ATOSSA GENETICS INC
Form S-1
April 05, 2013

As filed with the Securities and Exchange Commission on April 5, 2013

Registration Statement No. 333-

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM S-1

Registration Statement

Under

The Securities Act of 1933

ATOSSA GENETICS INC.

(Exact name of registrant as specified in its charter)

Delaware	**3841**	**26-4753208**
(State or other jurisdiction of incorporation or organization)	**(Primary Standard Industrial Classification Code Number)**	**(I.R.S. Employer Identification No.)**

4105 E. Madison Street, Suite 320

Seattle, Washington 98112

Telephone: (206) 325-6086

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

Steven C. Quay

Chairman, Chief Executive Officer and President

4105 E. Madison Street, Suite 320

Seattle, Washington 98112

Telephone: (206) 325-6086

(Name, address, including zip code, and telephone

number, including area code, of agent for service)

_____

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

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933 check the following box. x

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of “large accelerated filer,” “accelerated filer” and “smaller reporting company” in Rule 12b-2 of the Exchange Act. (Check one):

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

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

CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	Amount to be registered	Proposed maximum offering price per share	Proposed maximum aggregate offering price	Amount of registration fee
Common Stock, par value $0.001 per share	2,833,519(1)	$9.01	(2) $ 25,530,006	$ 3,483

(1) Represents 333,333 shares of Common Stock, par value $0.001 per share (the "***Common Stock***") currently outstanding, and 2,500,186 shares of Common Stock that are issuable as of the date of this Registration Statement pursuant to a common stock purchase agreement with the selling stockholder named herein. Pursuant to Rule 416(a) of the Securities Act of 1933, as amended, this Registration Statement also covers any additional shares of Common Stock which may become issuable to prevent dilution from stock splits, stock dividends and similar events.

(2) Pursuant to Rule 457(c), calculated on the basis of the average of the high and low prices per share of the registrant's Common Stock reported on the NASDAQ Capital Market on April 1, 2013.

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

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

PRELIMINARY PROSPECTUS (Subject to Completion)

dated April _, 2013

ATOSSA GENETICS INC.

2,833,519 shares of Common Stock

This prospectus covers the sale of an aggregate of 2,833,519 shares of our common stock, $0.001 par value per share (the " ***Common Stock*** "), by Aspire Capital Fund, LLC ("***Aspire Capital***" or the "***Selling Stockholder***").

The prices at which the Selling Stockholder may sell the shares of Common Stock 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 have received $1 million in gross proceeds, and in the future may receive up to $29 million in gross proceeds, 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 March 27, 2013 (the "***Purchase Agreement***") once the registration statement, of which this prospectus is a part, is declared effective.

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.

The Company's Common Stock is traded on the NASDAQ Capital Market under the symbol "ATOS". On April 4, 2013, the closing sale price of our Common Stock on the NASDAQ Capital Market was $8.29 per share. Our principal executive offices are located at 4105 E. Madison Street, Suite 320, Seattle, Washington 98112 and our telephone number is (206) 325-6086.

Investing in our securities involves risks. You should carefully consider the risk factors beginning on page 10 of this prospectus before you make an investment in our securities.

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

The date of this prospectus is , 2013

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

- 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 technologies currently in development and in the time frames currently expected;
- our ability to engage third-party suppliers to manufacture the MASCT or Microcatheter System and its components at quantities and costs acceptable to us;
- our ability to satisfy ongoing Food and Drug Administration requirements for the MASCT and Microcatheter System and to obtain regulatory approvals for our other products and services in development, including our ability to timely and adequately respond to the warning letter we received from the FDA on February 21, 2013 and any issues resulting therefrom;

- the benefits and clinical accuracy of the ForeCYTE and ArgusCYTE tests and whether any product or service that we commercialize is safer or more effective than competing products and services;

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

- the willingness of health insurance companies, including those who are members of the MultiPlan and FedMed networks, and other third-party payors to approve our products and services for coverage and reimbursement;

- our ability to establish and maintain an independent sales representative force, including with Clarity Women's Health, a division of Diagnostic Test Group LLC, and its distributors, to market our products and services that we may develop, both regionally and nationally;

- 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; and

- our ability to sell additional shares of our Common Stock to Aspire Capital under the terms of our Purchase Agreement with them.

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

PROSPECTUS SUMMARY

This summary highlights some information from this prospectus. It may not contain all the information important to making an investment decision. You should 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. Unless otherwise noted, (1) the term "Atossa Genetics" refers to Atossa Genetics Inc., a Delaware corporation, (2) the terms "Atossa," the "Company," "we," "us," and "our," refer to the ongoing business opera of Atossa and its wholly-owned subsidiary, whether conducted through Atossa Genetics or its subsidiary and (3) the term "Common Stock" refers to shares of Atossa Genetics Inc.'s Common Stock and the term "stockholder(s)" refers to the holders of Common Stock or securities exercisable for Common Stock.

