

ATOSSA GENETICS INC
Form S-1/A
March 28, 2017

As filed with the Securities and Exchange Commission on March 28, 2017

Registration Statement No. 333-216031

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

AMENDMENT NO. 4 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

(State or other jurisdiction
of incorporation or organization)

3841

(Primary Standard Industrial
Classification Code Number)

26-4753208

(I.R.S.
Employer
Identification
No.)

107 Spring Street

Seattle, Washington 98104

Telephone: (800) 351-3902

(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: (800) 351-3902

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

Kyle Guse

Chief Financial Officer and General Counsel

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Seattle, Washington 98104

(800) 351-3902

Ryan A. Murr

Gibson, Dunn & Crutcher LLP

555 Mission Street, Suite 3000

San Francisco, California 94105

Telephone: (415) 398-8200

Approximate date of commencement of proposed sale to the public: From time to time after this Registration Statement becomes effective.

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 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. "

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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" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer "

Accelerated filer "

Non-accelerated filer "

Smaller reporting company x

(Do not check if a smaller reporting company)

The registrant is an emerging growth company, as defined in Section 2(a) of the Securities Act. This Registration Statement complies with the requirements that apply to an issuer that is an emerging growth company.

CALCULATION OF REGISTRATION FEE

| Title of each class of securities to be registered | Proposed maximum aggregate offering price(1) | Amount of registration fee(2) |
|--|--|-------------------------------|
| Class A Units consisting of: | | |
| (i) Shares of Common Stock, par value \$0.015 | \$ 1,345,500 | \$ 156 |
| (ii) Warrants to purchase Common Stock, par value \$0.015 | | |
| Class B Units consisting of: | \$ 4,600,000 | \$ 533 |
| (i) Series A Convertible Preferred Stock, par value \$0.001 | | |
| (ii) Shares of Common Stock, par value \$0.015, issuable upon conversion of Series A Convertible Preferred Stock | | |
| (iii) Warrants to purchase Common Stock, par value \$0.015 | | |
| Common Stock, par value \$0.015, issuable upon exercise of Warrants | \$ 7,431,875 | \$ 861 |
| Total | \$ 13,377,375 | \$ 1,550 |

(1) Pursuant to Rule 457(o) of the Securities Act of 1933, estimated solely for the purpose of calculating the registration fee. Includes offering price of shares and warrants which the underwriters have the option to purchase to cover over-allotments, if any.

(2) Filing fee of \$1,040 previously paid.

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 preliminary 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 preliminary prospectus is not an offer to sell these securities and it is not soliciting offers to buy these securities in any jurisdiction where the offer or sale is not permitted.

PRELIMINARY PROSPECTUS, SUBJECT TO COMPLETION DATED MARCH 28, 2017

1,000,000 Class A Units Consisting of

Common Stock and Warrants and

4,000 Class B Units Consisting of Series A Convertible

Preferred Stock and Warrants

This is a firm commitment offering of 1,000,000 Class A Units (consisting of one share of our Common Stock and a warrant to purchase one share of our Common Stock (the “Warrants”). The Warrants will have an exercise price of \$___, will be exercisable upon issuance and will expire five years from the date of issuance. The shares of Common Stock and Warrants part of a Class A Unit are immediately separable and will be issued separately in this offering.

We are also offering to those purchasers whose purchase of Class A Units in this offering would otherwise result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% of our outstanding Common Stock immediately following the consummation of this offering, the opportunity, in lieu of purchasing Class A Units, to purchase an aggregate of 4,000 Class B Units (together with the Class A Units, the “Units”). Each Class B Unit will consist of one share of our Series A Convertible Preferred Stock (the “Series A Preferred”), with a stated value of \$1,000 and each convertible into ___ shares of our Common Stock, together with ___ Warrants. The Series A Preferred do not generally have any voting rights but are convertible into shares of Common Stock. The shares of Series A Preferred and Warrants part of a Class B Unit are immediately separable and will be issued separately in this offering.

We are issuing in this offering (i) up to an aggregate of 1,000,000 shares of our Common Stock and Warrants to purchase 1,000,000 shares of Common Stock as components of the Class A Units, and (ii) up to an aggregate of 4,000 shares of our Series A Preferred and Warrants as components of the Class B Units in an aggregate amount equal to the number of shares of Common Stock into which the Series A Preferred are convertible. The Series A Preferred included in the Class B Units will be convertible into an aggregate number of shares of Common Stock equal to total proceeds from the sale of Class B Units divided by the price per Class A Unit.

