ATOSSA GENETICS INC
Form 10-K
March 16, 2017

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark one)

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

For the fiscal year ended December 31, 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 16, 2017 was 3,786,913.

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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 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, 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 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.

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 $6,479,193 and $8,846,963, 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 application has been approved by the regulatory authorities in that country. The current approval process varies from country to country, and the time spent in gaining approval varies from that required for FDA approval. In certain countries, the sales price of a product must also be approved. The pricing review period often begins after market approval is granted. Even if a product is approved by a regulatory authority, satisfactory prices may not be approved for such product.

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

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

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

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

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

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

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

Post-Approval Regulation

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

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

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

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

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

Sales and Marketing Regulations

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

Anti-Corruption Legislation

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

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

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

Data Privacy and Protection

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

United States Medical Device Regulation

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

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

All clinical trials must be conducted in accordance with regulations and requirements collectively known as Good Clinical Practice, or GCP. GCPs include the FDA's Investigational Device Exemption, or IDE, regulations, which describe the conduct of clinical trials with medical devices, including the recordkeeping, reporting and monitoring

responsibilities of sponsors and investigators, and labeling of investigation devices. They also prohibit promotion, test marketing, or commercialization of an investigational device, and any representation that such a device is safe or effective for the purposes being investigated. GCPs also include FDA's regulations for institutional review board approval and for protection of human subjects (informed consent), as well as disclosure of financial interests by clinical investigators.

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

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

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

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

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

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

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

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

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

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

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

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

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

We are subject to state and federal laws and implementing regulations relating to the privacy and security of the medical information of the patients it treats. The principal federal legislation is part of HIPAA. Pursuant to HIPAA, the Secretary of the Department of Health and Human Services, or HHS, has issued final regulations designed to improve the efficiency and effectiveness of the healthcare system by facilitating the electronic exchange of information in certain financial and administrative transactions, while protecting the privacy and security of the patient information exchanged. International regulations also provide privacy protection to clinical trial participants of their personal health care information. We take appropriate steps to protect the privacy of our clinical study participants.

Federal and State Fraud and Abuse Laws

The federal healthcare Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting, or receiving remuneration to induce referrals or in return for purchasing, leasing, ordering, or arranging for the purchase, lease, or order of any healthcare item or service reimbursable under a governmental payor program. The definition of "remuneration" has been broadly interpreted to include anything of value, including gifts, discounts, the furnishing of supplies or equipment, credit arrangements, payments of cash, waivers of payments, ownership interests, opportunity to earn income, and providing anything at less than its fair market value. The Anti-Kickback Statute is broad, and it prohibits many arrangements and practices that are lawful in businesses outside of the healthcare industry. Recognizing that the Anti-Kickback Statute is broad and may technically prohibit many innocuous or beneficial arrangements within the healthcare industry, HHS has issued a series of regulatory "safe harbors." These safe harbor regulations set forth certain provisions that, if met, will provide healthcare providers and other parties with an affirmative defense against prosecution under the federal Anti-Kickback Statute. Although full compliance with these provisions ensures against prosecution under the federal Anti-Kickback Statute, the failure of a transaction or arrangement to fit within a specific safe harbor does not necessarily mean that the transaction or arrangement is illegal or that prosecution under the federal Anti-Kickback Statute will be pursued.

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

Regulation of Medical Devices Outside the United States

Before we can market a medical device in the European Union and the European Free Trade Association, we must comply with the Essential Requirements set forth in Annex I to the Directive 93/42/EEC of 14 June 1993 concerning medical devices, commonly known as the Medical Devices Directive. The Essential Requirements relate to the quality, safety and performance of the medical devices. Compliance with the Essential Requirements entitles a manufacturer to affix the Conformité Européenne mark, or CE mark, without which the products cannot be placed on the market in the European Union and the European Free Trade Association countries. To demonstrate compliance with the Essential Requirements and obtain the right to affix the CE mark, medical device manufacturers must undergo a conformity assessment procedure, which varies according to the type of medical device and its classification.

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

Compliance Program

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

Legal Proceedings

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

Employees

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

Insurance

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

ITEM 1A. RISK FACTORS

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

Risks Relating to our Business

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

We were incorporated in Delaware in April 2009. Initially, our operations were focused on establishing our CLIA-certified laboratory, commercializing our ForeCYTE and FullCYTE Breast Aspirators and manufacturing our intraductal microcatheters. In December 2015, we sold our laboratory, ceased generating revenue and refocused our business on the development of novel therapeutics and delivery methods for the treatment of breast cancer and other breast conditions. Because of our limited operating history, particularly in the area of pharmaceutical development, our revenue and income potential cannot be based on prior results and is uncertain. Any evaluation of our business and prospects must be considered in light of these factors and the risks and uncertainties often encountered by companies in the development stage. Some of these risks and uncertainties include our ability to:

- obtain successful results from our clinical studies;
- obtain regulatory approvals in the United States and elsewhere for our pharmaceuticals and intraductal microcatheters we are developing;

- work with contract manufacturers to produce our pharmaceuticals under development and our intraductal microcatheter in clinical and commercial quantities on acceptable terms and in accordance with required standards;

- respond effectively to competition;

- manage growth in operations;

- respond to changes in applicable government regulations and legislation;

- access additional capital when required; and

- attract and retain key personnel.

We may not continue as a going concern.

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

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

For the year ended December 31, 2016, we incurred a net loss of $6,368,885 and we had an accumulated deficit of $57,303,748. As of the date of filing this Annual Report, we expect that our existing resources will be sufficient to fund our planned operations for at least the next two to four months. We have not yet established an ongoing source of revenue sufficient to cover our operating costs and allow us to continue as a going concern. Our ability to continue as a going concern is dependent on obtaining adequate capital to fund operating losses until we become profitable. The revenue we have generated to date consisted of mainly laboratory services; however, we sold our laboratory business on December 16, 2015 and we currently have no other products and services approved for commercialization. Although the laboratory is obligated to pay us a royalty of 6% of revenue starting December 2016, we have not received any payments to date and may not receive any in the future. We may not receive or maintain regulatory clearance for our products and other sources of capital may not be available when we need them or on acceptable terms. If we are unable to raise in a timely fashion the amount of capital we anticipate needing; we would be forced to curtail or cease operations.

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

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

If we raise additional funds by issuing equity securities, our stockholders will experience dilution. Debt financing, if available, would result in increased fixed payment obligations and may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Any debt financing or additional equity, including securities convertible into or exercisable for equity securities, that we raise may contain terms, such as liquidation, conversion and other preferences, that are not favorable to us or our stockholders. If we raise additional funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish valuable rights to our technologies, future revenue streams or product candidates or to grant licenses on terms that may not be favorable to us. Should the financing we require to sustain our working capital needs be unavailable or prohibitively expensive when we require it, our business, operating results, financial condition and prospects could be materially and adversely affected and we may be unable to continue our operations.

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

We expect to spend substantial amounts of capital to:

·develop our pharmaceutical and microcatheter programs under development;

·perform clinical studies for the pharmaceuticals and microcatheters we are developing;

·continue our research and development activities to advance our product pipeline; and

·obtain clinical supplies of the pharmaceuticals and microcatheters we are developing.

We have not identified other sources for additional funding, other than our equity line of credit with Aspire Capital, which we will only be able to utilize when the price per share of our Common Stock is above $1.50, and we cannot be certain that additional funding will be available on acceptable terms, or at all. If we are unable to raise additional capital in sufficient amounts or on acceptable terms, we may have to significantly delay, scale back or discontinue the commercialization of our products or our research and development activities. Furthermore, such lack of funds may inhibit our ability to respond to competitive pressures or unanticipated capital needs, or may force us to reduce operating expenses, which could significantly harm the business and development of operations. Because our independent auditors have emphasized in their report on our financial statements doubt as to our ability to continue as a “going concern,” our ability to raise capital may be severely hampered. Similarly, our ability to borrow any such capital may be more expensive and difficult to obtain until this “going concern” issue is eliminated.

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

We have a limited operating history and have incurred net loss each year. Our net loss for the year ended December 31, 2016 was $6,368,885. We will continue to incur further losses in connection with research and development costs for development of our programs, including ongoing and additional clinical studies.

Our business may be affected by legal proceedings.

We have been in the past, and may become in the future, involved in legal proceedings. For example, on October 10, 2013, a securities class action complaint was filed against us, certain of our directors and officers and the underwriters from our initial public offering. This action was purportedly brought on behalf of a class of persons and entities who purchased our Common Stock between November 8, 2012 and October 4, 2013, inclusive. The complaint alleges that the defendants made false or misleading statements. The Company and other defendants filed motions to dismiss the amended complaint on May 30, 2014. The plaintiffs filed briefs in opposition to these motions on July 11, 2014. The Company replied to the opposition briefs on August 11, 2014. On October 6, 2014, the Court granted defendants' motion dismissing all claims against us and all other defendants. The Court's order provided plaintiffs with a deadline of October 26, 2014 to file a motion for leave to amend their complaint and the plaintiffs did not file such a motion by that date. On October 30, 2014, the Court entered a final order of dismissal. On November 3, 2014, plaintiffs filed a notice of appeal with the Court and have appealed the Court's dismissal order to the U.S. Court of Appeals for the Ninth Circuit. On February 11, 2015, plaintiffs filed their opening appellate brief. Defendants filed their answering brief on April 13, 2015, and plaintiffs filed their reply brief on May 18, 2015. Oral argument for the appeal has been set to begin on May 18, 2017. Although we believe this complaint is without merit and plan to defend it vigorously, the costs associated with defending and resolving the complaint and ultimate outcome cannot be predicted.

On January 28, 2016, we filed a complaint in the United States District Court for the District of Delaware captioned *Atossa Genetics Inc. v. Besins Healthcare Luxembourg SARL,* Case No. 1:16-cv-00045-UNA. The complaint asserts claims for breach of contract, breach of the implied covenant of good faith and fair dealing, and for declaratory relief against Besins. Our Company's claims arise from Besins' breach of an Intellectual Property License Agreement dated May 14, 2015 (the "***License Agreement***"), under which Besins licensed to the Company the worldwide exclusive rights to develop and commercialize Afimoxifene Topical Gel, or AfTG, for the potential treatment and prevention of hyperplasia of the breast. The complaint seeks compensatory damages, a declaration of the parties' rights and obligations under the License Agreement, and injunctive relief. On March 7, 2016 Besins responded to our complaint by denying our claims and asserting counterclaims including breach of contract, fraud and negligent misrepresentation, and seeking relief in the forms of compensatory damages, injunctive relief, and declaratory relief. In August 2016, we resolved and settled this dispute by transferring the Afimoxifene program to Besins for a payment to us of approximately $1.8 million.

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

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

If we raise additional capital by issuing equity securities, including sales of shares of Common Stock to Aspire Capital pursuant to the May 2016 Aspire Purchase Agreement, the value of the then outstanding Common Stock may be reduced. If the additional equity securities are issued at a per share price less than the per share value of the outstanding shares, then all of the outstanding shares would suffer a dilution in value with the issuance of such additional shares. Further, the issuance of debt securities in order to obtain additional funds may impose restrictions on our operations and may impair our working capital as we service any such debt obligations.

The products we may develop may never achieve significant commercial market acceptance.

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

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

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

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

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

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

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

- delay or failure in obtaining necessary U.S. and international regulatory approvals, or the imposition of a partial or full regulatory hold on a clinical trial;
- difficulties in formulating a compound, scaling the manufacturing process, timely attaining process validation for particular drug products, and completing manufacturing to support clinical studies;
- pricing or reimbursement issues or other factors that may make the product uneconomical to commercialize;
- production problems, such as the inability to obtain raw materials or supplies satisfying acceptable standards for the manufacture of our products;
- equipment obsolescence, malfunctions or failures, product quality/contamination problems or changes in regulations requiring manufacturing modifications;
- inefficient cost structure of a compound, finished drug, or device compared to alternative treatments;
- obstacles resulting from proprietary rights held by others, such as patent rights for a particular compound;
- lower than anticipated rates of patient enrollment as a result of factors, such as the number of patients with the relevant conditions, the proximity of patients to clinical testing centers, perceived cost/benefit of participating in the study, eligibility criteria for tests, and competition with other clinical testing programs;
- preclinical or clinical testing requiring significantly more time than expected, resources or expertise than originally expected and inadequate financing, which could cause clinical trials to be delayed or terminated;
- failure of clinical testing to show potential products to be safe and efficacious, and failure to demonstrate desired safety and efficacy characteristics in human clinical trials;
- suspension of a clinical trial at any time by us, an applicable collaboration partner or a regulatory authority on the basis that the participants are being exposed to unacceptable health risks or for other reasons;

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

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

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

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

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

We are subject to rigorous and extensive regulation by the FDA in the U.S. and by comparable agencies in other jurisdictions, including the European Medicines Agency (the "***EMA***") in the E.U.

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

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

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

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

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

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

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

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

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

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

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

· they may fail to achieve market acceptance; or

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

If we fail to commercialize products or if our future products do not achieve significant market acceptance, we will not likely generate significant revenues or become profitable.

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

To the extent our products are developed, commercialized, and successfully introduced to market, they may not be considered cost-effective and third-party or government reimbursement might not be available or sufficient. Globally, governmental and other third-party payors are becoming increasingly aggressive in attempting to contain health care costs by strictly controlling, directly or indirectly, pricing and reimbursement and, in some cases, limiting or denying coverage altogether on the basis of a variety of justifications, and we expect pressures on pricing and reimbursement from both governments and private payors inside and outside the U.S. to continue.

In the U.S., we are subject to substantial pricing, reimbursement, and access pressures from state Medicaid programs, private insurance programs and pharmacy benefit managers, and implementation of U.S. health care reform legislation is increasing these pricing pressures. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (collectively, the "***PPACA***" or the "***Affordable Care Act***"), instituted comprehensive health care reform, and includes provisions that, among other things, reduce and/or limit Medicare reimbursement, require all individuals to have health insurance (with limited exceptions), and impose new and/or increased taxes. The future of the Affordable Care Act and its constituent parts are uncertain at this time.

In almost all markets, pricing and choice of prescription pharmaceuticals are subject to governmental control. Therefore, the price of our products and their reimbursement in Europe and in other countries is and will be determined by national regulatory authorities. Reimbursement decisions from one or more of the European markets may impact reimbursement decisions in other European markets. A variety of factors are considered in making reimbursement decisions, including whether there is sufficient evidence to show that treatment with the product is more effective than current treatments, that the product represents good value for money for the health service it provides, and that treatment with the product works at least as well as currently available treatments.

The continuing efforts of government and insurance companies, health maintenance organizations, and other payors of health care costs to contain or reduce costs of health care may affect our future revenues and profitability or those of

our potential customers, suppliers, and collaborative partners, as well as the availability of capital.

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

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

We may not be able to obtain sufficient quantities of our products if we are unable to secure manufacturers when needed, or if our designated manufacturers do not have the capacity or otherwise fail to manufacture compounds according to our schedule and specifications or fail to comply with cGMP regulations. Furthermore, in order to ultimately obtain and maintain applicable regulatory approvals, any manufacturers we utilize are required to consistently produce the respective products in commercial quantities and of specified quality or execute fill-finish services on a repeated basis and document their ability to do so, which is referred to as process validation. In order to obtain and maintain regulatory approval of a compound, the applicable regulatory authority must consider the result of the applicable process validation to be satisfactory and must otherwise approve of the manufacturing process. Even if our compound manufacturing processes obtain regulatory approval and sufficient supply is available to complete clinical trials necessary for regulatory approval, there are no guarantees we will be able to supply the quantities necessary to effect a commercial launch of the applicable drug, or once launched, to satisfy ongoing demand. Any product shortage could also impair our ability to deliver contractually required supply quantities to applicable collaborators, as well as to complete any additional planned clinical trials.

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

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

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

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

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

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

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

- Failure to obtain on a timely basis, or at all, approval from the applicable institutional review board or ethics committee to open a clinical study
- lower than anticipated patient enrollment for reasons such as existing conditions, eligibility criteria or if patients perceive a lack of benefit to enroll in the study for whatever reason;
- delays in reaching agreements on acceptable terms with prospective CROs; and
- failure of Montefiore Medical Center, CROs, or other third parties to effectively and timely monitor, oversee, and maintain the clinical trials.

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

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

- failure of our microcatheters to inject a sufficient amount of drug into the desired location, which could lead to ineffective treatment; and

· adverse events related to drugs we are developing.

