

ATOSSA GENETICS INC  
Form 424B3  
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**Registration Statement No. 333-208236**

***PROSPECTUS***

***DATED DECEMBER 16, 2015***

**6,086,207 Shares**

**Common Stock**

This prospectus relates to the sale of up to 6,086,207 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 \$25.0 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 November 11, 2015 (the “*Purchase Agreement*”).

The Selling Stockholder is an “underwriter” within the meaning of the Securities Act of 1933, as amended. We will pay 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 December 16, 2015, the last reported sale price per share of our common stock was \$0.38 per share.

**Investing in our securities involves a high degree of risk. See “Risk Factors” on page 7 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 December 16, 2015

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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 20 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:

whether we maintain our clearances from the U.S. Food and Drug Administration, or FDA, and foreign regulatory bodies, and the CE Certificates of Conformity granted by our notified body, to sell, market and distribute our medical devices;

whether we can achieve our revenue forecast and other financial projections for 2015;

our ability to successfully commercialize the FullCYTE Breast Aspirator in the United States and our ForeCYTE Breast Aspirator outside the United States;

our ability to successfully develop and commercialize our pharmaceutical candidates, including Afimoxifene Topical Gel and our ability to manufacture sufficient quantities of the active ingredients, enroll and successfully complete clinical studies and obtain necessary approvals from the FDA and other regulatory authorities;

our ability to successfully sell our products and services at currently expected prices or otherwise at prices acceptable to us;

our ability to successfully develop and commercialize new tests, tools and treatments currently in development and in the time frames currently expected;

our ability to maintain our business relationships, including with our distributors, suppliers and customers, while we launch and commercialize the FullCYTE Breast Aspirator in the United States and ForeCYTE Breast Aspirator and laboratory tests outside the United States;

our ability to engage third party suppliers to manufacture the ForeCYTE Breast Aspirator, FullCYTE Breast Aspirator, FullCYTE Microcatheter, other devices under development and their components at quantities and costs acceptable to us;

our ability to satisfy ongoing FDA, European Union (EU) and foreign requirements for manufacturing, distributing, and promoting the FullCYTE Breast Aspirator, NAF cytology test and FullCYTE Microcatheter and to obtain regulatory approvals, clearances and CE Certificate of Conformity for our other products and services in development;

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 and services;

our ability to establish and maintain an independent sales representative force, including with our current and future distributors and their sub-distributors, to market our current products and services and those that we may develop;

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 liquidity sources;

our ability to attract and retain key personnel;

our ability to sell additional shares of our common stock to Aspire Capital under the terms of our purchase agreement with them; and

our ability to obtain, maintain and defend our intellectual property rights covering our devices, specimens, collection kits, diagnostic tests and compositions.

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 healthcare company focused on the development of locally-administered pharmaceuticals for the treatment of pre-cancer and early stage breast cancer. Our leading pharmaceutical under development is Afimoxifene Topical Gel, or AfTG, which is in Phase II clinical development. We are also developing our patented intraductal Microcatheters to deliver anti-cancer therapies for breast cancer and pre-cancerous changes which we believe may open up new combinations of drugs and biologics that may deliver higher local doses with lower systemic exposure compared to traditional therapies. We are planning a Phase II clinical trial using our patented intraductal Microcatheters to deliver fulvestrant to treat ductal carcinoma in-situ, or DCIS, and breast cancer.

In May 2015, we acquired the worldwide exclusive rights to develop and commercialize AfTG for the potential treatment and prevention of hyperplasia of the breast and the rights to expand the license to other indications including breast cancer (which would require that we pay milestone payments for each additional indication). AfTG has been used in 16 Phase I and Phase II 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 plan to commence a Phase II clinical trial in mid-2016. The National Cancer Institute, Division of Cancer Prevention, has approved a Letter of Intent submitted by a member of the Consortia for Cancer Prevention Clinical Trials Program for the study of AfTG in women with DCIS. 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.

In October 2015 the FDA accepted our investigational new drug application, or IND, to commence a Phase II clinical study using fulvestrant administered via our patented intraductal Microcatheters to treat DCIS and breast cancer. We expect this study will be performed by Columbia University Medical Center and will commence in late-December 2015 or early 2016.

