ATOSSA GENETICS INC
Form POS AM
April 15, 2014

As filed with the Securities and Exchange Commission on April 15, 2014

Registration Statement No. 333-186248

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Post-Effective Amendment No. 1 to

FORM S-1

ON FORM S-3

Registration Statement

Under

The Securities Act of 1933

ATOSSA GENETICS INC.

(Exact name of registrant as specified in its charter)

Delaware	**26-4753208**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

1616 Eastlake Ave. East, Suite 510

Seattle, Washington 98102

Telephone: (800) 351-3902

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

Steven C. Quay

Chairman, Chief Executive Officer and President

1616 Eastlake Ave. East, Suite 510

Seattle, Washington 98102

Telephone: (800) 351-3902

(Name, address, including zip code, and telephone

number, including area code, of agent for service)

Copy to:

Ryan A. Murr

Lisa M. Kahle

Ropes & Gray LLP

Three Embarcadero Center, 3rd Floor

San Francisco, California 94111

Telephone: (415) 315-6300

Kyle Guse

Chief Financial Officer and General Counsel

1616 Eastlake Ave. East, Suite 510

Seattle, Washington 98102

(800) 351-3902

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

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

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

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

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

If this Form is a registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box. ¨

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box: ¨

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

Large accelerated filer	¨	Accelerated filer	¨
Non-accelerated filer	¨ (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.

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.

EXPLANATORY NOTE

On January 28, 2013, Atossa Genetics Inc. (the "***Company***") filed a registration statement with the Securities and Exchange Commission (the "***Commission***") on Form S-1 (Registration No. 333-186248), which was amended on each of February 6, 2013 and April 17, 2013 (as so amended, the "***Registration Statement***" or the "***Form S-1***"). The Registration Statement was declared effective by the Commission on April 23, 2013 to register for resale by the selling stockholders identified in the prospectus an aggregate of 6,474,300 shares of our Common Stock, $0.001 par value per share (the "***Common Stock***"). This Post-Effective Amendment No. 1 to Form S-1 on Form S-3 (the "***Post Effective Amendment No. 1***") is being filed by the registrant to convert the Form S-1 into a registration statement on Form S-3, and contains an updated prospectus relating to the offering and sale of the shares that were registered for resale on the Form S-1.

All filing fees payable in connection with the registration of the shares of the Common Stock covered by the Registration Statement were paid by the registrant at the time of the initial filing of the Form S-1.

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 15, 2014

ATOSSA GENETICS INC.

6,474,300 shares of Common Stock

This prospectus covers the sale of an aggregate of 6,474,300 shares (the "***Shares***") of our Common Stock, $0.001 par value per share (the "***Common Stock***"), 5,611,800 of which are issuable upon the exercise of warrants (the "***Warrants***") at exercise prices ranging from $1.25 to $5.00, by the selling stockholders identified in this prospectus (collectively with any holder's transferee, pledgee, donee or successor, the "***Selling Stockholders***").

The Company will not receive any proceeds from the sale by the Selling Stockholders of the Shares. However, the Company may indirectly receive proceeds to the extent that any Selling Stockholders exercise Warrants for cash and then resell those shares of Common Stock under this prospectus. We are paying the cost of registering the Shares covered by this prospectus as well as various related expenses. The Selling Stockholders are responsible for all selling commissions, transfer taxes and other costs related to the offer and sale of their Shares. If required, the number of Shares to be sold, the public offering price of those Shares, the names of any broker-dealers and any applicable commission or discount will be included in a supplement to this prospectus, called a prospectus supplement.

The Company's Common Stock is traded on the NASDAQ Capital Market under the symbol "ATOS". On April 11, 2014, the closing sale price of our Common Stock on the NASDAQ Capital Market was $1.52 per share. Our principal executive offices are located at 1616 Eastlake Ave. East, Suite 510, Seattle, Washington 98102 and our telephone number is (800) 351-3902.