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

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

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

The degree of future protection for our proprietary rights is uncertain, and we cannot ensure that:

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

· we or others were the first to file patent applications for our claimed inventions;

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

- any of our patent applications will result in issued patents;

- any of our patents will be valid or enforceable;

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

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

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

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

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

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

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

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

As is the case with other medical device and pharmaceutical companies, our success is heavily dependent on intellectual property, particularly on obtaining and enforcing patents. Obtaining and enforcing patents in the medical device and pharmaceutical industries involve both technological and legal complexity, and is therefore costly, time-consuming and inherently uncertain. In addition, the United States has recently enacted and is currently implementing wide-ranging patent reform legislation. Further, recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In particular, on March 20, 2012, the U.S. Supreme Court issued the *Prometheus* decision, holding that several claims drawn to measuring drug metabolite levels from patient samples were not patentable subject matter. The full impact of the *Prometheus* decision on diagnostic claims is uncertain. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents once obtained. Depending on decisions by the U.S. Congress, the federal courts, and the

USPTO, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

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

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

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

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

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

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

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

We cannot assure you that our current or future products will not infringe on existing or future patents. We may not be aware of patents that have already issued that a third-party might assert are infringed by one of our current or future products.

Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents of which we are currently unaware with claims to materials, formulations, methods of manufacture, or methods for treatment related to the use or manufacture of our products. Because patent applications can take many

years to issue and may be confidential for eighteen months or more after filing, there may be currently pending third-party patent applications which may later result in issued patents that our products may infringe, or which such third-parties claim are infringed by our products and services.

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

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

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

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

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

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

We use third-party suppliers to produce our intraductal microcatheters, which are currently manufactured in small quantities. If such suppliers are not capable of producing quantities sufficient for ongoing and future clinical studies as well as for commercial sale when we are ready, we may not generate significant revenue or become profitable.

We rely on third-party suppliers for the continued manufacture and supply of the intraductal microcatheters. If our third-party suppliers cannot produce the microcatheter in quantities sufficient for our studies and commercial needs on

acceptable terms when needed, we may be unable to commercialize our microcatheters and generate revenue from their sales as planned. In addition, if at any time after commercialization of our products, we are unable to secure essential equipment or supplies in a timely, reliable and cost-effective manner, we could experience disruptions in our services that could adversely affect anticipated results.

Risks Related to Our Industry

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

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

For example, the FDA may change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions which may prevent or delay approval or clearance of our products under development or impact our ability to modify our currently cleared products on a timely basis. Any change in the laws or regulations that govern the clearance and approval processes relating to our current and future products could make it more difficult and costly to obtain clearance or approval for new products, or to produce, market and distribute existing products. Significant delays in receiving clearance or approval, or the failure to receive clearance or approval for our new products would have an adverse effect on our ability to expand our business.

The statements and actions of the Trump administration could negatively affect our business.

President Trump has stated that he will repeal the Affordable Care Act, as amended, reduce government regulation, and lower the prices of pharmaceuticals. He has also placed temporary bans on immigration from certain countries. These statements and potential actions on these topics could negatively impact our stock price and could make it more difficult to develop our programs. For example, lower pharmaceutical prices could reduce the potential market for our drugs under development and reduced government regulation could encourage competition. The recent temporary bans on immigration from certain countries could make it more difficult for us and our partners to hire qualified personnel.

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

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

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

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

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

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

We are subject to extensive federal and state laws and regulations relating to the submission of claims for payment for services, including those that relate to coverage of services under Medicare, Medicaid, and other governmental healthcare programs, the amounts that may be billed for services, and to whom claims for services may be submitted, such as billing Medicare as the secondary, rather than the primary, payor. The failure to comply with applicable laws and regulations, for example, enrollment in the Medicare Provider Enrollment, Chain and Ownership System, could result in our inability to receive payment for our services or attempts by third-party payors, such as Medicare and Medicaid, to recover payments from us that we have already received. Submission of claims in violation of certain statutory or regulatory requirements can result in penalties, including civil money penalties of up to $10,000 for each item or service billed to Medicare in violation of the legal requirement, and exclusion from participation in Medicare and Medicaid. Government authorities may also assert that violations of laws and regulations related to submission of claims violate the federal False Claims Act or other laws related to fraud and abuse, including submission of claims for services that were not medically necessary. The Company will be generally dependent on independent physicians

to determine when its services are medically necessary for a particular patient. Nevertheless, we could be adversely affected if it were determined that the services we provided were not medically necessary and not reimbursable, particularly if it were asserted that we contributed to the physician's referrals of unnecessary services. It is also possible that the government could attempt to hold us liable under fraud and abuse laws for improper claims submitted by us if it were found that we knowingly participated in the arrangement that resulted in submission of the improper claims.

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

The Affordable Care Act, enacted in March 2010, makes changes that are expected to significantly impact the pharmaceutical and medical device industries.

Other significant measures contained in the PPACA include coordination and promotion of research on comparative clinical effectiveness of different technologies and procedures, initiatives to revise Medicare payment methodologies, such as bundling of payments across the continuum of care by providers and physicians, and initiatives to promote quality indicators in payment methodologies. The PPACA also includes significant new fraud and abuse measures, including required disclosures of financial arrangements with physician customers, lower thresholds for violations, and increasing potential penalties for such violations.

In addition to the PPACA, the effect of which cannot presently be quantified, various healthcare reform proposals have also emerged from federal and state governments. Changes in healthcare policy could adversely affect our business.

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

Risks Related to the Securities Markets and Investment in our Securities

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

Although our shares of Common Stock are listed on The NASDAQ Capital Market, we cannot ensure that we will be able to satisfy the continued listing standards of The NASDAQ Capital Market going forward. If we cannot satisfy the continued listing standards going forward, NASDAQ may commence delisting procedures against us, which could result in our stock being removed from listing on The NASDAQ Capital Market. On September 28, 2015, we received a letter from NASDAQ stating that the Company was not in compliance with NASDAQ Listing Rule 5550(a)(2), because the Company's Common Stock failed to maintain a minimum closing bid price of $1.00 per share for 30 consecutive business days. We regained compliance with the $1.00 minimum bid price requirement in September 2016 after effectuating a reverse stock split.

If our stock price does not satisfy the $1.00 minimum bid price requirement or we otherwise fail to satisfyother continued listing requirements, we may be delisted from NASDAQ, which could adversely affect our stock price, liquidity, and our ability to raise funding.

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

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

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

Our stock price is highly volatile. During the one year prior to March 1, 2017, our stock price has ranged from $1.30 to $7.35. In addition to the factors discussed in this report, the trading price of our Common Stock may fluctuate significantly in response to numerous factors, many of which are beyond our control, including:

- results of clinical studies;
- regulatory and FDA actions, including inspections and warning letters;
- actions of securities analysts who initiate or maintain coverage of us, and changes in financial estimates by any securities analysts who follow our Company, or our failure to meet these estimates or the expectations of investors;
- any ongoing litigation that we are currently involved in or litigation that we may become involved in in the future;
- additional shares of our Common Stock being sold into the market by us or our existing stockholders or the anticipation of such sales; and

· media coverage of our business and financial performance.

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

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

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

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

Our ownership is concentrated among a small number of stockholders, including our founders, directors, officers, and entities related to these persons. Our directors, officers and entities affiliated with them beneficially own approximately 12.3% of our outstanding voting securities. Accordingly, these stockholders, acting together, will have the ability to exert substantial influence over all matters requiring approval by our stockholders, including the election and removal of directors and any proposed merger, consolidation or sale of all or substantially all of our assets. This concentration of ownership could have the effect of delaying, deferring, or preventing a change in control of the Company or impeding a merger or consolidation, takeover or other business combination that could be favorable to you.

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

our Common Stock may be negatively affected.

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

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

We are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of The NASDAQ Capital Market, and other applicable securities rules and regulations. Compliance with these rules and regulations will increase our legal and financial compliance costs, make some activities more difficult, time-consuming, or costly, and increase demand on our systems and resources. As a result, management's attention may be diverted from other business concerns, which could harm our business and operating results.

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

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

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

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

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

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

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, and we intend to adopt certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies" including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We may remain an "emerging growth company" for up to five full fiscal years following our initial public offering. We would cease to be an "emerging growth company," and therefore not be able to rely upon the above

exemptions, if we have more than $1 billion in annual revenue in a fiscal year, we issue more than $1 billion of non-convertible debt over a three-year period, or we have more than $700 million in market value of our Common Stock held by non-affiliates as of any June 30 before the end of the five full fiscal years. Additionally, we cannot predict if investors will find our Common Stock less attractive because we will rely on these exemptions. If some investors find our Common Stock less attractive as a result, there may be a less active trading market for our Common Stock and our stock price may be more volatile.

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

The extent to which we utilize the Aspire Purchase Agreement as a source of funding will depend on a number of factors, including the prevailing market price of our Common Stock, the volume of trading in our Common Stock, and the extent to which we are able to secure funds from other sources. The number of shares that we may sell to Aspire Capital under the Purchase Agreement on any given day and during the term of the Purchase Agreement is limited. Additionally, we and Aspire Capital may not effect any sales of shares of our Common Stock under the Aspire Purchase Agreement during the continuance of an event of default or on any trading day that the closing sale price of our Common Stock is less than $1.50 per share. Even if we are able to access the full $10 million available under the Aspire Purchase Agreement, we will still need additional capital to fully implement our business, operating, and development plans.

We may elect to raise additional funds from time to time through public or private equity offerings, debt financings, corporate collaboration, and licensing arrangements, or other financing alternatives, as well as through sales of Common Stock to Aspire Capital under the purchase agreement. Additional equity or debt financing or corporate collaboration and licensing arrangements may not be available on acceptable terms, if at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we will be prevented from pursuing acquisition, licensing, development and commercialization efforts and our ability to generate revenues and achieve or sustain profitability will be substantially harmed.

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

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 2. PROPERTIES

As of December 31, 2016, we leased a total of approximately 512 square feet of office space in two locations in Seattle, Washington, from Sanders Properties, LLC, and WW 107 Spring Street LLC. The lease with Sanders Properties will expire on March 31, 2017. We believe that our current facilities will be adequate to meet our needs for the next 24 months. This information is incorporated in this report under "PART II, ITEM 7. MANAGEMENT DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS – Commercial Lease Arrangements."

ITEM 3. LEGAL PROCEEDINGS

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

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

motion by that date. On October 30, 2014, the Court entered a final order of dismissal. On November 3, 2014, plaintiffs filed a notice of appeal with the Court and have appealed the Court's dismissal order to the U.S. Court of Appeals for the Ninth Circuit. On February 11, 2015, plaintiffs filed their opening appellate brief. Defendants' filed their answering brief on April 13, 2015, and plaintiffs filed their reply brief on May 18, 2015. A hearing for the appeal has been set to begin on May 18, 2017.

We believe this complaint is without merit and plan to defend against it vigorously; however failure to obtain a favorable resolution of the claims set forth in the complaint could have a material adverse effect on the Company's business, results of operations and financial condition. Currently, the amount of such material adverse effect cannot be reasonably estimated, and no provision or liability has been recorded for these claims as of December 31, 2016. The costs associated with defending and resolving the complaint and ultimate outcome cannot be predicted. These matters are subject to inherent uncertainties and the actual cost, as well as the distraction from the conduct of our business, will depend upon many unknown factors and management's view of these may change in the future.

Please refer to the section titled "ITEM 1A. RISK FACTORS – Historical Operations – Afimoxifene Topical Gel (AfTG)" for discussion of the Besins Litigation, which is no longer pending as of August 4, 2016.

ITEM 4. MINE SAFETY DISCLOSURE

Not applicable.

PART II

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

Market Information

Our Common Stock, par value $0.015 per share, began trading on the NASDAQ Capital Market under the symbol "ATOS" on November 8, 2012. The following table sets forth, for the periods indicated, the intraday high and low prices of our Common Stock as reported by NASDAQ.

	2016		2015	
	High	Low	High	Low
First Quarter	$10.65	$3.15	$39.75	$16.80
Second Quarter	$6.02	$3.75	$27.60	$16.80
Third Quarter	$4.95	$2.00	$18.45	$10.50
Fourth Quarter	$2.60	$1.30	$12.60	$4.20

On March 14, 2017, the closing price of our Common Stock was $1.58. As of March 1, 2017, there were approximately 34 shareholders of record of our Common Stock, one of which is Cede & Co., a nominee for Depository Trust Company, or DTC and approximately 4,637 beneficial holders. All of the shares of Common Stock held by brokerage firms, banks and other financial institutions as nominees for beneficial owners are deposited into participant accounts at DTC, and are therefore considered to be held of record by Cede & Co. as one shareholder.

Certain Unregistered Sales of Securities

In the first quarter of 2016, Ensisheim Partners LLC, which is under sole ownership and control by Steven Quay, CEO, President and Chairman of the Board, and Shu-Chih Chen, Director, purchased a total of 5,333 shares of Common Stock directly from the Company in at-the-market transactions which were approved by the Company's audit committee at purchase prices of $3.30 to $7.95 per share. The issuance of the shares 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.

On May 25, 2016 we entered into the Aspire Purchase Agreement, 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 Purchase Agreement, and pursuant to which we issued 49,736 shares of Common Stock to Aspire as a commitment fee. The issuance of the commitment fee 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.

Dividends

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

Issuer Purchases of Securities

We did not repurchase any of our equity securities during the fourth quarter of the year ended December 31, 2016.

Use of Proceeds

Not applicable.

ITEM 6. SELECTED FINANCIAL DATA

Not applicable.

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

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

Overview

We are a clinical-stage pharmaceutical company focused on the development of novel therapeutics and delivery methods for the treatment of breast cancer and other breast conditions. Our leading program uses our patented intraductal microcatheters which 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 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 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.

Our Common Stock is currently quoted on The NASDAQ Capital Market under the symbol "ATOS."

Revenue Sources

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

Commercial Lease Agreements

Laboratory operations

On March 24, 2014, we entered into a commercial lease agreement with ARE LLC (Alexandria) which extended the term of the existing lab lease with Fred Hutchison Research Center through November 30, 2016. The lease provided for monthly rent payments of $22,736 from December 2014 through November 2015, and $23,258 from December 2015 through November 2016. This lease was terminated in November 2016.

Office space

On March 4, 2011, we entered into a commercial lease agreement with Sanders Properties, LLC for office space located in Seattle, WA. The lease terminates on March 31, 2017 and we do not plan to renew the lease for another term.

On August 8, 2014, we entered into a new commercial lease agreement with the Legacy Group Inc., to lease office space in Seattle, Washington in conjunction with expiration of the current office space lease with Fred Hutchinson Research Center on November 29, 2014. The lease provided for monthly rent payments of $16,695 from December 1, 2014 through June 30, 2015, $17,172 from July 1, 2015 through June 30, 2016 and $17,649 from July 1, 2016 through June 30, 2017. On October 2015, we terminated the lease with the Legacy Group and entered into another commercial lease with the same landlord for similar office space which terminated at the end of 2016. For the year ended December 31, 2016, we incurred $301,666 of rent expense for the lease.

On August 3, 2016, we entered into a one year commercial lease agreement with WW 107 Spring Street LLC to lease office space at 107 Spring Street, Seattle, Washington for $2,465 per month.

Critical Accounting Policies and Estimates

Our management’s discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States, or GAAP. The preparation of these financial statements requires us to make estimates and judgments that

affect the reported amounts of assets, liabilities and expenses. On an ongoing basis, we evaluate these estimates and judgments, including those described below. We base our estimates on our historical experience and on various other assumptions that we believe to be reasonable under the circumstances. These estimates and assumptions form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results and experiences may differ materially from these estimates.

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

Revenue Recognition

The Company is not currently recognizing any revenue and all the revenue earned from testing services were generated by NRLBH. As a result of our sale of 81% of the outstanding stock in the NRLBH on December 16, 2015 all of the revenue generated by the NRLBH is included in discontinued operations for the year ended December 31, 2015.

Fair Value Measurements

The Company records recurring and non-recurring financial assets and liabilities as well as all non-financial assets and liabilities subject to fair value measurement at the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. These fair value principles prioritize valuation inputs across three broad levels. Level 1 inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities. Level 2 inputs are quoted prices for similar assets and liabilities in active markets or inputs that are observable for the asset or liability, either directly or indirectly through market corroboration, for substantially the full term of the financial instrument. Level 3 inputs are unobservable inputs based on the Company's assumptions used to measure assets and liabilities at fair value. An asset or liability's classification within the various levels is determined based on the lowest level input that is significant to the fair value measurement.

Intangible Assets

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

We have evaluated our research and development pipeline, and as a result, have changed our plans to develop and invest further in the Acueity patents and technologies. Because of these changed business plans related to the Acueity assets, we have re-evaluated the assets for potential impairment. We have concluded that these assets are partially impaired and have recorded asset impairment charges of $718,970 for the year ended December 31, 2016 to adjust the carrying value of these intangible assets to their estimated fair values as of December 31, 2016.

We determined the fair values of the Acueity intangibles using an income approach (Level 3 of the fair value hierarchy). For purposes of the income approach, fair value was determined based on the present value of estimated future cash flows that a market participant could be expected to generate from the development of products using the patented technology we acquired in the Acueity transaction, discounted at an appropriate risk-adjusted rate reflecting the weighted average cost of capital for a potential market participant. The discount rate used in valuation for these intangible assets was approximately 18%. The estimated future cash flows, including an estimate of long-term future growth rates, reflect our own assumptions of what market participants would utilize to price the assets pursuant to ASC 820, *Fair Value Measurements*.

