ATOSSA GENETICS INC
Form 10-K
March 28, 2019

Table of Contents

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark one)

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

For the fiscal year ended December 31, 2018

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: **(206) 325-6068**

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

Title of each class	Name of each exchange on which registered
Common Stock, $0.18 par value	The NASDAQ Capital Market

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes No

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically, if any, every Interactive Data File required to be submitted 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 such files). Yes No

1

Table of Contents

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.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer Accelerated filer Non-accelerated filer Smaller reporting company

Emerging growth company

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

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

As of June 30, 2018, the last business day of the registrant’s most recently completed second fiscal quarter, the aggregate market value of the voting and non-voting common equity held by non-affiliates was $4,874,099. 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 $0.18, as of March 25, 2019 was 9,116,490.

Table of Contents

ATOSSA GENETICS INC.
2018 FORM 10-K REPORT
TABLE OF CONTENTS

Table of Contents

NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

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

our ability to successfully initiate and complete clinical trials of our pharmaceutical candidates under development, including our oral and topical Endoxifen (an active metabolite of Tamoxifen) and our intraductal microcatheters to administer therapeutics, including our study using fulvestrant;

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

whether we will successfully complete our clinical study of topical Endoxifen to reduce mammographic breast density and whether the study will fail to achieve its objective, including because some participants have discontinued the study prior to completing the full six months of dosing because of skin irritation issues or for other reasons;

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;

4

Table of Contents

our ability to successfully defend litigation and other similar complaints that may be brought in the future, in a timely manner and within the coverage, scope and limits of our insurance policies;

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

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

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

whether the final study results will vary from preliminary study results that we may announce;

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

our ability to attract and retain key personnel; and

our ability to raise capital.

This Annual Report also contains estimates and other statistical data provided by third parties and by us relating to market size and growth and other industry data. These and other forward-looking statements are presented as of the date on which the statements are made. We have included important factors in the cautionary statements included in this Annual Report, particularly in the section titled “ITEM 1A. RISK FACTORS,” that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any new information, future events or circumstances that may affect our business after the date of this Annual Report. Except as required by law, we do not intend to update any forward-looking statements after the date on which the statement is made, whether as a result of new information, future events, circumstances or otherwise.

CORPORATE INFORMATION

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

Unless otherwise noted, the term “Atossa Genetics” “Atossa,” the “Company,” “we,” “us,” and “our” refers to Atossa Genetics Inc., a Delaware corporation. We were incorporated in Delaware in April 2009. Our principal executive offices are located at 107 Spring Street, Seattle, Washington 98104, and our telephone number is 206-325-6086.

Our name and logo, Atossa, and Atossa Genetics (stylized) are our registered trademarks. This report also includes additional trademarks, trade names and service marks of third parties, which are the property of their respective owners. You are advised to read this Annual Report on Form 10-K in conjunction with other reports and documents that we file from time to time with the Securities and Exchange Commission (the “SEC”). In particular, please read our definitive proxy statement, which will be filed with the SEC in connection with our 2019 Annual Meeting of Stockholders, our Quarterly Reports on 10-Q and any Current Reports on Form 8-K, and any amendments thereto, 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.

Table of Contents

PART I

ITEM 1. BUSINESS

Overview

Company Overview

We are a clinical-stage biopharmaceutical company focused on developing novel, proprietary therapeutics and delivery methods for the treatment of breast cancer and other breast conditions. Our lead program is the development of Endoxifen, which is an active metabolite of tamoxifen, an FDA-approved drug to treat and prevent breast cancer. We are developing an oral and topical form of Endoxifen. Our Endoxifen is being developed to potentially treat a number of conditions, including: mammographic breast density (or, MBD); breast cancer in the "window of opportunity" between diagnosis of breast cancer and surgery; gynecomastia, which is male breast enlargement; and the recurrence of breast cancer in patients who do not benefit from taking tamoxifen meaning that they are "refractory" to tamoxifen. We are also developing our patented intraductal microcatheter technology to potentially target the delivery of therapies, including fulvestrant, immunotherapies and Chimeric Antigen Receptor T-cell therapies (CAR-T therapies), directly to the site of breast cancer.

In 2017, we completed a Phase 1 placebo-controlled clinical study of our proprietary oral and topical formulations of Endoxifen in 48 healthy women. All objectives were met: there were no clinically significant safety signals and no clinically significant adverse events, and both the oral and topical Endoxifen were well tolerated. In the topical arm of the study, low but measurable Endoxifen levels were detected in the blood in a dose-dependent fashion. In the oral arm of the study, participants exhibited dose-dependent Endoxifen levels that met or exceeded the published therapeutic level. The median time for patients in the study to reach the steady-state serum levels of Endoxifen while taking daily doses of oral Endoxifen was 7 days. Published literature indicates that it takes approximately 50-200 days for patients to reach steady-state Endoxifen levels from daily doses of oral tamoxifen. In September 2018, we completed a Phase 1 placebo-controlled clinical study of our proprietary topical Endoxifen in 24 healthy men. All of our objectives of safety, tolerability and pharmacokinetics were successfully met.

We are currently conducting two Phase 2 studies of our proprietary Endoxifen: one in Stockholm, Sweden using our topical Endoxifen for reduction of MBD and another in Australia using our oral Endoxifen for patients in the window of opportunity between diagnosis of breast cancer and surgery. In October 2018, the MBD study in Sweden was fully-enrolled with all 90 participants: 60 participants on two different dose levels and 30 participants on placebo. We expect dosing in this study to be completed in April 2019 and to report preliminary results in the second quarter 2019.

In December 2018, we began providing our oral Endoxifen to a pre-menopausal, estrogen-receptor positive (ER+), lacking CYP2D6 function, breast cancer patient under an FDA-approved "expanded access" program. The purpose of this therapeutic approach was to reduce activity of the cancer cells prior to surgery. The patient received daily doses of our oral Endoxifen for approximately three weeks prior to surgery. There were no safety or tolerability issues and her surgery was successfully completed. The cancer cell biological activity was reduced, based on the estrogen receptor activity of the tumor cells and a 50% reduction in Ki-67. The FDA has also issued a "safe to proceed" letter allowing the patient to continue oral Endoxifen therapy post-surgery. Under the FDA expanded access IND program, the use of our proprietary oral Endoxifen is restricted solely to this patient.

Table of Contents

We are currently conducting a Phase 2 study at Montefiore Medical Center, Bronx, New York, using our intraductal microcatheter technology to deliver fulvestrant directly to the site of the tumor via the breast ducts. Our program to use our intraductal microcatheters to deliver CAR-T and other immunotherapies is in the pre-clinical phase.

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

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

Our Programs Under Development

Endoxifen

Background

Oral tamoxifen has been widely used for over 40 years to both treat and prevent breast cancer. It is a “pro-drug”, in that it must be metabolized into active components (“metabolites”) in order to be effective. One of these active metabolites is endoxifen. Despite the success of tamoxifen in reducing the risk of estrogen-receptor-positive breast cancer, its systemic side effects have led to generally low acceptance. These systemic side effects relate to estrogen agonist activity on the endometrium and the activation of coagulation pathways, leading to an increased risk of uterine events and thromboembolism. Hot flashes and vaginal symptoms are additional barriers to acceptance.

Up to 50% of breast cancer survivors who are taking tamoxifen do not produce therapeutic endoxifen levels (meaning they are “refractory”) for a number of reasons including that they, due to their genotype, do not have the requisite liver enzymes. Additionally, it can take from 50-200 days for tamoxifen to reach “steady-state” meaning that the drug may be providing little or no benefit for up to several months after starting treatment. By providing endoxifen directly to the body, a steady-state is achieved within ~7 days.

Phase 1 Studies

In 2017 we completed a comprehensive Phase 1 study in 48 healthy women in Australia using both the topical and oral forms of our proprietary Endoxifen. The objectives of this double-blinded, placebo-controlled, Phase 1 study were to assess the pharmacokinetics of our proprietary Endoxifen dosage forms as single (oral) and repeat (oral and topical) doses, as well as to assess safety and tolerability. The study was conducted in two parts based on route of administration.

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

Table of Contents

Potential Treatment of MBD

Legislation that has been recently enacted in approximately 35 states requiring that women be notified if they have MBD and those notifications typically state that women with MBD have a higher risk of developing breast cancer, and that mammography may not be as effective in detecting breast cancer because the MBD can “mask” the detection of cancers. In February 2019, Federal legislation was enacted that requires that the FDA adopt rules requiring that mammography reports include information about breast density and inform women about their breast density.

We estimate that approximately ten million women in the Unites States have MBD, for which there is no FDA-approved treatment. Although oral tamoxifen is approved to prevent breast cancer in “high-risk” women (usually described as having been diagnosed with estrogen receptor positive breast cancer), it is used by less than 5% of women with an increased risk of developing breast cancer because of the actual or perceived side effects and risks of tamoxifen. We believe our Endoxifen may provide an option for women to proactively reduce the density of their breasts. Moreover, our Endoxifen may improve mammography accuracy and patient care by unmasking cancerous tumors that are otherwise hidden by breast density. In two separate reports of film-screen mammography, mammographic sensitivity decreased from a level of 85.7%–88.8% in patients with almost entirely fatty tissue to 62.2%–68.1% in patients with extremely dense breast tissue.

In September 2017, we contracted Stockholm South General Hospital in Sweden to conduct a Phase 2 study of our topical Endoxifen in women with high MBD. The study is being led by principal investigator Dr. Per Hall, MD, Ph.D., Head of the Department of Medical Epidemiology and Biostatistics at Karolinska Institutet. The primary endpoint of this pilot study is to determine if topical Endoxifen results in an individual reduction of MBD as measured by mammography. Secondary endpoints include demonstrating safety and tolerability. The primary objective is to determine the effect size of breast density between placebo and topical Endoxifen to permit sample size calculations for statistical significance in a future Phase 3 trial. The study was fully enrolled in October 2018 with 90 participants who were equally randomized to three different groups (30 per group): placebo; lower dose topical Endoxifen; and higher dose topical Endoxifen. Participants receive the active drug or placebo for a maximum of six months. The study calls for each participant to have a baseline (pre-treatment) mammogram, and additional mammograms at month 3 and 6, or at the time of study exit. Once the study has been completed, all mammograms will be interpreted and MBD determined and any changes that occur per patient recorded. Some participants have chosen to exit the study before receiving a full six months of drug or placebo for a number of reasons: for example, some exit for non-compliance with the study protocol and some have exited because of skin rashes and irritation. As of the date of this annual report, approximately 72 participants have exited the study primarily because of skin rashes and irritation. Because the study is double blinded and results-to-date are not known, we do not know how or if the fact that some study participants exited the study before six months of dosing will result in sufficient data to achieve the primary objective which is to design a subsequent study. We expect that all dosing in the study will be completed in April 2019 with preliminary result to be reported in the second quarter of 2019.

Refractory Patients

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

Table of Contents

In December 2018, we began providing our oral Endoxifen to a pre-menopausal, estrogen-receptor positive (ER+) breast cancer patient under an FDA-approved "expanded access" program. The purpose of this therapeutic approach was to reduce activity of the cancer cells prior to surgery. The patient received daily doses of our oral Endoxifen for approximately three weeks prior to surgery. There were no safety or tolerability issues and her surgery was completed successfully. To determine if the oral Endoxifen reduced the biological activity of the cancer cells, the test results obtained from the initial biopsy were compared with those from the specimen obtained during surgery. There were no safety or tolerability issues and her surgery was successfully completed. The cancer cell biological activity was reduced, based on the estrogen receptor activity of the tumor cells and a 50% reduction in Ki-67. Under the FDA expanded access IND program, the use of our proprietary oral Endoxifen is restricted solely to this patient.

Window of Opportunity

We are also currently conducting a Phase 2 study of our oral Endoxifen in Australia in the window of opportunity between diagnosis of breast cancer and surgery. The Pilot Phase of the study will initially enroll up to eight newly-diagnosed patients with ER+ and HER2 negative (HER2-) stage 1 or 2 invasive breast cancer, requiring mastectomy or lumpectomy. Patients will receive our proprietary oral Endoxifen for at least 21 days from the time of diagnosis up to the day of surgery. Provided tumor activity reduction is demonstrated in at least two patients, an additional 17 patients will be enrolled for a total of 25. The primary endpoint is to determine if the administration of oral Endoxifen reduces the tumor activity as measured by Ki-67 (a measure of cellular proliferation that correlates with tumor growth). The secondary endpoints are safety and tolerability and assessment of the study drug on expression levels of both estrogen and progesterone receptors. The impact on additional markers of cellular activity will also be explored. The Phase 2 study is being conducted on behalf of Atossa by Avance Clinical (formerly CPR Pharma Services Pty Ltd.), Thebarton, SA, Australia. Avance Clinical recently completed the successful Phase 1 study of our oral and topical Endoxifen.

Proprietary Intraductal Delivery Technology

We believe intraductal delivery technology may be useful in delivering CAR-T, immunotherapies and a number of drugs to the ducts in the breast, the site of the majority of early breast cancers. Doing so is intended to provide a therapeutic directly to the breast tissue while at the same time reducing delivery of the drug to healthy tissue. We must obtain FDA approval of any therapy delivered via intraductal delivery technology, which will require expensive and time-consuming studies in the current regulatory framework. For example, we must complete clinical studies to demonstrate the safety and tolerability of fulvestrant using our delivery method. We may not be successful in completing these studies or obtaining approval from the FDA or other applicable foreign regulatory authority.