Our Business

Overview

We are a healthcare company focused on the prevention of breast cancer through the commercialization of diagnostic medical devices and laboratory developed tests that can detect precursors to breast cancer, and through the research, development, and ultimate commercialization of treatments for pre-cancerous lesions and ductal carcinoma in situ, or DCIS.

Our leading diagnostic test, the ForeCYTE Breast Health Test, consists of a patented medical device that can collect fluid samples from the breast milk ducts, where, according to the National Cancer Institute, over 95% of breast cancers arise. These samples are processed at our wholly-owned National Reference Laboratory for Breast Health, which has been certified pursuant to the Clinical Laboratory Improvement Amendments, or CLIA. CLIA certification is legally required to receive reimbursement from federal or state medical benefit programs, like Medicare and Medicaid, and is a practical requirement for most third-party insurance benefit programs. Our CLIA-certified laboratory, which is permitted to accept samples from all 50 states under its CLIA certification, its state licenses, or, in New York under recognized exemption provisions while its license application is pending, examines the specimens by microscopy for the presence of normal, pre-malignant, or malignant changes as determined by cytopathology and biomarkers that distinguish "usual" ductal hyperplasia, a benign condition, from atypical ductal hyperplasia, which may lead to cancer. These cytopathological results provide patients and physicians with information about the care path that should be followed, depending on the individual risk of future cancer as determined by the results. Our other diagnostic test is the ArgusCYTE Breast Health Test for breast cancer survivors. This is a blood sample test that provides information to help inform treatment options and to help monitor risk of recurrence. Other tests under development are the FullCYTE Breast Health Test and the NextCYTE Breast Cancer Test.

Additionally, we are conducting research on the treatment of these pre-cancerous cells and DCIS by using our patented and FDA-cleared microcatheters to deliver, directly into the milk ducts, pharmaceutical formulations that can be used to treat these conditions. By using this localized delivery method, patients are expected to receive high local concentrations of these drugs at the site of the pre-cancerous lesions or DCIS potentially promoting efficacy of the treatment while limiting systemic exposure, which has the potential to lower the overall toxicity of these treatments.

We launched our commercial operations in late 2011 and, as of December 31, 2012, have enrolled and sold MASCT System kits or provided ArgusCYTE collection kits to 37 doctors and clinics as providers of the ForeCYTE and/or ArgusCYTE tests. We have received, processed, and reported the results to physicians from 1,664 ForeCYTE samples and 41 ArgusCYTE samples as of December 31, 2012. When we launched operations in December 2011, we did so as part of our field experience trial to collect information about the ease or difficulty of adoption of the ForeCYTE and ArgusCYTE tests in both mammography clinics and physicians' offices, the number of sales calls to receive the first orders, and the growth of sales of specimen collection kits on a monthly basis. We are using the data from this field experience trial to form our national marketing efforts as we scale up our commercial operations going forward.

For the year ended December 31, 2012, we generated $481,842 in revenue from the sale of our products and services and we incurred a net loss of $5,079,851. Through December 31, 2012 we had an accumulated deficit of approximately $9.7 million. As of the date of this prospectus, we expect that our existing resources to be sufficient to fund our planned operations for at least the next four months. However, to fund our operations for at least the next 12 months under our current business plan, we estimate that we will need between $4 million and $10 million of additional capital. We have not yet established an ongoing source of revenue sufficient to cover our operating costs and allow us to continue as a going concern. Our ability to continue as a going concern is dependent on obtaining adequate capital to fund operating losses until we become profitable. We plan to obtain additional capital resources by selling our equity securities, selling the MASCT System and generating laboratory service revenue from our tests, and making short-term borrowings when needed. For example, we have the right under our Purchase Agreement with Aspire Capital Fund, LLC, or Aspire Capital, to sell to Aspire Capital during the three-year term of the agreement up to $29 million in Common Stock after the registration statement, of which this prospectus forms a part, becomes effective. The Aspire Capital registration statement may not become effective, may not remain effective and we cannot be certain that we will be able to sell Common Stock to Aspire Capital when necessary. If we are unable to raise the amount of capital we anticipate needing, from Aspire Capital or otherwise, we would be forced to curtail or cease operations.

In September 2012, we acquired the assets of Acueity Healthcare, Inc., which included 35 issued patents (18 issued in the U.S. and 17 issued in foreign countries) and 41 patent applications (32 in the U.S. and 9 in foreign countries), six 510(k) FDA marketing authorizations related to the manufacturing, use, and sale of the Viaduct Miniscope and accessories, the Manoa Breast Biopsy system, the Excisor Bioptome, the Acueity Medical Light Source, the Viaduct Microendoscope and accessories, and cash in the amount of $400,000. In January 2013, we announced the launch of our national sales effort of the ForeCYTE Breast Health test through Clarity Women's Health, a division of Diagnostic Test Group LLC, or Clarity, which together with its subdistributors has over 5,000 sales representatives calling on 33,000 obstetric-gynecologists. As of the date of this prospectus, we have entered into contracts with two reimbursement organizations, MultiPlan, Inc. and FedMed, Inc.