Share-Based Payments

We follow the provisions of the Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 718, *Compensation – Stock Compensation* ("ASC 718"), which requires the measurement and recognition of compensation expense for all share-based payment awards made to employees, non-employee directors, and consultants, including employee stock options. Stock compensation expense based on the grant date's fair value was estimated in accordance with the provisions of ASC 718 and is recognized as an expense over the requisite service period.

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

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

Results of Operations

Comparison of Years Ended December 31, 2016 and 2015

Revenue and Cost of Revenue: For the year ended December 31, 2016, we have no source of sustainable revenue. For the year ended December 31, 2015, substantially all of the revenue we recognized consisted of pharmacogenomics testing by the NRLBH. As a result of the sale of the NRLBH, the revenue and cost of revenue is presented as discontinued operations for the year ended 2015. The NRLBH had total net revenue of $5,523,116, which is included in discontinued operations for the year ended December 31, 2015 consisting of mainly pharmacogenomics testing. In March 2015, we began the launch of the FullCYTE Breast Aspirator in the U.S. and the ForeCYTE Breast Aspirator in the E.U., focusing initially on the Netherlands, Germany, Switzerland, and the United Kingdom; however, we generated no revenue from device sales during the year.

Total cost of revenue for the year ended December 31, 2015 was $3,671,545, which consisted of costs relating primarily to pharmacogenomics testing services and which, as noted above is also included as a component of discontinued operations due to the sale of the NRLBH. Gross profit for the year ended December 31, 2015 was $1,853,329, which was entirely attributable to pharmacogenomics testing. Since there was no revenue generated for the year ended December 31, 2016, there was no associated cost of revenue or gross profit.

Operating Expenses: As a result of the sale of NRLBH, operating expenses related to the NRLBH are included in discontinued operations for the year ended December 31, 2015.

Total operating expenses from continuing operations were $7,968,590 for the year ended December 31, 2016, which is a decrease of $4,659,375 or 37%, from the year ended December 31, 2015. Operating expenses from continuing operations for 2016 consisted of general and administrative (G&A) expenses of $6,479,193, R&D expenses of $770,427, and impairment of our Acueity intangible assets of $718,970.

Total operating expenses from continuing operations were $12,627,965 for the year ended December 31, 2015, consisting of G&A expenses of $8,846,963, R&D expenses of $2,359,593, and selling expenses of $1,421,409.

Operating expenses from discontinued operations were $5,051,999, including $399,394 in exit costs.

Selling Expenses: We had no selling expenses for the year ended December 31, 2016, compared to total selling expense from continuing operations for the year ended December 31, 2015 of $1,421,409. Selling expenses from discontinued operations were $1,303,425 for the year ended December 31, 2015.The total decrease in selling expenses from continuing and discontinued operations is due to the sale of the NRLBH in December 2015, which resulted in the discontinuation of our revenue producing activities at the end of 2015.

General and Administrative Expenses: G&A expenses from continuing operations were $6,479,193 for the year ended December 31, 2016, a decrease of $2,363,770, or 27% from the total G&A expenses from continuing operations for the year ended December 31, 2015 of $8,846,963. G&A expenses from discontinued operations were $1,665,840 for the year ended December 31, 2015. G&A expenses consist primarily of personnel and related benefit costs, facilities, professional services, insurance, and public company related expenses. The 2016 decrease in G&A expense from continuing operations and discontinued operations was primarily attributable to the sale of the NRLBH in December 2015, which resulted in a reduction of G&A expenses related to the operations of the NRLBH, and from the shift in our business strategy at the beginning of 2016 away from commercialization of medical devices towards focusing exclusively on development of our pharmaceutical and microcatheter candidates.

Research and Development Expenses: R&D expenses from continuing operations for the year ended December 31, 2016, were $770,427, a decrease of $1,589,166, or 67% from R&D expenses from continuing operations in 2015 of $2,359,593. R&D expenses from discontinued operations were $1,012,392 in 2015. The decrease in R&D expenses is attributed to discontinuing further development of the FullCYTE Microcatheters, FullCYTE Breast Aspirator, NextCYTE test and AfTG late in 2015 and early in 2016. During the first quarter of 2016, we focused all our R&D efforts on the fulvestrant clinical trial that commenced in March 2016 and in the second and third quarter of 2016, we focused our R&D efforts on initiating our oral endoxifen program. We expect our R&D expenses to increase throughout 2017 as we continue the clinical trial of fulvestrant administered via our microcatheters and as we continue the development of endoxifen and potentially other indications and pharmaceuticals.

Impairment of Intangible Assets: During the years ended December 31, 2016 and 2015, we evaluated our Acueity intangible assets for impairment and concluded that the fair value as of December 31, 2016, was below the carrying value of $1,237,970. Therefore, we reduced the carrying value of these assets to their fair value of $519,000, or a $718,970 decrease. No such impairment existed in 2015.

Discontinued operations: We have determined that the disposition of the NRLBH in December 2015 qualifies for reporting as a discontinued operation because the sale represents a strategic shift that has had a major effect on our operations and financial results. Financial results of the NRLBH are therefore included in discontinued operations for 2015. Discontinued operations for the year ended December 31, 2015 include $3,002,136 net loss from the NRLBH operations, $670,943 loss from the sale of the NRLBH, and $399,395 in exit costs related to discontinuing the laboratory business.

The results of the NRLBH are disclosed as discontinued operations in the Company's Consolidated Statements of Operations and Comprehensive Loss for the year ending December 31, 2015:

	2015
Revenue	$5,523,116
Cost of revenue	(3,539,134)
Gross profit	1,983,982
Expenses:	
Selling expenses	(1,303,425)
Research and development expenses	(1,012,392)
General and administrative expenses	(1,665,840)
Loss on disposal	(670,943)
Exit and disposal expenses	(399,399)
Other income	65,881
Net loss from discontinued operations	$(3,002,136)

Income taxes: We have incurred net operating losses from inception; we did not record an income tax benefit for our incurred losses for the years ended December 31, 2016 and 2015 due to uncertainty regarding utilization of our net operating carryforwards and due to our history of losses.

Liquidity and Capital Resources

We have a history of operating losses as we have focused our efforts on raising capital and building our products and services in our pipeline. Our consolidated financial statements are prepared using generally accepted accounting

principles in the United States of America applicable to a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. We have incurred net losses and negative operating cash flows since inception. For the year ended December 31, 2016, we recorded a net loss of approximately $6.4 million and used approximately $5.4 million of cash in operating activities. As of December 31, 2016, we had approximately $3.0 million in cash and cash equivalents and working capital of approximately $2.2 million. 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 our obtaining adequate capital to fund operating losses until we become profitable. We can give no assurances that any additional capital that we can obtain, if any, will be sufficient to meet our needs, or that any such financing will be obtainable on acceptable terms. If we are unable to obtain adequate capital, we could be forced to cease operations or substantially curtail our commercial activities. These conditions raise substantial doubt as to our ability to continue as a going concern. The accompanying financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts and classification of liabilities should we be unable to continue as a going concern.

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. No shares remain available for sale to Aspire under the terms of the November 8, 2013 agreement with them and the agreement was subsequently terminated.

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

On November 11, 2015, we terminated the May 26, 2015 agreement with Aspire and entered into a new Common Stock purchase agreement which provides that, upon the terms and subject to the conditions and limitations set forth therein, Aspire Capital is committed to purchase up to an aggregate of $25.0 million of our shares of Common Stock over the approximately 30-month term of the Purchase Agreement. Concurrently with entering into the Purchase Agreement, we also entered into a registration rights agreement with Aspire Capital in which we agreed to register 405,747 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 at a purchase price of $17.10 per share for total gross proceeds of $5.8 million. As of December 31, 2015, all of the pre-funded warrants have been exercised.

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 to us of $2,177,083, or net proceeds of $2,133,973 after deducting costs of the offering. 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 report with the SEC.

On August 4, 2016, we entered into a settlement agreement with Besins Healthcare pursuant to which Besins paid us a total of approximately $1.8 million. See “Part I, Item 3 Legal Proceedings.”

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 allowance and expense reimbursement.

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

Cash Flows

As of December 31, 2016, we had cash and cash equivalents of $3,027,962.

Net Cash Flows from Operating Activities: Net cash used in operating activities was $5,374,589 for the year ended December 31, 2016, a decrease of $8,578,707, or 61.5%, compared to net cash used in operating activities for the year ended December 31, 2015 of $13,953,296, including $2,633,943 from discontinued operations. The decrease in the 2016 period as compared to 2015 resulted primarily from reductions in compensation, occupancy expenses, and outside consulting; offset by severance payments in 2016.

Net Cash Flows from Investing Activities: Net cash used in investing activities for the year ended December 31, 2016 was $9,213, a decrease of $279,206, or 96.8% compared to net cash used in investing activities for the year ended December 31, 2015 of $288,419, including $157,684 from discontinued operations. The decrease was primarily attributable to the reduction in purchases of fixed asset equipment in 2016 as compared to 2015.

Net Cash Flows from Financing Activities: Net cash provided by financing activities was $4,695,869 for the year ended December 31, 2016, a decrease of $4,761,023, or 50.3%, compared to net cash provided by financing activities of $9,456,892 for the year ended December 31, 2015. The decrease is mainly attributed to lower prices at which we were able to sell our stock and in financing activities in 2016 compared to 2015.

Funding Requirements

We expect to incur ongoing operating losses for the foreseeable future as we continue to develop our planned therapeutic programs including related clinical studies and other programs in the pipeline. We expect that our existing resources will be sufficient to fund our planned operations for at least the next two to four months. In addition to our cash and cash equivalents at December 31, 2016 of approximately $3 million, we may sell securities that are registered on our Form S-3 registration statement (File No. 333-192390), our pending Form S-1 registration statement and by raising capital through sales of securities to third parties and existing stockholders. If we are unable to raise additional capital when needed, however, we could be forced to curtail or cease operations. Our future capital uses and requirements will depend on the time and expenses needed to begin and continue clinical trials for our new drug developments.

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

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

Off-Balance Sheet Arrangements

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

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (the "FASB") issued Accounting Standards Update ("ASU") No. 2014-09, *Revenue from Contracts with Customers: Topic 606* ("ASU 2014-09"), to supersede nearly all existing revenue recognition guidance under U.S. GAAP. The core principle of ASU 2014-09 is to recognize revenues when promised goods or services are transferred to customers in an amount that reflects the consideration that is expected to be received for those goods or services. ASU 2014-09 defines a five step process to achieve this core principle and, in doing so, it is possible more judgment and estimates may be required within the revenue recognition process than required under existing GAAP including identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation. ASU 2014-09 is effective in the first quarter of 2018 using either of two methods: (i) retrospective to each prior reporting period presented with the option to elect certain practical expedients as defined within ASU 2014-09; or (ii) retrospective with the cumulative effect of initially applying ASU 2014-09 recognized at the date of initial application and providing certain additional disclosures as defined per ASU 2014-09. Given that we are not currently generating revenue and most likely will not be generating revenue at the date of adoption, the adoption of this guidance will not materially impact our consolidated financial statements.

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

In April 2016, the FASB issued ASU No. 2016-09, *Stock Compensation Topic 718.* This ASU simplifies the accounting for stock compensation on income tax accounting, award classification, estimating forfeitures, and cash flow presentation. Based on this ASU, an entity should recognize all excess tax benefits and tax deficiencies, including tax benefits of dividends on share-based payment awards, as income tax expense or benefit in the income statement; they do not need to include the effects of windfalls and shortfalls in the annual effective tax rate estimate from continuing operations used for interim reporting purposes. As a result of including income tax effects from windfalls and shortfalls in income tax expense, the calculation of both basic and diluted EPS will be affected. The ASU also provides an accounting policy election for awards with service conditions to either estimate the number of awards that are expected to vest (consistent with existing U.S. GAAP) or account for forfeitures when they occur. The ASU increases the allowable statutory tax withholding threshold to qualify for equity classification from the minimum statutory withholding requirements up to the maximum statutory tax rate in the applicable jurisdiction(s). The ASU clarifies that cash paid to a taxing authority by an employer when directly withholding equivalent shares for tax withholding purposes should be considered similar to a share repurchase, and thus classified as a financing activity. All other employer withholding taxes on compensation transactions and other events that enter into the determination of net income continue to be presented within operating activities. The new standard takes effect in 2017 for public business entities and 2018 for all other entities. We have not adopted the provisions of ASU No. 2016-09. We do not anticipate that the adoption of ASU 2016-09 will have a significant affect on our consolidated financial statements.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

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

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

None.

ITEM 9A. CONTROLS AND PROCEDURES

Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures

At the end of the period covered by this report, we carried out an evaluation, under the supervision and with the participation of our management, including our principal executive officer and principal accounting and financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures, as such term is defined under Rule 13a-15(e) promulgated under the Exchange Act. Based on this evaluation, our principal executive officer and our principal accounting and financial officer concluded that our disclosure controls and procedures were not effective as of December 31, 2016 because of a material weakness in our internal control over financial reporting, described below in Management’s Report on Internal Control Over Financial Reporting.

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms and that such information is accumulated and communicated

to our management, including our chief executive officer and principal accounting and financial officer, as appropriate, to allow for timely decisions regarding required disclosure. Based on that evaluation, other than the material weakness noted below in Management's Report on Internal Control Over Financial Reporting, there were no changes in our internal control over financial reporting during the quarter ended December 31, 2016 that have materially affected, or are reasonably likely to materially affect our internal control over financial reporting.

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

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f). Under the supervision and with the participation of our management, including our principal executive officer and principal accounting and financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in *Internal Control—Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our evaluation under the framework in Internal *Control—Integrated Framework*, our management concluded that our internal control over financial reporting was not effective as of December 31, 2016 due to the material weakness described below. Because we are a smaller reporting company, BDO USA LLP, our independent registered public accounting firm, is not required to attest to and or issue a report on the effectiveness of our internal control over financial reporting.

A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. We have identified a material weakness in that we did not design and maintain effective controls over the preparation of the 2016 impairment analysis of the Acueity patents, primarily because we did not include potential income taxes in the discounted cash flow model we used to estimate the fair value of the Acueity patents at December 31, 2016. This resulted in an initial overstatement of the fair value of the Acueity patents at December 31, 2016 in the amount of $366,000 and an initial understatement of the 2016 impairment charge and net loss by the same amount. We corrected our estimate and the related accounts prior to the issuance of the consolidated financial statements contained in this Annual Report on Form 10-K. Management's remediation plan is to use appropriate valuation methodologies in future analyses that may be required to determine the fair value of these intangible assets and to seek the assistance of outside valuation resources, if necessary, in performing such analyses.

ITEM 9B. OTHER INFORMATION

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

DIRECTORS

The Certificate of Incorporation of the Company provides that the Board is to be divided into three classes as nearly equal in number as reasonably possible, with directors in each class serving three-year terms. The total Board size is currently fixed at six directors. Currently, the Class I directors (whose terms expire at the 2019 annual meeting of stockholders) are Steven C. Quay, M.D., Ph.D., and Gregory L. Weaver. The Class II directors (whose terms expire at the 2017 annual meeting of stockholders) are Stephen J. Galli, M.D., and Richard I. Steinhart. The Class III directors (whose terms expire at the 2018 annual meeting of stockholders) are Shu-Chih Chen, Ph.D., and H. Lawrence Remmel, Esq. Directors elected at an annual meeting will hold office until the next annual meeting of stockholders and until their successors are elected and qualified, unless they resign or their seats become vacant due to death, removal, or other cause in accordance with the Bylaws of the Company.

