

ATOSSA GENETICS INC
Form 424B3
June 20, 2016

Filed Pursuant to Rule 424(b)(3)

Registration Statement No. 333-211797

PROSPECTUS

DATED June 15, 2016

7,760,810 Shares

Common Stock

This prospectus relates to the sale of up to 7,760,810 shares of our Common Stock by Aspire Capital Fund, LLC, an Illinois limited liability company (“*Aspire Capital*” or the “*Selling Stockholder*”). The prices at which the Selling Stockholder may sell the shares will be determined by the prevailing market price for the shares or in negotiated transactions. We will not receive proceeds from the sale of the shares by the Selling Stockholder. However, we may receive proceeds of up to \$10.0 million from the sale of our Common Stock to the Selling Stockholder, pursuant to a common stock purchase agreement entered into with the Selling Stockholder on May 25, 2016 (the “*Purchase Agreement*”).

The Selling Stockholder is an “underwriter” within the meaning of the Securities Act of 1933, as amended. We have paid the expenses of registering these shares, but all selling and other expenses incurred by the Selling Stockholder will be paid by the Selling Stockholder.

Our Common Stock trades on the NASDAQ Capital Market, or NASDAQ, under the ticker symbol “ATOS.” On June 15, 2016, the last reported sale price per share of our common stock was \$0.30 per share.

Investing in our securities involves a high degree of risk. See “Risk Factors” on page 9 of this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

The date of this prospectus is June 15, 2016

TABLE OF CONTENTS

<u>PROSPECTUS SUMMARY</u>	1
<u>RISK FACTORS</u>	9
<u>USE OF PROCEEDS</u>	11
<u>DIVIDEND POLICY</u>	11
<u>SELLING STOCKHOLDER</u>	11
<u>THE ASPIRE CAPITAL TRANSACTION</u>	13
<u>PLAN OF DISTRIBUTION</u>	18
<u>DESCRIPTION OF SECURITIES TO BE REGISTERED</u>	20
<u>DISCLOSURE OF COMMISSION POSITION ON INDEMNIFICATION FOR SECURITIES ACT LIABILITIES</u>	22
<u>LEGAL MATTERS</u>	22
<u>EXPERTS</u>	22
<u>WHERE YOU CAN FIND ADDITIONAL INFORMATION</u>	22
<u>INCORPORATION OF CERTAIN INFORMATION BY REFERENCE</u>	23
PART II INFORMATION NOT REQUIRED IN PROSPECTUS	II-1
SIGNATURES	II-6
EXHIBIT INDEX	II-7

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 9 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

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 version of these words or other comparable words. Forward-looking statements contained in this prospectus include, but are not limited to, statements about:

- our ability to raise additional capital necessary to fund our ongoing operations;

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

- our ability to successfully complete clinical trials of our pharmaceutical candidates under development, including Afimoxifene Gel and our intraductal microcatheters to administer therapeutics, including the study we recently opened using fulvestrant;

- the success, cost and timing of our product and drug development activities and clinical trials;

- our ability to succeed in our lawsuit against Besins Healthcare Luxembourg SARL (“Besins”) for breach of contract and other claims against them and to defend against their counterclaims;

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

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

our ability to successfully defend ongoing litigation, including the securities class action law suit filed against us on October 10, 2013, 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; and

- our ability to attract and retain key personnel.

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 pharmaceutical agents 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 is being conducted by Columbia University Medical Center Breast Cancer Programs. Our second pharmaceutical program is Afimoxifene Topical Gel, or AfTG, for the treatment and prevention of hyperplasia of the breast; however, this program is currently on hold.

In addition to our clinical-stage pharmaceutical programs, we are in the process of evaluating other therapeutic candidates to treat other 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.

Through mid-2015, we were primarily focused on the development and commercialization of our medical devices and laboratory tests. Our medical devices include the ForeCYTE Breast Aspirator and the FullCYTE Breast Aspirator. These devices are intended for the collection of nipple aspirate fluid, or NAF, for cytological testing at a laboratory. Our laboratory tests have historically been developed and performed by The National Reference Laboratory for Breast Health, Inc., or the “NRLBH.” The NRLBH was our wholly-owned subsidiary until December 16, 2015 when, pursuant to a stock purchase agreement, we sold approximately 81% of the capital stock of the NRLBH to the NRL Investment Group, LLC. Other devices under development also include intraductal microcatheters for the potential administration of targeted pharmaceuticals, and various tools for potential use by breast surgeons.

We are now focusing our business on our pharmaceutical programs and drug delivery methods. Our key objectives are to advance our pharmaceutical candidates through Phase 2 trials and then evaluate further development independently

or through partners and to advance one or more of our pre-clinical programs into the clinical trial stage.

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

Our Clinical-Stage Programs Under Development

Delivery of Therapeutics via our Microcatheters

We believe our patented intraductal microcatheters may be useful in delivering a number of therapeutics to the ducts in the breast. Doing so is intended to provide a therapeutic directly to the affected breast 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 intraductal delivery method. We may not be successful in completing these studies and obtaining FDA approval.

Although breast cancers and precancerous lesions are detected at an earlier stage, and despite the use of systemically administered agents such as tamoxifen and Faslodex®, serious treatment side effects remain a major challenge, and may lead to poor patient compliance with the drug regimens. The American Cancer Society estimates over 292,000 American women were diagnosed with breast cancer (both local and invasive) in 2015. They also estimate that over 40,000 women died in 2015 due to their disease. Providing a therapeutic agent directly into the ducts targeting the site of the localized cancerous lesions could reduce the need for systemic anti-cancer drugs, and potentially reducing or eliminating the systemic side effects of the drugs and morbidity in such patients, and ultimately improve patient compliance and ultimately reduce mortality.

One potential market for intraductal therapy is to take advantage of the large difference in the amount of drug that potentially gets into the breast tissue with the intraductal administration versus the intramuscular injection. One analysis suggests that the drug levels in breast tissue might be over 20,000-times higher with the intraductal route than the drug levels following systemic delivery of the same dose. This provides the potential to test a ‘one and done’ intraductal treatment modality instead of the monthly injections and with potentially higher tissue levels than are possible with intramuscular injection which should represent a significant cost savings to the healthcare system.

A second potential indication for intraductal therapy is in the neoadjuvant setting, meaning that the drug would be delivered before the primary treatment of surgery. High drug concentration at the site of the tumor and lack of systemic exposure and subsequent toxicity could represent treatment advances. The current neoadjuvant schedules can run for three months before surgery and the ability to shorten that by one or even two months has value for the patient and the healthcare system.

Fulvestrant Delivered Via our Microcatheters

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

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

We do not yet have FDA’s input, but our preliminary analysis, subject to FDA feedback, is 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

could be both faster and less expensive than a standard new drug application, or NDA, program.

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

In March 2016, we opened enrollment in the study ATOS-2015-007, which will be conducted by The Columbia University Medical Center Breast Cancer Program and is known as the “007 Trial”. The 007 Trial is a Phase 2 study in 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 first six study participants will receive the standard intramuscular fulvestrant dose of 500 mg to establish the reference drug distribution. The subsequent 24 participants will receive fulvestrant by intraductal instillation utilizing our microcatheter device. The total dose administered in this manner will not exceed 500 mg.

