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

FORM 10-K

(Mark one)

☒ **Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

For the fiscal year ended December 31, 2012

OR

☐ **Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

For the transition period from: to

Commission File Number 001-35610

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.)**

4105 E. Madison Street, Suite 320
Seattle, Washington 98112
(Address of principal executive offices)
Registrant's telephone number, including area code: **(206) 325-6086**

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Name of each exchange on which registered
Common Stock, $0.001 par value	The NASDAQ Capital Market

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer or a non-accelerated filer, as defined 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 ☒

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes £ No ☒

As of June 29, 2012, the last business day of the registrant's most recently completed second fiscal quarter there was no public market for the registrant's common stock. The registrant's common stock began trading on The NASDAQ Capital Market on November 8, 2012.

The number of shares outstanding of the registrant's Common Stock, par value $0.001, as of March 27, 2013 was 14,174,686.

Documents Incorporated by Reference

Portions of the registrant's Proxy Statement, which will be filed with the Securities and Exchange Commission (SEC) pursuant to Regulation 14A in connection with the registrant's 2013 Annual Meeting of Shareholders, expected to be held on or about May 6, 2013, are incorporated by reference in Part III of this Form 10-K.

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NOTE REGARDING FORWARD-LOOKING STATEMENTS

Statements made in this report on Form 10-K that are not statements of historical information are 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 report we cannot assure you that the forward-looking statements set out in this report will prove to be accurate. We typically identify these forward-looking statements by the use of forward-looking words such as "expect," "potential," "continue," "may," "will," "should," "could," "would," "seek," "intend," "plan," "estimate," "anticipate" or the negative version of those words or other comparable words. Forward-looking statements contained in this report include, but are not limited to, statements about:

- our ability to successfully sell our products and services at currently expected prices or otherwise at prices acceptable to us;
- our ability to successfully develop and commercialize new tests, tools and technologies currently in development and in the time frames currently expected;
- our ability to engage third-party suppliers to manufacture the MASCT or Microcatheter System and its components at quantities and costs acceptable to us;
- our ability to satisfy ongoing Food and Drug Administration requirements for the MASCT and Microcatheter System and to obtain regulatory approvals for our other products and services in development, including our ability to timely and adequately respond to the warning letter we received from the FDA on February 21, 2013 and any issues resulting therefrom;
- the benefits and clinical accuracy of the ForeCYTE and ArgusCYTE tests and whether any product or service that we commercialize is safer or more effective than competing products and services;
- our ability to establish and maintain intellectual property rights covering our products and services;
- the willingness of health insurance companies, including those who are members of the MultiPlan and FedMed networks, and other third-party payors to approve our products and services for coverage and reimbursement;
- our ability to establish and maintain an independent sales representative force, including with Clarity Women's Health, a division of Diagnostic Test Group LLC, and its distributors, to market our products and services that we may develop, both regionally and nationally;
- our expectations regarding, and our ability to satisfy, federal, state and foreign regulatory requirements;
- the accuracy of our estimates of the size and characteristics of the markets that our products and services may address;
- our expectations as to future financial performance, expense levels and liquidity sources; and
- our ability to attract and retain key personnel.

Factors that could cause actual results or conditions to differ from those anticipated by these and other forward-looking statements include those more fully described in the "ITEM 1A. RISK FACTORS" section and elsewhere in this report. Except as required by law, we assume no obligation to update any forward-looking statements publicly, or to revise any forward looking statement to reflect events or developments occurring after the date of this report, even if new information becomes available in the future. Thus, you should not assume that our silence over time means that actual events are bearing out as expressed or implied in any such forward-looking statement.

CORPORATE INFORMATION

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 report. We make available, free of charge through our website or upon written request, our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and other periodic SEC reports, along with amendments to all of those reports, as soon as reasonably practicable after we file the reports with the SEC.

Unless otherwise noted, the term "Atossa Genetics" refers to Atossa Genetics Inc., a Delaware corporation, the terms "Atossa," the "Company," "we," "us," and "our," refer to the ongoing business operations of Atossa and its wholly-owned subsidiary, whether conducted through Atossa Genetics or its subsidiary. 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.

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 report also includes additional trademarks, trade names and service marks of third parties, which are the property of their respective owners.

PART I

ITEM 1. BUSINESS

Overview

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

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

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

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

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

On March 27, 2013 we entered into a stock purchase agreement with Aspire Capital Fund, LLC, which provides that, upon the terms and subject to the conditions and limitations set forth therein, Aspire is committed to purchase up to an aggregate of $30 million of shares of our common stock over the three-year term of the agreement. Under the agreement, Aspire purchased $1,000,000 of our common stock on March 27, 2013 for $12 per share. Before we can sell any additional shares under the agreement, we must register the shares and have the registration statement declared effective by the SEC. Other terms and conditions of the agreement, including our issuance of 250,000 shares to Aspire as a commitment fee, are described below.

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

Summary of Our Diagnostic Tests

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

ForeCYTE The ForeCYTE Breast Health Test, launched in December 2011, provides personalized information about the 10-year and lifetime risk of breast cancer for women between ages 18 and 73. It involves collecting a specimen of nipple aspirate fluid, or NAF, using our patented *Mammary Aspirate Specimen Cytology Test*, or MASCT, System (our MASCT device received 510(k) clearance from the FDA in 2003). The NAF specimen is collected by a physician and returned to our CLIA-certified laboratory. We study the patient's NAF specimen and use a proprietary molecular and cellular biomarker test that detects basal or luminal cells to identify the presence of atypical ductal hyperplasia, or ADH, which is considered a precursor to breast cancer. We then input these cytopathological test results, together with the patient's personal medical and reproductive history and family history, into a clinically-validated risk assessment algorithm that calculates 10-year and lifetime risk of breast cancer and presents these results in one of three risk tiers developed by The National Comprehensive Cancer Network: Normal (<15% lifetime risk), Intermediate (15 – 20% lifetime risk), or High (>20% lifetime risk). The ForeCYTE Test results contain recommendations for care paths in each risk group and personalized information so that patients and healthcare providers can make more informed treatment decisions. The algorithm was developed from a Swedish registry of 158,041 individuals, in whom 3,257 cancers occurred, and was validated by E. Amir, D.G. Evans, A. Shenton, and others in an independent study of 3,150 women, 64 of whom developed breast cancer. The algorithm incorporates family history, personal reproductive history, and the presence or absence of usual ductal hyperplasia, or UDH (which is benign), ADH (which is pre-malignant), or malignant changes. The present methods used by pathologists to analyze traditional biopsy specimens, i.e., microscopy and, when needed, immunohistochemistry, are the same methods used to analyze ForeCYTE specimens and would be expected to achieve similar results for patients with similar medical conditions.

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

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

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

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

Our Diagnostic Tools

The assets we acquired from Acueity included 35 issued patents (18 issued in the U.S. and 17 issued in foreign countries) and 41 patent applications (32 in the U.S. and 9 in foreign countries), six 510(k) FDA marketing authorizations related to the manufacturing, use, and sale of the Viaduct Miniscope and accessories, the Manoa Breast Biopsy system, the Excisor Bioptome, the Acueity Medical Light Source, the Viaduct Microendoscope and accessories, and cash in the amount of $400,000. The microendoscopes are less than 0.9 mm outside diameter and can be inserted into a milk duct. This permits a physician to pass a microendoscope into the milk duct system of the breast and view the duct system via fiberoptic video images. Abnormalities that are visualized can then be biopsied from inside the duct with the biopsy tools that are inserted adjacent to the microendoscope. The patents relate to intraductal diagnostic and therapeutic devices and methods of use. We did not, however, acquire an inventory of these diagnostic tools, manufacturing capabilities or any personnel to market and sell the tools. Following the launch of our four diagnostic tests in the U.S., we will then begin to allocate human and financial resources to further develop and ultimately commercialize these medical devices. We intend to complete the steps necessary to begin marketing and selling these tools, such as re-establishment of the supply chain of component parts, securing manufacturers, performing test builds and commercial scale manufacturing, in late 2013. This asset purchase is not expected to have an impact on the development and commercialization timetables of our existing product lines. We cannot, however, provide any assurances that delays related to the launch of our four diagnostic tests, independent of the asset purchase, would not delay the expected development of these diagnostic tools or that we will ultimately be successful selling these tools.

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

Intraductal Treatment Research

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

An October 2011 peer-reviewed paper published in *Science Translational Medicine* documented a study conducted at the Johns Hopkins Medical School demonstrating the prevention of breast cancer in rats with intraductal non-systemic chemotherapy, and a proof-of-principle Phase 1 clinical trial involving 17 women with breast cancer who subsequently received surgery. An accompanying editorial commented that "intraductal treatment could be especially useful for women with premalignant lesions or those at high risk of developing breast cancer, thus drastically improving upon their other, less attractive options of breast-removal surgery or surveillance (termed 'watch and wait')."

In a December 2012 peer-reviewed paper published in *Cancer Prevention Research,* Dr. Susan Love and her colleagues report a Phase I clinical trial to show the safety and feasibility of intraductal administration of chemotherapy drugs into multiple ducts within one breast in women awaiting mastectomy for treatment of invasive cancer. Thirty subjects were enrolled in this dose escalation study conducted at a single center in Beijing, China. Under local anesthetic, one of two chemotherapy drugs, carboplatin or pegylated liposomal doxorubicin (PLD), was administered into five to eight ducts at three dose levels. Pharmacokinetic analysis has shown that carboplatin was rapidly absorbed into the bloodstream, whereas PLD, though more erratic, was absorbed after a delay. Pathologic analysis showed marked effects on breast duct epithelium in ducts treated with either drug compared with untreated ducts. The investigators concluded the study showed the safety and feasibility of intraductal administration of chemotherapy into multiple ducts for the purpose of breast cancer prevention and that this was an important step toward implementation of this strategy as a "chemical mastectomy", potentially eliminating the need for surgery.

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

Our Commercialization Strategy

The ForeCYTE Test provides us with two revenue sources:

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

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

The ArgusCYTE test provides only laboratory service revenue.

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

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

Our National Launch Through Clarity

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

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

In January 2013, we launched the ForeCYTE Breast Health Test with Clarity and its distributors, however, we 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.

Our Common Stock Purchase Agreement with Aspire Capital Fund, LLC

On March 27, 2013 we entered into a stock purchase agreement with Aspire Capital Fund, LLC, which provides that, upon the terms and subject to the conditions and limitations set forth therein, Aspire is committed to purchase up to an aggregate of $30 million of shares of our common stock over the three-year term of the agreement. Under the agreement, Aspire purchased 83,333 shares of our common stock on March 27, 2013 for $12 per share. Before we can sell any additional shares under the agreement, we must register the shares and have the registration statement declared effective by the SEC. Other terms and conditions of the agreement are described below.