We have also developed medical devices, which include our ForeCYTE Breast Aspirator for distribution outside the United States and the FullCYTE Breast Aspirator for the U.S. market. These devices are intended for the collection of

nipple aspirate fluid, or NAF, for cytological testing at a laboratory. The current version of the ForeCYTE Breast Aspirator is CE-marked and the FullCYTE Breast Aspirator has been cleared by the FDA. We are not, however, currently marketing and promoting our breast aspirators as we are devoting substantially all of our resources to our pharmaceutical business. Other devices under development include intraductal Microcatheters for the potential administration of targeted pharmaceuticals, and various tools for potential use by breast surgeons.

We have also developed laboratory tests, which 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. The NRLBH currently markets pharmacogenomics tests.

Our key objective is to advance our pharmaceutical candidates through Phase II trials.



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

## **Our Pharmaceutical Programs Under Development**

We have two locally-administered pharmaceutical programs under development: AfTG, which is a gel that the patient applies daily directly to the breast, and our patented intraductal Microcatheters which we are developing for the delivery of anti-cancer therapies with fulvestrant as our leading pharmaceutical candidate for this delivery method.

### ***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. 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 high breast density; and women with a biopsy showing either atypical hyperplasia or DCIS. We plan to start enrolling patients in a Phase 2 study of AfTG in mid-2016.

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).

#### Potential Funding by NCI

The National Cancer Institute, Division of Cancer Prevention, has approved a Letter of Intent submitted by a member of the Consortia for Cancer Prevention Clinical Trials Program for the study of AfTG in women with DCIS. 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. If this program is ultimately approved, 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, and having the NCI pay for the study would be less costly than if we were to pay for the study ourselves.

#### Existing Data on AfTG

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. So, 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, so there is potential for this currently underserved breast cancer population.

These studies demonstrate that tamoxifen is quite effective in preventing breast cancer in these patient populations. We hope that our studies will show that AfTG is also effective but because it is delivered topically rather than orally and we hope that our studies will demonstrate that AfTG does not cause strokes, cataracts, blood clots in the legs and lungs, and cancer of the uterus.

In a previous study done 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 where it causes 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 the oral tamoxifen. The blood markers of stroke, blood clots, and uterine cancer were increased by oral tamoxifen but not AfTG. And 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. 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 commences a Phase 3 clinical trial for each additional indication.

If and when we decide to sublicense our rights to commercialize the AfTG in a country in the territory, Besins has the right of first refusal to commercialize the 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. We are in discussions with Besins to resolve this dispute and clarify the parties' respective rights with respect to the development of AfTG for the reduction of breast density.

## Next steps with AfTG

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

Our next step with our AFTG program is to obtain feedback from the FDA on potential clinical programs. This will occur in the first quarter of 2016. Our goal is to enroll the first patient in a trial in mid-2016.

*Intraductal Delivery of Anti-Cancer Therapies via our Microcatheters*

Intraductal delivery of anti-cancer therapies for breast cancer and pre-cancerous changes opens up new combinations of drugs and biologicals that potentially deliver higher local doses with lower systemic exposure compared to conventional therapies. We are a leader in this novel approach. One potential advantage of Microcatheter intraductal therapy is to take advantage of the large difference in the amount of drug that gets into the tissue with the intraductal administration versus conventional systemic administration. One analysis suggests that the drug levels in tissue might be over 20,000-times higher with the Microcatheter intraductal route. This provides the potential to test a 'one and done' intraductal treatment approach instead of the monthly injections and with potentially higher tissue levels than are possible with systemic administration (for example, intravenous, injection or oral routes). This drug delivery method could result in better patient outcomes and significant cost savings to the healthcare system.

While this approach could apply to many potential pharmaceuticals, our initial study is with Fulvestrant. Fulvestrant is an FDA-approved drug for metastatic breast cancer. It is given as a monthly injection of two shots, typically given into the buttocks. In 2012 a published study documented that the single dose cost of intramuscular Fulvestrant was approximately \$12,000, which is over \$140,000 per patient per year.

A second potential indication for Microcatheter intraductal fulvestrant (and potentially other anti-cancer therapies) 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 two or even one month has value for the patient and the healthcare system.

We will be developing the clinical path and intend to request an FDA meeting during the first quarter of 2016 to discuss the program. Although we do not yet have FDA's input, our preliminary assessment is that the Microcatheter intraductal fulvestrant program could qualify for designation under the 505(b)(2) status. This would allow us to seek marketing approval with only clinical data and without having to perform additional, significant clinical or pre-clinical studies since the drug has been used systemically and the safety profile is well-characterized. So the path to market is both faster and less expensive than a traditional NDA program.

