ATOSSA GENETICS INC
Form 10-K/A
March 21, 2017

**UNITED STATES**

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K/A

(Amendment no. 1)

**(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, 2016**

**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.)**

**107 Spring Street**

**Seattle, WA 98104**

**(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, $0.015 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, 2016, 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 $9,717,239. 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 $0.015, as of March 20, 2017 was 3,786,913.

EXPLANATORY NOTE

This Amendment No. 1 to the Annual Report on Form 10-K (the “Amended Form 10-K”) of Atossa Genetics Inc. (the “Company”) amends the Company’s Annual Report on Form 10-K for the year ended December 31, 2016, filed with the Securities and Exchange Commission on March 16, 2017 (the “Original Form 10-K”) to correct an inadvertent error in the weighted average shares outstanding in the financial statements for the year ended December 31, 2016. The Company incorrectly stated the weighted average number of shares outstanding – basic and diluted for the year ended December 31, 2016 as 2,277,775 rather than the correct number of 2,947,282. The Company also incorrectly stated the loss per common share from continuing operations - basic and diluted, and loss per common share – basic and diluted, for the year ended December 31, 2016 as $(2.80) rather than the correct amount of $(2.16). As a result, the following items in the original filing have been amended:

Part II, Item 9A. Controls and Procedures;

Part II, Item 15. Financial Statements, Consolidated Statements of Operations; and

Part II, Item 15. Notes to Consolidated Financial Statements, Note 11 – Net Loss Per Share

In accordance with applicable generally accepted accounting principles, the Company has calculated and recognized adjustments accordingly. The following table shows the effect of the restatement on the Company's financial statements for the year ended December 31, 2016:

| | Year Ended December 31, 2016 | |
|---|---|---|
| | As Previously Reported | Restated |
| Weighted average common shares outstanding used to compute net loss per share, basic and diluted | 2,277,775 | 2,947,282 |
| Net loss per share of common stock, basic and diluted: | | |
| Net loss per share from continuing operations | $ (2.80) | $ (2.16) |
| Net loss per share | $ (2.80) | $ (2.16) |

Except as specifically noted above, this Form 10-K/A does not modify or update the Original 10-K or modify or update any related or other disclosures as originally filed, other than as required to reflect the effects of the amendment discussed above. Management has discussed the matters set forth above with the Company's independent registered public accounting firm. On March 20, 2017, the Company's Chief Financial Officer concluded that the financial statements and other financial data for the year ended December 31, 2016, as reported in the Original Form 10-K, should not be relied upon because of the error described above which has been corrected in the Amended Form 10-K. Additionally, investors, analysts and other persons should not rely upon any press releases, investor presentations or other communications that relate to that information.

**ATOSSA GENETICS INC.**
**2016 FORM 10-K REPORT**
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**NOTE REGARDING FORWARD-LOOKING STATEMENTS**

Statements made in this report on Form 10-K/A 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 endoxifen and our intraductal microcatheters to administer therapeutics, including our study using fulvestrant;

- the success, cost and timing of our product and drug development activities and clinical trials, including whether the ongoing clinical study using our intraductal microcatheters to administer fulvestrant will enroll a sufficient number of subjects, if any, or be completed in a timely fashion or at all;

- 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 appeal from dismissal filed against us on November 3, 2014, 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, including our ability to sell up to 467,650 shares of Common Ctock to Aspire Capital Fund LLC ("***Aspire Capital***") under the terms of the May 25, 2016 Common Stock purchase agreement with Aspire Capital (the "***Aspire Purchase Agreement***").

This Annual Report also contains estimates and other statistical data provided by third parties and by us relating to market size and growth and other industry data. These and other forward-looking statements are presented as of the date on which the statements are made. We have included important factors in the cautionary statements included in this Annual Report, particularly in the section titled "ITEM 1A. RISK FACTORS," that we believe could cause actual results or events to differ materially from 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 Annual 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, 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/A, 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 107 Spring Street, Seattle, Washington 98104, and our telephone number is (800) 351-3902.

Our name and logo, Atossa, and Atossa Genetics (stylized) are our registered trademarks. ArgusCYTE is our registered service mark. 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/A 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 2017 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 was initiated at Columbia University Medical Center Breast Cancer Programs and is in the process of being transferred to Montefiore Medical Center.