Concurrently with entering into the purchase agreement, we also entered into a registration rights agreement with Aspire. The registration rights agreement provides that the Company will file one or more registration statements, as necessary, to register under the Securities Act of 1933, as amended, the sale of the shares of common stock that have been and may be issued to Aspire under the purchase agreement. The Company agreed to file an initial registration statement registering the sale of the shares by Aspire with the SEC within 10 days of entering into the purchase agreement with Aspire. We further agreed to keep the registration statement effective and to indemnify Aspire for liabilities in connection with the sale of the shares under the terms of the registration rights agreement.

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

Under the purchase agreement we issued 250,000 shares of our common stock to Aspire in consideration for entering into the purchase agreement. Immediately upon executing the purchase agreement, we also sold 83,333 shares of common stock for $12 per share, for an aggregate purchase price of $1,000,000. After the SEC declares the initial registration statement effective, on any business day on which the closing sale price of our common stock equals or exceeds $2.00 per share, over the three-year term of the purchase agreement, we have the right, in our sole discretion, to present Aspire with a purchase notice directing Aspire to purchase up to 100,000 shares of our common stock per business day; however, no sale pursuant to such purchase notice may exceed $400,000 per business day. The purchase price per share is the lower of (i) the lowest sale price for our common stock on the purchase date or (ii) the arithmetic average of the three lowest closing sale prices for our common stock during the 12 consecutive business days ending on the business day immediately preceding the purchase date. The applicable purchase price will be determined prior to delivery of any purchase notice.

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

We have the right to sell up to $30 million of our shares of common stock to Aspire, including the 83,333 shares sold to Aspire on March 27, 2013 and the 250,000 shares issued to Aspire as a commitment fee. We are obligated to register these shares with the SEC. Also, we have agreed to initially register 2,500,186 additional shares which we may sell to Aspire in the future. Under the rules of the Nasdaq Capital Market, in no event may we issue more than 19.99% of our shares outstanding (which is approximately 2,833,519 shares based on 14,174,686 outstanding on March 27, 2013) under the purchase agreement unless we obtain stockholder approval.

The number of Purchase Shares covered by, and the timing of, each purchase are determined by us, at our sole discretion. We may deliver multiple purchase notices to Aspire from time to time during the term of the purchase agreement, so long as the most recent purchase has been completed. There are no trading volume requirements or other restrictions under the purchase agreement. Aspire has no right to require any sales from us, but is obligated to make purchases as directed in accordance with the purchase agreement.

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

Our gross proceeds will depend on the purchase prices and the frequency of sales of shares to Aspire; *provided, however,* that the maximum aggregate proceeds from sales of shares, including the initial 83,333 shares sold to Aspire on March 27, 2013, is $30 million. Our delivery of purchase notices will be made subject to market conditions, in light of our anticipated capital needs from time to time and under the limitations contained in the purchase agreement. We expect to use proceeds from sales of shares for general corporate purposes and working capital requirements.

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

Reimbursement Organizations

As of the date of this report, we have two contracts with third parties to facilitate the reimbursement process from insurers, one with MultiPlan, Inc. and another with FedMed, Inc. MultiPlan is a leading provider of healthcare cost management solutions for diagnostic laboratory testing involving our tests. Approximately 20% of Americans are covered by MultiPlan. The agreement allows us to participate in the MultiPlan, PHCS and PHCS Savility Networks. In March of 2013, we entered into an agreement with FedMed, which is a National Provider Network and Healthcare Financial Services Organization. FedMed is one of the largest proprietary Preferred Provider Organization (PPO) networks in the U.S. for diagnostic laboratory testing. FedMed's network is comprised of over 550,000 total providers, including 4,000 hospitals and more than 60,000 ancillary facilities, serving over 40 million Americans.

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

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

Clinical Development and FDA-clearance of the MASCT System

Under the direction of Steven Quay, a clinical trial of the MASCT System was conducted at the State University of New York, Stony Brook, New York in 2003 to test the efficiency of NAF collection in normal women. Thirty-one healthy, non-pregnant, pre-menopausal female volunteer subjects were tested with the MASCT System device for the ability to collect NAF samples and to observe the morphology of breast gland cells in the NAF (cytological examination), using the NAF cytology classification system of the College of American Pathologists, or CAP, as described in the table below.

Category	Interpretation	Cytology Characteristics
Category 0	Scant ductal epithelial cells and negative for atypical or malignant cells	No or <10 ductal cells.
Category I	Normal ductal cytology	Normal ductal epithelial cells.
Category II	Usual ductal hyperplasia	Cell groups with >10 – 50 cells.
Category III	Atypical ductal hyperplasia	Distinct large nuclei with irregular nuclear borders.
Category IV	Suspicious for malignancy	Single cells and groups of cells suspicious for cancer.

Of the 31 subjects, 30, or 97%, had measurable NAF; 24 from both breasts and six from only one breast. NAF samples ranged from less than one to 37 microliters, and all samples collected were deemed to be clinically useful. 58 of 60 NAF samples were reported as cytology Category I, and two of 60 were reported as cytology Category II under the CAP's classification system for NAF cytology. No adverse events were reported in the study. Based on the results of the study, a premarket notification for the intended use of the MASCT System for the collection of NAF for cytological testing was submitted to the FDA and subsequently cleared by the FDA, indicating that the NAF collected using the MASCT System can be used in the determination and/or differentiation of normal versus premalignant versus malignant cells.

The ForeCYTE Breast Health Test

The ForeCYTE Test uses the patented, FDA-cleared MASCT System medical device for the collection, shipment and clinical laboratory analysis of NAF. The ForeCYTE test involves cytopathology and five biomarkers of hyperplasia and one biomarker of sample integrity and has been validated to CLIA standards. The product components of the MASCT System consist of a reusable hand-held pump for the collection of NAF, single-use patient kits that include two NAF sample collection tools per kit, and shipment boxes for the transportation of NAF samples to the National Reference Laboratory for Breast Health, our wholly-owned, CLIA-certified specialized cytology and molecular diagnostics laboratory in Seattle, Washington. Through our laboratory we provide the ForeCYTE Test, which consists of receiving and accessioning the two NAF samples from each patient, preparing routine and immunohistochemistry, or IHC, staining of slides from the NAF samples, and generating a report of the findings. The NAF is analyzed by microscopy for cytological abnormalities and by a patent-pending IHC staining technique for five biomarkers of hyperplasia and a sample integrity marker.

We offer each component of the MASCT System for sale separately. Our NAF sample collection devices are currently priced to physicians at approximately $299 per starter kit, which includes the pump and five patient collection kits, and our patient collection kits are priced currently at approximately $35 per kit, however, our sale prices to our distributors are significantly below these prices and these prices are subject to change. During our initial launch, we plan to provide a rebate to the physician after the physician submits patient collection kits to our lab. The cytology and molecular diagnostics testing and analysis services are billed to federal and/or state health plans at the 2012 Medicare reimbursement rates of either $384 or $1,275 per patient, depending on the complexity of the analysis performed. 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 1,664 ForeCYTE samples processed through December 31, 2012 (which is equivalent to 832 patients). 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. We have received reimbursement from insurance carriers and Medicare for our ForeCYTE test.

The ArgusCYTE Breast Health Test

The ArgusCYTE test has been tested and validated and provides information to help inform breast cancer treatment options and to help monitor potential recurrence. It uses a proprietary blood collection tube to obtain a blood sample for shipment and analysis at the NRLBH. In June 2011, we entered into a non-exclusive supply agreement with Biomarkers LLC for the blood collection tubes and laboratory reagents and supplies for the ArgusCYTE test. The agreement provides for fixed purchase prices which decrease as we place larger orders. The ArgusCYTE test consists of a two-step "Combination-of-Combinations-Principle" involving (1) cell isolation, whereby tumor cells are enriched by a three antibody-mix linked to magnetic particles and mRNA is isolated from the selected tumor cells, and (2) molecular biological detection and analysis, whereby the isolated mRNA is transcribed into cDNA and a multiplex PCR is carried out for the analysis of epithelial cell related transcripts and tumor associated gene expression. Due to the combination of different selection and tumor markers, both the heterogeneity of the tumor cells and possible individual or therapy-induced deviations in the expression patterns are taken into account.

As far as we know, the ArgusCYTE test is the only CLIA-certified circulating breast tumor cell test available that identifies mRNA expression levels for estrogen receptors (ER), progesterone receptors (PR), and HER-2 antigen in a single blood draw to help guide treatment selection by determining which of the most commonly used therapies may be effective for the individual patient. The test can identify circulating tumor cells immediately after a woman begins breast cancer therapy or at the time of diagnosis or biopsy so that she and her healthcare provider can make better-informed decisions about effective treatment options. Analytical validation studies demonstrated a sensitivity of 94% and specificity of 100% at the 5 cancer cell/5 mL blood sample level (n=106). Clinical validation has been performed by unaffiliated research institutions in breast cancer patients in trials in Europe and the United States over the last eight years.

We provide the proprietary, blood collection tube free of charge and currently charge approximately $1,500 for the ArgusCYTE test. Because we do not currently have a sufficiently reliable prior history of reimbursement with respect to the ArgusCYTE test, we currently do not recognize revenue until we have received reimbursement. We have billed the testing and analysis regarding the 41 ArgusCYTE samples processed through December 31, 2012 at $1,500 per patient. We have received reimbursement from insurance carriers for our ArgusCYTE test.

The FullCYTE Breast Health Test

The FullCYTE Breast Health Test uses our patented Mammary Duct Microcatheter System, invented by Dr. Susan Love, author, breast surgeon, and founder of the Dr. Susan Love Research Foundation, Santa Monica, California to lavage, or irrigate, each of the five to seven breast ducts and to collect the lavage fluid for analysis of biomarkers of hyperplasia by immunohistochemistry for protein biomarkers, Next Generation Sequencing for somatic DNA mutations, and transcriptome microarray analysis for mRNA expression patterns.