Breast cancers and precancerous lesions are typically treated with systemically administered agents such as tamoxifen, Faslodex®, Perjeta® and Herceptin®. However, these therapies can cause serious side effects which may lead to poor patient compliance with the treatment regimens. Providing therapies directly into the breast ducts targeting the site of

the localized cancerous lesions could reduce the need for systemic anti-cancer therapies, and potentially reduce or eliminate the systemic side effects of the therapies and morbidity in such patients, and ultimately improve patient compliance and ultimately reduce mortality.

Transpapillary CAR-T

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

Table of Contents

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

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

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

Delivery of Drugs via our Microcatheters

The initial drug we are studying using our microcatheters for intraductal delivery is fulvestrant. Fulvestrant is FDA-approved for metastatic breast cancer. It is administered as a monthly injection of two shots, typically into the buttocks, and costs ~$11,000 per dose.

We own several pending patent applications directed to the treatment of breast conditions, including cancer, by the intraductal administration of therapeutics including fulvestrant, and expect to file additional patent applications as and when applicable.

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

Table of Contents

The primary endpoint of the clinical trial is to compare the safety, tolerability and distribution of fulvestrant between the two routes of administration (intramuscular injection or through our microcatheters). The secondary endpoint of the study is to determine if there are changes in the expression of Ki-67 as well as estrogen and progesterone receptors between a pre-fulvestrant biopsy and post-fulvestrant surgical specimens. Digital breast imaging before and after drug administration in both groups will also be performed to determine the effect of fulvestrant on any lesions as well as breast density of the participant.

Other Studies of Intraductal Administration using our Microcatheters

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

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

Markets

Potential Market Opportunities

We believe that, based in part on a January 2017 study by Defined Health Inc., a leading market research firm, the potential U.S. market for intraductal administration of fulvestrant or similar drugs in DCIS patients is up to $800 million annually. This estimate includes treatment of DCIS patients prior to surgery as well as patients who would use

intraductal treatment as an alternative to surgery. We believe that the potential U.S. market for our Endoxifen in the treatment and prevention settings is up to $1 billion annually.

The Breast Cancer and Related Markets

The American Cancer Society ("ACS") estimates that in 2019, 269,000 women will be diagnosed with breast cancer in the United States. Every two minutes an American woman is diagnosed with breast cancer and 42,000 die each year. Although about 100 times less common than in women, breast cancer also affects men. The ACS estimates that the lifetime risk of men getting breast cancer is about 1 in 1,000; 2,670 new cases of invasive breast cancer will be diagnosed in 2019; and 500 men will die from breast cancer in 2019.

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

Our Medical Devices

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

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

Additionally, we, as a pharmaceutical company, are not maintaining the device patents directed to any of our medical devices due to the short patent term remaining on them.

Table of Contents

Our Capital Resources

We have not yet established an ongoing source of revenue sufficient to cover our operating costs and allow us to continue as a going concern. Our ability to continue as a going concern is dependent on obtaining adequate capital to fund operating losses until we become profitable. We plan to obtain additional capital resources by selling our equity securities and borrowing from stockholders or others when needed. However, we cannot assure you that we will be successful in accomplishing any of these plans and, if we are unable to obtain adequate capital, we could be forced to cease operations. We do not anticipate any revenue until our pharmaceutical programs are developed, including receiving all necessary regulatory approvals, and until we successfully commercialize these programs.

As of December 31, 2018, we had cash and cash equivalents of $10,380,493 and in March 2019 we received approximately $11.3 million from the exercise of warrants that were issued on May 30, 2018. Our capital raising activity in 2017 and 2018 consisted of the following (all share and per-share amounts in this report have been adjusted to reflect the 1:12 reverse stock split we effectuated on April 20, 2018):

2017 Financing Activities

On March 28, 2017, the Company entered into an underwriting agreement with Aegis Capital Corp. relating to a public offering which closed on April 3, 2017. The offering generated gross proceeds to the Company of approximately $4.4 million and net proceeds of approximately $3.9 million after deducting underwriting discounts and commissions and other offering expenses paid by the Company.

On October 26, 2017, the Company entered into an underwriting agreement with Maxim Group LLC relating to a public offering of common stock which closed on October 30, 2017. The offering generated gross proceeds to the Company of approximately $5.5 million and net proceeds of $4.9 million after deducting underwriting discounts, commissions and other offering expenses paid by the Company.

On December 20, 2017, the Company entered into a placement agent agreement with Maxim Group LLC relating to the sale of the Company’s securities. Pursuant to the placement agent agreement, on December 20, 2017, the Company entered into a securities purchase agreement with certain purchasers named therein relating to the offering and sale of 441,667 shares of Company common stock at a public offering price of $3.24 per share. The offering generated gross proceeds to the Company of approximately $1.4 million and net proceeds of $1.2 million after deduction of underwriting discounts, commissions, and other offering expenses paid by the Company.

2018 Financing Activities

On May 30, 2018, we completed a rights offering pursuant to which we sold an aggregate of 13,624 units consisting of an aggregate of 13,624 shares of Series B convertible preferred stock, convertible into 3,869,216 shares of common stock, and 3,869,216 warrants, with each warrant exercisable for one share of common stock at an exercise price of $4.048 per share, resulting in net proceeds to us of approximately $12.3 million, after deducting expenses relating to the rights offering, including dealer-manager fees and expenses, and excluding any proceeds received upon exercise of any warrants.

Research and Development Phase

All of our programs are in the pre-clinical or clinical 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, 2018 and 2017 were $4,209,981 and $2,328,087, respectively.

Intellectual Property

Our owned and licensed patents and patent applications are directed to Endoxifen and Fulvestrant, and immunotherapies such as CAR-T therapy. We commonly seek patent claims directed to compositions of matter, including Endoxifen, Fulvestrant, and other Selective Estrogen Receptor Modulators (SERMs), Selective Estrogen Receptor Downregulators (SERDs), and Aromatase Inhibitors (AI), as well as methods of using such compositions. When appropriate, we also seek claims to related technologies, such as treatment methods via transpappillary and intraductal delivery of therapeutics to breast ducts of an individual. For each of our products, we filed and expect to file multiple patent applications . As of February 28, 2019, and based on a recent periodic review of our patent estate, we own 13 issued patents (11 US and 2 international) and 29 pending patent applications (5 in the United States, and 24 international applications) directed to our programs on Endoxifen, Fulvestrant, CAR-T therapeutics and intraductal delivery of therapeutics using devices such as microcatheters. This list above does not identify all patents and patent applications currently in Atossa's patent portfolio. For example, the foregoing patent counts exclude certain applications and device patents with short patent terms remaining on them and those covering our ForeCyte, FullCyte and Acueity devices and various tests that are no longer core to our business. We continue to evaluate our patent portfolio and, as a clinical-stage pharmaceutical company, will no longer maintain our device and test patents and applications.

Of the 29 pending patent applications in Atossa's patent portfolio, 3 of the 5 United States pending applications and 16 of the 24 pending international applications include at least one claim directed to Endoxifen; 4 of the 5 United States pending applications and 16 of the 24 pending international applicatons include at least one claim directed to Fulvestrant; and 1 of the 5 United States pending application and 2 of the 24 international pending applications are directed to our intraductal program delivering CAR-T therapeutics and other immunotherapy.

The following table provides the patent counts[4] related to our programs.

	Pending Applications[1, 2]		Approximate Expiry Date[3]
	U.S.	International	
Endoxifen Program	3	16	2034 - 2037
Fulvestrant Program	4	16	2034 - 2037
Immunotherapy/ CAR-T Program	1	2	2037 - 2038

[1] Each patent application includes at least one claim directed to a listed therapeutic/program.

[2] The patent counts in the table above are greater than the total numbers of the patent applications in the Atossa portfolio as the patent counts in the table above reflect that a patent application may have claims directed to more than one type of therapeutic/program.

[3] The patent counts and the approximate expiry dates disclosed herein and in our patent estate are subject to change, for example, in the event of changes in the law or legal rulings affecting our patents and applications or if we become aware of new information. The standards that the U.S. Patent and Trademark Office, or USPTO, and foreign patent offices use to grant patents are not always applied predictably or uniformly and can change. Consequently, our pending patent applications may not be allowed and, if allowed, may not contain the type and extent of patent claims that will be adequate to conduct our business as planned. Additionally, any issued patents we currently own or obtain in the future may have a shorter patent term than expected or may not contain claims that will permit us to stop competitors from using our technology or similar technology or from copying our products.

[4]The standards that the U.S. Patent and Trademark Office, or USPTO, and foreign patent offices use to grant patents are not always applied predictably or uniformly and can change. Consequently, our pending patent applications may not be allowed and, if allowed, may not contain the type and extent of patent claims that will be adequate to conduct our business as planned. Additionally, any issued patents we currently own or obtain in the future may have a shorter patent term than expected or may not contain claims that will permit us to stop competitors from using our technology or similar technology or from copying our product .

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

Table of Contents

Manufacturing, Clinical Studies and Associated Operations

Our drug development strategy utilizes third party contractors for the procurement and manufacture, as applicable, of raw materials, active pharmaceutical ingredients and finished drug products, as well as for storage, and distribution of our products and associated supply chain operations. We also plan to rely on third parties to conduct pre-clinical and clinical studies of our drugs and microcatheter technology under development. As our development programs advance, we expect that our manufacturing, pre-clinical and clinical studies, and related operational requirements will correspondingly increase. Each third-party contractor undergoes a 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.

Table of Contents

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 a 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 are typically 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.

Table of Contents

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 review user fee to the FDA, which is $2,588,478 for fiscal year 2019. 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.

Table of Contents

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.

Table of Contents

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: 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.

Table of Contents

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. 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.

Further, the EU has recently adopted a comprehensive overhaul of its data protection regime from the current national legislative approach to a single European Economic Area Privacy Regulation, the General Data Protection Regulation 2016/679/EU (“GDPR”), which comes into effect in May 2018. The EU data protection regime extends the scope of the EU data protection law to all foreign companies controlling, processing, and/or using data of EU residents. It imposes a strict data protection compliance regime with severe penalties of up to the greater of 4% of worldwide turnover and €20 million and includes new rights such as the “right to be forgotten” and “portability” of personal data, with more onerous requirements related to pseudo-anonymization and anonymization of personal data. Further, the scope of “personal data” has been expanded to include genetic data, and data concerning health and adverse event reporting from clinical trials. The Company is evaluating its ability and the cost to comply with the new EU regulations. Failure to comply with these laws could lead to government enforcement actions and significant penalties against us, and adversely impact our operating results.

Table of Contents

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.

Table of Contents

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.

Table of Contents

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 (such as the current Directive 95/46/EC and from May 25, 2018, the GDPR) 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. We are evaluating our ability and cost to comply with the new EU GDPR regulations, and as a result of that evaluation we may make changes to our business practices and may incur additional costs.

Table of Contents

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.

Table of Contents

Legal Proceedings

See “Part I, ITEM 3. LEGAL PROCEEDINGS” in this Annual Report, which is incorporated into this Part I, 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.

Executive officers

The names of our executive officers and their ages as of December 31, 2018 are as follows:

Name	Age	Position
Executive Officers:		
Steven C. Quay, M.D., Ph.D.	68	Chairman of the Board, President and Chief Executive Officer
Kyle Guse, Esq., CPA (inactive)	55	Chief Financial Officer, General Counsel and Secretary

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. Dr. Quay is certified in Anatomic Pathology with the American Board of Pathology and completed both an internship and residency in anatomic pathology at Massachusetts General Hospital, a Harvard Medical School teaching hospital. He is a former faculty member of the Department of Pathology, Stanford University School of Medicine. Dr. Quay is an inventor, with 87 U.S. patents, 133 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.

Kyle Guse, Esq., CPA (inactive). Mr. Guse has served as Chief Financial Officer, General Counsel and Secretary since January 2013. His experience includes more than 25 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 (inactive) and member of the Bar 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.

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.

Research and Development Phase

We are in the research and development phase and are not currently marketing any products or services. We do not anticipate generating revenue unless and until we develop and launch our pharmaceutical or device programs.

Table of Contents

ITEM 1A. RISK FACTORS

Purchasing of our shares of common stock is an investment in our securities and involves a high degree of risk. You should carefully consider the following information about these risks, together with the other information contained in this Annual Report, before purchasing 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 is uncertain and cannot be based on prior results. 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:

- commence, execute and 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. 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.

Table of Contents

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

For the year ended December 31, 2018, we incurred a net loss of $11,404,934 and we had an accumulated deficit of $76,831,263. 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 twelve to eighteen 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. We currently have no other products and services approved for commercialization. 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 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.

Table of Contents

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 losses each year. Our net loss for the year ended December 31, 2018 was $11,404,934. 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, damages of an unspecific amount. On March 23, 2018, the parties filed a stipulation of settlement with the court to settle the matter for $3.5 million, completely funded by defendants' insurers, and on July 20, 2018 the Court approved the settlement. This case is considered closed.

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 or through the exercise of warrants currently outstanding or that we may issue in the future, 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.

Table of Contents

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:

an unacceptable safety profile;

lack of efficacy;

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 or “preliminary” 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 or “preliminary” 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.

