ATOSSA GENETICS INC
Form 10-K
March 08, 2018

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark one)

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

For the fiscal year ended December 31, 2017

OR

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

For the transition period from: to

Commission File Number 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: **866-893-4927**

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

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

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 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 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

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

Emerging growth company

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

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

As of June 30, 2017, 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 $4,852,826. 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 February 28, 2018 was 31,822,741.

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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," "anticipate" or the ne 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 commence our clinical studies and to sell, market and distribute our therapeutics and devices under development;

our ability to successfully initiate and complete clinical trials of our pharmaceutical candidates under development, including endoxifen (Endoxifen; an active metabolite of Tamoxifen) 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 litigation 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.

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, 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” “Atossa,” the “Company,” “we,” “us,” and “our” refers to Atossa Genetics Inc., a Delaware corporation. 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 866-893-4927.

Our name and logo, Atossa, and Atossa Genetics (stylized) are our registered trademarks. 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 2018 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 developing novel, proprietary therapeutics and delivery methods for the treatment of breast cancer and other breast conditions. We are developing Endoxifen with two routes of delivery: a topical formulation, applied like a lotion, for the treatment of a condition called mammographic breast density (or, MBD); and an oral formulation for breast cancer survivors who do not benefit from taking oral tamoxifen, a current FDA-approved standard of care. We are also developing our patented intraductal microcatheter technology to potentially target the delivery of therapies, including fulvestrant, immunotherapies and Chimeric Antigen Receptor T-cell therapies (CAR-T therapies), directly to the site of breast cancer.

In 2017, we completed a Phase 1 clinical study of our proprietary oral and topical formulations of Endoxifen. All objectives were met: there were no clinically significant safety signals and no clinically significant adverse events, and both the oral and topical Endoxifen were well tolerated. In the topical arm of the study, low but measurable Endoxifen levels were detected in the blood in a dose-dependent fashion. In the oral arm of the study, participants exhibited dose-dependent Endoxifen levels that met or exceeded the published therapeutic level. The median time for patients in the study to reach the steady-state serum levels of Endoxifen while taking daily doses of oral Endoxifen was 7 days. Published literature indicates that it takes approximately 50-200 days for patients to reach steady-state Endoxifen levels when taking daily doses of oral tamoxifen.

We are currently conducting a Phase 2 study at Montefiore Medical Center, Bronx, New York, using our intraductal microcatheter technology to deliver fulvestrant. Our program to use our intraductal microcatheters to deliver CAR-T and other immunotherapies is in the research and development phase.

We plan to open enrollment in two Phase 2 studies of our proprietary Endoxifen in the first half of 2018: a study in Stockholm, Sweden using our topical Endoxifen to treat MBD and a study of our oral Endoxifen in Australia to treat patients who do not benefit from taking tamoxifen. We expect to complete these studies in the second half of 2018.

Our key objectives are to advance our programs through Phase 2 trials and then evaluate further development independently or with partners.

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

Our Programs Under Development

Endoxifen

Oral tamoxifen has been widely used for over 30 years to both treat and prevent breast cancer. Tamoxifen, however, has significant drawbacks: First, it can cause side effects including headaches, nausea and early menopausal symptoms as well as rare but serious side effects such as cataracts, stokes and cancer of the uterus. Second, tamoxifen is a “pro-drug,” meaning that it must be processed by the liver in order to produce therapeutic metabolites. The metabolite in tamoxifen that accounts for most of its therapeutic activity is called Endoxifen. Unfortunately, up to 50% of breast cancer survivors who are taking tamoxifen do not produce therapeutic levels of Endoxifen (meaning they are “refractory”) for a number of reasons including that they, due to their genotype, do not have the requisite liver enzymes. Additionally, it can take from 50-200 days for tamoxifen to reach “steady-state” meaning that the drug may be providing little or no benefit for up to several months after starting treatment. We are developing Endoxifen to address the shortcomings of tamoxifen.