Investing in our securities involves risks. You should carefully consider the risk factors beginning on page 9 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 , 2014

TABLE OF CONTENTS

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 17 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:

- whether we will obtain in a timely manner clearance from the Food and Drug Administration ("***FDA***") to sell, market and distribute our MASCT System, which we also refer to as the ForeCYTE Breast Aspirator;

- our ability to successfully re-launch our ForeCYTE Breast Aspirator and NAF cytology test;

- the estimated costs associated with our product recall;

- 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 timeframes currently expected;

.

our ability to maintain our business relationships, including with our distributors, suppliers and customers, while we are undergoing the recall we commenced in October 2013 and while we seek additional regulatory clearance to market, sell and distribute our ForeCYTE Breast Aspirator and NAF cytology test;

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

- our ability to satisfy ongoing FDA requirements for the ForeCYTE Breast Aspirator, NAF cytology test and Microcatheter System and to obtain regulatory approvals and/or clearances for our other products and services in development, including our ability to timely and adequately respond to and ultimately close out the warning letter we received from the FDA on February 21, 2013 and the inspectional observations and discussion points we received on March 14, 2014 and any issues resulting therefrom;

- our ability to defend 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;

- the benefits and clinical accuracy of the NAF cytology test and ArgusCYTE test 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, FedMed and HealthSmart 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 our current and future distributors and their sub-distributors, to market our products and services that we may develop, both regionally and nationally;

1

- 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 the Purchase Agreement.

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

PROSPECTUS SUMMARY

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, The National Reference Laboratory for Breast Health, Inc. (the "NRLBH"), whether conducted through Atossa Genetics or the NRLBH, although such references as they relate to our laboratory tests and services generally refer to the NRLBH, 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.

Overview

We are a healthcare company focused on improving breast health through the development of a suite of laboratory developed tests, or LDTs, medical devices and therapeutics. Our laboratory tests are being developed by our subsidiary, The National Reference Laboratory for Breast Health, Inc., or the NRLBH, and are intended to address each of the four stages of the breast health care path: the cytological analysis of nipple aspirate fluid, or NAF; the cytological analysis of ductal lavage fluid collected from each individual breast duct with our proprietary microcatheters; the profiling of newly diagnosed breast cancers through the determination of gene expression profiles in breast cancer biopsy tissue; and the monitoring of breast cancer survivors for pre-clinical recurrence through a blood test for circulating tumor cells.

Our medical devices under development include the ForeCYTE Breast Aspirator (510(k) pending, not for sale in the United States) intended for the collection of NAF for cytological testing at a laboratory, intra ductal microcatheters for the collection of ductal lavage fluid and for the potential administration of a targeted therapeutic, and various tools for potential use by breast surgeons. Our ForeCYTE Breast Aspirator (previously called the MASCT System) was launched nationally in early 2013 and was recalled in October 2013. It will not be re-launched in the United States unless and until we receive additional clearance from the FDA. We submitted a new 510(k) for the ForeCYTE Breast Aspirator on December 23, 2013; we received questions from the FDA regarding this submission on February 28, 2014 and are in the process of addressing such questions as of the date of this prospectus.

We plan to develop certain of our medical devices and laboratory tests so that they can be used as companions to pharmaceutical therapies. For example, we plan to develop our patented intra ductal microcatheters for the potential delivery of a pharmaceutical targeted to a condition called ductal carcinoma in-situ, or DCIS. We also plan to develop our medical devices and laboratory tests as companion diagnostics to pharmaceutical therapies to treat women at high risk of breast cancer and for the treatment of proliferative epithelial disease, or PED. These programs are in the early pre-clinical stage and will require testing and approval and/or clearance from the FDA prior to commercialization.

Our strategy consists of the following:

(1) Re-launch ForeCYTE : We hope to obtain FDA clearance for the ForeCYTE Breast Aspirator, our lead medical device, and if FDA clearance is obtained, to re-launch it in the United States through a direct sales force and our distributors, including Fisher Healthcare and PSS McKesson. We also intend to introduce the ForeCYTE Breast Aspirator into one or more foreign markets.

(2) Introduce our other Laboratory Tests and other Medical Devices along the Care Path : We plan to make each of the NRLBH's individual laboratory tests and our medical devices available to healthcare providers by completing any necessary development and obtaining any necessary regulatory clearances and/or approvals.

(3) Develop Pharmaceutical Therapies to be used as Companions with our Devices and Laboratory Services : We plan to develop our patented microcatheters to deliver pharmaceuticals to initially treat DCIS. We also plan to develop our devices and laboratory services for use as companion diagnostics. For example, we intend to use our devices to collect specimens of NAF, test the NAF specimens in our laboratory, provide pharmaceutical treatment options for the breast health conditions detected by our tests and then use our medical devices to monitor treatment response. We expect that these companion diagnostic systems will initially target PED and/or high risk women and will require lengthy and costly clinical trials that we will undertake only with input and direction from the FDA.