For example, some participants in the Phase 2 MBD study we are conducting in Stockholm, Sweden have exited the study before completing a full six months of dosing for a number of reasons including because of skin irritation and rashes and, as of the date of filing this Annual Report, approximately 72 of the 90 participants in the study have exited the study. This is a higher rate of attrition than we expected and as a result the study may not produce sufficient data to achieve the primary study objective which is to determine sample size for a subsequent Phase 3 study.

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.

27

Table of Contents

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.

Table of Contents

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 has a goal (but is not required) to take action on an application within a total of eight months (6 months to take action following a 60 day period to determine if the application is acceptable) instead of the 12- months (10 months to take action following a 60 day period to determine if the application is acceptable) 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.

Table of Contents

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.

Table of Contents

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 deliver fulvestrant and we will be substantially dependent on the organizations conducting the clinical trials of our proprietary Endoxifen. 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, CAR-T or other immunotherapy into the desired location, which could lead to ineffective treatment; and
- adverse events related to drugs and therapies 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.

Table of Contents

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 and products 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 products, 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.

Table of Contents

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 under the Leahy-Smith America Invents Act, or the America Invents Act, including changes from a "first-to-invent" system to a "first to file" system, changes to examination of U.S. patent applications and changes to the processes for challenging issued patents. These changes include provisions that affect the way patent applications are being filed, prosecuted and litigated. For example, the America Invents Act enacted proceedings involving post-issuance patent review procedures, such as inter partes review, or IPR, and post-grant review and covered business methods. These proceedings are conducted before the Patent Trial and Appeal Board, or PTAB, of the USPTO. Each proceeding has different eligibility criteria and different patentability challenges that can be raised. In this regard, the IPR process permits any person (except a party who has been

litigating the patent for more than a year) to challenge the validity of some patents on the grounds that it was anticipated or made obvious by prior art. As a result, non-practicing entities associated with hedge funds, pharmaceutical companies who may be our competitors and others have challenged certain valuable pharmaceutical U.S. patents based on prior art through the IPR process. A decision in such a proceeding adverse to our interests could result in the loss of valuable patent rights which would have a material adverse effect on our business, financial condition, results of operations and growth prospects. In any event, the America Invents Act and any other potential future changes to the U.S. patent system could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and growth prospects. 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 and Alice* 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 and Alice* 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. The standards that courts use to interpret patents are not always applied predictably or uniformly and may evolve, particularly as new technologies develop. In addition, changes to patent laws in the United States or other countries may be applied retroactively to affect the validity, enforceability, or term of our patent. For example, the U.S. Supreme Court has modified some legal standards applied by the USPTO in examination of U.S. patent applications, which may decrease the likelihood that we will be able to obtain patents and may increase the likelihood of challenges to patents we obtain or license.

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.

Table of Contents

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 pharmaceuticals, CAR-T cell technology or immunotherapy from a third-party. We may not be able to secure such a license on acceptable terms. Litigation or patent derivation 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.

Table of Contents

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.

Table of Contents

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.

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. In April 2016, the EU adopted the new GDPR to replace the Directive 95/46/EC, which is expected to come into effect in May 2018 with no transition period, and which has enhanced penalties for noncompliance. We are evaluating our ability and cost to comply with the new EU GDPR regulations, and as a result of that evaluation we may make changes to our business practices and may incur additional costs.

Failure to comply with the requirements of the Data Protection Directive (or GDPR when it takes effect), and the related national data protection laws of the E.U. Member States may result in fines and other administrative penalties, litigation, government enforcement actions (which could include civil and/or criminal penalties), and harm our business. Moreover, patients about whom we or our partners obtain information, as well as the providers who share this information with us, may have contractual rights that may limit our ability to use this information, Claims that we have violated patient’s or any individual’s rights or breached our contractual obligations, even if ultimately we are not found liable, could be expensive and time-consuming to defend, and could result in adverse publicity 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.

Table of Contents

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.

If our stock price does not satisfy the $1.00 minimum bid price requirement or we otherwise fail to satisfy other continued listing requirements (and such other continued listing requirements may be enhanced during the period our stock price is below the $1.00 minimum bid requirement including a requirement that we maintain at least $5 million in stockholders' equity rather than the $2.5 million that is typically required for continued listing), 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, holders of our warrants to purchase common stock 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, our warrant holders 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 February 28, 2019, our stock price has ranged from $0.80 to $9.96. 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 warrant holders 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.

Table of Contents

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 may be concentrated among a small number of stockholders. 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.

Table of Contents

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 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.

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 sales of common stock through a 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.

Table of Contents

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 2. PROPERTIES

As of December 31, 2018, we leased a total of approximately 202 square feet of office space in one location in Seattle, Washington, from WW 107 Spring Street LLC. 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 alleged that all defendants violated Sections 11 and 12(a)(2), and that we and certain of our directors and officers violated Section 15, of the Securities Act by making material false and misleading statements and omissions in the offering's registration statement, and that we and certain of our directors and officers violated Sections 10(b) and 20A of the Exchange Act and SEC Rule 10b-5 promulgated thereunder by making false and misleading statements and omissions in the registration statement and in certain of our subsequent press releases and SEC filings with respect to our NAF specimen collection process, our ForeCYTE Breast Health Test and our MASCT device. The complaint sought, on behalf of persons who purchased our common stock between November 8, 2012 and October 4, 2013, inclusive, damages of an unspecific amount. On March 23, 2018, the parties filed a stipulation of settlement with the court to settle the matter for $3.5 million, completely funded by defendants' insurers, and on July 20, 2018 the Court approved the settlement. This case is considered closed.

Table of Contents

ITEM 4. MINE SAFETY DISCLOSURE

Not applicable.

PART II

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

Market Information

Our common stock, par value $0.18 per share, began trading on the NASDAQ Capital Market under the symbol "ATOS" on November 8, 2012.

Stockholders

As of March 25, 2019, there were approximately 33 stockholders of record of our common stock, one of which is Cede & Co., a nominee for Depository Trust Company, or DTC and approximately 15,000 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 stockholder.

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, 2018.

Use of Proceeds

Not applicable.

ITEM 6. SELECTED FINANCIAL DATA

Not applicable.

Table of Contents

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

Overview

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 Annual 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.

Company Overview

We are a clinical-stage biopharmaceutical company focused on developing novel, proprietary therapeutics and delivery methods for the treatment of breast cancer and other breast conditions. Our lead program is the development of Endoxifen, which is an active metabolite of tamoxifen, an FDA-approved drug to treat and prevent breast cancer. We are developing an oral and topical form of Endoxifen. Our Endoxifen is being developed to potentially treat a number of conditions, including: mammographic breast density (or, MBD); breast cancer in the "window of opportunity" between diagnosis of breast cancer and surgery; gynecomastia, which is male breast enlargement; and the recurrence of breast cancer in patients who do not benefit from taking tamoxifen meaning that they are "refractory" to tamoxifen. We are also developing our patented intraductal microcatheter technology to potentially target the delivery of therapies, including fulvestrant, immunotherapies and Chimeric Antigen Receptor T-cell therapies (CAR-T therapies), directly to the site of breast cancer.

In 2017, we completed a Phase 1 placebo-controlled clinical study of our proprietary oral and topical formulations of Endoxifen in 48 healthy women. All objectives were met: there were no clinically significant safety signals and no clinically significant adverse events, and both the oral and topical Endoxifen were well tolerated. In the topical arm of the study, low but measurable Endoxifen levels were detected in the blood in a dose-dependent fashion. In the oral arm of the study, participants exhibited dose-dependent Endoxifen levels that met or exceeded the published therapeutic level. The median time for patients in the study to reach the steady-state serum levels of Endoxifen while taking daily doses of oral Endoxifen was 7 days. Published literature indicates that it takes approximately 50-200 days for patients to reach steady-state Endoxifen levels from daily doses of oral tamoxifen. In September 2018, we completed a Phase 1 placebo-controlled clinical study of our proprietary topical Endoxifen in 24 healthy men. All of our objectives of safety, tolerability and pharmacokinetics were successfully met.

We are currently conducting two Phase 2 studies of our proprietary Endoxifen: one in Stockholm, Sweden using our topical Endoxifen for reduction of MBD and another in Australia using our oral Endoxifen for patients in the window of opportunity between diagnosis of breast cancer and surgery. In October 2018, the MBD study in Sweden was fully-enrolled with all 90 participants: 60 participants on two different dose levels and 30 participants on placebo. We expect dosing in this study to be completed in April 2019 and to report preliminary results in the second quarter 2019.

In December 2018, we began providing our oral Endoxifen to a pre-menopausal, estrogen-receptor positive (ER+), lacking CYP2D6 function, breast cancer patient under an FDA-approved "expanded access" program. The purpose of this therapeutic approach was to reduce activity of the cancer cells prior to surgery. The patient received daily doses of our oral Endoxifen for approximately three weeks prior to surgery. There were no safety or tolerability issues and her surgery was successfully completed. The cancer cell biological activity was reduced, based on the estrogen receptor activity of the tumor cells and a 50% reduction in Ki-67. Under the FDA expanded access IND program, the use of our proprietary oral Endoxifen is restricted solely to this patient.

We are currently conducting a Phase 2 study at Montefiore Medical Center, Bronx, New York, using our intraductal microcatheter technology to deliver fulvestrant directly to the site of the tumor via the breast ducts. Our program to use our intraductal microcatheters to deliver CAR-T and other immunotherapies is in the pre-clinical phase.

Table of Contents

Research and Development Phase

We are in the research and development phase and are not currently marketing any products or services. We do not anticipate generating revenue unless and until we develop and launch our pharmaceutical programs.

Commercial Lease Agreements

On November 1, 2018, the Company entered into an operating lease to pay $3,660 monthly rent for a term of 22 months with WW 107 Spring Street LLC to lease office space at 107 Spring Street, Seattle, Washington.

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.

Table of Contents

Financial Instruments with Characteristics of Both Liabilities and Equity

During the year ended December 31, 2017, the Company issued certain financial instruments, consisting of warrants to purchase common stock, which have characteristics of both liability and equity. Financial instruments such as warrants that are classified as liabilities are fair valued upon issuance and are re-measured at fair value at subsequent reporting periods with the resulting change in fair value recorded in "change in fair value of common stock warrants" in the consolidated statements of operations. The fair value of warrants is estimated using valuation models that require the input of subjective assumptions including stock price volatility, expected life, and the probability of future equity issuances and their impact to the price protection feature. No warrants that are classified as liabilities were outstanding at December 31, 2017 and 2018.

Share-Based Payments

We follow the provisions of ASC 718, *Compensation – Stock Compensation*, 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 with forfeitures recognized when they occur.

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 one to 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.

Table of Contents

Results of Operations

Comparison of Years Ended December 31, 2018 and 2017

Revenue and Cost of Revenue:

For the years ended December 31, 2018 and 2017, we have no source of sustainable revenue and no associated cost of revenue.

Operating Expenses: Total operating expenses were $11,434,000 for the year ended December 31, 2018, which is an increase of $3,785,000 or 49%, from the year ended December 31, 2017. Operating expenses for 2018 consisted of research and development (R&D) expenses of $4,210,000 and general and administrative (G&A) expenses of $7,224,000. Operating expenses for 2017 consisted of R&D expenses of $2,328,000, G&A expenses of $4,859,000 and impairment of our Acueity intangible assets of $462,000.

Research and Development Expenses: R&D expenses for the year ended December 31, 2018, were $4,210,000, an increase of $1,882,000 or 81% from total R&D expenses in 2017 of $2,328,000. The increase in R&D expense is attributed to salaries, stock-based compensation, manufacturing and clinical trial expenses associated with our Endoxifen program. Our R&D expenses have increased because we commenced two Phase 2 studies of our proprietary Endoxifen during the year ended December 31, 2018. There were no Phase 2 studies of Endoxifen in 2017. Stock-based compensation expense also increased approximately $627,000 in 2018 as compared to 2017. We expect our R&D expenses to increase throughout 2019 as we commence additional Phase 2 clinical studies of Endoxifen, continue the clinical trial of Fulvestrant administered via our microcatheters and continue the development of other indications and therapeutics, including CAR-T and immunotherapies administered via our intraductal microcatheters.

General and Administrative Expenses: G&A expenses were $7,224,000 for the year ended December 31, 2018, an increase of $2,365,000, or 49% from the total G&A expenses for the year ended December 31, 2017, of $4,859,000. G&A expenses consist primarily of personnel and related benefit costs, facilities, professional services, insurance, and public company related expenses. The increase in G&A expenses for year ended December 31, 2018, is mainly attributed to an increase in stock-based compensation expense of approximately $1,049,000, payroll expenses resulting from salary increases, one-time bonus payments of $350,000 and increased legal and professional consulting expenses of approximately $600,000 over the prior year.

Impairment of Intangible Assets: During the years ended December 31, 2017, we evaluated our Acueity intangible assets for impairment and concluded that the fair values as of December 31, 2017, were below the carrying values of $462,000. Therefore, we reduced the carrying value of these assets to zero as of December 31, 2017. There were no write downs of intangible assets during the year ended December 31, 2018.

Warrant Financing Costs and Change in Fair Value of Common Stock Warrants: The Company's April 2017 financing included the issuance of common stock liability warrants, which were exercised during 2017 and were no longer outstanding as December 31, 2017. The Company incurred financing costs associated with these common stock liability warrants of $192,817 upon issuance. The Company also recorded changes in the fair value of the liability warrants during the year ended December 31, 2017, of $280,747. There were no common stock liability warrants issued during the year ended December 31, 2018.