Our Common Stock is listed on The NASDAQ Capital Market under the symbol “ATOS.” On March 27, 2017, the last reported sale price of our Common Stock was \$1.17 per share. We do not intend to list any of the Units, Warrants or Series A Preferred on The NASDAQ Capital Market, any other national securities exchange or any other trading system.

We are an “emerging growth company” as that term is used in the Jumpstart Our Business Startups Act of 2012 (the “*JOBS Act*”) and, as such, have elected to comply with certain reduced public company reporting requirements for this prospectus and future filings.

Our business and an investment in our securities involve a high degree of risk. See “Risk Factors” beginning on page 5 of this prospectus for a discussion of information that you should consider before investing 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.

| | Per Class A Unit | Per Class B Unit | Total |
|---|---------------------|---------------------|-------|
| Public offering price | \$ | \$ | \$ |
| Underwriting discounts and commissions ⁽¹⁾ | \$ | \$ | \$ |
| Proceeds, before expenses, to us | \$ | \$ | \$ |

We have also agreed to pay the underwriter a non-accountable expense allowance of 1% of gross offering proceeds (excluding the over-allotment option) and reimbursement for certain of its accountable expenses up to a maximum of \$79,500. See “Underwriting” beginning on page 21 of this prospectus for a description of compensation payable to the underwriters.

We have granted a 45-day option to the underwriters to purchase additional shares of Common Stock and/or additional Warrants to purchase shares of Common Stock, in amounts up to 15% of the Common Stock, Warrants

and/or Common Stock issuable upon conversion of the Series A Preferred included in the Units sold in the offering, solely to cover over-allotments, if any.

The underwriters expect to deliver the Common Stock and Warrants against payment therefor on or about _____, 2017.

Aegis Capital Corp.

, 2017

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Neither we nor the underwriters have 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 shares 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 the Units. Our business, financial condition, results of operations and prospects may have changed since that date. We are not, and the underwriters are 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 underwriters have 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.

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 _ 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.

NOTE REGARDING FORWARD-LOOKING STATEMENTS

Statements made in this prospectus 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 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 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, (the “*FDA*”), and foreign regulatory bodies, to sell, market and distribute our therapeutics and devices under development;

· our ability to successfully complete clinical trials of our pharmaceutical candidates under development, including endoxifen and our intraductal microcatheters to administer therapeutics, including our study using fulvestrant;

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

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

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

· our ability to successfully defend ongoing litigation, including the November 3, 2014 appeal of a dismissal of a securities class action lawsuit that was filed against us, and other similar complaints that may be brought in the future, in a timely manner and within the coverage, scope and limits of our insurance policies;

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

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

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

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

- our ability to attract and retain key personnel; and

- our ability to raise capital, including our ability to sell up to 467,650 shares of Common Stock to Aspire Capital Fund LLC (“*Aspire Capital*”) under the terms of the May 25, 2016 Common Stock purchase agreement with Aspire Capital (the “*Aspire Purchase Agreement*”).

This 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 titled “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

The following summary of our business highlights certain of the information contained elsewhere in or incorporated by reference into this prospectus. Because this is only a summary, however, it may not contain all of the information that may be important to you. You should carefully read the following summary together with the more detailed information regarding our Company and the securities being sold in this offering, including “Risk Factors” and other information incorporated by reference herein.

Our Company

We are a clinical-stage pharmaceutical company focused on the development of novel therapeutics and delivery methods for the treatment of breast cancer and other breast conditions. Our leading program uses our patented intraductal microcatheters which deliver pharmaceuticals through the breast ducts. We initiated a Phase 2 clinical study in March 2016 using our microcatheters to deliver fulvestrant as a potential treatment of ductal carcinoma in-situ, or DCIS, and breast cancer. This study was initiated at Columbia University Medical Center Breast Cancer Programs and is in the process of being transferred to Montefiore Medical Center.

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

We 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.

On March 23, 2017, we opened an endoxifen Phase 1 clinical study. We plan to commence a Phase 2 clinical study of endoxifen in the second half of 2017. We anticipate completing enrollment in the fulvestrant microcatheter study by August 2017.

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

Summary of Our Clinical-Stage Programs Under Development

Delivery of Therapeutics via our Microcatheters

We believe our patented intraductal microcatheters may be useful in delivering a number of therapeutics to the ducts in the breast, the site of the majority of early breast cancers. Doing so is intended to provide a therapeutic directly to the breast tissue while at the same time reducing the delivery of the drug to healthy tissue. We must obtain FDA approval of any drug delivered via our intraductal microcatheters devices, which will require expensive and time-consuming studies. 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 and obtaining FDA approval.