The primary endpoint of the clinical trial is to assess the safety, tolerability and distribution of intraductally administered fulvestrant in women with DCIS or Stage 1 or 2 invasive ductal carcinoma prior to mastectomy or lumpectomy. The secondary objective of the study is to determine if there are changes in the expression of Ki-67 (an antigen that can be measured to indicate proliferation rates) 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. Additional information about the study can be found at: <https://clinicaltrials.gov/ct2/show/NCT02540330?term=atossa&rank=2>.

Competition

Our intraductal microcatheters face competition from other microcatheters on the market or under development that may be used, including “off-label,” to administer therapeutics into the breast ducts. Our microcatheter devices also face competition from drugs administered by more traditional methods, including orally and intramuscularly. We may not be able to compete with our competitors for a number of reasons, including because our competitors may have greater resources and because their products may be adopted more quickly than ours.

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.

Afimoxifene Topical Gel (AfTG)

Overview

We hold the worldwide exclusive rights to develop and commercialize AfTG for the potential treatment and prevention of hyperplasia of the breast. The active pharmaceutical ingredient in AfTG is Afimoxifene (4-hydroxytamoxifen), which is an active metabolite of tamoxifen (an estrogen receptor blocker that is used to prevent and treat breast cancer). Afimoxifene is an anti-estrogen with an affinity for estrogen receptor that is up to 50-fold higher compared with that of tamoxifen. AfTG is a proprietary transdermal gel formulation of Afimoxifene protected by 10 patent families. We are evaluating AfTG for potential use in several patient populations, including but not limited to: high risk women as determined by family history, etc.; women with breast hyperplasia; and women with a biopsy showing either atypical hyperplasia or DCIS.

AfTG can be dispensed from a convenient metered-dose container. We have rights to a comprehensive preclinical pharmacology and toxicology package on AfTG and its manufacturing CMC package is expected to be sufficient to support our Phase 2 and 3 programs. A total of 16 Phase 1 and Phase 2 studies have been conducted in a variety of indications in the United States, United Kingdom, France, Poland, and Czech Republic. These studies enrolled over 450 patients total, and results were published in leading medical journals such as the Journal of Clinical Oncology (J Clin Oncol 2005;23:2980-87), Clinical Cancer Research (Clin Cancer Res 2014;20:3672-82), and Breast Cancer Research and Treatment (Breast Cancer Res Treat 2007;106:389-97).

We have engaged AAIPharma/Cambridge Major Laboratories to manufacture Afimoxifene, the API in AfTG. They are an experienced pharmaceutical manufacturer with a good FDA track record and we expect they will be able to produce the cGMP quantities in a timely manner to support our study plans.

We have also received written FDA guidance pertaining to our AfTG development program.

Potential Funding by NCI

The National Cancer Institute, Division of Cancer Prevention, has indicated that a member of the Consortia for Cancer Prevention Clinical Trials Program will be conducting a study of AfTG in women with DCIS and another in women with breast density. The Consortia includes five major medical research centers: the University of Arizona, Northwestern University, Mayo Clinic Foundation, M. D. Anderson Cancer Center and the University of Wisconsin. The next step is for the academic investigator to develop a clinical protocol. The majority of the cost of the clinical trial is expected to be paid for by the NCI. This program could provide major clinical validation of AfTG by the NCI and leading breast cancer academic investigators.

Existing Data on AfTG

AfTG has been used in 16 Phase 1 and Phase 2 studies conducted in a variety of indications with over 450 patients. We are in the process of re-establishing the clinical supply of AfTG and would be able to commence a Phase 2 clinical trial starting in mid-2016, but subject to resolution of our ongoing dispute with Besins (described below).

The results of previous studies show that the efficacy of oral tamoxifen in preventing cancer in the study patient populations varies from a low of about 50% to a high of almost 85%. The cancers that did occur in the patients in these studies had a common theme: none of them were estrogen-receptor positive. Accordingly, the most common kind of breast cancer, estrogen positive, is almost entirely prevented by oral tamoxifen. The most common form of male breast cancer is also estrogen receptor positive, which indicates that there is also potential for this currently underserved breast cancer population.

These studies demonstrate that tamoxifen is quite effective in preventing breast cancer in these patient populations. Based on preclinical work done to date, we anticipate that our clinical studies will show that AfTG has similar efficacy, while demonstrating a superior safety profile due to the topical administration (as compared to the oral administration of tamoxifen).

In a previous study conducted by the National Cancer Institute and academic centers in women with DCIS, oral tamoxifen or AfTG was given to women for a month and the amount of drug was measured in the breast, and in the blood: blood levels are associated with toxicity. The results show that there were similar amounts of active drug in the breast of both groups but <5% of drug in the blood with our gel compared to oral tamoxifen. The blood markers of stroke, blood clots, and uterine cancer were increased by oral tamoxifen but not AfTG. Additionally, the biomarker in the breast of blocking estrogen effect, called Ki-67, showed similar blockage of cell growth.

Summary of our Rights to AfTG

These AfTG rights were granted to us pursuant to a May 14, 2015, Intellectual Property License Agreement with Besins Healthcare Luxembourg SARL (“Besins”). The agreement requires that we pay a royalty of 8% to 9% of net sales for the first 15 years of commercialization. We have the non-exclusive right to also develop AfTG for breast cancer and other breast diseases, which would require the payment of the following milestone payments for these additional indications: (i) \$5,000,000 for the exclusive right to review, access, and reference a Besins investigational new drug application (IND) for each additional indication, and (ii) \$20,000,000 when we commence a Phase 3 clinical trial for each additional indication.

Besins has a limited right of first refusal to commercialize AfTG on a country-by-country basis in countries where Besins has a marketing presence.

The agreement automatically expires on a country-by-country basis fifteen years after the first commercial sale of AfTG in the particular country. The agreement may be terminated (i) by either party upon a material breach of the agreement that is not cured by the breaching party, (ii) by mutual agreement of the parties, (iii) by Atossa at its discretion if it elects to stop developing or commercializing AfTG, (iv) by Besins on a country-by-country basis or indication-by-indication basis if we fail to commercialize or commence commercial sales within a specified time, or (v) by Besins if we fail to accomplish any aspect of the development plan within six months of target date set forth in the development plan. The development plan covers an 18-month period and is required to be updated by us every six months during the term of the agreement.

Besins has informed us that they plan to develop AfTG for the reduction of breast density, which we believe is within the scope of our exclusive rights under the License Agreement. We have informed Besins that its efforts to develop AfTG for breast density would infringe our exclusive rights under the License Agreement, including our exclusive rights to develop AfTG for treatment and prevention of hyperplasia of the breast, and would constitute a breach of the License Agreement by Besins.

On January 28, 2016, we filed a complaint in the United States District Court for the District of Delaware captioned *Atossa Genetics Inc. v. Besins Healthcare Luxembourg SARL*. The complaint asserts claims for breach of contract, breach of the implied covenant of good faith and fair dealing, and for declaratory relief against Besins. On March 7, 2016, Besins responded to our complaint by denying our claims and asserting counterclaims against us for breach of contract, fraud, and negligent misrepresentation and declaratory relief. We believe that these counterclaims are without merit and we plan to defend our self vigorously; however, failure by us to obtain a favorable resolution of the counterclaims could have a material adverse effect on our business, results of operations and financial condition.

