ATOSSA GENETICS INC
Form S-1/A
April 23, 2018

As filed with the Securities and Exchange Commission on April 23, 2018

Registration Statement No. 333-223949

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

AMENDMENT NO. 1 TO

FORM S-1

REGISTRATION STATEMENT

UNDER

THE SECURITIES ACT OF 1933

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, Washington 98104

Telephone: (866) 893-4927

(Address, including zip code, and telephone number, including area code, of Registrant's principal executive offices)

Steven C. Quay

Chairman, Chief Executive Officer and President

107 Spring Street

Seattle, Washington 98104

Telephone: (866) 893-4927

(Name, address, including zip code, and telephone

number, including area code, of agent for service)

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Approximate Date of Commencement of Proposed Sale to the Public: From time to time after this Registration Statement becomes effective, as determined by the registrant.

If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act Registration Statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act Registration Statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act Registration Statement number of the earlier effective registration statement for the same offering.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting 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. (Check one):

Large accelerated filer		Accelerated filer
Non-accelerated filer	(Do not check if a smaller reporting company)	Smaller reporting company
		Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided to Section 7(a)(2)(B) of the Securities Act.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the Registration Statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

Subject to Completion, dated April 23, 2018

PRELIMINARY PROSPECTUS

Subscription Rights to Purchase Up to 20,000 Units

Consisting of an Aggregate of Up to 20,000 Shares of Series B Convertible Preferred Stock

and Warrants to Purchase Up to 5,680,000 Shares of Common Stock

at a Subscription Price of $1,000 Per Unit

We are distributing to holders of our common stock and warrants we issued on December 22, 2017, at no charge, non-transferable subscription rights to purchase units. Each unit consists of one share of Series B Convertible Preferred Stock and 284 warrants. Each warrant will be exercisable for one share of our common stock. We refer to the offering that is the subject of this prospectus as the rights offering. In the rights offering, you will receive one subscription right for each share of common stock owned at 5:00 p.m., Eastern Time, on May 9, 2018, the record date of the rights offering. The Series B Convertible Preferred Stock and the warrants comprising the units will be separate upon the closing of the rights offering and will be issued separately, however, they may only be purchased as a unit, and the units will not trade as a separate security. The subscription rights will not be tradable. Holders of warrants as of the record date that we issued on December 22, 2017 will also receive subscription rights pursuant to the terms of those warrants..

Each subscription right will entitle you to purchase one unit, at a subscription price of $1,000 per unit, which we refer to as the basic subscription right. Each warrant entitles you to purchase one share of common stock at an exercise price of $4.05 per share from the date of issuance through its expiration four years after the date of issuance. The subscription price was determined by our board of directors after a review of recent historical trading prices of our common stock on the Nasdaq Capital Market. If you fully exercise your basic subscription right, you may also exercise an over-subscription privilege to purchase additional units that remain unsubscribed to at the expiration of the

rights offering, subject to the availability and pro rata allocation of units among holders of common stock and warrants entitled to receive subscription rights pursuant to this rights offering (which we refer to as participating warrants) exercising this over-subscription privilege. If all the rights are exercised, the total purchase price of the units offered in the rights offering will be approximately $20 million.

The subscription rights will expire if they are not exercised by 5:00 p.m., Eastern Time, on May 24, 2018, unless we extend the rights offering period. In our sole discretion, we may extend the rights offering and the period for exercising your subscription rights. You should carefully consider whether to exercise your subscription rights prior to the expiration of the rights offering. All exercises of subscription rights are irrevocable, even if the rights offering is extended by our board of directors.

We have not entered into any standby purchase agreement or other similar arrangement in connection with the rights offering. The rights offering is being conducted on a best-efforts basis and there is no minimum amount of proceeds necessary to be received in order for us to close the rights offering.

Our board of directors is making no recommendation regarding your exercise of the subscription rights. The subscription rights may not be sold, transferred or assigned and will not be listed for trading on any stock exchange or market or on the NASDAQ Capital Market. Our board of directors may cancel the rights offering at any time prior to the expiration of the rights offering for any reason. In the event the rights offering is cancelled, all subscription payments received by the subscription agent will be returned, without interest, as soon as practicable.