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

Nominee/Director Name and Year First Became a Director	Age	Position(s) with the Company	Year Current Term Expires	Current Director Class
Steven C. Quay, M.D., Ph.D. (2009)	66	Chairman of the Board of Directors, President and Chief Executive Officer	2019	I
Gregory L. Weaver (2013)	60	Director	2019	I
Stephen J. Galli, M.D. (2011)	70	Director	2017	II
Richard I. Steinhart (2014)	59	Director	2017	II

Shu-Chih Chen, Ph.D. (2009)	55	Director	2018	III
H. Lawrence Remmel, Esq. (2012)	65	Director	2018	III

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Steven C. Quay, M.D., Ph.D. Dr. Quay has served as Chief Executive Officer, President and Chairman of the Board of Directors of the Company since the Company was incorporated in April 2009. Prior to his work at the Company, Dr. Quay served as Chairman of the Board, President and Chief Executive Officer of MDRNA, Inc., a biotechnology company focused on the development and commercialization of RNAi-based therapeutic products, from August 2000 to May 2008, and as its Chief Scientific Officer until November 30, 2008 (MDRNA, Inc. was formerly known as Nastech Pharmaceutical Company Inc. and is currently known as Marina Biotech, Inc.). From December 2008 to April 2009, Dr. Quay was involved in acquiring the Company's assets and preparing the Company's business plan. Dr. Quay is certified in Anatomic Pathology with the American Board of Pathology, completed both an internship and residency in anatomic pathology at Massachusetts General Hospital, a Harvard Medical School teaching hospital, is a former faculty member of the Department of Pathology, Stanford University School of Medicine, and is a named inventor on 14 U.S. and foreign patents covering the ForeCYTE Breast Aspirator. Including the patents for the ForeCYTE Breast Aspirator, Dr. Quay is a named inventor on 86 U.S. patents, 129 pending patent applications and is a named inventor on patents covering five pharmaceutical products that have been approved by the U.S. Food and Drug Administration. Dr. Quay received an M.D. in 1977 and a Ph.D. in 1975 from the University of Michigan Medical School. He also received his B.A. degree in biology, chemistry and mathematics from Western Michigan University in 1971. He was selected to serve on the Company's Board of Directors because of his role as a founder of the Company and the inventor of the ForeCYTE Breast Aspirator, as well as his qualifications as a physician and the principal researcher overseeing the clinical and regulatory development of the Company's pharmaceutical programs.

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

Stephen J. Galli, M.D. Dr. Galli has served as a director of the Company since July 2011. Dr. Galli is a Professor of Pathology and of Microbiology & Immunology and the Mary Hewitt Loveless, M.D., Professor, Stanford University School of Medicine, Stanford, California since February 1999. He served as Chair of the Department of Pathology at Stanford University School of Medicine from 1999 to 2016. Before joining Stanford, he was on the faculty of Harvard Medical School. He holds 14 U.S. patents and has over 400 publications. He is past president of the American Society for Investigative Pathology and past president of the Collegium Internationale Allergologicum. In addition to receiving awards for his research, he was recognized with the 2010 Stanford University President's Award for Excellence through Diversity for his recruitment and support of women and underrepresented minorities at Stanford University. He received his B.A. degree in biology, magna cum laude, from Harvard College in 1968 and his M.D. degree from Harvard Medical School in 1973 and completed a residency in anatomic pathology at the Massachusetts

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

Richard I. Steinhart. Mr. Steinhart has served as a director of the Company since March 2014. Mr. Steinhart is currently the Vice President and CFO of Remedy Pharmaceuticals, Inc. a privately held pharmaceuticals company a position he assumed in October 2015. From January 2014 until he joined Remedy Pharmaceuticals, Mr. Steinhart acted as an independent financial consultant to the Biotechnology and Medical Device Industries. From April 2006 to December 2013, Mr. Steinhart was an executive at MELA Sciences, Inc., most recently serving as its Senior Vice President, Chief Financial Officer, Treasurer and Secretary. From 1992 to 2006, Mr. Steinhart was Managing Director at Forest St. Capital/SAE Ventures. Earlier, he served as Vice President and Chief Financial Officer at Emisphere Technologies from 1991 to 1992 and as General Partner and Chief Financial Officer of CW Group Inc. Mr. Steinhart is a Member of the Board of Directors of Actinium Pharmaceuticals where he is Chairman of the Audit Committee and a member of the Compensation Committee. From 2004 to 2012, Mr. Steinhart was a Member of the Board of Directors of Manhattan Pharmaceuticals and was Chairman of the Audit Committee. Mr. Steinhart received his B.B.A. and M.B.A. degrees from Pace University. Mr. Steinhart has been selected to serve on the Company's Board of Directors because of his qualifications as a business executive and audit committee financial expert, and his prior experience as a Chief Financial Officer, director and committee member of public companies.

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

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

EXECUTIVE OFFICERS AND KEY EMPLOYEES:

The names of our executive officers and their ages as of December 31, 2016 are as follows:

Name	Age	Position
Executive Officers:		
Steven C. Quay, M.D., Ph.D.	66	Chairman of the Board, President and Chief Executive Officer
Kyle Guse, Esq., CPA	53	Chief Financial Officer, General Counsel and Secretary

Former Executive Officers:

Scott Youmans	50	Chief Operating Officer

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Steven C. Quay, M.D., Ph.D. Dr. Quay has served as Chief Executive Officer, President and Chairman of the Board of Directors of the Company since the Company was incorporated in April 2009. Prior to his work at the Company, Dr. Quay served as Chairman of the Board, President and Chief Executive Officer of MDRNA, Inc., a biotechnology company focused on the development and commercialization of RNAi-based therapeutic products, from August 2000 to May 2008, and as its Chief Scientific Officer until November 30, 2008 (MDRNA, Inc. was formerly known as Nastech Pharmaceutical Company Inc. and is currently known as Marina Biotech, Inc.). From December 2008 to April 2009, Dr. Quay was involved in acquiring the Company's assets and preparing the Company's business plan. Dr. Quay is certified in Anatomic Pathology with the American Board of Pathology, completed both an internship and residency in anatomic pathology at Massachusetts General Hospital, a Harvard Medical School teaching hospital, is a former faculty member of the Department of Pathology, Stanford University School of Medicine, and is a named inventor on 14 U.S. and foreign patents covering the ForeCYTE Breast Aspirator. Including the patents for the ForeCYTE Breast Aspirator, Dr. Quay is a named inventor on 86 U.S. patents, 129 pending patent applications and is a named inventor on patents covering five pharmaceutical products that have been approved by the U.S. Food and Drug Administration. Dr. Quay received an M.D. in 1977 and a Ph.D. in 1975 from the University of Michigan Medical School. He also received his B.A. degree in biology, chemistry and mathematics from Western Michigan University in 1971. Dr. Quay is a member of the American Society of Investigative Pathology, the Association of Molecular Pathology, the Society for Laboratory Automation and Screening and the Association of Pathology Informatics. He was selected to serve on the Company's Board of Directors because of his role as a founder of the Company and the inventor of the ForeCYTE Breast Aspirator, as well as his qualifications as a physician and the principal researcher overseeing the clinical and regulatory development of the Company's pharmaceutical programs.

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

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

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

CORPORATE GOVERNANCE

Director Independence

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

Corporate Code of Business Conduct and Ethics

We believe that our Board and committees, led by a group of strong and independent directors, provide the necessary leadership, wisdom and experience that the Company needs in making sound business decisions. We have adopted a Code of Business Conduct and Ethics that applies to all of our officers and employees, including our President and Chief Executive Officer, our Chief Financial Officer and other employees who perform financial or accounting functions. The Code of Business Conduct and Ethics sets forth the basic principles that guide the business conduct of our employees. Our Corporate Code of Business Conduct and Ethics helps clarify the operating standards and ethics that we expect of all of our officers, directors and employees in making and implementing those decisions. Waivers of our Corporate Code of Business Conduct and Ethics may only be granted by the Board or the Audit Committee and will be publicly announced promptly on our website. In furthering our commitment to these principles, we invite you to review our Corporate Code of Business Conduct and Ethics located on our website at *www.atossagenetics.com*.

Stockholder Communications

Generally, stockholders who have questions or concerns regarding the Company should contact our Investor Relations representative at (800) 351-3902. However, any stockholders who wish to address questions regarding the business or affairs of the Company directly with the Board, or any individual director, should direct his or her questions in writing to the Chairman of the Board, Atossa Genetics Inc., 107 Spring Street, Seattle, Washington 98104. Upon receipt of any such communications, the correspondence will be directed to the appropriate person, including individual directors.

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Audit Committee

Our Board of Directors has appointed an Audit Committee, comprised of Messrs. Steinhart (Chairman), Weaver and Remmel. The Audit Committee selects the Company's independent registered public accounting firm, approves its compensation, oversees and evaluates the performance of the independent registered public accounting firm, oversees the accounting and financial reporting policies and internal control systems of the Company, reviews the Company's interim and annual financial statements, independent registered public accounting firm reports and management letters, and performs other duties, as specified in the Audit Committee Charter, a copy of which is available on the Company's website at *www.atossagenetics.com.* Additionally, the Audit Committee is involved in the oversight of the Company's risk management through its review of policies relating to risk assessment and management. The Audit Committee met six times in fiscal 2016. All members of the Audit Committee satisfy the current independence standards promulgated by NASDAQ and the SEC and the Board has determined that Richard Steinhart qualifies as an "audit committee financial expert," as the SEC has defined that term in Item 407 of Regulation S-K.

Equity Compensation Plan Information

The following table sets forth certain information, as of December 31, 2016, regarding the Company's 2010 Stock Option and Incentive Plan, as well as other stock options and warrants previously issued by the Company as compensation for services.

Plan category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights		Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights	**Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in First Column)** [1]
Equity compensation plans approved by security holders	310,257		$ 30.45	156,388
Equity compensation plans not approved by security holders	68,667	(2)	$ 50.10	—
Total	378,924		$ 34.20	156,388

(1) Excludes shares that may be added after December 31, 2016 pursuant to the “evergreen” feature under the 2010 Stock Option and Incentive Plan. For example, on January 1, 2017, 151,477 shares were automatically added to the 2010 Stock Option and Incentive Plan under the evergreen feature.

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

SECTION 16(A) BENEFICIAL OWNERSHIP REPORTING COMPLIANCE

Section 16(a) of the Exchange Act requires our executive officers and directors, and persons who own more than 10% of a registered class of our equity securities, to file reports of beneficial ownership and changes in beneficial ownership with the SEC. Executive officers, directors and greater-than-10% stockholders are required by SEC regulations to furnish us with copies of all reports filed under Section 16(a). To the Company’s knowledge, based solely on the review of copies of the reports filed with the SEC, all reports required to be filed by our executive officers, directors and greater-than-10% stockholders were timely filed in fiscal 2016.

ITEM 11. EXECUTIVE COMPENSATION

Remuneration of Officers

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

Summary Compensation Table

The following table sets forth the compensation earned by our President and Chief Executive Officer, Chief Financial Officer, and former Chief Operating Officer (collectively, the " ***Named Executive Officers*** "), for fiscal years 2015 and 2016:

Name and Position	Year	Salary	**Option Award** [(1)]	Nonequity Incentive Plan Compensation	**All Other Compensation** [(2)]	Total
Steven C. Quay, M.D., Ph.D. President and Chief Executive Officer	2016	$520,000	$ 177,952	$ 300,000	$ 10,600	$1,008,552
	2015	$520,000	$ 437,577	$ 208,000	$ 10,600	$1,176,177
Kyle Guse Chief Financial Officer, General Counsel and Secretary	2016	$364,000	$ 415,582	$ 170,000	$ 10,600	$950,582
	2015	$364,000	$ 302,325	$ 131,040	$ 10,600	$807,965
Scott Youmans [(3)] Chief Operating Officer	2016	$34,280	—	$ 104,292	—	$138,572
	2015	$239,200	$ 88,866	$ 80,371	$ 2,870	$411,307

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

(2) Amounts represent 401(k) match paid by the Company on behalf of the Named Executive Officer.

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

Outstanding Equity Awards at Fiscal Year-End

The following table shows information regarding our outstanding equity awards at December 31, 2016 for the Named Executive Officers, all of which are subject to the terms and conditions of the 2010 Stock Option and Incentive Plan, which is described below:

Name	Grant Date	Number of Securities Underlying Unexercised Options (#) Exercisable		Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price	Option Expiration Date
Steven Quay	3/11/2013	2,946	(1)	—	$ 98.55	3/11/2023
President and Chief Executive	5/6/2014	10,283	(2)	6,384	$ 18.30	5/06/2024
Officer	3/16/2015	8,023	(2)	10,310	$ 28.20	5/16/2025
	5/18/16	14,229	(3)	23,716	$ 3.945	5/18/2026
Kyle Guse	1/4/2013	33,333	(4)	—	$ 61.65	1/04/2023
Chief Financial Officer, General	6/4/2013	4,000	(1)	—	$ 64.65	6/04/2023
Counsel and Secretary	1/8/2014	6,417	(2)	2,916	$ 33.00	1/08/2024
	5/6/2014	8,333	(2)	5,000	$ 18.30	5/06/2024
	3/16/2015	5,542	(2)	7,125	$ 28.20	3/16/2025
	5/18/16	4,833	(3)	67,834	$ 3.945	5/18/2026
Scott Youmans,	9/2/2014	7,500	(4)	5,833	$ 27.90	9/02/2024
Chief Operating Officer(5)	3/16/2015	1,057	(2)	1,359	$ 22.56	3/16/2025
	9/21/2015	208	(2)	3,125	$ 11.40	1/01/2026

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

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

(3) Option vests quarterly over two years from the date of grant.

(4) One quarter of the shares of Common Stock underlying the option vested on the first anniversary of employment and the remaining 75% vest in equal quarterly installments over the next three years.

(5) Mr. Youmans options stopped vesting on February 12, 2016 when he resigned as the Chief Operating Officer of the Company. Pursuant to his severance agreement he had the right to exercise his options until February 12, 2017. His options expired unexercised on February 12, 2017.

Employment Agreements

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

The Company has entered into an employment agreement with Dr. Quay to act as the Company's Chief Executive Officer. The agreement provides for an initial base salary of $250,000, which was subsequently increased to $520,000 for 2015 and 2016, with an annual target bonus of up to 50% of Dr. Quay's then-current base salary, payable upon the achievement of performance goals to be established annually by the Compensation Committee.

The goals for fiscal 2016 included raising at least $5 million in capital, initiating and continuing the fulvestrant microcatheter Phase 2 study, effectively managing the dispute with Besins, and developing one additional pharmaceutical candidate. In February 2017, the Compensation Committee reviewed the performance of Dr. Quay for 2016 against these goals and determined that his bonus for 2016 would be 120% of potential, or $300,000.

Under his employment agreement, Dr. Quay received an option to purchase up to 16,667 shares of Common Stock at an exercise price of $75.00 per share, the fair market value of the Common Stock on the date of grant, as determined by the Board of Directors. One-quarter of the shares of Common Stock underlying the option, or 4,167 shares, vested on December 31, 2010, and the remaining 75%, or 12,500 shares, vested in equal quarterly installments over the next three years. The options were fully vested as of December 31, 2013 and subsequently expired unexercised on July 22, 2015.

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

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

Employment Agreement with Kyle Guse

The Company has entered into an employment agreement with Mr. Guse to act as the Company's Chief Financial Officer, General Counsel and Secretary. The agreement provides for an initial base salary of $225,000, which has been increased to $364,000 for 2015 and 2016 and an annual target bonus of up to 45% of Mr. Guse's then-current base salary, payable upon the achievement of performance goals to be established annually by the Compensation Committee.

The goals for fiscal 2016 included raising at least $5 million in capital, initiating and continuing the fulvestrant microcatheter Phase 2 study, effectively managing the dispute with Besins, and developing one additional pharmaceutical candidate. In February 2017, the Compensation Committee reviewed the performance of Mr. Guse for 2016 against these goals and determined that his bonus for 2016 would be 103% of potential, or $170,000.

Under his employment agreement, on January 4, 2014, Mr. Guse received an option to purchase up to 33,333 shares of Common Stock at an exercise price of $61.65 per share, the fair market value of the Common Stock on the date of grant, as determined by the Board of Directors. One-quarter of the shares of Common Stock underlying the option, or 8,333 shares, vested on January 4, 2014, and the remaining 75%, or 25,000 shares, vest in equal quarterly installments over the next three years, so long as Mr. Guse remains employed with the Company. In lieu of a cash signing and relocation bonus payable to Mr. Guse under the terms of his employment agreement, on June 4, 2013 he received a fully-vested option to purchase 4,000 shares of Common Stock exercisable at $64.65 per share, the fair value of the Company's Common Stock on the date of grant.

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

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

Employment Agreement with Scott Youmans

In connection with the hiring of Mr. Youmans, the Company entered into an offer letter agreement which provided for an initial base salary of $230,000, which was increased to $287,000 on September 1, 2015 when Mr. Youmans was promoted to the Chief Operating Officer with a bonus of up to 25%. Mr. Youmans was also granted an option to purchase 13,333 shares of Common Stock at $27.90 per share upon joining Atossa and 3,333 at the time of his promotion at market value of $11.40, the fair market value of the Common Stock on the date of grant, as determined by the Board of Directors. The offer letter agreement provides that Mr. Youmans will be offered employment benefits similar to other members of management and that he is terminable at will. His options will accelerate upon a change of control. Mr. Youmans resigned as the Chief Operating Officer of the Company on February 12, 2016. Based on the employment separation agreement, Mr. Youmans received $23,920 in severance pay and received one-half of his 2015 bonus of $40,186 in a lump sum payment in February 2016 and the other one-half bonus of $40,186 will be paid in equal monthly payments over six months following his departure and an extension to one year of the time by which Mr. Youmans has the right to exercise stock options previously granted to him.