We are developing two different presentations of proprietary Endoxifen for two different potential treatment settings: First, we are developing topical Endoxifen for women with MBD for transdermal or “topical” administration. Legislation that has been recently enacted in approximately 30 states requires that women be notified if they have MBD and those notifications typically state that women with MBD have a higher risk of developing breast cancer, and that mammography may not be as effective in detecting breast cancer because the MBD can “mask” the detection of cancers. We estimate that approximately ten million women in the Unites States have MBD, for which there is no FDA-approved treatment. Although oral tamoxifen is approved to prevent breast cancer in “high-risk” women, it is used by less than 5% of women with an increased risk of developing breast cancer because of the actual or perceived side effects and risks of tamoxifen. We believe our topical Endoxifen may provide an effective treatment for MBD because, unlike an oral medication, it is applied directly to the breast and penetrates the skin; it does not require metabolism by the liver; and it may produce fewer side effects than tamoxifen. Moreover, our topical Endoxifen may improve mammography accuracy and patient care by unmasking cancerous tumors that are otherwise hidden by breast density. In two separate reports of film-screen mammography, mammographic sensitivity decreased from a level of 85.7%–88.8% in patients with almost entirely fatty tissue to 62.2%–68.1% in patients with extremely dense breast tissue.

Second, we are developing oral Endoxifen for breast cancer patients who are refractory to tamoxifen. Approximately one million breast cancer patients take tamoxifen to prevent recurrent and new breast cancer; however, up to 50% of those patients are refractory to tamoxifen. We believe our oral Endoxifen may provide an effective treatment supplement or option for these refractory patients because Endoxifen, unlike tamoxifen, does not require liver metabolism.

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We recently completed a comprehensive Phase 1 study in 48 healthy women in Australia using both the topical and oral forms of our proprietary Endoxifen. The objectives of this double-blinded, placebo-controlled, Phase 1 study were to assess the pharmacokinetics of our proprietary Endoxifen dosage forms as single (oral) and repeat (oral and topical) doses, as well as to assess safety and tolerability. The study was conducted in two parts based on route of administration.

In September 2017, we reported preliminary results for the topical arm of the study and in October 2017 we reported preliminary results for the oral arm of the study. We concluded that all objectives were successfully met in both arms of the study: there were no clinically significant safety signals and no clinically significant adverse events and both the oral and topical Endoxifen were well tolerated. In the topical arm of the study, there were low but measurable Endoxifen levels detected in the blood in a dose-dependent fashion and in the oral arm of the study participants exhibited dose-dependent Endoxifen levels in published reports of the therapeutic range. The median time for patients in the study to reach the steady-state serum levels of Endoxifen while taking daily doses of oral Endoxifen was 7 days. Published literature indicates that it takes approximately 50-200 days for patients to reach steady-state Endoxifen levels when taking daily doses of oral tamoxifen. Finally, the median time for patients in the study to reach the maximum serum level of Endoxifen after taking Atossa's oral Endoxifen ranged from 4 to 8 hours (depending on dose). The 4 mg dose of Endoxifen produced a maximum serum level of Endoxifen in 4 to 8 hours at levels above the generally accepted threshold for a therapeutic effect on estrogen-dependent breast cancer.

In September 2017, we contracted Stockholm South General Hospital in Sweden to conduct a Phase 2 study of our topical Endoxifen. The study will be led by principal investigator Dr. Per Hall, MD, Ph.D., Head of the Department of Medical Epidemiology and Biostatistics at Karolinska Institutet. We have applied for approval from the Institutional Review Board and Swedish regulatory authority (Medical Products Agency) to begin enrollment. The primary endpoint is MBD reduction, as well as safety and tolerability. We are planning to open this study in the first half of 2018 and to complete it in the second half of 2018.

We plan to commence a Phase 2 clinical study in Australia using our oral Endoxifen for patients who are refractory to tamoxifen. We have retained a clinical research organization to manage the study and we plan to open the study in the first half of 2018 and to complete it in the second half of 2018.

Proprietary Intraductal Microcatheter Technology

We believe our patented intraductal microcatheters may be useful in delivering CAR-T, immunotherapies and a number of drugs 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 therapy 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 therapies can cause serious side effects which may lead to poor patient compliance with the treatment regimens. Providing therapies directly into the breast ducts targeting the site of the localized cancerous lesions could reduce the need for systemic anti-cancer therapies, and potentially reduce or eliminate the systemic side effects of the therapies and morbidity in such patients, and ultimately improve patient compliance and ultimately reduce mortality.

TRAP CAR-T

Much of the recent success in the field of chimeric antigen receptor therapy, or CAR-T, has relied on the systemic delivery (for example a needle injection into the blood stream) of the CAR-T which is intended to treat various non-solid tumor cancers, such as blood cancers. One concern with this systemic approach is that it does not target the location of the cancer and it can have adverse affects, including deadly “cytokine storms.” Moreover, CAR-T treatments delivered systemically can be as high as $500,000 per patient.