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, 2018 and 2017, due to uncertainty regarding utilization of our net operating carryforwards and due to our history of losses.

Table of Contents

Liquidity and Capital Resources

The Company has incurred net losses and negative operating cash flows since inception. For the year ended December 31, 2018, the Company recorded a net loss of approximately $11.4 million and used approximately $9.0 million of cash in operating activities. As of December 31, 2018, the Company had approximately $10.4 million in cash and cash equivalents and working capital of approximately $8.6 million. However, in March 2019, the Company received $11.3 million in cash upon exercises of certain of the Company's previously outstanding warrants to purchase its common stock. As of March 25, 2019, the Company had approximately $19.3 million in cash and cash equivalents. The Company has not yet established an ongoing source of revenue sufficient to cover its operating costs and is currently expending funds in research and development activities that are expected to continue to require funding. Management believes its currently available funding, including the funds received from warrant exercises in March 2019, will be sufficient to finance the Company's operations for at least one year from the date these consolidated financial statements are issued. However, the Company will likely require additional funding to continue its activities beyond that date. If adequate funds are not available, the Company may be required to reduce the scope, delay, or eliminate some or all of its planned commercial activities. The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and the settlement of liabilities in the normal course of business. The consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from uncertainty related to the Company's ability to continue as a going concern.

Cash Flows

As of December 31, 2018, we had cash, cash equivalents and restricted cash of $10.5 million.

Net Cash Flows from Operating Activities: Net cash used in operating activities was $8,962,000 for the year ended December 31, 2018, an increase of $2,368,000, or 36%, compared to net cash used in operating activities for the year ended December 31, 2017 of $6,594,000. The increase in the 2018 period as compared to 2017 resulted primarily from increased spending on R&D activities. We spent approximately $4.2 million on research and development for the year ended December 31, 2018, compared to $2.3 million in 2017. Increases in compensation expense also contributed to the increase in cash used in operations over 2017.

Net Cash Flows from Investing Activities: Net cash used in investing activities for the year ended December 31, 2018 was $111,000. There was no comparable spending for the year ended December 31, 2017. The increase was attributable to the purchase of fixed asset equipment and the replacement of our website during 2018.

Net Cash Flows from Financing Activities: Net cash provided by financing activities was $12,291,000 for the year ended December 31, 2018, an increase of $1,508,000, or 14%, compared to net cash provided by financing activities of $10,783,000, for the year ended December 31, 2017. The increase was attributable to higher financing proceeds received in 2018 as compared to proceeds received from 2017 financings.

Table of Contents

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 combined with the $11.3 million proceeds from the March 2019 warrant exercise will be sufficient to fund our planned operations for at least the next 12 to 18 months from the date of this report. If we meet certain requirements, we may sell securities that are registered on our Form S-3 registration statement (File No. 333-220572), 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.

Table of Contents

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 February 2016, Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2016-02, *Lease Accounting Topic 842.* The new standard is effective for reporting periods beginning after December 15, 2018 and early adoption is permitted. The standard will require lessees to report most leases as assets or liabilities on the balance sheet, while lessor accounting will remain substantially unchanged. The standard permits two approaches, one requiring retrospective application of the new guidance with restatement of prior years, and one requiring prospective application of the new guidance. We plan to adopt the new lease standard effective January 1, 2019 and apply it prospectively. We do not expect the new lease standard to have a material effect on our financial position, results of operations or cash flows. Upon adoption of ASU 2016-02, we will be required to recognize an operating lease liability and right-of-use asset of approximately $100,000, based on the lease composition disclosed in footnote 13.

In November 2016, the FASB issued ASU No. 2016-18, *Statement of Cash Flows*, amending the presentation of restricted cash within the statement of cash flows. The new guidance requires that restricted cash be included within cash and cash equivalents on the statement of cash flows. The Company adopted the provisions of ASU No. 2016-18 as of January 1, 2018 on a retrospective basis. For the years ended December 31, 2018 and 2017, we included $110,000 and $55,000, respectively, of restricted cash within cash, cash equivalents, and restricted cash on the statement of cash flows. The restricted cash represents a required deposit for the Company credit card and is restricted until the Company no longer has the credit card or the limit changes on the credit card.

In July 2017, the FASB issued ASU 2017-11, *Accounting for Certain Financial Instruments with Down Round Features and Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception*. Part I of this ASU addresses the complexity of accounting for certain financial instruments with down round features. Down round features are features of certain equity-linked instruments (or embedded features) that result in the strike price being reduced on the basis of future equity offerings. Current accounting guidance requires financial instruments with down round features to be accounted for at fair value. Part II of the Update applies only to nonpublic companies and is therefore not applicable to the Company. The amendments in Part I of the Update change the classification analysis of certain equity-linked financial instruments (or embedded features) with down round features. When determining whether certain financial instruments should be classified as liabilities or equity instruments, a down round feature no longer precludes equity classification when assessing whether the instrument is indexed to an entity's own stock. As a result, a freestanding equity-linked financial instrument (or embedded conversion option) no longer would be accounted for as a derivative liability at fair value as a result of the existence of a down round feature. For freestanding equity-classified financial instruments, the amendments require entities that present earnings per share

(EPS) in accordance with Topic 260 to recognize the effect of the down round feature when it is triggered. That effect is treated as a dividend and as a reduction of income available to common shareholders in basic EPS. This update is effective for public entities for fiscal years beginning after December 15, 2018. Early adoption is permitted. The Company early adopted the provisions of ASU No. 2017-11 as of January 1, 2018. As the Company does not have any financial instruments with down round features, this ASU did not have a material impact on the financial statements upon adoption.

In June 2018, the FASB issued ASU 2018-07, *Compensation-Stock Compensation Improvements to Nonemployee Share Based Payment Accounting.* This ASU simplifies several aspects of the accounting for non-employee share-based payment transactions resulting from expanding the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. An entity should apply the requirements of Topic 718 to nonemployee awards except for specific guidance on inputs to an option pricing model and the attribution of cost. The amendments also clarify that Topic 718 does not apply to share-based payments used to effectively provide financing to the issuer or was granted in conjunction with selling goods or services to customers as part of a contract accounted for under Topic 606, *Revenue from Contracts with Customers*. This update is effective for public entities for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year. Early adoption is permitted. The Company early adopted the provisions of ASU No. 2018-07 as of April 1, 2018, and it did not have a material impact on the financial statements upon adoption.

In June 2018, the FASB issued ASU 2018-08, *Not-for-Profit Entities (Topic 958): Clarifying the Scope and the Accounting Guidance for Contributions Received and Contributions Made.* This ASU affects not-for-profit entities and business entities that receive or make contributions of cash. The ASU clarifies and improves the scope and accounting guidance to assist entities in evaluating if those transactions should be accounted for as contributions under the scope of Topic 958 or as an exchange transaction subject to other guidance. This update is effective for public entities for fiscal years beginning after December 15, 2018. The Company is currently evaluating the impact that adoption will have on its financial statements.

Table of Contents

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 53 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

Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2018. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (“Exchange Act”), means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the Securities and Exchange Commission’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our principal executive officer and principal financial officer concluded that, as of December 31, 2018, the Company’s disclosure controls and procedures were not effective at the reasonable assurance level for the reasons described below.

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the quarter ended December 31, 2018, that has materially affected, or is reasonably likely to materially affect, our disclosure controls and procedures.

During the quarter ended June 30, 2018, we identified a material weakness in our internal controls over the calculation of the deemed dividend on Series B convertible preferred stock (the “deemed dividend”) for the three and six months ended June 30, 2018, due to a lack of appropriately detailed knowledge of the technical accounting guidance with respect to complex financial instruments. Because of this error, an incorrect deemed dividend was included in net loss applicable to common stockholders which caused an incorrect calculation of loss per common share, basic and diluted, as presented in our originally filed Form 10-Q for the three months ended June 30, 2018. The error resulted in a restatement of our originally filed Form 10-Q for the three months ended June 30, 2018. Management misinterpreted the technical guidance contained in *ASC 470- Debt* in calculating the deemed dividend. An appropriately detailed knowledge of *ASC 470 -Debt* was not present to prevent or detect this error. We incorrectly stated the amount of the deemed dividend as $4,782,100, rather than $11,479,308, for the three and six months ended June 30, 2018. We also incorrectly stated the loss per common share - basic and diluted, for the three and six months ended June 30, 2018 as $(2.90) and $(3.77) respectively, rather than the correct amount of $(5.08) and $(6.11), respectively.

Management’s remediation plan is discussed in Management's Report on Internal Control Over Financial Reporting.

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 ineffective as of December 31, 2018. Because we are a smaller reporting company, BDO USA LLP, our independent registered public accounting firm, is not required to attest to or issue a report on the effectiveness of our internal control over financial reporting.

During the quarter ended June 30, 2018, we identified a material weakness in our internal controls over the calculation of the deemed dividend on Series B convertible preferred stock (the “deemed dividend”) for the three and six months June 30, 2018, due to a lack of appropriately detailed knowledge of the technical accounting guidance with respect to complex financial instruments. Because of this error, an incorrect deemed dividend was included in net loss applicable to common stockholders which caused an incorrect calculation of loss per common share, basic and diluted, as presented in our originally filed Form 10-Q for the three months ended June 30, 2018. The error resulted in a restatement of our originally filed Form 10-Q for the three months ended June 30, 2018. Management misinterpreted the technical guidance contained in *ASC 470- Debt* in calculating the deemed dividend. An appropriately detailed knowledge of *ASC 470 -Debt* was not present to prevent or detect this error. We incorrectly stated the amount of the deemed dividend as $4,782,100, rather than $11,479,308, for the three and six months ended June 30, 2018. We also

incorrectly stated the loss per common share - basic and diluted, for the three and six months ended June 30, 2018 as $(2.90) and $(3.77) respectively, rather than the correct amount of $(5.08) and $(6.11), respectively.

Management’s remediation plan is to enhance the procedures performed to independently review technical accounting memorandums for accuracy and completeness including when appropriate with an outside independent accounting firm in future periods.

ITEM 9B. OTHER INFORMATION

None.

Table of Contents

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Information regarding our executive officers is set forth in Item 1 of Part I of this Report under the caption “Executive Officers.”

The information required by this item is incorporated herein by reference to the sections entitled “Proposal No. 1 — Election of Directors,” “Beneficial Owners and Management,” “Section 16(a) Beneficial Ownership Reporting Compliance,” “Director Compensation,” “Corporate Governance” and “Board of Directors and Committees” in our definitive Proxy Statement for the Annual Meeting of Shareholders to be held on May 9, 2019 (the “Proxy Statement”).

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item is incorporated by reference to the sections entitled “Executive Compensation,” “Director Compensation,” “Proposal No. 3 — To approve the 2019 Amendments to the Atossa Genetics Inc. 2010 Stock Option and Incentive Plan and to increase the number of shares authorized for issuance under the Plan by 3,600,000,” and “Corporate Governance”, in the Proxy Statement.

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

The information required by this item is incorporated by reference to the sections entitled “Executive Compensation-Equity Compensation Plan Information,” "Proposal No. 3 - To approve the 2019 Amendments to the Atossa Genetics Inc. 2010 Stock Option and Incentive Plan and to increase the number of shares authorized for issuance under the plan by 3,600,000," and “Beneficial Owners and Management” in the Proxy Statement.

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

The information required by this item is incorporated by reference to the section entitled “Certain Relationships and Related Party Transactions” and “Corporate Governance” in the Proxy Statement.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by this item is incorporated by reference to the sections entitled “Proposal No. 2 — Ratification of Selection of Independent Registered Public Accounting Firm” in the Proxy Statement.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) The following documents are filed as a part of this 10-K:

1. Financial Statements

The following financial statements are included in Part II, Item 8 of this 10-K:

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 75 of this report.

ITEM 16. FORM 10-K SUMMARY

Not applicable.

Table of Contents

ATOSSA GENETICS INC.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Audited Consolidated Financial Statements:

Table of Contents

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders

Atossa Genetics Inc.

Seattle, Washington

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Atossa Genetics Inc. (the "Company") and subsidiaries as of December 31, 2018 and 2017, the related consolidated statements of operations, stockholders' equity, and cash flows for each of the two years in the period ended December 31, 2018, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company and subsidiaries at December 31, 2018 and 2017, and the results of their operations and their cash flows for each of the two years in the period ended December 31, 2018, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting 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.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ BDO USA, LLP

We have served as the Company's auditor since 2014.

Seattle, Washington

March 28, 2019

Table of Contents

ATOSSA GENETICS INC.