Severance Benefits and Change in Control Arrangements

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

Dr. Steven Quay

Pursuant to his employment agreement, if (i) the Company terminates the employment of Dr. Quay without cause, or (ii) Dr. Quay terminates his employment for good reason, then Dr. Quay will be entitled to receive all accrued but unpaid compensation, plus a severance payment equal to 12 months of base salary. In addition, upon such event, the vesting of all shares of Common Stock underlying options then held by Dr. Quay will accelerate, and the options will remain exercisable for the remainder of their terms. The cash severance payment is required to be paid in substantially

equal installments over a period of six months beginning on the Company's first payroll date that occurs following the 30th day after the effective date of termination of Dr. Quay's employment, subject to certain conditions. The Company will not be required, however, to pay any severance pay for any period following the termination date if Dr. Quay materially violates certain provisions of his employment agreement and the violation is not cured within 30 days following receipt of written notice from the Company containing a description of the violation and a demand for immediate cure.

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

Kyle Guse

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

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

2010 Stock Option and Incentive Plan

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

Plan Administration. The 2010 Plan may be administered by the full Board or the Compensation Committee. It is the current intention of the Company that the 2010 Plan be administered by the Compensation Committee. The Compensation Committee has full power to select, from among the individuals eligible for awards, the individuals to whom awards will be granted, to make any combination of awards to participants, and to determine the specific terms

and conditions of each award, subject to the provisions of the 2010 Plan. The Compensation Committee may delegate to our Chief Executive Officer the authority to grant stock options to employees who are not subject to the reporting and other provisions of Section 16 of the Exchange Act and not subject to Section 162(m) of the Code, subject to certain limitations and guidelines.

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

Plan Limits. Initially, the total number of shares of Common Stock available for issuance under the 2010 Plan is 66,667 shares (or 1,000,000 shares prior to the reverse stock-split in August 2016). As of January 1, 2012 and each January 1 thereafter, the number of shares of Common Stock reserved and available for issuance under the 2010 Plan will be cumulatively increased by 4% of the number of shares of Common Stock issued and outstanding on the immediately preceding December 31.

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

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

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

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

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

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

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

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

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

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

Other Benefits

The Company offers health, dental, disability, 401(k) matching up to 4% of salary and life insurance to its full-time employees.

REPORT OF THE AUDIT COMMITTEE

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

provided by NASDAQ and the SEC.

No member of the Audit Committee is a professional accountant or auditor. The members' functions are not intended to duplicate or to certify the activities of management and the independent registered public accounting firm. The Audit Committee serves a board-level oversight role in which it provides advice, counsel and direction to management and the auditors on the basis of the information it receives, discussions with management and the auditors, and the experience of the Audit Committee's members in business, financial and accounting matters. The Audit Committee oversees the Company's financial reporting process on behalf of the Board. The Company's management has the primary responsibility for the financial statements and reporting process, including the Company's system of internal controls. In fulfilling its oversight responsibilities, the Audit Committee reviewed with management the audited financial statements included in the Annual Report on Form 10-K for the fiscal year ended December 31, 2016. This review included a discussion of the quality and the acceptability of the Company's financial reporting, including the nature and extent of disclosures in the financial statements and the accompanying notes. The Audit Committee also reviewed the progress and results of the testing of the design and effectiveness of its internal controls over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act of 2002. The Audit Committee also reviewed with the Company's independent registered public accounting firm, which is responsible for expressing an opinion on the conformity of the audited financial statements with accounting principles generally accepted in the United States of America, their judgments as to the quality and the acceptability of the Company's financial reporting and discussed with the independent auditors matters required to be discussed under Public Company Accounting Oversight Board (PCAOB) Auditing Standard No. 16. *Communication with Audit Committees*. The Audit Committee has received from the independent auditors the written disclosures regarding the auditor's independence required by the PCAOB Rule 3526, *Communications with Audit Committees Concerning Independence*. The Audit Committee discussed with the independent registered public accounting firm their independence from management and the Company, including the matters required by the applicable rules of the Public Company Accounting Oversight Board.

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

In reliance on the reviews and discussions referred to above, the Audit Committee recommended to the Board of Directors that the Company's audited financial statements should be included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2016.

Submitted by the Audit Committee of the Board of Directors

Richard I. Steinhart (Chairman)

Gregory L. Weaver

H. Lawrence Remmel, Esq.

DIRECTOR COMPENSATION

Non-employee director compensation is generally reviewed and set annually at the Board meeting held in connection with the Annual Stockholder Meeting. The non-employee directors of the Company received the following for service on the Board from May 2016 through May 2017:

- upon joining the Board, an initial fee of $50,000 in cash;
- an annual cash payment of $40,000 for each board member; and
- an annual grant of options exercisable for 40,000 shares; however, because all outstanding options were significantly underwater as of the 2016 annual stockholder meeting, the Board instead granted options to in an amount equal to the total number of shares issuable upon exercise of all previously granted options to such directors, vesting quarterly over one year.

In lieu of the above 40,000 share annual option grant, Dr. Chen's outstanding options granted to her during her service as Chief Scientific Officer continue to vest and be exercisable during her services as a member of the Board. Dr. Chen also provided consulting services to the Company related to the manufacturing of the Company's endoxifen drug in Taiwan. The Company paid $27,439 to Dr. Chen for such services in 2016.

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

The employee directors receive no compensation for their board service. Pursuant to the policies of Pryor Cashman, the law firm of which Mr. Remmel is a partner, the compensation Mr. Remmel receives for his services as a director (other than expense reimbursement) is paid to the firm directly, the cash portion of which was waived in 2016. All directors receive reimbursement for reasonable travel expenses. The following table sets forth information regarding compensation earned by our non-employee directors during the fiscal year ended December 31, 2016:

Name	Fees Earned or Paid in Cash	Option Awards Dollar Amount[1]	Option Awards Number of Shares	Total
Shu-Chih Chen, Ph.D. [2]	$ 40,000	$ 25,811	10,101	$65,811
Stephen Galli, M.D.	$ 65,000	$ 27,657	12,065	$92,657
H. Lawrence Remmel, Esq. [3]	$ —	$ 24,571	8,842	$24,571
Gregory L. Weaver	$ 70,000	$ 23,267	7,479	$93,267
Richard Steinhart	$ 70,000	$ 20,669	4,765	$90,669

(1) The value of the awards has been computed in accordance with FASB ASC 718, excluding the effect of estimated forfeitures. Assumptions used in the calculations for these amounts are included in notes to our financial statements included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2016.

Option awards consist of 2016 annual option grants, to purchase shares of Common Stock with an exercise price of $3.945, which was the fair value of our common shares at the time of grant. Options vest quarterly over a year.

(2) Dr. Chen retired as the Chief Scientific Officer in August 2014. The options granted to her as an executive officer continue to vest and be exercisable during her service as a member of the Board of Directors. See PART III Item 11 “Executive Compensation.” The table excludes $27,439 paid to Dr. Chen for services she provided to the Company as a consultant in 2016.

(3) The compensation Mr. Remmel receives for his services as a director in the form of an option grant is assigned to the Pryor Cashman law firm of which Mr. Remmel is a partner. All cash fees payable to Mr. Remmel have been waived by Mr. Remmel and credited back to the Company.

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

BENEFICIAL OWNERS AND MANAGEMENT

Based on information available to us and filings with the SEC, the following table sets forth certain information regarding the beneficial ownership (as defined by Rule 13d-3 under the Securities Exchange Act) of our outstanding Common Stock for (i) each of our directors, (ii) each of our “named executive officers,” as defined in Executive Compensation below, (iii) all of our directors and executive officers as a group, and (iv) persons known to us to beneficially hold more than 5% of our outstanding Common Stock. The following information is presented as of March 10, 2017 or such other date as may be reflected below.

Beneficial ownership and percentage ownership are determined in accordance with the rules of the SEC and include voting or investment power with respect to shares of stock. This information does not necessarily indicate beneficial ownership for any other purpose. Under these rules, shares of Common Stock issuable under stock options or warrants that are exercisable within 60 days of March 10, 2017 are deemed outstanding for the purpose of computing the percentage ownership of the person holding the options or warrant(s), but are not deemed outstanding for the purpose of computing the percentage ownership of any other person.

The address of each person listed on the table is c/o Atossa Genetics Inc., 107 Spring Street, Seattle, Washington 98104.

	Shares Beneficially Owned		
Name of Beneficial Owner	Number	**Percent of Class** [1]	
Steven C. Quay, M.D., Ph.D. [2]	377,126	9.1	%
Shu-Chih Chen, Ph.D. [3]	304,616	7.4	%
Kyle Guse, Esq., CPA, Esq. [8]	95,012	2.4	%
Stephen J. Galli, M.D. [5]	22,290	*	
Gregory L. Weaver [4]	13,753	*	
Scott Youmans [9]	0	*	
Richard I Steinhart [6]	8,338	*	
H. Lawrence Remmel, Esq. [7]	623	*	
All current executive officers and directors as a group (8 persons)	531,874	12.3	%

*Less than one percent.

(1) Based on 3,786,913 shares of Common Stock issued and outstanding as of March 10, 2017.

(2) Consists of (i) 31,902 shares of Common Stock directly owned by Dr. Quay, (ii) 289,887 shares of Common Stock owned by Ensisheim Partners LLC, and (iii) 55,337 shares of Common Stock issuable upon the exercise of stock options held by Dr. Quay and exercisable within 60 days after March 10, 2017. Drs. Quay and Chen share voting and investment power over the securities held by Ensisheim. Ensisheim is solely owned and controlled by Drs. Quay and Chen, and, as a result, Drs. Quay and Chen are deemed to be beneficial owners of the shares held by this entity.

(3) Consists of (i) 289,887 shares of Common Stock owned by Ensisheim, and (ii) 14,729 shares of Common Stock issuable upon the exercise of stock options held by Dr. Chen and exercisable within 60 days after March 10, 2017. Drs. Quay and Chen share voting and investment power over the securities held by Ensisheim. Ensisheim is solely owned and controlled by Drs. Quay and Chen, and, as a result, Drs. Quay and Chen are deemed to be beneficial owners of the shares held by this entity.

(4) Consists of 13,087 shares of Common Stock issuable upon the exercise of stock options held by Mr. Weaver and exercisable within 60 days of March 10, 2017 and 666 shares of Common Stock held by Mr. Weaver.

(5) Consists of (i) 1,178 shares of Common Stock held by Dr. Galli, and (ii) 21,112 shares of Common Stock issuable upon the exercise of stock options held by Dr. Galli and exercisable within 60 days of March 10, 2017.

(6) Consists of 8,338 shares of Common Stock issuable upon the exercise of stock options held by Mr. Steinhart and exercisable within 60 days of March 10, 2017.

(7) Consists of 493 shares of Common Stock held by Mr. Remmel and 133 shares of Common Stock held by Mr. Remmel’s spouse. Mr. Remmel disclaims beneficial ownership of the 133 shares of Common Stock held by his spouse.

(8) Consists of 95,012 shares of Common Stock issuable upon the exercise of stock options held by Mr. Guse and exercisable within 60 days of March 10, 2017.

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

Transactions with Related Parties

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

Ensisheim Partners LLC, which is under sole ownership and control by Drs. Quay and Chen, purchased the following shares of Common Stock directly from the Company in at-the-market transactions which were approved by the Company’s audit committee:

Purchase Date	Number of Shares	Price per Share
January 19, 2016	3,333	$ 3.30
February 16, 2016	1,000	$ 7.95
March 9, 2016	1,000	$ 5.55

Related-Party Transaction Review and Approval

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

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The following is a summary of the fees for services rendered by BDO for professional services rendered for fiscal years ended December 31, 2016 and 2015.

	2016	2015
Audit Fees:		
Consists of fees billed for audit of our annual financial statements and the review of the financial statements included in our quarterly reports on Form 10-Q, and services that are normally provided by BDO in connection with statutory and regulatory filings or engagements	$135,000	$218,796

for that fiscal year.

Other Fees:		
Audit-Related Fees	$29,583	-
Total All Fees	$164,583	$218,796

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PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a)

1. Financial Statements

2. Financial Statement Schedules

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

3. Exhibits

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

ITEM 16. FORM 10-K SUMMARY

Not applicable.

ATOSSA GENETICS, INC.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Audited Consolidated Financial Statements:

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders

Atossa Genetics Inc.

Seattle, Washington

We have audited the accompanying consolidated balance sheets of Atossa Genetics Inc. (the "Company") as of December 31, 2016 and 2015, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the two years in the period ended December 31, 2016. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Atossa Genetics Inc. at December 31, 2016 and 2015, and the results of its operations and its cash flows for the years then ended**,** in conformity with accounting principles generally accepted in the United States of America.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As described in Note 2 to the consolidated financial statements, the Company has suffered recurring losses from operations and has an accumulated deficit that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ BDO USA, LLP

Seattle, Washington

March 16, 2017

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ATOSSA GENETICS, INC.

CONSOLIDATED BALANCE SHEETS

	As of December 31,	
	2016	2015
Assets		
Current assets:		
Cash and cash equivalents	$3,027,962	$3,715,895
Restricted cash	55,000	275,000
Prepaid expenses	171,601	193,293
Other current assets	-	110,663
Total current assets	3,254,563	4,294,851
Furniture and equipment, net	55,119	171,568
Intangible assets, net	640,440	1,700,565
Other assets	194,250	76,337
Total assets	$4,144,372	$6,243,321
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$254,320	$814,448
Accrued expenses	16,964	463,676
Payroll liabilities	769,899	1,159,335
Other current liabilities	6,083	64,128
Total current liabilities	1,047,266	2,501,587
Total liabilities	1,047,266	2,501,587
Commitments and contingencies (note 14)		
Stockholders' equity		
Preferred stock - $.001 par value; 10,000,000 shares authorized, 0 shares issued and outstanding	-	-
Common stock - $.015 par value; 75,000,000 shares authorized, 3,786,913 and 2,177,151 shares issued and outstanding at December 31, 2016 and December 31, 2015, respectively	56,804	32,657
Additional paid-in capital	60,344,050	54,643,940
Accumulated deficit	(57,303,748)	(50,934,863)
Total stockholders' equity	3,097,106	3,741,734
Total liabilities and stockholders' equity	$4,144,372	$6,243,321

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

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ATOSSA GENETICS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

	For the Years Ended December 31,	
	2016	2015
Revenue		
Product sales	$ -	$ 1,758
Total revenue	-	1,758
Cost of revenue		
Product sales	-	132,411
Total cost of revenue	-	132,411
Gross loss from operations	-	(130,653)
Selling expenses	-	1,421,409
Research and development expenses	770,427	2,359,593
General and administrative expenses	6,479,193	8,846,963
Impairment of intangible assets	718,970	-
Total operating expenses	7,968,590	12,627,965
Operating loss	(7,968,590)	(12,758,618)
Other income	1,599,705	431
Loss before income taxes	(6,368,885)	(12,758,187)
Income taxes	-	-
Loss from continuing operations	(6,368,885)	(12,758,187)
Loss from discontinued operations (including loss on disposal of $670,943 for the year ended December 31, 2015)	-	(3,002,136)
Net loss	$ (6,368,885)	$ (15,760,323)
Loss per common share from continuing operations - basic and diluted	$ (2.80)	$ (6.73)
Loss per common share from discontinued operations - basic and diluted	$ -	$ (1.58)
Loss per common share - basic and diluted	$ (2.80)	$ (8.31)
Weighted average shares outstanding, basic and diluted	2,277,775	1,895,168

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

ATOSSA GENETICS, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

	Common Stock		Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Deficit	Equity
Balance at December 31, 2014	1,637,604	$24,564	$ 44,648,103	$(35,174,540)	$9,498,127
Issuance of common shares and warrants (net of issuance costs of $1,011,574)	539,547	8,093	9,101,181	-	9,109,274
Compensation cost for stock options granted to executives and employees	-	-	894,656	-	894,656
Net loss	-	-	-	(15,760,323)	(15,760,323)
Balance at December 31, 2015	2,177,151	$32,657	$ 54,643,940	$(50,934,863)	$3,741,734
Issuance of common shares (net of issuance costs of $356,214)	1,561,080	23,417	4,672,452	-	4,695,869
Issuance of common shares as commitment fees	49,736	746	197,777	-	198,523
Amortization of commitment shares	-	-	(42,864)		(42,864)
Settlement of fractional shares	(1,054)	(16)	(3,444)		(3,460)
Compensation cost for stock options granted to executives and employees	-	-	876,189	-	876,189
Net loss	-	-	-	(6,368,885)	(6,368,885)
Balance at December 31, 2016	3,786,913	$56,804	$ 60,344,050	$(57,303,748)	$3,097,106

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

ATOSSA GENETICS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

	For the Year Ended December 31,	
	2016	**2015**
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (6,368,885)	$ (15,760,323)
Net loss from discontinued operations	-	3,002,136
Adjustments to reconcile net loss to net cash used in operating activities:		
Compensation cost for stock options granted	876,189	840,103
Loss on disposal of an asset	163,333	
Impairment of intangible assets	718,970	-
Depreciation and amortization	303,482	272,627
Changes in operating assets and liabilities:		
Restricted cash	220,000	(275,000)
Inventory	-	9,276
Other assets	124,301	(110,663)
Prepaid expenses	21,692	671
Security deposits	20,650	(28,144)
Accounts payable	(560,128)	301,403
Payroll liabilities	(389,436)	199,594
Deferred rent	-	(2,483)
Accrued expenses	(446,712)	209,550
Other current liabilities	(58,045)	21,900
Net cash used in continuing operating activities	(5,374,589)	(11,319,353)
Net cash used in discontinued operating activities	-	(2,633,943)
Net cash used in operating activities	(5,374,589)	(13,953,296)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchases of furniture and equipment	(9,213)	(130,735)
Net cash used in continuing investing activities	(9,213)	(130,735)
Net cash used in discontinued investing activities	-	(157,684)
Net cash used in investing activities	(9,213)	(288,419)
CASH FLOWS FROM FINANCING ACTIVITIES		
Net proceeds from issuance of common stock	4,695,869	9,456,892
Net cash provided by financing activities	4,695,869	9,456,892
NET (DECREASE) IN CASH AND CASH EQUIVALENTS	(687,933)	(4,784,823)
CASH AND CASH EQUIVALENTS, BEGINNING OF YEAR	3,715,895	8,500,718
CASH AND CASH EQUIVALENTS, ENDING OF YEAR	$ 3,027,962	$ 3,715,895
SUPPLEMENTAL DISCLOSURES:		
Interest paid	$ -	$ 317

NONCASH INVESTING AND FINANCING ACTIVITIES:		
Amortization of deferred financing costs	$ 42,864	$ 355,711

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

NOTE 1: NATURE OF OPERATIONS

Atossa Genetics Inc. (the "Company") was incorporated on April 30, 2009 in the State of Delaware. The Company was formed to develop and market medical devices, laboratory tests and therapeutics to address breast health conditions. The Company's fiscal year ends on December 31.

