals after Becoming a Public Company

Now that our stock is publicly traded, we are not able to accept referrals from physicians who own, directly or indirectly, shares of our stock unless we comply with the Stark Law exception for publicly traded securities. This requires, among other things, $75 million in stockholders' equity (total assets minus total liabilities). The parallel safe harbor requires, among other things, $50 million in undepreciated net tangible assets, in order for any distributions to such stockholders to be protected under the Anti-Kickback Statute.

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Regulation of Medical Devices and Laboratory Tests Outside the United States

In the EU and the European Free Trade Association countries, the ForeCYTE Breast Aspirator has been marketed as a medical device.

The intended purpose for use of Atossa's ForeCYTE device is to collect NAF for cytological testing. The physician or researcher may choose to use the NAF and the resulting analysis for any clinical process as they deem appropriate. Before we can market a medical device in the European Union and the European Free Trade Association, we must comply with the Essential Requirements set forth in Annex I to the Directive 93/42/EEC of 14 June 1993 concerning medical devices, commonly known as the Medical Devices Directive. The Essential Requirements relate to the quality, safety and performance of the medical devices. Compliance with the Essential Requirements entitles a manufacturer to affix the Conformité Européenne mark, or CE mark, without which the products cannot be placed on the market in the European Union and the European Free Trade Association countries. To demonstrate compliance with the Essential Requirements and obtain the right to affix the CE mark, medical device manufacturers must undergo a conformity assessment procedure, which varies according to the type of medical device and its classification.

The Medical Devices Directive establishes a classification system placing devices into Class I, IIa, IIb, or III, depending on the risks and characteristics of the medical device. For certain types of low risk medical devices, the manufacturer may prepare a CE Declaration of Conformity based on a self-assessment of the conformity of its products with the Essential Requirements set forth in Annex I to the Medical Devices Directive. Other devices are subject to a conformity assessment procedure requiring the intervention of a "notified body," which is a private organization designated by the competent authorities of an EU Member State to conduct conformity assessments and verify the conformity of manufacturers and their medical devices with the Essential Requirements. The notified body issues a CE Certificate of Conformity following successful completion of a conformity assessment procedure conducted in relation to the medical device and its manufacturer and their conformity with the Essential Requirements. This Certificate entitles the manufacturer to affix the CE mark to its medical devices after having prepared and signed a related Declaration of Conformity.

The ForeCYTE Breast Aspirator is classified as a Class II medical device. Although we received a CE mark for this device in October 2014, we are not currently marketing and selling the device and we are therefore not planning on maintaining the CE mark.

Compliance Program

Compliance with government rules and regulations is a significant concern throughout the industry, in part due to evolving interpretations of these rules and regulations. We seek to conduct our business in compliance with all statutes and regulations applicable to our operations. To this end, we have established a compliance program that reviews for regulatory compliance procedures, policies, and facilities throughout our business. Failure to comply with applicable requirements may subject us to administrative or judicial sanctions, such as clinical holds, refusal of regulatory authorities to approve or authorize pending product applications, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions and/or criminal prosecution.

Legal Proceedings

See “Part 1, Item 3. Legal Proceedings” in this report which is incorporated into this Part 1, Item 1 by this reference.

Employees

As of the date of filing this report, we employed two executive officers, six full-time employees and one part-time employee. We expect that we will hire more employees as we expand.

Insurance

We currently maintain director's and officer's insurance, key-man life insurance for our Chief Executive Officer, commercial general and office premises liability insurance, and product errors and omissions liability insurance for our products and services.

ITEM 1A. RISK FACTORS

In addition to other information in this report, the following factors should be considered carefully in evaluating an investment in our securities. If any of the following risks actually occur, our business, financial condition and results of operations would likely suffer. In that case, the market price of the common stock could decline, and you may lose part or all of your investment in our company. Additional risks of which we are not presently aware or that we currently believe are immaterial may also harm our business and results of operations.

Risks Relating to our Business

We have only a limited operating history, and, as such, an investor cannot assess our profitability or performance based on past results.

We began operations in December 2008 focused on acquiring the Mammary Aspiration Specimen Cytology Test System ("MASCT") patent rights and assignments and the FDA clearance for marketing the MASCT System, which was completed in January 2009. We were incorporated in Delaware in April 2009 and our operations to date have consisted primarily of securing manufacturing for the MASCT System (now called the ForeCYTE Breast Aspirator), the FullCYTE Breast Aspirator and the intraductal microcatheter, establishing our CLIA-certified laboratory, validating our laboratory developed tests, launching our aspirator devices and laboratory tests and conducting research and development of locally-administered pharmaceuticals. We will require significant additional capital to achieve our business objectives, and the inability to obtain such financing on acceptable terms or at all could lead to closure of the business.

Our revenue and income potential is uncertain. Any evaluation of our business and prospects must be considered in light of these factors and the risks and uncertainties often encountered by companies in the development stage. Some of these risks and uncertainties include our ability to:

- obtain successful results from our clinical studies;
- obtain regulatory approvals for our pharmaceuticals we are developing;
- work with contract manufacturers to produce our pharmaceuticals under development and our intra ductal microcatheter in clinical and commercial quantities on acceptable terms and in accordance with required standards;
- obtain a favorable resolution to our litigation with Besins;
- respond effectively to competition;
- manage growth in operations;
- respond to changes in applicable government regulations and legislation;
- access additional capital when required;
- sell our products and service at the prices currently expected; and
- attract and retain key personnel.

We may not continue as a going concern.

We have not yet established an ongoing source of revenue sufficient to cover operating costs and allow us to continue as a going concern. The report issued by our independent auditors also emphasized our ability to continue as a going concern. Our ability to continue as a going concern is dependent on obtaining adequate capital to fund operating losses until we become profitable. If we are unable to obtain adequate capital, we may be unable to expand our product offerings or geographic reach and we could be forced to cease operations.

If we do not raise additional capital, we anticipate liquidity issues in the next two to four months.

For the year ended December 31, 2015, we incurred a net loss of $15,760,323 and we had an accumulated deficit of $50,934,863. As of the date of filing this report, we expect that our existing resources will be sufficient to fund our planned operations for at least the next four to six months. We have not yet established an ongoing source of revenue sufficient to cover our operating costs and allow us to continue as a going concern. Our ability to continue as a going concern is dependent on obtaining adequate capital to fund operating losses until we become profitable. The revenue we have generated to date consisted of mainly laboratory services; however, we sold our laboratory business on December 16, 2015 and we currently have no other products and services approved for commercialization while we develop our pharmaceutical pipeline. We may not receive or maintain regulatory clearance for our products and services and other sources of capital may not be available when we need them or on acceptable terms. If we are unable to raise in a timely fashion the amount of capital we anticipate needing; we would be forced to curtail or cease operations.

We will need to raise substantial additional capital in the future to fund our operations and we may be unable to raise such funds when needed and on acceptable terms.

When we elect to raise additional funds or additional funds are required, we may raise such funds from time to time through public or private equity offerings, debt financings, corporate collaboration and licensing arrangements or other financing alternatives, Additional equity or debt financing or corporate collaboration and licensing arrangements may not be available on acceptable terms, if at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we will be prevented from pursuing acquisition, licensing, development and commercialization efforts and our ability to generate revenues and achieve or sustain profitability will be substantially harmed.

If we raise additional funds by issuing equity securities, our stockholders will experience dilution. Debt financing, if available, would result in increased fixed payment obligations and may involve agreements that include covenants

limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Any debt financing or additional equity that we raise may contain terms, such as liquidation and other preferences, which are not favorable to us or our stockholders. If we raise additional funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish valuable rights to our technologies, future revenue streams or product candidates or to grant licenses on terms that may not be favorable to us. Should the financing we require to sustain our working capital needs be unavailable or prohibitively expensive when we require it, our business, operating results, financial condition and prospects could be materially and adversely affected and we may be unable to continue our operations.

Failure to raise additional capital as needed could adversely affect us and our ability to grow.

We expect to spend substantial amounts of capital to:

- develop our pharmaceutical programs under development;
- perform clinical studies for the pharmaceuticals we are developing;
- continue our research and development activities to advance our product pipeline;
- obtain clinical supplies of the pharmaceuticals we are developing; and
- obtain a successful resolution of the legal actions we commenced against Besins, including successfully defending against the counterclaims Besins has asserted against us..

We have not identified other sources for additional funding and cannot be certain that additional funding will be available on acceptable terms, or at all. Historically, a significant amount of our capital needs have been provided by Aspire Capital; however, in the first quarter of 2016 we sold all shares available for sale to Aspire under the November 2015 agreement with Aspire and no shares remain available for sale to them. If we are unable to raise additional capital in sufficient amounts or on acceptable terms, we may have to significantly delay, scale back or discontinue the commercialization of our products and services or our research and development activities. Furthermore, such lack of funds may inhibit our ability to respond to competitive pressures or unanticipated capital needs, or may force us to reduce operating expenses, which could significantly harm the business and development of operations. Because our independent auditors have emphasized in their report on our financial statements doubt as to our ability to continue as a “going concern,” our ability to raise capital may be severely hampered. Similarly, our ability to borrow any such capital may be more expensive and difficult to obtain until this “going concern” issue is eliminated.

We have a history of operating losses and we expect to continue to incur losses in the future.

We have a limited operating history and have incurred total net losses of $50,934,863 from our incorporation in April 2009 through December 31, 2015. We will continue to incur further losses in connection with research and development costs for development of our pharmaceutical programs, including ongoing and additional clinical studies.

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Our business may be affected by legal proceedings.

We have been in the past, and may become in the future, involved in legal proceedings. For example, on October 10, 2013, a securities class action complaint was filed against us, certain of our directors and officers and the underwriters from our initial public offering. This action was purportedly brought on behalf of a class of persons and entities who purchased our common stock between November 8, 2012 and October 4, 2013, inclusive. The complaint alleges that the defendants made false or misleading statements. The Company and other defendants filed motions to dismiss the amended complaint on May 30, 2014. The plaintiffs filed briefs in opposition to these motions on July 11, 2014. The Company replied to the opposition briefs on August 11, 2014. On October 6, 2014 the Court granted defendants' motion dismissing all claims against Atossa and all other defendants. The Court's order provided plaintiffs with a deadline of October 26, 2014 to file a motion for leave to amend their complaint and the plaintiffs did not file such a motion by that date. On October 30, 2014, the Court entered a final order of dismissal. On November 3, 2014, plaintiffs filed a notice of appeal with the Court and have appealed the Court's dismissal order to the U.S. Court of Appeals for the Ninth Circuit. On February 11, 2015, plaintiffs filed their opening appellate brief. Defendants filed their answering brief on April 13, 2015, and plaintiffs filed their reply brief on May 18, 2015. A hearing for the appeal has not been set. Although we believe this complaint is without merit and plan to defend it vigorously, the costs associated with defending and resolving the complaint and ultimate outcome cannot be predicted.

On January 28, 2016, we filed a complaint in the United States District Court for the District of Delaware captioned *Atossa Genetics Inc. v. Besins Healthcare Luxembourg SARL,* Case No. 1:16-cv-00045-UNA. The complaint asserts claims for breach of contract, breach of the implied covenant of good faith and fair dealing, and for declaratory relief against Besins. Our Company's claims arise from Besins' breach of an Intellectual Property License Agreement dated May 14, 2015 (the "License Agreement"), under which Besins licensed to the Company the worldwide exclusive rights to develop and commercialize Afimoxifene Topical Gel, or AfTG, for the potential treatment and prevention of hyperplasia of the breast. The complaint seeks compensatory damages, a declaration of the parties' rights and obligations under the License Agreement, and injunctive relief. On March 7, 2016 Besins responded to our complaint by denying our claims and asserting counterclaims including breach of contract, fraud and negligent misrepresentation, and seeking relief in the forms of compensatory damages, injunctive relief, and declaratory relief. We believe that these counterclaims are without merit and plan to defend our self vigorously; however, failure to obtain a favorable resolution of the counterclaims could have a material adverse effect on our business, results of operations and financial condition.

You should carefully review and consider the various disclosures we make in our reports filed with the SEC regarding legal matters that may affect our business. Civil and criminal litigation is inherently unpredictable and outcomes can result in excessive verdicts, fines, penalties and/or injunctive relief that affect how we operate our business. Monitoring and defending against legal actions, whether or not meritorious, and considering stockholder demands, is time-consuming for our management and detracts from our ability to fully focus our internal resources on our business activities. In addition, legal fees and costs incurred in connection with such activities may be significant. We cannot predict with certainty the outcome of any legal proceedings in which we become involved, including our dispute with Besins, and it is difficult to estimate the possible costs to us stemming from these matters. Settlements and decisions adverse to our interests in legal actions could result in the payment of substantial amounts and could have a material

adverse effect on our cash flow, results of operations and financial position.

Raising funds by issuing equity or debt securities could dilute the value of the common stock and impose restrictions on our working capital.

If we raise additional capital by issuing equity securities, including sales of shares of common stock to Aspire, the value of the then outstanding common stock may be reduced. If the additional equity securities were issued at a per share price less than the per share value of the outstanding shares, then all of the outstanding shares would suffer a dilution in value with the issuance of such additional shares. Further, the issuance of debt securities in order to obtain additional funds may impose restrictions on our operations and may impair our working capital as we service any such debt obligations.

The products and services that we have developed or may develop may never achieve significant commercial market acceptance.

We may not succeed in achieving commercial market acceptance of any of our products and services. In order to gain market acceptance for the drugs underdevelopment, we will need to demonstrate to physicians and other healthcare professionals the benefits of these therapies including the clinical and economic application for their particular practice. Many physicians and healthcare professionals may be hesitant to introduce new services, or techniques, into their practice for many reasons, including lack of time and resources to administer the test, the learning curve associated with the adoption of such new services or techniques into already established procedures and the uncertainty of the applicability or reliability of the results of a new product. In addition, the availability of full or even partial payment for our products and tests, whether by third party payors (e.g., insurance companies), or the patients themselves, will likely heavily influence physicians' decisions to recommend or use our products and services.

The loss of the services of our Chief Executive Officer could adversely affect our business.

Our success is dependent in large part upon the ability to execute our business plan, manufacture our pharmaceutical drugs and medical devices, maintain our laboratory, and attract and retain highly skilled professional, sales and marketing personnel. In particular, due to the relatively early stage of our business, our future success is highly dependent on the services of Steven C. Quay, our Chief Executive Officer and founder, who provides much of the necessary experience to execute our business plan.

We may experience difficulty in locating, attracting, and retaining experienced and qualified personnel, which could adversely affect our business.

We will need to attract, retain, and motivate experienced clinical development and other personnel, particularly in the greater Seattle area as we expand our pharmaceutical development activities. These employees may not be available in this geographic region. In addition, competition for these employees is intense and recruiting and retaining skilled employees is difficult, particularly for a development-stage organization such as ours. If we are unable to attract and retain qualified personnel, our development activities may be adversely affected.

We use third party suppliers for the production of the intraductal microcatheters, which are currently manufactured in small quantities. If such suppliers are not capable of producing quantities of these systems sufficient for commercial sale when we are ready, we may not generate significant revenue or become profitable.

We rely on third party suppliers for the continued manufacture and supply of the intraductal microcatheters. If our third party suppliers cannot produce the microcatheter in quantities sufficient for our commercial needs on acceptable terms when needed, we may be unable to commercialize our microcatheters and generate revenue from their sales as planned. In addition, if at any time after commercialization of our products, we are unable to secure essential equipment or supplies in a timely, reliable and cost-effective manner, we could experience disruptions in our services that could adversely affect anticipated results.

Compounds that appear promising in research and development may fail to reach later stages of development for a number of reasons, including, among others, that clinical trials may take longer to complete than expected or may not be completed at all, and top-line or preliminary clinical trial data reports may ultimately differ from actual results once existing data are more fully evaluated.

Successful development of anti-cancer and other pharmaceutical products is highly uncertain, and obtaining regulatory approval to market drugs to treat cancer is expensive, difficult and speculative. Compounds that appear promising in research and development may fail to reach later stages of development for several reasons, including, but not limited to:

- delay or failure in obtaining necessary U.S. and international regulatory approvals, or the imposition of a partial or full regulatory hold on a clinical trial;
- difficulties in formulating a compound, scaling the manufacturing process, timely attaining process validation for particular drug products and obtaining manufacturing approval;
- pricing or reimbursement issues or other factors that may make the product uneconomical to commercialize;
- production problems, such as the inability to obtain raw materials or supplies satisfying acceptable standards for the manufacture of our products;
- equipment obsolescence, malfunctions or failures, product quality/contamination problems or changes in regulations requiring manufacturing modifications;

- inefficient cost structure of a compound compared to alternative treatments;

- obstacles resulting from proprietary rights held by others with respect to a compound, such as patent rights;

- lower than anticipated rates of patient enrollment as a result of factors, such as the number of patients with the relevant conditions, the proximity of patients to clinical testing centers, eligibility criteria for tests and competition with other clinical testing programs;

- preclinical or clinical testing requiring significantly more time than expected, resources or expertise than originally expected and inadequate financing, which could cause clinical trials to be delayed or terminated;

- failure of clinical testing to show potential products to be safe and efficacious, and failure to demonstrate desired safety and efficacy characteristics in human clinical trials;

- suspension of a clinical trial at any time by us, an applicable collaboration partner or a regulatory authority on the basis that the participants are being exposed to unacceptable health risks or for other reasons;

- delays in reaching or failing to reach agreement on acceptable terms with prospective clinical research organizations, or CROs, and trial sites; and

- failure of third parties, such as CROs, academic institutions, collaborators, cooperative groups and/or investigator sponsors, to conduct, oversee and monitor clinical trials and results.

In addition, from time to time we expect to report top-line data for clinical trials. Such data are based on a preliminary analysis of then-available efficacy and safety data, and such findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. Top-line or preliminary data are based on important assumptions, estimations, calculations and information then available to us to the extent we have had, at the time of such reporting, an opportunity to fully and carefully evaluate such information in light of all surrounding facts, circumstances, recommendations and analyses. As a result, top-line results may differ from future results, or different conclusions or considerations may qualify such results once existing data have been more fully evaluated. In addition, third parties, including regulatory agencies, may not accept or agree with our assumptions, estimations, calculations or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular compound and our business in general.

If the development of our products is delayed or fails, or if top-line or preliminary clinical trial data reported differ from actual results, our development costs may increase and the ability to commercialize our products may be harmed, which could harm our business, financial condition, operating results or prospects.

We may not obtain or maintain the regulatory approvals required to develop or commercialize some or all of our products.

We are subject to rigorous and extensive regulation by the FDA in the U.S. and by comparable agencies in other jurisdictions, including the EMA in the E.U.