To support this development program, we have successfully completed the clinical build of Microcatheters for the clinical trial. The FDA has also issued a “Safe to Proceed” letter for our first Investigational New Drug application, or IND, which is anticipated to occur at the Columbia University Medical Center Breast Cancer Program in the very near future.

We have an issued patent and pending applications for the Microcatheter intraductal administration of many anti-cancer drugs.

## **NRLBH**

The NRLBH, located in Seattle, Washington, is certified under CLIA and ISO 15189:2012 and is certified by the College of American Pathologists. We believe the NRLBH is one of fewer than ten laboratories in the United States to hold the ISO 15189:2012 certification and it was the first commercial lab in the country to offer enhanced pharmacogenomics testing based on the Luminex xTAG platform. Historically, substantially all of our revenue in had been generated by the NRLBH from its pharmacogenomics test services.

On December 16, 2015 we announced the sale of approximately 81% of the capital stock of the NRLBH to the NRL Investment Group, LLC.

## **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**

We were incorporated in Delaware in April 2009. Our principal executive offices are located at 2300 Eastlake Ave. East, Suite 200, Seattle, Washington 98102 and our telephone number is (800) 351-3902. Our corporate website is located at [www.atossagenetics.com](http://www.atossagenetics.com). Information contained on, or that can be accessed through, our website is not a part of this prospectus.

We currently have approximately 15 full-time employees.

MASCT is our registered trademark and our name and logo are our trademarks. FullCYTE, NextCYTE and ArgusCYTE are our service marks. This prospectus 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 6,086,207 shares of Common Stock.

**Common stock outstanding as of September 30, 2015:** 30,446,260 shares.

**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 \$25.0 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 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 7.

**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 November 11, 2015, 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 \$25.0 million of our shares of Common Stock over the approximately 30-month term of the Purchase Agreement. Concurrently with entering into the Purchase Agreement, we also entered into a registration rights agreement with Aspire Capital (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.

As of November 11, 2015, there were 30,446,260 shares of our Common Stock outstanding (25,667,728 shares held by non-affiliates), excluding the 6,086,207 shares offered that have not been issued but may become issuable to

Aspire Capital pursuant to the Purchase Agreement. If all of the 6,086,207 shares of our Common Stock offered hereby were issued and outstanding as of the date thereof, such shares would represent 19.99% of the total Common Stock outstanding or 23.71% 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 November 27, 2015 there were 30,446,260 shares of our Common Stock outstanding (25,667,728 shares held by non-affiliates), excluding the 6,086,207 shares offered by this prospectus that have not been issued but may become issuable to Aspire Capital pursuant to 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.

Pursuant to the Purchase Agreement and the Registration Rights Agreement, we have registered 6,086,207 shares of our Common Stock under the Securities Act, which we may issue to Aspire Capital.

On December 17, 2015, the conditions necessary for purchases under the Purchase Agreement to commence were satisfied. 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 \$25.0 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 \$0.50 per share of Common Stock, we also have the right, in our sole discretion, to present Aspire Capital with a volume-weighted average price purchase notice (each, a “**VWAP Purchase Notice**”) directing Aspire Capital to purchase an amount of stock equal to up to 30% of the aggregate shares of our Common Stock traded on the NASDAQ on the next trading day (the “**VWAP Purchase Date**”), subject to a maximum number of shares we may determine (the “**VWAP Purchase Share Volume Maximum**”) and a minimum trading price (the “**VWAP Minimum Price Threshold**”) (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 affect 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, 2014, as updated in our Quarterly Reports 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 \$25.0 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 6,086,207 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 \$25.0 million of Common Stock that 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.

*If our stock price does not appreciate above \$1.00 per share, we may be delisted from NASDAQ which would adversely affect our stock price, liquidity and our ability to raise capital.*

On September 28, 2015, we received a letter from NASDAQ stating that the Company was not in compliance with NASDAQ Listing Rule 5550(a)(2), because the Company's common stock failed to maintain a minimum closing bid price of \$1.00 per share for 30 consecutive business days. We have until March 28, 2016 to regain compliance. In the event we do not regain compliance by then, we may be eligible for additional time if at that time we meet the continued listing requirement for market value of publicly held shares and all other initial listing standards, with the exception of the bid price requirement, and provide written notice to NASDAQ of our intention to cure the deficiency during the second compliance period, including by effecting a reverse stock split, if necessary. The letter also states that the NASDAQ staff will provide written notification that we have regained compliance if the bid price of our common stock closes at \$1.00 per share or more for a minimum of 10 consecutive business days.