On March 27, 2013, we entered into the Purchase Agreement with 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 $30 million of shares of our Common Stock over the three-year term of the agreement. Under the agreement, Aspire Capital purchased $1 million of our Common Stock on March 27, 2013 for $12 per share. Before we can sell any additional shares under the Purchase Agreement, we must register the shares and have the registration statement, of which this prospectus forms a part, declared effective by the SEC. Other terms and conditions of the Purchase Agreement, including our issuance of 250,000 shares to Aspire Capital as a commitment fee, are described below.

Our operations began in December 2008 around acquiring the MASCT System patent rights and assignments and the FDA clearance for marketing, which was completed in January 2009. We were incorporated in Delaware in April 2009. Our operations to date have consisted primarily of securing manufacturing for the MASCT and the Mammary Duct Microcatheter Systems, establishing our CLIA-certified laboratory, validating the laboratory developed tests we use in the ForeCYTE and ArgusCYTE tests, conducting research and development on the FullCYTE and NextCYTE tests, beginning the national launch of the ForeCYTE test and preparing for the commercialization of our products.

Summary of Our Diagnostic Tests

We currently offer two diagnostic tests and plan to offer two additional tests in 2013. The tests that we currently offer and that are in development consist of the following:

ForeCYTE The ForeCYTE Breast Health Test, launched in December 2011, provides personalized information about the 10-year and lifetime risk of breast cancer for women between ages 18 and 73. It involves collecting a specimen of nipple aspirate fluid, or NAF, using our patented *Mammary Aspirate Specimen Cytology Test*, or MASCT, System (our MASCT device received 510(k) clearance from the FDA in 2003). The NAF specimen is collected by a physician and returned to our CLIA-certified laboratory. We study the patient's NAF specimen and use a proprietary molecular and cellular biomarker test that detects basal or luminal cells to identify the presence of atypical ductal hyperplasia, or ADH, which is considered a precursor to

breast cancer. We then input these cytopathological test results, together with the patient's personal medical and reproductive history and family history, into a clinically-validated risk assessment algorithm that calculates 10-year and lifetime risk of breast cancer and presents these results in one of three risk tiers developed by The National Comprehensive Cancer Network: Normal (<15% lifetime risk), Intermediate (15 – 20% lifetime risk), or High (>20% lifetime risk). The ForeCYTE Test results contain recommendations for care paths in each risk group and personalized information so that patients and healthcare providers can make more informed treatment decisions. The algorithm was developed from a Swedish registry of 158,041 individuals, in whom 3,257 cancers occurred, and was validated by E. Amir, D.G. Evans, A. Shenton, and others in an independent study of 3,150 women, 64 of whom developed breast cancer. The algorithm incorporates family history, personal reproductive history, and the presence or absence of usual ductal hyperplasia, or UDH (which is benign), ADH (which is pre-malignant), or malignant changes. The present methods used by pathologists to analyze traditional biopsy specimens, i.e., microscopy and, when needed, immunohistochemistry, are the same methods used to analyze ForeCYTE specimens and would be expected to achieve similar results for patients with similar medical conditions.

ArgusCYTE

The ArgusCYTE Breast Health Test, launched in December 2011, provides information to help inform breast cancer treatment options and to help monitor potential recurrence. It involves collecting a blood specimen from a patient using our patented blood collection tube and submitting it to our CLIA-certified laboratory (our ArgusCYTE Breast Health Test blood collection tube was registered with the FDA in 2011 as a 510(k)-exempt device). It can monitor breast cancer distant recurrence by obtaining a "liquid biopsy" or blood sample, and analyzing it for the presence of circulating tumor cells, which can then be analyzed to determine the expression of ER/PR and Her2 in those cells, a predictor of the cancer's sensitivity to existing treatment options. The presence of circulating tumor cells in the blood sample may serve as an early indicator of the recurrence of breast cancer and the data obtained from the ArgusCYTE sensitivity analysis may help physicians better select which treatment options to use with a particular patient. The ArgusCYTE test uses a proprietary blood collection tube to obtain a blood sample for shipment and analysis at our CLIA-certified laboratory. The supplier of the blood collection tube owns patents with respect to the tube, while we own patents concerning laboratory features utilized in the testing process. Because the ArgusCYTE test involves the collection of a blood sample to be analyzed for the presence of circulating tumor cells, there is no comparable method relating to the analysis of traditional biopsy specimens that could be used to achieve results similar to or better than those provided by our ArgusCYTE test.