Some of our product candidates are currently in research or development and, we have not received marketing approval for our products. Our products may not be marketed in the U.S. until they have been approved by the FDA and may not be marketed in other jurisdictions until they have received approval from the appropriate foreign regulatory agencies. Each product candidate requires significant research, development and preclinical testing and extensive clinical investigation before submission of any regulatory application for marketing approval. Our products may be considered “combination” products in that they use both medical devices and drugs. For example, our intraductal microcatheters utilize both a medical device and the drug they are intended to deliver. As a result, the regulatory pathway for these products may be more complex and obtaining regulatory approvals may be more difficult.

Obtaining regulatory approval requires substantial time, effort and financial resources, and we may not be able to obtain approval of any of our products on a timely basis, or at all. The number, size, design and focus of preclinical and clinical trials that will be required for approval by the FDA, the EMA or any other foreign regulatory agency varies depending on the compound, the disease or condition that the products is designed to address and the regulations applicable to any particular products . Preclinical and clinical data can be interpreted in different ways, which could delay, limit or preclude regulatory approval. The FDA, the EMA and other foreign regulatory agencies can delay, limit or deny approval of a product for many reasons, including, but not limited to:

- a product may not be shown to be safe or effective;
- the clinical and other benefits of a product may not outweigh its safety risks;
- clinical trial results may be negative or inconclusive, or adverse medical events may occur during a clinical trial;
- the results of clinical trials may not meet the level of statistical significance required by regulatory agencies for approval;
- regulatory agencies may interpret data from pre-clinical and clinical trials in different ways than we do;
- regulatory agencies may not approve the manufacturing process of a compound or determine that a third party contract manufacturers manufactures a compound in accordance with current good manufacturing practices, or cGMPs;
- a product may fail to comply with regulatory requirements; or
- regulatory agencies might change their approval policies or adopt new regulations.

If our products are not approved at all or quickly enough to provide net revenues to defray our operating expenses, our business, financial condition, operating results and prospects could be harmed.

In the event that we seek and the FDA does not grant accelerated approval or priority review for a drug candidate, we would experience a longer time to commercialization in the U.S., if commercialized at all, our development costs may increase and our competitive position may be harmed.

We may in the future decide to seek accelerated approval pathway for our products. The FDA may grant accelerated approval to a product designed to treat a serious or life-threatening condition that provides meaningful therapeutic benefit over available therapies upon a determination that the product has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. A surrogate endpoint under an accelerated approval pathway may be used in cases in which the advantage of a new drug over available therapy may not be a direct therapeutic advantage, but is a clinically important improvement from a patient and public health perspective. There can be no assurance that the FDA will agree that any endpoint we suggest with respect to any of our drug candidates is an appropriate surrogate endpoint. Furthermore, there can be no assurance that any application will be accepted or that approval will be granted. Even if a product candidate is granted accelerated approval, such accelerated approval is contingent on the sponsor's agreement to conduct one or more post-approval confirmatory trials. Such confirmatory trial(s) must be completed with due diligence and, in some cases, the FDA may require that the trial(s) be designed and/or initiated prior to approval. Moreover, the FDA may withdraw approval of a product candidate or indication approved under the accelerated approval pathway for a variety of reasons, including if the trial(s) required to verify the predicted clinical benefit of a product candidate fail to verify such benefit or do not demonstrate sufficient clinical benefit to justify the risks associated with the drug, or if the sponsor fails to conduct any required post-approval trial(s) with due diligence.

In the event of priority review, the FDA has a goal to (but is not required to) take action on an application within a total of eight months (rather than a goal of twelve months for a standard review). The FDA grants priority review only if it determines that a product treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness when compared to a standard application. The FDA has broad discretion whether to grant priority review, and, while the FDA has granted priority review to other oncology product candidates, our drug candidates may not receive similar designation. Moreover, receiving priority review from the FDA does not guarantee completion of review or approval within the targeted eight-month cycle or thereafter.

A failure to obtain accelerated approval or priority review would result in a longer time to commercialization of the applicable compound in the U.S., if commercialized at all, could increase the cost of development and could harm our competitive position in the marketplace.

Even if our products are successful in clinical trials and receive regulatory approvals, we may not be able to successfully commercialize them.

The development and ongoing clinical trials for our drug candidates may not be successful and, even if they are, the resulting products may never be successfully developed into commercial products. Even if we are successful in our clinical trials and in obtaining other regulatory approvals, the respective products may not reach or remain in the market for a number of reasons including:

- they may be found ineffective or cause harmful side effects;
- they may be difficult to manufacture on a scale necessary for commercialization;
- they may experience excessive product loss due to contamination, equipment failure, inadequate transportation or storage, improper installation or operation of equipment, vendor or operator error, inconsistency in yields or variability in product characteristics;
- they may be uneconomical to produce;
- we may fail to obtain reimbursement approvals or pricing that is cost effective for patients as compared to other available forms of treatment or that covers the cost of production and other expenses;
- they may not compete effectively with existing or future alternatives;

- we may be unable to develop commercial operations and to sell marketing rights;

- they may fail to achieve market acceptance; or

- we may be precluded from commercialization of a product due to proprietary rights of third parties.

In particular, our ability to develop and commercialize AfTG will be heavily dependent on a successful resolution of our dispute with our licensor Besins. The failure of Besins to fulfill its respective manufacturing obligations with respect to AfTG, or the occurrence of any of the events in the list above, could adversely affect the commercialization of AfTG and our other products. If we fail to commercialize products or if our future products do not achieve significant market acceptance, we will not likely generate significant revenues or become profitable.

The pharmaceutical business is subject to increasing government price controls and other restrictions on pricing, reimbursement and access to drugs, which could adversely affect our future revenues and profitability.

To the extent our products are developed, commercialized and successfully introduced to market, they may not be considered cost-effective and third party or government reimbursement might not be available or sufficient. Globally, governmental and other third party payors are becoming increasingly aggressive in attempting to contain health care costs by strictly controlling, directly or indirectly, pricing and reimbursement and, in some cases, limiting or denying coverage altogether on the basis of a variety of justifications, and we expect pressures on pricing and reimbursement from both governments and private payors inside and outside the U.S. to continue. In the U.S., we are subject to substantial pricing, reimbursement and access pressures from state Medicaid programs, private insurance programs and pharmacy benefit managers, and implementation of U.S. health care reform legislation is increasing these pricing pressures. The Patient Protection and Affordable Care Act instituted comprehensive health care reform, which includes provisions that, among other things, reduce and/or limit Medicare reimbursement, require all individuals to have health insurance (with limited exceptions) and impose new and/or increased taxes. In almost all European markets, pricing and choice of prescription pharmaceuticals are subject to governmental control. Therefore, the price of our products and their reimbursement in Europe is and will be determined by national regulatory authorities. Reimbursement decisions from one or more of the European markets may impact reimbursement decisions in other European markets. A variety of factors are considered in making reimbursement decisions, including whether there is sufficient evidence to show that treatment with the product is more effective than current treatments, that the product represents good value for money for the health service it provides and that treatment with the product works at least as well as currently available treatments. The continuing efforts of government and insurance companies, health maintenance organizations and other payors of health care costs to contain or reduce costs of health care may affect our future revenues and profitability or those of our potential customers, suppliers and collaborative partners, as well as the availability of capital.

We are dependent on third party service providers for a number of critical operational activities including, in particular, for the manufacture, testing and distribution of our products and associated supply chain operations, as well as for clinical trial activities. Any failure or delay in these undertakings by third parties could harm our business.

Our business is dependent on the performance by third parties of their responsibilities under contractual relationships. In particular, heavily we rely on third parties for the manufacture and testing of our products. We do not have internal analytical laboratory or manufacturing facilities to allow the testing or production of products in compliance with cGMP. As a result, we rely on third parties to supply us in a timely manner with manufactured products/product candidates. We may not be able to adequately manage and oversee the manufacturers we choose, they may not perform as agreed or they may terminate their agreements with us. In particular, we depend on third party manufacturers to conduct their operations in compliance with GLP or similar standards imposed by the U.S. and/or applicable foreign regulatory authorities, including the FDA and EMA. Any of these regulatory authorities may take action against a contract manufacturer who violates cGMP. Failure of our manufacturers to comply with FDA, EMA or other applicable regulations may cause us to curtail or stop the manufacture of such products until we obtain regulatory compliance.

We may not be able to obtain sufficient quantities of our products if we are unable to secure manufacturers when needed, or if our designated manufacturers do not have the capacity or otherwise fail to manufacture compounds

according to our schedule and specifications or fail to comply with cGMP regulations. In particular, in connection with the transition of the manufacturing of AfTG drug supply to successor vendors, respectively, we could face logistical, scaling or other challenges that may adversely affect supply. Furthermore, in order to ultimately obtain and maintain applicable regulatory approvals, any manufacturers we utilize are required to consistently produce the respective products in commercial quantities and of specified quality or execute fill-finish services on a repeated basis and document their ability to do so, which is referred to as process validation. In order to obtain and maintain regulatory approval of a compound, the applicable regulatory authority must consider the result of the applicable process validation to be satisfactory and must otherwise approve of the manufacturing process. Even if our compound manufacturing processes obtain regulatory approval and sufficient supply is available to complete clinical trials necessary for regulatory approval, there are no guarantees we will be able to supply the quantities necessary to effect a commercial launch of the applicable drug, or once launched, to satisfy ongoing demand. Any product shortage could also impair our ability to deliver contractually required supply quantities to applicable collaborators, as well as to complete any additional planned clinical trials.

We also rely on third party service providers for certain warehousing, transportation, sales, order processing, distribution and cash collection services. With regard to the distribution of our compounds, we depend on third party distributors to act in accordance with GDP, and the distribution process and facilities are subject to continuing regulation by applicable regulatory authorities with respect to the distribution and storage of products.

In addition, we depend on medical institutions and CROs (together with their respective agents) to conduct clinical trials and associated activities in compliance with GCP and in accordance with our timelines, expectations and requirements. We are substantially dependent on Columbia University Medical Center Breast Cancer Program for the clinical study they are conducting for us using our intraductal microcatheters. To the extent any such third parties are delayed in achieving or fail to meet our clinical trial enrollment expectations, fail to conduct our trials in accordance with GCP or study protocol or otherwise take actions outside of our control or without our consent, our business may be harmed. Furthermore, we conduct clinical trials in foreign countries, subjecting us to additional risks and challenges, including, in particular, as a result of the engagement of foreign medical institutions and foreign CROs, who may be less experienced with regard to regulatory matters applicable to us and may have different standards of medical care.

With regard to certain of the foregoing clinical trial operations and stages in the manufacturing and distribution chain of our compounds, we rely on single vendors. In particular, our current business structure contemplates, at least in the foreseeable future, use of a single commercial supplier for Afimoxifene drug substance. In addition, in the event AfTG is approved, we are initially preparing to have only one commercial supplier for AfTG. The use of single vendors for core operational activities, such as clinical trial operations, manufacturing and distribution, and the resulting lack of diversification, expose us to the risk of a material interruption in service related to these single, outside vendors. As a result, our exposure to this concentration risk could harm our business.

Although we monitor the compliance of our third party service providers performing the aforementioned services, we cannot be certain that such service providers will consistently comply with applicable regulatory requirements or that they will otherwise timely satisfy their obligations to us. Any such failure and/or any failure by us to monitor their services and to plan for and manage our short and long term requirements underlying such services could result in shortage of the compound, delays in or cessation of clinical trials, failure to obtain or revocation of product approvals or authorizations, product recalls, withdrawal or seizure of products, suspension of an applicable wholesale distribution authorization and/or distribution of products, operating restrictions, injunctions, suspension of licenses, other administrative or judicial sanctions (including civil penalties and/or criminal prosecution) and/or unanticipated related expenditures to resolve shortcomings.

Such consequences could have a significant impact on our business, financial condition, operating results or prospects.

We may encounter delays in our clinical trials, or may not be able to conduct our trials timely.

Clinical trials are expensive and subject to regulatory approvals. Potential trial delays may arise from, but are not limited to:

- U.S and international regulatory approval might not be obtained or may be delayed;
- lower than anticipated patient enrollment for reasons such as existing conditions and eligibility criteria;
- delays in reaching agreements on acceptable terms with prospective CRO's; and
- failure of The Columbia University Medical Center and CRO's or other third parties to effectively and timely monitor, oversee, and maintain the clinical trials.

Our products and services may expose us to possible litigation and product liability claims.

Our business may expose us to potential product liability risks inherent in the testing, marketing and processing personalized medical products, particularly those products and services we offered prior to shifting our focus on pharmaceutical development. Product liability risks may arise from, but are not limited to:

- the inability of our microcatheters to inject sufficient amount of drug into the breast, which could lead to an inaccurate treatment result;

- Adverse events related to the drugs;

- failure by healthcare professionals to properly safeguard NAF samples collected using our aspirators;

- improper fitting of the aspirator device to the breast; and

- cleaning of the breast prior to applying the aspirator.

A successful product liability claim, or the costs and time commitment involved in defending against a product liability claim, could have a material adverse effect on our business. Any successful product liability claim may prevent us from obtaining adequate product liability insurance in the future on commercially desirable or reasonable terms. An inability to obtain sufficient insurance coverage at an acceptable cost, or otherwise, to protect against potential product liability claims could prevent or inhibit the commercialization of our products.

If we are not able to protect our proprietary technology, others could compete against us more directly, which would harm our business.

Our commercial success will depend, in part, on our ability to obtain additional patents and licenses and protect our existing patent position, both in the United States and in other countries, for devices, kits, diagnostics tests, Therapeutics and related technologies, processes, methods, compositions and other inventions that we believe are patentable. Our ability to preserve our trade secrets and other intellectual property is also important to our long-term success. If we do not adequately protect our intellectual property, competitors may be able to use our technologies and erode or negate any competitive advantage we may have, which could harm our business and ability to maintain profitability. Patents may also issue to third parties which could interfere with our ability to bring our molecular diagnostic tests or therapeutics to market. The laws of some foreign countries do not protect our proprietary rights to the same extent as U.S. laws, and we may encounter significant problems in protecting our proprietary rights in these countries. The patent positions of diagnostic companies and pharmaceutical and biotechnology companies, including our patent position, are generally highly uncertain and particularly after the Supreme Court decisions, *Mayo Collaborative Services v. Prometheus Laboratories*, 132 S. Ct. 1289 (2012), Association for Molecular Pathology v. Myriad , 133 S. Ct. 2107 (2013), and Alice Corp. v. CLS Bank Int'l , 134 S. Ct. 2347 (2014), and involve complex legal and factual questions, and, therefore, any patents issued to us may be challenged, deemed unenforceable, invalidated or circumvented. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our proprietary technologies and any future tests are covered by valid and enforceable patents or are effectively maintained as trade secrets. Our patent applications may never issue as patents, and the claims of any issued patents may not afford meaningful protection for our technology or tests. In addition, any patents issued to us or our licensors may be challenged, and subsequently narrowed, invalidated or circumvented.

· the degree of future protection for our proprietary rights is uncertain, and we cannot ensure that;

· we or our licensors were the first to make the inventions covered by each of our patent applications;

· we or our licensors were the first to file patent applications for these inventions;

· others will not independently develop similar or alternative technologies or duplicate any of our technologies;

· any of our or our licensors' patent applications will result in issued patents;

· any of our or our licensors' patents will be valid or enforceable;

- any patents issued to us or our licensors and collaborators will provide a basis for commercially viable tests and/or Therapeutics, will provide us with any competitive advantages or will not be challenged by third parties;

- we will develop additional proprietary technologies or tests that are patentable;

- the patents of others will not have an adverse effect on our business; or

- our patents or patents that we license from others will survive legal challenges, and remain valid and enforceable.

If a third party files a patent application with claims to a biomarker or a drug we have discovered or developed, a derivation proceeding may be initiated regarding competing patent applications. If a derivation proceeding is initiated, we may not prevail in the derivation proceeding. If the other party prevails in the derivation proceeding, we may be precluded from commercializing services or tests based on the biomarker or the drug, or may be required to seek a license. A license may not be available to us on commercially acceptable terms, if at all.

We also rely upon unpatented proprietary technologies. Although we require employees, consultants and collaborators to sign confidentiality agreements, we may not be able to adequately protect our rights in such unpatented proprietary technologies, which could have a material adverse effect on our business. For example, others may independently develop substantially equivalent proprietary information or techniques or otherwise gain access to our proprietary technologies or disclose our technologies to our competitors

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent process. Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on any issued patents and/or applications are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patents and/or applications. We have systems in place to remind us to pay these fees, and we employ an outside firm and rely on our outside counsel to pay these fees. While an inadvertent lapse may sometimes be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to enter the market earlier than should otherwise have been the case, which would have a material adverse effect on our business.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our products and services.

As is the case with other diagnostic, medical device and pharmaceutical companies, our success is heavily dependent on intellectual property, particularly on obtaining and enforcing patents. Obtaining and enforcing patents in the diagnostic, medical device and pharmaceutical industries involve both technological and legal complexity, and is therefore costly, time-consuming and inherently uncertain. In addition, the United States has recently enacted and is currently implementing wide-ranging patent reform legislation. Further, recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In particular, on March 20, 2012, the U.S. Supreme Court issued a decision in *Mayo Collaborative Services, DBA Mayo Medical Laboratories, et al. v. Prometheus Laboratories, Inc* ., No. 10-1150, holding that several claims drawn to measuring drug metabolite levels from patient samples were not patentable subject matter. The full impact of the *Prometheus* decision on diagnostic claims is uncertain. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents once obtained. Depending on decisions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

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

Filing, prosecuting and defending patents on our products and services in all countries throughout the world would be prohibitively expensive. In addition, the laws of some foreign countries do not protect intellectual property rights in the same manner and to the same extent as laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection but enforcement of such patent protection is not as strong as that in the United States. These products may compete with our products and services, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing with our products and services.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products and services in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop.

Our current patent portfolio may not include all patent rights needed for the full development and commercialization of our products and services. We cannot be sure that patent rights we may need in the future will be available for license on commercially reasonable terms, or at all.

We may be unable to obtain any licenses or other rights to patents, technology or know-how from third parties necessary to conduct our business as described in this report and such licenses, if available at all, may not be available on commercially reasonable terms. Others may seek licenses from us for other technology we use or intend to use. Any failure to obtain such licenses could delay or prevent us from developing or commercializing our proposed products and services, which would harm our business. For example, we may seek to develop our intraductal treatment program by licensing a pharmaceutical from a third party. We may not be able to secure such a license on acceptable terms. Litigation or patent interference proceedings need to be brought against third parties, as discussed below, to enforce any of our patents or other proprietary rights, or to determine the scope and validity or enforceability of the proprietary rights of such third parties.

Third party claims alleging intellectual property infringement may prevent or delay our drug discovery and development efforts.

