ATOSSA GENETICS INC
Form S-1/A
November 06, 2012

As filed with the Securities and Exchange Commission on November 5, 2012

Registration No. 333-179500

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Amendment No. 12 to
FORM S-1
REGISTRATION STATEMENT
UNDER THE SECURITIES ACT OF 1933

ATOSSA GENETICS INC.

(Exact name of registrant as specified in its charter)

Delaware	3841	26-4753208
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

4105 E. Madison Street, Suite 320
Seattle, Washington 98112
(206) 325-6086

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

Steven C. Quay, M.D., Ph.D.
Chairman, Chief Executive Officer and President
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(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: As soon as practicable after the effective date of this Registration Statement.

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. o

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. o

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 registration statement for the same offering. o

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 number of the earlier effective registration statement for the same offering. o

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 definitions large accelerated filer, accelerated file, and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

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

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

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 or until the registration statement shall become effective on such date as the Commission acting pursuant to said section 8(a), may determine.

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The information contained in this prospectus is not complete and may be changed. A registration statement relating to these securities has been filed with the Securities and Exchange Commission and these securities may not be sold until that registration statement becomes 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 November 5, 2012**

1,300,000 Shares

This is the initial public offering of 1,300,000 shares of our common stock. We expect the initial public offering price will be between $4.00 and $6.00 per share. Currently, no public market exists for our securities. Provided we raise at least $4 million in gross proceeds in this offering, our common stock has been approved for listing on the NASDAQ Capital Market under the symbol ATOS .

	Per Share	Total
Public offering price	$	$
Underwriting discounts and commissions*	$	$
Proceeds, before expenses, to Company	$	$

* Does not include a non-accountable expense reimbursement fee of 3% of the gross proceeds of this offering.

We are an emerging growth company under applicable Securities and Exchange Commission rules and will be subject to reduced public company reporting requirements.
Investing in these securities involves a high degree of risk.
See Risk Factors contained in this prospectus beginning on page 12.

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

We have granted the underwriters an option for a period of 45 days to purchase from us, on the same terms and conditions set forth above, up to an additional 195,000 shares to cover overallotments.

Delivery of the shares of common stock will be made on or about , 2012.

DAWSON JAMES SECURITIES, INC.

The date of this prospectus is , 2012.

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No dealer, salesperson or other person is authorized to give any information or to represent anything not contained in this prospectus. You must not rely on any unauthorized information or representations. This prospectus is an offer to sell only the shares offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus is current only as of its date.

Unless the context requires otherwise, in this prospectus the terms we, us and our as well as the Company refer t Atossa Genetics Inc. and our wholly-owned subsidiary, National Reference Laboratory for Breast Health Inc.

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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 Management s Discussion and Analysis of Financial Condition and Results of Operations and our financial statements and related notes, included elsewhere in this prospectus.

The Company

We are a healthcare company focused on the prevention of breast cancer through the commercialization of diagnostic tests that can detect precursors to breast cancer, and through the research, development, and ultimate commercialization of treatments for pre-cancerous lesions.

Our diagnostic tests consist of patented medical devices cleared by the Food and Drug Administration, or FDA, 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, has been licensed in the states of California, Florida, Maryland, Rhode Island, and Washington, and is in the process of obtaining a license to accept testing samples from New York (which requires out-of-state laboratories to hold a state license). 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.

Additionally, we are conducting research on the treatment of these pre-cancerous cells by using our patented and FDA-cleared microcatheters to deliver, directly into the milk ducts, pharmaceutical formulations that can be used to treat these pre-cancerous lesions. 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, 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 September 14, 2012, have enrolled and sold MASCT System kits or provided ArgusCYTE collection kits to 34 doctors and clinics as providers of the ForeCYTE and/or ArgusCYTE tests. We have received, processed, and reported the results to physicians from 956 ForeCYTE samples and 41 ArgusCYTE samples as of June 30, 2012 and 1,256 ForeCYTE samples and 41 ArgusCYTE samples as of September 14, 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 intend to use the data from this field experience trial to form our national marketing efforts as we scale up our commercial operations going forward. As of December 31, 2011 and June 30, 2012, we have generated $1,500 and $277,810 in revenue, respectively, from the sale of our products and

services. We incurred net operating losses of approximately $2.2 million, $1.1 million and $3.4 million for our six months ended June 30, 2012 and our fiscal years ended December 31, 2010 and 2011, respectively. As of June 30, 2012, we had an accumulated deficit of approximately $6.9 million. 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 from stockholders or other related parties when needed. However, we cannot assure you that we will be successful in accomplishing any of these plans and, if we are unable to obtain adequate capital, we could be forced to cease operations.