We have engaged Maxim Group LLC to act as dealer-manager for this offering.

Broadridge Corporate Issuer Solutions, Inc. will serve as the subscription agent for the rights offering. The subscription agent will hold in escrow the funds we receive from subscribers until we complete, abandon or terminate the rights offering. If you want to participate in this rights offering and as of the record date you are the record holder of your shares of common stock or December 22, 2017 warrants, we recommend that you submit your subscription documents to the subscription agent well before the deadline of the rights offering period. If you want to participate in this rights offering and you hold shares through your broker, dealer, custodian bank or other nominee, you should promptly contact your broker, dealer, custodian, bank or other nominee and submit your subscription documents in accordance with the instructions and within the time period provided by your nominee.

Our board of directors reserves the right to terminate the rights offering for any reason any time before the closing of the rights offering. If we terminate the rights offering, all subscription payments received will be returned within 10 business days, without interest or deduction. We expect the rights offering to expire on or about May 24, 2018, subject to our right to extend the rights offering as described above, and that we would close on subscriptions within five business days.

Our common stock is currently quoted on the NASDAQ Capital Market under the symbol “ATOS”. On April 20, 2018, the last reported sale price per share of our common stock on the NASDAQ Capital Market was $3.52. We do not currently intend to apply for listing of the Series B Convertible Preferred Stock or the warrants on any securities exchange or recognized trading system.

Our principal executive offices are located at 107 Spring Street, Seattle, Washington 98104.

	Per Unit	Total (2)
Subscription price	$ 1,000	$ 20,000,000
Dealer-manager fees and expenses (1)	$ 70	$ 1,400,000
Proceeds to us, before expenses	$ 930	$ 18,600,000

(1) In connection with the rights offering, we have agreed to pay Maxim Group LLC as the dealer-manager a cash fee equal to 7.0% of the gross proceeds received by us directly from exercises of the subscription rights. We have also agreed to reimburse the dealer-manager for its expenses up to $85,000. Please see “*Plan of Distribution*.”

(2) Assumes the rights offering is fully subscribed, but excludes proceeds from the exercise of warrants included in the units.

Investing in our securities involves risks. You should carefully consider the Risk Factors beginning on page 18 of this prospectus before you make an investment in our securities.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

Dealer-Manager

Maxim Group LLC

The date of this prospectus is , 2018

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Neither we nor the dealer-manager has authorized anyone to provide any information or to make any representations other than those contained in this prospectus or in any free writing prospectus prepared by or on behalf of us or to

which we have referred you. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. This prospectus is an offer to sell only the units offered hereby, but only under the circumstances and in the jurisdictions where it is lawful to do so. The information contained in this prospectus or in any applicable free writing prospectus is current only as of its date, regardless of its time of delivery or any sale of shares of our common stock. Our business, financial condition, results of operations and prospects may have changed since that date. We are not, and the dealer-manager is not, making an offer of these securities in any jurisdiction where such offer is not permitted.

For investors outside the United States: Neither we nor the dealer-manager has done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of securities and the distribution of this prospectus outside the United States.

Unless the context otherwise requires, references in this prospectus to "Atossa" "the Company," "we," "us" and "our" refer to Atossa Genetics Inc. Solely for convenience, our trademarks and tradenames referred to in this registration statement, may appear without the ® or ™ symbols, but such references are not intended to indicate in any way that we will not assert, to the fullest extent under applicable law, our rights to these trademarks and tradenames. All other trademarks, service marks and trade names included or incorporated by reference into this prospectus supplement or the accompanying prospectus are the property of their respective owners.