We are developing a novel method to deliver CAR-T cells into the ducts of the breast for the potential targeted treatment of breast cancer. This approach uses our proprietary intraductal microcatheter technology for the potential transpapillary, or “TRAP,” delivery of either T-cells that have been genetically modified to attack breast cancer cells or various immune-therapies. We believe this method has several potential advantages including the reduction of toxicity by limiting systemic exposure of the T-cells or immunotherapy; improved efficacy by placing the T-cells or immunotherapy in direct contact with the target ductal epithelial cells that are undergoing malignant transformation; and, lymphatic migration of the CAR-T cells or immunotherapy potentially extending their cytotoxic actions into the regional lymph system, which could limit tumor cell dissemination. Moreover, our proprietary approach may be more cost effective if lower doses of therapy can be delivered compared to systemic CAR-T. Our approach is in the R&D stage and is currently not FDA approved. In 2018 we intend to commence studies that will help demonstrate safety and efficacy of this novel approach.

The TRAP delivery of therapeutics in breast cancer clinical trials have demonstrated “that cytotoxic drugs can be safely administered into breast ducts with minimal toxicity” (Zhang B, et al. Chin J Cancer Res. 2014 Oct;26(5):579-87; www.ncbi.nlm.nih.gov/pubmed/25400424). T cells are removed from a patient and modified so that they express receptors specific to the patient's particular breast cancer. The T cells, which can then recognize and kill the cancer cells, are reintroduced into the patient using a microcatheter into the natural ducts of the breast. Chimeric antigen receptors (or, “CARs” and also known as chimeric immunoreceptors, chimeric T cell receptors, artificial T cell receptors or CAR-T) are engineered receptors, which graft an arbitrary specificity onto an immune effector cell (“T cell”). Typically, these receptors are used to graft the specificity of a monoclonal antibody onto a T cell, with transfer of their coding sequence facilitated by retroviral vectors. The receptors are called chimeric because they are composed of parts from different sources.

We have developed a foundational intellectual property position with respect to TRAP CAR-T, and we intend to continue research and development through partnership with leading investigators, institutions, and organizations around the world, bringing our technology and expertise in TRAP delivery together with experts in cancer immunology and T-cell biology.

Delivery of Drugs 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.

We are currently conducting a Phase 2 study using our microcatheter technology to deliver fulvestrant at Montefiore Medical Center. This trial is a Phase 2 study in women with ductal carcinoma in situ ("DCIS") or Stage 1 or 2 breast cancer (invasive ductal carcinoma) scheduled for mastectomy or lumpectomy within 30 to 45 days. This study is assessing the safety, tolerability, cellular activity and distribution of fulvestrant when delivered directly into breast milk ducts of these patients compared to those who receive the same drug by injection. Of the 30 patients required for full enrollment, six will receive the standard intramuscular injection of fulvestrant and 24 will receive fulvestrant with our microcatheter device.

The primary endpoint of the clinical trial is to compare the safety, tolerability and distribution of fulvestrant between the two routes of administration (intramuscular injection or through our microcatheters). The secondary endpoint of the study is to determine if there are changes in the expression of Ki67 (a measure of cellular proliferation that correlates with tumor growth) as well as estrogen and progesterone receptors between a pre-fulvestrant biopsy and post-fulvestrant surgical specimens. 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.

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.

Markets

Potential Market Opportunities

We believe that, based in part on a January 2017 study by Defined Health, a leading market research firm, the potential U.S. market for intraductal administration of fulvestrant or similar drugs in DCIS patients is up to $800

million annually. This estimate includes treatment of DCIS patients prior to surgery as well as patients who would use intraductal treatment as an alternative to surgery. We believe that the potential U.S. market for endoxifen in the treatment and prevention settings is up to $1 billion annually.

The Breast Cancer and Related Markets

The American Cancer Society ("ACS") estimates that in 2017, 250,000 women will be diagnosed with breast cancer in the United States. Every two minutes an American woman is diagnosed with breast cancer and 40,000 die each year. Although about 100 times less common than in women, breast cancer also affects men. The ACS estimates that the lifetime risk of men getting breast cancer is about 1 in 1,000; 2,470 new cases of invasive breast cancer will be diagnosed; and 460 men will die from breast cancer in 2017.