Our second development program involves the drug endoxifen, which we believe could be a potential treatment for a variety of conditions, including for post-breast cancer therapy, preventative therapy as well as a potential therapy for breast density and other breast health conditions. Endoxifen is an active metabolite of tamoxifen, which is an FDA approved drug used by breast cancer patients to prevent recurrence as well as the occurrence of new breast cancer. Within the endoxifen program, our initial pharmaceutical under development is oral endoxifen for breast cancer patients who are refractory, or non-responsive, to tamoxifen. Certain research indicates that low endoxifen levels in breast cancer patients taking oral tamoxifen may be correlated with a higher risk of recurrence as compared to breast cancer patients with adequate endoxifen levels. We estimate that up to 50% of the one million women eligible to take tamoxifen in the United States each year are refractory, meaning that they have inadequate endoxifen levels (for any number of reasons including low levels of a liver enzyme) and they have an increased risk for breast cancer recurrence.

We expect to complete the manufacturing of an initial supply of proprietary endoxifen and to initiate the endoxifen Phase 1 clinical study in the second quarter of 2017. We plan to commence a Phase 2 clinical study of endoxifen in the second half of 2017. We anticipate completing enrollment in the fulvestrant microcatheter study by August 2017.

We were incorporated in April of 2009 and 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, the site of the majority of early breast cancers. Doing so is intended to provide a therapeutic directly to the breast tissue while at the same time reducing delivery of the drug to healthy tissue. We must obtain FDA approval of any drug delivered via our intraductal microcatheters devices, which will require expensive and time-consuming studies in the current regulatory framework. 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 or obtaining approval from the FDA or other applicable foreign regulatory authority.

Breast cancers and precancerous lesions are typically treated with systemically administered agents such as tamoxifen, Faslodex, Perjeta and Herceptin; however, these drugs can cause serious side effects which may lead to poor patient compliance with the drug regimens. Providing drug directly into the breast ducts targeting the site of the localized cancerous lesions could reduce the need for systemic anti-cancer drugs, and potentially reduce or eliminate the systemic side effects of the drugs and morbidity in such patients, and ultimately improve patient compliance and ultimately reduce mortality.

***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 several pending patent applications directed to the treatment of breast conditions, including cancer, by the intraductal administration of therapeutics including fulvestrant, and one issued patent directed to intraductal treatment of breast conditions following a diagnosis of breast conditions using ductal fluid.

We do not yet have the FDA's input, but based on our preliminary analysis, subject to FDA feedback, we believe 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 potentially 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 fulvestrant microcatheter study, which was initially being conducted by The Columbia University Medical Center Breast Cancer Program. The principal investigator for this study transferred from Columbia to Montefiore Medical Center in January 2017, and as a result we are in the process of transferring the study to Montefiore. We expect to complete enrollment in the study by August 2017.

The study includes women with DCIS or Stage 1 or 2 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. Six study participants will receive the standard intramuscular fulvestrant dose of 500 mg to establish the reference drug distribution, and 24 participants will receive fulvestrant by intraductal instillation utilizing our microcatheter device. The total dose administered via our microcatheters will not exceed 500 mg.

The study was presented at the CTRC-AARC San Antonio Breast Cancer Symposium, which was held December 6-10, 2016. The study was presented in the “Ongoing Clinical Trials” category, which features studies that have not been completed and which does not permit the presentation of study results.

Additional information about the study can be found at: *https://clinicaltrials.gov/ct2/show/NCT02540330?term=atossa&rank=2*.

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***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.

***Endoxifen***

Our second development program involves the drug endoxifen, which is the most active metabolite of tamoxifen, and which we believe could be a potential treatment for a variety of conditions, including for post-breast cancer therapy, preventative therapy, as well as a potential therapy for breast density and other breast health conditions.

Within the endoxifen program, our initial pharmaceutical under development is oral endoxifen for breast cancer patients who are refractory to tamoxifen. Endoxifen is an active metabolite of tamoxifen, which is an FDA approved drug used by breast cancer patients to prevent recurrence as well as the occurrence of new breast cancer. Certain research indicates that low endoxifen levels in breast cancer patients taking oral tamoxifen may be correlated with a higher risk of recurrence as compared to breast cancer patients with adequate endoxifen levels. We believe that up to 50% of the one million women eligible to take tamoxifen in the United States each year are refractory, meaning that they have inadequate endoxifen levels (for any number of reasons including low levels of a liver enzyme) and they have an increased risk for breast cancer recurrence. We are also evaluating endoxifen as a potential preventive therapy for breast cancer, a potential therapy to reduce mammographic density, and other breast health conditions.