Competition

AfTG faces competition from other pharmaceutical and therapeutic companies, including companies developing or offering competitive products, including “off-label,” that are administered topically or orally. We may not be able to compete with our competitors for a number of reasons, including because our competitors may have greater resources and because their products may be adopted more quickly than ours.

Next steps with AfTG

Because of the dispute with Besins, work on this program is currently on hold.

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

The ForeCYTE Breast Aspirator is a medical device which consists of a reusable hand-held pump for the collection of NAF, single-use patient kits that include two NAF sample collection tools per kit, and shipment boxes for the transportation of NAF samples to any testing laboratory for cytological analysis. The FullCYTE Breast Aspirator is FDA-cleared and is simpler in design as it contains four parts in a fully disposable, single-use aspirator. This device operates slightly differently than the ForeCYTE Breast Aspirator in that the NAF sample is captured via capillary tubes prior to being sent to any lab for analysis. We have also developed a universal transport kit to assist with the packaging and transport of NAF samples to a laboratory. NAF cytology testing is a Laboratory Developed Test (LDT) consisting of receiving and accessioning the two NAF samples from each patient, preparing routine and immunohistochemistry, or IHC, in the case of NAF collected with the current ForeCYTE or FullCYTE device, staining of slides from the NAF samples, and generating a report of the findings. The NAF is analyzed by microscopy for cytological abnormalities and by a patent-pending IHC staining technique for five biomarkers of hyperplasia and a sample integrity marker. The NAF cytology test on samples collected with the ForeCYTE device also involves one biomarker of sample integrity and has been validated to CLIA standards. However, we are not currently commercializing our breast aspirator devices nor any NAF cytology tests.

In 2012 we acquired from Acueity Healthcare various medical devices consisting primarily of tools to assist breast surgeons. Our breast aspirator devices, universal transport kit and devices acquired from Acueity are not currently being marketed and sold as we are devoting substantially all of our resources to the development of our pharmaceutical programs.

Our patented intraductal microcatheter devices are being developed for the targeted delivered of potential pharmaceuticals, as described above.

Implications of being an Emerging Growth Company

We are an “emerging growth company,” as defined in the Jumpstart Our Business Startups Act of 2012, or 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, 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 Securities Exchange Act of 1934, as amended, 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 report. We make available, free of charge through our website or upon written request, our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and other periodic SEC reports, along with amendments to all of those reports, as soon as reasonably practicable after we file the reports with the SEC.

Unless otherwise noted, the term “Atossa Genetics” refers to Atossa Genetics Inc., a Delaware corporation, the terms “Atossa,” the “Company,” “we,” “us,” and “our,” refer to the ongoing business operations of Atossa and the historic business of The National Reference Laboratory for Breast Health, Inc. (the “NRLBH”), whether conducted through Atossa Genetics or the NRLBH; however unless the context otherwise indicates, references to “we,” “our” or the “Company” as they relate to laboratory tests generally refers to activities conducted by the NRLBH. We were incorporated in Delaware in April 2009. Our principal executive offices are located at 2300 Eastlake Ave. East, Suite 200, Seattle WA 98102, and our telephone number is (800) 351-3902.

Mammary Aspiration Specimen Cytology Test (MASCT), is our registered trademark and Oxy-MASCT and our name and logo are our trademarks. ForeCYTE, FullCYTE, NextCYTE, ForeCYTE Breast Aspirator and ArgusCYTE are our service marks. This report also includes additional trademarks, trade names and service marks of third parties,

which are the property of their respective owners.

THE OFFERING

Common stock covered by this Prospectus: Up to 7,760,810 shares of Common Stock, including 746,046 shares previously issued to Aspire Capital as a commitment fee.

Common stock outstanding as of May 25, 2016: 39,569,510, including the 746,046 shares previously issued to Aspire Capital as a commitment fee.

Use of proceeds: The Selling Stockholder will receive all of the proceeds from the sale of the shares offered for sale by it under this prospectus. We will not receive proceeds from the sale of the shares by the Selling Stockholder. However, we may receive up to \$10 million in proceeds from the sale of our Common Stock to the Selling Stockholder under the Purchase Agreement described below. Any proceeds from the Selling Stockholder that we receive under the Purchase Agreement are expected to be used for working capital and general corporate purposes. See “Use of Proceeds.”

Risk factors: The shares offered hereby involve a high degree of risk. See “Risk Factors” beginning on page 9.

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”.

Our Common Stock Purchase Agreement with Aspire Capital Fund, LLC

On May 25, 2016, we entered into a common stock purchase agreement (referred to in this prospectus as the “**Purchase Agreement**”), with Aspire Capital Fund, LLC, an Illinois limited liability company (referred to in this prospectus as “**Aspire Capital**” or the “**Selling Stockholder**”), which provides that, upon the terms and subject to the conditions and limitations set forth therein, Aspire Capital is committed to purchase up to an aggregate of \$10.0 million of our shares of Common Stock over the approximately 30-month term of the Purchase Agreement. In consideration for entering into the Purchase Agreement, and concurrently with the execution of such agreement, we issued to Aspire Capital 746,046 shares of our Common Stock as a commitment fee (referred to in this prospectus as the “**Commitment Shares**”). Concurrently with entering into the Purchase Agreement, we also entered into a registration rights agreement with Aspire Capital (referred to in this prospectus as the “**Registration Rights Agreement**”), in which we agreed to file one or more registration statements, including the registration statement of which this prospectus is a part, as permissible and necessary to register under the Securities Act of 1933, as amended, or the Securities Act, the sale of the shares of our Common Stock that have been and may be issued to Aspire Capital under the Purchase Agreement.

Edgar Filing: ATOSSA GENETICS INC - Form 424B3

As of May 25, 2016, there were 39,569,510 shares of our Common Stock outstanding (33,231,137 shares held by non-affiliates), including the 746,046 Commitment Shares, but excluding the 7,014,764 shares offered that have not been issued but may become issuable to Aspire Capital pursuant to the Purchase Agreement. If all of the 7,760,810 shares of our Common Stock offered hereby were issued and outstanding as of the date thereof, such shares would represent 19.6% of the total Common Stock outstanding or 24% of the non-affiliate shares of Common Stock outstanding as of the date we entered into the Purchase Agreement. The number of shares of our Common Stock ultimately offered for sale by Aspire Capital is dependent upon the number of shares purchased by Aspire Capital under the Purchase Agreement.

As of May 31, 2016 there were 39,569,510 shares of our Common Stock outstanding (33,231,137 shares held by non-affiliates), including the 746,046 Commitment Shares, but excluding the 7,014,764 shares offered by this prospectus that have not been issued but may become issuable to Aspire Capital pursuant to the Purchase Agreement.

Pursuant to the Purchase Agreement and the Registration Rights Agreement, we have registered 7,760,810 shares of our Common Stock under the Securities Act, which includes the 746,046 Commitment Shares that have already been issued to Aspire Capital and 7,014,764 shares of Common Stock, which we may issue to Aspire Capital. On June 20, 2016, the conditions necessary for purchases under the Purchase Agreement were satisfied. All 7,760,810 shares of Common Stock are being offered pursuant to this prospectus.