In December 2011, the Company established the National Reference Laboratory for Breast Health, Inc., or NRLBH, as a wholly-owned subsidiary. NRLBH was the Company's CLIA-certified laboratory, which performed the Company's nipple aspirate fluid, or NAF, cytology test on NAF specimens including those collected with the Company's Mammary Aspiration Specimen Cytology Test (MASCT) System. The current version of the MASCT System is called the ForeCYTE Breast Aspirator. The NRLBH provides other test services, including pharmacogenomics tests. On December 16, 2015, the Company sold approximately 81% of the capital stock of the NRLBH to the NRL Investment Group, LLC, with the Company retaining a 19% ownership through preferred stock. The Company received $50,000 at the time of the sale and the right to receive, commencing December 2016, monthly earn-out payments equal to 6% of gross revenue of NRLBH up to $10,000,000, and the right to sell its preferred stock after four years for the greater of $4,000,000 or fair market value. The Company has elected to recognize any subsequent gain from the earn-out payments as they are determined realizable.

As a result of the sale of the laboratory business, the Company is now focusing on development of its pharmaceutical programs.

NOTE 2: GOING CONCERN

The Company's consolidated financial statements are prepared using generally accepted accounting principles in the United States of America applicable to a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The Company has incurred net losses and negative operating cash flows since inception. For the year ended December 31, 2016, the Company recorded a net loss of approximately $6.4 million and used approximately $5.4 million of cash in operating activities. As of December 31, 2016, the Company had approximately $3.0 million in cash and cash equivalents and working capital of approximately $2.2 million. The Company has not yet established an ongoing source of revenue sufficient to cover its operating costs and allow it to continue as a going concern. The ability of the Company to continue as a going concern is dependent on the Company obtaining adequate capital to fund operating losses until it becomes profitable. The Company can give no assurances that any additional capital that it is able to obtain, if any, will be sufficient to meet its needs, or that any such capital will be obtained on acceptable terms. If the Company is unable to obtain adequate capital, it could be forced to cease operations or substantially curtail its activities. These conditions raise substantial doubt as to the Company's ability to continue as a going concern. The accompanying consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts and

classification of liabilities should the Company be unable to continue as a going concern.

Management’s plan to continue as a going concern is as follows. In order to continue as a going concern, the Company will need, among other things, additional capital resources. Management’s plans to obtain such resources for the Company include obtaining capital from the sale of its equity securities and short-term borrowings from banks, stockholders or other related party(ies), if needed. However, management cannot provide any assurance that the Company will be successful in accomplishing any of its plans.

The ability of the Company to continue as a going concern is dependent upon its ability to successfully accomplish the plans described in the preceding paragraph and eventually to secure other sources of financing and attain profitable operations.

NOTE 3: SUMMARY OF ACCOUNTING POLICIES

Basis of Presentation:

The accompanying consolidated financial statements have been prepared pursuant to the rules of the Securities and Exchange Commission ("SEC") and in accordance with U.S. generally accepted accounting principles ("GAAP"). The accompanying consolidated financial statements include the financial statements of Atossa Genetics Inc. and its formerly wholly-owned subsidiary, NRLBH. The Company sold a majority of its interest in the NRLBH in December 2015 and all of its activities are reported as discontinued operations in the accompanying consolidated financial statements. All significant intercompany account balances and transactions have been eliminated in consolidation. Certain amounts from prior years have been reclassified to conform with the 2016 presentation.

On August 26, 2016, the Company completed a 1-for-15 reverse stock split of the shares of the Company's common stock (the "Reverse Stock Split"). As a result of the Reverse Stock Split, every 15 shares of issued and outstanding common stock were combined into one issued and outstanding share of Common Stock, and the par value per share was changed to $.015 per share. No fractional shares were issued because of the Reverse Stock Split and any fractional shares that would otherwise have resulted from the Reverse Stock Split were paid in cash. As a result of the Reverse Stock Split, as of November 11, 2016, there are 3,786,913 shares of common stock outstanding and fractional shares totaling approximately 1,054 shares of common stock were rounded down and paid in cash. The number of authorized shares of common stock was not reduced as a result of the Reverse Stock Split. The Company's common stock began trading on a reverse stock split-adjusted basis on August 26, 2016. All share and per share data included in this report has been retroactively restated to reflect the Reverse Stock Split.

Use of Estimates:

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Actual results could differ from those estimates.

Recently Issued Accounting Pronouncements:

In May 2014, the Financial Accounting Standards Board (the "FASB") issued Accounting Standards Update ("ASU") No. 2014-09, *Revenue from Contracts with Customers: Topic 606* ("ASU 2014-09"), to supersede nearly all existing revenue recognition guidance under U.S. GAAP. The core principle of ASU 2014-09 is to recognize revenues when promised goods or services are transferred to customers in an amount that reflects the consideration that is expected to be received for those goods or services. ASU 2014-09 defines a five step process to achieve this core principle and, in doing so, it is possible more judgment and estimates may be required within the revenue recognition process than required under existing GAAP including identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation. ASU 2014-09 is effective for the Company in the first quarter of 2017 using either of two methods: (i) retrospective to each prior reporting period presented with the option to elect certain practical expedients as defined within ASU 2014-09; or (ii) retrospective with the cumulative effect of initially applying ASU 2014-09 recognized at the date of initial application and providing certain additional disclosures as defined per ASU 2014-09. Given that the Company is not currently generating revenue and most likely will not be generating revenue at the date of adoption, the adoption of this guidance will not materially impact our consolidated financial statements.

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

In April 2016, the FASB issued ASU No. 2016-09, *Stock Compensation Topic 718: Improvements to Employee Share-based Payment Accounting.* This ASU simplifies the accounting for stock compensation on income tax accounting, classification of awards as either equity or liabilities, estimating forfeitures, and cash flow presentation. Based on this ASU, an entity should recognize all excess tax benefits and tax deficiencies, including tax benefits of dividends on share-based payment awards, as income tax expense or benefit in the income statement; they do not need to include the effects of windfalls and shortfalls in the annual effective tax rate estimate from continuing operations used for interim reporting purposes. As a result of including income tax effects from windfalls and shortfalls in income tax expense, the calculation of both basic and diluted EPS will be affected. The ASU also provides an accounting policy election for awards with service conditions to either estimate the number of awards that are expected to vest (consistent with existing U.S. GAAP) or account for forfeitures when they occur. The ASU increases the allowable statutory tax withholding threshold to qualify for equity classification from the minimum statutory withholding requirements up to the maximum statutory tax rate in the applicable jurisdiction(s). The ASU clarifies that cash paid to a taxing authority by an employer when directly withholding equivalent shares for tax withholding purposes should be considered similar to a share repurchase, and thus classified as a financing activity. All other employer withholding taxes on compensation transactions and other events that enter into the determination of net income continue to be presented within operating activities. The new standard takes effect in 2017 for public business entities and 2018 for all other entities. The Company has not adopted the provisions of ASU No. 2016-09. The Company does not anticipate the impact of adopting ASU 2016-09 will be material to its consolidated financial

statements.

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Revenue Recognition

The Company is not currently recognizing any revenue and all the revenue recognized in 2015 was from testing services performed by the NRLBH. The Company sold approximately 81% of the capital stock in the NRLBH on December 16, 2015 and as a result all of the revenue is included in discontinued operations for 2015.

Cost of Revenue

Cost of revenue consists of the costs of laboratory testing services and costs of product sales. Costs of testing services primarily include direct costs of material, direct labor, equipment, and shipping to process the patient samples (including pathology, quality control analysis, and shipping charges to transport tissue sample) in the NRLBH. Costs associated with performing the Company's tests were recorded as tests are processed. Costs recorded for sample processing and shipping charges represent the cost of all the tests processed during the period regardless of whether revenue was recognized with respect to that test. The cost of service from laboratory testing is included in discontinued operations for 2015.

Research and Development

All research and development costs are expensed as incurred.

Income Taxes

The Company accounts for income taxes under the asset and liability method. Under this method, deferred tax assets and liabilities are determined based on differences between financial reporting and tax bases of assets and liabilities and are measured using enacted tax rates and laws that are expected to be in effect when the differences are expected to be recovered or settled. Realization of deferred tax assets is dependent upon future taxable income. A valuation allowance is recognized if it is more likely than not that some portion or all of a deferred tax asset will not be realized based on the weight of available evidence, including expected future earnings. The Company recognizes an uncertain tax position in its financial statements when it concludes that a tax position is more likely than not to be sustained upon examination based solely on its technical merits. Only after a tax position passes the first step of recognition will measurement be required. Under the measurement step, the tax benefit is measured as the largest amount of benefit that is more likely than not to be realized upon effective settlement. This is determined on a cumulative probability basis. The full impact of any change in recognition or measurement is reflected in the period in which such change

occurs. The Company elects to accrue any interest or penalties related to income taxes as part of its income tax expense.

Cash and Cash Equivalents

Cash and cash equivalents include cash and all highly liquid instruments with original maturities of three months or less.

Furniture and Equipment

Furniture and equipment are stated at cost less accumulated depreciation. Expenditures for maintenance and repairs are charged to earnings as incurred; additions, renewals and betterments are capitalized. When furniture and equipment are retired or otherwise disposed of, the related cost and accumulated depreciation are removed from the respective accounts, and any gain or loss is included in operations.

Depreciation is computed using the straight-line method over the estimated useful lives of the assets as follows:

	Useful Life (in years)
Machinery and equipment	3 - 5
Leasehold improvements	lease term

The Company applies the provisions of FASB ASC Topic 360 (ASC 360), “Property, Plant, and Equipment” which addresses financial accounting and reporting for the impairment or disposal of long-lived assets. The Company periodically evaluates the carrying value of long-lived assets to be held and used in accordance with ASC 360, at least on an annual basis. ASC 360 requires the impairment losses to be recorded on long-lived assets used in operations when indicators of impairment are present and the undiscounted cash flows estimated to be generated by those assets are less than the assets’ carrying amounts. In that event, a loss is recognized based on the amount by which the carrying amount exceeds the fair market value of the long-lived assets. Loss on long-lived assets to be disposed of is determined in a similar manner, except that fair market values are reduced for the cost of disposal. For the years ended December 31, 2016 and 2015, no impairment of property and equipment was recorded.

Fair Value Measurements

The Company records recurring and non-recurring financial assets and liabilities as well as all non-financial assets and liabilities subject to fair value measurement at the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. These fair value principles prioritize valuation inputs across three broad levels. Level 1 inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities. Level 2 inputs are quoted prices for similar assets and liabilities in active markets or inputs that are observable for the asset or liability, either directly or indirectly through market corroboration, for substantially the full term of the financial instrument. Level 3 inputs are unobservable inputs based on the Company's assumptions used to measure assets and liabilities at fair value. An asset or liability's classification within the various levels is determined based on the lowest level input that is significant to the fair value measurement.

Intangible Assets

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

We continuously evaluate and reprioritize our research and development pipeline based on the most recent business strategies, and as a result, have changed our plans to develop and invest further in the Acueity patents and technologies. Because of these changed business plans related to the Acueity assets, we have re-evaluated the assets for potential impairment. We have concluded that these assets are partially impaired and have recorded asset impairment charges of $718,970 for the year ended December 31, 2016 to adjust the carrying value of these intangible assets to their estimated fair values as of December 31, 2016.

We determined the fair values of the Acueity intangibles using an income approach (Level 3 of the fair value hierarchy). For purposes of the income approach, fair value was determined based on the present value of estimated future cash flows that a market participant could expect to generate from the development of products using the patented technology acquired in the Acueity transaction, discounted at an appropriate risk-adjusted rate reflecting the weighted average cost of capital for a potential market participant. The discount rate used in valuation for these intangible assets was 20%. The estimated future cash flows, including an estimate of long-term future growth rates, reflect our own assumptions of what market participants would utilize to price the assets pursuant to ASC 820, *Fair Value Measurements*.

Amortization is computed using the straight-line method over the estimate useful lives of the assets as follows:

	Useful Life (in years)
Patents	7 - 12
Software	3

Share-Based Payments

The Company follows the provisions of ASC Topic 718, *Compensation - Stock Compensation* ("ASC 718"), which requires the measurement and recognition of compensation expense for all share-based payment awards made to employees, non-employee directors, and consultants, including employee stock options. Stock compensation expense based on the grant date fair value estimated in accordance with the provisions of ASC 718 is recognized as an expense over the requisite service period.

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

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

NOTE 4: RESTRICTED CASH

Our restricted cash balance of $55,000 and $275,000 as of December 31, 2016 and 2015, consists entirely of cash pledged as security for the Company's issued commercial credit cards.

NOTE 5: PREPAID EXPENSES

Prepaid expenses consisted of the following:

	December 31, 2016	December 31, 2015
Prepaid insurance	$ 121,333	$ 104,954
Tradeshows	20,000	-
Retainer and security deposits	14,218	39,218
Other	16,050	49,121
Total prepaid expenses	$ 171,601	$ 193,293

NOTE 6: FURNITURE AND EQUIPMENT

Furniture and equipment consisted of the following:

	December 31, 2016	December 31, 2015
Furniture and equipment	$ 210,528	$ 206,337
Leasehold improvements	-	79,518
Furniture and equipment	210,528	285,855
Less: accumulated depreciation	(155,409)	(114,287)
Total furniture and equipment, net	$ 55,119	$ 171,568

Depreciation expense for the years ended December 31, 2016 and 2015 was $125,661 and $73,094, respectively.

NOTE 7: INTANGIBLE ASSETS

Intangible assets consisted of the following:

	December 31, 2016	December 31, 2015
Patents	$ 639,000	$ 1,630,000
Capitalized license costs	-	200,000
Software	113,540	113,540
Intangible assets	752,540	1,943,540
Less: accumulated amortization	(112,100)	(242,975)
Total intangible assets, net	$ 640,440	$ 1,700,565

Intangible assets amounted to $640,440 and $1,700,565 as of December 31, 2016, and December 31, 2015, respectively, and consisted of patents, capitalized license costs and software acquired. The amortization period for the purchased software is three years. Amortization expense related to software for the years ended December 31, 2016 and 2015 was $28,806 and $30,820, respectively.

Patents amounted to $696,718 and $1,630,000 as of December 31, 2016, and December 31, 2015, respectively. Patent assets are amortized based on their determined useful life, and tested annually for impairment. We continuously evaluate and reprioritize our research and development pipeline based on the most recent business strategies, and as a result have delayed plans to develop and invest further in Acueity patents and technologies. In 2016 and 2015, we evaluated the Acueity assets and determined that the assets were impaired for the year ended December 31, 2016 and we reduced the net carrying value of the patents by $718,970. No such impairment was recorded in 2015.

The amortization period of the patents is from 7 to 12 years. Amortization expense related to intangible assets was $149,015 and $199,437 for the years ended December 31, 2016 and 2015, respectively.