In April 2011 we acquired from Hologic, Inc. all of the ownership rights to the U.S. trademark, FirstCYTE, the 23 U.S. issued patents and 84 issued foreign counterparts (in Europe, France, Germany, Ireland, United Kingdom, Australia, Canada, Israel, Italy, The Netherlands, Spain, and Switzerland) covering the manufacture, use, and sale of the FirstCyte ^{TM} Breast Aspirator, the Micro-Stylet Dilator, and the FullCYTE Microcatheter for ductal lavage, the related manufacturing documentation, and the related regulatory documentation, including the FDA marketing authorization for these medical devices. We also paid an up-front fee and are obliged to pay patent-based royalties between 2% and 6% on aggregate net sales in the countries with issued patents. The FDA-cleared indications for use of the Breast Aspirator are to elicit fluid from multiple ductal orifices for subsequent cytological evaluation and/or to identify ductal orifices for subsequent cannulation with the microcatheter. The FDA-cleared indication for use of the Micro-Stylet Dilator is to dilate breast milk ducts prior to enhanced radiography (i.e., ductography) or ductal lavage procedures. The FDA-cleared indication for use of the microcatheter is to perform contrast enhanced radiography of breast milk ducts; it may also be used for the collection of cells and/or fluid for cytological analysis.

This project is in the research and development phase, and the Company has studied the use of the FullCYTE microcatheter in six patients to establish the feasibility of performing next-generation tests on samples taken with the microcatheters. The purpose of the study was to see if ductal lavage specimens provided sufficient quantities of DNA and RNA to perform full genome sequencing and transcriptome profiling. All specimens from the six patients contained sufficient, high-quality DNA and RNA to proceed to sequencing and transcriptome profiling. Results are expected in the first half of 2013 and the Company intends to launch the FullCYTE test in 2013.

In August 2011, we entered into an agreement with Accellent to perform development work to re-establish the supply chain for the FullCYTE microcatheter and manufacture the microcatheter for commercialization. The agreement divided the development work into three phases with a fixed time and budget for each phase. In aggregate, the budget to complete all phases is approximately $713,000. The agreement also contains a fixed price schedule for manufacturing the microcatheter following commercial launch. The price schedule contains a volume-based reduction in the cost per microcatheter.

The NextCYTE Breast Cancer Test

The NextCYTE Breast Cancer Test, which is in the prevalidation phase and which we intend to launch in 2013, is designed to profile breast cancer specimens for prediction of treatment outcomes and distant recurrence in women newly diagnosed with breast cancer. It involves using surgery specimens and advanced genome sequencing techniques to quantify and analyze the entire tumor genetic transcriptome, which represents all genes that are being actively expressed within the tumor. Because our NextCYTE test analyzes traditional biopsy specimens using advanced genome sequencing techniques, we believe that other present methods of analyzing traditional biopsy specimens would not achieve results similar to or better than results provided by our NextCYTE test and we expect that physicians will be able to use the information provided by the NextCYTE test to better customize treatment options for women, based on the genetic composition of the individual tumor. The NextCYTE Breast Cancer Test is intended to use microarray-based genome-wide transcriptome data from surgical breast cancer biopsy specimens to predict a patient's 10-year survival probability and response to treatment. The algorithm was created from 2,400 unique genome-wide microarrays and validated against a separate sample of over 1,600 microarray data sets. A correct classification was obtained for over 85% of both estrogen receptor negative and positive tumors. We have signed a term sheet for the exclusive license of the intellectual property related to this algorithm and we expect to complete the license in the first half of 2013 and to complete validation of the test in our laboratory soon thereafter, with an intent to launch this product before year end 2013.

Our Diagnostic Tools

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) 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 based on the following assumptions: fair value of common stock on date of grant of $5.00 per share, the exercise price of the warrants is $5.00, the expected life of the warrants is 5 years, the dividend yield is 0.0%, the expected volatility is 56.54%, the risk-free interest rate is 0.62%, and the expected forfeiture per year is 0%. The risk-free interest rate reflects the interest rate for United States Treasury Note with similar time-to-maturity to that of the warrants. The expected life of the warrants was derived from the output of the valuation model and represents the period of time that the warrants are expected to be outstanding. We did not have a historical trading history sufficient to develop an internal volatility rate for use in the model. As a result, as required by FASB ASC 718-10-30, the Company has accounted for the warrants using the calculated value method. The Company identified seven public entities in a similar industry for which share price information was available, and considered the historical volatilities of those public entities' share prices in calculating the expected volatility appropriate to the Company. 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 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. 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. 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.

The Market

United States Market for ForeCYTE Test

Testing in Women at High Risk for Breast Cancer

The Company expects that the MASCT System will initially be adopted by physicians and other healthcare professionals for use in women at high risk for breast cancer.

Women Undergoing Diagnostic Mammograms. Breast cancer screening by mammography involves performing a screening mammogram and typically reviewing the mammogram while the patient is still present in the clinic. If the screening mammogram shows suspicious changes, a more extensive diagnostic mammogram is performed, usually on the same day. In an audit of 46,857 consecutive mammograms performed in the radiology department at the University of California, San Francisco between 1997 and 2000, 10,007, or 21%, were diagnostic mammograms. The audit also documented an increased incidence of future cancer in those women who underwent a diagnostic mammogram, regardless of the diagnosis at the time. Applying this frequency to the estimated 39.0 million total mammograms performed each year in the United States yields approximately 8.1 million diagnostic mammograms. The Company believes all women undergoing a diagnostic mammogram, who may be at higher risk of developing breast cancer in the future, would be candidates for MASCT System testing.

Breast Cancer Survivors. Women who have had breast cancer are at a higher risk for the recurrence of cancer or for a new malignancy. The American Cancer Society, or ACS, has estimated that as of 2012, there were approximately 2.9 million breast cancer survivors in the United States. The Company believes these women would be candidates for regular MASCT System screening.

High Risk Women. The Breast Cancer Risk Assessment Tool (based on the Gail model) has been established by the NCI and the National Surgical Adjuvant Breast and Bowel Project, or NSABP, to identify women with an increased risk of breast cancer. The risk factors included in the test are: personal history of breast abnormalities, age, age at first menarche, age at first live birth, breast cancer among first-degree relatives (sisters, mother, or daughters), breast biopsies, obesity and race. Approximately 12 million women in the United States are in the high risk group. A study of 6,904 women for an average follow up of 14.6 years demonstrated that NAF cytology may be most useful for women at highest absolute risk by the Risk Assessment Tool because modest differences in relative risk are amplified. In this group, the incidence of breast cancer detected by NAF cytology ranged from 5.3 to 10.3 per 1,000 women (non-yielder to hyperplasia/atypia).

Breast cancer risk stratification

The Company believes that if it is able to develop, produce and successfully market the MASCT System for use as an additional test in conjunction with all mammography and all cervical cancer screenings (Pap smear), the potential annual U.S. market size for breast cancer risk stratification would be between 39.3 million and 55 million women. This conclusion is based on the following data:

MASCT System in conjunction with mammography, all ages According to the Mammography Quality Standards Act (MQSA) National Statistics, th total annual mammography procedures in the United States, as of January 1, 2012, was 39,311,535.

MASCT System in conjunction with cervical cancer screening (Pap smear), all ages According to the National Cancer Institute, as of Decembe 2011, approximately 55 million Pap smear examinations are performed annually in the United States.

United States Market for ArgusCYTE Test

Breast Cancer Survivors. The ACS has estimated that, as of 2012, there were more than 2.9 million breast cancer survivors, who we believe would be potential candidates for a blood test for circulating tumor cells.

Newly diagnosed breast cancer patients. According to the National Cancer Institute, as of 2012, approximately 232,340 women are diagnosed with breast cancer each year. These women would be candidates for a blood test for circulating tumor cells during the staging of their tumor and as a method to monitor treatment effects.

United States Laboratory Testing Market

Anatomic Pathology . Anatomic pathology involves the diagnosis of cancer and other medical conditions through the examination of tissues (biopsies) and the analysis of cells (cytology) taken from patients. Generally, the anatomic pathology process involves the preparation of slides by trained histo-technologists or cytologists and the review of those slides by anatomic pathologists. Although anatomic pathologists do not treat patients, they establish a definitive diagnosis and may also consult with the referring physician. As a result of the greater degree of complexity and sophistication in anatomic pathology services, 2012 Medicare reimbursement rates for the anatomic pathology services of the type that the Company expects to perform are either $384 or $1,275 per patient. The patient fee schedule for self-pay or private payors for these tests is typically higher.

Molecular Diagnostics. Molecular diagnostics typically involve unique and complex genetic and molecular tests performed by skilled personnel using sophisticated instruments. As a result, molecular diagnostics are typically offered by a limited number of commercial laboratories. According to PriceWaterhouseCoopers, molecular diagnostics represents one of the fastest growing segments of the $37 billion market for *in vitro* diagnostics, which includes test tube diagnostics such as glucose monitoring for diabetes care but excludes diagnostics for research use. The Medicare reimbursement rate in 2011 for microarray-based molecular diagnostics tests is $1,250, while the reimbursement rate for fluorescent cellular probe-based tests is $479 per probe. According to PriceWaterhouseCoopers, this market segment is expected to grow 14% annually between 2007 and 2012, from $2.6 billion to $5.0 billion.

Commercialization Strategy

The Company's commercialization strategy is based on creating two main revenue sources: (i) product sales-based revenue from the sale of the MASCT System, including the NAF specimen collection kits, to physicians, breast health clinics, mammography clinics and distributors, and (ii) service-based revenue for the preparation and interpretation of the NAF samples sent to the Company's laboratory. This is intended to result in revenue from both the sale and the use of the MASCT System.

In order to achieve its two-pronged revenue base, the Company manufactures, through medical device suppliers, the MASCT System components (i.e., the collection device and patient NAF specimen kits) and will establish a network of independent sales representatives to call on physicians and breast health and mammography clinics to market and sell the MASCT System. The collection device is reusable when sanitized between patients. The kit contains the patient contact materials, preservative fluid for the collected samples, and bar-coded patient identification labeling. The kit components are designed to work properly with the collection device and the Company is not aware of any commercially available parts or components which could be substituted for the Company's kits.

The Company's product- and service-based income plan is intended to provide revenue from multiple, different sources with different timing in the procedure cycle. The Company expects to generate product revenue from the sale of kits in bulk to distributors and to clinics and physicians for the testing of their patients, and laboratory service revenue after its laboratory analyzes the results of these tests and renders a diagnosis.

Specialty Sales Team

To market the MASCT System and its related laboratory diagnostic services, the Company will need to hire independent sales representatives with technical knowledge in, for example, molecular diagnostics, mammography, obstetrics/gynecology office practices, and women's health clinics. As a result, the Company will expect its sales representatives to develop long-lasting, consultative relationships with the referring physicians they serve.

The Company will focus its marketing and sales efforts on encouraging physicians and breast health and mammography clinics to use the MASCT System in conjunction with other health screening examinations, including annual physical examinations and regularly scheduled cervical Pap smears and mammograms. The sales representatives will concentrate on a geographic area based on the number of physician clients and prospects, which will be identified using several national physician databases that provide physician address information, patient demographic information, and other data. The Company also expects to use the FDA website containing contact information on the approximately 8,600 MQSA-certified clinics to identify potential clients.