On any trading day on which the closing sale price of our common stock exceeds \$0.10, we have the right, in our sole discretion, to present Aspire Capital with a purchase notice (each, a “**Purchase Notice**”), directing Aspire Capital (as principal) to purchase up to 150,000 shares of our common stock per trading day, provided that the aggregate price of such purchase shall not exceed \$500,000 per trading day, up to \$10 million of our Common Stock in the aggregate at a per share price (the “**Purchase Price**”) calculated by reference to the prevailing market price of our common stock (as more specifically described below).

In addition, on any date on which we submit a Purchase Notice for 150,000 shares to Aspire Capital and the closing sale price of our stock is equal to or greater than \$0.25 per share of Common Stock, we also have the right, in our sole discretion, to present Aspire Capital with a volume-weighted average price purchase notice (each, a “**VWAP Purchase Notice**”) directing Aspire Capital to purchase an amount of stock equal to up to 30% of the aggregate shares of our Common Stock traded on the NASDAQ on the next trading day (the “**VWAP Purchase Date**”), subject to a maximum number of shares we may determine (the “**VWAP Purchase Share Volume Maximum**”) and a minimum trading price (the “**VWAP Minimum Price Threshold**”) (as more specifically described below). The purchase price per share pursuant to such VWAP Purchase Notice (the “**VWAP Purchase Price**”) is calculated by reference to the prevailing market price of our Common Stock (as more specifically described below).

The Purchase Agreement provides that the Company and Aspire Capital shall not effect any sales under the Purchase Agreement on any purchase date where the closing sale price of our Common Stock is less than \$0.10 per share (the “**Floor Price**”). This Floor Price and the respective prices and share numbers in the preceding paragraphs shall be appropriately adjusted for any reorganization, recapitalization, non-cash dividend, stock split, reverse stock split or other similar transaction. There are no trading volume requirements or restrictions under the Purchase Agreement, and we will control the timing and amount of any sales of our common stock to Aspire Capital. Aspire Capital has no right to require any sales by us, but is obligated to make purchases from us as we direct in accordance with the Purchase Agreement. There are no limitations on use of proceeds, financial or business covenants, restrictions on future fundings, rights of first refusal, participation rights, penalties or liquidated damages in the Purchase Agreement. Aspire Capital may not assign its rights or obligations under the Purchase Agreement. The Purchase Agreement may be terminated by us at any time, at our discretion, without any penalty or cost to us.

The issuance of the all shares to Aspire Capital under the Purchase Agreement is exempt from registration under the Securities Act, pursuant to the exemption for transactions by an issuer not involving any public offering under Section 4(a)(2) of the Securities Act and Rule 506 of Regulation D promulgated thereunder.

RISK FACTORS

A purchase of our shares of Common Stock 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 risks and uncertainties discussed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2015, as updated in our Quarterly Report(s) on Form 10-Q. All of these risk factors are incorporated by reference herein in their entirety. 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 will need to raise substantial additional capital in the future to fund our operations and we may be unable to raise such funds when needed and on acceptable terms.

The extent to which we utilize the Purchase Agreement with Aspire Capital as a source of funding will depend on a number of factors, including the prevailing market price of our Common Stock, the volume of trading in our Common Stock and the extent to which we are able to secure funds from other sources. The number of shares that we may sell to Aspire Capital under the Purchase Agreement on any given day and during the term of the Purchase Agreement is limited. See “Our Common Stock Purchase Agreement with Aspire Capital Fund, LLC” section of this prospectus for additional information. Additionally, we and Aspire Capital may not effect any sales of shares of our Common Stock under the Purchase Agreement during the continuance of an event of default or on any trading day that the closing sale price of our Common Stock is less than \$0.10 per share. Even if we are able to access the full \$10.0 million under the Purchase Agreement, we will still need additional capital to fully implement our business, operating and development plans.

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

If we raise additional funds by issuing equity securities, our stockholders will experience dilution. Debt financing, if available, would result in increased fixed payment obligations and may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Any debt financing or additional equity that we raise may contain terms, such as

liquidation and other preferences, which are not favorable to us or our stockholders. If we raise additional funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish valuable rights to our technologies, future revenue streams or product candidates or to grant licenses on terms that may not be favorable to us. Should the financing we require to sustain our working capital needs be unavailable or prohibitively expensive when we require it, our business, operating results, financial condition and prospects could be materially and adversely affected and we may be unable to continue our operations.

The sale of our Common Stock to Aspire Capital may cause substantial dilution to our existing stockholders and the sale of the shares of Common Stock acquired by Aspire Capital could cause the price of our Common Stock to decline.

We have registered for sale the 746,046 Commitment Shares that we have issued and the 7,014,764 shares that we may sell to Aspire Capital under the Purchase Agreement. It is anticipated that these shares will be sold over a period of up to approximately 30 months from the date of this prospectus. The number of shares ultimately offered for sale by Aspire Capital under this prospectus is dependent upon the number of shares we elect to sell to Aspire Capital under the Purchase Agreement. Depending upon market liquidity at the time, sales of shares of our common stock under the Purchase Agreement may cause the trading price of our Common Stock to decline.

Aspire Capital may ultimately purchase all, some or none of the \$10.0 million of Common Stock that, together with the 746,046 Commitment Shares, is the subject of this prospectus. Aspire Capital may sell all, some or none of our shares that it holds or comes to hold under the Purchase Agreement. Sales by Aspire Capital of shares acquired pursuant to the Purchase Agreement under the registration statement, of which this prospectus is a part, may result in dilution to the interests of other holders of our Common Stock. The sale of a substantial number of shares of our Common Stock by Aspire Capital in this offering, or anticipation of such sales, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect sales. However, we have the right to control the timing and amount of sales of our shares to Aspire Capital, and the Purchase Agreement may be terminated by us at any time at our discretion without any penalty or cost to us.

USE OF PROCEEDS

This prospectus relates to shares of our Common Stock that may be offered and sold from time to time by Aspire Capital. We will not receive any proceeds upon the sale of shares by Aspire Capital. However, we may receive proceeds up to \$10.0 million under the Purchase Agreement with Aspire Capital.

The proceeds received from the sale of the shares under the Purchase Agreement will be used for working capital and general corporate purposes. However, we cannot guarantee that we will receive any proceeds in connection with the Purchase Agreement because we may be unable or choose not to issue and sell any securities pursuant to the Purchase Agreement. This anticipated use of net proceeds from the sale of our Common Stock to Aspire Capital under the Purchase Agreement represents our intentions based upon our current plans and business conditions.

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.

SELLING STOCKHOLDER

The Selling Stockholder may from time to time offer and sell any or all of the shares of our Common Stock set forth below pursuant to this prospectus. When we refer to the "Selling Stockholder" in this prospectus, we mean the entity listed in the table below, and its respective pledgees, donees, permitted transferees, assignees, successors and others who later come to hold any of the Selling Stockholder's interests in shares of our Common Stock other than through a public sale.

The following table sets forth, as of the date of this prospectus, the name of the Selling Stockholder for whom we have registered shares for sale to the public, the number of shares of Common Stock beneficially owned by the Selling Stockholder prior to this offering, the total number of shares of Common Stock that the Selling Stockholder may offer pursuant to this prospectus and the number of shares of Common Stock that the Selling Stockholder will beneficially own after this offering. Except as noted below, the Selling Stockholder does not have, or within the past three years

has not had, any material relationship with us or any of our predecessors or affiliates and the Selling Stockholder is not or was not affiliated with registered broker-dealers.