Capitalized license costs consisted of fees paid to A5 Genetics KFT, Corporation, pursuant to which the Company received the world-wide (other than the European Union) exclusive license to use the software in the NextCYTE test. The Company terminated this agreement in 2016 and wrote-off the remaining balance of the asset of $163,333 in 2016. Amortization expense related to license costs was $0 and $16,667 for the years ended December 31, 2016 and 2015, respectively.

Future estimated amortization expenses as of December 31, 2016, for the five succeeding years and thereafter is as follows:

Years Ending December 31,	Amounts
2017	$90,846
2018	70,893
2019	70,285
2020	70,285
2021	70,285
Thereafter	267,846
	$640,440

NOTE 8: PAYROLL LIABILITIES

Payroll liabilities consisted of the following:

	December 31, 2016	December 31, 2015
Accrued bonus payable	$ 609,337	$ 555,345
Accrued payroll liabilities	94,514	510,179
Accrued payroll tax liabilities	66,048	93,811
Total payroll liabilities	$ 769,899	$ 1,159,335

NOTE 9: DISCONTINUED OPERATIONS

On December 16, 2015, the Company entered into a Stock Purchase Agreement (the “Purchase Agreement”) with the NRLBH and NRL Investment Group, LLC (the “NRL Group”) pursuant to which the Company sold to the NRL Group all of its shares of common stock in the NRLBH as of that date. Under the terms of the Purchase Agreement, the Company retained its ownership of the Preferred Stock of the NRLBH, which constitutes approximately 19% of the outstanding capital stock of the NRLBH, and which the Company will have the right to sell to the NRL Group on or after the fourth anniversary of the Purchase Agreement at the greater of $4,000,000 or fair market value. The Company has the right to receive earn-out payments from NRL Group starting in December 2016 up to a total of $10,000,000. The earn-out payments are payable to us each calendar month commencing with December 2016 and are 6% of NRLBH gross sales calculated in accordance with U.S. Generally Accepted Accounting Principles. No earn-out payments have been received to date. The Company concluded that the operations of the NRLBH sold to the NRL Group were accounted for as discontinued operations as the operations and cash flows of the discontinued company

were eliminated from ongoing operations of the Company and there would not be significant involvement in the NRLBH's operations after the disposal transaction.

During the year ended December 31, 2015 the Company completed its obligations under the Purchase Agreement with the NRL and recognized a loss on disposal of assets of $670,943 within discontinued operations as detailed below:

	Year Ended December 31, 2015
Proceeds recognized pursuant to Stock Purchase Agreement	$ 50,000
Investment in NRL	11,728
Less carrying value of assets sold and liabilities assumed:	
Accounts receivable	(923,266)
Intangible assets	(20,949)
Property and equipment	(314,628)
Other assets	(62,854)
Liabilities assumed by buyer	589,026
Net loss on disposal of assets	$ 670,943

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

	For the Year Ended December 31, 2015
Revenue	$ 5,523,116
Cost of revenue	(3,539,134)
Gross profit	1,983,982
Expenses:	
Selling expenses	(1,303,425)
Research and development expenses	(1,012,392)
General and administrative expenses	(1,665,840)
Loss on disposal	(670,943)
Exit and disposal expenses	(399,399)
Other expense, net	65,881
Net loss from discontinued operations	$ (3,002,136)

NOTE 10: STOCKHOLDERS' EQUITY

The Company is authorized to issue a total of 85,000,000 shares of stock consisting of 75,000,000 shares of common stock, par value $0.015 per share, and 10,000,000 shares of preferred stock, par value $0.001 per share. The Company has designated 750,000 shares of Series-A Junior Participating Preferred Stock, par value $0.001 per share through the filing of a certificate of designation with the Delaware Secretary of State.

On May 19, 2014, the Company adopted a stockholder rights agreement which provides that all stockholders of record on May 26, 2014 received a non-taxable distribution of one preferred stock purchase right for each share of the Company's common stock held by such stockholder. Each right is attached to and trades with the associated share of common stock. The rights will become exercisable only if one of the following occurs: (1) a person becomes an "Acquiring Person" by acquiring beneficial ownership of 15% or more of the Company's common stock (or, in the case of a person who beneficially owned 15% or more of the Company's common stock on the date the stockholder rights agreement was executed, by acquiring beneficial ownership of additional shares representing 2.0% of the Company's common stock then outstanding (excluding compensatory arrangements)), or (2) a person commences a tender offer that, if consummated, would result in such person becoming an Acquiring Person. If a person becomes an Acquiring Person, each right will entitle the holder, other than the Acquiring Person and certain related parties, to purchase a number of shares of the Company's common stock with a market value that equals twice the exercise price of the right. The initial exercise price of each right is $15.00, so each holder (other than the Acquiring Person and certain related parties) exercising a right would be entitled to receive $30.00 worth of the Company's common stock. If the Company is acquired in a merger or similar business combination transaction at any time after a person has become an Acquiring Person, each holder of a right (other than the Acquiring Person and certain related parties) will be entitled

to purchase a similar amount of stock of the acquiring entity.

2015 and 2016 Issuance of Additional Shares to Aspire Capital

During the first quarter of 2015, we sold a total of 176,879 shares of common stock to Aspire Capital Fund, LLC ("Aspire Capital") under the stock purchase agreement dated November 8, 2013 with aggregate gross proceeds to us of $4,292,349. No shares remain available for sale to Aspire Capital under the terms of the November 8, 2013 agreement with them.

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

On November 11, 2015, we terminated the May 26, 2015 agreement with Aspire and entered into a new common stock purchase 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.

During the first quarter of 2016, we sold a total of 405,747 shares of Common Stock to Aspire Capital Fund LLC under the stock purchase agreement dated November 11, 2015 with aggregate gross proceeds to the Company of $2,177,083, or net proceeds of $2,133,973 after deducting costs of the offering.

On May 25, 2016, we terminated the November 11, 2015 stock purchase agreement with Aspire Capital and entered into a new common stock purchase agreement with Aspire Capital which provided 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 $10.0 million of shares of our common stock over the 30-month term of the purchase agreement, subject to the terms and conditions set forth therein. 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. As part of the stock purchase agreement we issued 49,736 common shares as a commitment fee. The value of the common shares issued as a commitment fee of $198,523 have been reflected as an addition to common stock of $746 and $197,777 in additional paid in capital which will be amortized over the life of the stock purchase agreement. As of March 10, 2017

no shares of stock have been sold to Aspire Capital under the May 25, 2016 purchase agreement

2015 Offering of Common Stock and Pre-Funded Warrants

In June 2015, the Company entered into a Placement Agent Agreement with Roth Capital Partners, LLC. and Dawson James Securities, Inc. (the "2015 Placement Agents"), pursuant to which the Company issued and sold an aggregate of 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 net proceeds of $5.2 million after deducting $577,790 of offering expenses (the "2015 Offering"). Each Pre-Funded Warrant is exercisable for $0.15 per share. As of December 31, 2015, all of the pre-funded warrants have been exercised.

2016 Public Offering of Common Stock

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

Outstanding Warrants

As of December 31, 2016, warrants to purchase 402,228 shares of common stock were outstanding including:

	Outstanding Warrants to Purchase Shares	Exercise Price	Expiration Date
2011 private placement	283,470	$18.75-24.00	May 8, 2018
Acueity warrants	21,667	75.00	September 30, 2017
2014 public offering	77,790	45.00	January 29, 2019
Placement agent fees for Company's offerings	16,135	32.00 – 186.45	March - November, 2018
Outside consulting	3,166	$63.75	January 14, 2018
	402,228		

NOTE 11: NET LOSS PER SHARE

Basic net loss per common share is computed by dividing net loss attributable to common stockholders by the weighted average number of common shares outstanding. Diluted net loss per common share is computed by dividing net loss attributable to common stockholders by the weighted average number of common shares that would have been outstanding during the period assuming the issuance of common shares for all potential dilutive common shares outstanding. Potential common shares consist of shares issuable upon the exercise of stock options and warrants. Because the inclusion of potential common shares would be anti-dilutive.

The following table sets forth the calculation of basic and diluted net loss per share for the years ended December 31, 2016 and 2015:

	Year Ended December 31,	
	2016	2015
Numerator		
Net loss from continuing operations	$(6,368,885)	$(12,758,187)
Net loss from discontinued operations	-	(3,002,136)
Net Loss	$(6,368,885)	$(15,760,323)
Denominator		
Weighted average common share outstanding used to compute net loss per share, basic and diluted	2,277,775	1,895,168
Net loss per share of common stock, basic and diluted:		
Net loss per share from continuing operations	$(2.80)	$(6.73)
Net loss per share from discontinued operations	-	(1.58)
Net loss per share	$(2.80)	$(8.31)

The following table sets forth the number of potential common shares excluded from the calculation of net loss per diluted share for the years ended December 31, 2016 and 2015 because the effect of them would be anti-dilutive:

	Year Ended December 31,	
	2016	**2015**
Options to purchase common stock	378,924	240,930
Warrants to purchase common stock	402,228	402,228
Total	781,152	643,158

NOTE 12: INCOME TAXES

The Company accounts for income taxes using the asset and liability method, under which deferred income tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between the financial reporting and tax bases of assets and liabilities and are measured using enacted tax rates in effect for the year in which those temporary differences are expected to be recovered or settled. A valuation allowance is provided for the amount of deferred tax assets that, based on available evidence, are not expected to be realized.

The Company did not record an income tax benefit for its losses incurred for the years ending December 31, 2016 or 2015 due to uncertainty regarding utilization of its net operating loss carryforwards and due to its history of losses. The benefit for income taxes differs from the benefit computed by applying the federal statutory rate to loss before income taxes as follows:

	Year Ended December 31,	
	2016	2015
Expected federal income tax benefit at statutory federal rate	$(2,165,421)	$(6,015,321)
Share-based compensation	214,430	194,676
Other permanent items	1,034	17,947
Loss of tax attributes of NRLBH	437,763	
Effect of change in valuation allowance	843,386	5,788,496
Prior year true-up	656,812	-
Other	11,996	14,202
Actual federal income tax benefit	$-	$-

The components of net deferred tax assets are as follows:

	As of December 31,	
	2016	2015
Deferred tax assets, current:		
Accrued bonuses	$207,175	165,642
Obsolete inventory	35,426	35,426
Accrued vacation	32,135	31,896
Valuation allowance, current	(274,736)	(232,964)
Net deferred tax asset, current	-	-
Deferred tax assets, long term:		
Net operating loss carryforwards	16,382,515	15,840,922
Intangible assets, net	949,088	768,232
Share-based compensation	934,995	851,521
Basis difference in fixed assets	53,819	53,819
Contribution, carryforward	315	272
Valuation allowance, long term	(18,283,243)	(17,481,629)
Deferred tax asset, long term	37,489	33,137
Deferred tax liabilities		
Other	(37,489)	(33,137)
Net deferred tax asset, long term	-	-
Net deferred tax asset	$-	$-

The Company has incurred net operating losses from inception. At December 31, 2016, the Company had domestic federal net operating loss carryforwards of approximately $48.6 million, which are available to reduce future taxable income. These federal net operating loss carryforwards, expire at various dates beginning in 2030 through 2037. The Company recorded a valuation allowance against all of its net deferred tax assets of approximately $18.3 million and

$17.5 million as of December 31, 2016 and 2015, respectively, for a net increase of $0.8 million from 2015.

Based on an assessment of all available evidence including, but not limited to the Company's limited operating history in its core business and lack of profitability, uncertainties of the commercial viability of its technology, the impact of government regulation and healthcare reform initiatives, and other risks normally associated with biotechnology companies, the Company has concluded that it is more likely than not that these net operating loss carryforwards and credits will not be realized and, as a result, a full valuation allowance has been recorded against the Company's deferred income tax assets. Utilization of the net operating loss carryforwards may be subject to a substantial annual limitation due to ownership change limitations that may have occurred or that could occur in the future, as required by the Internal Revenue Code Section 382. In general, an "ownership change," as defined by the code, results from a transaction or series of transactions over a three-year period resulting in an ownership change of more than 50 percentage points of the outstanding stock of a company by certain stockholders or public groups. Any limitation may result in expiration of all or a portion of the net operating loss carryforwards before utilization.

The Company files income tax returns in the U.S. The Company is subject to tax examinations for the 2011 tax year and beyond. The Company has no unrecognized tax positions and does not believe there will be any material changes in its unrecognized tax positions over the next 12 months. The Company has not incurred any interest or penalties related to unrecognized tax positions. In the event that the Company is assessed interest or penalties at some point in the future, they will be classified in the financial statements as general and administrative expense.

NOTE 13: CONCENTRATION OF CREDIT RISK

Financial instruments that potentially subject the Company to concentration of credit risk consist principally of cash deposits. Accounts at each institution are insured by the Federal Deposit Insurance Corporation ("FDIC") up to $250,000. As of December 31, 2016 and 2015, the Company had $2,777,962 and $3,465,895 in excess of the FDIC insured limit, respectively.

NOTE 14: COMMITMENTS AND CONTINGENCIES

Lease Commitments

The future minimum lease payments due subsequent to December 31, 2016 under all non-cancelable operating leases for the next five years are as follows: For the year ending December 31, 2017, $23,470 and zero for all subsequent years.

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The total rent expense for the years ended December 31, 2016 and 2015 was $325,960 and $234,322, respectively. Rent expense was included in general and administrative expenses for both years.

Purchase Commitments

Effective May 19, 2016 the Company entered into a services agreement with KriSan Biotech Co. Ltd., a corporation organized under the laws of Taiwan, Republic of China ("KSB"). The agreement directs KSB to research and develop for the Company processes for manufacturing endoxifen and to produce an initial supply of endoxifen so that release and stability studies may be conducted. The Company has agreed to pay $136,000 to KSB when certain benchmarks have been delivered by KSB under the services agreement.

Besins Healthcare Luxembourg SARL Agreement

On May 14, 2015, the Company entered into an Intellectual Property License Agreement with Besins Healthcare Luxembourg SARL. The agreement provides the Company with an exclusive worldwide license to develop and commercialize Besins' patented gel formulation of 4-Hydroxytamoxifen, or Afimoxifene Topical Gel, for the potential treatment and prevention of hyperplasia of the breast.

On January 28, 2016, the Company filed a complaint in the United States District Court for the District of Delaware captioned *Atossa Genetics Inc. v. Besins Healthcare Luxembourg SARL*, Case No. 1:16-cv-00045-UNA. The complaint asserts claims for breach of contract, breach of the implied covenant of good faith and fair dealing, and for declaratory relief against Defendant Besins Healthcare Luxembourg SARL ("Besins"). The complaint was served upon Besins on February 15, 2016. The Company's claims arise from Besins' breach of an Intellectual Property License Agreement dated May 14, 2015 (the "License Agreement"), under which Besins licensed to the Company the worldwide exclusive rights to develop and commercialize Afimoxifene Topical Gel, or AfTG, for the potential treatment and prevention of hyperplasia of the breast. The complaint seeks compensatory damages, a declaration of the parties' rights and obligations under the License Agreement, and injunctive relief. On March 7, 2016, Besins filed its response to the Company's complaint, generally denying liability for the Company's claims and asserting counterclaims for breach of contract, fraud, negligent misrepresentation, and declaratory judgment. Besins seeks unspecified money damages and preliminary and permanent injunctive relief, among other forms of relief, for its counterclaims. The Company filed its 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, the parties entered into a settlement agreement pursuant to which the parties dismissed this legal action and have settled all claims and counterclaims. Pursuant to the settlement agreement, Besins assumed, and Atossa shall have no further rights to, 4-hydroxy tamoxifen and AfTG in return for a termination payment to Atossa in the total amount of approximately $1.8 million. The termination payment was received in August 2016 and has been included in other income on the Condensed Consolidated Statement of Operations for year ended December 31, 2016.

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Columbia University Agreement

On February 29, 2016, the Company entered into a Company sponsored agreement with Columbia University Medical Center (CUMC) related to the ATOS-2015-007 clinical study of intraductal administration of fulvestrant in patients with DCIS and invasive breast cancer, which CUMC is conducting with Dr. Sheldon Feldman as the principal investigator. Under this agreement, the Company is obligated to pay to CUMC non-refundable start-up fees of approximately $23,000, patient enrollment fees of approximately $15,000/patient for 30 patients, and other pass through costs of approximately $30,000. The Company may be required to pay an additional fee up to $4,600 per patient who is screened but does not meet the entry criteria for the trial (screen failure). The anticipated screen failure rate is about 25%. The agreement terminates on completion of the clinical trial unless terminated earlier by Atossa for any reason or by either party for material breach or reasons of patient safety. The Company is in the process of moving this study to Montefiore Medical Center.