In September 2012 we entered into a co-exclusive marketing agreement with Diagnostic Test Group (DTG), operating through its division Clarity Women's Health (Clarity) for the supply and distribution of the MASCT System under the Clarity brand. Under the terms of the agreement, we granted to DTG the co-exclusive right to sell and distribute our MASCT breast health test in the Territory (U.S., Canada, and Puerto Rico, with other territories available with written consent). We retain co-exclusive rights to sell and distribute the MASCT breast health test in the Territory under the terms of the agreement. DTG has agreed to purchase all breast health tests only from us during the term of the agreement. DTG also has a 30-day right of first refusal for the co-exclusive right to sell our other products on terms and conditions to be negotiated by us and DTG. The term of the agreement is a rolling six years, with automatic extension if DTG achieves its annual minimum sales requirements. Following an initial launch period, minimum sales have been set for the first 12-month period.

Under the terms of the agreement, DTG will purchase the MASCT System from us at a fixed price and will use its best efforts to market and sell the MASCT System, including establishing product codes and contracted agreements, if these are deemed necessary by DTG, for the sale and placement of the Clarity branded MASCT product line with the following distributors: Henry Schein, McKesson, PSS World Medical, Cardinal Health, VWR, Vaxserve, Mercedes Medical, Fisher, NDC members, Imco members, B&H Surgical, Marshall Medical and Cascade HealthCare Products. These distributors have collectively over 5,000 employee sales representatives and/or independent sales representatives selling their products and calling on 33,000 obstetric-gynecologists in the United States.

We will coordinate the sales and marketing effort, plan, and budget with DTG, with us paying agreed expenses, as well as a marketing and sales fee that is less than 10% of the Medicare reimbursement rate for the ForeCYTE test. DTG earns warrants in Atossa common stock based on a low, double-digit percentage of the annual number of ForeCYTE tests performed by the National Reference Laboratory for Breast Health, priced at the fair market value on the date of issuance, with a maximum number of warrants issuable under the life of the agreement equal to 1,000,000 shares of common stock.

We announced the launch of our national sales effort of the ForeCYTE test with DTG in January 2013. 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.

The National Reference Laboratory for Breast Health

The Company has established the National Reference Laboratory for Breast Health, a wholly-owned CLIA-certified clinical laboratory for the cytology and molecular diagnostics testing and reading of results of collected NAF samples and ArgusCYTE blood samples. The Company believes that by maintaining its own clinical laboratory, it will be positioned to generate substantial additional service revenue through cytology and molecular diagnostic testing, in addition to the sale of the MASCT System pumps and specimen collection kits.

The Company has established a comprehensive quality assurance program for its laboratory, designed to drive accurate and timely test results and to ensure the consistent high quality of its testing services. In addition to the compulsory proficiency programs and external inspections required by CMS and other regulatory agencies, the Company intends to develop a variety of internal systems and procedures to emphasize, monitor, and continuously improve the quality of its operations. The Company also participates in externally administered quality surveillance programs.

Growth Strategy

The Company launched the ForeCYTE and ArgusCYTE Tests at the end of the fourth quarter of 2011. The Company markets to both mammography clinics and physicians' offices. The Company conducted a field experience trial to collect information about the ease or difficulty of adoption of the products in each location, the number of sales calls needed to receive the first orders, and the growth of sales of specimen collection kits on a monthly basis. We are using the outcome of this initial marketing efforts to form our national marketing strategies, for example, we may decide to emphasize physicians' offices over mammography clinics.

The Company plans to market the ForeCYTE Test nationally through DTG and other distributors and sales representatives.

Research and Development

Our Intraductal Treatment Research

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

An October 2011 peer-reviewed paper published in *Science Translational Medicine* documented a study conducted at the Johns Hopkins Medical School demonstrating the prevention of breast cancer in rats with intraductal non-systemic chemotherapy, and a proof-of-principle Phase 1 clinical trial involving 17 women with breast cancer who subsequently received surgery. An accompanying editorial commented that "intraductal treatment could be especially useful for women with premalignant lesions or those at high risk of developing breast cancer, thus drastically improving upon their other, less attractive options of breast-removal surgery or surveillance (termed 'watch and wait')."

In a December 2012 peer-reviewed paper published in *Cancer Prevention Research,* Dr. Susan Love and her colleagues report a Phase I clinical trial to show the safety and feasibility of intraductal administration of chemotherapy drugs into multiple ducts within one breast in women awaiting mastectomy for treatment of invasive cancer. Thirty subjects were enrolled in this dose escalation study conducted at a single center in Beijing, China. Under local anesthetic, one of two chemotherapy drugs, carboplatin or pegylated liposomal doxorubicin (PLD), was administered into five to eight ducts at three dose levels. Pharmacokinetic analysis has shown that carboplatin was rapidly absorbed into the bloodstream, whereas PLD, though more erratic, was absorbed after a delay. Pathologic analysis showed marked effects on breast duct epithelium in ducts treated with either drug compared with untreated ducts. The investigators concluded the study showed the safety and feasibility of intraductal administration of chemotherapy into multiple ducts for the purpose of breast cancer prevention and that this was an important step toward implementation of this strategy as a "chemical mastectomy", potentially eliminating the need for surgery.

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

Billing and Reimbursement

Billing for the MASCT System Medical Device and Patient Kits and the NAF Collection Procedure

Medicare and certain insurance carriers do not currently cover the cost of collecting the NAF sample. We intend to work with physicians and other interest groups to attempt to obtain coverage for the procedures but this process can be lengthy, costly, and might not be successful. Failure to receive reimbursement could limit the adoption and utilization of the MASCT System. Because the process can be done by a nurse or physician's assistant, takes less than five minutes, and the MASCT System supplies will contain everything to obtain, label, and ship the NAF samples, the charge for collecting NAF samples should b below the average cost of a mammogram.

Billing for Diagnostic Services

Although Medicare and certain insurance carriers do not currently cover the cost of collecting the NAF sample, Medicare and certain insurance carriers d reimburse for the laboratory analysis of the NAF sample. We have received reimbursement from insurance carriers and Medicare for the ForeCYTE test an from insurance carriers for the ArgusCYTE test. Billing for diagnostic services is generally complex. As a result, we rely on a third-party billing company t perform all of our billing and collection services. Laboratories must bill various payors, such as private insurance companies, managed care companies, governmental payors such as Medicare and Medicaid, physicians, hospitals, and employer groups, each of whom may have different billing requirements. We expect to be obligated to bill in the specific manner prescribed by the various payors. Additionally, the audit requirements that must be met to ensure compliance with applicable laws and regulations, as well as internal compliance policies and procedures, add further complexity to the billing process. Other factors that complicate billing include:

- additional billing procedures required by government payor programs;
- variability in coverage and information requirements among various payors;
- missing, incomplete or inaccurate billing information provided by referring physicians;
- billings to payors with whom we do not have contracts;
- disputes with payors as to who is responsible for payment;
- disputes with payors as to the appropriate level of reimbursement;
- training and education of employees and clients;
- compliance and legal costs; and
- costs related to, among other factors, medical necessity denials and the absence of advance beneficiaries' notices.

In general, we perform the requested tests and report test results even if the billing information is incorrect or missing. We will subsequently attempt to obtain any missing information and correct incomplete or erroneous billing information received from the healthcare provider. Missing or incorrect information on requisitions adds complexity to and slows the billing process, creates backlogs of unbilled requisitions, and generally increases the aging of accounts receivable and the length of time to recognize revenue. When all issues relating to the missing or incorrect information are not resolved in a timely manner, the related receivables will be written off to the allowance for doubtful accounts.

Reimbursement

Depending on the billing arrangement and applicable law, the party that reimburses us for our services will be (i) a third party who provides coverage to the patient, such as an insurance company, managed care organization, or a governmental payor program; (ii) the physician or other authorized party (such as another laboratory) who ordered the test or otherwise referred the test to us; or (iii) the patient.

The National Reference Laboratory for Breast Health, our wholly-owned subsidiary, bills Medicare for the laboratory services provided for the ForeCYTE and ArgusCYTE testing.

Reimbursement for services under the Medicare program is based principally on two sets of fee schedules. Generally, anatomic pathology services, including most of the services we provide, are paid based on the Medicare physician fee schedule. The physician fee schedule is designed to set compensation rates for those medical services provided to Medicare beneficiaries that require a degree of physician supervision. Outpatient diagnostic laboratory tests are typically paid according to the laboratory fee schedule.

For the anatomic pathology services that we will provide, we will be reimbursed under the Medicare physician fee schedule, and beneficiaries are responsible for applicable coinsurance and deductible amounts. The physician fee schedule is based on assigned relative value shares for each procedure or service, and an annually determined conversion factor is applied to the relative value shares to calculate the reimbursement. The formula used to calculate the fee schedule conversion factor has resulted in significant decreases in payment levels in recent years.

Future decreases in the Medicare physician fee schedule are expected unless Congress acts to change the fee schedule methodology or mandates freezes or increases each year. Because the vast majority of our laboratory services will be reimbursed based on the physician fee schedule, changes to the physician fee schedule could result in a greater impact on our revenue than changes to the Medicare laboratory fee schedule.

We expect to bill the Medicare program directly. Generally, we will be permitted to directly bill the Medicare beneficiary for clinical laboratory tests only when the service is considered not medically necessary and the patient has signed an Advanced Beneficiary Notice, or ABN, reflecting acknowledgment that Medicare is likely to deny payment for the service. In most situations, we are required to rely on physicians to obtain an ABN from the patient. When we are not provided an ABN, we are generally unable to recover payment for a service for which Medicare has denied payment for lack of medical necessity.

In billing Medicare, we are required to accept the lowest of: our actual charge, the fee schedule amount for the state or local geographical area, or a national limitation amount, as payment in full for covered tests performed on behalf of Medicare beneficiaries. Payment under the laboratory fee schedule has been limited by Congressional action such as freezes on the otherwise applicable annual Consumer Price Index, or CPI, update to the fee schedule amount. The CPI update of the laboratory fee schedule for 2010 was minus 1.9%.

The Medicare statute permits Federal Health and Human Services Centers for Medicare and Medicaid Services, or CMS, to adjust statutorily prescribed fees for some medical services, including clinical laboratory services, if the fees are "grossly excessive." Medicare regulations provide that if CMS or a carrier determines that an overall payment adjustment of less than 15% is needed to produce a realistic and equitable payment amount, then the payment amount is not considered "grossly excessive or deficient." However, if a determination is made that a payment adjustment of 15% or more is justified, CMS could provide an adjustment of 15% or less, but not more than 15%, in any given year. We cannot provide any assurance that fees payable by Medicare for clinical laboratory services could not be reduced as a result of the application of this rule or that the government might not assert claims for recoupment of previously paid amounts by retroactively applying these principles.