CONSOLIDATED BALANCE SHEETS

	As of December 31,	
Assets	**2018**	**2017**
Current assets		
Cash and cash equivalents	$10,380,493	$7,217,469
Restricted cash	110,000	55,000
Prepaid expenses	509,833	250,944
Research and development tax rebate receivable	518,098	358,277
Other current assets	30,942	16,344
Total current assets	11,549,366	7,898,034
Furniture and equipment, net	54,487	11,467
Intangible assets, net	99,375	75,686
Other assets	17,218	178,907
Total Assets	$11,720,446	$8,164,094
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$353,328	$334,901
Accrued expenses	177,074	90,105
Payroll liabilities	935,070	784,867
Stock-based compensation liability	1,410,025	
Other current liabilities	39,939	15,534
Total Current Liabilities	2,915,436	1,225,407
Commitments and contingencies (note 13)		
Stockholders' equity		
Preferred stock - $0.001 par value; 10,000,000 shares authorized, consisting of Series A convertible preferred stock- $0.001 par value; 4,000 shares authorized, and 0 shares outstanding as of December 31, 2018 and December 31, 2017; Series B convertible preferred stock- $0.001 par value; 25,000 and 0 shares authorized, and 2,379 and 0 shares issued and outstanding as of December 31, 2018 and December 31, 2017, respectively	2	
Additional paid-in capital- Series B convertible preferred stock	2,378,997	
Common stock - $0.18 par value; 175,000,000 shares authorized, and 5,846,552 and 2,651,952 shares issued and outstanding, as of December 31, 2018 and December 31, 2017, respectively	1,052,372	477,342
Additional paid-in capital	82,204,902	71,887,674
Accumulated deficit	(76,831,263)	(65,426,329)
Total Stockholders' Equity	8,805,010	6,938,687
Total Liabilities and Stockholders' Equity	$11,720,446	$8,164,094

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

Table of Contents

ATOSSA GENETICS INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

	For the Years Ended December 31,	
	2018	**2017**
Operating Expenses		
Research and development	$4,209,981	$2,328,087
General and administrative	7,224,252	4,859,369
Impairment of intangible assets		461,715
Total operating expenses	11,434,233	7,649,171
Operating loss	(11,434,233)	(7,649,171)
Change in fair value of common stock warrants		(280,747)
Warrant financing expense		(192,817)
Other income	29,299	154
Loss before income taxes	(11,404,934)	(8,122,581)
Income taxes		
Net loss	$(11,404,934)	$(8,122,581)
Deemed dividend attributable to preferred stock	(11,479,308)	(2,568,132)
Net loss applicable to common shareholders	$(22,884,242)	$(10,690,713)
Loss per common share - basic and diluted	$(5.50)	$(10.97)
Weighted average shares outstanding - basic and diluted	4,157,746	974,773

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

Table of Contents

ATOSSA GENETICS INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

	Series A Convertible Preferred Stock			Series B Convertible Preferred Stock			Common Stock			
	Shares	Amount	Additional Paid-in Capital	Shares	Amount	Additional Paid-in Capital	Shares	Amount	Additional Paid-in Capital	Accumu Deficit
Balance at December 31, 2016							315,576	$56,804	$60,344,050	$(57,303
Issuance of common stock and warrants net of issuance costs of $768,412							1,483,333	267,001	5,895,587	
Issuance of common stock in Class A units, net of issuance costs of $65,816							99,500	17,910	811,774	
Allocation of Class A unit proceeds to warrant liability									(328,350)	
Issuance of Series A convertible preferred stock in Class B units, net of issuance costs of $267,231	292	4	3,234,769							
Allocation of Series A convertible			(2,568,132)						1,284,066	

preferred stock to warrants and beneficial conversion feature										
Deemed dividend on Series A convertible preferred stock			2,568,132						(2,568,132)	
Conversion of Series A convertible preferred stock to common stock	(292)	(4)	(3,234,769)				389,111	70,040	3,164,733	
Reclassification of warrant liability upon exercise of common stock warrants							124,236	22,362	1,870,798	
Issuance of common stock upon warrant exercise for cash on liability warrant exercise							240,196	43,225	706,008	
Amortization of commitment shares									(79,410)	
Compensation cost for stock options granted									786,550	
Net loss										(8,122,
Balance at December 31, 2017							2,651,952	477,342	71,887,674	(65,426
Issuance of Series B convertible preferred stock and warrants, net of issuance costs of $1,333,449				13,624	14	6,926,778			5,363,759	
Allocation of Series B						(4,782,100)			4,782,100	

convertible preferred stock proceeds to beneficial conversion feature							
Deemed dividend on Series B convertible preferred stock			11,479,308			(11,479,308)	
Conversion of Series B convertible preferred stock to common stock	(11,245)	(12)	(11,244,989)	3,194,600	575,030	10,669,971	
Amortization of commitment shares						(72,790)	
Compensation cost for stock options granted						1,053,496	
Net loss							(11,404
Balance at December 31, 2018	2,379	$2	$2,378,997	5,846,552	$1,052,372	$82,204,902	$(76,831

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

Table of Contents

ATOSSA GENETICS INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

	For the Years Ended December 31,	
	2018	**2017**
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$(11,404,934)	$(8,122,581)
Adjustments to reconcile net loss to net cash used in operating activities		
Compensation cost for stock options granted	1,053,496	786,550
Loss on disposal of assets		17,695
Impairment of intangible assets		461,715
Depreciation and amortization	44,197	128,994
Change in fair value of common stock warrants		280,747
Warrant financing expense		192,817
Change in stock-based compensation liability	1,410,025	
Changes in operating assets and liabilities:		
Prepaid expenses	(258,889)	(79,343)
Research and development tax rebate receivable	(159,821)	(358,277)
Other assets	74,301	(80,408)
Accounts payable	18,427	80,581
Payroll liabilities	150,203	14,968
Accrued expenses	86,969	73,141
Other current liabilities	24,405	9,451
Net cash used in operating activities	(8,961,621)	(6,593,950)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of furniture and equipment	(110,906)	
Net cash used in investing activities	(110,906)	
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from issuance of Series B convertible preferred stock and warrants, net of issuance costs	12,290,551	
Proceeds from issuance of Class A and Class B Units, net of issuance costs		3,871,636
Proceeds from exercise of warrants		749,233
Proceeds from issuance of common stock and warrants, net of issuance costs		6,162,588
Net cash provided by financing activities	12,290,551	10,783,457
NET INCREASE IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH	3,218,024	4,189,507
CASH, CASH EQUIVALENTS AND RESTRICTED CASH, BEGINNING BALANCE	7,272,469	3,082,962
CASH, CASH EQUIVALENTS AND RESTRICTED CASH, ENDING BALANCE	$10,490,493	$7,272,469

SUPPLEMENTAL DISCLOSURES		
Interest Paid	$	$330
NONCASH INVESTING AND FINANCING ACTIVITIES		
Amortization of commitment shares	$72,790	$79,410

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

Table of Contents

NOTE 1: NATURE OF OPERATIONS

Atossa Genetics Inc. (the “Company”) was incorporated on April 30, 2009, in the State of Delaware. The Company was initially 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. The Company is currently focused on development of its pharmaceutical and drug delivery programs for the treatment of breast cancer and other breast conditions.

NOTE 2: LIQUIDITY AND CAPITAL RESOURCES

The Company has incurred net losses and negative operating cash flows since inception. For the year ended December 31, 2018, the Company recorded a net loss of approximately $11.4 million and used approximately $9.0 million of cash in operating activities. As of December 31, 2018, the Company had approximately $10.4 million in cash and cash equivalents and working capital of approximately $8.6 million. However, in March 2019, the Company received $11.3 million in cash upon exercises of certain of the Company’s previously outstanding warrants to purchase its common stock. As of March 25, 2019, the Company had approximately $19.3 million in cash and cash equivalents. The Company has not yet established an ongoing source of revenue sufficient to cover its operating costs and is currently expending funds in research and development activities that are expected to continue to require funding. Management believes its currently available funding, including the funds received from warrant exercises in March 2019, will be sufficient to finance the Company’s operations for at least one year from the date these consolidated financial statements are issued. However, the Company will likely require additional funding to continue its activities beyond that date. If adequate funds are not available, the Company may be required to reduce the scope, delay, or eliminate some or all of its planned commercial activities. The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and the settlement of liabilities in the normal course of business. The consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from uncertainty related to the Company’s ability to continue as a going concern.

Table of Contents

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 accounting principles generally accepted in the United States of America ("GAAP"). The accompanying consolidated financial statements include the financial statements of Atossa Genetics Inc. and its wholly-owned subsidiaries. All significant intercompany account balances and transactions have been eliminated in consolidation.

On April 20, 2018, the Company completed a 1-for-12 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 12 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 $0.18 per share. 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 April 20, 2018. 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 February 2016, Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2016-02, *Lease Accounting Topic 842.* The new standard is effective for reporting periods beginning after December 15, 2018 and early adoption is permitted. The standard will require lessees to report most leases as assets or liabilities on the balance sheet, while lessor accounting will remain substantially unchanged. The standard permits two approaches, one requiring retrospective application of the new guidance with restatement of prior years, and one requiring prospective application of the new guidance. We plan to adopt the new lease standard effective January 1,

2019 and apply it prospectively. We do not expect the new lease standard to have a material effect on our financial position, results of operations or cash flows. Upon adoption of ASU 2016-02, we will be required to recognize an operating lease liability and right-of-use asset of approximately $100,000, based on the lease composition disclosed in footnote 13.

Table of Contents

In November 2016, the FASB issued ASU No. 2016-18, *Statement of Cash Flows*, amending the presentation of restricted cash within the statement of cash flows. The new guidance requires that restricted cash be included within cash and cash equivalents on the statement of cash flows. The Company adopted the provisions of ASU No. 2016-18 as of January 1, 2018 on a retrospective basis. For years ended December 31, 2018 and 2017, we included $110,000 and $55,000, respectively, of restricted cash within cash, cash equivalents, and restricted cash on the statement of cash flows. The restricted cash represents a required deposit for the Company credit card and is restricted until the Company no longer has the credit card or the limit changes on the credit card.

In July 2017, the FASB issued ASU 2017-11, *Accounting for Certain Financial Instruments with Down Round Features and Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception*. Part I of this ASU addresses the complexity of accounting for certain financial instruments with down round features. Down round features are features of certain equity-linked instruments (or embedded features) that result in the strike price being reduced on the basis of future equity offerings. Current accounting guidance requires financial instruments with down round features to be accounted for at fair value. Part II of the Update applies only to nonpublic companies and is therefore not applicable to the Company. The amendments in Part I of the Update change the classification analysis of certain equity-linked financial instruments (or embedded features) with down round features. When determining whether certain financial instruments should be classified as liabilities or equity instruments, a down round feature no longer precludes equity classification when assessing whether the instrument is indexed to an entity's own stock. As a result, a freestanding equity-linked financial instrument (or embedded conversion option) no longer would be accounted for as a derivative liability at fair value as a result of the existence of a down round feature. For freestanding equity-classified financial instruments, the amendments require entities that present earnings per share (EPS) in accordance with Topic 260 to recognize the effect of the down round feature when it is triggered. That effect is treated as a dividend and as a reduction of income available to common shareholders in basic EPS. This update is effective for public entities for fiscal years beginning after December 15, 2018. Early adoption is permitted. The Company early adopted the provisions of ASU No. 2017-11 as of January 1, 2018. As the Company does not have any financial instruments with down round features, this ASU did not have a material impact on the financial statements upon adoption.

In June 2018, the FASB issued ASU 2018-07, *Compensation-Stock Compensation Improvements to Nonemployee Share Based Payment Accounting.* This ASU simplifies several aspects of the accounting for non-employee share-based payment transactions resulting from expanding the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. An entity should apply the requirements of Topic 718 to nonemployee awards except for specific guidance on inputs to an option pricing model and the attribution of cost. The amendments also clarify that Topic 718 does not apply to share-based payments used to effectively provide financing to the issuer or was granted in conjunction with selling goods or services to customers as part of a contract accounted for under Topic 606, *Revenue from Contracts with Customers*. This update is effective for public entities for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year. Early adoption is permitted. The Company early adopted the provisions of ASU No. 2018-17 as of April 1, 2018 and it did not have a material impact on the financial statements upon adoption.

In June 2018, the FASB issued ASU 2018-08, *Not-for-Profit Entities (Topic 958): Clarifying the Scope and the Accounting Guidance for Contributions Received and Contributions Made.* This ASU affects not-for-profit entities and business entities that receive or make contributions of cash. The ASU clarifies and improves the scope and accounting guidance to assist entities in evaluating if those transactions should be accounted for as contributions under the scope of Topic 958 or as an exchange transaction subject to other guidance. This update is effective for public entities for fiscal years beginning after December 15, 2018. The Company is currently evaluating the impact that adoption will have on its financial statements.

Table of Contents

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 ranging from three to five years.

Furniture and equipment amounted to $216,000 and $171,000 at December 31, 2018 and 2017, respectively. Accumulated depreciation was $162,000 and $160,000 at December 31, 2018 and 2017, respectively. Depreciation expense for the years ended December 31, 2018 and 2017 was $14,386 and $25,956, respectively.

The Company periodically evaluates the carrying value of long-lived assets to be held and used and, if necessary, records impairment losses 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-loved 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, 2018 and 2017, no impairment of furniture and equipment was recorded.

Table of Contents

Fair Value Measurements

The Company records financial assets and liabilities measured on a recurring and non-recurring basis 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 for impairment whenever events or changes in circumstances indicate that the carrying value of the assets might not be recoverable. Impairment losses must be recorded 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 assets. 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.

During the year ended December 31, 2017, we determined certain intangible assets acquired from Acueity Healthcare, Inc. ("Acueity") were impaired and recorded an asset impairment charge of $461,715 for the year ended December 31, 2017, to adjust the carrying value of these intangible assets to zero as of December 31, 2017. No impairment charges were recorded during the year ended December 31, 2018.

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 48.50%. 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 of intangible assets is computed using the straight-line method over the estimated useful lives ranging from three to ten years.

Intangible assets amounted to $192,000 and $234,000 for at December 31, 2018 and 2017, respectively. Accumulated amortization was $93,000 and $158,000 at December 31, 2018 and 2017, respectively. Amortization expense for the years ended December 31, 2018 and 2017 was $29,811 and $103,038, respectively.