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Our Diagnostic Tests

We currently offer two diagnostic tests and plan to offer two additional tests in early 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 65. It involves collecting a specimen of nipple aspirate fluid, or NAF, using our patented, FDA-cleared *Mammary Aspirate Specimen Cytology Test*, or MASCT, System (our MASCT System 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, FDA 510(k)-Exempt 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). 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 Estrogen Receptor/Progesterone Receptor, or ER/PR, and Human Epidermal Growth Factor Receptor, or 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.

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FullCYTE	The FullCYTE Breast Health Test, which we intend to launch in early 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 five to seven individual breast milk ducts using our patented and FDA-cleared 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 early 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. We are currently conducting non-clinical trial research to verify the superiority of the technology regarding NextCYTE by profiling gene expression from breast cancer biopsy specimens obtained from commercial archival tissue banks, in which the five-year survival or death for the patients from whom the specimens are taken is known, and seeing if the algorithm can accurately predict the known outcome. The experiments are being conducted in a blinded fashion, without knowledge of the survival data, and we will not have knowledge of the outcome until the blind is broken (currently planned for February 2013). We own a pending PCT patent application on the NextCYTE technology to the use of full transcriptome analysis of 22,000 human genes in predicting breast cancer recurrence and have an option through February 2013 to license additional technology (specifically certain algorithms involving over 900 of these genes) to augment our existing technology from the University of Oslo in Norway. We do not believe this additional technology is essential to the operation or future development of the NextCYTE test, should we decide not to exercise this option.

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Our Diagnostic Tools	In September 2012, we acquired the assets of Acueity Healthcare, Inc. The assets included six 510(k)-cleared medical devices, 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). The FDA-cleared, patented medical devices consist of microendoscopes, light sources, and biopsy tools. 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, ductal carcinoma in situ, or DCIS, and breast cancers. The method uses our Mammary Ductal Microcatheter System, invented by Dr. Susan Love, President of the Dr. Susan Love Research Foundation, and her colleagues, to administer proprietary pharmaceutical formulations into milk ducts that display pre-cancerous changes, 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

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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). We intend to build on these academic studies with a research program targeted initially at neoadjuvant therapy in DCIS and to begin preclinical studies during 2012. We have not yet begun the process of applying for FDA approval of our Intraductal Treatment Research Program.

Intellectual Property and FDA Marketing Clearances

As of the date of this prospectus, we own 179 issued patents (56 in the United States and 123 in foreign countries), and 50 pending patent applications (38 in the United States, 11 pending foreign applications and 1 pending International Patent Cooperation Treaty (PCT) application) directed to our products, services, and technologies. We have eleven 510(k)-cleared medical devices and two 510(k)-exempt medical devices, six of which were acquired in the Acueity asset purchase. The Acueity asset purchase also provided 35 of the issued patents (18 issued in the U.S. and 17 issued in foreign countries) and 41 of the patent applications (32 in the U.S. and 9 in foreign countries).

Our Founder

Our founder and chief executive officer, Steven C. Quay, M.D., Ph.D., FCAP, invented the MASCT System. Dr. Quay is a board-certified anatomic pathologist who completed both an internship and residency in anatomic pathology at the Massachusetts General Hospital, a Harvard Medical School teaching hospital, and is a former faculty member of the pathology department of Stanford University School of Medicine. He holds 76 U.S. patents and has invented and developed five FDA-approved pharmaceuticals.

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, and mammography clinics; 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. We currently price our NAF sample collection device at approximately $250 per device and our patient kits at approximately $30 per kit, and 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. 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. We have billed the testing and analysis regarding the 956 ForeCYTE samples processed through June 30, 2012 (which is equivalent to 478 patients) at the 2012 Medicare reimbursement rate of $384 per patient. We bill third-party payors at higher rates, as is customary for our industry. 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.