Based on the information provided to us by the Selling Stockholder, assuming that the Selling Stockholder sells all of the shares of our Common Stock beneficially owned by it that have been registered by us and does not acquire any additional shares during the offering, the Selling Stockholder will not own any shares other than those appearing in the column entitled “Beneficial Ownership After This Offering.” We cannot advise you as to whether the Selling Stockholder will in fact sell any or all of such shares of Common Stock. In addition, the Selling Stockholder may have sold, transferred or otherwise disposed of, or may sell, transfer or otherwise dispose of, at any time and from time to time, the shares of our Common Stock in transactions exempt from the registration requirements of the Securities Act after the date on which it provided the information set forth in the table below.

Selling Stockholder	Shares Beneficially Owned Before Offering	Percentage of Outstanding Shares Beneficially Owned Before Offering	Shares to be Sold in the Offering	Shares Beneficially Owned After Offering (1)	Percentage of Outstanding Shares Beneficially Owned After Offering
Aspire Capital Fund, LLC (2)	2,266,879 (3)	5.7 %	7,760,810	1,520,833 (4)	3.8 %(5)

- (1) Assumes the sale of all shares of Common Stock registered pursuant to this prospectus, although the Selling Stockholder is under no obligation known to us to sell any shares at this time.

Aspire Capital Partners LLC (“Aspire Partners”) is the Managing Member of Aspire Capital Fund LLC (“Aspire Fund”). SGM Holdings Corp (“SGM”) is the Managing Member of Aspire Partners. Mr. Steven G. Martin (“Mr. Martin”) is the president and sole shareholder of SGM, as well as a principal of Aspire Partners. Mr. Erik J. Brown (“Mr. Brown”) is the president and sole shareholder of Red Cedar Capital Corp (“Red Cedar”), which is a principal of (2) Aspire Partners. Mr. Christos Komissopoulos (“Mr. Komissopoulos”) is president and sole shareholder of Chrisko Investors Inc (“Chrisko”), which is a principal of Aspire Partners. Each of Aspire Partners, SGM, Red Cedar, Chrisko, Mr. Martin, Mr. Brown, and Mr. Komissopoulos may be deemed to be a beneficial owner of common stock held by Aspire Fund. Each of Aspire Partners, SGM, Red Cedar, Chrisko, Mr. Martin, Mr. Brown, and Mr. Komissopoulos disclaims beneficial ownership of the common stock held by Aspire Fund.

As of the date hereof, 2,266,879 shares of our common stock are owned by Aspire Capital, consisting of 746,046 shares we issued to Aspire Capital as a commitment fee under the Purchase Agreement and 1,520,833 shares (3) previously purchased by Aspire Capital. We may elect in our sole discretion to sell to Aspire Capital up to an additional 7,014,764 shares under the Purchase Agreement and included in this prospectus but Aspire Capital does not presently beneficially own those shares as determined in accordance with the rules of the SEC.

Amount equals shares beneficially owned before the offering less 746,046 shares of Common Stock beneficially (4) owned before the offering that are being sold in the offering and assumes no additional sales of the remaining 1,520,833 shares.

- (5) Based on 39,569,510 shares of Common Stock outstanding as of May 31, 2016.

THE ASPIRE CAPITAL TRANSACTION

General

On May 25, 2016, we entered into the Purchase Agreement which provides that, upon the terms and subject to the conditions and limitations set forth therein, Aspire Capital is committed to purchase up to an aggregate of \$10.0 million of our shares of Common Stock over the term of the Purchase Agreement. In consideration for entering into the Purchase Agreement, and concurrently with the execution of such Agreement, we issued to Aspire Capital the 746,046 Commitment Shares. Concurrently with entering into the Purchase Agreement, we also entered into the Registration Rights Agreement, in which we agreed to file one or more registration statements as permissible and necessary to register under the Securities Act, the sale of the shares of our Common Stock that have been and may be issued to Aspire Capital under the Purchase Agreement.

As of May 25, 2016, there were 39,569,510 shares of our Common Stock outstanding (33,569,510 shares held by non-affiliates), including the 746,046 Commitment Shares, but excluding the 7,014,764 shares offered that have not been issued but may become issuable to Aspire Capital pursuant to the Purchase Agreement. If all of the 7,760,810 shares of our Common Stock offered hereby were issued and outstanding as of the date thereof, such shares would represent 19.6% of the total Common Stock outstanding or 23.3% of the non-affiliate shares of Common Stock outstanding as of the date thereof. The number of shares of our Common Stock ultimately offered for sale by Aspire Capital is dependent upon the number of shares purchased by Aspire Capital under the Purchase Agreement.

As of May 31, 2016, there were 39,569,510 shares of our Common Stock outstanding (33,569,510 shares held by non-affiliates), including the 746,046 Commitment Shares, but excluding the 7,014,764 shares offered that have not been issued but may become issuable to Aspire Capital pursuant to the Purchase Agreement.

Pursuant to the Purchase Agreement and the Registration Rights Agreement, we have registered 7,760,810 shares of our Common Stock under the Securities Act, which includes the 746,046 Commitment Shares that have already been issued to Aspire Capital and 7,014,764 shares of Common Stock which we may issue to Aspire Capital. All 7,760,810 shares of Common Stock are being offered pursuant to this prospectus. Under the Purchase Agreement, we have the right but not the obligation to issue more than the 7,760,810 shares of Common Stock included in this prospectus to Aspire Capital. As of the date hereof, we do not have any plans or intent to issue to Aspire Capital any shares of Common Stock in addition to the 7,760,810 shares of Common Stock offered hereby.

On any trading day on which the closing sale price of our Common Stock is not less than \$0.10 per share, we have the right, in our sole discretion, to present Aspire Capital with a Purchase Notice, directing Aspire Capital (as principal) to

purchase up to 150,000 shares of our Common Stock per business day, up to \$10.0 million of our Common Stock in the aggregate at a Purchase Price calculated by reference to the prevailing market price of our Common Stock over the preceding 12-business day period (as more specifically described below).

In addition, on any date on which we submit a Purchase Notice to Aspire Capital for 150,000 shares of our Common Stock and our stock price is not less than \$0.25 per share, we also have the right, in our sole discretion, to present Aspire Capital with a VWAP Purchase Notice directing Aspire Capital to purchase an amount of stock equal to up to 30% of the aggregate shares of the Company's common stock traded on the NASDAQ on the next trading day, subject to the VWAP Purchase Share Volume Maximum and the VWAP Minimum Price Threshold. The VWAP Purchase Price is calculated by reference to the prevailing market price of our Common Stock (as more specifically described below).

The Purchase Agreement provides that the Company and Aspire Capital shall not effect any sales under the Purchase Agreement on any purchase date where the closing sale price of our Common Stock is less than \$0.10. There are no trading volume requirements or restrictions under the Purchase Agreement, and we will control the timing and amount of any sales of our Common Stock to Aspire Capital. Aspire Capital has no right to require any sales by us, but is obligated to make purchases from us as we direct in accordance with the Purchase Agreement. There are no limitations on use of proceeds, financial or business covenants, restrictions on future fundings, rights of first refusal, participation rights, penalties or liquidated damages in the Purchase Agreement. Aspire Capital may not assign its rights or obligations under the Purchase Agreement. The Purchase Agreement may be terminated by us at any time, at our discretion, without any penalty or cost to us. The Purchase Agreement provides that on the date of its execution, the certain Purchase Agreement, dated as of November 11, 2015, by and between the Company and Aspire Capital, was terminated.