Table of Contents

Financial Instruments with Characteristics of Both Liabilities and Equity

During the year ended December 31, 2017, the Company issued certain financial instruments, consisting of warrants to purchase common stock, which have characteristics of both liability and equity. Financial instruments such as warrants that are classified as liabilities are fair valued upon issuance and are re-measured at fair value at subsequent reporting periods with the resulting change in fair value recorded in "change in fair value of common stock warrants" in the consolidated statement of operations. The fair value of warrants is estimated using valuation models that require the input of subjective assumptions including stock price volatility, expected life, and the probability of future equity issuances and their impact to the price protection feature. There were no outstanding warrants accounted for as liabilities as of December 31, 2018 or 2017.

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 and the Company made a policy election to recognize forfeitures when they occur.

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 vesting term, typically one to 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.

NOTE 4: RESTRICTED CASH

Our restricted cash balance of $110,000 and $55,000 as of December 31, 2018 and 2017, 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, 2018	December 31, 2017
Prepaid insurance	$ 160,576	$ 125,056
Prepaid research and development	218,090	
Professional services	110,094	97,788
Retainer and security deposits	16,718	14,218
Other	4,355	13,882
Total prepaid expenses	$ 509,833	$ 250,944

Table of Contents

NOTE 6: RESEARCH AND DEVELOPMENT TAX REBATE RECEIVABLE

On May 23, 2017, Atossa formed a wholly-owned subsidiary in Australia called Atossa Genetics AUS Pty Ltd. The purpose of this subsidiary is to perform research and development activities ("R&D") including our Phase 1 and Phase 2 Endoxifen clinical trials. Australia offers an R&D cash rebate of $0.435 per dollar spent on qualified R&D activities incurred in the country. For the years ended December 31, 2018 and 2017, the Company incurred qualified R&D expenses in Australia of approximately $851,000 and $824,000, respectively. The Company recorded a rebate receivable of approximately $370,000 and $358,000 at December 31, 2018 and 2017, respectively, and a corresponding credit to R&D expenses for the years then ended. At December 31, 2018, we had a total R&D rebate receivable of approximately $518,000 that included approximately $148,000 receivable remaining from the year ended December 31, 2017.

NOTE 7: PAYROLL LIABILITIES

Payroll liabilities consisted of the following:

	December 31, 2018	December 31, 2017
Accrued bonus payable	$ 697,995	$ 566,000
Accrued vacation	160,740	147,861
Accrued payroll liabilities	76,335	71,006
Total payroll liabilities	$ 935,070	$ 784,867

NOTE 8: FAIR VALUE OF FINANCIAL INSTRUMENTS

There were no financial assets outstanding that were required to be measured at fair value on a recurring basis at December 31, 2018 or December 31, 2017.

Warrants issued in the April 3, 2017, offering, which are discussed further in Note 9, contained provisions that could have required the Company to settle the warrants in cash in an event outside the Company's control or had price protection rights and were therefore accounted for as liabilities while they were outstanding, with changes in the fair values included in net loss for the respective periods. Because some of the inputs to the valuation model were either

not observable or were not derived principally from or corroborated by observable market data by correlation or other means, the warrant liability was classified as Level 3 in the fair value hierarchy.

The following table summarizes the changes in the Company's Level 3 warrant liability for the year ended December 31, 2017:

Warrant liability	
Beginning balance	$
Issuances of warrants	1,612,413
Warrant exercises	(1,893,160)
Change in fair value	280,747
Ending balance	$

The Company's intangible assets are classified within Level 3 of the fair value hierarchy, measured at fair value on a nonrecurring basis. Refer to Note 3 for further discussion.

There were no transfers between Level 1, Level 2 or Level 3 for the years ended December 31, 2018 or December 31, 2017.

Table of Contents

NOTE 9: STOCKHOLDERS' EQUITY

The Company is authorized to issue a total of 185,000,000 shares of stock consisting of 175,000,000 shares of common stock, par value $0.18 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, 4,000 shares of Series A convertible preferred stock, par value $0.001 per share, and 25,000 shares of Series B convertible preferred stock, par value $0.001 per share, through the filings of certificates of designation with the Delaware Secretary of State. No shares of Series A junior participating preferred stock or Series A convertible preferred stock are issued or outstanding as of December 31, 2018.

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.

2017 Public Offering of Class A and Class B Units Consisting of Common Stock, Series A Convertible Preferred Stock and Warrants

On March 28, 2017, the Company entered into an underwriting agreement with Aegis Capital Corp. relating to a public offering which closed on April 3, 2017. The offering generated gross proceeds to the Company of approximately $4.4 million and net proceeds of approximately $3.9 million after deducting underwriting discounts and commissions and other offering expenses paid by the Company.

The offering included 55,333 Class A Units at a public offering price of $9.00 per Class A Unit, which consisted of 55,333 shares of common stock and warrants to purchase 55,333 shares of common stock. The offering also included

292 Class B Units at a public offering price of $12,000 per Class B Unit, which consisted of 292 shares of Series A convertible preferred stock convertible into a total of 389,111 shares of common stock and warrants to purchase 389,111 shares of common stock. In addition, the underwriter exercised the over-allotment option to purchase an additional 44,167 shares of common stock and warrants to purchase 44,167 shares of common stock, which are included in the gross proceeds of $4.4 million. The warrants had a per share exercise price of $11.25, were exercisable immediately and were scheduled to expire five years from the date of issuance.

As of December 31, 2017, all of the warrants issued in the April 3, 2017 offering have been exercised and are no longer outstanding and all of the shares of Series A convertible preferred stock have been converted into shares of common stock.

Accounting Treatment

The Company allocated the proceeds from the sale of the Class A and Class B units to the separate securities issued. The Company determined that, on the date of issuance, the warrants were not indexed to its stock because they did not meet the “fixed-for-fixed” criterion due to the price protection and fundamental transaction provisions and, therefore, the warrants were accounted for as liabilities with changes in fair value recorded in non-operating income (expense) in the consolidated statement of operations.

The Company allocated the amount representing the fair value of the warrants at the date of issuance separately to the warrant liability and recorded the remaining proceeds as common stock, in the case of the Class A units, or as Series A convertible preferred stock, in the case of the Class B units. Due to the allocation of a portion of the proceeds to the warrants, the Series A convertible preferred stock contained a beneficial conversion feature upon issuance, which was recorded in the amount of $1,284,066 based on the intrinsic value of the beneficial conversion feature. The discount on the Series A convertible preferred stock of $1,284,066 caused by allocation of the proceeds to the warrant was recorded as a deemed dividend upon issuance of the Series A convertible preferred stock. As a result, total deemed dividends of $2,568,132 were recorded upon issuance of the Series A convertible preferred stock, which is reflected as an addition to net loss in the consolidated statement of operations to arrive at net loss applicable to common shareholders.

Table of Contents

Exercise of 2017 Warrants

On June 29, 2017, the Company offered to modify the rights of the holders of the warrants issued in the public offering the Company completed on April 3, 2017. The temporary modification included (a) lowering the exercise price of the warrants to $3.12 per share, (b) setting the applicable volume-weighted average price (VWAP) at $6.24 per share, and (c) allowing for temporary cashless exercise of the warrants for all holders that accepted the temporary modification before 8:00 a.m. Eastern daylight time on June 30, 2017. Holders of warrants to purchase a total of approximately 250,000 shares of common stock accepted the offer resulting in the cancellation of those warrants and the issuance by the Company of a total of approximately 125,000 shares of common stock (including shares held in abeyance). The shares of common stock are registered under the Securities Act of 1933, as amended. In connection with the temporary modification, the Company agreed to extend the “Lock-up Period” of the underwriting agreement between the Company and Aegis Capital Corp., dated March 28, 2017, by 45 days and the Company agreed not to enter into any further amendments to the warrants during such extended Lock-up Period without the prior written consent of each holder. During the third quarter of 2017, all remaining warrants were exercised for cash so that no warrants issued in the April 3, 2017, financing remained outstanding. Upon exercise of these warrants, the amount of the warrant liability at the date of exercise was reclassified from warrant liability to additional paid-in capital.

The following table summarizes the 2017 liability warrant activity:

	Shares	**Weighted Average Exercise Price**
Outstanding as of January 1, 2017		
Warrants granted	488,611	$ 11.25
Warrants exercised	(488,611)	3.12
Outstanding as of December 31, 2017		

The Company estimated the fair value of the warrants using the Monte Carlo simulation (MCS) model, which is a type of income approach, where the current value of an asset is expressed as the sum of probable future cash flows across various scenarios and time frames discounted for risk and time. The significant assumptions included timing of future rounds of financing, timing and success rates of oncology clinical trials, and the probability of a merger and acquisition adjusted for a lack of marketability discount. The MCS model also included a full term and an early conversion scenario that were each weighted at 50% in the final concluded fair value.

Inputs used in the valuation of the warrants at the issuance date of April 3, 2017 and June 30, 2017, are set forth below. All of the warrants issued in the April 2017 financing were exercised during 2017 and none remained outstanding at December 31, 2017.

Initial valuation			
Common stock price		$9.00	
Exercise price		$11.25	
Expected volatility		50%	
Dividend yield		0%	
Risk-free interest rate	0.79%	-	1.88%
Expected term (in years)	0.24	-	5

June 30, 2017 valuation			
Common stock price		$6.00	
Exercise price		$3.12	
Expected volatility		50%	
Dividend yield		0%	
Risk-free interest rate	0.79	-	1.88%
Expected term (in years)	0.08	-	4.76

Table of Contents

Conversion of Series A Convertible Preferred Stock

During the year ended December 31, 2017, certain holders of the Series A convertible preferred stock exercised their conversion option and converted an aggregate of 292 shares of Series A convertible preferred stock into 389,111 shares of the Company's common stock based on the conversion ratio of 111 shares of common stock for each share of Series A convertible preferred stock. As of December 31, 2017 and 2018, no shares of Series A convertible preferred stock were outstanding.

October 2017 Public Offering

On October 26, 2017, the Company entered into an underwriting agreement with Maxim Group LLC relating to a public offering of common stock which closed on October 30, 2017. The offering generated gross proceeds to the Company of approximately $5.5 million and net proceeds of $4.9 million after deducting underwriting discounts, commissions and other offering expenses paid by the Company.

The offering included 958,333 shares of common stock at a public offering price of $5.28 per share. In addition, the underwriter exercised the over-allotment option to purchase an additional 83,333 shares of common stock at the offering price of $5.28 per share, which are included in the gross proceeds of $5.5 million.

December 2017 Public Offering and Private Placement

On December 20, 2017, the Company entered into a placement agent agreement with Maxim Group LLC relating to the sale of the Company's securities. Pursuant to the placement agent agreement, on December 20, 2017, the Company entered into a securities purchase agreement with certain purchasers named therein relating to the offering and sale of 441,667 shares of Company common stock at a public offering price of $3.24 per share. The offering generated gross proceeds to the Company of approximately $1.4 million and net proceeds of $1.2 million after deduction of underwriting discounts, commissions, and other offering expenses paid by the Company.

Concurrently with the public offering the Company also commenced a private placement whereby it issued and sold Class A and Class B Warrants, exercisable for an aggregate of 883,333 shares of common stock, at an exercise price of $3.78 per share. The public offering and the private placement involved the same purchasers. The Class A and Class B Warrants exercise price was fixed at $3.78 per warrant, and the warrants became exercisable commencing six months from issuance. The Class A Warrants and Class B Warrants expired on the first anniversary of the date of issuance. None of the Class A Warrants, the Class B Warrants nor the shares issuable upon exercise of such Warrants

were registered with the Securities and Exchange Commission. The Warrants could not be exercised on a cashless basis. There were no redemption features embodied in the Warrants and they met the conditions for equity classification. On December 22, 2018, the Class A and Class B warrants expired unexercised.

2018 Subscription Rights Offering of Units Consisting of Series B Convertible Preferred Stock and Warrants

On May 9, 2018, the Company's Registration Statement on Form S-1 with the Securities and Exchange Commission was declared effective to offer subscription rights to purchase up to 25,000 units at $1,000 per unit with each unit consisting of one share of Series B convertible preferred stock and warrants to purchase 284 shares of common stock.

On May 29, 2018, the Company filed a Certificate of Designation of Preferences, Rights and Limitations of Series B convertible preferred stock with the Delaware Secretary of State creating a new series of its authorized preferred stock, par value $0.001 per share, designated as the Series B convertible preferred stock. The number of shares initially constituting the Series B preferred stock was set at 25,000 shares.

On May 30, 2018, the Company completed its previously announced rights offering pursuant to which the Company sold an aggregate of 13,624 units consisting of an aggregate of 13,624 shares of Series B convertible preferred stock and 3,869,216 warrants, with each warrant exercisable for one share of common stock at an exercise price of $4.048 per share (the "2018 Warrants"), resulting in net proceeds to the Company of approximately $12.3 million, after deducting expenses relating to the rights offering, including dealer-manager fees and expenses, and excluding any proceeds received upon exercise of any warrants.

Table of Contents

Series B Convertible Preferred Stock.