You should read this prospectus, any applicable prospectus supplement and the information incorporated by reference in this prospectus before making an investment in the securities of Atossa Genetics Inc. See "*Where You Can Find Additional Information*" on page 53 for more information. You should rely only on the information contained in or incorporated by reference in this prospectus or a prospectus supplement. The Company has not authorized anyone to provide you with different information. This document may be used only in jurisdictions where offers and sales of these securities are permitted. You should assume that information contained in this prospectus, or in any document incorporated by reference, is accurate only as of any date on the front cover of the applicable document. Our business, financial condition, results of operations and prospects may have changed since that date. Unless indicated otherwise, all share numbers are expressed in this prospectus reflect the one-for-12 reverse stock split effected on April 20, 2018.

NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus and the documents incorporated by reference into it contain, in addition to historical information, certain information, assumptions and discussions that may constitute 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 prospectus, we cannot assure you that the forward-looking statements set out in this prospectus 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 negative versio words or other comparable words. Forward-looking statements contained in this prospectus include, but are not limited to, statements about:

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

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

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

our ability to contract with third-party suppliers, manufacturers and service providers, including clinical research organizations, and their ability to perform adequately;

our ability to successfully develop and commercialize new therapeutics currently in development or that we might identify in the future and in the time frames currently expected;

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

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

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

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

our expectations as to future financial performance, expense levels and capital sources;
our ability to attract and retain key personnel; and

our ability to raise capital.

This prospectus also contains estimates and other statistical data provided by independent parties and by us relating to market size and growth and other industry data. These and other forward-looking statements made in this prospectus are presented as of the date on which the statements are made. We have included important factors in the cautionary statements included in this prospectus, particularly in the section entitled "*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 prospectus. Except as required by law, we do not intend to update any forward-looking statements after the date on which the statement is made, whether as a result of new information, future events or circumstances or otherwise.

PROSPECTUS SUMMARY

Our Company

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

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

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

In March 2018, we expanded our breast health program by launching a mens' breast health initiative with enrollment opening in a Phase 1 study of our topical Endoxifen in men. The objectives of the placebo-controlled, repeat dose study of 24 healthy male volunteers are to assess the pharmacokinetics of proprietary topical Endoxifen dosage forms over 28 days, as well as to assess safety and tolerability. Depending on the results of this study, we plan to develop our topical Endoxifen for gynecomastia.

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

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

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

Our Programs Under Development

Endoxifen - Background

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

Proprietary Endoxifen - Completed Phase 1 Study

We recently completed a comprehensive Phase 1 study in 49 healthy women in Australia using both the topical and oral forms of our proprietary Endoxifen. The objectives of this double-blinded, placebo-controlled, Phase 1 study were to assess the pharmacokinetics of our proprietary Endoxifen dosage forms as single (oral) and repeat (oral and topical) doses, as well as to assess safety and tolerability. The study was conducted in two parts based on route of administration.

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

Proprietary Topical Endoxifen

We are developing topical, or "transdermal," Endoxifen for several potential indications. One potential indication is women with MBD. Legislation that has been recently enacted in approximately 30 states requires that women be notified if they have MBD and those notifications typically state that women with MBD have a higher risk of developing breast cancer, and that mammography may not be as effective in detecting breast cancer because the MBD can "mask" the detection of cancers. We estimate that approximately ten million women in the Unites States have MBD, for which there is no FDA-approved treatment. Although oral tamoxifen is approved to prevent breast cancer in "high-risk" women, it is used by less than 5% of women with an increased risk of developing breast cancer because of the actual or perceived side effects and risks of tamoxifen.

We believe our topical Endoxifen may provide an effective treatment for MBD because, unlike an oral medication, it is applied directly to the breast and penetrates the skin, it does not require metabolism by the liver, and it may produce fewer side effects than tamoxifen. Moreover, our topical Endoxifen may improve mammography accuracy and patient care by unmasking cancerous tumors that are otherwise hidden by breast density. In two separate reports of film-screen mammography, mammographic sensitivity decreased from a level of 85.7%–88.8% in patients with almost

entirely fatty tissue to 62.2%–68.1% in patients with extremely dense breast tissue.