FullCYTE The FullCYTE Breast Health Test, which we intend to launch in 2013 and is currently in development, is designed to assess the individual breast ducts for pre-cancerous changes in women previously identified to be at high risk for breast cancer. It involves collecting ductal lavage samples from each of the 5 to 7 individual breast milk ducts using our patented Mammary Ductal Microcatheter System (our Microcatheter System received 510(k) clearances from the FDA in 1999 and 2000) and analyzing the samples by the same molecular and cellular biomarkers used in the ForeCYTE test described above. From these tests, we are able to ascertain which individual duct contains pre-malignant or malignant changes, which may allow the physician to better target treatment to the specific duct with the pre-malignant changes or malignant changes and therefore avoid side effects associated with systemic treatment. Traditional biopsies, involving invasive procedures in which tissue is removed surgically, typically cut across the natural anatomy of the breast ductal system, making subsequent intraductal treatment difficult or, in certain cases, impossible. The present methods used by pathologists to analyze traditional biopsy specimens, i.e., microscopy and, when needed, immunohistochemistry, are the same methods used to analyze FullCYTE specimens and would be expected to achieve similar results for patients with similar medical conditions.

NextCYTE The NextCYTE Breast Cancer Test, which is in the prevalidation phase and which we intend to launch in 2013, is designed to profile breast cancer specimens for prediction of treatment outcomes and distant recurrence in women newly diagnosed with breast cancer. It involves using surgery specimens and advanced genome sequencing techniques to quantify and analyze the entire tumor genetic transcriptome, which represents all genes that are being actively expressed within the tumor. Because our NextCYTE test analyzes traditional biopsy specimens using advanced genome sequencing techniques, we believe that other present methods of analyzing traditional biopsy specimens would not achieve results similar to or better than results provided by our NextCYTE test and we expect that physicians will be able to use the information provided by the NextCYTE test to better customize treatment options for women, based on the genetic composition of the individual tumor. The NextCYTE Breast Cancer Test is intended to use microarray-based genome-wide transcriptome data from surgical breast cancer biopsy specimens to predict a patient's 10-year survival probability and response to treatment. The algorithm was created from 2,400 unique genome-wide microarrays and validated against a separate sample of over 1600 microarray data sets. A correct classification was obtained for over 85% of both estrogen receptor negative and positive tumors. We have signed a term sheet for the exclusive license of the intellectual property related to this algorithm and we expect to complete the license in the first half of 2013 and to complete validation of the test in our laboratory soon thereafter, with an intent to launch this product before year end 2013.

The Medicare reimbursement rates set forth in this prospectus are the 2012 rates, unless otherwise noted. These rates may be different than the 2013 rates.

Our Diagnostic Tools

The assets we acquired from Acueity included 35 issued patents (18 issued in the U.S. and 17 issued in foreign countries) and 41 patent applications (32 in the U.S. and 9 in foreign countries), six 510(k) FDA marketing authorizations related to the manufacturing, use, and sale of the Viaduct Miniscope and accessories, the Manoa Breast Biopsy system, the Excisor Bioptome, the Acueity Medical Light Source, the Viaduct Microendoscope and

accessories, and cash in the amount of $400,000. The microendoscopes are less than 0.9 mm outside diameter and can be inserted into a milk duct. This permits a physician to pass a microendoscope into the milk duct system of the breast and view the duct system via fiberoptic video images. Abnormalities that are visualized can then be biopsied from inside the duct with the biopsy tools that are inserted adjacent to the microendoscope. The patents relate to intraductal diagnostic and therapeutic devices and methods of use. We did not, however, acquire an inventory of these diagnostic tools, manufacturing capabilities or any personnel to market and sell the tools. Following the launch of our four diagnostic tests in the U.S., we will then begin to allocate human and financial resources to further develop and ultimately commercialize these medical devices. We intend to complete the steps necessary to begin marketing and selling these tools, such as re-establishment of the supply chain of component parts, securing manufacturers, performing test builds and commercial scale manufacturing, in late 2013. This asset purchase is not expected to have an impact on the development and commercialization timetables of our existing product lines. We cannot, however, provide any assurances that delays related to the launch of our four diagnostic tests, independent of the asset purchase, would not delay the expected development of these diagnostic tools or that we will ultimately be successful selling these tools.

We may not, however, achieve commercial market acceptance of any of our products and services. We must first demonstrate to physicians and other healthcare professionals the benefits of our tests and the MASCT System for their practice and these physicians and healthcare professionals may be reluctant to introduce new services into their practice due to uncertainty regarding reliability of the results of a new product or the learning curve associated with adoption of new services and techniques. Moreover, if third-party payors continue to refuse to cover the cost of collection of the NAF sample, whether from our MASCT System or competitors' NAF collection devices, physicians may be less likely to recommend or use our products and services if the cost of performing a particular test will not be reimbursed. Even if we are successful in convincing physicians and other healthcare professionals to utilize our tests and services, we must obtain adequate capital to fund our operations until we become profitable and we may not be able to do so. Additionally, we have no prior experience with commercializing any products or services and will need to create an infrastructure to scale operations for commercialization, including hiring experienced personnel (including anatomic pathologists, cytologists, histotechnologists, skilled laboratory and information technology staff, and sales representatives) and building a network of regional, specialty distributors, each with a staff of independent sales representatives who have experience in women's health products to target physicians and mammography clinics in the United States.