According to The American Cancer Society, breast cancer is the most common cancer in American women, other than skin cancer. The American Cancer Society estimates that in 2017 there will be 252,710 new cases of breast cancer in women in the United States, in addition to 63,410 cases of carcinoma in situ. They also estimate that 40,610 women will die from breast cancer in the United States in 2017.

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

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 the 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. As a result, the path to market could be both faster and less expensive than a standard new drug application program.

To support this development program, we have successfully produced microcatheters for the fulvestrant Phase 2 clinical trial. The FDA has also issued a "Safe to Proceed" letter for our first Investigational New Drug application (an "IND") for the Phase 2 study and the institutional review board approval has also been received.

In March 2016, we opened enrollment in the fulvestrant microcatheter study, which was initially being conducted by The Columbia University Medical Center Breast Cancer Program. The principal investigator for this study transferred from Columbia to Montefiore Medical Center in January 2017, and as a result we are in the process of transferring the study to Montefiore Medical Center. We expect to complete enrollment in the study by August 2017.

The study includes women with DCIS or invasive breast cancer slated for mastectomy or lumpectomy. This study will assess the safety, tolerability and distribution of fulvestrant when delivered directly into breast milk ducts of these patients compared to those who receive the same product intramuscularly. The secondary objective of the study is to determine if there are changes in the expression of Ki67 as well as estrogen and progesterone receptors between a pre-fulvestrant biopsy and post-fulvestrant surgical specimen. 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. Six study participants will receive the standard intramuscular fulvestrant dose of 500 mg to establish the reference drug distribution, and 24 participants will receive fulvestrant by intraductal instillation utilizing our microcatheter device. The total dose administered via our microcatheters will not exceed 500 mg.

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

Additional information about the study can be found at:

<https://clinicaltrials.gov/ct2/show/NCT02540330?term=atossa&rank=2>.

Endoxifen

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

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

On March 23, 2017, we opened a Phase 1 study of endoxifen, which we are conducting through a clinical research organization in Australia. The anticipated primary endpoint of this placebo-controlled, repeat dose study of 48 healthy female volunteers is to assess the pharmacokinetics of both an oral and topical formulation of endoxifen over 28 days. The secondary endpoint is to assess safety and tolerability.

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

We believe that the potential U.S. market for endoxifen in the treatment and prevention settings is up to \$1 billion in annual sales.

Our Pre-Clinical Programs Under Development

In addition to our clinical-stage pharmaceutical programs, we are in the process of evaluating other therapeutic candidates to treat breast conditions, including breast cancer. Factors we are considering in evaluating potential drug candidates include, for example, the ability to obtain expedited regulatory approval, significance of unmet medical need, size of the patient population, intellectual property opportunities, and the anticipated pre-clinical and clinical pathway.

Our Medical Devices

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

Our patented intraductal microcatheter devices are being developed for the targeted delivery of potential pharmaceuticals and are currently being used in a Phase 2 clinical trial, as described above.

Intellectual Property

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

| Description | U.S. Patents | | U.S. Pending ⁽¹⁾ | Foreign Patents | | Foreign Pending ⁽¹⁾ |
|-------------------------------|-----------------------|------------|-----------------------------|------------------------|------------|--------------------------------|
| | Issued ⁽¹⁾ | Expiration | | Granted ⁽¹⁾ | Expiration | |
| Intraductal Treatment Program | 0 | N/A | 3 | 2 | | 1 |

| | | | | | | |
|---|----|----------------|---|----|----------------|---|
| | | | | | 2017 - 2031 | |
| Therapeutics | 0 | N/A | 3 | 0 | N/A | 2 |
| ForeCyte Breast Aspirator Program | 2 | 2017 - 2031 | 0 | 12 | 2017 - 2031 | 0 |
| Fullcyte Microcatheters, Fullcyte Breast aspirator and Diagnostics/tests Programs | 29 | 2017 - 2031 | 1 | 31 | 2017 - 2031 | 3 |
| Acueity Tools | 12 | 2017 - 2024 | 0 | 0 | 2017 - 2024 | 0 |

(1) The total number of patents issued or pending, as applicable, in the respective descriptive columns exceed the totals because some patents and applications contain more than one type of claim directed to methods, kits, compositions, devices and/or technology. The patent counts disclosed herein and in our patent estate are subject to change.