We were incorporated in April of 2009 and our common stock is currently quoted on The NASDAQ Capital Market under the symbol "ATOS."

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.

Our Medical Devices

The use of our patented intraductal microcatheter devices is being developed for the targeted delivery of potential drugs, CAR-T and immunotherapies, as described above.

Our medical devices also 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 and NAF cytology tests.

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. 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, 2017, we had cash and cash equivalents of $7,217,469. Our capital raising activity in 2016 and 2017 consisted of the following (all amounts have been adjusted to reflect the 1:15 reverse stock split we effectuated on August 26, 2016):

2016 Financing Activities

During the first quarter of 2016, we sold 405,747 shares of common stock to Aspire Capital pursuant to an arrangement that we had entered into with them in November 2015 for aggregate gross proceeds of $2.2 million, or net proceeds of $2.1 million 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.

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 $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 $2.9 million, or proceeds of $2.6 million after deducting underwriter discounts, commissions, non-accountable expense allowances and expense reimbursements.

2017 Financing Activities

On April 3, 2017, we closed an underwritten public offering that generated gross proceeds to us of approximately $4.4 million and net proceeds of approximately $3.9 million after deducting underwriting discounts and commissions and other offering expenses paid by the Company.

The offering included 664,000 Class A Units at a public offering price of $0.75 per Class A Unit, which consisted of 664,000 shares of common stock and warrants to purchase 664,000 shares of common stock. The offering also included 3,502 Class B Units at a public offering price of $1,000 per Class B Unit, which consisted of 3,502 shares of Series A convertible preferred stock convertible into a total of 4,669,329 shares of common stock and warrants to purchase 4,669,329 shares of common stock. In addition, the underwriter exercised the over-allotment to purchase an additional 530,000 shares of common stock and warrants to purchase 530,000 shares of common stock, which are included in the gross proceeds of $4.4 million. The warrants had a per share exercise price of $0.9375, were exercisable immediately and were scheduled to expire five years from the date of issuance.

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On October 30, 2017, we closed a public offering which generated gross proceeds to us of approximately $5.5 million and net proceeds of $4.9 million after deducting underwriting discounts, commissions and other offering expenses paid by the company.

The offering included 11,500,000 shares of common stock at a public offering price of $0.44 per share. In addition, the underwriter exercised the over-allotment to purchase an additional 1,000,000 shares of common stock at the offering price of $0.44 per share, which are included in the gross proceeds of $5.5 million.

On December 20, 2017, we entered into a securities purchase agreement, which closed on December 22, 2017, with certain purchasers named therein relating to the offering and sale of 5,300,000 shares of our common stock at a public offering price of $0.27 per share. The offering generated gross proceeds to the Company of approximately $1.4 million and net proceeds of $1.2 million after deducting underwriting discounts, commissions, and other offering expenses paid by the company.

Concurrently with the December 22, 2017 public offering we also commenced a private placement in which we issued and sold Class A and Class B Warrants, exercisable for an aggregate of 10,600,000 shares of common stock, at an exercise price of $0.315 per share. The public offering and the private placement involve the same purchasers. The Class A and Class B Warrants exercise price is fixed at $0.315 per warrant, and will become exercisable commencing six months from issuance. The Class A Warrants will expire eight months from issuance, while the Class B Warrants will expire on the first anniversary of the date of issuance. Other than the different expiration dates, the Class A Warrants and Class B Warrants have identical terms. None of the Class A Warrants, the Class B Warrants nor the shares issuable upon exercise of such Warrants have been registered with the Securities and Exchange Commission, although we plan to register the shares issuable upon exercise of the Warrants prior to the dates on which they become exercisable.

Research and Development

Our pharmaceutical programs and delivery methods using intraductal microcatheter 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, 2017 and 2016 were $2,328,087 and $770,472, respectively.

Intellectual Property

As of February 28, 2018, and based on a recent periodic review of our patent estate, we own 13 issued patents (11 US and 2 international) and 24 pending patent applications (9 in the United States, and 15 international applications) directed to our programs on Endoxifen, Fulvestrant, CAR-T therapeutics and intraductal delivery using devices such as microcatheters. The foregoing patent counts exclude certain patents and applications with short patent terms remaining on them and those covering our ForeCyte, FullCyte and Acueity devices and various tests that are no longer core to our business. 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 and microcatheter technology 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