Intraductal Treatment Research

Our Intraductal Treatment Research Program comprises our patented microcatheter-delivery technology and our patented pharmaceutical formulations for the intraductal treatment of breast pre-cancerous changes and DCIS. The method uses our Mammary Ductal Microcatheter System, invented by Dr. Susan Love, President of the Dr. Susan Love Research Foundation, and her colleagues, and acquired by us, to administer proprietary pharmaceutical formulations into milk ducts that display pre-cancerous changes or DCIS with high local concentrations of the drugs in order to promote greater efficacy and limited systemic exposure, potentially lowering the overall toxicity of the treatment.

An October 2011 peer-reviewed paper published in *Science Translational Medicine* documented 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 report a Phase I clinical trial to show the safety and feasibility of intraductal administration of chemotherapy drugs 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 into multiple ducts for the purpose of breast cancer prevention and that this was an important step toward implementation of this strategy as a "chemical mastectomy", potentially eliminating the need for surgery.

We intend to build on these academic studies with a research program targeted initially as neoadjuvant therapy in DCIS and to begin preclinical studies during 2013. We may partner with a third party to provide the pharmaceutical for the program. However, we have not as of the date of this prospectus contracted with such a partner nor have we begun the process of applying for FDA approval of our Intraductal Treatment Research Program.

Our Commercialization Strategy

The ForeCYTE Test provides us with two revenue sources:

(i) revenue from the sale of the MASCT System device and patient kits to physicians, breast health clinics, mammography clinics and distributors; and

(ii) service revenue from the preparation and interpretation of the NAF samples sent to our laboratory for analysis.

The ArgusCYTE test provides only laboratory service revenue.

We offer each component of the MASCT System for sale separately. Our NAF sample collection devices are currently priced to physicians at approximately $299 per starter kit, which includes the pump device and five patient collections kits, and our patient collection kits are currently priced at approximately $35 per kit, however, our sale prices to our distributors are significantly below these prices and these prices are subject to change. During our initial launch, we plan to provide a rebate to the physician after the physician submits patient collection kits to our lab. The cytology and molecular diagnostics testing and analysis services are billed to federal and/or state health plans at the 2012 Medicare reimbursement rates of either $384 or $1,275 per patient, depending on the complexity of the analysis performed and at higher rates for patients covered by private insurance plans as is customary for our industry. We expect that the substantial majority of patients will be billed at the $384 rate and that we would perform the more complex tests, corresponding with a reimbursement rate of $1,275, for only those patients who have an initial test result that requires further analysis. Currently, Medicare and certain insurance carriers do not reimburse for the NAF collection procedure by our MASCT System or for other NAF collection device systems similar to our MASCT System, although Medicare and certain insurance carriers do reimburse for the laboratory analysis of the NAF sample. Although we have received reimbursement from insurance carriers and Medicare for our ForeCYTE test, any lack of Medicare or insurance coverage for the NAF collection procedure will require patients to bear the full costs of the NAF sample acquisition process used with the MASCT System, which may result in physicians and other healthcare professionals not adopting the MASCT System or recommending its use in patients. If this were to occur, we may be forced to reduce the price of the MASCT System, provide discounted pricing arrangements to secure sales, or we may not be

able to sell the product and services components of the MASCT System at acceptable margins, all of which could limit our ability to generate revenue.

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During our initial marketing efforts we are not charging for our ArgusCYTE collection kits and we currently price the ArgusCYTE test at approximately $1,500. Because we do not currently have sufficiently reliable prior history of reimbursement with respect to the ArgusCYTE test, we currently do not recognize revenue until we have received reimbursement. We have billed the testing and analysis regarding the 41 ArgusCYTE samples processed through December 31, 2012 at $1,500 per patient. We have received reimbursement from insurance carriers for our ArgusCYTE test.

Our National Launch Through Clarity

In September 2012, we entered into a co-exclusive marketing agreement with Diagnostic Test Group LLC, or DTG, for the supply and distribution of the MASCT System, under the DTG Clarity brand. Under the terms of the agreement, DTG will purchase the MASCT System from us and will use its best efforts to establish product codes and contracted agreements for the sale and placement of the Clarity branded MASCT product line with the following distributors: Henry Schein, McKesson, PSS World Medical, Cardinal Health, VWR, Vaxserve, Mercedes Medical, Fisher, NDC members, Imco members, B&H Surgical, Marshall Medical and Cascade HealthCare Products. These distributors have collectively over 5,000 employee sales representatives and/or independent sales representatives selling their products to a target market of 33,000 obstetric-gynecologists in the United States.