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

Implications of being an Emerging Growth Company

We are an “emerging growth company,” as defined in the JOBS Act, and, for as long as we continue to be an “emerging growth company,” we may choose to take advantage of exemptions from various reporting requirements applicable to other public companies but not to “emerging growth companies,” including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002 (the “*Sarbanes-Oxley Act*”), reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could be an “emerging growth company” for up to five years, or until the earliest of (i) the last day of the first fiscal year in which our annual gross revenues exceed \$1 billion, (ii) the date that we become a “large accelerated filer” as defined in Rule 12b-2 under the Exchange Act, which would occur if the market value of our Common Stock that is held by non-affiliates exceeds \$700 million as of the last business day of our most recently completed second fiscal quarter, or (iii) the date on which we have issued more than \$1 billion in non-convertible debt during the preceding three-year period. We are choosing to “opt out” of the extended transition periods available under the JOBS Act for complying with new or revised accounting standards, and intend to take advantage of the other exemptions.

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 prospectus. We make available, free of charge through our website or upon written request, our Annual Reports on Form 10-K/A, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and other periodic SEC reports, along with amendments to all of those reports, as soon as reasonably practicable after

we file the reports with the SEC.

Unless otherwise noted, the term “Atossa Genetics” refers to Atossa Genetics Inc., a Delaware corporation, the terms “Atossa,” the “Company,” “we,” “us,” and “our,” refer to the ongoing business operations of Atossa and the historic business of the NRLBH, whether conducted through Atossa Genetics or the NRLBH; however unless the context otherwise indicates, references to “we,” “our” or the “Company” as they relate to laboratory tests generally refers to activities conducted by the NRLBH. We were incorporated in Delaware in April 2009. Our principal executive offices are located at 107 Spring Street, Seattle WA 98104, and our telephone number is (800) 351-3902.

Our name and logo, Atossa and Atossa Genetics (stylized) are our registered trademarks. ArgusCYTE is our registered service mark. This prospectus also includes additional trademarks, trade names and service marks of third parties, which are the property of their respective owners.

THE OFFERING

Class A Units covered by this Preliminary Prospectus:

1,000,000 Class A Units with each Class A Unit consisting of one share of Common Stock and one Warrant to purchase one share of Common Stock.

Class B Units covered by this Preliminary Prospectus:

4,000 Class B Units are also being offered to those purchasers, if any, whose purchase of Class A Units in this offering that would otherwise result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% of our outstanding Common Stock immediately following the consummation of this offering, the opportunity, in lieu of purchasing Class A Units, to purchase Class B Units. Each Class B Unit will consist of one share of Series A Preferred, with a stated value of \$1,000 and convertible into ___ shares of our Common Stock, together with ___ Warrants. The Series A Preferred do not have any voting rights but are convertible into shares of Common Stock. The Class B Units will not be certificated and the shares of Series A Preferred and Warrants part of such unit are immediately separable and will be issued separately in this offering.

Common Stock outstanding as of March 27, 2017:

3,786,913 shares.

Use of proceeds:

The net proceeds from this offering after deducting estimated underwriting discounts and commissions and offering expenses payable by us will be approximately \$4.6 million (or \$5.3 million if the underwriters exercise in full their option to purchase additional shares of Common Stock and/or Warrants from us), assuming an offering price per Class A Unit of \$1.17, the last reported sale price of our Common Stock on The NASDAQ Capital Market on March 24, 2017, and an offering price per Class B Unit of \$1,000, excluding proceeds, if any, from exercise of the Warrants. We intend to use the net proceeds from this offering for working capital and general corporate purposes. See "Use of Proceeds" for a more detailed description of the intended use of proceeds from this offering.

Risk factors:

The Units offered hereby involve a high degree of risk. See "Risk Factors" beginning on page 5.

Dividend policy:

We currently intend to retain any future earnings to fund the development and growth of our business. Therefore, we do not currently anticipate paying cash dividends on our Common Stock.

Trading symbol:

Our Common Stock currently trades on The NASDAQ Capital Market under the symbol "ATOS." We do not intend to list the Units, Warrants or Series A Preferred on The NASDAQ Capital Market, any other national securities exchange or any other trading system.