We have filed patent applications covering endoxifen and we are in the process of manufacturing an initial supply of our proprietary endoxifen drug for initial Phase 1 studies. We expect to initiate the Phase 1 study in the second quarter of 2017. We plan to conduct the Phase 1 study through a clinical research organization in Australia, pending approval from the associated ethics committee. The anticipated primary endpoint of this placebo-controlled, repeat dose study of 48 healthy female volunteers is to assess the pharmacokinetics of both an oral and topical formulation of endoxifen over 28 days. The secondary endpoint is to assess safety and tolerability.

Subject to successful completion of the Phase 1 study and other regulatory requirements, we plan to initiate a Phase 2 study of endoxifen in the second half of 2017.

**Historical Operations**

***Afimoxifene Topical Gel (AfTG)***

On May 14, 2015, we were granted the worldwide exclusive rights to develop and commercialize AfTG for the potential treatment and prevention of hyperplasia of the breast pursuant to an Intellectual Property License Agreement with Besins Healthcare Luxembourg SARL. The active pharmaceutical ingredient in AfTG is Afimoxifene (4-hydroxytamoxifen), which is an active metabolite of tamoxifen.

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 "***Besins Litigation***"). 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 filed our answer to Besins' counterclaims on March 31, 2016, in which the Company disputed Besins' allegations and denied that Besins is entitled to relief on its counterclaims. On August 4, 2016, we and Besins agreed, pursuant to a Termination Agreement, to terminate the License Agreement, dismiss the Besins Litigation, and settle all claims and counterclaims asserted in the Besins Litigation. We and Besins have further agreed, pursuant to and as set forth in the Termination Agreement, that Besins will assume, and we shall have no further rights to, all clinical, regulatory, manufacturing, and all other development and commercialization of 4-hydroxy tamoxifen and Afimoxifene Topical Gel (the "AfTG Program"). In consideration for our comprehensive relinquishment of all rights granted in the License Agreement, termination of the License Agreement, cessation of all efforts to develop Afimoxifene Topical Gel, delivery of all API manufactured to date, assignment of a Drug Master File, delivery to Besins of the work product we have completed to date, and other consideration, Besins reimbursed us for out-of-pocket expenses incurred by us to pursue the AfTG Program and made a termination payment to us in August 2016 in the total amount of $1,762,931.

***NRLBH and our Laboratory Tests***

The National Reference Laboratory for Breast Health Inc., or the "NRLBH," was our wholly-owned subsidiary until December 16, 2015. Historically, substantially all of our revenue has been generated by the NRLBH from its testing services.

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. To date, we have not received any earn-out payments from the NRLBH and we may not receive any payments in the future. 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 to be realizable.

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 included in discontinued operations for 2015.

**Our Pre-Clinical Programs Under Development**

In addition to our clinical-stage pharmaceutical programs, we are in the process of evaluating additional potential indications of endoxifen and other therapeutic candidates to treat breast conditions, including breast cancer. Factors we are considering in evaluating additional indications and 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.

**Our Medical Devices**

Our medical devices include the ForeCYTE Breast Aspirator and the FullCYTE Breast Aspirator, which collect specimens of nipple aspirate fluid (NAF) for cytological testing at a laboratory, and a universal transport kit to assist with the packaging and transport of NAF samples to a laboratory. We also own the exclusive rights to manufacture and sell various medical devices (although we do not currently maintain an inventory of our devices) consisting primarily of tools to assist breast surgeons, which we acquired from Acueity Healthcare in 2012. We are not currently commercializing our breast aspirator devices, transportation kits, tools for breast surgeons nor any NAF cytology tests.

Our patented intraductal microcatheter devices are being developed for the targeted delivery 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, 2016, we had cash and cash equivalents of $3,027,962. Our capital raising activity in 2015 and 2016 consisted of the following (all amounts have been adjusted to reflect the 1:15 reverse stock split we effectuated on August 26, 2016):

**2015 Financing Activities**

During the first quarter of 2015, we sold a total of 176,879 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, 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 25,000 shares of our Common Stock.

In June 2015, we sold 96,933 shares of Common Stock at the purchase price of $17.25 per share and pre-funded warrants to purchase 240,733 shares of Common Stock (the “Pre-Funded Warrants”) at a purchase price of $17.10 per share for total gross proceeds of $5.8 million (the “2015 Offering”). Each Pre-Funded Warrant was exercisable for $0.15 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 Capital and entered into a new Common Stock purchase agreement which provides that, upon the terms and subject to the conditions and limitations set forth therein, Aspire Capital is committed to purchase up to an aggregate of $25.0 million of our shares of Common Stock over the approximately 30-month term of the purchase agreement. Concurrently with entering into the Purchase Agreement, we also entered into a registration rights agreement with Aspire Capital in which we agreed to register 405,747 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 $1.50, 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 10,000 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 10,000 shares to Aspire Capital and the closing sale price of our stock is equal to or greater than $7.50 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 effect any sales under the purchase agreement on any purchase date where the closing sale price of our Common Stock is less than $1.50 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, or restrictions on future financings, 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 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 Financing Activities**

During the first quarter of 2016, we sold 405,747 shares of Common Stock to Aspire Capital under the November 2015 agreement with them for aggregate gross proceeds of $2,177,083, or net proceeds of $2,133,973 after deducting costs of the offering.