We are also developing our proprietary topical Endoxifen for gynecomastia. Gynecomastia is male breast enlargement and accompanying pain. It is the most common male breast disorder and is caused by a hormone imbalance where testosterone is low compared to estrogen. Gynecomastia is caused by, among other things, any number of commonly prescribed medications, such as androgen deprivation therapy to treat prostate enlargement and prostate cancer, anti-anxiety medications, cancer treatments (chemotherapy), and some heart medications. Gynecomastia is not only painful and embarrassing, it can also cause men to stop taking these important medications. In prostate cancer treatment, testosterone is suppressed resulting is higher estrogen levels that usually triggers gynecomastia. Prophylactic breast bud irradiation is commonly used in prostate cancer patients, but must often be repeated. One recent study indicates that up to 90% of men taking androgen deprivation therapy suffer from gynecomastia and breast pain (Handoo Rhee, et al., October 18, 2014, *BJU International*).

There are no FDA-approved therapeutics for gynecomastia. Breast-bud irradiation, use of compression garments and plastic surgery are the most common approaches used to treat gynecomastia.

Similar to women, the treatment for male breast cancer is typically surgery (with or without radiation) and chemotherapy. Breast cancer in men is deadlier than breast cancer in women: men with early-stage breast cancer have a lower five-year survival rate than women and breast cancer in men tends to be detected at a later stage of development than women (Jon M. Greif, DO, FACS, et al., May 2012, *American Society of Breast Surgeons*). Although tamoxifen is the standard of care for women to prevent new and recurrent breast cancer, there is no FDA-approved treatment for male breast cancer.

Proprietary Oral Endoxifen

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

Proprietary Endoxifen – Current and Future Clinical Studies

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

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

In March 2018, we opened enrollment in a Phase 1 study of our topical Endoxifen in men. The objectives of the placebo-controlled, repeat dose study of 24 healthy male volunteers are to assess the pharmacokinetics of proprietary topical Endoxifen dosage forms over 28 days, as well as to assess safety and tolerability. The study is being conducted

on behalf of Atossa by CPR Pharma Services Pty Ltd., Thebarton, SA, Australia. CPR Pharma recently completed the successful Phase 1 study of our oral and topical Endoxifen in women.

Proprietary Intraductal Microcatheter Technology

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

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

TRAP CAR-T

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

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

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

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

Delivery of Drugs via our Microcatheters

The initial drug we are studying using our microcatheters for intraductal delivery is fulvestrant. Fulvestrant is FDA-approved for metastatic breast cancer. It is administered as a monthly injection of two shots, typically into the buttocks. In 2012 a published study documented that the single dose cost of intramuscular fulvestrant was approximately $12,000.

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

We do not yet have the FDA’s input, but based on our preliminary analysis, subject to FDA feedback, we believe that the intraductal fulvestrant program could qualify for designation under the 505(b)(2) status. This would allow us to file with only clinical data and without having to perform additional, significant clinical or pre-clinical studies. So the path to market is potentially both faster and less expensive than a standard new drug application, or NDA, program.

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

The primary endpoint of the clinical trial is to compare the safety, tolerability and distribution of fulvestrant between the two routes of administration (intramuscular injection or through our microcatheters). The secondary endpoint of the study is to determine if there are changes in the expression of Ki67 (a measure of cellular proliferation that correlates with tumor growth) as well as estrogen and progesterone receptors between a pre-fulvestrant biopsy and post-fulvestrant surgical specimens. Digital breast imaging before and after drug administration in both groups will also be performed to determine the effect of fulvestrant on any lesions as well as breast density of the participant.

Other Studies of Intraductal Administration using our Microcatheters

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

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

Markets

Potential Market Opportunities

We believe that, based in part on a January 2017 study by Defined Health, a leading market research firm, the potential U.S. market for intraductal administration of fulvestrant or similar drugs in DCIS patients is up to $800 million annually. This estimate includes treatment of DCIS patients prior to surgery as well as patients who would use intraductal treatment as an alternative to surgery. We believe that the potential U.S. market for endoxifen in the treatment and prevention settings is up to $1 billion annually.