Litigation and Contingencies

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

On February 14, 2014, the Court appointed plaintiffs Miko Levi, Bandar Almosa and Gregory Harrison (collectively, the "Levi Group") as lead plaintiffs, and approved their selection of co-lead counsel and liaison counsel. The Court also amended the caption of the case to read In re Atossa Genetics, Inc. Securities Litigation. No. 2:13-cv-01836-RSM. An amended complaint was filed on April 15, 2014. The Company and other defendants filed motions to dismiss the amended complaint on May 30, 2014. The plaintiffs filed briefs in opposition to these motions on July 11, 2014. The Company replied to the opposition brief on August 11, 2014. On October 6, 2014 the Court granted defendants' motion dismissing all claims against Atossa and all other defendants. The Court's order provided plaintiffs with a deadline of October 26, 2014 to file a motion for leave to amend their complaint and the plaintiffs did not file such a motion by that date. On October 30, 2014, the Court entered a final order of dismissal. On November 3, 2014, plaintiffs filed a notice of appeal with the Court and have appealed the Court's dismissal order to the U.S. Court of Appeals for the Ninth Circuit. On February 11, 2015, plaintiffs filed their opening appellate brief. Defendants' filed their answering brief on April 13, 2015, and plaintiffs filed their reply brief on May 18, 2015. A hearing for the appeal has been set to

begin on May 18, 2017.

The Company believes these lawsuits are without merit and plans to defend itself vigorously; however, failure by the Company to obtain a favorable resolution of the claims set forth in the complaint could have a material adverse effect on the Company’s business, results of operations and financial condition. Currently, the amount of such material adverse effect cannot be reasonably estimated, and no provision or liability has been recorded for these claims as of December 31, 2016. The costs associated with defending and resolving the lawsuit and ultimate outcome cannot be predicted. These matters are subject to inherent uncertainties and the actual cost, as well as the distraction from the conduct of the Company’s business, will depend upon many unknown factors and management’s view of these may change in the future.

NOTE 15: STOCK BASED COMPENSATION

Stock Options and Incentive Plan

On September 28, 2010, the Board of Directors approved the adoption of the 2010 Stock Option and Incentive Plan, or the 2010 Plan, to provide for the grant of equity-based awards to employees, officers, non-employee directors and other key persons providing services to the Company. Awards of incentive options may be granted under the 2010 Plan until September 2020. No other awards may be granted under the 2010 Plan after the date that is 10 years from the date of stockholder approval. An aggregate of 66,667 shares were initially reserved for issuance in connection with awards granted under the 2010 Plan.

The following table presents the automatic additions to the 2010 Plan since inception pursuant to the “evergreen” terms of the 2010 Plan:

January 1,	Number of shares
2012	30,018
2013	34,452
2014	49,532
2015	65,557
2016	220,419
Total additional shares	399,978

The Company granted options to purchase 185,245 shares of common stock to employees and directors and issued zero shares of common stock in connection with the exercise of directors stock options during the year ended December 31, 2016. There are 156,388 options available for grant under the 2010 Plan as of December 31, 2016, and as a result of the evergreen provision contained in the 2010 Plan, an additional 151,477 shares were added to the 2010 Plan on January 1, 2017.

Compensation costs associated with the Company’s stock options are recognized, based on the grant-date fair values of these options, over the requisite service period, or vesting period. Accordingly, the Company recognized stock based compensation expense of $876,189 and $840,103 for the years ended December 31, 2016 and 2015, respectively, which was included in the following captions in the consolidated statements of operations.

	Year Ended December 31,	
	2016	2015
General and administrative	$ 850,378	$ 747,255
Research and development	25,811	67,475
Selling	-	25,373
Total stock compensation expense	$ 876,189	$ 840,103

The fair value of stock options granted for the years ended December 31, 2016 and 2015 was calculated using the Black-Scholes option-pricing model applying the following assumptions:

	Year ended December 31,	
	2016	2015
Risk free interest rate	1.48% - 1.55%	1.64% - 1.82%
Expected term	5.58- 6.06 years	5.31 - 6.61 years
Dividend yield	- %	- %
Expected volatility	115.52% - 115.58%	105.00% - 115.01%

Options issued and outstanding as of December 31, 2016 and their activities during the year then ended are as follows:

	Number of Underlying Shares	Weighted-Average Exercise Price Per Share	Weighted-Average Contractual Life Remaining in Years	Aggregate Intrinsic Value
Outstanding as of January 1, 2016	240,930	$ 38.89		$ -
Granted	185,245	3.90		-
Forfeited	(47,251)	23.85		-
Expired	-	69.15		-
Outstanding as of December 31, 2016	378,924	26.25	7.08	$ -
Exercisable as of December 31, 2016	272,998	37.80	5.74	$ -
Vested and expected to vest [1]	327,101	$ 28.65	6.82	$ -

[1] vested shares and unvested shares after a forfeiture rate is applied

At December 31, 2016, there were 105,926 unvested options outstanding and the related unrecognized total compensation cost associated with these options was $976,056. This expense is expected to be recognized over a weighted-average period of 1.91 years.

NOTE 16: RELATED PARTY TRANSACTIONS

Shu-Chih Chen, Ph.D., a member of the Board of Directors and spouse of Steve C. Quay, Ph.D., M.D., the Company's CEO, has provided consultancy services to the Company. Those services primarily include providing scientific and technical expertise in Atossa's negotiations and ongoing arrangements with the manufacturer of endoxifen which is located in Taiwan. The cost of the services provided by Dr. Chen are approximately $27,000 through December 31, 2016 and have been approved by the Company's audit committee.

Ensisheim Partners LLC, which is under sole ownership and control by Drs. Quay and Chen, purchased the following shares of common stock directly from the Company in at-the-market transactions which were approved by the Company's audit committee:

Purchase Date	Number of Shares	Price per Share
January 19, 2016	3,333	$ 3.30
February 16, 2016	1,000	$ 7.95
March 9, 2016	1,000	$ 5.55

SIGNATURES

Pursuant to the requirements Section 13 or 15(d) of the Securities Exchange Act of 1934, the issuer, a corporation organized and existing under the laws of the State of Delaware, has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized in the City of Seattle, State of Washington, on the 16th day of March, 2017.

Atossa Genetics Inc.

By: /s/ Steven C. Quay
Steven C. Quay, M.D., Ph.D.
Chairman, Chief Executive Officer and President

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints Steven C. Quay and Kyle Guse and each of them acting individually, as his true and lawful attorneys-in-fact and agents, each with full power of substitution, for him in any and all capacities, to sign any and all amendments to this report on Form 10-K and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, with full power of each to act alone, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully for all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or his or their substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this Annual Report on Form 10-K has been signed by the following persons in the capacities and on the dates indicated

Signature	**Office(s)**	**Date**
/s/ Steven C. Quay **Steven C. Quay, M.D., Ph.D.**	Chairman, Chief Executive Officer and President (Principal Executive Officer)	March 16, 2017
/s/ Kyle Guse **Kyle Guse**	Chief Financial Officer, General Counsel and Secretary (Principal Financial and	March 16, 2017

	Accounting Officer)	
/s/ Richard I. Steinhart **Richard I. Steinhart**	Director	March 16, 2017
/s/ Shu-Chih Chen **Shu-Chih Chen, Ph.D.**	Director	March 16, 2017
/s/ Gregory Weaver **Gregory Weaver**	Director	March 16, 2017
/s/ Stephen J. Galli **Stephen J. Galli, M.D.**	Director	March 16, 2017
/s/ H. Lawrence Remmel **H. Lawrence Remmel**	Director	March 16, 2017

EXHIBIT INDEX

Exhibit No.	Description	Incorporated by Reference Herein Form	Date
1.1	Underwriting Agreement between the Company and Aegis Capital Corp., dated August 30, 2016	Current Report on Form 8-K, as Exhibit 1.1	September 2, 2016
3.1	Amended and Restated Certificate of Incorporation of Atossa Genetics Inc.	Registration Statement on Form S-1, as Exhibit 3.2	June 11, 2012
3.2	Certificate of Amendment to Amended and Restated Certificate of Incorporation of Atossa Genetics Inc.	Current Report on Form 8-K, as Exhibit 4.1	August 26, 2016
3.3	Bylaws of Atossa Genetics Inc.	Registration Statement on Form S-1, as Exhibit 3.4	June 11, 2012
3.4	Amendment to Bylaws of Atossa Genetics Inc.	Current Report on Form 8-K, as Exhibit 3.1	December 20, 2012
3.5	Certificate of Designation, Preferences, and Rights of Series A Junior Participating Preferred Stock of Atossa Genetics, Inc.	Current Report on Form 8-K, as Exhibit 3.1	May 22, 2014
4.1	Specimen common stock certificate	Registration Statement on Form S-1, as Exhibit 4.1	May 21, 2012
4.2	Form of Warrant from 2011 private placement	Registration Statement on Form S-1, as Exhibit 4.2	October 4, 2012
4.3	Form of Placement Agent Warrant from 2011 private placement	Registration Statement on Form S-1, as Exhibit 4.3	October 4, 2012
4.4	Form of Warrant dated September 30, 2012	Registration Statement on Form S-1, as Exhibit 4.4	October 4, 2012

4.5	Registration Rights Agreement, dated as of May 25, 2016, by and between the Company and Aspire Capital Fund, LLC.	Current Report on Form 8-K, as Exhibit 4.1	May 27, 2016
4.6	Form of Warrant Agreement from January 2014 Public Offering	Current Report on Form 8-K, as Exhibit 4.1	January 20, 2014
4.7	Form of Warrant issued to Dawson James Securities Inc. in January 2014	Current Report on Form 8-K, as Exhibit 4.2	January 20, 2014
4.8	Rights Agreement dated as of May 19, 2014, by and between the Company and VStock Transfer LLC, as rights agent, which includes as Exhibit B the Form of Rights Certificate	Current Report on Form 8-K, as Exhibit 4.1	May 22, 2014
4.9	Form of Pre-Funded Warrant dated June 5, 2015	Current Report on Form 8-K, as Exhibit 4.1	June 10, 2015
10.1#	Restated and Amended Employment Agreement with Steven Quay	Registration Statement on Form S-1, as Exhibit 10.3	February 14, 2012
10.2#	Restated and Amended Employment Agreement with Shu-Chih Chen	Registration Statement on Form S-1, as Exhibit 10.4	February 14, 2012
10.3	Form of Indemnification Agreement	Registration Statement on Form S-1, as Exhibit 10.5	May 21, 2012

10.4#	Atossa Genetics Inc. 2010 Stock Option and Incentive Plan, as amended	Quarterly Report on Form 10-Q, as Exhibit 10.3	November 14, 2016
10.5#	Form of Incentive Stock Option Agreement	Registration Statement on Form S-1, as Exhibit 10.7	June 11, 2012
10.6#	Form of Non-Qualified Stock Option Agreement for Employees	Registration Statement on Form S-1, as Exhibit 10.8	June 11, 2012
10.7#	Form of Non-Qualified Stock Option Agreement for Non-Employee Directors	Registration Statement on Form S-1, as Exhibit 10.9	June 11, 2012
10.8	Form of Subscription Agreement	Registration Statement on Form S-1, as Exhibit 10.10	February 14, 2012
10.9	Patent Assignment Agreement by and between the Company and Ensisheim Partners, LLC	Registration Statement on Form S-1, as Exhibit 10.12	April 6, 2012
10.10#	Form of Restricted Stock Award Agreement	Registration Statement on Form S-1, as Exhibit 10.13	June 11, 2012
10.11	Office Lease with Sander Properties, LLC, dated March 4, 2011	Registration Statement on Form S-1, as Exhibit 10.20	April 6, 2012
10.12	Office Lease with Sander Properties, LLC, dated July 8, 2011	Registration Statement on Form S-1, as Exhibit 10.21	April 6, 2012
10.13	Office Lease with Sander Properties, LLC, dated September 20, 2011	Registration Statement on Form S-1, as Exhibit 10.22	April 6, 2012
10.14	Sublease with Fred Hutchinson Cancer Research Center, dated December 9, 2011	Registration Statement on Form S-1, as Exhibit 10.23	April 6, 2012

10.15#	Amended and Restated Employment Agreement between the Company and Kyle Guse dated May 18, 2016	Current Report on Form 8-K, as Exhibit 10.1	May 20, 2016
10.16	OwnerChip Program Agreement dated September 1, 2013, between the National Reference Laboratory for Breast Health, Inc. and Affymetrix, Inc.	Quarterly Report on Form 10-Q, as Exhibit 10.1	November 12, 2013
10.17	Office space Lease dated July 18, 2013 between Alexandria (ARE) and the Company.	Annual Report on Form 10-K, as Exhibit 10.33	March 27, 2014
10.18	Common Stock Purchase Agreement, dated as of November 8, 2013, by and between the Company and Aspire Capital Fund, LLC.	Quarterly Report on Form 10-Q, as Exhibit 10.2	November 12, 2013
10.19	Common Stock Purchase Agreement, dated May 26, 2015, between Atossa Genetics Inc. and Aspire Capital Fund, LLC.	Current Report on Form 8-K, as Exhibit 10.1	May 26, 2015
10.20	Common Stock Purchase Agreement, between the Company and Aspire Capital Fund, LLC, dated as of November 11, 2015.	Quarterly Report on Form 10-Q, as Exhibit 10.1	November 12, 2015
10.21	Common Stock Purchase Agreement, between the Company and Aspire Capital Fund, LLC, dated as of May 25, 2016.	Current Report on Form 8-K, as Exhibit 10.1	May 27, 2016
10.22	Lab and Office space Lease Agreement dated March 24, 2014 between Alexandria (ARE) and the Company.	Annual Report on Form 10-K, as Exhibit 10.33	March 27, 2014
10.23#	Offer Letter Agreement with Peter Carbonaro dated May 23, 2013.	Quarterly Report on Form 10-Q, as Exhibit 10.1	May 14, 2014
10.24#	Offer Letter Agreement with Chris Destro dated May 23, 2013.	Quarterly Report on Form 10-Q, as Exhibit 10.2	May 14, 2014
10.25	Severance Agreement and General Release by and between Christopher Destro and Atossa Genetics Inc. Destro executed April 14, 2015.	Current Report on Form 8-K/A, as Exhibit 10.1	April 17, 2015
10.26	Office Space Assignment and Assumption of Lease and Consent to Assignment dated August 8, 2014 between Legacy Group, Inc. and the Company.	Quarterly Report on Form 10-Q, as Exhibit 10.1	August 12, 2014
10.27#	Offer Letter Agreement dated May 23, 2014 between the Company and John Sawyer	Annual Report on Form 10-K, as Exhibit 10.30	March 30, 2015

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10.28	Form of Subscription Agreement dated June 5, 2015	Current Report on Form 8-K, as Exhibit 10.2	June 10, 2015
10.29	Placement Agent Agreement, dated June 5, 2015, among Atossa Genetics Inc., Roth Capital Partners, LLC and Dawson James Securities, Inc.	Current Report on Form 8-K, as Exhibit 10.1	June 10, 2015
10.30	Intellectual Property License Agreement between Atossa Genetics Inc. and Besins Healthcare Luxembourg SARL, dated May 14, 2015.	Current Report on Form 8-K, as Exhibit 10.1	May 18, 2015
10.31	Settlement and Termination of License Agreement between Besins Healthcare Luxembourg SARL and its Affiliates and Atossa Genetics, Inc. dated August 4, 2016.	Current Report on Form 8-K, as Exhibit 10.1	August 5, 2016
10.32	Stock Purchase Agreement by and among the Company, the National Reference Laboratory for Breast Health, Inc. and NRL Investment Group, LLC, dated December 16, 2015.	Current Report on Form 8-K, as Exhibit 10.1	December 16, 2015
10.33	Office space Lease Agreement dated October 1, 2015 between Hughes-Northwest and the Company.	Annual Report on Form 10-K, as Exhibit 10.35	March 30, 2016
22.1	List of Subsidiaries	Filed herewith	
23.1	Consent of BDO USA LLP	Filed herewith	
24.1	Powers of Attorney	Filed herewith on the signature page	
31.1	Certification pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934 of Steven C. Quay	Filed herewith	
31.2	Certification pursuant to Rule 13a-14(a) under the Securities Exchange Act of Kyle Guse	Filed herewith	
32.1	Certification pursuant to 18 U.S.C. Section 1350 of Steven C. Quay	Filed herewith	
32.2	Certification pursuant to 18 U.S.C. Section 1350 of Kyle Guse	Filed herewith	
101.INS	XBRL Instance Document		
101.SCH	XBRL Taxonomy Extension Schema Document		
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document		

101.DEF XBRL Taxonomy Extension Definition Linkbase Document

101.LAB XBRL Taxonomy Extension Labels Linkbase Document

101.PRE XBRL Taxonomy Extension Presentation Linkbase Document

# Indicates management contract or compensatory plan, contract or agreement.
†† Schedules and exhibits omitted pursuant to Item 601 of Regulation S-K.