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.