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties, including the intellectual property rights of competitors. There is a substantial amount of litigation, both within and outside the United States, involving patents and other intellectual property rights in the diagnostic, medical device and pharmaceutical fields, as well as administrative proceedings for challenging patents, including interference and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in various foreign jurisdictions. Recently, the America Invents Act (AIA) introduced new procedures including inter partes review and post grant review. The implementation of these procedures brings uncertainty to the possibility of challenges to our patents in the future, including those patents perceived by our competitors as blocking entry into the market for their products and services, and the outcome of such challenges. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing our products and services. As the diagnostic, medical device and pharmaceutical industries expand and more patents are issued, the risk increases that our activities related to our products may give rise to claims of infringement of the patent rights of others.

We cannot assure you that our current or future products and services will not infringe on existing or future patents. We may not be aware of patents that have already issued that a third party might assert are infringed by one of our current or future products or services. Nevertheless, we are not aware of any issued patents that will prevent us from marketing our products and services.

Third parties may assert that we are employing their proprietary technology without authorization. There may be third party patents of which we are currently unaware with claims to materials, formulations, methods of manufacture, or methods for treatment related to the use or manufacture of our products. Because patent applications can take many years to issue and may be confidential for eighteen (18) months or more after filing, there may be currently pending third party patent applications which may later result in issued patents that our products may infringe, or which such third parties claim are infringed by our products and services.

Parties making claims against us for infringement or misappropriation of their intellectual property rights may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our products and services. Defense of these claims, regardless of their merit, would involve substantial expenses and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us by a third party, we may have to (i) pay substantial damages, including treble damages and attorneys' fees if we are found to have willfully infringed the third party's patents; (ii) obtain one or more licenses from the third party; (iii) pay royalties to the third party; or (iv) redesign any infringing products. Redesigning any infringing products may be impossible or require substantial time and monetary expenditure. Further, we cannot predict whether any required license would be available at all or whether it would be available on commercially reasonable terms. In the event that we could not obtain a license, we may be unable to further develop and commercialize our products, which could harm our business significantly. Even if we were able to obtain a license, the rights may be nonexclusive, which may give our competitors access to the same intellectual property.

In addition to infringement claims against us, if third parties have prepared and filed patent applications in the United States that also claim technology related to our products and services, we may have to participate in interference proceedings in the USPTO to determine the priority of invention. Third parties may also attempt to initiate reexamination, post grant review or inter partes review of our patents in the USPTO. We may also become involved in similar proceedings in the patent offices in other jurisdictions regarding our intellectual property rights with respect to our products and technology.

We may be involved in proceedings to protect or enforce our patents or the patents of our licensors, which could be expensive, time-consuming and unsuccessful.

Third parties may infringe, misappropriate or otherwise violate our patents, or patents that may be issued to us in the future. To counter infringement or unauthorized use, we may be required to file infringement claims. Infringement

claims can be expensive and time-consuming. Further, we may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States.

In addition, if we initiated legal proceedings against a third party to enforce a patent, the defendant could counterclaim that our patents are invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover our products and services. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection for our products and services. Such a loss of patent protection could have a material adverse impact on our business.

Litigation proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Finally, we may not be able to prevent, alone or with the support of our licensors, misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the United States.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.

We have received confidential and proprietary information from third parties. In addition, we employ individuals who were previously employed at other diagnostic, medical device or pharmaceutical companies. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise improperly used or disclosed confidential information of these third parties or our employees' former employers. Further, we may be subject to ownership disputes in the future arising, for example, from conflicting obligations of consultants or others who are involved in developing our products. We may also be subject to claims that former employees, consultants, independent contractors, collaborators or other third parties have an ownership interest in our patents or other intellectual property. Litigation may be necessary to defend against these and other claims challenging our right to and use of confidential and proprietary information. If we fail in defending any such claims, in addition to paying monetary damages, we may lose our rights therein. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against these claims, litigation could result in substantial cost and be a distraction to our management and employees.

We may be unable to adequately prevent disclosure of trade secrets and other proprietary information.

We rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable or that we elect not to patent, processes for which patents are difficult to enforce, and any other elements of our discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. However, trade secrets can be difficult to protect. We require all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology, to enter into confidentiality agreements. However, we cannot be certain that all such confidentiality agreements have been duly executed, that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Misappropriation or unauthorized disclosure of our trade secrets could impair our competitive position and may have a material adverse effect on our business. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret.

Risks Related to our Industry

If our products, or malfunction of our products, cause or contribute to a death or a serious injury, we will be subject to medical device reporting regulations, which can result in voluntary corrective actions or agency enforcement actions.

Under the FDA's medical device reporting, or MDR, regulations, we are required to report to the FDA any incident in which our product may have caused or contributed to a death or serious injury or in which our product malfunctioned and, if the malfunction were to occur, would likely cause or contribute to death or serious injury. Repeated product malfunctions may result in a voluntary or involuntary product recall, which could divert managerial and financial resources, impair our ability to manufacture our products in a cost-effective and timely manner, and have an adverse effect on our reputation, results of operations and financial condition.

In the EU, we must comply with the EU Medical Device Vigilance System (MEDDEV 2.12/1 rev.8) which is intended to protect the health and safety of patients, users and others by establishing reporting procedures and reducing the likelihood of reoccurrence of incidents related to the use of a medical device. Under this system, incidents (which are defined as any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labeling or the instructions for use which, directly or indirectly, may lead to or may have led to the death of a patient, or user or other persons or to a serious deterioration in such person's state of health) must be reported by manufacturers through a Manufacturer's Incident Reports to competent authorities within periods of time specified in the MEDDEV 2.12/1 rev. 8. Such incidents are evaluated and, where appropriate, information is disseminated between the competent authorities of the EU Member States. The MEDDEV 2.12/1 rev. 8 is also intended to facilitate a direct, early and harmonized establishment of Field Safety Corrective Actions, or FSCAs, across the EU Member States in which the device is being marketed. A FSCA is an action taken by a manufacturer to reduce a risk of death or serious deterioration in the state of health associated with the use of a medical device that is already placed on the market. A FSCA may include device recall, modification, exchange, or destruction. FSCAs must be reported by the manufacturer or the manufacturer's European Authorized Representative, to its customers and/or the end users of the device through a Field Safety Notice. FSCAs must also be reported to the competent authorities of the EU Member States. Failure to comply with any of these requirements could significantly and adversely affect our business.

Our inadvertent or unintentional failure to comply with the complex government regulations concerning privacy of medical records could subject us to fines and adversely affect our reputation.

The federal privacy regulations, among other things, restrict our ability to use or disclose protected health information in the form of patient-identifiable laboratory data, without written patient authorization, for purposes other than payment, treatment, or healthcare operations (as defined under the Health Insurance Portability and Accountability Act, or HIPAA) except for disclosures for various public policy purposes and other permitted purposes outlined in the privacy regulations. The privacy regulations provide for significant fines and other penalties for wrongful use or disclosure of protected health information, including potential civil and criminal fines and penalties. Although the HIPAA statute and regulations do not expressly provide for a private right of damages, we could incur damages under state laws to private parties for the wrongful use or disclosure of confidential health information or other private personal information.

We intend to implement policies and practices that we believe will make us compliant with the privacy regulations. However, the documentation and process requirements of the privacy regulations are complex and subject to interpretation. Failure to comply with the privacy regulations could subject us to sanctions or penalties, loss of business, and negative publicity.

The HIPAA privacy regulations establish a “floor” of minimum protection for patients as to their medical information and do not supersede state laws that are more stringent. Therefore, we are required to comply with both HIPAA privacy regulations and various state privacy laws. The failure to do so could subject us to regulatory actions, including significant fines or penalties, and to private actions by patients, as well as to adverse publicity and possible loss of business. In addition, federal and state laws and judicial decisions provide individuals with various rights for violation of the privacy of their medical information by healthcare providers such as us.

The collection and use of personal health data in the EU is governed by the provisions of Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data, commonly known as the Data Protection Directive. The Directive imposes a number of requirements including an obligation to seek the consent of individuals to whom the personal data relates, the information that must be provided to the individuals, notification of data processing obligations to the competent national data protection authorities of individual EU Member States and the security and confidentiality of the personal data. The Data Protection Directive also imposes strict rules on the transfer of personal data out of the EU to the U.S. Failure to comply with the requirements of the Data Protection Directive and the related national data protection laws of the EU Member States may result in fines and other administrative penalties and harm our business.

Legislative or regulatory reforms may make it more difficult and costly for us to obtain regulatory approval of our product candidates and to manufacture, market and distribute our products after approval is obtained.

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the regulatory approval, manufacture and marketing of regulated products or the reimbursement thereof. In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of future products. In addition, FDA regulations and guidance are often revised or reinterpreted by the agency in ways that may significantly affect our business and our products. It is impossible to predict whether legislative changes will be enacted or FDA regulations, guidance or interpretations changed, and what the impact of such changes, if any, may be. Similar changes and revisions can also occur in foreign countries.

For example, the FDA may change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions which may prevent or delay approval or clearance of our products under development or impact our ability to modify our currently cleared products on a timely basis. For example, in 2011, the FDA initiated a review of the premarket clearance process in response to internal and external concerns regarding the 510(k) program, announcing 25 action items designed to make the process more rigorous and transparent. In addition, as part of the Food and Drug Administration Safety and Innovation Act of 2012, or the FDASIA, Congress enacted several reforms entitled the Medical Device Regulatory Improvements and additional miscellaneous provisions which will further affect medical device regulation both pre- and post-approval. The FDA has implemented, and continues to implement, these reforms, which could impose additional regulatory requirements upon us and delay our ability to obtain new 510(k) clearances, increase the costs of compliance or restrict our ability to maintain our current clearances. For example, the FDA recently issued guidance documents intended to explain the procedures and criteria the FDA will use in assessing whether a 510(k) submission meets a minimum threshold of acceptability and should be accepted for review. Under the “Refuse to Accept” guidance, the FDA conducts an early review against specific acceptance criteria to inform 510(k) submitters if the submission is administratively complete, or if not, to identify the missing element(s). Submitters are given the opportunity to provide the FDA with the identified information, but if the information is not provided within a defined time, the submission will not be accepted for FDA review. Any change in the laws or regulations that govern the clearance and approval processes relating to our current and future products could make it more difficult and costly to obtain clearance or approval for new products, or to produce, market and distribute existing products. Significant delays in receiving clearance or approval, or the failure to receive clearance or approval for our new products would have an adverse effect on our ability to expand our business.

The failure to comply with complex federal and state laws and regulations related to submission of claims for services could result in significant monetary damages and penalties and exclusion from the Medicare and Medicaid programs.

We are subject to extensive federal and state laws and regulations relating to the submission of claims for payment for services, including those that relate to coverage of services under Medicare, Medicaid, and other governmental healthcare programs, the amounts that may be billed for services, and to whom claims for services may be submitted, such as billing Medicare as the secondary, rather than the primary, payor. The failure to comply with applicable laws and regulations, for example, enrollment in PECOS, the Medicare Provider Enrollment, Chain and Ownership System, could result in our inability to receive payment for our services or attempts by third party payors, such as Medicare and Medicaid, to recover payments from us that we have already received. Submission of claims in violation of certain statutory or regulatory requirements can result in penalties, including civil money penalties of up to $10,000 for each item or service billed to Medicare in violation of the legal requirement, and exclusion from participation in Medicare and Medicaid. Government authorities may also assert that violations of laws and regulations related to submission of claims violate the federal False Claims Act or other laws related to fraud and abuse, including submission of claims for services that were not medically necessary. The Company will be generally dependent on independent physicians to determine when its services are medically necessary for a particular patient. Nevertheless, we could be adversely affected if it was determined that the services we provided were not medically necessary and not reimbursable, particularly if it were asserted that we contributed to the physician’s referrals of unnecessary services. It is also possible that the government could attempt to hold us liable under fraud and abuse laws for improper claims submitted by us if it were found that we knowingly participated in the arrangement that resulted in submission of the improper claims.

Healthcare policy changes, including recently enacted legislation reforming the United States healthcare system, may have a material adverse effect on our financial condition and results of operations

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, collectively, the PPACA, enacted in March 2010, makes changes that are expected to significantly impact the pharmaceutical and medical device industries

Other significant measures contained in the PPACA include coordination and promotion of research on comparative clinical effectiveness of different technologies and procedures, initiatives to revise Medicare payment methodologies, such as bundling of payments across the continuum of care by providers and physicians, and initiatives to promote quality indicators in payment methodologies. The PPACA also includes significant new fraud and abuse measures, including required disclosures of financial arrangements with physician customers, lower thresholds for violations and increasing potential penalties for such violations. In addition, the PPACA establishes an Independent Payment Advisory Board, or IPAB, to reduce the per capita rate of growth in Medicare spending. The IPAB has broad discretion to propose policies to reduce health care expenditures, which may have a negative impact on payment rates for services, including our tests. The IPAB proposals may impact payments for clinical laboratory services that our future diagnostics customers use our technology to deliver beginning in 2016 and for hospital services beginning in 2020, and may indirectly reduce demand for our diagnostic products.

In addition to the PPACA, the effect of which cannot presently be quantified, various healthcare reform proposals have also emerged from federal and state governments. Changes in healthcare policy, such as the creation of broad test utilization limits for diagnostic products in general or requirements that Medicare patients pay for portions of clinical laboratory tests or services received, could substantially impact the sales of our tests, increase costs and divert management’s attention from our business. Such co-payments by Medicare beneficiaries for laboratory services were discussed as possible cost savings for the Medicare program as part of the debt ceiling budget discussions in mid-2011 and may be enacted in the future. In addition, sales of our tests outside of the United States will subject us to foreign regulatory requirements, which may also change over time.

We cannot predict whether future healthcare initiatives will be implemented at the federal or state level or in countries outside of the United States in which we may do business, or the effect any future legislation or regulation will have on us. The taxes imposed by the new federal legislation and the expansion in government’s effect on the United States healthcare industry may result in decreased profits to us, lower reimbursements by payors for our products or reduced medical procedure volumes, all of which may adversely affect our business, financial condition and results of operations.

Risks Related to the Securities Markets and Investment in our Securities

Our shares of common stock are listed on the NASDAQ Capital Market, but we cannot guarantee that we will be able to satisfy the continued listing standards going forward.

Although our shares of common stock are listed on the NASDAQ Capital Market, we cannot ensure that we will be able to satisfy the continued listing standards of the NASDAQ Capital Market going forward. If we cannot satisfy the continued listing standards going forward, NASDAQ may commence delisting procedures against us, which could result in our stock being removed from listing on the NASDAQ Capital Market. On September 28, 2015, we received a letter from NASDAQ stating that the Company was not in compliance with NASDAQ Listing Rule 5550(a)(2), because the Company's common stock failed to maintain a minimum closing bid price of $1.00 per share for 30 consecutive business days. We had until March 28, 2016 to either regain compliance, or request additional time to regain compliance. We had not regained compliance as of March 28, 2016 so we requested an extension of the deadline to regain compliance and notified NASDAQ of our intention to cure the deficiency during the extended compliance period, including by effecting a reverse stock split, if necessary. In response to our request, on March 29, 2016, NASDAQ granted us a 180 day extension, until September 26, 2016, to regain compliance with the $1.00 minimum bid price requirement.

If our stock price does not appreciate above $1.00 per share for a minimum of 10 consecutive business days by September 26, 2016, and if we don’t otherwise meet the other continued listing requirements, we may be delisted from NASDAQ which could adversely affect our stock price, liquidity and our ability to raise funding.

The sale of a substantial number of shares of our common stock into the market may cause substantial dilution to our existing stockholders and the sale, actual or anticipated, of a substantial number of shares of common stock could cause the price of our common stock to decline.

Any actual or anticipated sales of shares by us, Aspire or other stockholders may cause the trading price of our common stock to decline. Additional issuances of shares by us may result in dilution to the interests of other holders of our common stock. The sale of a substantial number of shares of our common stock by us, Aspire or other stockholders or anticipation of such sales, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect sales.

Additionally, sales of common stock by the investors in our 2011 private placement, including shares of common stock issuable upon exercise of warrants that were issued to them in 2011, as well as sales of common stock by investors upon exercise of warrants we issued in the public offering we completed in January 2014, could cause the price of our common stock to decline.

The trading price of our common stock has been, and is likely to continue to be volatile.

Since shares of our common stock were sold in our IPO in November 2012 at a price of $5.00 per share, our stock price has ranged from $0.14 to $12.40 through March 28, 2016. In addition to the factors discussed in this report, the trading price of our common stock may fluctuate significantly in response to numerous factors, many of which are beyond our control, including:

- results of clinical studies;
- litigation with Besins or others;
- regulatory and FDA actions, including inspections and warning letters;
- actions of securities analysts who initiate or maintain coverage of us, and changes in financial estimates by any securities analysts who follow our Company, or our failure to meet these estimates or the expectations of investors;
- any ongoing litigation that we are currently involved in or litigation that we may become involved in in the future;

- additional shares of our common stock being sold into the market by us or our existing stockholders or the anticipation of such sales; and

- media coverage of our business and financial performance.

In addition, the stock markets have experienced extreme price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many healthcare companies. Stock prices of many healthcare companies have fluctuated in a manner unrelated or disproportionate to the operating performance of those companies. As a result, an investment in our common stock may decrease in value.

If our common stock is delisted from the NASDAQ Capital Market, we may be subject to the risks relating to penny stocks.

If our common stock were to be delisted from trading on the NASDAQ Capital Market and the trading price of the common stock were below $5.00 per share on the date the common stock was delisted, trading in our common stock would also be subject to the requirements of certain rules promulgated under the Exchange Act. These rules require additional disclosure by broker-dealers in connection with any trades involving a stock defined as a “penny stock” and impose various sales practice requirements on broker-dealers who sell penny stocks to persons other than established customers and accredited investors, generally institutions. These additional requirements may discourage broker-dealers from effecting transactions in securities that are classified as penny stocks, which could severely limit the market price and liquidity of such securities and the ability of purchasers to sell such securities in the secondary market. A penny stock is defined generally as any non-exchange listed equity security that has a market price of less than $5.00 per share, subject to certain exceptions.

The ownership of our common stock is concentrated among a small number of stockholders, and if our principal stockholders, directors and officers choose to act together, they may be able to significantly influence management and operations, which may prevent us from taking actions that may be favorable to you.

Our ownership is concentrated among a small number of stockholders, including our founders, directors, officers and entities related to these persons. Our directors, officers and entities affiliated with them beneficially own approximately 16% of our outstanding voting securities. Accordingly, these stockholders, acting together, will have the ability to exert substantial influence over all matters requiring approval by our stockholders, including the election and removal of directors and any proposed merger, consolidation or sale of all or substantially all of our assets. This concentration of ownership could have the effect of delaying, deferring or preventing a change in control of the Company or impeding a merger or consolidation, takeover or other business combination that could be favorable to you.