While we are conducting our field experience trial 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 a

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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 June 30, 2012 at $1,500 per patient. We have received reimbursement from insurance carriers for our ArgusCYTE test.

In December 2011, we began limited marketing of the ForeCYTE Test to physicians, primarily obstetric-gynecologists, as well as breast health and mammography clinics, for use in conjunction with other health screening examinations, including annual physical examinations and regularly scheduled cervical Pap smears and mammograms. We are establishing relationships with breast cancer centers to provide the ArgusCYTE Test to their patients. We plan to use regional specialty product distributors, with independent sale representatives specializing in women s health, to commercialize the ForeCYTE and ArgusCYTE Tests; however, we currently do not have distributor relationships and we cannot be certain that we will be able to build these relationships to adequately address the regional or national market. As of March 1, 2012 we had one person involved in sales.

Risk Factors

Our business is subject to numerous risks as discussed more fully in the section entitled Risk Factors beginning on page 12. Principal risks of our business include, but are not limited to, the following:

we will need significant additional capital to execute our business strategy as currently contemplated and have not identified significant alternative sources of funding, should this offering be unsuccessful;
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;
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.

Recent Developments

In December 2011, we began limited marketing of the ForeCYTE Test to physicians, primarily obstetric-gynecologists, as well as breast health and mammography clinics, for use in conjunction with other health screening examinations, including annual physical examinations and regularly scheduled cervical Pap smears and mammograms. We are establishing relationships with breast cancer centers to provide the ArgusCYTE Test to their patients. As of September 30, 2012, we had one person involved in sales.

In September 2012, we entered into a co-exclusive marketing agreement with Diagnostics Test Group LLC (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

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and Cascade HealthCare Products. These distributors have collectively over 5,000 employee sales representatives and/or independent sales representatives selling their products.

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.

We currently plan to launch the ForeCYTE Breast Health Test with DTG under DTG s Clarity brand name by the end of the calendar year 2012. DTG and its distributors, however, may not be successful in selling the Clarity branded MASCT product line and we may not achieve any level of commercial success from their efforts.

In September 2012, we entered into an agreement with MultiPlan, Inc. (MultiPlan), 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. Our agreement with MultiPlan will give MultiPlan s participating providers and their patients access to our tests, including the ForeCYTE and ArgusCYTE Breast Health Tests. We anticipate that the agreement with MultiPlan 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 agreement with MultiPlan provides that reimbursement will be provided at a prescribed rate when insurers agree to reimburse for the ForeCYTE and ArgusCYTE Breast Health Tests. The prescribed rate of reimbursement is within the range of reimbursement that we have historically received. Our agreement with MultiPlan does 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.

In September 2012, in order to demonstrate that we will satisfy the minimum stockholders equity requirement of the listing standards of the NASDAQ Capital Market upon completion of this offering, we reported unaudited balance sheet data as of August 31, 2012, as set forth in our free writing prospectus filed with the Securities and Exchange Commission on September 13, 2012.

On September 30, 2012, we acquired substantially all of the assets of Acueity Healthcare, Inc. (Acueity). The acquisition was effected through an asset purchase in which we acquired 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), and 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; no liabilities were assumed in the transaction. In consideration for the assets, we issued 862,500 shares of common stock (valued at $5.00 per share, the midpoint of the range listed on the cover page of this prospectus) 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 because it embodies all of the requisite assumptions (including trading volatility, estimated terms and risk-free rates) necessary to determine the fair value of the warrants. There are no future financial obligations from us to Acueity from the commercialization of the acquired assets.

The acquired patents and patent applications relate to intraductal diagnostic and therapeutic devices and methods of use. 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

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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.

We did not, however, acquire an inventory of these diagnostic tools, manufacturing capabilities or any personnel to market and sell the tools. We intend to complete the steps necessary to commercialize the tools, such as securing manufacturers, in late 2013. Acueity never achieved commercial success with these products and we have no experience marketing and selling diagnostic tools; we therefore may not be successful commercializing them.

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.

Company 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.

Our company name comes from Queen Atossa, daughter of Cyrus the Great and wife of Darius I, the King of the Achaemenid Empire. In about 470 BC, she became the first woman in recorded history to be diagnosed with breast cancer, of which she died.

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THE OFFERING

Securities offered by us:

1,300,000 shares of common stock (or 1,495,000 if the underwriters exercise their overallotment option in full).