We will coordinate the sales and marketing effort, plan, and budget with DTG, with us paying agreed expenses. We can terminate the agreement if DTG fails to achieve set minimum sales over a certain period of time. In consideration for DTG's marketing of the MASCT System, we have agreed to pay DTG a minimal cash fee for each test performed by us on MASCT samples sold by DTG, as well as warrants to purchase our Common Stock, which warrants are earned based on the annual number of ForeCYTE tests performed by the National Reference Laboratory for Breast Health, provided that the total number of warrants cannot exceed 1,000,000. These warrants have an exercise price equal to the fair market value of our Common Stock on the day of issuance.

In January 2013, we launched the ForeCYTE Breast Health Test with Clarity and its distributors. We may not be successful, however, in selling the Clarity branded MASCT product line and we may not achieve any level of commercial success from Clarity's efforts.

Reimbursement Organizations

As of the date of this prospectus, we have two contracts with third parties to facilitate the reimbursement process from insurers, one with MultiPlan, Inc. and another with FedMed, Inc. MultiPlan is a leading provider of healthcare cost management solutions for diagnostic laboratory testing involving our tests. Approximately 20% of Americans are covered by MultiPlan. The agreement allows us to participate in the MultiPlan, PHCS and PHCS Savility Networks.

In March of 2013, we entered into an agreement with FedMed, which is a National Provider Network and Healthcare Financial Services Organization. FedMed is one of the largest proprietary Preferred Provider Organization (PPO) networks in the U.S. for diagnostic laboratory testing. FedMed's network is comprised of over 550,000 total providers, including 4,000 hospitals and more than 60,000 ancillary facilities, serving over 40 million Americans.

Our agreements with MultiPlan and FedMed will give their participating providers and their patients greater access to our tests, including the ForeCYTE and ArgusCYTE Breast Health Tests. We anticipate that the agreements with MultiPlan and FedMed will help ensure that more doctors and their patients have access to the ForeCYTE and ArgusCYTE Breast Health Tests and that patients will receive insurance reimbursement for the laboratory costs associated with these tests.

Our agreements with MultiPlan and FedMed provide that reimbursement will be provided to us at a prescribed rate when insurers agree to reimburse for the ForeCYTE and ArgusCYTE Breast Health Tests. The prescribed rates of reimbursement are within the range of reimbursement that we have historically received. Our agreements do not, however, ensure that each test performed will be deemed medically necessary and ultimately reimbursed by insurers as the insurers may still determine the medical necessity of each test on a case-by-case basis. Our strategy is to contract with additional reimbursement organizations and insurers.

Risk Factors

Our business is subject to numerous risks as discussed more fully in the section entitled "Risk Factors" beginning on page 10. Principal risks of our business include, but are not limited to, the following:

- our existing capital resources may only be sufficient for the next four to twelve months and as a result we may face issues related to a lack of funding;
- we will need significant additional capital to execute our business strategy as currently contemplated and additional capital maybe not be available from Aspire Capital or otherwise;
- we have a history of operating losses and expect to incur losses for the foreseeable future and may never achieve profitability;
- the MASCT System and other risk assessment tools, diagnostic tests and tools and other predictive and personalized medicine products that we may develop may never achieve significant commercial market acceptance;
- we are dependent on the commercial success of the MASCT System and the ForeCYTE and ArgusCYTE Tests;
- we may not be successful in commercializing the MASCT System because physicians and clinicians may be slow to adopt our product and, even if commercialized, the fees we receive for our products and services may be significantly lower than currently expected;
- additional shares becoming available for sale on the market, for example because of expiration of the lock-up agreement with our stockholders entered into in connection with our initial public offering or because of the sale and subsequent resale of shares we may sell to Aspire Capital or other sources of capital, could adversely affect our stock price and could dilute our existing stockholders;
- our ability to commercialize the MASCT System may be limited because Medicare and certain insurance carriers are not expected to provide reimbursement for the NAF sample collections which are necessary for our tests (even though Medicare and certain insurance carriers do provide reimbursement for the laboratory analysis of the collected NAF samples through our ForeCYTE and ArgusCYTE tests); and
- we may not be able to hire, train or maintain the independent sales representatives and build the distributorship arrangements necessary to market and sell the MASCT System and our services as planned.

Implications of being an Emerging Growth Company

As a company with less than $1 billion in revenue during our last fiscal year, we qualify as an “emerging growth company” as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. As an emerging growth company, we may take advantage of specified reduced disclosure and other requirements that are otherwise applicable generally to public companies. These provisions include:

- Only two years of audited financial statements in addition to any required unaudited interim financial statements with correspondingly reduced “Management's Discussion and Analysis of Financial Condition and Results of Operations” disclosure.
- Reduced disclosure about our executive compensation arrangements.
- Not having to obtain non-binding advisory votes on executive compensation or golden parachute arrangements.

·Exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting.