If our stock price does not appreciate above \$1.00 per share we may be delisted from NASDAQ which could adversely affect our stock price, liquidity and our ability to raise funding.

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

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

- The degree of future protection for our proprietary rights is uncertain, and we cannot ensure that:
- we or our licensors were the first to make the inventions covered by each of our patent applications;
- we or our licensors were the first to file patent applications for these inventions;
- others will not independently develop similar or alternative technologies or duplicate any of our technologies;
- any of our or our licensors' patent applications will result in issued patents;
- any of our or our licensors' patents will be valid or enforceable;
- any patents issued to us or our licensors and collaborators will provide a basis for commercially viable tests and/or Therapeutics, will provide us with any competitive advantages or will not be challenged by third parties;

- we will develop additional proprietary technologies or tests that are patentable;
- the patents of others will not have an adverse effect on our business; or
- our patents or patents that we license from others will survive legal challenges, and remain valid and enforceable.

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

We also rely upon unpatented proprietary technologies. Although we require employees, consultants and collaborators to sign confidentiality agreements, we may not be able to adequately protect our rights in such unpatented proprietary technologies, which could have a material adverse effect on our business. For example, others may independently develop substantially equivalent proprietary information or techniques or otherwise gain access to our proprietary technologies or disclose our technologies to our competitors.

***If we were sued for patent infringement by third parties, we might incur significant costs and delays in test or drug introduction.***

Our tests and drug candidates may also conflict with patents that have been or may be granted to others. Our industry includes many organizations that have or are seeking to discern biomarkers and develop genomic, proteomic and other technologies and also develop drugs. To the extent any patents are issued or have been issued to those organizations, the risk increases that the sale of our molecular diagnostic and companion diagnostic tests, and drugs under development may give rise to claims of patent infringement. Others may have filed and in the future are likely to file patent applications covering biomarkers that are similar or identical to our tests and/or drugs that are similar to our drugs. Any of these patent applications may have priority over our patent applications and these entities or persons could bring legal proceedings against us seeking damages or seeking to enjoin us from testing or marketing our tests. Patent litigation is costly, and even if we prevail, the cost of such litigation could have a material adverse effect on us. If the other parties in any such actions are successful, in addition to any liability for damages, we could be required to cease the infringing activity or obtain a license. Any license required may not be available to us on commercially acceptable terms, if at all. Our failure to obtain a license to any technology that we may require to commercialize our tests could have a material adverse effect on our business. We believe that there may be significant litigation in the industry regarding patent and other intellectual property rights. If we become involved in this litigation, it could consume a substantial portion of our managerial and financial resources.

***If we fail to comply with our obligations under license or technology agreements with third parties, we could lose license rights that are critical to our business.***

We license intellectual property that is critical to our business, including licenses underlying the technology in our molecular diagnostic and pharmaceutical and clinical services and therapeutics and in the future we may enter into additional agreements that provide us with licenses to valuable intellectual property or technology. These licenses impose various royalty payments, milestones, and other obligations on us. If we fail to comply with any of these obligations, the licensor may have the right to terminate the license. Termination by the licensor would cause us to lose valuable rights, and could prevent us from distributing our current tests and/or drugs, or inhibit our ability to commercialize future test and/or therapeutics candidates. Our business would suffer if any current or future licenses terminate, if the licensors fail to abide by the terms of the license, if a dispute with the licensors, including Besins, delays or limits our ability to exercise our rights under the licenses, if the licensors fail to prevent infringement by third parties, if the licensed patents or other rights are found to be invalid or unenforceable, or if we are unable to enter into necessary licenses on acceptable terms.

## **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 \$25.0 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)	1,520,833	(3) 4.995 %	6,086,207	1,520,833	(4) 4.160 % (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 Capital”). 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 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 Capital. 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 Capital, except to extent of their pecuniary interest therein. Aspire Capital is not a licensed broker dealer nor is any of its affiliate a licensed broker dealer.

As of the date hereof, 1,520,833 shares of our common stock are owned by Aspire Capital, consisting of 1,520,833 shares previously purchased by Aspire Capital. We may elect in our sole discretion to sell to Aspire Capital up to an additional 6,086,207 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.

(4) Amount equals shares beneficially owned before the offering and assumes no additional sales of the remaining 1,520,833 shares.