(4) Advance Partnering Opportunities : We plan to work with third parties and partners to develop our business. For example, we plan to work with Fisher Healthcare and PSS McKesson to distribute the ForeCYTE Breast Aspirator and we may partner with one or more laboratories to act as NAF collection sites using our ForeCYTE Breast Aspirator if and when we receive FDA clearance for the device. We plan to retain clinical research organizations, or CROs, for clinical development of potential therapeutic programs and we intend to partner with pharmaceutical companies to develop companion diagnostic systems, which may include therapeutics to treat PED, DCIS and/or high risk women.

(5) Promote Physician and Patient Awareness : Our products and services are highly innovative and gaining adoption will require that physicians change the way they practice medicine. To facilitate adoption, we will continue to educate physicians and patients by engaging key opinion leaders, publishing in peer reviewed journals and working with patient advocacy groups.

All of our medical devices and the NRLBH's laboratory tests, as well as the breast health companion diagnostic systems, are currently under development and we must receive additional regulatory clearances and/or approvals prior to marketing and commercialization.

The NRLBH 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 NAF specimens by cytological analysis.

Our Diagnostic Tools

In 2012 we acquired the rights from Acueity to manufacture, use and sell a number of diagnostic tools, including: the Viaduct Miniscope and accessories, the Manoa Breast Biopsy system, the Excisor Bioptome, the Acueity Medical Light Source, the Viaduct Microendoscope and accessories. We also acquired 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. Based on a recent periodic review of the Acueity patent estate, these tools are covered by 15 issued patents (13 U.S. patents, one U.K. patent and one German patent). 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 United States, 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 2015. 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 ForeCYTE Breast Aspirator 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 ForeCYTE Breast Aspirator 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.

Therapeutic Programs Under Development

We plan to develop certain of our medical devices and laboratory tests so that they can be used as companions to pharmaceutical therapies. For example, we plan to develop our medical devices and laboratory tests as companion diagnostics to pharmaceutical therapies to treat women at high risk of breast cancer and for the treatment of conditions known as proliferative epithelial disease (PED). These programs are in the early pre-clinical stage and will require testing and approval and/or clearance from the FDA prior to commercialization.

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, or 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 2014. 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. We must perform a significant amount of additional work prior to commercializing an intraductal therapy using our microcatheters, including, for example, developing or otherwise procuring a pharmaceutical candidate alone or with partners, performing pre-clinical studies, developing a clinical trial protocol, successfully completing clinical trials and obtaining FDA approval. We may not be successful in completing any of these tasks or other steps necessary to successfully develop and launch an intraductal treatment program.

Current Operations

Our leading device, the MASCT System (which we also currently refer to as the ForeCYTE Breast Aspirator), and our NAF cytology test, were launched in a "field experience" trial in 2012 and nationally in the beginning of 2013. In October 2013, we voluntarily recalled the MASCT System to address concerns raised by the FDA in a Warning Letter we received in February 2013. In December 2013, we submitted a pre-market notification to the FDA for 510(k) clearance of the ForeCYTE Breast Aspirator, and on February 28, 2014 we received questions from the FDA regarding this submission which we are in the process of addressing as of the date of this prospectus. As a result of this recall, we are not currently marketing this product in the U.S. If we obtain clearance from the FDA, we intend to re-launch the ForeCYTE Breast Aspirator and our NAF cytology test. However, the regulatory pathway to obtaining a 510(k) clearance can be lengthy, expensive and unpredictable; we therefore cannot provide any assurances that we will receive a new 510(k) clearance for ForeCYTE Breast Aspirator or any of our other tests under development in a timely fashion or at all.

Our Voluntary Product Recall

On October 4, 2013 we initiated a voluntary recall to remove the MASCT device (which was also called the "ForeCYTE Test" prior to the recall) from the market. This voluntary recall includes the MASCT System Kit and Patient Sample Kit. The vast majority of these products (approximately ninety percent) were in inventory with our distributors and the remaining quantities were at customer sites across the United States. As of the date of this prospectus, the recall has been substantially completed.