If we are unable to implement and maintain effective internal control over financial reporting in the future, investors may lose confidence in the accuracy and completeness of our financial reports and the trading price of

our common stock may be negatively affected.

We are required to maintain internal controls over financial reporting and to report any material weaknesses in such internal controls. If we identify material weaknesses in our internal control over financial reporting, if we are unable to comply with the requirements of the Sarbanes-Oxley Act in a timely manner or assert that our internal control over financial reporting is effective, or if our independent registered public accounting firm is unable to express, if required, an opinion as to the effectiveness of our internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our financial reports and the trading price of our common stock could be negatively affected, and we could become subject to investigations by the stock exchange on which our securities is listed, the Securities and Exchange Commission, or other regulatory authorities, which could require additional financial and management resources.

The requirements of being a public company may strain our resources and divert management's attention.

We are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act, the Dodd-Frank Act, the listing requirements of the NASDAQ Capital Market, and other applicable securities rules and regulations. Compliance with these rules and regulations will increase our legal and financial compliance costs, make some activities more difficult, time-consuming, or costly, and increase demand on our systems and resources. As a result, management's attention may be diverted from other business concerns, which could harm our business and operating results. Although we have hired additional employees to comply with these requirements, we may need to hire more employees in the future, which will increase our costs and expenses.

In addition, complying with public disclosure rules makes our business more visible, which we believe may result in threatened or actual litigation, including by competitors and other third parties. If such claims are successful, our business and operating results could be harmed, and even if the claims do not result in litigation or are resolved in our favor, these claims, and the time and resources necessary to resolve them, could divert the resources of our management and harm our business and operating results.

Our Stockholder Rights Agreement, the Anti-Takeover provisions in our charter documents and Delaware law could delay or prevent a change in control which could limit the market price of our common stock and could prevent or frustrate attempts by the our stockholders to replace or remove current management and the current Board of Directors.

Our Stockholder Rights Agreement we adopted in May 2014, our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could delay or prevent a change in control or changes in our Board of Directors that our stockholders might consider favorable. These provisions include the establishment of a staggered Board of Directors, which divides the board into three classes, with directors in each class serving staggered three-year terms. The existence of a staggered board can make it more difficult for a third party to effect a takeover of our Company if the incumbent board does not support the transaction. These and other provisions in our corporate documents, our Shareholder Rights Plan and Delaware law might discourage, delay or prevent a change in control or changes in the Board of Directors of the Company. These provisions could also discourage proxy contests and make it more difficult for an investor and other stockholders to elect directors not nominated by our Board. Furthermore, the existence of these provisions, together with certain provisions of Delaware law, might hinder or delay an attempted takeover other than through negotiations with the Board of Directors.

We do not expect to pay dividends in the future, which means that investors may not be able to realize the value of their shares except through a sale.

We have never, and do not anticipate that we will, declare or pay a cash dividend. We expect to retain future earnings, if any, for our business and do not anticipate paying dividends on common stock at any time in the foreseeable future. Because we do not anticipate paying dividends in the future, the only opportunity for our stockholders to realize the creation of value in our common stock will likely be through a sale of those shares.

We are an "emerging growth company" and we cannot be certain if we will be able to maintain such status or if the reduced disclosure requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are an “emerging growth company,” as defined in the Jumpstart our Business Startups Act of 2012, or JOBS Act, and we intend to adopt certain exemptions from various reporting requirements that are applicable to other public companies that are not “emerging growth companies” including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, 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 stockholder approval of any golden parachute payments not previously approved. We may remain as an “emerging growth company” for up to five full fiscal years following our initial public offering. We would cease to be an “emerging growth company,” and therefore not be able to rely upon the above exemptions, if we have more than $1 billion in annual revenue in a fiscal year, we issue more than $1 billion of non-convertible debt over a three-year period, or we have more than $700 million in market value of our common stock held by non-affiliates as of any June 30 before the end of the five full fiscal years. Additionally, we cannot predict if investors will find our common stock less attractive because we will 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.

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 2. PROPERTIES

As of December 31, 2015, we leased approximately 17,991 square feet of office and laboratory space in three locations in Seattle, Washington, which includes space rented from Sanders Properties, LLC, Eastlake Properties LLC, and the Legacy Groups. We believe that our current facilities will be adequate to meet our needs for the next 24 months. This information is incorporated in this report under "PART II, ITEM 7. MANAGEMENT DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS – Commercial Lease Arrangements".

ITEM 3. LEGAL PROCEEDINGS

On October 10, 2013, a putative securities class action complaint, captioned *Cook v. Atossa Genetics, Inc.*, et al., No. 2:13-cv-01836-RSM, was filed in the United States District Court for the Western District of Washington against us, certain of our directors and officers and the underwriters of our November 2012 initial public offering. The complaint alleges that all defendants violated Sections 11 and 12(a)(2), and that we and certain of our directors and officers violated Section 15, of the Securities Act by making material false and misleading statements and omissions in the offering's registration statement, and that we and certain of our directors and officers violated Sections 10(b) and 20A of the Exchange Act and SEC Rule 10b-5 promulgated thereunder by making false and misleading statements and omissions in the registration statement and in certain of our subsequent press releases and SEC filings with respect to our NAF specimen collection process, our ForeCYTE Breast Health Test and our MASCT device. This action seeks, on behalf of persons who purchased our common stock between November 8, 2012 and October 4, 2013, inclusive, damages of an unspecific amount.

On February 14, 2014, the Court appointed plaintiffs Miko Levi, Bandar Almosa and Gregory Harrison (collectively, the "Levi Group") as lead plaintiffs, and approved their selection of co-lead counsel and liaison counsel. The Court also amended the caption of the case to read In re Atossa Genetics, Inc. Securities Litigation. No. 2:13-cv-01836-RSM. An amended complaint was filed on April 15, 2014. The Company and other defendants filed motions to dismiss the amended complaint on May 30, 2014. The plaintiffs filed briefs in opposition to these motions on July 11, 2014. The Company replied to the opposition briefs on August 11, 2014. On October 6, 2014 the Court granted defendants' motion dismissing all claims against Atossa and all other defendants. The Court's order provided plaintiffs with a deadline of October 26, 2014 to file a motion for leave to amend their complaint and the plaintiffs did not file such a

motion by that date. On October 30, 2014, the Court entered a final order of dismissal. On November 3, 2014, plaintiffs filed a notice of appeal with the Court and have appealed the Court's dismissal order to the U.S. Court of Appeals for the Ninth Circuit. On February 11, 2015, plaintiffs filed their opening appellate brief. Defendants' filed their answering brief on April 13, 2015, and plaintiffs filed their reply brief on May 18, 2015. A hearing for the appeal has not been set.

The Company believes this complaint is without merit and plans to defend itself vigorously; however failure to obtain a favorable resolution of the claims set forth in the complaint could have a material adverse effect on the Company's business, results of operations and financial condition. Currently, the amount of such material adverse effect cannot be reasonably estimated, and no provision or liability has been recorded for these claims as of December 31, 2015. The costs associated with defending and resolving the complaint and ultimate outcome cannot be predicted. These matters are subject to inherent uncertainties and the actual cost, as well as the distraction from the conduct of our business, will depend upon many unknown factors and management's view of these may change in the future.

On January 28, 2016, the Company filed a complaint in the United States District Court for the District of Delaware captioned *Atossa Genetics Inc. v. Besins Healthcare Luxembourg SARL*, Case No. 1:16-cv-00045-UNA. The complaint asserts claims for breach of contract, breach of the implied covenant of good faith and fair dealing, and for declaratory relief against defendant Besins Healthcare Luxembourg SARL. The Company's claims arise from Besins' breach of an Intellectual Property License Agreement dated May 14, 2015 (the "License Agreement"), under which Besins licensed to the Company the worldwide exclusive rights to develop and commercialize Afimoxifene Topical Gel, or AfTG, for the potential treatment and prevention of hyperplasia of the breast. The complaint seeks compensatory damages, a declaration of the parties' rights and obligations under the License Agreement, and injunctive relief. On March 7, 2016, Besins responded to our complaint by denying our claims and issuing counterclaims based on breach of contract, fraud and negligent misrepresentation, and seeking relief in the forms of compensatory damages, injunctive relief, and declaratory relief. We believe that these counterclaims are without merit and we plan to defend our self vigorously; however, failure by us to obtain a favorable resolution of the counterclaims could have a material adverse effect on our business, results of operations and financial condition.

ITEM 4. MINE SAFETY DISCLOSURE

Not applicable.

PART II

ITEM 5. MARKET FOR THE REGISTRANT'S COMMON EQUITY, RELATED SHAREHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

Our common stock, par value $0.001 per share, began trading on the NASDAQ Capital Market under the symbol "ATOS" on November 8, 2012. The following table sets forth, for the periods indicated, the intraday high and low prices of our common stock as reported by NASDAQ.

	2015		2014	
	High	Low	High	Low
First Quarter	$2.65	$1.12	$3.28	$1.68
Second Quarter	$1.84	$1.12	$1.90	$1.15
Third Quarter	$1.23	$0.70	$2.57	$1.68
Fourth Quarter	$0.84	$0.28	$2.10	$0.80

On March 28, 2016, the closing price of our common stock was $0.33. As of March 28, 2016, there were approximately 35 shareholders of record of our common stock, one of which is Cede & Co., a nominee for Depository Trust Company, or DTC and approximately 5,100 beneficial holders. All of the shares of common stock held by brokerage firms, banks and other financial institutions as nominees for beneficial owners are deposited into participant accounts at DTC, and are therefore considered to be held of record by Cede & Co. as one shareholder.

Certain Unregistered Sales of Securities

None

Dividends

The Company has never declared or paid any cash dividends on our common stock. We currently intend to retain any future earnings to finance the growth and development of our business.

Issuer Purchases of Securities

We did not repurchase any of our equity securities during the fourth quarter of the year ended December 31, 2015.

Use of Proceeds

Not applicable.

ITEM 6. SELECTED FINANCIAL DATA

Not applicable.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion of the financial condition and results of operations should be read in conjunction with the financial statements and the related notes included elsewhere in this report. This discussion contains forward-looking statements, which are based on assumptions about the future of the Company's business. The actual results could differ materially from those contained in the forward-looking statements. Please read "Forward-Looking Statements" included elsewhere in this report for additional information regarding forward-looking statements.

Overview

We are a clinical-stage pharmaceutical company focused on the development of novel therapeutics and delivery methods for the treatment of breast cancer and other breast conditions. Our leading program uses our patented intraductal microcatheters which delivers pharmaceuticals through the breast ducts. We initiated a Phase 2 clinical study in March 2016 using our microcatheters to deliver fulvestrant as a potential treatment of ductal carcinoma in-situ, or DCIS, and breast cancer. This study is being conducted by Columbia University Medical Center Breast Cancer Programs. Our second pharmaceutical program under development is Afimoxifene Topical Gel, or AfTG, for the treatment and prevention of hyperplasia of the breast.

In addition to our clinical-stage pharmaceutical programs, we are in the process of evaluating other therapeutic candidates to treat other breast conditions, including breast cancer. Factors we are considering in evaluating potential drug candidates include, for example, the ability to obtain expedited regulatory approval, significance of unmet medical need, size of the patient population, intellectual property opportunities and the anticipated pre-clinical and clinical pathway.

Through mid-2015 we were primarily focused on the development and commercialization of our medical devices and laboratory tests. Our medical devices include the ForeCYTE Breast Aspirator for distribution outside the United States and the FullCYTE Breast Aspirator for the U.S. market. These devices are intended for the collection of nipple aspirate fluid, or NAF, for cytological testing at a laboratory. The current version of the ForeCYTE Breast Aspirator is CE-marked and the FullCYTE Breast Aspirator has been cleared by the FDA. We are not, however, currently marketing and promoting our breast aspirators as we are devoting substantially all of our resources to our pharmaceutical business. Other devices under development include intraductal Microcatheters for the potential administration of targeted pharmaceuticals, and various tools for potential use by breast surgeons.

Our laboratory tests have historically been developed and performed by The National Reference Laboratory for Breast Health, Inc., or the "NRLBH." The NRLBH was our wholly-owned subsidiary until December 16, 2015 when, pursuant to a stock purchase agreement, we sold approximately 81% of the capital stock of the NRLBH to the NRL Investment Group, LLC We have determined that the disposition of the lab business qualifies for reporting as a discontinued operation since the sale represents a strategic shift that will have a major effect on our operations and financial results. We have elected to recognize any subsequent gain from the earn-out payments as they are determined realizable.

We are now focusing our business on our pharmaceutical programs. Our key objectives are to advance our pharmaceutical candidates through Phase 2 trials and then evaluate further development independently or through partners and to advance one or more of our pre-clinical programs into the clinical trial stage.

Revenue Sources

Our business has provided us with two revenue sources: (i) sales-based revenue from the sale of our medical devices, such as our ForeCYTE Breast Aspirator and FullCYTE Breast Aspirator and patient kits to distributors, physicians, breast health clinics, and mammography clinics and (ii) service, or use-based, revenue from laboratory services performed by the NRLBH, such as preparation and interpretation of the NAF samples sent to our laboratory for analysis and pharmacogenomics tests. Our main source of revenue beginning in October 2014 has been from pharmacogenomics testing. As of the date of this report, we are not selling our medical devices and because of the sale of 81% of the stock in the NRLBH, we are no longer generating revenue from laboratory testing. NRLBH revenue is disclosed as discontinued operations for both years ended 2014 and 2015. We do not anticipate generating additional revenue from other resources unless and until we develop and launch new pharmaceutical programs.

Commercial Lease Agreements

On March 4, 2011, we entered into a commercial lease agreement with Sanders Properties, LLC for office space located in Seattle, WA. The lease terminates on March 31, 2016 and we plan to renew the lease for another term.

On December 9, 2011, we entered into another commercial lease agreement with Fred Hutchinson Research Center for lab and office space located in Seattle, WA. The lease provides for monthly rent of $16,395 for the period from February 24, 2012 to August 31, 2012, $19,923 for the period from September 1, 2012 to August 31, 2013, and $20,548 for the period from September 1, 2013 to November 29, 2014. The security deposit of $32,789 was paid in March 2012 and recorded as Security Deposit on the consolidated balance sheet. On March 24, 2014, we entered into another commercial lease agreement with ARE LLC (Alexandria) which extends the term of the existing lab lease with Fred Hutchison Research Center which expires in November 2014 through November 30, 2016. The lease provided for monthly rent payments of $22,736 from December 2014 through November 2015 and $23,258 from December 2015 through November 2016. The NRLBH vacated this space in February 2016 and we are actively looking for tenants to sublease this space.

In July 2013, we entered into an agreement with ARE LLC (Alexandria) to lease additional office spaces under a separate lease agreement. The lease was from August 2013 through November 2014, and the gross rent was $4,800 per month.

As of December 31, 2014 we incurred and recorded a security deposit of $25,000. For the year ended December 31, 2014, we incurred $340,938 of rent expenses for the lease, which included leasing office management expenses and the new agreement with ARE LLC.

On August 8, 2014, we entered into a new commercial lease agreement with the Legacy Group Inc., to lease office space in Seattle, WA in conjunction with expiration of the current office space lease with Fred Hutchinson Research Center on November 29, 2014. The lease provides for monthly rent payments of $16,695 from December 1, 2014 through June 30, 2015, $17,172 from July 1, 2015 through June 30, 2016 and $17,649 from July 1, 2016 through June 30, 2017. On October 2015, we terminated the lease with the Legacy Group and entered into another commercial lease with the same landlord for similar office space which terminates in November 2016. For the year ended December 31, 2015, we incurred $227,238 of rent expense for the lease.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States, or GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses. On an ongoing basis, we evaluate these estimates and judgments, including those described below. We base our estimates on our historical experience and on various other assumptions that we believe to be reasonable under the circumstances. These estimates and assumptions form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results and experiences may differ materially from these estimates.

While our significant accounting policies are more fully described in Note 3 to our financial statements, we believe that the following accounting policies are the most critical to aid you in fully understanding and evaluating our reported financial results and affect the more significant judgments and estimates that we use in the preparation of our financial statements.

Revenue Recognition

The Company is not currently recognizing any revenue and all the revenue earned from testing services were generated by NRLBH. As a result of our sale of 81% of the outstanding stock in the NRLBH on December 16, 2015 all of the revenue generated by the NRLBH is disclosed as discontinued operations for both years ended 2014 and 2015.

The Company's revenue recognition policy is in accordance with GAAP when the following overall fundamental criteria are met: (i) persuasive evidence of an arrangement exists, (ii) delivery has occurred or the service has been performed, (iii) the Company's price to the customer is fixed or determinable and (iv) collection of the resulting accounts receivable is reasonably assured.

Intangible Assets

Intangible assets consist of intellectual property and software acquired. Intangibles are reviewed at least annually for impairment or whenever events or changes in circumstances indicate that the carrying value of the assets might not be recoverable. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of the asset and its eventual disposition are less than its carrying amount. Estimating future cash flows related to an intangible asset involves significant estimates and assumptions. If our assumptions are not correct, there could be an impairment loss or, in the case of a change in the estimated useful life of the asset, a change in amortization expense.

We continuously evaluate and reprioritize our research and development pipeline based on the most recent business strategies, and as a result have indefinitely delayed plans to develop and invest further in Acueity patents and technologies for at least the next several years. Because of these changed business plans related to the Acueity assets, we concluded that these assets were partially impaired in 2014 and recorded impairment of $2,352,626. In 2015, we conducted our annual evaluation of the Acueity assets and determined that the assets were not impaired for the year ended December 31, 2015.

We determined the fair values of the Acueity intangibles using an income approach. When available and appropriate, we use comparative market multiples to corroborate discounted cash flow results. For purposes of the income approach, fair value is determined based on the present value of estimated future cash flows to be generated from development of products using the patented technology acquired in the Acueity transaction based on our current plans, discounted at an appropriate risk-adjusted rate. We use our internal forecasts to estimate future cash flows and include an estimate of long-term future growth rates based on our most recent views of the outlook of the business. We use discount rates that are commensurate with the risk and uncertainty inherent in the business and in our internally developed forecasts. Discount rates used in valuations for these intangible assets ranged from 18% to 21%.

Share-Based Payments

We follow the provisions of the Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 718, *Compensation – Stock Compensation* ("ASC 718"), which requires the measurement and recognition

of compensation expense for all share-based payment awards made to employees, non-employee directors, and consultants, including employee stock options. Stock compensation expense based on the grant date's fair value was estimated in accordance with the provisions of ASC 718 and is recognized as an expense over the requisite service period.