RISK FACTORS

A purchase of our shares of the Units, including the Common Stock Warrants included in the Units, is an investment in our securities and involves a high degree of risk. You should carefully consider the risks and uncertainties and all other information contained in or incorporated by reference in this prospectus, including the risk and uncertainties discussed in our Annual Report on Form 10-K/A for the fiscal year ended December 31, 2016. If any of these 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.

We may not continue as a going concern.

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

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

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

The Warrants and Series A Preferred are new issues of securities with no established trading market.

The Warrants and Series A Preferred are new issues of securities with no established trading market. The Warrants and Series A Preferred will not be listed on any securities exchange or quotation system. A trading market for the Warrants and Series A Preferred may not develop and even if a market develops it may not provide meaningful liquidity. The absence of a trading market or liquidity for the Warrants and Series A Preferred may adversely affect their values.

The Warrants may not have any value.

The Warrants may not have any value because, for example, the exercise price of the Warrants may be higher than the price of our Common Stock. On the issuance date, the exercise price of the Warrants will be 125% above the price of the Common Stock issued in the offering. The price of the Common Stock may not at any time appreciate above the exercise price of the Warrants and as a result the Warrants may not develop any value.

USE OF PROCEEDS

We estimate that the net proceeds from our issuance and sale of 1,000,000 Class A Units and 4,000 Class B Units in this offering will be approximately \$4.6 million excluding the proceeds, if any, from exercise of the Warrants (or approximately \$5.3 million if the underwriters exercise their option to purchase additional shares of Common Stock and/or Warrants from us in full), assuming a public offering price of \$1.17 per Class A Unit, which was the last reported sale price of our Common Stock on The NASDAQ Capital Market on March 24, 2017, and \$1,000 per Class B Unit, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

A \$0.25 increase (decrease) in the assumed public offering price of \$1.17 per Class A Unit (and a proportionate increase (decrease) in the assumed offering price per Class B Unit) would increase or decrease the net proceeds from this offering by approximately \$1.0 million (\$1.0 million), assuming the number of Units offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. An increase (decrease) by 10% (or 100,000 Class A Units and 400 Class B Units) offered by us would increase (decrease) the net proceeds to us from this offering by approximately \$0.5 million (\$0.5 million), assuming that the public offering price remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. We do not expect that a change in the public offering price or the number of Units by these amounts would have a material effect on our anticipated uses of the net proceeds from this offering, although it may accelerate the time at which we will need to seek additional capital.

We anticipate that we will use the net proceeds from this offering for working capital and general corporate purposes. We may also use a portion of the net proceeds from this offering for the acquisition of, or investment in, complementary business, products, or technologies, although we have no present commitments or agreements for any specific acquisitions or investments. Pending our use of the net proceeds from this offering, we intend to invest the net proceeds in a variety of capital preservation investments, including short-term, investment grade, interest bearing instruments and U.S. government securities

These expected uses of the net proceeds from this offering represent our intentions based upon our current financial condition, results of operations, business plans, and conditions. As of the date of this prospectus, we cannot predict with certainty all of the particular uses for the net proceeds to be received upon the closing of this offering or the amounts that we will actually spend on the uses set forth above. The amounts and timing of our actual expenditures may vary significantly depending on numerous factors. As a result, our management will retain broad discretion over the allocation of the net proceeds from this offering.

DIVIDEND POLICY

We have not declared any dividends and do not anticipate that we will declare dividends in the foreseeable future; rather, we intend to retain any future earnings for the development of the business. Payment of future cash dividends, if any, will be at the discretion of our Board of Directors after taking into account various factors, including our financial condition, operating results, current and anticipated cash needs, outstanding indebtedness and plans for expansion and restrictions imposed by lenders, if any.

DILUTION

If you invest in our Units, your interest will be diluted immediately to the extent of the difference between the public offering price per Unit (on an as-converted to Common Stock basis) and the adjusted net tangible book value per share of our Common Stock after this offering.

The net tangible book value of our Common Stock as of December 31, 2016, was approximately \$2,456,666, or approximately \$0.65 per share. Net tangible book value per share represents the amount of our total tangible assets, excluding goodwill and intangible assets, less total liabilities, divided by the total number of shares of our Common Stock outstanding.

Dilution per share to new investors represents the difference between the amount per share paid by purchasers for each share of Common Stock included in the Units (including the number of shares of Common Stock issuable upon conversion of the Series A Preferred) in this offering and the net tangible book value per share of our Common Stock, including Common Stock issuable upon conversion of the Series A Preferred, immediately following the completion of this offering.