The purpose of this voluntary recall is to address concerns raised by the FDA in a Warning Letter received by Atossa in February 2013. In that Warning Letter, the FDA raised concerns about (1) the current instructions for use, or IFU; (2) certain promotional claims used to market these devices; and (3) the need for FDA clearance for certain changes made to the NAF specimen collection process identified in the current IFU.

The MASCT device was originally cleared by the FDA for use as a sample collection device, with the provision that the fluid collected using this device can be used to determine and/or differentiate between normal, pre-malignant, and malignant cells. The MASCT device has not been cleared by the FDA for the screening or diagnosis of breast cancer. In addition, our NAF cytology test has not been cleared or approved by the FDA for any indication as the company considered this to be a Laboratory Developed Test – or within a class of tests that has historically not required a 510(k) application. Our NAF cytology test and the MASCT device are not intended to serve as a replacement for screening mammograms, diagnostic imaging tests, or biopsies. Patients are instructed to follow the recommendations and instructions of their physician with respect to breast cancer screening and diagnosis.

To date, we are unaware of any adverse incidents or injuries associated with the use of our NAF cytology test and the MASCT device or the processing method identified in the latest version of the IFU. However, there is a risk that these devices may produce false positive or false negative results. Although not cleared or intended for this use, if these devices are used as a substitute for recommended screening or diagnosis of breast cancer, the FDA is concerned that patients may choose to forgo recommended mammograms and necessary biopsies.

We submitted a new 510(k) application to the FDA on December 23, 2013 for the ForeCYTE Breast Aspirator which is intended for use in the collection of nipple aspirate fluid for cytological testing. On February 28, 2014 we received a request from the FDA to submit additional information in support of the application. We have until August 20, 2014 to respond to the FDA. We cannot market or distribute the ForeCYTE Breast Aspirator within the United States until we receive clearance for this device from the FDA.

As of December 31, 2013, we have incurred actual recall expenses of $223,750 and have recorded $211,493 as a loss contingency related to the estimated remaining costs of the recall, including the estimated costs of pursuing the additional 510(k) clearance. The recall and 510(k) process may take longer than expected; for example the FDA may require additional actions that we have not anticipated. As a result, we may incur costs that we have not anticipated. Accordingly, the actual amount of the loss contingency for the recall may be higher than we currently expect. Prior to the commencement of the recall in October 2013, substantially all of our revenue was from sales of the MASCT System and patient collection kits and from testing services performed by our laboratory. As a result of the recall of the MASCT System and patient collection kits, we have ceased generating product revenue. Our laboratory services revenue has also virtually ceased as of October 2013.

If and when we re-launch our ForeCYTE Breast Aspirator, we will incur additional sales and marketing expenses. We will need to revise our sales and marketing tools and continue hiring direct sales employees in an effort to build a regional, and ultimately national, sales force. We also expect to continue to hire clinical consultants to assist in the sale of our NAF cytology tests. The indication for use that we are seeking from the FDA for the ForeCYTE Breast Aspirator may be more limited than the indication sought in our 510(k) pre-market notification and may be more limited that the indication for the MASCT System that we previously marketed. If so, our potential sales will be negatively impacted.

Follow-up FDA Inspection

On March 14, 2014 the FDA completed a follow up inspection at our Seattle facility. A Form 483 was provided to us at the conclusion of the inspection. In the FDA’s most recent Form 483, five inspectional observations were identified

regarding our quality management system. The FDA inspector also verbally identified five additional discussion points related to our product labeling prior to the recall of the MASCT System; sufficiency of the content of our pending 510(k) submission for the ForeCYTE Breast Aspirator; and other compliance issues. On March 26, 2014, we submitted a response to the FDA, which included our proposed corrective actions to address the FDA's observations and discussion points. Whether the FDA will accept our response is uncertain, particularly in light of the similar nature of certain of the current inspectional observations to previous inspectional observations. If the FDA does not agree with our proposed corrective actions, or accepts them but finds that we have not implemented them adequately, or if we otherwise are found to be out of compliance with applicable regulatory requirements at a later date, the FDA could initiate an enforcement action including additional warning letters, fines and penalties. The FDA also may not clear our pending 510(k) for the ForeCYTE Breast Aspirator or our other devices and services under development. Any of the foregoing would have a material adverse effect on our business.