Purchase of shares under the Purchase Agreement

Under the Purchase Agreement, on any trading day selected by us on which the closing sale price of our Common Stock exceeds \$0.10 per share, we may direct Aspire Capital to purchase up to 150,000 shares of our Common Stock per trading day. The Purchase Price of such shares is equal to the lesser of:

· the lowest sale price of our Common Stock on the purchase date; or

· the arithmetic average of the three lowest closing sale prices for our Common Stock during the twelve consecutive trading days ending on the trading day immediately preceding the purchase date.

In addition, on any date on which we submit a Purchase Notice to Aspire Capital for purchase of 150,000 shares and our stock price is not less than \$0.25 per share, we also have the right to direct Aspire Capital to purchase an amount of stock equal to up to 30% of the aggregate shares of the our Common Stock traded on the NASDAQ on the next trading day, subject to the VWAP Purchase Share Volume Maximum and the VWAP Minimum Price Threshold, which is equal to the greater of (a) 80% of the closing price of our Common Stock on the business day immediately preceding the VWAP Purchase Date or (b) such higher price as set forth by the Company in the VWAP Purchase Notice. The VWAP Purchase Price of such shares is the lower of:

· the closing sale price on the VWAP Purchase Date; or

· 95% of the volume-weighted average price for our Common Stock traded on the NASDAQ :

on the VWAP Purchase Date, if the aggregate shares to be purchased on that date have not exceeded the VWAP Purchase Share Volume Maximum or

during that portion of the VWAP Purchase Date until such time as the sooner to occur of (i) the time at which the aggregate shares traded on the NASDAQ exceed the VWAP Purchase Share Volume Maximum or (ii) the time at which the sale price of our Common Stock falls below the VWAP Minimum Price Threshold.

The purchase price will be adjusted for any reorganization, recapitalization, non-cash dividend, stock split, or other similar transaction occurring during the trading day(s) used to compute the purchase price. We may deliver multiple Purchase Notices and VWAP Purchase Notices to Aspire Capital from time to time during the term of the Purchase Agreement, so long as the most recent purchase has been completed.

Minimum Share Price

Under the Purchase Agreement, the Company and Aspire Capital may not effect any sales of shares of our Common Stock on any trading day that the closing sale price of our Common Stock is less than \$0.10 per share.

Compliance with the NASDAQ Capital Market Rules

The Purchase Agreement provides that the number of shares that may be sold pursuant to the Purchase Agreement shall be limited to 7,760,810, or the Exchange Cap, which represents 19.99% of our outstanding shares as of May 25, 2016, unless shareholder approval or an exception pursuant to the rules of the NASDAQ Capital Market is obtained to issue more than 19.99%, to be in compliance with the applicable listing maintenance rules of the NASDAQ Capital Market. We are not required or permitted to issue any shares of Common Stock under the Purchase Agreement if such issuance would breach our obligations under the rules or regulations of the NASDAQ Capital Market.

Beneficial Ownership Limitation

Under the Purchase Agreement, we and Aspire Capital may not effect any sales of shares of our Common Stock if such shares proposed to be issued and sold, when aggregated with all other shares of our Common Stock beneficially owned by Aspire Capital and its affiliates, would result in the beneficial ownership by Aspire Capital and its affiliates of more than 19.99% of our then issued and outstanding shares of Common Stock.

Events of Default

Generally, Aspire Capital may terminate the Purchase Agreement upon the occurrence of any of the following events of default:

the effectiveness of any registration statement that is required to be maintained effective pursuant to the terms of the Registration Rights Agreement between us and Aspire Capital lapses for any reason (including, without limitation, the issuance of a stop order) or is unavailable to Aspire Capital for sale of our shares of Common Stock, and such lapse or unavailability continues for a period of ten consecutive business days or for more than an aggregate of thirty business days in any 365-day period, which is not in connection with a post-effective amendment to any such registration statement; in connection with any post-effective amendment to such registration statement that is required to be declared effective by the Securities and Exchange Commission (the “*SEC*”) such lapse or unavailability may continue for a period of no more than 40 consecutive business days;

the suspension from trading or failure of our Common Stock to be listed on our principal market for a period of ten consecutive business days;

the delisting of our Common Stock from the NASDAQ, provided however, that in the event our Common Stock is not immediately thereafter listed and traded on the New York Stock Exchange, the NYSE MKT, the Nasdaq Global Select Market, the Nasdaq Global Market, the Over-The-Counter Bulletin Board interdealer quotation system or either one of the OTCQB or the OTCQX market places of the OTC Markets Group, Inc.;

our transfer agent’s failure to issue to Aspire Capital shares of our Common Stock which Aspire Capital is entitled to receive under the Purchase Agreement within five business days after an applicable purchase date;

any breach by us of the representations or warranties or covenants contained in the Purchase Agreement or any related agreements which could have a material adverse effect on us, subject to a cure period of five business days;

- if we become insolvent or are generally unable to pay our debts as they become due; or
- any participation or threatened participation in insolvency or bankruptcy proceedings by or against us.

Minimum Share Price

Under the Purchase Agreement, we and Aspire Capital may not effect any sales of shares of our common stock under the Purchase Agreement on any trading day that the closing sale price of our common stock is less than \$0.10 per share.

Our Termination Rights

The Purchase Agreement may be terminated by us at any time, at our discretion, without any cost to us.

No Short-Selling or Hedging by Aspire Capital

Aspire Capital has agreed that neither it nor any of its agents, representatives and affiliates shall engage in any direct or indirect short-selling or hedging, which establishes a net short position with respect to our Common Stock during any time prior to the termination of the Purchase Agreement.

Effect of Performance of the Purchase Agreement on Our Stockholders

The Purchase Agreement does not limit the ability of Aspire Capital to sell any or all of the 7,760,810 shares registered in this offering. It is anticipated that shares registered in this offering will be sold over a period of up to approximately 30 months from the date of this prospectus. The sale by Aspire Capital of a significant amount of shares registered in this offering at any given time could cause the market price of our Common Stock to decline and/or to be highly volatile. Aspire Capital may ultimately purchase all, some or none of the 7,014,764 shares of Common Stock not yet issued but registered in this offering. After it has acquired such shares, it may sell all, some or none of such shares. Therefore, sales to Aspire Capital by us pursuant to the Purchase Agreement also may result in substantial dilution to the interests of other holders of our Common Stock. However, we have the right to control the timing and amount of any sales of our shares to Aspire Capital and the Purchase Agreement may be terminated by us at any time at our discretion without any penalty or cost to us.