The payment amounts under the Medicare fee schedules are important not only for reimbursement under Medicare, but also because the schedule is often used as a reference for the payment amounts set by other third-party payors. For example, state Medicaid programs are prohibited from paying more than the Medicare fee schedule limit for laboratory services furnished to Medicaid recipients, and insurance companies and managed care organizations typically reimburse at a percentage of the Medicare fee schedule.

Our reimbursement rates also vary depending on whether we are considered an "in-network," or participating, provider. If we enter into a contract with an insurance company, our reimbursement will be governed by our contractual relationship, and we will typically be reimbursed on a fee-for-service basis at a discount from the patient fee schedule. If we do not have a contract with an insurance company, we will be classified as "out-of-network," or as a non-participating provider. In such instances, we would have no contractual right to reimbursement for services.

Reimbursement Strategy

CPT Code for MASCT System NAF Collection Procedure

The NAF collection procedure of the MASCT System does not currently have a procedure-specific Category I CPT code, which is important for reimbursement by Medicare for eligible patients, and which is part of the basis by which insurance companies make reimbursement decisions. A non-specific Category I CPT code, 19499 (unlisted procedure, breast), can be used initially by physicians and insurance carriers will often pay for such procedures with proper documentation. Medicare does not typically reimburse for CPT 19499 procedures.

CPT Code for ForeCYTE Cytology and IHC Biomarker Testing

Category I laboratory procedure codes for cytology and IHC biomarker tests currently exist and reimbursement for these codes by Medicare has been established for 2012 at either $384 or $1,275, depending on the complexity of the test.

Laboratories typically set patient fee schedules at higher rates for the same procedure.

Intellectual Property

As of the date of this report, we own 178 issued patents (56 in the United States and 122 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 United States and 17 issued in foreign countries) and 41 of the patent applications (32 in the U.S. and 9 in foreign countries).

	United States			Foreign/PCT		
Description	Issued [1]	Expiration	Pending [1]	Issued [1]	Expiration	Pending
MASCT (ForeCYTE) Test	6	2016-2031	1	11	2016-2031	1
Microcatheter (FullCYTE) Test	19	2019-2031	2	55	2019-2031	0
NextCYTE Test	0	2031	0	0	2031	1
ArgusCYTE Test	1	2020	0	1	2031	0
Intraductal Treatment Program	11	2030	1	34	2030	1
Carbohydrate biomarkers	1	2022	2	3	2022	0
Microendoscopes	18	2015-2027	32	17	2015-2027	9

(1) The total patents issued or pending, as applicable, exceed the totals in the respective columns because some patents and applications contain claims directed to more than one technology.

MASCT is our registered trademark and we have applied with the United States Patent and Trademark Office for registration of the use of the mark Atossa (word and design), ForeCYTE, FullCYTE, NextCYTE, ArgusCYTE, and Oxy-MASCT.

Competition

We believe that the MASCT System for NAF collection will compete in the medical device product industry with Neomatrix and with academic scientists and physicians who use "homemade" NAF fluid collection systems for research purposes. The Neomatrix device is automated and provides warmth and nipple aspiration simultaneously and is the only non-"homemade" NAF collection system of which we are currently aware. The advantages of the MASCT System compared to the Neomatrix device include a lower acquisition cost and portability. The disadvantages of the MASCT System compared to the Neomatrix device include the requirement that a nurse or other healthcare provider manually operate the device, which may result in increased risks of human error and improper sample collection, and the reduced availability of experience with the device among the medical community.

We believe we will compete in the anatomic pathology laboratory industry based on the patent portfolio for the MASCT System, the technical expertise provided by our focus on diagnoses utilizing NAF, service-focused relationships with referring physicians, and our advanced technology. Based on the scope of our patent claims and the terms of use accompanying the MASCT System, we do not believe that our competitors can transport or process NAF samples collected with the MASCT System without infringing our patent estate and the contractual terms of use.

Laboratories that could process NAF samples not collected with the MASCT System include thousands of local and regional pathology groups, national laboratories, hospital pathologists, and academic laboratories. The largest such competitors include Laboratory Corporation of America and Quest Diagnostics Incorporated.

Characteristics of each source of competition include:

Local and Regional Pathology Groups. Local and regional pathology groups focus on servicing hospitals, often maintaining a staff of pathologists on site that can provide support in the interpretation of certain results. The business models of these laboratories tend to be focused on the efficient delivery of individual tests for a multitude of diseases rather than the comprehensive assessment of only NAF samples, and their target groups tend to be hospital pathologists as opposed to community physicians.

National Laboratories. National laboratories typically offer a full suite of tests for a variety of medical professionals, including general practitioners, hospitals, and pathologists. Their emphasis on providing a broad product portfolio of commoditized tests at the lowest possible price often limits such laboratories' ability to handle difficult or complex specimens requiring special attention, such as NAF samples. In addition, national laboratories typically do not provide ready access to a specialized pathologist for interpretation of test results.

Hospital Pathologists. Pathologists working in a hospital traditionally provide most of the diagnostic services required for hospital patients and sometimes also serve non-hospital patients. Hospital pathologists typically have close interaction with treating physicians, including face-to-face contact. However, hospital pathologists often do not have the depth of experience, specialization, and expertise necessary to perform the specialized services needed for NAF samples.

Academic Laboratories. Academic laboratories generally offer advanced technology and know-how. In fact, the vast majority of NAF sample processing over the last several years has been in academic laboratories primarily for research purposes. These laboratories typically pursue multiple activities and goals, such as research and education, or are generally committed to their own hospitals. Turn-around time for specimen results reporting from academic laboratories is often slow. This limits the attractiveness of academic laboratories to outside physicians who tend to have focused specialized needs and require results to be reported in a timely manner.

Alternative Diagnostic Tools. We also anticipate that the MASCT System will face challenges in market adoption due to the reliance of physicians and other medical professionals on existing diagnostic tools for breast cancer, including mammograms, ultrasound examinations, magnetic resonance imaging, or MRI, fine needle aspiration and core biopsies, among others. These methods are currently more widely used and accepted by physicians, and may continue to be more widely used than our proposed products and services because they are currently reimbursed by third-party payors. In addition, physicians and other medical professionals may view the MASCT System as a screening tool for existing breast cancer, like mammography, rather than as an adjunctive procedure to mammography. As a result, the MASCT System could be deemed to compete directly with mammography, an established procedure, which could impair market adoption of the MASCT System. The advantages of the MASCT System compared to ultrasound, mammography, or magnetic resonance imaging include obtaining cytology and molecular information, the ease and simplicity of the procedure, and the cost, especially compared to MRI. The disadvantages of the MASCT System compared to ultrasound, mammography, and MRI include a lower sensitivity to detection of cancer. The advantage of the MASCT System compared to fine needle aspiration and core biopsies include the ease and simplicity of the procedure, the cost, and the patient comfort. The disadvantages of the MASCT System compared to fine needle aspiration and core biopsies include the reduced sample size and the consequent limitation of the range of molecular studies that can be conducted.

In addition to facing competition with respect to our MASCT System and the processing of collected NAF samples, we also face competition regarding our ArgusCYTE diagnostic test. The detection and analysis of circulating tumor cells, or CTCs, in the blood of patients with breast cancer is an active area of medical research, and many companies and academic research institutes that have substantially greater financial and research resources than we do are involved in such detection and analysis. For example, The Massachusetts General Hospital, Harvard Medical School, received a multimillion dollar grant from Stand Up To Cancer in 2009 for a CTC chip to diagnose cancer. Additionally, Johnson & Johnson markets an FDA-cleared test for breast cancer CTCs and Clariant Laboratories, a GE Healthcare company, also markets a breast cancer CTC test.

Information Systems

We have acquired and implemented a third-party pathology laboratory report management system that supports our operations and physician services. Our information systems, to the extent such systems hold or transmit patient medical information, are believed to operate in compliance with state and federal laws and regulations relating to the privacy and security of patient medical information, including a comprehensive federal law and regulations referred to as HIPAA. While we have endeavored to establish our information systems to be compliant with such laws, including HIPAA, such laws are complex and subject to interpretation.

Government Regulation

United States Medical Device Regulation

The Federal Food, Drug, and Cosmetic Act, or FDCA, and the FDA's implementing regulations, govern registration and listing, manufacturing, labeling, storage, advertising and promotion, sales and distribution, and post-market surveillance. Medical devices and their manufacturers are also subject to inspection by the FDA. The FDCA, supplemented by other federal and state laws, also provides civil and criminal penalties for violations of its provisions. We manufacture and market a medical device that is regulated by the FDA, comparable state agencies and regulatory bodies in other countries. We also operate a clinical and diagnostic laboratory which uses reagents and test kits some of which are regulated medical devices.

The FDA classifies medical devices into one of three classes (Class I, II or III) based on the degree of risk the FDA determines to be associated with a device and the extent of control deemed necessary to ensure the device's safety and effectiveness. Devices requiring fewer controls because they are deemed to pose lower risk are placed in Class I or II. Class I devices are deemed to pose the least risk and are subject only to general controls applicable to all devices, such as requirements for device labeling, premarket notification, and adherence to the FDA's current good manufacturing practice requirements, as reflected in its QSR. Most pathology staining kits, reagents, and routine antibody-based immunohistochemistry protocols which we intend to use initially are Class I devices. Class II devices are intermediate risk devices that are subject to general controls and may also be subject to special controls such as performance standards, product-specific guidance documents, special labeling requirements, patient registries or postmarket surveillance. The MASCT System is a Class II device. Class III devices are those for which insufficient information exists to assure safety and effectiveness solely through general or special controls, and include life-sustaining, life-supporting, or implantable devices, and devices not "substantially equivalent" to a device that is already legally marketed.