The terms and provisions of our Series B convertible preferred stock are:

Conversion. Each share of Series B convertible preferred stock is convertible at our option at any time on or after the first anniversary of the closing of the rights offering or at the option of the holder at any time, into the number of shares of our common stock determined by dividing the $1,000 stated value per share of the Series B convertible preferred stock by a conversion price of $3.52 per share. In addition, the conversion price per share is subject to adjustment for stock dividends, distributions, subdivisions, combinations or reclassifications. Subject to limited exceptions, a holder of the Series B convertible preferred stock will not have the right to convert any portion of the Series B convertible preferred stock to the extent that, after giving effect to the conversion, the holder, together with its affiliates, would beneficially own in excess of 9.99% of the number of shares of our common stock outstanding immediately after giving effect to its conversion.

Fundamental Transactions. In the event we effect certain mergers, consolidations, sales of substantially all of our assets, tender or exchange offers, reclassifications or share exchanges in which our common stock is effectively converted into or exchanged for other securities, cash or property, we consummate a business combination in which another person acquires 50% of the outstanding shares of our common stock, or any person or group becomes the beneficial owner of 50% of the aggregate ordinary voting power represented by our issued and outstanding common stock, then, upon any subsequent conversion of the Series B convertible preferred stock, the holders of the Series B convertible preferred stock will have the right to receive any shares of the acquiring corporation or other consideration it would have been entitled to receive if it had been a holder of the number of shares of common stock then issuable upon conversion in full of the Series B convertible preferred stock.

Dividends. Holders of Series B convertible preferred stock shall be entitled to receive dividends (on an as-if-converted-to-common-stock basis) in the same form as dividends actually paid on shares of the common stock when, as and if such dividends are paid on shares of common stock.

Voting Rights. Except as otherwise provided in the certificate of designation or as otherwise required by law, the Series B convertible preferred stock has no voting rights.

Liquidation Preference. Upon our liquidation, dissolution or winding-up, whether voluntary or involuntary, holders of Series B convertible preferred stock will be entitled to receive out of our assets, whether capital or surplus, the same amount that a holder of common stock would receive if the Series B convertible preferred stock were fully converted (disregarding for such purpose any conversion limitations under the certificate of designation) to common stock, which amounts shall be paid pari passu with all holders of common stock.

Redemption Rights. We are not obligated to redeem or repurchase any shares of Series B convertible preferred stock. Shares of Series B convertible preferred stock are not otherwise entitled to any redemption rights, or mandatory sinking fund or analogous provisions.

2018 Warrants

The terms and conditions of the warrants included in the 2018 rights offering are as follows:

Exercisability. Each warrant is exercisable at any time and will expire four years from the date of issuance. The warrants are exercisable, at the option of each holder, in whole or in part by delivering to us a duly executed exercise notice and payment in full for the number of shares of our common stock purchased upon such exercise, except in the case of a cashless exercise as discussed below.

The number of shares of common stock issuable upon exercise of the warrants is subject to adjustment in certain circumstances, including a stock split of, stock dividend on, or a subdivision, combination or recapitalization of the common stock. Upon the merger, consolidation, sale of substantially all of our assets, or other similar transaction, the holders of warrants shall, at the option of the company, be required to exercise the warrants immediately prior to the closing of the transaction, or such warrants shall automatically expire. Upon such exercise, the holders of warrants shall participate on the same basis as the holders of common stock in connection with the transaction.

Cashless Exercise. If at any time there is no effective registration statement registering, or the prospectus contained therein is not available for issuance of, the shares issuable upon exercise of the warrant, the holder may exercise the warrant on a cashless basis. When exercised on a cashless basis, a portion of the warrant is cancelled in payment of the purchase price payable in respect of the number of shares of our common stock purchasable upon such exercise.

Table of Contents

Exercise Price. Each warrant represents the right to purchase one share of common stock at an exercise price of $4.048 per share. In addition, the exercise price per share is subject to adjustment for stock dividends, distributions, subdivisions, combinations, or reclassifications, and for certain dilutive issuances. Subject to limited exceptions, a holder of warrants will not have the right to exercise any portion of the warrant to the extent that, after giving effect to the exercise, the holder, together with its affiliates, and any other person acting as a group together with the holder or any of its affiliates, would beneficially own in excess of 4.99% of the number of shares of our common stock outstanding immediately after giving effect to its exercise. The holder, upon notice to the Company, may increase or decrease the beneficial ownership limitation provisions of the warrant, provided that in no event shall the limitation exceed 9.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise of the warrant.

Transferability. Subject to applicable laws and restrictions, a holder may transfer a warrant upon surrender of the warrant to us with a completed and signed assignment in the form attached to the warrant. The transferring holder will be responsible for any tax that liability that may arise as a result of the transfer.

Exchange Listing. We do not intend to apply to list the warrants on any securities exchange or recognized trading system.

Rights as Stockholder. Except as set forth in the warrant, the holder of a warrant, solely in such holder’s capacity as a holder of a warrant, will not be entitled to vote, to receive dividends, or to any of the other rights of our stockholders.

Redemption Rights. We may redeem the warrants for $0.18 per warrant if the volume-weighted-average-price of our common stock equals or exceeds $10.56 per share for ten consecutive trading days, provided that we may not do so prior to the first anniversary of closing of the rights offering.

Accounting Treatment

The Company allocated the proceeds from the sale of the Series B convertible preferred stock and the warrants to purchase common stock to the separate securities issued. The Company allocated the amount representing the fair value of the warrants at the date of issuance to common stock based on the relative warrant fair value in the amount of $5,363,759, which is net of issuance costs allocated to the warrants. Due to the allocation of a portion of the proceeds to the warrants, the convertible preferred stock contained a beneficial conversion feature upon issuance, which was recorded in the amount of $4,782,100 based on the relative fair value of the beneficial conversion feature. The discount on the convertible preferred stock was $11,479,308, which consists of the beneficial conversion feature of $4,782,100, the allocation of a portion of the proceeds to the warrants in the amount of $5,363,759, and the total issuance costs related to the financing of $1,333,449. The discount on the convertible preferred stock of $11,479,308

was recorded as a deemed dividend upon issuance of the convertible preferred stock. The deemed dividend is reflected as an addition to net loss in the consolidated statements of operations to arrive at net loss applicable to common shareholders. The Company has made an accounting policy election to record the deemed dividend related to discounts on convertible instruments at the time of issuance of the convertible instruments.

Outstanding Warrants

As of December 31, 2018, warrants to purchase 3,875,699 shares of common stock were outstanding including:

	Outstanding Warrants to Purchase Shares	Exercise Price	Expiration Date
2014 public offering	6,483	$540.00	January 29, 2019
2018 warrants	3,869,216	4.05	May 30, 2022
	3,875,699		

Conversion of Series B Convertible Preferred Stock

During the year ended December 31, 2018, certain holders of the Series B convertible preferred stock exercised their conversion option and converted an aggregate of 11,245 shares into 3,194,600 shares of the Company's common stock based on the conversion ratio of approximately 284 shares of common stock for each share of Series B convertible preferred stock.

Table of Contents

NOTE 10: NET LOSS PER SHARE

The Company accounts for and discloses net income (loss) per common share in accordance with Accounting Standards Codification ("ASC") Topic 260, *Earnings 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. In addition, in computing the dilutive effect of convertible securities, the numerator is adjusted to add back any convertible preferred dividends. 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 potential future exercises of outstanding stock options and common stock warrants. Because the inclusion of potential common shares would be anti-dilutive for all periods presented they have been excluded from the calculation.

The following table summarizes the Company's calculation of net loss per common share:

	Year Ended December 31,	
	2018	**2017**
Numerator		
Net loss	$(11,404,934)	$(8,122,581)
Deemed dividend attributable to preferred stock	(11,479,308)	(2,568,132)
Net loss attributable to common shareholders	$(22,884,242)	$(10,690,713)
Denominator		
Weighted average common shares outstanding used to compute net loss per share, basic and diluted	4,157,746	974,773
Net loss per share of common stock, basic and diluted:	$(5.50)	$(10.97)

The following table sets forth the number of potential common shares excluded from the calculation of net loss per diluted share, because including them would be anti-dilutive:

	Year Ended December 31,	
	2018	**2017**
Options to purchase common stock	487,941	117,301
Series A convertible preferred stock		55,835
Series B convertible preferred stock	774,983	
Warrants to purchase common stock	3,054,481	202,063
	4,317,405	375,199

NOTE 11: 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.

On December 22, 2017, the President signed into law the Tax Cut and Jobs Act of 2017 (the "2017 Tax Act"). The 2017 Tax Act provisions applicable to the Company include a permanent reduction to the U.S. federal corporate income tax rate from 35% to 21%, the capitalization and amortization of research and development related expenses, and placing additional limits on the use of net operating losses. Under ASC Topic 740, *Accounting for Income Taxes*, companies are required to recognize the changes in the period of enactment.

During the year ended December 31, 2017, the Company recorded a reduction in the amount of $1.9 million in the carrying value of the Company's U.S. deferred tax assets resulting from the 2017 Tax Act's reduction in the U.S. federal corporate income tax rate from 35% to 21%, which is fully offset by the valuation allowance.

Table of Contents

The Company did not record an income tax benefit for its losses incurred for the years ending December 31, 2018 or 2017, 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:

	As of December 31,	
	2018	**2017**
Expected federal income tax benefit	$(2,395,036)	$(2,761,678)
Stock compensation	169,957	197,336
Other permanent items	1,616	2,668
Effect of change in valuation allowance	2,223,463	(15,344,015)
Prior year true-up		(126,031)
Tax rate change		1,912,427
Effect of NOL limitation		16,119,293
Actual federal income tax benefit	$	$

The components of net deferred tax assets and liabilities are as follows:

	Year Ended December 31,	
	2018	**2017**
Deferred tax assets		
Obsolete inventory	$21,881	$21,881
Accrued vacation	33,755	31,051
Accrued bonuses	99,666	
Stock-based compensation	968,170	620,789
Basis difference in fixed assets	33,241	33,241
Intangible assets, net	572,687	634,521
Contribution, carryforward	707	677
Net operating loss carryforwards	2,588,401	747,589
Capital loss carryforward	1,027,111	1,027,111
Valuation allowance	(5,312,769)	(3,089,306)
Deferred tax asset	$32,850	$27,554
Deferred tax liabilities		
Other	$(32,850)	$(27,554)
Net deferred tax asset	$	$

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. Since the Company's initial public offering, ownership changes have triggered a Section 382 limitation, which limits the ability to utilize net operating loss carryforwards.

The Company has incurred net operating losses from inception. At December 31, 2018, the Company had domestic federal net operating loss carryforwards of approximately $58.2 million. In May of 2018 and October 2017, the Company completed public offerings, which triggered ownership changes under section 382. We believe that as of December 31, 2018, the gross net operating loss carryforwards have been limited to approximately $12.3 million, which are available to reduce future taxable income. Federal net operating loss carryforwards generated through December 31, 2017 expire at various dates beginning in 2029 through 2038, while federal net operating loss carryforwards generated in 2018 do not expire. The Company recorded a valuation allowance against all of its net deferred tax assets of approximately $5.3 million and $3.1 million as of December 31, 2018 and 2017, respectively, for a net increase of $2.2 million from 2017 to 2018 and a net decrease of $15.5 million from 2016 to 2017.

The Company files income tax returns in the U.S. The Company is subject to tax examinations for the 2012 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.

Table of Contents

NOTE 12: 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, 2018 and 2017, the Company had $10,052,914 and $6,967,469 in excess of the FDIC insured limit, respectively.

NOTE 13: COMMITMENTS AND CONTINGENCIES

Lease Commitments

On November 1, 2018, the Company entered into an operating lease to pay $3,660 monthly rent for a term of 22 months. The total future minimum lease payments due under this lease are $73,200, of which $43,920 and $29,280 are due in 2019 and 2020, respectively.

The total rent expense for the years ended December 31, 2018 and 2017, was $31,457 and $33,285, respectively. Rent expense was included in general and administrative expenses for both years.

On October 30, 2018, the Company entered into an operating lease for a copier system for a term of 36 months. The total future minimum lease payments due under this lease are $42,228, of which $14,904, $14,904 and $12,420 are due in 2019, 2020 and 2021, respectively.

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 our directors and officers and the underwriters of our November 2012 initial public offering. The complaint alleged that all defendants violated Sections 11 and 12(a)(2), and that we and certain of our directors and officers violated Section 15, of the Securities Act by making material false and misleading statements and omissions in the offering's registration statement, and that we and certain of our directors and officers violated Sections 10(b) and 20A

of the Exchange Act and SEC Rule 10b-5 promulgated thereunder by making false and misleading statements and omissions in the registration statement and in certain of our subsequent press releases and SEC filings with respect to our NAF specimen collection process, our ForeCYTE Breast Health Test and our MASCT device. The complaint sought, on behalf of persons who purchased our common stock between November 8, 2012 and October 4, 2013, inclusive, damages of an unspecific amount. On March 23, 2018, the parties filed a stipulation of settlement with the court to settle the matter for $3.5 million, completely funded by defendants' insurers, and on July 20, 2018 the Court approved the settlement. This case is considered closed.

We are subject to other legal proceedings and claims that arise in the normal course of business. We believe these matters are either without merit or of a kind that should not have a material effect, individually or in the aggregate, on our financial position, results of operations or cash flows.