Amount of Potential Proceeds to be Received under the Purchase Agreement

In connection with entering into the Purchase Agreement, we authorized the sale to Aspire Capital of up to \$10.0 million of our shares of Common Stock. However, we estimate that we will sell no more than 7,014,764 shares to Aspire Capital under the Purchase Agreement (exclusive of the 746,046 Commitment Shares), all of which are included in this offering. Subject to any required approval by our Board of Directors, we have the right but not the obligation to issue more than the 7,760,810 shares included in this prospectus to Aspire Capital under the Purchase Agreement. In the event we elect to issue more than 7,760,810 shares under the Purchase Agreement, we will be required to file a new registration statement and have it declared effective by the SEC. The number of shares ultimately offered for sale by Aspire Capital in this offering is dependent upon the number of shares purchased by Aspire Capital under the Purchase Agreement. The following table sets forth the number and percentage of outstanding shares to be held by Aspire Capital after giving effect to the sale of shares of Common Stock issued to Aspire Capital at varying purchase prices:

Assumed Average Purchase Price	Proceeds from the Sale of Shares to Aspire Capital Under the Purchase Agreement Registered in this Offering	Number of Shares to be Issued in this Offering at the Assumed Average Purchase Price(1)	Percentage of Outstanding Shares After Giving Effect to the Purchased Shares Issued to Aspire Capital (2)	
\$ 0.10	\$ 701,476	7,014,764	19.99	%
\$ 0.25	\$ 1,753,691	7,014,764	19.99	%
\$ 0.50	\$ 3,507,382	7,014,764	19.99	%
\$ 1.00	\$ 7,014,764	7,014,764	19.99	%

Edgar Filing: ATOSSA GENETICS INC - Form 424B3

\$ 2.00	\$ 10,000,000	5,000,000	12.88	%
\$ 3.00	\$ 10,000,000	3,333,333	8.59	%
\$ 4.00	\$ 10,000,000	2,500,000	6.44	%
\$ 6.00	\$ 10,000,000	1,666,667	4.29	%

(1) Excludes 746,046 Commitment Shares issued under the Purchase Agreement between the Company and Aspire Capital.

The denominator is based on 38,823,464 shares outstanding as of May 25, 2016, which excludes the 746,046 Commitment Shares previously issued to Aspire Capital and the number of shares set forth in the adjacent column which we would have sold to Aspire Capital at the corresponding assumed purchase price set forth in the adjacent column. The numerator is based on the number of shares which we may issue to Aspire Capital under the Purchase Agreement (that are the subject of this offering) at the corresponding assumed purchase price set forth in the adjacent column.

DILUTION

The sale of our common stock to Aspire Capital pursuant to the Purchase Agreement will have a dilutive impact on our stockholders. As a result, our net income per share, if any, would decrease in future periods and the market price of our Common Stock could decline. In addition, the lower our stock price is at the time we exercise our right to sell shares to Aspire Capital, the more shares of our Common Stock we will have to issue to Aspire Capital pursuant to the Purchase Agreement and our existing stockholders would experience greater dilution.

Our net tangible book value as of March 31, 2016 was approximately \$2.3 million, or \$0.06 per share. Net tangible book value per share is determined by dividing our total tangible assets, less total liabilities, by the number of shares of our common stock outstanding as of March 31, 2016.

After giving effect to the sale in this offering of 7,760,810 shares of common stock at an assumed average sale price of \$0.29 per share (based on the lowest sales price of our common stock as of May 27, 2016), our pro forma as adjusted net tangible book value as of March 31, 2016 would have been approximately \$4.5 million, or \$0.10 per share of Common Stock. This represents an immediate increase in pro forma as adjusted net tangible book value of \$0.04 per share to our existing stockholders and an immediate dilution of \$0.19 per share to our new stockholders.

PLAN OF DISTRIBUTION

The Common Stock offered by this prospectus is being offered by Aspire Capital, the Selling Stockholder. The Common Stock may be sold or distributed from time to time by the Selling Stockholder directly to one or more purchasers or through brokers, dealers, or underwriters who may act solely as agents at market prices prevailing at the time of sale, at prices related to the prevailing market prices, at negotiated prices, or at fixed prices, which may be changed. The sale of the Common Stock offered by this prospectus may be effected by one or more of the following methods:

· ordinary brokers' transactions;

· transactions involving cross or block trades;

· through brokers, dealers, or underwriters who may act solely as agents;

· "at the market" into an existing market for the common stock;

· in other ways not involving market makers or established business markets, including direct sales to purchasers or sales effected through agents;

· in privately negotiated transactions; or

· any combination of the foregoing.

In order to comply with the securities laws of certain states, if applicable, the shares may be sold only through registered or licensed brokers or dealers. In addition, in certain states, the shares may not be sold unless they have been registered or qualified for sale in the state or an exemption from the registration or qualification requirement is available and complied with.

The Selling Stockholder may also sell shares of Common Stock under Rule 144 promulgated under the Securities Act, if available, rather than under this prospectus. In addition, the Selling Stockholder may transfer the shares of our Common Stock by other means not described in this prospectus.

Brokers, dealers, underwriters, or agents participating in the distribution of the shares as agents may receive compensation in the form of commissions, discounts, or concessions from the selling stockholder and/or purchasers of the common stock for whom the broker-dealers may act as agent. Aspire Capital has informed us that each such broker-dealer will receive commissions from Aspire Capital which will not exceed customary brokerage commissions.

Aspire Capital is an “underwriter” within the meaning of the Securities Act.

Neither we nor Aspire Capital can presently estimate the amount of compensation that any agent will receive. We know of no existing arrangements between Aspire Capital, any other shareholder, broker, dealer, underwriter, or agent relating to the sale or distribution of the shares offered by this prospectus. At the time a particular offer of shares is made, a prospectus supplement, if required, will be distributed that will set forth the names of any agents, underwriters, or dealers and any compensation from the selling stockholder, and any other required information. Pursuant to a requirement of the Financial Industry Regulatory Authority, or FINRA, the maximum commission or discount and other compensation to be received by any FINRA member or independent broker-dealer shall not be greater than eight percent (8%) of the gross proceeds received by us for the sale of any securities being registered pursuant to Rule 415 under the Securities Act.

We will pay all of the expenses incident to the registration, offering, and sale of the shares to the public other than commissions or discounts of underwriters, broker-dealers, or agents. We have agreed to indemnify Aspire Capital and certain other persons against certain liabilities in connection with the offering of shares of our Common Stock offered hereby, including liabilities arising under the Securities Act or, if such indemnity is unavailable, to contribute amounts required to be paid in respect of such liabilities. Aspire Capital has agreed to indemnify us against liabilities under the Securities Act that may arise from certain written information furnished to us by Aspire Capital specifically for use in this prospectus or, if such indemnity is unavailable, to contribute amounts required to be paid in respect of such liabilities.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers, and controlling persons, we have been advised that in the opinion of the SEC this indemnification is against public policy as expressed in the Securities Act and is therefore, unenforceable.

Aspire Capital and its affiliates have agreed not to engage in any direct or indirect short selling or hedging of our Common Stock during the term of the Purchase Agreement.

We have advised Aspire Capital that while it is engaged in a distribution of the shares included in this prospectus it is required to comply with Regulation M promulgated under the Securities Exchange Act of 1934, as amended. With certain exceptions, Regulation M precludes the Selling Stockholder, any affiliated purchasers, and any broker-dealer or other person who participates in the distribution from bidding for or purchasing, or attempting to induce any person to bid for or purchase any security which is the subject of the distribution until the entire distribution is complete. Regulation M also prohibits any bids or purchases made in order to stabilize the price of a security in connection with the distribution of that security. All of the foregoing may affect the marketability of the shares offered hereby this prospectus.

We may suspend the sale of shares by Aspire Capital pursuant to this prospectus for certain periods of time for certain reasons, including if the prospectus is required to be supplemented or amended to include additional material information.

This offering will terminate on the date that all shares offered by this prospectus have been sold by Aspire Capital.