The fair value of each option grant is estimated using the Black-Scholes option-pricing model, which requires assumptions regarding the expected volatility of our stock options, the expected life of the options, an expectation regarding future dividends on our common stock, and estimation of an appropriate risk-free interest rate. Our expected common stock price volatility assumption is based upon the volatility of our stock price. The expected life assumption for stock option grants was based upon the simplified method provided for under ASC 718-10, which averages the contractual term of the options of ten years with the average vesting term of four years. The dividend yield assumption of zero is based upon the fact that we have never paid cash dividends and presently have no intention of paying cash dividends in the future. The risk-free interest rate used for each grant was based upon prevailing short-term interest rates over the expected life of the options.

We have estimated an annualized forfeiture rate of 10.0% for options granted. We will record additional expense if the actual forfeitures are lower than estimated and will record a recovery of prior expense if the actual forfeiture rates are higher than estimated.

Results of Operations

Comparison of Years Ended December 31, 2015 and 2014

Revenue and Cost of Revenue: For the year ended December 31, 2015, substantially all of the revenue we recognized consisted of pharmacogenomics testing by the NRLBH. As a result of the sale of the NRLBH, the revenue and cost of revenue is presented as discontinued operations for both years ended 2015 and 2014. The NLRBH had a total net revenue of $5,524,874, for the year ended December 31, 2015 consisting of mainly pharmacogenomics testing. This represents an increase of approximately $5 million from the total net revenue of $525,954 from our ForeCYTE device sales and laboratory testing for the year ended December 31, 2014. Substantially all of our revenue for the year ended December 31, 2014 was recognized during the fourth quarter of 2014 when we launched the new pharmacogenomics testing in our laboratory. In March 2015, we began the launch of the FullCYTE Breast Aspirator in the U.S. and the ForeCYTE Breast Aspirator in the EU, focusing initially on the Netherlands, Germany, Switzerland, and the United Kingdom; however, we generated no revenue from device sales during the year.

Total cost of revenue for the year ended December 31, 2015 was $3,671,545 which consisted of costs relating primarily to pharmacogenomics testing services; compared to $340,658 for the year ended December 31, 2014. Gross profit for the year ended December 31, 2015 was $1,853,329 which was entirely attributable to pharmacogenomics testing, as compared to a gross profit of $185,296 for the year ended December 31, 2014.

Operating Expenses: As a result of the sale of NRLBH, operating expenses related to the NRLBH are presented separately as discontinued operations for both years ended 2015 and 2014. Total operating expenses from continuing operations were $12,627,965 for the year ended December 31, 2015, consisting of general and administrative (G&A) expenses of $8,842,938, R&D expenses of $2,359,593, and selling expenses of $1,421,409. Operating expenses from discontinued operations were $2,331,192, including $399,394 in exit costs.

Operating expenses from continuing operations increased $416,799, or 3%, from $12,211,166 for the year ended December 31, 2014, which consisted of G&A expenses of $8,052,281, R&D expenses of $1,110,329, selling expenses of $695,930, and impairment expenses of $2,352,626. Operating expenses from discontinued operations totaled $3,002,136 for the year ended December 31, 2015, compared to $2,487,158 for the same period in 2014. The increase in both continuing and discontinuing operating expenses year over year is mainly attributed to the 2015 launch of new

devices and services and investing more in new R&D programs.

Selling Expenses: Selling expenses from continuing operations of $1,421,409 and discontinued operations of $1,303,425 totaled $2,724,834 for the year ended December 31, 2015, an increase of $1,453,129, or 114%, from total selling expenses from continuing operations of $695,930 and discontinued operations of $575,775 that totaled $1,271,705 for the year ended December 31, 2014. The total increase in selling expenses from continuing and discontinued operations was attributed to increases in salaries, professional fees, and marketing expenses as we built a sales force in the United States and outside the United States to support the launch and commercialization of the ForeCYTE and FullCYTE Breast Aspirators and our laboratory service offerings. We anticipate selling expenses will significantly decrease in 2016 as we completed the transition of our discontinued operations in both the U.S. and outside the U.S. in the first quarter of 2016.

General and Administrative Expenses: G&A expenses from continuing operations of $8,846,963 and discontinued operations of $ $1,775,840 for the year ended December 31, 2015, which totaled $10,512,805, an increase of $1,886,887, or 22% from the total general and administrative expenses of $8,625,918, comprising of general and administrative expense from continuing operations of $8,052,281 and of discontinued operations of $573,637 for the same period in 2014. G&A expenses consist primarily of personnel and related benefit costs, facilities, professional services, insurance, and public company related expenses. The increase of $1,866,887 was primarily attributable to increases in personnel costs and bad debt expense as we expanded our pharmacogenomics business. We expect our G&A expenses to decrease as we exit the device and laboratory business.

Research and Development Expenses: R&D expenses for the year ended December 31, 2015 were $3,371,985, consisting of $2,359,593 from continuing operations and $1,012,392 from discontinued operations. This represents an increase of $794,520, or 31%, from total R&D expense from continuing and discontinued operations of $2,577,465 for the year ended December 31, 2014, which consisted of $1,110,329 from continuing operations and $1,467,137 from discontinued operations. The increase in total R&D expenses from continuing and discontinued operations in 2015 as compared to 2014 is attributed to additional R&D expenditures on the development of our new products and tests in the pipeline, including AfTG, the NextCYTE Breast Cancer test, intraductal microcatheters and the FullCYTE Breast Aspirator.

Impairment of Intangible Assets: During the year ended December 31, 2015, we evaluated our Acueity intangible assets for impairment and concluded no assets were impaired. In 2014, we recorded an impairment charge related to the intangible assets purchased in the Acueity transaction in 2012 of $2,352,626.

Discontinued operations: We have determined that the disposition of the NRLBH qualifies for reporting as a discontinued operation because the sale represents a strategic shift that will have a major effect on our operations and financial results. Financial results of the NRLBH are presented separately as discontinued operations for both years presented. Discontinued operations for the year ended December 31, 2015 include $1,931,798 net loss from the NRLBH operations, $670,943 loss from the sale of the NRLBH, and $399,395 in exit costs related to discontinuing the laboratory business. This compares to $2,487,158 in loss from discontinued operations for the year ended December 31, 2014, all from net loss from the laboratory operations.

The results of the NRLBH are disclosed as discontinued operations in the Company's Consolidated Statements of Operations and Comprehensive Loss for all periods presented:

	For the Years Ended December 31,	
	2015	2014
Revenue	$ 5,523,116	$ 485,816
Cost of revenue	(3,539,134)	(340,658)
Gross profit	1,983,982	145,158
Expenses:		
Selling expenses	(1,303,425)	(575,775)
Research and development expenses	(1,012,392)	(1,467,136)
General and administrative expenses	(1,665,840)	(573,637)
Loss on disposal	(670,943)	-
Exit and disposal expenses	(399,399)	-
Other (income) expense, net	65,881	(15,769)
Net loss from discontinued operations	$ (3,002,136)	$ (2,487,159)

Income taxes: We have incurred net operating losses from inception; we did not record an income tax benefit for our incurred losses for both 2014 and 2015 due to uncertainty regarding utilization of our net operating carryforwards and due to our history of losses.

Liquidity and Capital Resources

We have a history of operating losses as we have focused our efforts on raising capital and building our products and services in our pipeline. The Company's consolidated financial statements are prepared using generally accepted accounting principles in the United States of America applicable to a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The Company has incurred net losses and negative operating cash flows since inception. For the year ended December 31, 2015, the Company recorded a net loss of approximately $15.8 million and used approximately $14.0 million of cash in operating activities. As of December 31, 2015, the Company had approximately $3.7 million in cash and cash equivalents and working capital of approximately $1.9 million. The Company has not yet established an ongoing source of revenue sufficient to cover its operating costs and allow it to continue as a going concern. The ability of the Company to continue as a going concern is dependent on the Company obtaining adequate capital to fund operating losses until it becomes profitable. The Company can give no assurances that any additional capital that it is able to obtain, if any, will be sufficient to meet its needs, or that any such financing will be obtainable on acceptable terms. If the Company is unable to obtain adequate capital, it could be forced to cease operations or substantially curtail is commercial activities. These conditions raise substantial doubt as to the Company's ability to continue as a going concern. The accompanying financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts and classification of liabilities should the Company be unable to continue as a going concern.

During the first quarter of 2015, we sold a total of 2,653,199 shares of common stock to Aspire Capital under the stock purchase agreement dated November 8, 2013 with aggregate gross proceeds to us of $4,292,349. No shares remain available for sale to Aspire under the terms of the November 8, 2013 agreement with them and the agreement was subsequently terminated.

On May 26, 2015, we entered into a new common stock purchase agreement with Aspire Capital Fund, LLC, which provides that, upon the terms and subject to the conditions and limitations set forth therein, Aspire Capital is committed to purchase up to an aggregate of $25.0 million of shares of our common stock over the 30-month term of the purchase agreement. Concurrently with entering into the purchase agreement, we also entered into a registration rights agreement with Aspire Capital, in which we agreed to file one or more registration statements, as permissible and necessary to register under the Securities Act of 1933, registering the sale of the shares of our common stock that have been and may be issued to Aspire Capital under the purchase agreement.

On November 11, 2015, we terminated the May 26, 2015 agreement with Aspire and entered into a new common stock purchase agreement which provides that, upon the terms and subject to the conditions and limitations set forth therein, Aspire Capital is committed to purchase up to an aggregate of $25.0 million of our shares of Common Stock over the approximately 30-month term of the Purchase Agreement. Concurrently with entering into the Purchase Agreement, we also entered into a registration rights agreement with Aspire Capital in which we agreed to register 6,086,207 shares of our common stock.

In June 2015, we sold 1,454,003 shares of common stock at the purchase price of $1.15 per share and pre-funded warrants to purchase 3,610,997 shares of common stock (the "Pre-Funded Warrants") at a purchase price of $1.14 per share for total gross proceeds of $5.8 million (the "2015 Offering"). Each Pre-Funded Warrant is exercisable for $0.01 per share, subject to adjustments from time to time and certain limits on each holder's beneficial ownership of common stock of the Company. As of December 31, 2015, all of the pre-funded warrants have been exercised.

In 2016 through the date of filing this report, we have sold 6,086,207 shares of common stock to Aspire under the November 2015 agreement with them for aggregate gross proceeds to us of $2,153,583. As a result, no shares remain available for sale to Aspire under this agreement.

Our ability to continue as a going concern is dependent on our obtaining additional adequate capital to fund additional operating losses until we become profitable. If we are unable to obtain adequate capital, we could be forced to cease operations.

Cash Flows

As of December 31, 2015, we had cash and cash equivalents of $3,715,895.

Net Cash Flows from Operating Activities: Net cash used in operating activities was approximately $13,953,296, including $2,633,943 from discontinued operations for the year ended December 31, 2015, compared with $10,555,450, including $2,093,588 from discontinued operations for the year ended December 31, 2014. The increase in cash used in operating activities of $3,397,845 resulted primarily from an increase in R&D activities related to our new product developments, additional salaries to support the launch of new products and services, and legal expenses related to the ongoing litigation.

Net Cash Flows from Investing Activities: Net cash used in investing activities was $288,419, including $157,684 from discontinued operations for the year ended December 31, 2015, compared with $343,257, including $338,669 from discontinued operations for the year ended December 31, 2014. The decrease was primarily attributable to the reduction in purchases of fixed asset equipment in 2015 as compared to 2014.

Net Cash Flows from Financing Activities: Net cash provided by financing activities was $9,456,892 for the year ended December 31, 2015, compared with $13,057,264 for the year ended December 31, 2014. The decrease is mainly attributed to lower prices at which we were able to sell our stock and warrants in financing activities in 2015

compared to 2014.

Funding Requirements

We expect to incur ongoing operating losses for the foreseeable future as we continue to develop our planned therapeutic programs including related clinical studies and other programs in the pipeline. We expect that our existing resources will be sufficient to fund our planned operations for at least the next four to six months. In addition to our cash and cash equivalents at December 31, 2015 of approximately $3.7 million, we would be selling securities that are registered on our Form S-3 registration statement and seeking to raise capital through sales of securities to third parties and existing stockholders. If we are unable to raise additional capital when needed, however, we could be forced to curtail or cease operations. Our future capital uses and requirements depend on the time and expenses needed to begin and continue clinical trials for our new drug developments.

Additional funding may not be available to us on acceptable terms or at all. In addition, the terms of any financing may adversely affect the holdings or the rights of our stockholders. For example, if we raise additional funds by issuing equity securities or by selling debt securities, if convertible, further dilution to our existing stockholders would result. To the extent our capital resources are insufficient to meet our future capital requirements, we will need to finance our future cash needs through public or private equity offerings, collaboration agreements, debt financings or licensing arrangements.

If adequate funds are not available, we may be required to terminate, significantly modify or delay our development programs, reduce our planned commercialization efforts, or obtain funds through collaborators that may require us to relinquish rights to our technologies or product candidates that we might otherwise seek to develop or commercialize independently. Further, we may elect to raise additional funds even before we need them if we believe the conditions for raising capital are favorable.

Off-Balance Sheet Arrangements

We do not currently have, nor have we ever had, any relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities, established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. In addition, we do not engage in trading activities involving non-exchange traded contracts.

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (the "FASB") issued Accounting Standards Update ("ASU") No. 2014-09, *Revenue from Contracts with Customers: Topic 606* ("ASU 2014-09"), to supersede nearly all existing revenue recognition guidance under U.S. GAAP. The core principle of ASU 2014-09 is to recognize revenues when promised goods or services are transferred to customers in an amount that reflects the consideration that is expected to be received for those goods or services. ASU 2014-09 defines a five step process to achieve this core principle and, in doing so, it is possible more judgment and estimates may be required within the revenue recognition process than required under existing GAAP including identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation. ASU 2014-09 is effective in the first quarter of 2017 using either of two methods: (i) retrospective to each prior reporting period presented with the option to elect certain practical expedients as defined within ASU 2014-09; or (ii) retrospective with the cumulative effect of initially applying ASU 2014-09 recognized at the date of initial application and providing certain additional disclosures as defined per ASU 2014-09. We are currently evaluating the impact of our pending adoption of ASU 2014-09 on our consolidated financial statements.

In August 2014, FASB issued ASU No. 2014-15, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*. This ASU requires management to determine whether substantial doubt exists regarding the entity's going concern presumption, which generally refers to an entity's ability to meet its obligations as they become due. If substantial doubt exists but is not alleviated by management's plan, the footnotes must specifically state that "there is substantial doubt about the entity's ability to continue as a going concern within one year after the financial statements are issued". In addition, if substantial doubt exists, regardless of whether such doubt was alleviated, entities must disclose (a) principal conditions or events that raise substantial doubt about the entity's ability to continue as a going concern (before consideration of management's plans, if any); (b) management's evaluation of the significance of those conditions or events in relation to the entity's ability to meet its obligations; and (c) management's plans that are intended to mitigate the conditions or events that raise substantial doubt, or that did alleviate substantial doubt, about the entity's ability to continue as a going concern. If substantial doubt has not been alleviated, these disclosures should become more extensive in subsequent reporting periods as additional information becomes available. In the period that substantial doubt no longer exists (before or after considering management's plans), management should disclose how the principal conditions and events that originally gave rise to substantial doubt have been resolved. The ASU applies prospectively to all entities for annual periods ending after December 15, 2016, and to annual and interim periods thereafter. Early adoption is permitted. We have not adopted the provisions of ASU No. 2014-15.

In February 2016, FASB issued ASU No. 2016-02, *Lease Accounting Topic 842*. This ASU requires a lessee to recognize lease assets and liabilities on the balance sheet for all arrangements with terms longer than 12 months. The new standard applies a right-of-use (ROU) model that requires a lessee to record, for all leases with a lease term of more than 12 months, an asset representing its right to use the underlying asset for the lease term and a liability to make lease payments. The lease term is the non-cancellable period of the lease, and includes both periods covered by an option to extend the lease, if the lessee is reasonably certain to exercise that option, and periods covered by an option to terminate the lease, if the lessee is reasonably certain not to exercise that termination option. For leases with a lease term of 12 months or less, a practical expedient is available whereby a lessee may elect, by class of underlying asset, not to recognize an ROU asset or lease liability. A lessee making this accounting policy election would recognize lease expense over the term of the lease, generally in a straight-line pattern. The Lessor accounting remains largely consistent with existing U.S. GAAP. The new standard takes effect in 2019 for public business entities and 2020 for all other entities. We have not adopted the provisions of ASU No. 2016-02. We are currently evaluating the impact of our pending adoption of ASU 2016-02 on our consolidated financial statements.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The financial statements required by this item are set forth beginning on page 75 of this report and are incorporated herein by reference.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures

At the end of the period covered by this report, we carried out an evaluation, under the supervision and with the participation of our management, including our principal executive officer and principal accounting and financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures, as such term is defined under Rule 13a-15(e) promulgated under the Exchange Act. Based on this evaluation, our principal executive officer and our principal accounting and financial officer concluded that our disclosure controls and procedures were effective as of December 31, 2015 to ensure that information to be disclosed by us in this Annual Report on Form 10-K was recorded, processed summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and Form 10-K.

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the

Securities and Exchange Commission's rules and forms and that such information is accumulated and communicated to our management, including our chief executive officer and principal accounting and financial officer, as appropriate, to allow for timely decisions regarding required disclosure. There were no changes in our internal controls over financial reporting during the year ended December 31, 2015 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

We intend to review and evaluate the design and effectiveness of our disclosure controls and procedures on an ongoing basis and to correct any material deficiencies that we may discover. Our goal is to ensure that our management has timely access to material information that could affect our business. While we believe the present design of our disclosure controls and procedures is effective to achieve our goal, future events affecting our business may cause us to modify our disclosure controls and procedures. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f). Under the supervision and with the participation of our management, including our principal executive officer and principal accounting and financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our evaluation under the framework in Internal *Control—Integrated Framework*, our management concluded that our internal control over financial reporting was effective as of December 31, 2015. Because we are a smaller reporting company, BDO USA LLP, our independent registered public accounting firm, is not required to attest to and or issue a report on the effectiveness of our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

DIRECTORS:

The Certificate of Incorporation of the Company provides that the Board is to be divided into three classes as nearly equal in number as reasonably possible, with directors in each class serving three-year terms. The total Board size is currently fixed at six directors. Currently, the Class I directors (whose terms expire at the 2016 annual meeting of stockholders) are Steven C. Quay, M.D., Ph.D., and Gregory L. Weaver. The Class II directors (whose terms expire at the 2017 annual meeting of stockholders) are Stephen J. Galli, M.D., and Richard I. Steinhart. The Class III directors (whose terms expire at the 2018 annual meeting of stockholders) are Shu-Chih Chen, Ph.D., and H. Lawrence Remmel, Esq. Directors elected at an annual meeting will hold office until the next annual meeting of stockholders and until their successors are elected and qualified, unless they resign or their seats become vacant due to death, removal, or other cause in accordance with the Bylaws of the Company.