The Breast Cancer and Related Markets

The American Cancer Society ("ACS") estimated that in 2018, 268,000 women will be diagnosed with breast cancer in the United States. Every two minutes an American woman is diagnosed with breast cancer and 41,000 die each year. Although about 100 times less common than in women, breast cancer also affects men. The ACS estimated that the lifetime risk of men getting breast cancer is about 1 in 1,000; 2,550 new cases of invasive breast cancer will be diagnosed; and 480 men will die from breast cancer in 2018.

Gynecomastia

According to the Mayo Clinic, although it can affect men at almost any age, gynecomastia is most prevalent in men ages 50-69, affecting at least 1 in 4 men in this age group.

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

SUMMARY OF THE RIGHTS OFFERING

Securities to be Offered:	We are distributing to you, at no charge, one non-transferable subscription right to purchase one unit for each share of our common stock (or share of common stock issuable upon exercise of our December 22, 2017 warrants) that you owned as of the record date. Each unit consists of one share of Series B Convertible Preferred Stock and 284 warrants.
Size of Offering:	20,000 units.
Subscription Price:	$1,000 per unit.
Series B Convertible Preferred Stock:	Each share of Series B Convertible Preferred Stock will be 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, subject to adjustment. The Series B Convertible Preferred Stock has certain conversion rights and dividend rights.
Warrants:	Each warrant entitles the holder to purchase one share of common stock at an exercise price of $4.05 per share, subject to adjustment, through its expiration four years from the date of issuance. The warrants will be exercisable for cash, or, solely during any period when a registration statement for the exercise of the warrants is not in effect, on a cashless basis. We do not intend to apply to list the warrants on any securities exchange or recognized trading system. We may redeem the warrants for $0.18 per warrant if the volume-weighted average price ("VWAP") 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.
Record Date:	5:00 p.m., Eastern Time, on May 9, 2018.
Basic Subscription Rights:	Each subscription right entitles you to purchase one unit at the subscription price. You may not purchase a partial unit.
Over-Subscription Privilege:	If you exercise your basic subscription rights in full, you may also choose to purchase a portion of the units that are not purchased by our other holders of common stock and participating warrants through the exercise of their basic subscription rights, subject to proration and stock ownership limitations described elsewhere in this prospectus.
Expiration Date:	5:00 p.m., Eastern Time, on May 24, 2018.
Procedure for Exercising Subscription	To exercise your subscription rights, you must take the following steps:

Rights: If as of the record date you are a record holder of our common stock or warrants issued December 22, 2017, you must deliver payment and a properly completed rights certificate to the subscription agent to be received before 5:00 p.m., Eastern Time, on May 24, 2018. You may deliver the documents and payments by first class mail or courier service. If you use first class mail for this purpose, we recommend using registered mail, properly insured, with return receipt requested.

If you are a beneficial owner of shares that are registered in the name of a broker, dealer, bank or other nominee, you should instruct your broker, dealer, bank or other nominee to exercise your subscription rights on your behalf. Please follow the instructions of your nominee, who may require that you meet a deadline earlier than 5:00 p.m., Eastern Time, on May 24, 2018.

Delivery of Shares and Warrants:	As soon as practicable after the expiration of the rights offering, and within five business days thereof, we expect to close on subscriptions and for the subscription agent to arrange for the issuance of the shares of Series B Convertible Preferred Stock and warrants purchased pursuant to the rights offering. All shares and warrants that are purchased in the rights offering will be issued in book-entry, or uncertificated, form meaning that you will receive a direct registration, or DRS, account statement from our transfer agent reflecting ownership of these securities if you are a holder of record of shares or warrants. If you hold your shares or participating warrants in the name of a bank, broker, dealer, or other nominee, DTC will credit your account with your nominee with the securities you purchased in the rights offering.
Non-Transferability of Subscription Rights:	Subscription rights may not be sold, transferred, assigned or given away under any circumstances, and will not be listed for trading on any stock exchange or market.