Most Class I devices, including the laboratory staining kits and reagents we use, and some Class II devices are exempted by regulation from the 510(k) clearance requirement and can be marketed without prior authorization from FDA. Class I and Class II devices that have not been so exempted are eligible for marketing through the 510(k) clearance pathway. By contrast, devices placed in Class III generally require premarket approval, or PMA, approval prior to commercial marketing. To obtain 510(k) clearance for a medical device, an applicant must submit a premarket notification to the FDA demonstrating that the device is "substantially equivalent" to a predicate device legally marketed in the United States. A device is substantially equivalent if, with respect to the predicate device, it has the same intended use and (i) the same technological characteristics, or (ii) has different technological characteristics and the information submitted demonstrates that the device is as safe and effective as a legally marketed device and does not raise different questions of safety or effectiveness. A showing of substantial equivalence sometimes, but not always, requires clinical data. In the case of the MASCT System, a clinical trial was conducted. Generally, the 510(k) clearance process can exceed 90 days and may extend to a year or more. After a device has received 510(k) clearance for a specific intended use, any modification that could significantly affect its safety or effectiveness, such as a significant change in the design, materials, method of manufacture or intended use, will require a new 510(k) clearance or (if the device as modified is not substantially equivalent to a legally marketed predicate device) PMA approval. While the determination as to whether new authorization is needed is initially left to the manufacturer, the FDA may review this determination and evaluate the regulatory status of the modified product at any time and may require the manufacturer to cease marketing and recall the modified device until 510(k) clearance or PMA approval is obtained. The manufacturer may also be subject to significant regulatory fines or penalties.

All clinical trials must be conducted in accordance with regulations and requirements collectively known as Good Clinical Practice, or GCP. GCPs include the FDA's Investigational Device Exemption, or IDE, regulations, which describe the conduct of clinical trials with medical devices, including the recordkeeping, reporting and monitoring responsibilities of sponsors and investigators, and labeling of investigation devices. They also prohibit promotion, test marketing, or commercialization of an investigational device, and any representation that such a device is safe or effective for the purposes being investigated. GCPs also include FDA's regulations for institutional review board approval and for protection of human subjects (informed consent), as well as disclosure of financial interests by clinical investigators.

Required records and reports are subject to inspection by the FDA. The results of clinical testing may be unfavorable or, even if the intended safety and effectiveness success criteria are achieved, may not be considered sufficient for the FDA to grant approval or clearance of a product. The commencement or completion of clinical trials, if any, that the Company may sponsor, may be delayed or halted, or be inadequate to support approval of a PMA application or clearance of a premarket notification for numerous reasons, including, but not limited to, the following:

- the FDA or other regulatory authorities do not approve a clinical trial protocol or a clinical trial (or a change to a previously approved protocol or trial that requires approval), or place a clinical trial on hold;
- patients do not enroll in clinical trials or follow up at the rate expected;
- institutional review boards and third-party clinical investigators may delay or reject the Company's trial protocol or changes to its trial protocol;
- third-party clinical investigators decline to participate in a trial or do not perform a trial on the Company's anticipated schedule or consistent with the clinical trial protocol, investigator agreements, good clinical practices or other FDA requirements;
- third-party organizations do not perform data collection and analysis in a timely or accurate manner;
- regulatory inspections of clinical trials or manufacturing facilities, which may, among other things, require the Company to undertake corrective action or suspend or terminate its clinical trials;
- changes in governmental regulations or administrative actions;
- the interim or final results of the clinical trial are inconclusive or unfavorable as to safety or effectiveness; and
- the FDA concludes that the Company's trial design is inadequate to demonstrate safety and effectiveness.

After a device is approved and placed in commercial distribution, numerous regulatory requirements apply. These include:

- establishment registration and device listing;
- the QSR, which requires manufacturers to follow design, testing, control, documentation and other quality assurance procedures;
- labeling regulations, which prohibit the promotion of products for unapproved or "off-label" uses and impose other restrictions on labeling;
- medical device reporting regulations, which require that manufacturers report to the FDA if a device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if malfunctions were to recur; and
- corrections and removal reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA caused by the device that may present a risk to health.

The FDA enforces regulatory requirements by conducting periodic, announced and unannounced inspections and market surveillance. Inspections may include the manufacturing facilities of our subcontractors. Failure to comply with applicable regulatory requirements, including those applicable to the conduct of our clinical trials, can result in enforcement action by the FDA, which may lead to any of the following sanctions:

- warning letters or untitled letters;
- fines and civil penalties;
- unanticipated expenditures;
- delays in clearing or approving or refusal to clear or approve products;
- withdrawal or suspension of FDA clearance;
- product recall or seizure;
- orders for physician notification or device repair, replacement, or refund;
- production interruptions;
- operating restrictions;

- injunctions; and
- criminal prosecution.

We and our contract manufacturers, specification developers and suppliers are also required to manufacture the MASCT and Microcatheter Systems in compliance with current Good Manufacturing Practice requirements set forth in the QSR. The QSR requires a quality system for the design, manufacture, packaging, labeling, storage, installation and servicing of marketed devices, and includes extensive requirements with respect to quality management and organization, device design, buildings, equipment, purchase and handling of components, production and process controls, packaging and labeling controls, device evaluation, distribution, installation, complaint handling, servicing and record keeping. The FDA enforces the QSR through periodic announced and unannounced inspections that may include the manufacturing facilities of our subcontractors. If the FDA believes we or any of our contract manufacturers or regulated suppliers is not in compliance with these requirements, it can shut down our manufacturing operations, require recall of the MASCT System, refuse to clear or approve new marketing applications, institute legal proceedings to detain or seize products, enjoin future violations, or assess civil and criminal penalties against us or our officers or other employees. Any such action by the FDA would have a material adverse effect on our business.

We received a Warning Letter ("Letter") from the FDA on February 21, 2013, regarding our MASCT System and MASCT System Collection Test (together, the "System"). The Letter arose from certain FDA findings during a July 2012 inspection, to which we responded in August 2012, explaining why we believed we are in compliance with applicable regulations and/or were implementing changes responsive to the findings of the FDA inspection. The FDA alleges in the Letter that following 510(k) clearance we changed the System in a manner that requires submission of an additional 510(k) notification to the FDA. Specifically, the FDA observes that the Instructions For Use (IFU) in the original 510(k) submission stated that the user must "Wash the collection membrane with fixative solution into the collection vial…" and the current IFU states "…apply one spray of Saccomanno's Fixative to the collection membrane…" and that "this change fixes the NAF specimen to the filter paper rather than washing it into a collection vial." At the time that the changes were made we determined that a new 510(k) was not required in accordance with the FDA's guidance document entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device."

The Letter also raises certain issues with respect to our marketing of the System and our compliance with FDA Good Manufacturing Practices (cGMP) regulations, among other matters. If the FDA does not agree with our position concerning clearance of the System, we may be required to submit and receive clearance of a new 510(k) notice for the current form of the System or revert to marketing the System using the prior NAF processing method.

We responded to the Letter on March 13, 2013, indicating the current actions taken and the timing of commitments we have made for future actions. The FDA could direct other compliance-verification activities or take other actions in connection with matters raised in the Letter, related to our response, and in connection with other matters that the FDA could identify in the future. Until these issues are resolved we may be subject to additional regulatory action by the FDA, and any such actions could disrupt our ongoing business and operations. Our business will be adversely affected if we cannot timely resolve the matters raised in the Letter, or other matters raised by the FDA, to the FDA's satisfaction or if we are not successful in continuing to market our existing System, reverting to marketing the System using the prior NAF processing method or obtaining an additional 510(k) clearance in a timely and cost-effective manner.

We are reasonably confident in our responses to the FDA. Consequently, no provision or liability has been recorded as of December 31, 2012 as a result of the Letter. However, it is at least reasonably possible that our estimate of related liability may change in the near term. Any payments by reason of an adverse determination in this matter will be charged to earnings in the period of determination.

CLIA and State Regulation

As a provider of cytology and molecular diagnostic services, we are required to hold certain federal, state and local licenses, certifications, and permits. Under CLIA, we are required to hold a certificate applicable to the type of work we perform and to comply with certain CLIA-imposed standards. CLIA regulates all laboratories by requiring they be certified by the federal government and comply with various operational, personnel, facilities administration, quality, and proficiency requirements intended to ensure that laboratory testing services are accurate, reliable, and timely. CLIA does not preempt state laws that are more stringent than federal law.

To obtain and renew our CLIA certificates, which we are required to renew every two years, we will be regularly subject to survey and inspection to assess compliance with program standards and may be subject to additional random inspections. Standards for testing under CLIA are based on the level of complexity of the tests performed by the laboratory. Laboratories performing high complexity testing are required to meet more stringent requirements than laboratories performing less complex tests where a CLIA certificate is required. Both NAF cytology and molecular diagnostic testing are high complexity tests. CLIA certification is a prerequisite to be eligible for reimbursement under Medicare and Medicaid.

In addition to CLIA requirements, we are subject to various state laws. CLIA provides that a state may adopt laboratory regulations that are more stringent than those under federal law, and a number of states, including Washington, where the Company is located, have done so. The Washington State Medical Test Site, or MTS, Licensure law was passed in May 1989 to allow the state to regulate clinical laboratory testing. In October 1993, Washington became the first state to have its clinical laboratory licensure program judged by the CMS as equivalent to CLIA and was granted an exemption. In addition, New York, Maryland, Pennsylvania, Rhode Island, and California have implemented their own laboratory regulatory schemes. State laws may require that laboratory personnel meet certain qualifications, specify certain quality controls, or prescribe record maintenance requirements.

Privacy and Security of Health Information and Personal Information; Standard Transactions

We are subject to state and federal laws and implementing regulations relating to the privacy and security of the medical information of the patients it treats. The principal federal legislation is part of HIPAA. Pursuant to HIPAA, the Secretary of the Department of Health and Human Services, or HHS, has issued final regulations designed to improve the efficiency and effectiveness of the healthcare system by facilitating the electronic exchange of information in certain financial and administrative transactions, while protecting the privacy and security of the patient information exchanged. These regulations also confer certain rights on patients regarding their access to and control of their medical records in the hands of healthcare providers such as us.

Four principal regulations have been issued in final form: privacy regulations, security regulations, standards for electronic transactions, and the National Provider Identifier regulations. The HIPAA privacy regulations, which fully came into effect in April 2003, establish comprehensive federal standards with respect to the uses and disclosures of an individual's personal health information, referred to in the privacy regulations as "protected health information," by health plans, healthcare providers, and healthcare clearinghouses. We are a healthcare provider within the meaning of HIPAA. The regulations establish a complex regulatory framework on a variety of subjects, including:

- the circumstances under which uses and disclosures of protected health information are permitted or required without a specific authorization by the patient, including but not limited to treatment purposes, activities to obtain payment for services, and healthcare operations activities;
- a patient's rights to access, amend, and receive an accounting of certain disclosures of protected health information;
- the content of notices of privacy practices for protected health information; and
- administrative, technical and physical safeguards required of entities that use or receive protected health information.

The federal privacy regulations, among other things, restrict our ability to use or disclose protected health information in the form of patient-identifiable laboratory data, without written patient authorization, for purposes other than payment, treatment, or healthcare operations (as defined by HIPAA) except for disclosures for various public policy purposes and other permitted purposes outlined in the privacy regulations. The privacy regulations provide for significant fines and other penalties for wrongful use or disclosure of protected health information, including potential civil and criminal fines and penalties. Although the HIPAA statute and regulations do not expressly provide for a private right of damages, we could incur damages under state laws to private parties for the wrongful use or disclosure of confidential health information or other private personal information.