The following table sets forth the following information for the Company's directors: the year each was first elected a director of the Company; their respective ages as of the date of filing of this report; the positions currently held with the Company; the year their current term will expire and their current class.

Nominee/Director Name and Year First Became a Director	Age	Position(s) with the Company	Year Current Term Expires	Current Director Class
Steven C. Quay, M.D., Ph.D. (2009)	65	Chairman of the Board of Directors, President and Chief Executive Officer	2016	I
Gregory L. Weaver (2013)	59	Director	2016	I
Stephen J. Galli, M.D. (2011)	69	Director	2017	II
Richard I. Steinhart (2014)	58	Director	2017	II

Shu-Chih Chen, Ph.D. (2009)	54	Director	2018	III
H. Lawrence Remmel, Esq. (2012)	64	Director	2018	III

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Steven C. Quay, M.D., Ph.D. Dr. Quay has served as Chief Executive Officer, President and Chairman of the Board of Directors of the Company since the Company was incorporated in April 2009. Prior to his work at the Company, Dr. Quay served as Chairman of the Board, President and Chief Executive Officer of MDRNA, Inc., a biotechnology company focused on the development and commercialization of RNAi-based therapeutic products, from August 2000 to May 2008, and as its Chief Scientific Officer until November 30, 2008 (MDRNA, Inc. was formerly known as Nastech Pharmaceutical Company Inc. and is currently known as Marina Biotech, Inc.). From December 2008 to April 2009, Dr. Quay was involved in acquiring the Company's assets and preparing the Company's business plan. Dr. Quay is certified in Anatomic Pathology with the American Board of Pathology, completed both an internship and residency in anatomic pathology at Massachusetts General Hospital, a Harvard Medical School teaching hospital, is a former faculty member of the Department of Pathology, Stanford University School of Medicine, and is a named inventor on 14 U.S. and foreign patents covering the ForeCYTE Breast Aspirator. Including the patents for the ForeCYTE Breast Aspirator, Dr. Quay is a named inventor on 83 U.S. patents, 125 pending patent applications and is a named inventor on patents covering five pharmaceutical products that have been approved by the U.S. Food and Drug Administration. Dr. Quay received an M.D. in 1977 and a Ph.D. in 1975 from the University of Michigan Medical School. He also received his B.A. degree in biology, chemistry and mathematics from Western Michigan University in 1971. He was selected to serve on the Company's Board of Directors because of his role as a founder of the Company and the inventor of the ForeCYTE Breast Aspirator, as well as his qualifications as a physician and the principal researcher overseeing the clinical and regulatory development of the Company's pharmaceutical programs.

Gregory L. Weaver. Mr. Weaver has served as a director of the Company since October 2013. Mr. Weaver currently serves as Chief Financial Officer of ProMetic Life Science, a publicly traded pharmaceutical company. From January to October 2015 he served as Global Chief Financial Officer of Oryzon Genomics, an epigenetics company. From August 2013 to October 2014, Mr. Weaver served as Chief Financial Officer, Senior Vice President, Treasurer and Corporate Secretary of Fibrocell Science, Inc., an autologous cellular therapeutic company. From June 2011 to July 2013, Mr. Weaver served as Chief Financial Officer and Senior Vice President of Celsion Corp., an oncology drug development company. From February 2009 to August 2010, Mr. Weaver served as Chief Financial Officer and Senior Vice President of Poniard Pharmaceuticals, Inc., a drug development company. From April 2007 to December 2008, Mr. Weaver served as Chief Financial Officer of Talyst, Inc., a healthcare technology services company. Mr. Weaver received his B.S. degree from Trinity University and his M.B.A. degree from Boston College. Mr. Weaver has been selected to serve on the Company's Board of Directors because of his qualifications as a business executive and audit committee financial expert, and his current and prior experience as a Chief Financial Officer, director and committee member of public companies.

Stephen J. Galli, M.D. Dr. Galli has served as a director of the Company since July 2011. Dr. Galli is Chair of the Department of Pathology, Professor of Pathology and of Microbiology & Immunology and the Mary Hewitt Loveless, M.D., Professor, Stanford University School of Medicine, Stanford, California, and has served in these capacities since February 1999. Before joining Stanford, he was on the faculty of Harvard Medical School. He holds 13 U.S. patents and has over 340 publications. He is past president of the American Society for Investigative Pathology and was president of the Collegium Internationale Allergologicum from 2010 – 2014. In addition to receiving awards for his research, he was recently recognized with the 2010 Stanford University President's Award for Excellence through Diversity for his recruitment and support of women and underrepresented minorities at Stanford University. He received his B.A. degree in biology, magna cum laude, from Harvard College in 1968 and his M.D. degree from Harvard Medical School in 1973 and completed a residency in anatomic pathology at the Massachusetts General

Hospital in 1977. Dr. Galli has been selected to serve on the Company's Board of Directors because of his qualifications as a professor and physician, and his specialized expertise as a pathologist.

Richard I. Steinhart. Mr. Steinhart has served as a director of the Company since March 2014. From April 2006 to December 2013, Mr. Steinhart was an executive at MELA Sciences, Inc., most recently serving as its Chief Financial Officer, Senior Vice President, Treasurer and Secretary. From 1992 to 2006, Mr. Steinhart was Managing Director at Forest St. Capital/SAE Ventures. Earlier, he served as Vice President and Chief Financial Officer at Emisphere Technologies from 1991 to 1992 and as General Partner and Chief Financial Officer of CW Group Inc. Mr. Steinhart is a member of the Board of Directors of Actinium Pharmaceuticals where he is Chairman of the Audit Committee and a member of the Compensation Committee. From 2004 to 2012, Mr. Steinhart was a member of the Board of Directors of Manhattan Pharmaceuticals and was Chairman of the Audit Committee. Mr. Steinhart received his B.B.A. and M.B.A. degrees from Pace University. Mr. Steinhart has been selected to serve on the Company's Board of Directors because of his qualifications as a business executive and audit committee financial expert, and his prior experience as a Chief Financial Officer, director and committee member of public companies.

Shu-Chih Chen, Ph.D. Dr. Chen served as Chief Scientific Officer of the Company since the Company was incorporated in April 2009 through August 2014. Dr. Chen has served as a director of the Company since April 2009. Prior to joining the Company, Dr. Chen served as President of Ensisheim beginning in 2008, was founder and President of SC2Q Consulting Company from 2006 to 2008, and served as Head, Cell Biology, Nastech Pharmaceutical Company, Inc. from 2002 to 2006. During 1995 and 1996, she was an Associate Professor at National Yang Ming University, Taipei, Taiwan, and served as the principal investigator of an NIH RO1 grant studying tumor suppression by gap junction protein connexin 43 at the Department of Molecular Medicine at Northwest Hospital before working in the research department at Nastech Pharmaceutical Company. She is named as an inventor on 18 patent applications related to cancer therapeutics. Dr. Chen received her Ph.D. degree in microbiology and public health from Michigan State University in 1992 and has published extensively on Molecular Oncology. She received her B.S. degree in medical technology from National Yang Ming University, Taipei, Taiwan in 1984. Dr. Chen was selected to serve on the Company's Board of Directors because of her role as a founder of the Company and her qualifications in medical technology and as a professor and researcher in the field of cancer therapeutics.

H. Lawrence Remmel, Esq. Mr. Remmel has served as a director of the Company since February 2012. He is currently a partner of the law firm Pryor Cashman LLP, located in New York City, where he chairs the Banking and Finance practice group. Mr. Remmel joined Pryor Cashman in 1988. His practice includes corporate and banking financings, issues relating to the Investment Company Act of 1940, and intellectual property and licensing issues, in particular in the biotechnology and biocosmeceutical areas. Mr. Remmel serves on the Board of Advisors of CytoDel, LLC, an early stage bio-pharmaceutical company developing products for bio-defense, neuronal drug delivery, and musculoskeletal and aesthetic medicine. He was an associate of the law firm Reboul, MacMurray, Hewitt, Maynard & Kristol from 1984 to 1988, and began his legal career at Carter, Ledyard & Milburn, where he was an associate from 1979 to 1984. He was admitted to the New York bar in 1980 and is a member of the New York State Bar Association. He received his J.D. from the Washington & Lee University School of Law in 1979 and his B.A. from Princeton University in 1975. He currently is a doctoral candidate in the Graduate School of Life Sciences of the University of Utrecht, in the Department of Clinical and Translational Oncology. Mr. Remmel has been selected to serve on the Company's Board of Directors because of his substantial experience as a corporate attorney advising biotechnology companies and his familiarity with the fiduciary duties and the regulatory requirements affecting publicly traded companies.

EXECUTIVE OFFICERS AND KEY EMPLOYEES:

The names of our executive officers and their ages as of December 31, 2015 are as follows:

Name	Age	Position
Executive Officers:		
Steven C. Quay, M.D., Ph.D.	65	Chairman of the Board, President and Chief Executive Officer
Kyle Guse, Esq., CPA	52	Chief Financial Officer, General Counsel and Secretary
Scott Youmans	49	Chief Operating Officer

Former Executive Officers :		
John E. Sawyer	61	Senior Vice President, Global Regulatory Affairs and Quality Assurance
Christopher S. Destro	46	Senior Vice President, Sales and Marketing

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Steven C. Quay, M.D., Ph.D. Dr. Quay has served as Chief Executive Officer, President and Chairman of the Board of Directors of the Company since the Company was incorporated in April 2009. Prior to his work at the Company, Dr. Quay served as Chairman of the Board, President and Chief Executive Officer of MDRNA, Inc., a biotechnology company focused on the development and commercialization of RNAi-based therapeutic products, from August 2000 to May 2008, and as its Chief Scientific Officer until November 30, 2008 (MDRNA, Inc. was formerly known as Nastech Pharmaceutical Company Inc. and is currently known as Marina Biotech, Inc.). From December 2008 to April 2009, Dr. Quay was involved in acquiring the Company's assets and preparing the Company's business plan. Dr. Quay is certified in Anatomic Pathology with the American Board of Pathology, completed both an internship and residency in anatomic pathology at Massachusetts General Hospital, a Harvard Medical School teaching hospital, is a former faculty member of the Department of Pathology, Stanford University School of Medicine, and is a named inventor on 14 U.S. and foreign patents covering the ForeCYTE Breast Aspirator. Including the patents for the ForeCYTE Breast Aspirator, Dr. Quay is a named inventor on 83 U.S. patents, 125 pending patent applications and is a named inventor on patents covering five pharmaceutical products that have been approved by the U.S. Food and Drug Administration. Dr. Quay received an M.D. in 1977 and a Ph.D. in 1975 from the University of Michigan Medical School. He also received his B.A. degree in biology, chemistry and mathematics from Western Michigan University in 1971. Dr. Quay is a member of the American Society of Investigative Pathology, the Association of Molecular Pathology, the Society for Laboratory Automation and Screening and the Association of Pathology Informatics. He was selected to serve on the Company's Board of Directors because of his role as a founder of the Company and the inventor of the ForeCYTE Breast Aspirator, as well as his qualifications as a physician and the principal researcher overseeing the clinical and regulatory development of the ForeCYTE Breast Aspirator.

Kyle Guse, Esq., CPA. Mr. Guse has served as Chief Financial Officer, General Counsel and Secretary since January 2013. His experience includes more than 20 years of counseling life sciences and other rapid growth companies through all aspects of finance, corporate governance, securities laws and commercialization. Mr. Guse has practiced law at several of the largest international law firms, including from January 2012 through January 2013 as a partner at Baker Botts LLP and, prior to that, from October 2007 to January 2012, as a partner at McDermott Will & Emery LLP. Before working at McDermott Will & Emery, Mr. Guse previously served as a partner at Heller Ehrman LLP. Mr. Guse began his career as an accountant at Deloitte & Touche and he is a licensed Certified Public Accountant in the State of California. Mr. Guse earned a B.S. in business administration and an M.B.A. from California State University, Sacramento, and a J.D. from Santa Clara University School of Law.

Scott Youmans Mr. Youmans joined Atossa on September 1, 2014 and served as the Senior Vice President of Operations until September 1, 2015, when he was promoted to the Chief Operating Officer. Mr. Youmans resigned on February 12, 2016 to pursue other career opportunities. Prior to joining Atossa, Mr. Youmans was the Director of Engineering at Impel Neuropharma from February to September 2014. He consulted for Bayer Interventional from December 2013 to February 2014. Before that he was VP of Engineering at Pathway Medical Technologies from September 2000 to November 2013 when Pathway was acquired by Bayer Interventional. Mr. Youmans brings 20 years of medical device development and manufacturing experience in both U.S. and international markets. Throughout his 20 year career, he has focused on developing, manufacturing and commercializing complex, innovative medical technologies in a wide variety of clinical applications including: targeted drug delivery, peripheral vascular atherectomy, coronary atherectomy, thrombectomy, biopsy tools, and beating heart support. He brings experience in rapid product iteration, design controls, continuous improvement, supply chain development and management, product life-cycle management, project management, pre-clinical studies, clinical studies and clinical

field support. Prior to joining Atossa Genetics, Mr. Youmans directed the development of the Precision Olfactory Device at Impel Neuropharma from February to September 2014. From 2000 to 2013, Mr. Youmans led the development of Pathway Medical's Jetstream Atherectomy System and held increasingly responsible roles, including VP of Engineering since 2003. Mr. Youmans holds a Bachelor of Science degree in Manufacturing Engineering Technology from Western Washington University.

John E. Sawyer. Mr. Sawyer served the Company as Senior Vice President, Global Regulatory Affairs and Quality Assurance from June 2, 2014 through June 8, 2015. Prior to joining Atossa Genetics, Mr. Sawyer owned his own consulting firm, Realistic Quality Solutions LLC, located in Snohomish, Washington from June 2010 until present. From April 2009 to June 2010, he was the Vice-President of Quality Assurance & Regulatory Affairs for Cardiac Science. He also served as the Vice-President, Quality Assurance & Regulatory Affairs for Welch-Allyn from May 2003 to April 2009. He has served in other leadership positions with Fujifilm Medical Systems and GE OEC Medical Systems. He is also affiliated with the Association of the Advancement of Medical Instrumentation (AAMI) where he teaches various quality management training courses, published articles and participated in various quality management webinars. Mr. Sawyer holds an MBA and a B.S. in business administration from Tampa College in Tampa, Florida. Mr. Sawyer resigned on June 8, 2015 to pursue other career opportunities,

Christopher Destro. Mr. Destro served the Company as Vice President of Sales and Marketing from December 2012 through May 28, 2015. Prior to joining Atossa, Mr. Destro served as Vice President of Sales at Magellan Biosciences from January 2011 to December 2014. Mr. Destro has over 18 years of successful sales and client management expertise within the clinical sector of diagnostic biotechnology. From January 2007 to July 2011, Mr. Destro served in increasingly responsible positions including Director of Sales, North America, for three divisions of Magellan Biosciences, where he managed sales of automated blood culture and susceptibility instrumentation for Trek Diagnostics, automated immunochemistry for Dynex and a blood-lead care platform for point of care testing. In July 2011, Magellan was acquired by Thermo Fisher Scientific, where Mr. Destro became a commercial leader of the Microbiology Division. Prior to joining Magellan, Mr. Destro served as Americas Sales Director for Biotrace International from 2000 to 2006, where he managed sales of core pathogen diagnostic (ELISA) products while leading 17 distributors for the United States, Canada, Mexico and Latin America. Mr. Destro holds a B.S. degree in microbiology from The Ohio State University. Mr. Destro resigned on May 28, 2015 to pursue other career opportunities.

CORPORATE GOVERNANCE

Director Independence

We believe that the Company benefits from having a strong and independent Board. For a director to be considered independent, the Board must determine that the director does not have any direct or indirect material relationship with the Company that would affect his or her exercise of independent judgment. On an annual basis, the Board reviews the independence of all directors under guidelines established by NASDAQ and in light of each director's affiliations with the Company and members of management, as well as significant holdings of Company securities. This review considers all known relevant facts and circumstances in making an independence determination. Based on this review, the Board has made an affirmative determination that all directors, other than Drs. Quay and Chen, are independent. It was determined that Dr. Quay lacks independence because of his status as the Company's President and Chief Executive Officer and that Dr. Chen lacks independence because of her marriage to Dr. Quay.

Corporate Code of Business Conduct and Ethics

We believe that our Board and committees, led by a group of strong and independent directors, provide the necessary leadership, wisdom and experience that the Company needs in making sound business decisions. We have adopted a Code of Business Conduct and Ethics that applies to all of our officers and employees, including our President and Chief Executive Officer, our Chief Financial Officer and other employees who perform financial or accounting functions. The Code of Business Conduct and Ethics sets forth the basic principles that guide the business conduct of our employees. Our Corporate Code of Business Conduct and Ethics helps clarify the operating standards and ethics that we expect of all of our officers, directors and employees in making and implementing those decisions. Waivers of

our Corporate Code of Business Conduct and Ethics may only be granted by the Board or the Audit Committee and will be publicly announced promptly on our website. In furthering our commitment to these principles, we invite you to review our Corporate Code of Business Conduct and Ethics located on our website at *www.atossagenetics.com* .

Stockholder Communications

Generally, stockholders who have questions or concerns regarding the Company should contact our Investor Relations representative at (800) 351-3902. However, any stockholders who wish to address questions regarding the business or affairs of the Company directly with the Board, or any individual director, should direct his or her questions in writing to the Chairman of the Board, Atossa Genetics Inc., 2300 Eastlake Ave. E, Suite 200, Seattle, WA 98102. Upon receipt of any such communications, the correspondence will be directed to the appropriate person, including individual directors.

Audit Committee

Our Board of Directors has appointed an Audit Committee, comprised of Messrs. Steinhart (Chairman), Weaver and Remmel. The Audit Committee selects the Company's independent registered public accounting firm, approves its compensation, oversees and evaluates the performance of the independent registered public accounting firm, oversees the accounting and financial reporting policies and internal control systems of the Company, reviews the Company's interim and annual financial statements, independent registered public accounting firm reports and management letters, and performs other duties, as specified in the Audit Committee Charter, a copy of which is available on the Company's website at *www.atossagenetics.com.* Additionally, the Audit Committee is involved in the oversight of the Company's risk management through its review of policies relating to risk assessment and management. The Audit Committee met four times in fiscal 2015. All members of the Audit Committee satisfy the current independence standards promulgated by NASDAQ and the SEC and the Board has determined that Richard Steinhart qualifies as an "audit committee financial expert," as the SEC has defined that term in Item 407 of Regulation S-K.

Equity Compensation Plan Information

The following table sets forth certain information, as of December 31, 2015, regarding the Company's 2010 Stock Option and Incentive Plan, as well as other stock options and warrants previously issued by the Company as compensation for services.