DESCRIPTION OF SECURITIES TO BE REGISTERED

Our authorized capital stock consists of 75,000,000 shares of Common Stock, \$0.001 par value per share, and 10,000,000 shares of preferred stock, \$0.001 par value per share.

Common Stock

Holders of Common Stock are entitled to receive ratably dividends out of funds legally available, if and when declared from time to time by our Board of Directors. We have never paid any cash dividends on our Common Stock and our Board of Directors does not anticipate that we will pay cash dividends in the foreseeable future. The future payment of dividends, if any, on our Common Stock is within the discretion of the Board of Directors and will depend upon earnings, capital requirements, financial condition and other relevant factors. Holders of Common Stock are entitled to one vote for each share held on each matter to be voted on by stockholders. There is no cumulative voting in the election of directors. In the event of liquidation, dissolution or winding up of the affairs of us, holders of Common Stock are to share in all assets remaining after the payment of liabilities and any preferential distributions payable to preferred stockholders, if any. The holders of Common Stock have no preemptive or conversion rights and are not subject to further calls or assessments. There are no redemption or sinking fund provisions applicable to the Common Stock. The rights of the holders of the Common Stock are subject to any rights that may be fixed for holders of preferred stock, if any. All of the outstanding shares of Common Stock are fully paid and non-assessable.

Certificate of Incorporation

Under our certificate of incorporation, as amended, our Board of Directors, without further action by our stockholders, currently has the authority to issue up to 10,000,000 shares of preferred stock and to fix the rights (including voting rights), preferences and privileges of these “blank check” preferred shares. Such preferred stock may have rights, including economic rights, senior to our Common Stock. As a result, the issuance of the preferred stock could have a material adverse effect on the price of our Common Stock and could make it more difficult for a third party to acquire a majority of our outstanding Common Stock.

Anti-Takeover Devices

Our certificate of incorporation and bylaws include a number of provisions that may have the effect of delaying, deferring or preventing another party from acquiring control of us and encouraging persons considering unsolicited

tender offers or other unilateral takeover proposals to negotiate with our Board of Directors rather than pursue non-negotiated takeover attempts. These provisions include the items described below.

Board Composition and Filling Vacancies. In accordance with our certificate of incorporation, our Board of Directors is divided into three classes serving staggered three-year terms, with one class being elected each year. Our certificate of incorporation also provides that directors may only be removed from office for cause and only by the affirmative vote of holders of 75% or more of the outstanding shares of capital stock then entitled to vote at an election of directors. Furthermore, any vacancy on our Board of Directors, however occurring, including any vacancy resulting from an increase in the size of the board, may only be filled by the affirmative vote of a majority of our directors then in office even if less than a quorum. The classification of directors, together with the limitations on removal of directors and treatment of vacancies, has the effect of making it more difficult for stockholders to change the composition of our Board of Directors.

Undesignated Preferred Stock. Our certificate of incorporation authorizes “blank-check” preferred stock, which means that our Board of Directors has the authority to designate one or more series of preferred stock without stockholder approval. These series of preferred stock may have superior rights, preferences and privileges over our Common Stock, including dividend rights, voting rights and liquidation preferences. The ability of our Board of Directors to issue shares of our preferred stock without stockholder approval could deter takeover offers and make it more difficult or costly for a third party to acquire us without the consent of our Board of Directors.

Section 203 of the Delaware General Corporation Law. In addition, our certificate of incorporation does not opt out of Section 203 of the Delaware General Corporation Law, which protects a corporation against an unapproved takeover by prohibiting a company from engaging in any business combination with any interested stockholder (defined as a stockholder owning more than 15% of the outstanding shares) for a period of three years from the time such stockholder became a 15% holder unless approved by our Board of Directors.

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

Transfer Agent and Registrar

We have appointed VStock Transfer, LLC, 18 Lafayette Place, Woodmere, New York 11598 (Telephone: (212) 828-8436; Facsimile (646) 536-3179) as our transfer agent and registrar.

Listing

Our Common Stock is listed on the NASDAQ Capital Market under the symbol “ATOS”.

DISCLOSURE OF COMMISSION POSITION ON INDEMNIFICATION FOR SECURITIES ACT LIABILITIES

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers, and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable.

LEGAL MATTERS

Certain legal matters relating to the validity of the Common Stock offered by this prospectus will be passed upon for us by Gibson, Dunn & Crutcher, LLP, San Francisco, California.

EXPERTS

The consolidated financial statements as of December 31, 2015 and 2014 and for each of the two years in the period ended December 31, 2015 incorporated by reference in this Prospectus have been so included in reliance on the report of BDO USA, LLP, an independent registered public accounting firm (the report on the consolidated financial statements contains an explanatory paragraph regarding the Company's ability to continue as a going concern) which is incorporated by reference in the Prospectus, given on the authority of said firm as experts in auditing and accounting.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We are required to file annual, quarterly and special reports, proxy statements and other information with the SEC. You may read and copy any document filed by us at the SEC's Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the public reference room. Our filings with the SEC are also available to the public at the SEC's Internet web site at <http://www.sec.gov>.

We have filed a registration statement, of which this prospectus is a part, covering the securities offered hereby. As allowed by SEC rules, this prospectus does not include all of the information contained in the registration statement

and the included exhibits, financial statements and schedules. You are referred to the registration statement, the included exhibits, financial statements and schedules for further information. This prospectus is qualified in its entirety by such other information.

INCORPORATION OF CERTAIN INFORMATION BY REFERENCE

The SEC allows us to “incorporate by reference” information from other documents that we file with it, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is considered to be part of this prospectus. Information in this prospectus supersedes information incorporated by reference that we filed with the SEC prior to the date of this prospectus.

We incorporate by reference into this prospectus and the registration statement of which this prospectus is a part the information or documents listed below that we have filed with the SEC (Commission File No. 001-35610):

- our Annual Report on Form 10-K for the year ended December 31, 2015, filed with the SEC on March 30, 2016;
- portions of our definitive Proxy Statement on Schedule 14A, filed with the SEC on April 13, 2016;
- our current reports on Form 8-K filed with the SEC on January 29, 2016, February 8, 2016, May 16, 2016, May 20, 2016 and May 27, 2016.
- our Quarterly Report on Form 10-Q for the quarter ended March 31, 2016, filed with the SEC on May 5, 2016.

We also elect to incorporate by reference information filed after the effective date of this prospectus. All documents subsequently filed by us pursuant to Section 13(a), 13(c) and 14 or 15(d) of the Exchange Act, prior to the termination date of the offering set forth herein shall be deemed incorporated by reference to this prospectus.

We will furnish without charge to you, on written or oral request, a copy of any or all of the documents incorporated by reference, including exhibits to these documents. You should direct any requests for documents to Kyle Guse, Chief Financial Officer, Atossa Genetics Inc., 2300 Eastlake Ave. East, Suite 200, Seattle, Washington, 98102, telephone: (800) 351-3902. Copies of the above reports may also be accessed from our web site at <http://www.atossagenetics.com>.

Any statement contained in a document incorporated or deemed to be incorporated by reference in this prospectus will be deemed modified, superseded or replaced for purposes of this prospectus to the extent that a statement contained in this prospectus modifies, supersedes or replaces such statement.

Up to 7,760,810 shares of Common Stock

ATOSSA GENETICS INC.