Capitalization after the offering:

13,419,367 shares of common stock outstanding after the offering (or 13,614,367 if the underwriters exercise their over allotment option in full).

Use of proceeds:

We intend to use the net proceeds from this offering to expand our cytology and molecular diagnostics laboratory, fund the manufacture of MASCT System units, hire and train sales and marketing personnel, continue the research and development of the FullCYTE and NextCYTE Tests, support the internal research and development of the Intraductal Treatment Research Program and our diagnostic tools, and for general corporate purposes. See Use of Proceeds.

Proposed NASDAQ trading symbol:

ATOS

The number of shares of our common stock outstanding is based on 12,119,367 shares of common stock outstanding as of the date of this prospectus, and excludes 627,757 shares issuable upon the exercise of options outstanding as of the date of this prospectus under our 2010 Stock Option and Incentive Plan, or 2010 Plan, as well as 822,517 shares of common stock reserved for future issuance under our 2010 Plan, in addition to 6,833,840 shares of common stock underlying outstanding warrants with a weighted-average exercise price of $1.56 per share and 325,000 shares of common stock issuable upon the exercise of warrants issued in connection with our acquisition of substantially all the assets of Acueity Healthcare, Inc.

Unless otherwise indicated, all information in this prospectus assumes that the underwriters do not exercise their right to purchase up to 195,000 additional shares to cover overallotments, if any.

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SUMMARY FINANCIAL DATA

The following summary financial data should be read together with our financial statements and the related notes and Management s Discussion and Analysis of Financial Condition and Results of Operations appearing elsewhere in this prospectus. The summary financial data in this section is not intended to replace our financial statements and the related notes. Our historical results are not necessarily indicative of the results to be expected for any future period.

We were incorporated on April 30, 2009. The following statement of operations data, including share data, for the fiscal years ended December 31, 2010 and 2011 have been derived from our audited financial statements and related notes included elsewhere in this prospectus. The statement of operations data, including share data, for the six months ended June 30, 2011 and 2012, and the balance sheet data as of June 30, 2012, have been derived from our unaudited financial statements included elsewhere in this prospectus. The unaudited interim financial statements have been prepared on the same basis as the audited financial statements and reflect all adjustments necessary to fairly state our financial position as of June 30, 2012 and results of operations for the six months ended June 30, 2011 and 2012. The operating results for any period are not necessarily indicative of financial results that may be expected for any future period.

	For The Years Ended December 31,		For The Six Months Ended June 30,		From April 30, 2009 (Inception) Through June 30, 2012
	2011	2010	2012	2011	
			(Unaudited)	(Unaudited)	(Unaudited)
Revenue					
Diagnostic Testing Service	$	$	$272,685	$	$272,685
Product Sales	1,500		5,125		6,625
Total Revenue	1,500		277,810		279,310
Cost of Revenue					
Diagnostic Testing Service			(20,985)		(20,985)
Product Sales	(5,164)				(5,164)
Total Cost of Revenue	(5,164)		(20,985)		(26,149)
Loss on Reduction of Inventory to LCM	(92,026)		(23,807)		(115,833)
Gross Profit (Loss)	(95,690)		233,018		137,328
Selling expenses	(160,851)	(12,204)	(194,267)		(367,322)
General and Administrative expenses	(3,172,649)	(1,065,792)	(2,266,731)	(1,007,717)	(6,628,030)
Total Operating Expenses	(3,333,500)	(1,077,996)	(2,460,998)	(1,007,717)	(6,995,352)
Operating Loss	(3,429,190)	(1,077,996)	(2,227,980)	(1,007,717)	(6,858,022)
Interest Income	4,914	455	1,173	1,161	6,542
Interest Expense	(17,992)	(9,139)	(4,060)	(7,630)	(31,191)
Net Loss before Income Taxes	(3,442,269)	(1,086,680)	(2,230,867)	(1,014,186)	(6,882,671)
Income Taxes		250			250
Net Loss	$(3,442,269)	$(1,086,930)	$(2,230,867)	$(1,014,186)	$(6,882,921)
Loss per common share basic	$(0.38)	$(0.18)	$(0.20)	$(0.15)	$(0.93)
Loss per common share diluted	$(0.38)	$(0.18)	$(0.20)	$(0.15)	$(0.93)