Plan category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights		Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights	**Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in First Column)** [1]
Equity compensation plans approved by security holders	2,583,944		$ 2.71	1,109,440
Equity compensation plans not approved by security holders	1,030,000	[2]	$ 2.19	—
Total	3,613,944		$ 2.57	1,109,440

(1)

Excludes shares that may be added after December 31, 2015 pursuant to the “evergreen” feature under the 2010 Stock Option and Incentive Plan. For example, on January 1, 2016, 1,306,290 shares were automatically added to the 2010 Stock Option and Incentive Plan under the evergreen feature.

(2) Represents options granted to new employees as inducements for employment which were not required to be approved by security holders. The options are subject to the 2010 Stock Option and Incentive Plan, but were granted outside of such plan. Excludes warrants granted and outstanding in connection with financing agreements.

SECTION 16(A) BENEFICIAL OWNERSHIP REPORTING COMPLIANCE

Section 16(a) of the Exchange Act requires our executive officers and directors, and persons who own more than 10% of a registered class of our equity securities, to file reports of beneficial ownership and changes in beneficial ownership with the SEC. Executive officers, directors and greater-than-10% stockholders are required by SEC regulations to furnish us with copies of all reports filed under Section 16(a). To the Company’s knowledge, based solely on the review of copies of the reports filed with the SEC, all reports required to be filed by our executive officers, directors and greater-than-10% stockholders were timely filed in fiscal 2015, except that a Form 4 that was required to be filed by Dr. Stephen J. Galli was required to be filed on May 14, 2015 but was not filed until May 18, 2015.

ITEM 11. EXECUTIVE COMPENSATION

Remuneration of Officers

Our Compensation Committee is responsible for reviewing and evaluating key executive employee base salaries, setting goals and objectives for executive bonuses and administering benefit plans. The Compensation Committee provides advice and recommendations to our Board of Directors on such matters.

Summary Compensation Table

The following table sets forth the compensation earned by our President and Chief Executive Officer, Chief Financial Officer, Chief Operating Officer, and former Senior Vice President of Global Regulatory Affairs and Quality Assurance, and Senior Vice president of Sales and Marketing (collectively, the " ***Named Executive Officers*** "), for fiscal years 2014 and 2015:

Name and Position	Year	Salary	**Option Award** (1)	Nonequity Incentive Plan Compensation	**All Other Compensation** (4)	Total
Steven C. Quay, M.D., Ph.D. President and Chief Executive Officer	2015	$520,000	$ 437,577	$ 208,000	$ 10,600	$1,176,177
	2014	$500,000	$ 129,138	$ 225,000	$ 10,400	$864,538
Kyle Guse Chief Financial Officer, General Counsel and Secretary	2015	$364,000	$ 302,325	$ 131,040	$ 10,600	$807,965
	2014	$350,000	$ 236,190	$ 149,625	$ 10,400	$746,215
Scott Youmans (5) Chief Operating Officer	2015	$239,200	$ 88,866	$ 80,371	$ 2,870	$411,307
	2014	$67,110	$ 156,643	$ 31,730	$ -	$255,483
John Sawyer Senior Vice President of Regulatory Affairs and Quality Assurance (2)	2015	$149,986	$ 94,302	$ -	$ -	$244,288
	2014	$163,334	$ 119,259	$ 43,288	$ -	$325,881

Christopher Destro						
Senior Vice President of Sales and Marketing [3]	2015	$103,323	$ 86,919	$ -	$ 125,470	$315,712
	2014	$205,000	$ 70,702	$ 46,638	$ 10,400	$332,740

(1) The value of the option awards has been computed in accordance with FASB ASC 718, excluding the effect of estimated forfeitures. Assumptions used in the calculations for these amounts are included in notes to our financial statements included in this report. Additional information about the terms of each option award is below under PART III Item 11 “Executive Compensation – Outstanding Equity Awards at Fiscal Year End.”

(2) Mr. Sawyer was hired as our Senior Vice President of Global Regulatory Affairs and Quality Assurance in June 2014 and resigned in June 2015.

(3) Mr. Destro resigned as our Senior Vice President of Sales and Marketing in May 2015. Based on the separation agreement between the company and Mr. Destro, Mr. Destro received the following in connection with his departure from the company, which is included in “All other compensation”: (i) $10,000, (ii) $87,689 based on sales performance of the NRLBH, and (iii) continuation of salary and partial bonus payment in the amount of $25,000.

(4) Amounts represent 401(k) match paid by the Company on behalf of the Named Executive Officer, except Mr. Destro’s 2015 balance, which includes $122,689 of severance compensation and $2,781 of 401(k) match paid by the Company.

(5) Mr. Youmans resigned as the Chief Operating Officer of the Company on February 12, 2016. Based on the employment separation agreement between the company and Mr. Youmans, Mr. Youmans received $23,920 in severance pay and received one-half of his 2015 bonus of $40,186 in a lump sum payment in February 2016 and the other one-half bonus of $40,186 will be paid in equal monthly payments over six months following his departure.

Outstanding Equity Awards at Fiscal Year-End

The following table shows information regarding our outstanding equity awards at December 31, 2015 for the Named Executive Officers, all of which are subject to the terms and conditions of the 2010 Stock Option and Incentive Plan which is described below:

Name	Grant Date	Number of Securities Underlying Unexercised Options (#) Exercisable		Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price	Option Expiration Date
Steven Quay	3/11/2013	44,194	(1)	—	$ 6.57	3/11/2023
President and Chief Executive	5/6/2014	91,750	(2)	156,250	$ 1.22	5/06/2024
Officer	3/16/2015	51,596	(2)	223,404	$ 1.88	5/16/2025
Kyle Guse[1]	1/4/2013	343,749	(3)	156,251	$ 4.11	1/04/2023
Chief Financial Officer, General	6/4/2013	60,000	(1)	—	$ 4.31	6/04/2023
Counsel and Secretary	1/8/2014	61,250	(2)	78,750	$ 2.20	1/08/2024
	5/6/2014	75,000	(2)	125,000	$ 1.22	5/06/2024
	3/16/2015	35,625	(2)	154,375	1.88	3/16/2025
Scott Youmans,	9/2/2014	62,500	(3)	137,500	$ 1.86	9/02/2024
Chief Operating Officer	3/16/2015	6,798	(2)	29,419	$ 1.88	3/16/2025
	1/01/2016	3,125		46,875	.76	1/01/2026
John Sawyer, Senior Vice President of Regulatory Affairs and Quality Assurance[3]	6/2/2014	—		200,000	$ 1.41	6/02/2024
Christopher Destro,	12/20/2012	100,000	(3)	100,000	$ 4.11	12/20/2022
Senior Vice President of Sales and	1/8/2014	9,375	(2)	40,625	$ 2.20	1/08/2024
Marketing	5/6/2014	5,632	(2)	39,368	$ 1.22	5/06/2024

(1) Option was granted in lieu of a cash bonus payable to the executive. The option was fully vested on the date of grant. See PART III Item 11 “Executive Compensation” above.

(2) Option vests quarterly over four years from the date of grant.

(3)

One quarter of the shares of common stock underlying the option vested on the first anniversary of employment and the remaining 75% vest in equal quarterly installments over the next three years.

Employment Agreements

Employment Agreement with Steven Quay, M.D., Ph.D.

The Company has entered into an employment agreement with Dr. Quay to act as the Company's Chief Executive Officer. The agreement provides for an initial base salary of $250,000, which was subsequently increased to $500,000 for 2014 and $520,000 for 2015, with an annual target bonus of up to 50% of Dr. Quay's then-current base salary, payable upon the achievement of performance goals to be established annually by the Compensation Committee.

The goals for fiscal 2015 included launching the FullCYTE Breast Aspirator, launching the ForeCYTE Breast Aspirator, advancing the pharmaceutical programs, achieving revenues, operating within budget, completing a capital raising transaction, relocating company offices and successfully selling the NRLBH. In February 2016, the Compensation Committee reviewed the performance of Dr. Quay for 2015 against these goals and determined that his bonus for 2015 would be 80% of potential, or $208,000. However, only 25% of this amount was paid to Dr. Quay and the remaining 75% is payable contingent upon completion of an equity financing of the Company. On March 28, 2016, the Compensation Committee concluded that such an equity financing had been completed and that the remaining 2015 bonus is payable.

Under his employment agreement, Dr. Quay received an option to purchase up to 250,000 shares of common stock at an exercise price of $5.00 per share, the fair market value of the common stock on the date of grant, as determined by the Board of Directors. One-quarter of the shares of common stock underlying the option, or 62,500 shares, vested on December 31, 2010, and the remaining 75%, or 187,500 shares, vested in equal quarterly installments over the next three years. The options were fully vested as of December 31, 2013 and subsequently expired unexercised on July 22, 2015.

During the employment term, the Company will make available to Dr. Quay employee benefits provided to other key employees and officers of the Company. To the extent these benefits are based on length of service with the Company, Dr. Quay will receive full credit for prior service with the Company. Participation in health, hospitalization, disability, dental and other insurance plans that the Company may have in effect for other executives, all of which shall be paid for by the Company with contribution by Dr. Quay as set for the other executives, as and if appropriate.

Dr. Quay has also agreed that, for the period commencing on the date of his employment agreement with the Company and during the term of his employment and for a period of 12 months following voluntary termination of his employment with the Company that he will not compete with the Company in the United States. The employment agreement also contains provisions relating to confidential information and assignment of inventions, which require Dr. Quay to refrain from disclosing any proprietary information and to assign to the Company any inventions which directly concern the ForeCYTE Breast Aspirator, or future products, research, or development, or which result from work they perform for the Company or using its facilities.

Employment Agreement with Kyle Guse

The Company has entered into an employment agreement with Mr. Guse to act as the Company's Chief Financial Officer, General Counsel and Secretary. The agreement provides for an initial base salary of $225,000, which has been increased to $350,000 for 2014 and $364,000 for 2015 and an annual target bonus of up to 45% of Mr. Guse's then-current base salary, payable upon the achievement of performance goals to be established annually by the Compensation Committee.

The goals for fiscal 2015 included launching the FullCYTE Breast Aspirator, launching the ForeCYTE Breast Aspirator, advancing the pharmaceutical programs, achieving revenues, operating within budget, completing a capital raising transaction, relocating company offices and successfully selling the NRLBH. In February 2016, the Compensation Committee reviewed the performance of Mr. Guse for 2015 against these goals and determined that his bonus for 2015 would be 80% of potential, or $131,040. However, only 25% of this amount was paid to Mr. Guse and the remaining 75% is payable contingent upon completion of an equity financing of the Company. On March 28, 2016, the Compensation Committee concluded that such an equity financing had been completed and that the remaining 2015 bonus is payable.

Under his employment agreement, on January 4, 2014, Mr. Guse received an option to purchase up to 500,000 shares of common stock at an exercise price of $4.11 per share, the fair market value of the common stock on the date of grant, as determined by the Board of Directors. One-quarter of the shares of common stock underlying the option, or 125,000 shares, vested on January 4, 2014, and the remaining 75%, or 375,000 shares, vest in equal quarterly installments over the next three years, so long as Mr. Guse remains employed with the Company. In lieu of a cash signing and relocation bonus payable to Mr. Guse under the terms of his employment agreement, on June 4, 2013 he

received a fully-vested option to purchase 60,000 shares of common stock exercisable at $4.31 per share, the fair value of the Company's common stock on the date of grant.

During the employment term, the Company will make available to Mr. Guse employee benefits provided to other key employees and officers of the Company. To the extent these benefits are based on length of service with the Company, Mr. Guse will receive full credit for prior service with the Company. Participation in health, hospitalization, disability, dental and other insurance plans that the Company may have in effect for other executives, all of which shall be paid for by the Company with contribution by Mr. Guse as set for the other executives, as and if appropriate.

Mr. Guse has also agreed that, for the period commencing on the date of his employment agreement with the Company and during the term of his employment and for a period of six months following voluntary termination of his employment with the Company that he will not compete with the Company in the United States.

Employment Agreement with Scott Youmans

In connection with the hiring of Mr. Youmans, the Company entered into an offer letter agreement which provides for an initial base salary of $230,000, which was increased to $287,000 on September 1, 2015 when Mr. Youmans was promoted to the Chief Operating Officer with a bonus of up to 25%. Mr. Youmans was also granted an option to purchase 200,000 shares of common stock at $1.86 per share upon joining Atossa and 50,000 at the time of his promotion at market value of $0.76, the fair market value of the common stock on the date of grant, as determined by the Board of Directors. The offer letter agreement provides that Mr. Youmans will be offered employment benefits similar to other members of management and that he is terminable at will. His options will accelerate upon a change of control. Mr. Youmans resigned as the Chief Operating Officer of the Company on February 12, 2016. Based on the employment separation agreement, Mr. Youmans received $23,920 in severance pay and received one-half of his 2015 bonus of $40,186 in a lump sum payment in February 2016 and the other one-half bonus of $40,186 will be paid in equal monthly payments over six months following his departure and an extension to one year of the time by which Mr. Youmans has the right to exercise stock options previously granted to him.

The goals for fiscal 2015 included launching the FullCYTE Breast Aspirator, launching the ForeCYTE Breast Aspirator, advancing the pharmaceutical programs, achieving revenues, operating within budget, completing a capital raising transaction, relocating company offices and successfully selling the NRLBH. In February 2016, the Compensation Committee reviewed the performance of Mr. Youmans for 2015 against these goals and determined that his bonus for 2015 would be 80% of potential, or $80,372.

Employment Agreement with Christopher Destro

In connection with the hiring of Mr. Destro, the Company entered into an offer letter agreement which provides for an initial base salary of $180,000, which was increased to $205,000 in 2014 and $209,100 in 2015 with a bonus of up to 35%. Mr. Destro was also granted an option to purchase 200,000 shares of common stock at $4.10 per share, the fair market value of the common stock on the date of grant, as determined by the Board of Directors. One-quarter of the shares of common stock underlying the option vest one year from commencement of employment and the remaining 75% vest in equal quarterly installments over the next three years, so long as Mr. Destro remains employed with the Company. The offer letter agreement provides that Mr. Destro will be offered employment benefits similar to other members of management and that he is terminable at will. His options will accelerate upon a change of control. Mr. Destro resigned on May 28, 2015. His severance benefits were (i) $10,000, (ii) $30,000 if Atossa's subsidiary, The National Reference Laboratory for Breast Health, Inc. (the "NRLBH") reports at least the number of pharmacogenomics tests required by Atossa's adjusted budget for April 2015, (iii) $30,000 if the NRLBH reports at least the number of pharmacogenomics tests required by Atossa's adjusted budget for May 2015, and (iv) extension by 60 days of the time by which Mr. Destro has the right to exercise stock options previously granted to him; with payments in clauses (ii) and (iii) subject to pro-rata upward adjustment for over achievement. Atossa and Mr. Destro agreed to a mutual release and Mr. Destro agreed not to compete for one year.

Employment Agreement with John Sawyer

In connection with the hiring of Mr. Sawyer, the Company entered into an offer letter agreement which provides for an initial base salary of $280,000, which was increased to $291,200 in 2015 with a bonus of up to 30%. Mr. Sawyer was also granted an option to purchase 200,000 shares of common stock at $1.41 per share exercisable, the fair market value of the common stock on the date of grant, as determined by the Board of Directors. One-quarter of the shares of common stock underlying the option vest one year from commencement of employment and the remaining 75% vest in equal quarterly installments over the next three years, so long as Mr. Sawyer remains employed with the Company. Mr. Sawyer resigned on June 8, 2015.

Severance Benefits and Change in Control Arrangements

The Company has agreed to provide the severance benefits and change in control arrangements described below to its named executive officers.

Dr. Steven Quay

Pursuant to his employment agreement, if (i) the Company terminates the employment of Dr. Quay without cause, or (ii) Dr. Quay terminates his employment for good reason, then Dr. Quay will be entitled to receive all accrued but unpaid compensation, plus a severance payment equal to 12 months of base salary. In addition, upon such event, the vesting of all shares of common stock underlying options then held by Dr. Quay will accelerate, and the options will remain exercisable for the remainder of their terms. The cash severance payment is required to be paid in substantially equal installments over a period of six months beginning on the Company's first payroll date that occurs following the 30th day after the effective date of termination of Dr. Quay's employment, subject to certain conditions. The Company will not be required, however, to pay any severance pay for any period following the termination date if Dr. Quay materially violates certain provisions of his employment agreement and the violation is not cured within 30 days following receipt of written notice from the Company containing a description of the violation and a demand for immediate cure.

In addition, under the terms of his employment agreement, in the event of a "change in control" of the Company (as defined in the employment agreement) during Dr. Quay's employment term, Dr. Quay will be entitled to receive a one-time payment equal to 2.9 times his base salary, and the vesting of all outstanding equity awards then held by Dr. Quay will accelerate such that they are fully vested as of the date of the change in control.

Kyle Guse

Pursuant to his employment agreement, if (i) the Company terminates the employment of Mr. Guse without cause, or (ii) Mr. Guse terminates his employment for good reason, then Mr. Guse will be entitled to receive all accrued but unpaid compensation including pro-rated bonus, plus a severance payment equal to 12 months of base salary. In addition, upon such event, the vesting of 50% of shares of common stock underlying unvested options then held by Mr. Guse will accelerate, and the options will remain exercisable for the remainder of their terms. The cash severance payment is required to be paid in substantially equal installments over a period of six months beginning on the Company's first payroll date that occurs following the 30th day after the effective date of termination of Mr. Guse's employment, subject to certain conditions. The Company will not be required, however, to pay any severance pay for any period following the termination date if Mr. Guse materially violates certain provisions of his employment agreement and the violation is not cured within 30 days following receipt of written notice from the Company containing a description of the violation and a demand for immediate cure.

In addition, under the terms of his employment agreement, in the event of a "change in control termination" of the Company (as defined in the employment agreement) during Mr. Guse's employment term, Mr. Guse will be entitled to receive a one-time payment equal to two times his base salary, and the vesting of all outstanding equity awards then held by Mr. Guse will accelerate such that they are fully vested as of the date of the change in control.

Messrs. Sawyer, Destro and Youmans

The options granted to Messrs. Sawyer and Destro generally accelerate and become exercisable upon a change of control. There are no options granted to Messrs. Sawyer and Destro that are exercisable as of the filing of this report due to the time laps and expiration of their options after their termination. The severance benefits provided to Messrs. Destro and Youmans are summarized above.

2010 Stock Option and Incentive Plan

The Company's 2010 Stock Option and Incentive Plan, or the 2010 Plan, provides for the grant of equity-based awards to employees, officers, non-employee directors and other key persons providing services to the Company. Awards of incentive options may be granted under the 2010 Plan until September 2020. No other awards may be granted under the 2010 Plan after the date that is 10 years from the date of stockholder approval.