Table of Contents

NOTE 14: STOCK BASED COMPENSATION

Stock Option and Incentive Plan

On September 28, 2010, the Board of Directors approved the adoption of the 2010 Stock Option and Incentive Plan 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 5,556 shares were initially reserved for issuance in connection with awards granted under the 2010 Plan and on May 18, 2016, an additional 11,111 shares were reserved for issuance under the 2010 Plan. On May 9, 2017, the stockholders approved an additional 125,000 shares for issuance under the 2010 Plan. On April 12, 2018, the stockholders approved an additional 500,000 shares for issuance 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	2,502
2013	2,871
2014	4,128
2015	5,463
2016	7,257
2017	12,623
2018	106,076
Total additional shares	140,920

The Company granted options to purchase 611,668 and 143,027 shares of common stock to employees and directors during the year ended December 31, 2018 and 2017, respectively. The weighted average grant date fair value of options granted during 2018 and 2017 was $2.02 and $4.80, respectively. There are 3,575 options available for grant under the 2010 Plan as of December 31, 2018, and as a result of the evergreen provision contained in the 2010 Plan, an additional 233,862 shares were added to the 2010 Plan on January 1, 2019.

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 $1,053,496 and $786,550 for the years ended December 31, 2018 and 2017, respectively, which was included in the following captions in the consolidated statements of operations.

	Year Ended December 31,	
	2018	**2017**
General and administrative	$809,110	$621,668
Research and development	244,386	164,882
Total stock compensation expense	$1,053,496	$786,550

The fair value of stock options granted for the years ended December 31, 2018 and 2017, was calculated using the Black-Scholes option-pricing model applying the following assumptions:

	Year ended December 31,	
	2018	**2017**
Risk free interest rate	2.47% - 2.71%	1.86% - 2.04%
Expected term (in years)	5.24 - 5.57	5.32 - 6.36
Dividend yield	-%	-%
Expected volatility	108.81% - 126.43%	112.86% - 114.19

Table of Contents

Options issued and outstanding as of December 31, 2018, 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, 2018	172,510	$ 49.27		$
Granted	611,668	2.39		
Forfeited	(795)	562.55		
Outstanding as of December 31, 2018	783,383	12.14	9.17	$
Exercisable as of December 31, 2018	317,042	24.39	8.97	$
Vested and expected to vest	783,383	12.14	9.17	$

At December 31, 2018, there were 466,341 unvested options outstanding and the related unrecognized total compensation cost associated with these options was $1,152,367. This expense is expected to be recognized over a weighted-average period of 1.45 years.

Executive Option Grants Classified as Liabilities (''2018 Liability Grants'')

On June 27, 2018, the Company granted 2,300,000 options to the Chief Executive Officer and 700,000 to the Chief Financial Officer. Each option is exercisable for an equivalent number of shares of Company's common stock. The options were granted pursuant to an option award agreement and were granted outside the Company’s 2010 Plan; however, they are subject to the terms and conditions of the 2010 Plan. On January 13, 2019, the 2018 liability options were canceled.

The Liability Grants were exercisable for shares of common stock at an exercise price of $2.38 per share, which was the fair value on the date of grant. The options had an exercise period of ten years from their date of issuance. If at the time the options were exercised the Company cannot deliver shares of common stock to the optionee including, for example, if there were insufficient shares available under the Plan at the time of exercise, then in lieu of the optionee paying the exercise price and the Company issuing shares of stock, the option only would be exercised on a cash “net basis” so that the Company would pay cash in an amount equal to the excess of the fair value of the common stock over the option exercise price. There were not sufficient shares available under the Plan. Therefore the Company would have been obligated to settle these options in cash if they were exercised. Because these options contained provisions that would require the Company to settle the options in cash in an event outside the Company’s control, they were accounted for as liabilities.

The Liability Grants were subject to vesting requirements. Twenty-five percent of the options were vested as of the grant date, 50% of the options would have vested quarterly over two years, and the remaining 25% would have vested upon achievement of certain milestones related to clinical trial progress. As of December 31, 2018, all of the options that vested upon achievement of clinical trial milestones were vested. At December 31, 2018, there were 1,125,000 unvested options outstanding and the related unrecognized total compensation cost associated with these options was $857,673. This expense was expected to be recognized over a weighted-average period of 1.5 years.

Compensation costs associated with the Liability Grants were initially recognized, based on the grant-date fair values of these options, over the requisite or vesting period for time-based options or when it is probable the performance criteria were achieved for options that vest based on performance. Compensation cost was remeasured each period based on the market value of our underlying stock until award vesting or settlement.

For the year ended December 31, 2018, the Company recognized compensation expense related to these options of $1,410,025, which was included in the following captions in the consolidated statements of operations.

	Year Ended December 31, 2018
General and administrative	$869,515
Research and development	540,510
Total stock compensation expense	$1,410,025

The fair value of liability options granted for the year ended December 31, 2018, was calculated using the Black-Scholes option-pricing model applying the following assumptions:

	Year Ended December 31, 2018
Risk free interest rate	2.51 - 2.94%
Expected term (in years)	4.5 - 5.0
Stock price	$1.02 - $2.38
Dividend yield	%

Expected volatility	122.0- 125.0%

Refer to footnote 16 for further description.

Table of Contents

NOTE 15: RESTATEMENT TO PREVIOUSLY ISSUED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

The Company has corrected an inadvertent error in the calculation of the deemed dividend on Series B convertible preferred stock in the financial statements for the three and six months ended June 30, 2018 that were included in the Company's Form 10-Q filed on August 13, 2018 (the "Original Form 10-Q"). Accounting principles generally accepted in the United States of America require that we allocate the proceeds from the May 2018 financing to the warrants and preferred stock issued in the financing and that we estimate and record any discount on the securities as a deemed dividend. In the financial statements included in the Original Form 10-Q, we did not properly allocate the proceeds to the warrants, and we did not properly record the deemed dividend related to the warrant discount as additional paid in capital to common stock. The Company incorrectly stated the deemed dividend for the three and six months ended June 30, 2018 as $4,782,100, rather than $11,479,308. The corrections result from application of technical accounting rules and do not impact cash or operations.

In accordance with applicable generally accepted accounting principles, the Company has calculated and recognized adjustments accordingly. The following table shows the effect of the restatement on certain line items within the Company's Condensed Consolidated Statement of Operations for the three months and six months ended June 30, 2018:

	For the Three Months Ended June 30, 2018		For the Six Months Ended June 30, 2018	
	Previously Reported	Restated	Previously Reported	Restated
Deemed dividend attributable to preferred stock	$(4,782,100)	$(11,479,308)	$(4,782,100)	$(11,479,308)
Net loss applicable to common stockholders	$(8,924,677)	$(15,621,885)	$(10,799,059)	$(17,496,267)
Loss per common share -basic and diluted	$(2.90)	$(5.08)	$(3.77)	$(6.11)

The following table shows the effect of the restatement on certain line items within the Company's Condensed Consolidated Statement of Stockholders' Equity for the six months ended June 30, 2018:

	Preferred Stock Additional Paid-in Capital		Common Stock Additional Paid-in Capital	
	Previously	Restated	Previously	Restated

	Reported		Reported	
Issuance of Series B convertible preferred stock, net of issuance costs	$12,290,537	$6,926,778	$0	$5,363,759
Deemed Dividend on Series B convertible preferred stock	$4,782,100	$11,479,308	$(4,782,100)	$(11,479,308)
Conversion of Series B convertible preferred stock to common stock	$(7,056,421)	$(7,821,992)	$6,656,442	$7,422,013

NOTE 16: SUBSEQUENT EVENTS

Stock Option and Incentive Plan

June 27, 2018, the Company granted 2,300,000 options to the Chief Executive Officer and 700,000 to the Chief Financial Officer (collectively, the “2018 Liability Options”). Each option was exercisable for an equivalent number of shares of Company common stock. The 2018 Liability Options contained a “Net Cash Exercise Provision” so that if at the time the 2018 Liability Options were exercised the Company could not deliver shares of Common Stock to the optionee (including, for example, if there were insufficient shares available under the Plan at the time of exercise), then in lieu of the optionee paying the exercise price and the Company issuing shares of stock, the option would only be exercised on a cash “net basis” requiring that the Company pay cash in an amount equal to the excess of the fair market value of the Common Stock over the option exercise price.

On January 13, 2019, the Company, CEO and CFO agreed to cancel and terminate the 2018 Liability Options so they are no longer outstanding and of no further force and effect. On January 13, 2019, the Company granted a new option to the CEO to purchase 2,300,000 shares of Common Stock and a new option to the CFO to purchase 800,000 shares of Common Stock (the “2019 Options”). The 2019 Options: (i) have an exercise price equal to the fair market value of Common Stock on the date of grant which was $1.36 per share, (ii) do not contain a Net Cash Exercise provision, (iii) are granted pursuant to the terms and conditions of the Plan as amended by the Board of Directors on January 13, 2019, to include shares issuable upon exercise of the 2019 Options and other changes to the Plan so that the 2019 Options do not conflict with the Plan (the “Amended Plan”), (iv) vest and are exercisable in accordance with the vesting schedule related to the 2018 Liability Options; provided, however, that the 2019 Options are not exercisable unless and until the Company’s stockholders approve the Amended Plan to increase the authorized number of shares available for grant under the Plan as only 3,575 options were available for grant as of December 31, 2018, and (vi) are subject to and conditioned the 2019 Option Agreements with the optionees and the employment agreements with the optionees.

The above actions were unanimously approved by the disinterested members of the Board of Directors. The above actions are intended to eliminate the Company’s potential liability associated with the Net Cash Exercise Provision of the liability options, and to allow the stockholders of the Company the opportunity to vote on the Amended Plan, which includes shares issuable upon exercise of the 2019 Options.

Warrant Exercises

In March 2019, the Company received approximately $11.3 million from exercises of warrants issued on May 30, 2018. As a result of the warrant exercises, the Company retired approximately 2.8 million warrants and issued approximately 2.8 million shares of common stock.

Table of Contents

EXHIBIT INDEX

Exhibit No.	Description	Incorporated by Reference Herein Form	Date
1.1	Form of Dealer-Manager Agreement	Amendment No. 1 to Registration Statement on Form S-1, as Exhibit 1.1	April 23, 2018
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
3.6	Certificate of Designation of Preference, Rights and Limitations of Series A Convertible Preferred Stock	Current Report on Form 10Q, as Exhibit 3.1	May 11, 2017
3.7	Form of Certificate of Designation of Preference, Rights and Limitations of Series B Convertible Preferred Stock	Amendment No. 1 to Registration Statement on Form S-1, as Exhibit 4.1	April 23, 2018
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 24, 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 24, 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 Common Stock Purchase Warrant A	Current Report on Form 8-K, as Exhibit 4.1	December 22, 2017
4.10	Form of Commons Stock Purchase Warrant B	Current Report on Form 8-K, as Exhibit 4.2	December 22, 2017
4.11	Certificate of Amendment to Amended and Restated Certificate of Incorporation of Atossa Genetics Inc.	Current Report on Form 8-K, as Exhibit 4.1	April 23, 2018
4.12	Form of Warrant Agreement	Amendment No.1 to Registration Statement on Form S-1, as Exhibit 4.2	April 23, 2018
4.13	Form of Warrant Certificate	Amendment No. 1 to Registration Statement on Form S-1, as Exhibit 4.3	April 23, 2018
4.14	Form of Non-Transferable Subscription Rights Certificate	Amendment No. 1 to Registration Statement on Form S-1, as Exhibit 4.4	April 23, 2018
4.15	Form of 2019 Option Award Agreement	Current Report on Form 8K, as Exhibit 4.1	January 13, 2019
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	Form of Indemnification Agreement	Registration Statement on Form S-1, as Exhibit 10.5	May 21, 2012

Table of Contents

10.3	Form of Incentive Stock Option Agreement	Registration Statement on Form S-1, as Exhibit 10.7	June 11, 2012
10.4	Form of Non-Qualified Stock Option Agreement for Employees	Registration Statement on Form S-1, as Exhibit 10.8	June 11, 2012
10.5	Form of Non-Qualified Stock Option Agreement for Non-Employee Directors	Registration Statement on Form S-1, as Exhibit 10.9	June 11, 2012
10.6	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
10.7	Form of Restricted Stock Award Agreement	Registration Statement on Form S-1, as Exhibit 10.13	June 11, 2012
10.8	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
10.9	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
10.10	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

Table of Contents

10.11	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
10.12	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
10.13	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
10.14	2010 Stock Option and Incentive Plan, as amended January 13, 2019	Current Report on Form 8-K, as Exhibit 4.2	January 15, 2019
10.15	Placement agreement between Atossa Genetics Inc. and Maxim Corp. as representative of the Purchasers, dated December 20, 2017	Current Report on Form 8-K, as Exhibit 10.1	December 22, 2017
10.16	Securities Purchase agreement between Atossa Genetics Inc. and each purchaser	Current Report on Form 8-K, as Exhibit 10.2	December 22, 2017
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.

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 28th day of March, 2019.

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 28, 2019
/s/ Kyle Guse **Kyle Guse**	Chief Financial Officer, General Counsel and Secretary (Principal Financial and Accounting Officer)	March 28, 2019

/s/ Richard I. Steinhart **Richard I. Steinhart**	Director	March 28, 2019
Shu-Chi Chen **Shu-Chih Chen, Ph.D.**	Director	March 28, 2019
/s/ Gregory Weaver **Gregory Weaver**	Director	March 28, 2019
/s/ Stephen J. Galli **Stephen J. Galli, M.D.**	Director	March 28, 2019
/s/ H. Lawrence Remmel **H. Lawrence Remmel**	Director	March 28, 2019