Weighted average shares outstanding, basic	9,117,746	5,935,897	11,256,867	6,931,057	7,371,184
Weighted average shares outstanding, diluted	9,117,746	6,004,721	11,256,867	6,931,057	7,371,184

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	As of June 30, 2012	
	Actual (Unaudited)	As-adjusted
Balance Sheet Data:		
Total assets	$842,912	$6,192,912
Total liabilities	$1,398,396	$1,398,396
Stockholders equity:		
Common Stock, $0.001 par value, 75,000,000 shares authorized, 11,256,867 shares outstanding, actual, as of June 30, 2012, and 12,556,867 shares outstanding, as-adjusted, as of June 30, 2012	11,257	12,557
Additional paid-in capital	6,316,182	11,664,882
Accumulated deficit	(6,882,922)	(6,882,922)
Total stockholders equity (deficit)	(555,484)	4,794,516
Total liabilities & stockholders equity	$842,912	$6,192,912

The June 30, 2012 as-adjusted balance sheet data reflects the sale of 1,300,000 shares in this offering at an assumed initial public offering price of $5.00 per share, which is the mid-point of the price range listed on the cover page of this prospectus, after deducting underwriting discounts and commissions of 7%, non-accountable expense reimbursement fee of 3% and estimated offering expenses of approximately $500,000 payable by us.

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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 following information about these risks, together with the other information contained in this prospectus, before purchasing our securities. If any of the following 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.

Risks Relating to our Business

We have only a limited operating history, and, as such, an investor cannot assess our profitability or performance based on past results.

We are a development stage company, with operations beginning 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 and our operations to date have consisted primarily of securing manufacturing for the MASCT and the 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, and beginning the commercialization of our products. We will require significant additional capital to achieve our business objectives, and the inability to obtain such financing on acceptable terms or at all could lead to closure of the business.

Our revenue and income potential is uncertain. Any evaluation of our business and prospects must be considered in light of these factors and the risks and uncertainties often encountered by companies in the development stage. Some of these risks and uncertainties include our ability to:

execute our business plan and commercialization strategy, including with respect to the assets we recently acquired from Acueity Healthcare, Inc.;
work with contract manufacturers to produce the MASCT and Microcatheter Systems in commercial quantities;
create brand recognition;
respond effectively to competition;
manage growth in operations;
respond to changes in applicable government regulations and legislation;
access additional capital when required;
sell our products and service at the prices currently expected; and
attract and retain key personnel.

Our independent auditors have issued a report questioning our ability to continue as a going concern.

The report of our independent auditors contained in our financial statements explains that we have not yet established an ongoing source of revenue sufficient to cover 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. If we are unable to obtain adequate capital, we may be unable to expand our product offerings or

geographic reach and we could be forced to cease operations.

We will depend on the proceeds from this offering to continue the commercial launch of the ForeCYTE and ArgusCYTE Tests, and we do not have specific plans to obtain funding from alternative sources; if the proceeds from this offering are insufficient, the further commercial launch of our tests may be delayed.

We expect to spend substantial amounts of capital to:

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launch and commercialize the ForeCYTE and ArgusCYTE Tests, including the manufacture of the device in commercial quantities and building an independent distributor sales force to address certain markets;

maintain laboratory facilities for our testing and analytical services, including necessary testing equipment;

continue our research and development activities to advance our product pipeline; and

develop and commercialize the assets we recently acquired from Acueity Healthcare, Inc.

We expect that we will require additional capital beyond the proceeds from this offering to complete our commercialization plans and may need to raise additional funds if we encounter delays or problems in the production of the MASCT System device in commercial quantities, or the establishment of a larger sales force. We have not identified sources for such additional funding and cannot be certain that additional funding will be available on acceptable terms, or at all. If we are unable to raise additional capital in sufficient amounts or on acceptable terms, we may have to significantly delay, scale back or discontinue the commercialization of our products and services or our research and development activities.

Failure to raise additional capital as needed could adversely affect us and our ability to grow.