Plan Administration. The 2010 Plan may be administered by the full Board or the Compensation Committee. It is the current intention of the Company that the 2010 Plan be administered by the Compensation Committee. The Compensation Committee has full power to select, from among the individuals eligible for awards, the individuals to whom awards will be granted, to make any combination of awards to participants, and to determine the specific terms and conditions of each award, subject to the provisions of the 2010 Plan. The Compensation Committee may delegate to our Chief Executive Officer the authority to grant stock options to employees who are not subject to the reporting and other provisions of Section 16 of the Exchange Act and not subject to Section 162(m) of the Code, subject to certain limitations and guidelines.

Eligibility. Persons eligible to participate in the 2010 Plan will be those full or part-time officers, employees, non-employee directors and other key persons (including consultants and prospective officers) of the Company and its subsidiaries as selected from time to time by the Compensation Committee in its discretion.

Plan Limits. Initially, the total number of shares of common stock available for issuance under the 2010 Plan is 1,000,000 shares (or 2,263,320 shares prior to the reverse stock-split on September 28, 2010). As of January 1, 2012 and each January 1 thereafter, the number of shares of common stock reserved and available for issuance under the 2010 Plan will be cumulatively increased by 4% of the number of shares of common stock issued and outstanding on the immediately preceding December 31. Subject to these overall limitations, the maximum aggregate number of shares of stock that may be issued in the form of incentive stock options or stock appreciation rights to any one individual will not exceed 50% of the initial 2010 Plan limit of 1,000,000, cumulatively increased on January 1, 2012 and each January 1 thereafter by the lesser of (i) the 4% annual increase applicable to the 2010 Plan for such year or (ii) 500,000 shares.

Stock Options. The 2010 Plan permits the granting of (i) options to purchase common stock intended to qualify as incentive stock options under Section 422 of the Code, and (ii) options that do not so qualify. Options granted under the 2010 Plan will be non-qualified options if they fail to qualify as incentive options or exceed the annual limit on incentive stock options. Incentive stock options may only be granted to employees of the Company and its subsidiaries. Non-qualified options may be granted to any persons eligible to receive incentive options and to non-employee directors and key persons. The option exercise price of each option will be determined by the Compensation Committee but may not be less than 100% of the fair market value of the common stock on the date of grant. Fair market value for this purpose will be the last reported sale price of the shares of common stock on the NASDAQ Capital Market on the date of grant. The exercise price of an option may not be reduced after the date of the option grant, other than to appropriately reflect changes in our capital structure.

The term of each option will be fixed by the Compensation Committee and may not exceed 10 years from the date of grant. The Compensation Committee will determine at what time or times each option may be exercised. Options may be made exercisable in installments and the exercisability of options may be accelerated by the Compensation Committee. In general, unless otherwise permitted by the Compensation Committee, no option granted under the 2010 Plan is transferable by the optionee other than by will or by the laws of descent and distribution, and options may be exercised during the optionee's lifetime only by the optionee, or by the optionee's legal representative or guardian in the case of the optionee's incapacity.

Upon exercise of options, the option exercise price must be paid in full either in cash, by certified or bank check or other instrument acceptable to the Compensation Committee or by delivery (or attestation to the ownership) of shares of common stock that are beneficially owned by the optionee for at least six months or were purchased in the open market. Subject to applicable law, the exercise price may also be delivered to the Company by a broker pursuant to irrevocable instructions to the broker from the optionee. In addition, the Compensation Committee may permit non-qualified options to be exercised using a net exercise feature which reduces the number of shares issued to the optionee by the number of shares with a fair market value equal to the exercise price.

To qualify as incentive options, options must meet additional federal tax requirements, including a $100,000 limit on the value of shares subject to incentive options that first become exercisable by a participant in any one calendar year.

Stock Appreciation Rights. The Compensation Committee may award stock appreciation rights subject to such conditions and restrictions as the Compensation Committee may determine. Stock appreciation rights entitle the recipient to shares of common stock equal to the value of the appreciation in the stock price over the exercise price. The exercise price is the fair market value of the common stock on the date of grant. The term of a stock appreciation right will be fixed by the Compensation Committee and may not exceed 10 years.

Restricted Stock. The Compensation Committee may award shares of common stock to participants subject to such conditions and restrictions as the Compensation Committee may determine. These conditions and restrictions may include the achievement of certain performance goals and/or continued employment with us through a specified restricted period.

Restricted Stock Shares. The Compensation Committee may award restricted stock shares to any participants. Restricted stock shares are generally payable in the form of shares of common stock, although restricted stock shares granted to the Chief Executive Officer may be settled in cash. These shares may be subject to such conditions and restrictions as the Compensation Committee may determine. These conditions and restrictions may include the achievement of certain performance goals (as summarized above) and/or continued employment with the Company through a specified vesting period. In the Compensation Committee's sole discretion, it may permit a participant to make an advance election to receive a portion of his or her future cash compensation otherwise due in the form of a restricted stock unit award, subject to the participant's compliance with the procedures established by the Compensation Committee and requirements of Section 409A of the Code. During the deferral period, the deferred stock awards may be credited with dividend equivalent rights.

Adjustments for Stock Dividends, Stock Splits, Etc. The 2010 Plan requires the Compensation Committee to make appropriate adjustments to the number of shares of common stock that are subject to the 2010 Plan, to certain limits in the 2010 Plan, and to any outstanding awards to reflect stock dividends, stock splits, extraordinary cash dividends and similar events.

Tax Withholding. Participants in the 2010 Plan are responsible for the payment of any federal, state or local taxes that the Company is required by law to withhold upon the exercise of options or stock appreciation rights or vesting of other awards. Subject to approval by the Compensation Committee, participants may elect to have the minimum tax withholding obligations satisfied by authorizing the Company to withhold shares of common stock to be issued pursuant to the exercise or vesting.

Amendments and Termination. The Board of Directors of the Company may at any time amend or discontinue the 2010 Plan and the Compensation Committee may at any time amend or cancel any outstanding award for the purpose of satisfying changes in the law or for any other lawful purpose. However, no such action may adversely affect any rights under any outstanding award without the holder's consent. To the extent required under the NASDAQ Capital Market rules, any amendments that materially change the terms of the 2010 Plan will be subject to approval by our stockholders. Without approval by our stockholders, the Compensation Committee may not reduce the exercise price of options or stock appreciation rights or effect repricing through cancellation or re-grants, including any cancellation in exchange for cash. Amendments shall also be subject to approval by our stockholders if and to the extent determined by the Compensation Committee to be required by the Code to preserve the qualified status of incentive options or to ensure that compensation earned under the 2010 Plan qualifies as performance-based compensation under Section 162(m) of the Code.

Other Benefits

The Company offers health, dental, disability, 401(k) matching up to 4% of salary (which became available in 2014) and life insurance to its full-time employees. Employees who elect Company-offered coverage pay a portion of health and dental premiums, while the Company pays all disability and life insurance premiums.

REPORT OF THE AUDIT COMMITTEE

The Audit Committee evaluates auditor performance, manages relations with the Company's independent registered public accounting firm, and evaluates policies and procedures relating to internal control systems. The Audit Committee operates under a written Audit Committee Charter that has been adopted by the Board, a copy of which is available on the Company's website at *www.atossagenetics.com*. All members of the Audit Committee currently meet

the independence and qualification standards for Audit Committee membership set forth in the listing standards provided by NASDAQ and the SEC.

No member of the Audit Committee is a professional accountant or auditor. The members' functions are not intended to duplicate or to certify the activities of management and the independent registered public accounting firm. The Audit Committee serves a board-level oversight role in which it provides advice, counsel and direction to management and the auditors on the basis of the information it receives, discussions with management and the auditors, and the experience of the Audit Committee's members in business, financial and accounting matters. The Audit Committee oversees the Company's financial reporting process on behalf of the Board. The Company's management has the primary responsibility for the financial statements and reporting process, including the Company's system of internal controls. In fulfilling its oversight responsibilities, the Audit Committee reviewed with management the audited financial statements included in the Annual Report on Form 10-K for the fiscal year ended December 31, 2015. This review included a discussion of the quality and the acceptability of the Company's financial reporting, including the nature and extent of disclosures in the financial statements and the accompanying notes. The Audit Committee also reviewed the progress and results of the testing of the design and effectiveness of its internal controls over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act of 2002. The Audit Committee also reviewed with the Company's independent registered public accounting firm, which is responsible for expressing an opinion on the conformity of the audited financial statements with accounting principles generally accepted in the United States of America, their judgments as to the quality and the acceptability of the Company's financial reporting and discussed with the independent auditors matters required to be discussed under Public Company Accounting Oversight Board (PCAOB) Auditing Standard No. 16. *Communication with Audit Committees*. The Audit Committee has received from the independent auditors the written disclosures regarding the auditor's independence required by the PCAOB Rule 3526, *Communications with Audit Committees Concerning Independence*. The Audit Committee discussed with the independent registered public accounting firm their independence from management and the Company, including the matters required by the applicable rules of the Public Company Accounting Oversight Board.

In addition to the matters specified above, the Audit Committee discussed with the Company's independent registered public accounting firm the overall scope, plans and estimated costs of their audit. The Committee met with the independent registered public accounting firm periodically, with and without management present, to discuss the results of the independent registered public accounting firm's examinations, the overall quality of the Company's financial reporting and the independent registered public accounting firm's reviews of the quarterly financial statements, and drafts of the quarterly and annual reports.

In reliance on the reviews and discussions referred to above, the Audit Committee recommended to the Board of Directors that the Company's audited financial statements should be included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2015.

Submitted by the Audit Committee of the Board of Directors

Richard I. Steinhart (Chairman)

Gregory L. Weaver

H. Lawrence Remmel, Esq.

DIRECTOR COMPENSATION

Non-employee director compensation is generally reviewed and set annually at the Board meeting held in connection with the Annual Stockholder Meeting. The non-employee directors of the Company received the following for service on the Board from May 2015 through May 2016:

- upon joining the Board, an initial fee of $50,000 in cash;
- an annual cash payment of $40,000 for each board member; and
- an annual grant of an option for 40,000 shares for each member, vesting quarterly over one year.

In lieu of the above annual option grant, Dr. Chen's outstanding options granted to her during her service as Chief Scientific Officer continue to vest and be exercisable during her services as a member of the Board.

In addition to the above, annual compensation for service on the Audit Committee is $20,000 for the Chair and $15,000 for each member, paid in cash quarterly. Annual compensation for service on the Compensation Committee and Nominating/Governance Committee is $15,000 for the Chair and $10,000 for each member, paid in cash quarterly. The independent board members are also reimbursed on a case by case basis up to a pre-set amount for actual out of pocket expenses for graduate level course work in fields related to the business of the Company.

The employee directors receive no compensation for their board service. Pursuant to the policies of Pryor Cashman, the law firm of which Mr. Remmel is a partner, the compensation Mr. Remmel receives for his services as a director (other than expense reimbursement) is paid to the firm directly, the cash portion of which was waived in 2015. All directors receive reimbursement for reasonable travel expenses. The following table sets forth information regarding compensation earned by our non-employee directors during the fiscal year ended December 31, 2015:

Name	Fees Earned or Paid in Cash	**Option Awards** [1]	Total
Shu-Chih Chen, Ph.D. [2]	$ 38,333	$ —	$38,333
Stephen Galli, M.D.	$ 60,000	$ 43,688	$103,688
H. Lawrence Remmel, Esq. [3]	$ 59,166	$ 43,688	$102,854
Gregory L. Weaver	$ 64,167	$ 43,688	$107,855
Richard Steinhart	$ 65,000	$ 43,688	$108,688

(1) The value of the awards has been computed in accordance with FASB ASC 718, excluding the effect of estimated forfeitures. Assumptions used in the calculations for these amounts are included in notes to our financial statements included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2015.

Option awards consist of 2015 annual option grants, to purchase 40,000 shares of common stock with an exercise price of $1.37, which was the fair value of our common shares at the time of grant. Options vest quarterly over a year.

(2) Dr. Chen retired as the Chief Scientific Officer in August 2014. The options granted to her as an executive officer continue to vest and be exercisable during her service as a member of the Board of Directors. See PART III Item 11 “Executive Compensation.”

(3) The compensation Mr. Remmel receives for his services as a director (other than expense reimbursement) is paid to the Pryor Cashman law firm of which Mr. Remmel is a partner. In 2015, all cash fees outstanding for the last two years were waived and credited back to the Company.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED SHAREHOLDER MATTERS

BENEFICIAL OWNERS AND MANAGEMENT

Based on information available to us and filings with the SEC, the following table sets forth certain information regarding the beneficial ownership (as defined by Rule 13d-3 under the Securities Exchange Act of 1934) of our outstanding common stock for (i) each of our directors, (ii) each of our “named executive officers,” as defined in Executive Compensation below, (iii) all of our directors and executive officers as a group, and (iv) persons known to us to beneficially hold more than 5% of our outstanding common stock. The following information is presented as of March 28, 2016 or such other date as may be reflected below.

Beneficial ownership and percentage ownership are determined in accordance with the rules of the SEC and include voting or investment power with respect to shares of stock. This information does not necessarily indicate beneficial ownership for any other purpose. Under these rules, shares of common stock issuable under stock options or warrants that are exercisable within 60 days of March 28, 2016 are deemed outstanding for the purpose of computing the percentage ownership of the person holding the options or warrant(s), but are not deemed outstanding for the purpose of computing the percentage ownership of any other person.

Unless otherwise indicated below, the address of each person listed on the table is c/o Atossa Genetics Inc., 2300 Eastlake Ave. East, Suite 200, Seattle, Washington 98102.

	Shares Beneficially Owned		
Name of Beneficial Owner	**Number**	**Percent of Class** [1]	
Steven C. Quay, M.D., Ph.D. [2]	5,064,808	13.0	%
Shu-Chih Chen, Ph.D. [3]	4,437,335	11.4	
Kyle Guse, Esq., CPA, Esq. [8]	692,499	1.8	%
Stephen J. Galli, M.D. [5]	198,661	*	
Gregory L. Weaver [4]	122,190	*	
Scott Youmans [9]	90,311	*	
Richard I Steinhart [6]	71,484	*	
H. Lawrence Remmel, Esq. [7]	4,000	*	
Chris Destro	-	*	
John Sawyer	-	*	
All current executive officers and directors as a group (9 persons)	6,332,973	16.0	%

*Less than one percent.

(1) Based on 38,823,464 shares of common stock issued and outstanding as of March 28, 2016.

(2) Consists of (i) 478,543 shares of common stock directly owned by Dr. Quay, (ii) 4,348,315 shares of common stock owned by Ensisheim, and (iii) 237,950 shares of common stock issuable upon the exercise of stock options held by Dr. Quay and exercisable within 60 days after March 28, 2016. Drs. Quay and Chen share voting and investment power over the securities held by Ensisheim. Ensisheim is solely owned and controlled by Drs. Quay and Chen, and, as a result, Drs. Quay and Chen are deemed to be beneficial owners of the shares held by this entity.

(3) Consists of (i) 4,348,315 shares of common stock owned by Ensisheim, and (ii) 89,020 shares of common stock issuable upon the exercise of stock options held by Dr. Chen and exercisable within 60 days after March 28, 2016. Drs. Quay and Chen share voting and investment power over the securities held by Ensisheim. Ensisheim is solely owned and controlled by Drs. Quay and Chen, and, as a result, Drs. Quay and Chen are deemed to be beneficial owners of the shares held by this entity.

(4) Consists of 112,190 shares of common stock issuable upon the exercise of stock options held by Mr. Weaver and exercisable within 60 days of March 28, 2016 and 10,000 shares of Common Stock held by Mr. Weaver.

(5) Consists of (i) 17,674 shares of common stock held by Dr. Galli, and (ii) 180,987 shares of common stock issuable upon the exercise of stock options held by Dr. Galli and exercisable within 60 days of March 28, 2016.

(6) Consists of 71,484 shares of common stock issuable upon the exercise of stock options held by Mr. Steinhart and exercisable within 60 days of March 28, 2016.

(7) Consists of 2,000 shares of Common Stock held by Mr. Remmel and 2,000 shares of Common Stock held by Mr. Remmel’s spouse. Mr. Remmel disclaims beneficial ownership of the 2,000 shares of Common Stock held by his spouse.

(8) Consists of 692,499 shares of common stock issuable upon the exercise of stock options held by Mr. Guse and exercisable within 60 days of March 28, 2016.

(9) Consists of 90,311 shares of common stock issuable upon the exercise of stock options held by Mr. Youmans and exercisable within 60 days of March 28, 2016.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

Transactions with Related Parties

Other than compensation arrangements described the captions “Executive Compensation” and “Director Compensation,” we are not a party to any transactions between us and certain “related parties,” which are generally considered to be our directors and executive officers, nominees for director, holders of 5% or more of our outstanding common stock and members of their immediate families.

Related-Party Transaction Review and Approval

Related party transactions that the Company is required to disclose publicly under the federal securities laws will require prior approval of the Company’s independent directors without the participation of any director who may have a direct or indirect interest in the transaction in question. Related parties include directors, nominees for director, principal stockholders, executive officers and members of their immediate families. For these purposes, a “transaction” will include all financial transactions, arrangements or relationships, ranging from extending credit to the provision of goods and services for value and will include any transaction with a company in which a director, executive officer immediate family member of a director or executive officer, or principal stockholder (that is, any person who beneficially owns five percent or more of any class of the Company’s voting securities) has an interest by virtue of a 10% or greater equity interest. The Company’s policies and procedures regarding related party transactions are not expected to be a part of a formal written policy, but rather, will represent a course of practice determined to be appropriate by the Board of Directors of the Company.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The following is a summary of the fees billed to the Company by BDO for professional services rendered for fiscal years ended December 31, 2015 and 2014. These fees are for work invoiced in the fiscal years indicated.

	2015	**2014**
Audit Fees:		
Consists of fees billed for audit of our annual financial statements and the review of the financial statements included in our quarterly reports on Form 10-Q, and services that are normally provided by BDO in connection with statutory and regulatory filings or engagements for that fiscal year.	$218,796	128,600
Other Fees:		
Audit-Related Fees	-	-
Total All Fees	$218,796	$128,600

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a)

1. Financial Statements

2. Financial Statement Schedules

All financial statement schedules are omitted because they are not required or the required information is included in the financial statements or notes thereto

3. Exhibits

See the Exhibit Index set forth on page 100 of this report.

ATOSSA GENETICS, INC.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Audited Consolidated Financial Statements:

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders

Atossa Genetics Inc.

Seattle, Washington

We have audited the accompanying consolidated balance sheets of Atossa Genetics Inc. (the “Company”) as of December 31, 2015 and 2014, and the related consolidated statements of operations, stockholders’ equity, and cash flows for each of t