We have implemented policies and practices that we believe brings us into compliance with the privacy regulations. However, the documentation and process requirements of the privacy regulations are complex and subject to interpretation. Failure to comply with the privacy regulations could subject us to sanctions or penalties, loss of business, and negative publicity.

The HIPAA privacy regulations establish a "floor" of minimum protection for patients as to their medical information and do not supersede state laws that are more stringent. Therefore, we are required to comply with both HIPAA privacy regulations and various state privacy laws. The failure to do so could subject us to regulatory actions, including significant fines or penalties, and to private actions by patients, as well as to adverse publicity and possible loss of business. In addition, federal and state laws and judicial decisions provide individuals with various rights for violation of the privacy of their medical information by healthcare providers such as us.

The final HIPAA security regulations, which establish detailed requirements for physical, administrative, and technical measures for safeguarding protected health information in electronic form, became effective on April 21, 2005. We have employed what we consider to be a reasonable and appropriate level of physical, administrative and technical safeguards for patient information. Failure to comply with the security regulations could subject us to sanctions or penalties and negative publicity.

The final HIPAA regulations for electronic transactions, referred to as the transaction standards, establish uniform standards for certain specific electronic transactions and code sets and mandatory requirements as to data form and data content to be used in connection with common electronic transactions, such as billing claims, remittance advices, enrollment, and eligibility. We have outsourced to a third-party vendor the handling of our billing and collection transactions, to which the transaction standards apply. Failure of the vendor to properly conform to the requirements of the transaction standards could, in addition to possible sanctions and penalties, result in payors not processing transactions submitted on our behalf, including claims for payment.

The HIPAA regulations on adoption of national provider identifiers, or NPI, required healthcare providers to adopt new, unique identifiers for reporting on claims transactions submitted after May 23, 2007. We intend to obtain NPIs for our laboratory facilities and pathologists so that we can report NPIs to Medicare, Medicaid, and other health plans.

The healthcare information of our patients includes social security numbers and other personal information that are not of an exclusively medical nature. The consumer protection laws of a majority of states now require organizations that maintain such personal information to notify each individual if their personal information is accessed by unauthorized persons or organizations, so that the individuals can, among other things, take steps to protect themselves from identity theft. The costs of notification and the adverse publicity can both be significant. Failure to comply with these state consumer protection laws can subject a company to penalties that vary from state to state, but may include significant civil monetary penalties, as well as to private litigation and adverse publicity. California recently enacted legislation that expanded its version of a notification law to cover improper access to medical information generally, and other states may follow suit.

Federal and State Fraud and Abuse Laws

The federal healthcare Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting, or receiving remuneration to induce referrals or in return for purchasing, leasing, ordering, or arranging for the purchase, lease, or order of any healthcare item or service reimbursable under a governmental payor program. The definition of "remuneration" has been broadly interpreted to include anything of value, including gifts, discounts, the furnishing of supplies or equipment, credit arrangements, payments of cash, waivers of payments, ownership interests, opportunity to earn income, and providing anything at less than its fair market value. The Anti-Kickback Statute is broad, and it prohibits many arrangements and practices that are lawful in businesses outside of the healthcare industry. Recognizing that the Anti-Kickback Statute is broad and may technically prohibit many innocuous or beneficial arrangements within the healthcare industry, HHS has issued a series of regulatory "safe harbors." These safe harbor regulations set forth certain provisions that, if met, will provide healthcare providers and other parties with an affirmative defense against prosecution under the federal Anti-Kickback Statute. Although full compliance with these provisions ensures against prosecution under the federal Anti-Kickback Statute, the failure of a transaction or arrangement to fit within a specific safe harbor does not necessarily mean that the transaction or arrangement is illegal or that prosecution under the federal Anti-Kickback Statute will be pursued.

From time to time, the Office of Inspector General, or OIG, issues alerts and other guidance on certain practices in the healthcare industry. In October 1994, the OIG issued a Special Fraud Alert on arrangements for the provision of clinical laboratory services. The Fraud Alert set forth a number of practices allegedly engaged in by some clinical laboratories and healthcare providers that raise issues under the "fraud and abuse" laws, including the Anti-Kickback Statute. These practices include: (i) laboratories providing employees to furnish valuable services for physicians (other than collecting patient specimens for testing for the laboratory) that are typically the responsibility of the physicians' staff; (ii) providing free testing to a physician's managed care patients in situations where the referring physicians benefit from such reduced laboratory utilization; (iii) providing free pick-up and disposal of bio-hazardous waste for physicians for items unrelated to a laboratory's testing services; (iv) providing general-use facsimile machines or computers to physicians that are not exclusively used in connection with the laboratory services; and (v) providing free testing for healthcare providers, their families, and their employees (professional courtesy testing).

The OIG emphasized in the Special Fraud Alert that when one purpose of an arrangement is to induce referrals of program-reimbursed laboratory testing, both the clinical laboratory and the healthcare provider, or physician, may be liable under the Anti-Kickback Statute, and may be subject to criminal prosecution and exclusion from participation in the Medicare and Medicaid programs.

Another issue about which the OIG has expressed concern involves the provision of discounts on laboratory services billed to customers in return for the referral of more lucrative federal healthcare program business. In a 1999 Advisory Opinion, the OIG concluded that a proposed arrangement whereby a laboratory would offer physicians significant discounts on non-federal healthcare program laboratory tests might violate the Anti-Kickback Statute. The OIG reasoned that the laboratory could be viewed as providing such discounts to the physician in exchange for referrals by the physician of business to be billed by the laboratory to Medicare at non-discounted rates. The OIG indicated that the arrangement would not qualify for protection under the discount safe harbor because Medicare and Medicaid would not get the benefit of the discount. Subsequently, in a year 2000 correspondence, the OIG stated that the Anti-Kickback Statute may be violated if there were linkage between the discount offered to the physician and the physician's referrals of tests covered under a federal healthcare program that would be billed by the laboratory directly. Where there was evidence of such linkage, the arrangement would be considered "suspect" if the charge to the physician was below the laboratory's "average fully loaded costs" of the test.

Generally, arrangements that would be considered suspect, and possible violations under the Anti-Kickback Statute, include arrangements between a clinical laboratory and a physician (or related organizations or individuals) in which the laboratory would (1) provide items or services to the physician or other referral source without charge, or for amounts that are less than their fair market value; (2) pay the physician or other referral source amounts that are in excess of the fair market value of items or services that were provided; or (3) enter into an arrangement with a physician or other entity because it is a current or potential referral source. HIPAA also applies to fraud and false statements. HIPAA created two new federal crimes: healthcare fraud and false statements relating to healthcare matters. The healthcare fraud statute prohibits knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private payors. A violation of this statute is a felony and may result in fines, imprisonment, or exclusion from governmental payor programs such as the Medicare and Medicaid programs. The false statements statute prohibits knowingly and willfully falsifying, concealing, or covering up a material fact or making any materially false, fictitious, or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items, or services, as well as the retention of any overpayment. A violation of this statute is a felony and may result in fines or imprisonment or exclusion from governmental payor programs.

Physician Referral Prohibitions

Under a federal law directed at "self-referral," commonly known as the Stark Law, prohibitions exist, with certain exceptions, on Medicare and Medicaid payments for laboratory tests referred by physicians who personally, or through a family member, have an investment interest in, or a compensation arrangement with, the laboratory performing the tests. A person who engages in a scheme to circumvent the Stark Law's referral prohibition may be fined up to $100,000 for each such arrangement or scheme. In addition, any person who presents or causes to be presented a claim to the Medicare or Medicaid programs in violation of the Stark Law is subject to civil monetary penalties of up to $15,000 per bill submission, an assessment of up to three times the amount claimed, and possible exclusion from participation in federal governmental payor programs. Bills submitted in violation of the Stark Law may not be paid by Medicare or Medicaid, and any person collecting any amounts with respect to any such prohibited bill is obligated to refund such amounts.

Any arrangement between a laboratory and a physician or physicians' practice that involves remuneration will prohibit the laboratory from obtaining payment for services resulting from the physicians' referrals, unless the arrangement is protected by an exception to the self-referral prohibition or a provision stating that the particular arrangement would not result in remuneration. Among other things, a laboratory's provision of any item, device, or supply to a physician would result in a Stark Law violation unless it was used only to collect, transport, process, or store specimens for the laboratory, or was used only to order tests or procedures or communicate related results. This may preclude a laboratory's provision of fax machines and computers that may be used for unrelated purposes. Most arrangements involving physicians that would violate the Anti-Kickback Statute would also violate the Stark Law. Many states also have "self-referral" and other laws that are not limited to Medicare and Medicaid referrals. These laws may prohibit arrangements which are not prohibited by the Stark Law, such as a laboratory's placement of a phlebotomist in a physician's office to collect specimens for the laboratory. Finally, recent amendments to these laws require self-disclosure of violations by providers.

Discriminatory Billing Prohibition

In response to competitive pressures, we will be increasingly required to offer discounted pricing arrangements to managed care payors and physicians and other referral services. Discounts to referral sources raise issues under the Anti-Kickback Statute. Any discounted charge below the amount that Medicare or Medicaid would pay for a service also raises issues under Medicare's discriminatory billing prohibition. The Medicare statute permits the government to exclude a laboratory from participation in federal healthcare programs if it charges Medicare or Medicaid "substantially in excess" of its usual charges in the absence of "good cause." In 2000, the OIG stated in informal correspondence that the prohibition was violated only if the laboratory's charge to Medicare was substantially more than the "median non-Medicare/ — Medicaid charge." On September 15, 2003, the OIG issued a notice of proposed rulemaking addressing the statutory prohibition. Under the proposed rule, a provider's charge to Medicare or Medicaid would be considered "substantially in excess of [its] usual charges" if it was more than 120% of the provider's mean or median charge for the service. The proposed rule was withdrawn in June 2007. At that time, the OIG stated that it would continue to evaluate billing patterns of individuals and entities on a case-by-case basis.