Recent Developments

On October 10, 2013, a putative securities class action complaint, captioned Cook v. Atossa Genetics, Inc., et al., No. 2:13-cv-01836-RSM, was filed in the United States District Court for the Western District of Washington against us, certain of our directors and officers and the underwriters of our November 2012 initial public offering. The complaint alleges that all defendants violated Sections 11 and 12(a)(2), and that we and certain of our directors and officers violated Section 15, of the Securities Act by making material false and misleading statements and omissions in the offering's registration statement, and that we and certain of our directors and officers violated Sections 10(b) and 20A of the Exchange Act and SEC Rule 10b-5 promulgated thereunder by making false and misleading statements and omissions in the registration statement and in certain of our subsequent press releases and SEC filings with respect to our NAF specimen collection process, our ForeCYTE Breast Health Test and our MASCT device. This action seeks, on behalf of persons who purchased our common stock between November 8, 2012 and October 4, 2013, inclusive, damages of an unspecified amount.

On February 14, 2014, the Court appointed plaintiffs Miko Levi, Bandar Almosa and Gregory Harrison (collectively, the "Levi Group") as lead plaintiffs, and approved their selection of co-lead counsel and liaison counsel. The Court also amended the caption of the case to read In re Atossa Genetics, Inc. Securities Litigation, No. 2:13-cv-01836-RSM. The Court ordered lead plaintiffs to file an amended class action complaint by April 15, 2014.

We believe this lawsuit is without merit and plan to defend ourselves vigorously; however, any failure by us to obtain a favorable resolution of the claims set forth in the complaint could have a material adverse effect on our business, results of operations and financial condition. Currently, the amount of such material adverse effect cannot be reasonably estimated, and no provision or liability has been recorded for these claims as of December 31, 2013. The costs associated with defending and resolving the lawsuit and ultimate outcome cannot be predicted. These matters are subject to inherent uncertainties and the actual cost, as well as the distraction from the conduct of our business, will depend upon many unknown factors and management's view of these may change in the future.

Risk Factors

Our business is subject to numerous risks as discussed more fully in the section entitled "Risk Factors" beginning on page 9. Principal risks of our business include, but are not limited to, the following:

- our existing capital resources may only be sufficient for the next eight to twelve months and, as a result, we may face issues related to a lack of funding;
- if we are not successful, or are delayed, in obtaining a new 510(k) clearance from the FDA for our ForeCYTE Breast Aspirator, our operations will be significantly and adversely affected;
- the scope of any 510(k) clearance that we might receive from the FDA covering our ForeCYTE Breast Aspirator could be more limited than we expect, potentially limiting our ability to market the test;
- our voluntary recall and market withdrawal of the MASCT device, and any future recalls and/or product withdrawals, will significantly and adversely affect our business, prospects, financial condition and results of operations;
- we will need significant additional capital to execute our business strategy as currently contemplated and additional capital may 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;

- our business may be affected by legal proceedings;

- the products and services that we have developed or may develop may never achieve significant commercial market acceptance;

- additional shares becoming available for sale on the market, for example 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; and

- if our patents do not adequately protect our products, others could compete with us more directly, which would adversely affect our business.

The Offering

This prospectus relates to the resale by the Selling Stockholders identified in this prospectus of up to 6,474,300 shares of Common Stock, 5,611,800 of which are issuable upon the exercise of Warrants. All of the Shares, when sold, will be sold by the Selling Stockholders. The Selling Stockholders may sell their Shares from time to time at market prices prevailing at the time of sale, at prices related to the prevailing market price, or at negotiated prices. We will not receive any proceeds from the sale of Shares by the Selling Stockholders, other than proceeds in the event that some or all of the Warrants held by the Selling Stockholders are exercised for cash.

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; and
- 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 from our initial public offering 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 1616 Eastlake Ave. East, Suite 510, Seattle, Washington 98102 and our telephone number is (800) 351-3902. 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, ForeCYTE Breast Aspirator 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.

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, 2013, 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.

USE OF PROCEEDS

The proceeds from the resale of the Shares under this prospectus are solely for the account of the Selling Stockholders. We may indirectly receive proceeds of up to approximately $10,064,630 to the extent that any Selling Stockholders exercise warrants to purchase shares of Common Stock for cash and then resell those shares under this prospectus; however, we will not directly receive any proceeds from the sale of Shares under this prospectus.