We may take advantage of these exemptions for up to five years or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company if we have more than $1 billion in annual revenue, we have more than $700 million in market value of our stock held by non-affiliates, or we issue more than $1 billion of non-convertible debt over a three-year period. We may choose to take advantage of some but not all of these reduced burdens. We have taken advantage of these reduced reporting burdens in this prospectus, and the information that we provide may be different than what you might get from other public companies in which you hold stock.

Corporate Information

We were incorporated in Delaware in April 2009. Our principal executive offices are located at 4105 East Madison Street, Suite 320, Seattle, Washington 98112, and our telephone number is (206) 325-6086. Our corporate website is located at *www.atossagenetics.com* and our laboratory website is located at *www.nrlbh.com*. Information contained on, or that can be accessed through, our websites is not a part of this prospectus.

MASCT is our registered trademark and Oxy-MASCT and our name and logo are our trademarks. ForeCYTE, 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 2,833,519 shares of Common Stock, including 333,333 shares currently outstanding.
Common stock outstanding as of March 31, 2013:	14,508,019 shares, including 333,333 shares issued to Aspire Capital on March 27, 2013.
Use of proceeds:	Aspire Capital 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 Aspire Capital. However, we may receive up to $30 million in gross proceeds from the sale of our Common Stock to Aspire Capital (including $1 million of shares sold to Aspire Capital on March 27, 2013) under the Purchase Agreement described below, which we currently intend to use 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 10.
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 Purchase Agreement with Aspire Capital Fund, LLC

On March 27, 2013, we entered into a purchase agreement, or the "Purchase Agreement," with Aspire Capital Fund, LLC, or Aspire Capital, 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 $30 million of shares of our Common Stock over the three-year term of the agreement. In consideration for entering into the Purchase Agreement, concurrently with the execution of the Purchase Agreement, we issued to Aspire Capital 250,000 shares of our Common Stock, or the "Commitment Shares," as a commitment fee. Upon execution of the Purchase Agreement, Aspire Capital purchased 83,333 shares on March 27, 2013 for $1 million, or the "Initial Purchase Shares." Before we can sell any additional shares under the Purchase Agreement, we must have the registration statement, of which this prospectus forms a part, declared effective by the SEC. Other terms and conditions of the Purchase Agreement are described below.

Concurrently with entering into the Purchase Agreement, we also entered into a registration rights agreement with Aspire Capital, or the "Registration Rights Agreement." The Registration Rights Agreement provides that we will file one or more registration statements, as necessary, to register under the Securities Act, the sale of the shares that have been and may be issued to Aspire Capital under the Purchase Agreement. We agreed to file an initial registration statement registering the sale of the shares by Aspire Capital with the Securities and Exchange Commission, or SEC,

within 10 business days of entering into the Purchase Agreement with Aspire Capital. We further agreed to keep the registration statement effective and to indemnify Aspire Capital for liabilities in connection with the sale of the shares under the terms of the Registration Rights Agreement.

As of March 31, 2013, there were 14,508,019 shares of our Common Stock outstanding, including the Initial Purchase Shares and the Commitment Shares, but excluding the 2,500,186 shares offered that may be sold to Aspire Capital pursuant to the Purchase Agreement. If all of the 2,833,519 shares of our Common Stock offered hereby were issued and outstanding as of the date hereof, such shares would represent approximately 16.7% of the total Common Stock outstanding or approximately 23.6% of the non-affiliate shares of Common Stock outstanding as of March 31, 2013. 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 are registering under the Securities Act 2,833,519 shares of our Common Stock, which includes the Commitment Shares and the Initial Purchase Shares that have already been issued to Aspire Capital, as well as an additional 2,500,186 shares of Common Stock that we may issue to Aspire Capital after the registration statement of which this prospectus is a part is declared effective under the Securities Act. All 2,833,519 shares of Common Stock are being offered pursuant to this prospectus.

As described in more detail below, generally under the Purchase Agreement we have two ways we can elect to sell shares of Common Stock to Aspire Capital on any business day we select: (1) through a regular purchase of up to 100,000 shares (but not to exceed $400,000) at a known price based on the market price of our Common Stock prior to the time of each sale, and (2) through a volume-weighted average price, or VWAP, purchase of a number of shares up to 30% of the volume traded on the purchase date at a price equal to the lesser of the closing sale price or 95% of the VWAP for such purchase date.

After the SEC declares effective the registration statement of which this prospectus is a part, on any business day on which the closing sale price of our Common Stock equals or exceeds $2.00 per share, over the three-year term of the Purchase Agreement, we have the right, in our sole discretion, to present Aspire Capital with a purchase notice directing Aspire Capital to purchase up to 100,000 shares of our Common Stock per business day; however, no sale pursuant to such purchase notice may exceed $400,000 per business day. The purchase price per share is the lower of (i) the lowest sale price for our Common Stock on the purchase date or (ii) the arithmetic average of the three lowest closing sale prices for our Common Stock during the 12 consecutive business days ending on the business day immediately preceding the purchase date. The applicable purchase price will be determined prior to delivery of any purchase notice.