(5) Based on 30,446,260 shares of Common Stock outstanding as of November 19, 2015.

## THE ASPIRE CAPITAL TRANSACTION

### General

On November 11, 2015, 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 \$25.0 million of our shares of Common Stock over the term of the Purchase Agreement. 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 November 11, 2015, there were 30,446,260 shares of our Common Stock outstanding (25,667,728 shares held by non-affiliates), excluding the 6,086,207 shares offered that have not been issued but may become issuable to Aspire Capital pursuant to the Purchase Agreement. If all of the 6,086,207 shares of our Common Stock offered hereby were issued and outstanding as of the date thereof, such shares would represent 19.99% of the total Common Stock outstanding or 23.71% 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 November 19, 2015, there were 30,446,260 shares of our Common Stock outstanding (25,667,728 shares held by non-affiliates), excluding the 6,086,207 shares offered that have not been issued but may become issuable to Aspire Capital pursuant to 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.

Pursuant to the Purchase Agreement and the Registration Rights Agreement, we have registered 6,086,207 shares of our Common Stock under the Securities Act, which we may issue to Aspire Capital. Under the Purchase Agreement, we have the right but not the obligation to issue more than the 6,086,207 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 6,086,207 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 \$25.0 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 \$0.50 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 May 26, 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 \$0.50 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 6,086,207, or the Exchange Cap, which represents 19.99% of our outstanding shares as of November 11, 2015, 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 6,086,207 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 6,086,207 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 \$25.0 million of our shares of Common Stock. However, we estimate that we will sell no more than 6,086,207 shares to Aspire Capital under the Purchase Agreement, 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 6,086,207 shares included in this prospectus to Aspire Capital under the Purchase Agreement. In the event we elect to issue more than 6,086,207 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	Percentage of Outstanding Shares After Giving Effect to the Purchased Shares Issued to Aspire Capital (1)	
\$ 0.10	\$ 608,620.70	6,086,207	16.66	%
\$ 0.25	\$ 1,521,551.75	6,086,207	16.66	%
\$ 0.50	\$ 3,043,103.50	6,086,207	16.66	%
\$ 1.00	\$ 6,086,207.00	6,086,207	16.66	%
\$ 2.00	\$ 12,172,414.00	6,086,207	16.66	%
\$ 3.00	\$ 18,258,621.00	6,086,207	16.66	%
\$ 4.00	\$ 24,344,828.00	6,086,207	16.66	%
\$ 6.00	\$ 25,000,000.00	4,166,666	12.04	%

The denominator is based on 30,446,260 shares outstanding as of November 19, 2015, which includes the number of shares set forth in the adjacent column which we would have sold to Aspire Capital at the corresponding (1) 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 September 30, 2015 was approximately \$7.3 million, or \$0.24 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 September 30, 2015.

After giving effect to the sale in this offering of 6,086,207 shares of common stock at an assumed average sale price of \$0.36 per share (based on the lowest sales price of our common stock as of December 11, 2015), our pro forma as adjusted net tangible book value as of September 30, 2015 would have been approximately \$9.3 million, or \$0.25 per share of Common Stock. This represents an immediate increase in pro forma as adjusted net tangible book value of \$0.02 per share to our existing stockholders and an immediate dilution of \$0.08 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, 2014 and for the year then ended 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. KCCW Accountancy Corp., an independent PCAOB registered public accounting firm, has audited the Company's consolidated balance sheets as of December 31, 2013 and the related consolidated statements of operations, stockholders' equity, and cash flows for the year then ended, which are incorporated by reference in this prospectus. The consolidated financial statements are included in reliance on the report of KCCW Accountancy Corp., given their authority as experts in accounting and auditing.

## **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, 2014, filed with the SEC on March 30, 2015;

· portions of our definitive Proxy Statement on Schedule 14A, filed with the SEC on April 15, 2015;

· our current reports on Form 8-K filed with the SEC on April 7, 2015, as amended, May 14, 2015, May 18, 2015, May 28, 2015, June 4, 2015, June 10, 2015, September 4, 2015 October 10, 2015 and December 16, 2015; and

· our Quarterly Reports on Form 10-Q for the quarter ended March 31, 2015, filed with the SEC on May 13, 2015, for the quarter ended June 30, 2015, filed with the SEC on August 6, 2015, and for the quarter ended September 30, 2015, filed with the SEC on November 12, 2015.

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 6,086,207 shares of Common Stock**

**ATOSSA GENETICS INC.**