We will need considerable amounts of capital to develop our business. We may raise funds through public or private equity offerings or debt financings. If we cannot raise funds on acceptable terms when needed, we may be unable to grow or maintain the business. Furthermore, such lack of funds may inhibit our ability to respond to competitive pressures or unanticipated capital needs, or may force us to reduce operating expenses, which could significantly harm the business and development of operations. Because our independent auditors have expressed doubt as to our ability to continue as a going concern, as reported in their report on our financial statements, our ability to raise capital may be severely hampered. Similarly, our ability to borrow any such capital may be more expensive and difficult to obtain until this going concern issue is eliminated.

We have a history of operating losses, we currently sell the MASCT System for significantly less than it costs to manufacture, and we expect to continue to incur losses in the future.

We have a limited operating history and have incurred total net operating losses of approximately $6.9 million from our incorporation in April 2009 through June 30, 2012. We have received $279,310 in revenue as of June 30, 2012 and we do not expect that we will be in a position to generate significant revenue until we are able to launch our tests more broadly. Additionally, we will continue to incur further losses in connection with inventory costs for our medical test products, marketing and sales expenses in launching our products and services, research and development costs for additional tests, and the maintenance of our CLIA-certified laboratory. For example, the sales price of our MASCT System is currently substantially lower than its cost because the MASCT System is currently manufactured only in sufficient quantities to be utilized in our field experience trial and because the Company s current marketing strategy is to attempt to quickly penetrate the market of the products and services offered by the Company by offering the MASCT System at a price substantially lower than its cost to attract market awareness. This practice of selling our MASCT System substantially below its cost negatively impacts our profitability. Although we expect that the cost to manufacture our MASCT System will be substantially lower when we increase the volume of production for post-trial commercial launch and once we have been more successful in penetrating the market, if our expectation is not realized we may not be able to generate significant revenue nor achieve profitability. Accordingly, we may never achieve

We will depend on the proceeds from this offering to continuethe commercial launch of the ForeCYTE and ArgusCY

profitability.

Raising funds by issuing equity or debt securities could dilute the value of the common stock and impose restrictions on our working capital.

If we were to raise additional capital by issuing equity securities, the value of the then outstanding common stock would be reduced, unless the additional equity securities were issued at a price equal to or greater than the market value of the common stock at the time of issuance of the new securities. If the additional equity securities were issued at a per share price less than the per share value of the outstanding shares, then all of the outstanding shares would suffer a dilution in value with the issuance of such additional

We have a history of operating losses, we currently sell theMASCT System for significantly less than it costs toman

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shares. Further, the issuance of debt securities in order to obtain additional funds may impose restrictions on our operations and may impair our working capital as we service any such debt obligations.

The products and services that we have developed or may develop may never achieve significant commercial market acceptance.

We may not succeed in achieving commercial market acceptance of any of our products and services. In order to market the MASCT System and to gain market acceptance for the MASCT System and our ForeCYTE and ArgusCYTE Tests, we will need to demonstrate to physicians and other healthcare professionals the benefits of the MASCT System and its practical and economic application for their particular practice. Despite FDA clearance for the MASCT System, many physicians and healthcare professionals may be hesitant to introduce new services, or techniques, into their practice for many reasons, including the learning curve associated with the adoption of such new services or techniques into already established procedures and the uncertainty of the applicability or reliability of the results of a new product. In addition, the availability of full or even partial payment for our products and tests, whether by third-party payors (e.g., insurance companies), or the patients themselves, will likely heavily influence physicians decisions to recommend or use our products and services.

We will likely be increasingly required to offer discounted pricing arrangements to managed care payors and physicians and other referral services in response to competitive pressures.

There are other companies within the medical device product industry that have products used in NAF collection and there are laboratories other than ours that can process NAF samples. Because of this existing competition, as well as potential future competition from additional companies and laboratories, we will likely be increasingly required to offer discounted pricing arrangements to managed care payors, physicians and other referral services so that our products and services are selected over the products and services of others. If we offer such discounted pricing arrangements, our revenue will decrease and we may not generate sufficient revenue to cover our operating costs, which could materially adversely affect our business.

Additionally, such discounts could raise issues under the federal Anti-Kickback Statute and Medicare s discriminatory billing prohibition. If we were found to be in violation of such statute or prohibition, we could be subject to significant fines, and these fines would likely materially adversely affect our business and results of operations.

We may encounter difficulties in operating or maintaining our laboratory facility, which could cause delays and unexpected problems.