In addition, on any date on which we have submitted a purchase notice to Aspire Capital in the amount of 100,000 shares, we also have the right, in our sole discretion, to present Aspire Capital with a volume-weighted average price purchase notice, or a "VWAP Purchase Notice," directing Aspire Capital to purchase an amount of our Common Stock equal to a percentage (not to exceed 30%) of the aggregate shares of Common Stock traded on the next business day subject to a maximum number of shares determined by us. The purchase price per share pursuant to such VWAP Purchase Notice shall be generally the lower of (i) the closing sale price on the purchase date and (ii) 95% of the VWAP of our Common Stock traded on the NASDAQ Capital Market on the purchase day.

The number of shares covered by, and the timing of, each purchase notice are determined by us, at our sole discretion. We may deliver multiple 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. There are no trading volume requirements or other restrictions under the Purchase Agreement. Aspire Capital has no right to require any sales from us, but is obligated to make purchases as directed in accordance with the Purchase Agreement.

The Purchase Agreement contains customary representations, warranties, covenants, closing conditions and indemnification and termination provisions. The Purchase Agreement may be terminated by us at any time, at our discretion, without any cost or penalty. Aspire Capital has covenanted not to cause or engage in any manner whatsoever, any direct or indirect short selling or hedging of our Common Stock. We did not pay any additional amounts to reimburse or otherwise compensate Aspire Capital in connection with the transaction other than the Commitment Shares. There are no limitations on use of proceeds, financial or business covenants, restrictions on future financings, rights of first refusal, participation rights, penalties or liquidated damages in the Purchase Agreement. Dawson James Securities, Inc. acted as our placement agent in connection with the transaction and we agreed to pay Dawson James a cash fee equal to 3% of proceeds from any sales of shares to Aspire Capital and a four-year warrant to purchase a number of shares equal to 3% of the total shares actually sold to Aspire Capital. The warrant may not be exercised on a cashless basis.

Our gross proceeds will depend on the purchase prices and the frequency of sales of shares to Aspire Capital; *provided, however,* that the maximum aggregate proceeds from sales of shares, including the Initial Purchase Shares, is $30 million. Our delivery of purchase notices will be made subject to market conditions, in light of our anticipated capital needs from time to time and under the limitations contained in the Purchase Agreement. We expect

to use proceeds from sales of shares for general corporate purposes and working capital requirements.

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.

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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 under “Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2012. 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.

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 an aggregate of $30 million in proceeds from the sale of our Common Stock to the Selling Stockholder under the Purchase Agreement (including the $1 million we already received upon the Selling Stockholder’s purchase of 83,333 shares of our Common Stock on March 27, 2013). We will bear all reasonable expenses incident to the registration of the shares under federal and state securities laws other than expenses incident to the delivery of the shares to be sold by the Selling Stockholder. Any transfer taxes payable on these shares and any commissions and discounts payable to underwriters, agents, brokers or dealers will be paid by the Selling Stockholder.

Assuming the sale by us of all $30 million of shares of our Common Stock to the Selling Stockholder and estimated expenses of $1 million, the total net proceeds to us under the Purchase Agreement would be $29 million, which we currently intend to use for general corporate purposes, including capital expenditures, the advancement of NextCYTE, FullCYTE and our intraductal treatment program and to meet working capital needs. The amounts and timing of the expenditures will depend on numerous factors, such as the timing and progress the national launch of ForeCYTE and research and development efforts. We expect from time to time to evaluate the acquisition of businesses, products and technologies for which a portion of the net proceeds may be used, although we currently are not planning or negotiating any such transactions. As of the date of this prospectus, we cannot specify with certainty all of the particular uses for the net proceeds to us from the sale of shares to the Selling Stockholder. Accordingly, we will retain broad discretion over the use of these proceeds, if any.

DIVIDEND POLICY

We have has 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

We have included in this prospectus 333,333 shares of Common Stock issued to the Selling Stockholder, Aspire Capital Fund, LLC, on March 27, 2013 and up to an additional 2,500,186 shares of Common Stock that may be issued in the future to Aspire Capital pursuant to the Purchase Agreement. Prior to entering into the Purchase Agreement, Aspire Capital did not own any shares of our Common Stock.

The following table sets forth certain information regarding the Selling Stockholder and the shares of Common Stock beneficially owned by it, which information is available to us as of March 31, 2013. The Selling Stockholder may offer shares under this prospectus from time to time and may elect to sell none, some or all of the shares set forth below. As a result, we cannot estimate the number of shares of Common Stock that the Selling Stockholder will beneficially own after termination of sales under this prospectus. However, for the purposes of the table below, we have assumed that the Selling Stockholder will sell all shares covered by this prospectus.