We terminated the November 2015 purchase agreement with Aspire Capital and on May 25, 2016, we entered into a new Common Stock purchase agreement with Aspire Capital which provides that we may sell up to $10 million in Common Stock to Aspire Capital over the 30 month term of the agreement, subject to the terms and conditions set out in the stock purchase agreement, none of which have been sold as of the date of filing this Annual Report. The May 25, 2016 agreement provides that on any trading day on which the closing sale price of our Common Stock exceeds $1.50, 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 10,000 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 $10 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 10,000 shares to Aspire Capital and the closing sale price of our stock is equal to or greater than $3.75 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.

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The purchase agreement provides that we and Aspire Capital shall not effect any sales under the purchase agreement on any purchase date where the closing sale price of our Common Stock is less than $1.50 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, or restrictions on future financings, 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.

In August 2016, we completed an underwritten public offering of 1,150,000 shares of Common Stock at a price per share of $2.50, with gross proceeds to us of $2,875,000, or proceeds of $2,561,896 after deducting underwriter discounts, commissions, non-accountable expense allowances and expense reimbursements.

**Research and Development**

Our pharmaceutical programs are in the research and development phase. Research and development costs are generally expensed as incurred. Our research and development expenses include, for example, manufacturing expenses for our drugs under development, expenses associated with clinical studies and associated salaries and benefits. Research and development expenses for the years ended December 31, 2016 and 2015 were $770,427 and $2,359,593, respectively.

**Intellectual Property**

As of February 15, 2017, and based on a recent periodic review of our patent estate, we own 78 issued patents (33 in the United States and approximately 45 in foreign countries), and 11 pending patent applications (5 in the United States, and 6 international applications) directed to ForeCyte, FullCyte, and Acueity devices, various tests, intraductal treatments, and therapeutics. Excluding certain patents and applications that are no longer being maintained or prosecuted, our patent estate consists primarily of the following:

| Description | U.S. Patents Issued [1] | Expiration | U.S. Pending[1] | Foreign Patents Granted[1] | Expiration | Foreign Pending[1] |
|---|---|---|---|---|---|---|
| Intraductal Treatment Program | 0 | N/A | 3 | 2 | 2017 - 2031 | 1 |
| Therapeutics | 0 | N/A | 3 | 0 | N/A | 2 |
| ForeCyte Breast Aspirator Program | 2 | 2017 - 2031 | 0 | 12 | 2017 - 2031 | 0 |
| FullCyte Microcatheters, FullCyte Breast aspirator and Diagnostics/tests Programs | 29 | 2017 - 2031 | 1 | 31 | 2017 - 2031 | 3 |
| Acueity Tools | 12 | 2017 - 2024 | 0 | 0 | 2017 - 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. The patent counts disclosed herein and in our patent estate are subject to change.

Atossa and Atossa Genetics (stylized) are our registered trademarks.

**Manufacturing, Clinical Studies and Associated Operations**

Our drug development 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. We also plan to rely on third parties to conduct pre-clinical and clinical studies of our drugs under development. As our development pipeline continues to expand, we expect that our manufacturing, pre-clinical and clinical studies, and related operational requirements will correspondingly increase. Each third-party contractor undergoes a formal qualification process by Atossa subject matter experts prior to signing any service agreement and initiating any third-party work.

Integral to our development strategy is our quality program, which includes standard operating procedures and specifications with the goal that our work complies with Good Clinical (GCP), Good Laboratory (GLP) and Good Manufacturing Practices (cGMP), and other applicable global regulations. We expect and confirm that selected service providers meet or exceed our expectations for compliance with these standards in providing services and products that meet our requirements.

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 clinical 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, regulations for the execution of clinical studies, and the 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 ultimately approval of NDAs. NDAs require extensive studies and submission of a large amount of data by the applicant, which is an amalgamation of data obtained under INDs and other supporting available information.

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 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 written and approved 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 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 an 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 a