SELLING STOCKHOLDERS

The Company has included in this prospectus the following shares of Common Stock:

- 862,500 shares of Common Stock issued in connection with our acquisition of the assets of Acueity;
- 325,000 shares of Common Stock issuable upon the exercise of warrants issued in connection with our acquisition of the assets of Acueity; and
- 5,286,800 shares of Common Stock issuable upon the exercise of warrants issued in private offerings that occurred between April 2011 and June 2011.

Acquisition of Assets from Acueity

In September 2012, we acquired substantially all of the assets of Acueity. The acquisition was effected through an asset purchase in which we acquired rights 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; no liabilities were assumed in the transaction. Based on a recent periodic review of the Acueity patent estate, these tools are covered by 15 issued patents (13 U.S. patents, one U.K. patent and one German patent).

In consideration for the assets, we issued 862,500 shares of common stock (valued at $5.00 per share) and warrants to purchase up to 325,000 shares of common stock at an exercise price of $5.00 per share, subject to a six-month lock up agreement. The warrants, which have a five-year term, do not have a cashless exercise provision. The warrants were valued at $2.3457 per warrant, using a Black-Scholes-Merton valuation technique.

In connection with the acquisition of assets from Acueity, we agreed to register the resale of the shares of Common Stock issued, as well as the shares of Common Stock underlying the warrants issued, in the acquisition.

Private Placements

In April 2011, we sold to certain institutional and accredited investors an aggregate of 1,612,000 units, with each unit consisting of one share of Common Stock at a per unit purchase price of $1.25, and a warrant to purchase an additional share of Common Stock, exercisable at $1.60 per share (the April Private Placement).

In May 2011, we sold to certain institutional and accredited investors an aggregate of 1,376,000 units, with each unit consisting of one share of Common Stock at a per unit purchase price of $1.25, and a warrant to purchase an additional share of Common Stock, exercisable at $1.60 per share (the May Private Placement).

On June 10, 2011, we sold to certain institutional and accredited investors an aggregate of 682,000 units, with each unit consisting of one share of Common Stock at a per unit purchase price of $1.25, and a warrant to purchase an additional share of Common Stock, exercisable at $1.60 per share (the June 10 Private Placement).

On June 23, 2011, we sold to certain accredited investors an aggregate of 1,586,800 units, with each unit consisting of one share of Common Stock at a per unit purchase price of $1.25, and a warrant to purchase an additional share of Common Stock, exercisable at $1.60 per share (the June 23 Private Placement).

On completion of the above private placements we sold to Dawson James Securities, Inc. an aggregate of 1,577,040 units, with each unit consisting of a warrant to purchase an additional Share of Common Stock, half of which are exercisable at $1.25 per share, and half exercisable at $1.60 per share (the Dawson James Placement).

The April Warrants, May Warrants, June 10 Warrants, June 23 Warrants and the Dawson James Warrants (collectively, the Private Placement Warrants), became exercisable on June 23, 2011 and expire on June 23, 2016.

In connection with the April, May, June 10, June 23 and Dawson James Placements, we agreed to register the resale of the Common Stock underlying the Private Placement Warrants.

The following table sets forth certain information regarding the Selling Stockholders and the shares of Common Stock beneficially owned by them prior to the offering. Selling Stockholders may offer Shares under this prospectus from time to time and may elect to sell none, some or all of the Shares set forth next to their name. As a result, we cannot estimate the number of shares of Common Stock that a Selling Stockholder will beneficially own after termination of sales under this prospectus. However, for the purposes of the table below, we have assumed that, after completion of the offering, none of the shares covered by this prospectus will be held by the Selling Stockholders. In addition, a Selling Stockholder may have sold, transferred or otherwise disposed of all or a portion of that holder’s shares of Common Stock since the date on which they provided information for this table. We have not made independent inquiries about this. We are relying on written commitments from the Selling Stockholders to notify us of any changes in their beneficial ownership after the date they originally provided this information. See “Plan of Distribution” beginning on page 14.

Selling Stockholder (1)	# of Shares held before Offering	Total # of Shares covered by this Prospectus	# of Shares Offered	# of Shares Underlying Warrants	# of Shares Beneficially owned after Offering	% of Shares Beneficially owned after Offering(2)
Private Placement Selling Stockholders						
Adam Linn	40,000	20,000	—	20,000	20,000	*
Alan David Cohen	40,000	20,000	—	20,000	20,000	*
Albert Poliak	110,000	110,000	—			