After giving effect to the sale of the Units that are offered by this prospectus (including shares of Common Stock included in the Class A Units and the Common Stock issuable upon exercise of the Series A Preferred), excluding the proceeds if any from the exercise of the Warrants included in the Units, at an offering price of \$1.17 per Class A Unit, which was the closing price of our Common Stock on The Nasdaq Capital Market on March 27, 2017, and \$1,000 per Class B Unit in connection with this offering and after deducting the estimated underwriting discounts, commissions and offering expenses, our pro forma net tangible book value as of December 31, 2016 would have been approximately \$7,053,566 or approximately \$0.86 per share. This represents an immediate increase in net tangible book value of approximately \$0.21 per share to our existing stockholders and an immediate dilution in pro forma net tangible book value of approximately \$0.31 per share to purchasers of Units in this offering, as illustrated by the following table:

| | |
|---|---------|
| Offering price per Class A Unit | \$ 1.17 |
| Net tangible book value per share as of December 31, 2016 | \$ 0.65 |

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| | |
|---|------------|
| Increase per share attributable to the offering | \$ 0.21 |
| As adjusted net tangible book value per share after this offering | \$ 0.86 |
| Dilution per share to new investors | \$ (0.31) |

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The discussion of dilution, and the table quantifying it, assumes no exercise of any outstanding options or warrants or the issuance of other potentially dilutive securities and no exercise of the underwriters overallotment option. The exercise of potentially dilutive securities having an exercise price less than the offering price would increase the dilutive effect to new investors.

The number of shares of Common Stock shown above to be outstanding after this offering is based on 3,786,913 shares outstanding as of December 31, 2016, and excludes shares of Common Stock issuable in connection with future option grants as well as the following as of December 31, 2016:

- Shares of our Common Stock issuable upon exercise of the Warrants included in the Units;

- 378,924 shares of our Common Stock subject to options outstanding having a weighted average exercise price of \$26.25 per share; and

- 402,228 shares of our Common Stock that have been reserved for issuance upon exercise of outstanding warrants having exercise prices ranging from \$18.75 to \$186.45 per share.

UNDERWRITING

Aegis Capital Corp. is acting as the representative of the underwriters and the sole book-running manager in this offering. We have entered into an underwriting agreement dated _____ with the representative. Subject to the terms and conditions of the underwriting agreement, we have agreed to sell to each underwriter named below and each underwriter named below has severally and not jointly agreed to purchase from us, at the public offering price per share less the underwriting discounts and commissions set forth on the cover page of this prospectus, the number of Units listed next to its name in the following table:

| Underwriters | Number of Class A Units | Number of Class B Units |
|---------------------|----------------------------------|----------------------------------|
| Aegis Capital Corp. | | |
| Total | | |

The underwriters are committed to purchase all the Units offered by us other than those covered by the option to purchase additional shares of Common Stock and/or Warrants described below, if they purchase any Units. The obligations of the underwriters may be terminated upon the occurrence of certain events specified in the underwriting agreement. Furthermore, pursuant to the underwriting agreement, the underwriters' obligations are subject to customary conditions and representations and warranties contained in the underwriting agreement, such as receipt by the underwriters of officers' certificates and legal opinions.

We have agreed to indemnify the underwriters against specified liabilities, including liabilities under the Securities Act, and to contribute to payments the underwriters may be required to make in respect thereof.

The underwriters are offering the Units, subject to prior sale, when, as and if issued to and accepted by them, subject to approval of legal matters by their counsel and other conditions specified in the underwriting agreement. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

Over-allotment Option. We have granted the underwriters an over-allotment option. This option, which is exercisable for up to 45 days after the date of this prospectus, permits the underwriters to purchase a maximum of ____ additional shares of Common Stock and/or Warrants to purchase a maximum of ____ shares of Common Stock (15% of the shares underlying the Units sold in this offering) from us to cover over-allotments, if any. If the underwriters exercise

all or part of this option, they will purchase such Common Stock covered by the option at the public offering price per Class A Unit minus one cent and the Warrants covered by the option at a price of one cent per Warrant, in each case less the underwriting discounts and commissions. If this option is exercised in full, the total offering price to the public will be \$ and the total net proceeds, before expenses, to us will be \$.

Discounts, Commissions and Non-Accountable Expense Allowance. The following table shows the public offering price, underwriting discount, non-accountable expense allowance and proceeds, before expenses, to us. The information assumes either no exercise or full exercise by the underwriters of their over-allotment option.