Corporate Practice of Medicine

Our contractual relationships with the licensed healthcare providers are subject to regulatory oversight, mainly by state licensing authorities. In certain states, for example, limitations may apply to the relationship with the pathologists that we intend to employ or engage, particularly in terms of the degree of control that we exercise or have the power to exercise over the practice of medicine by those pathologists. A number of states, including New York, Texas, and California, have enacted laws prohibiting business corporations, such as us, from practicing medicine and employing or engaging physicians to practice medicine. These requirements are generally imposed by state law in the states in which we operate, vary from state to state, and are not always consistent among states. In addition, these requirements are subject to broad powers of interpretation and enforcement by state regulators. Some of these requirements may apply to us even if we do not have a physical presence in the state, based solely on the employment of a healthcare provider licensed in the state or the provision of services to a resident of the state. We believe that we operate in material compliance with these requirements. However, failure to comply can lead to action against us and the licensed healthcare professionals that we employ, fines or penalties, receipt of cease and desist orders from state regulators, loss of healthcare professionals' licenses or permits, the need to make changes to the terms of engagement of those professionals that interfere with our business, and other material adverse consequences.

State Laboratory Licensure

We are certified by CLIA and have been licensed in the states of California, Florida, Maryland, Rhode Island, and Washington. We are 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, and are currently processing samples from New York under recognized exemption provisions. All other states do not have specific state licensing requirements and/or recognize our Federal CLIA certification as an out-of-state laboratory. Similarly, many of the states from which we will solicit specimens require that a physician interpreting specimens from that state be licensed by that particular state, irrespective of where the services are to be provided. In the absence of such a state license, the physician may be considered to be engaged in the unlicensed practice of medicine.

We may become aware from time to time of other states that require out-of-state laboratories or physicians to obtain licensure in order to accept specimens from the state, and it is possible that other states do have such requirements or will have such requirements in the future. We intend to follow instructions from the state regulators as how to comply with such requirements.

Referrals after Becoming a Public Company

Now that our stock is publicly traded, we are not able to accept referrals from physicians who own, directly or indirectly, shares of our stock unless we comply with the Stark Law exception for publicly traded securities. This requires, among other things, $75 million in stockholders' equity (total assets minus total liabilities). The parallel safe harbor requires, among other things, $50 million in undepreciated net tangible assets, in order for any distributions to such stockholders to be protected under the Anti-Kickback Statute.

Other Regulatory Requirements

Our laboratory is subject to federal, state, and local regulations relating to the handling and disposal of regulated medical waste, hazardous waste, and biohazardous waste, including chemical, biological agents and compounds, and human tissue. We use outside vendors who are contractually obligated to comply with applicable laws and regulations to dispose of such waste. These vendors are licensed or otherwise qualified to handle and dispose of such waste.

The Occupational Safety and Health Administration, or OSHA, has established extensive requirements relating to workplace safety for healthcare employers, including requirements mandating work practice controls, protective clothing and equipment, training, medical follow-up, vaccinations, and other measures designed to minimize exposure to, and transmission of, blood-borne pathogens. Pursuant to its authority under the FDCA, the FDA has regulatory responsibility over instruments, test kits, reagents, and other devices used to perform diagnostic testing by laboratories such as ours. Specifically, the manufacturers and suppliers of analyte specific reagents, or ASRs, which we will obtain for use in diagnostic tests, are subject to regulation by the FDA and are required to register their establishments with the FDA, to conform manufacturing operations to the FDA's Quality System Regulation and to comply with certain reporting and other record keeping requirements. The FDA also regulates the sale or distribution, in interstate commerce, of products classified as medical devices under the FDCA, including *in vitro* diagnostic test kits. Such devices must undergo premarket review by the FDA prior to commercialization unless the device is of a type exempted from such review by statute or pursuant to the FDA's exercise of enforcement discretion.

The FDA maintains that it has authority to regulate the development and use of LDTs or "home brews" as medical devices, but to date has not exercised its authority with respect to "home brew" tests as a matter of enforcement discretion. The FDA regularly considers the application of additional regulatory controls over the sale of ASRs and the development and use of "home brews" by laboratories such as ours.

The FDA has conducted public hearings to discuss oversight of LDTs. While the outcome of those hearings is unknown, it is probable that some form of pre-market notification or approval process will become a requirement for certain LDTs. Pre-market notification or approval of our future LDTs would be costly and delay our ability to commercialize such tests.

Compliance Program

Compliance with government rules and regulations is a significant concern throughout the industry, in part due to evolving interpretations of these rules and regulations. We seek to conduct our business in compliance with all statutes and regulations applicable to our operations. To this end, we have established a compliance program that reviews for regulatory compliance procedures, policies, and facilities throughout our business.

Legal Proceedings

On June 30, 2011, Robert Kelly, our former President, filed a counterclaim against the us in an arbitration proceeding, alleging breach of contract in connection with the termination of a consulting agreement between Mr. Kelly (dba Pitslayer LLC) and us that was entered into in July 2010 in connection with his resignation as President and a director. The consulting agreement was terminated by us in September 2010. Mr. Kelly seeks $450,000 in compensatory damages, which is the amount he claims would have been earned had the consulting agreement been fulfilled to completion.

On December 11, 2012, Mr. Kelly filed a complaint in the United States District Court, Western Division of Washington seeking compensatory damages, interest and attorneys' fees related to the termination of Mr. Kelly's consulting contract and the rescission of shares issued to him in July 2010 in connection with his resignation as President and a director. The specific amount of damages sought is to be proven at trial and is not specified.

On February 26, 2013, Mr. Victor Cononi filed a complaint in the United States District Court, Western Division of Washington seeking compensatory damages, interest and attorneys' fees related to the rescission of shares issued to him in July 2010 in connection with Mr. Kelly's resignation as President and a director. Mr. Cononi is the father of Mr. Kelly's paramour. The specific amount of damages sought is to be proven at trial and is not specified.

A hearing in the arbitration has been postponed pending certain procedures in the above Western Division action and may be delayed further to accommodate other third party civil and federal criminal proceedings alleging securities and wire fraud that have been brought against Mr. Kelly with respect to his prior employment and predating his service with us.

We are reasonably confident in our defenses to Mr. Kelly's and Mr. Cononi's claims. Consequently, no provision or liability has been recorded for these claims as of December 31, 2012. However, it is at least reasonably possible that the our estimate of liability may change in the near term. Any payments by reason of an adverse determination in this matter will be charged to earnings in the period of determination.

Employees

As of the date of this report, we employed three executive officers and seven other full-time employees. We expect that we will hire more employees as we expand.

Insurance

We currently maintain director's and officer's insurance, key-man life insurance on our Chief Executive Officer, commercial general and office premises liability insurance, and product errors and omissions liability insurance for our products and services.

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.

Scientific and Industry Background

Breast Anatomy and Nipple Aspirate Fluid Collection

The female breast has two main components: milk-producing, or glandular, tissue (lobes and ducts) and connective/fatty tissue. The breast is divided into 5 to 7 lobes that extend outward from the nipple and contain clusters of milk-producing glands. The lobes are further divided into smaller compartments called lobules. Each cluster drains into a duct, which connects the lobules and the nipple. In the ducts, cells closest to the outer portions of the lobules are called luminal cells and those deeper in the duct wall are called basal cells. The molecular-based determination of whether cells are luminal or basal in origin aids in the sub-typing of pre-cancerous changes and cancers. The breast is held together by fatty connective tissue, which provides support and contains nerves as well as blood and lymphatic vessels.

Since the early studies conducted in the 1950s by Dr. George Papanicolaou, the inventor of the "Pap smear" for cervical cancer, it has been understood that adult non-pregnant, non-lactating women continuously secrete fluid into the milk ducts of the breast. This fluid does not normally escape because the nipple orifices are occluded by smooth muscle contraction and dried secretions. This fluid contains several cell types, including breast duct cells that are shed, which may be normal, hyperplastic, atypical, or even malignant. The fluid also contains molecular diagnostic biomarkers, including associated proteins, complex lipids, ribonucleic acid, or RNA, and deoxyribonucleic acid, or DNA.

A number of medical devices have been designed over the years that apply negative pressure to the nipple to induce the expression of NAF, which is then collected by carefully touching a capillary tube to any apparent drops of NAF. The medical literature reports that in general, these devices are successful in obtaining NAF from 39% to 66% of all patients and that this sample collection variability has prevented the routine adoption of NAF cytology for breast cancer screening.

The MASCT System was designed to overcome this shortcoming by placing a hydrophilic, or water seeking, membrane in contact with the nipple during the cycles of negative pressure to "wick" fluid from the orifice of the ducts by capillary action, thereby increasing the frequency of obtaining NAF in women.

The Role of Atypical Ductal Hyperplasia as a Precursor to Breast Cancer

Atypical ductal hyperplasia, or ADH, is a condition in which the cells lining the breast duct grow excessively and abnormally. Without other risk factors, it produces up to a five-fold increased risk of breast cancer. With a family history of breast cancer, a diagnosis of ADH increases the risk of breast cancer 11- to 22-fold, and in one study, one-third of the women with a biopsy of ADH had a clinically inapparent malignancy, or occult cancer, growing nearby. Another study examined changes in chromosome markers in ADH that are typical for invasive ductal cancer to determine if ADH was monoclonal for these changes, as expected of cancer, or polyclonal, as expected of hyperplasia, or excessive cell proliferation. The results of this study showed that 40% of ADH was monoclonal and had the hallmarks of a cancerous growth.

The analysis of NAF for these chromosomal changes and the changes in expression of related proteins may help determine the malignant or non-malignant properties of ADH in a particular patient and thus provide information allowing a personalized medicine therapeutic approach.

The Role of Immunohistochemistry (IHC) in the Molecular Classification of Breast Cancer and Pre-Cancerous Lesions

Standard pathology and cytology criteria to classify breast cancer and pre-cancerous changes have limitations in predicting tumor behavior, sensitivity to molecular targeted treatments, such as Herceptin (trastuzumab), or the development of drug resistance. A method of predicting tumor behavior and treatment response that involves identifying molecular biomarkers in breast tissue is immunohistochemistry, or IHC. IHC is the process of localizing antigens (e.g. proteins) in cells of a tissue section exploiting the principle of antibodies binding specifically to antigens in cells. Specific molecular markers are characteristic of particular cellular events such as proliferation or cell death. Visualizing an antibody-antigen interaction can be accomplished in a number of ways. In the most common instance, an antibody is conjugated to an enzyme, such as peroxidase, that can catalyze a color-producing reaction. The use of IHC has become standard of care in many clinical settings, for example, the measurement of estrogen or progesterone receptors or HER2 antigens in breast cancer.

In May 2010, an international study from 21 academic institutions involving 42 investigators was published, describing the IHC-based molecular sub-typing of breast cancers from 10,159 women and the correlation with survival over 15 years. Five IHC biomarkers were used to identify six molecular sub-types. The five IHC markers were: the estrogen receptor and the progesterone receptors (two hormone receptors expressed by luminal cells), the human epidermal growth factors receptor-2 (HER2, a protein marker used to select specific adjuvant therapies), and cytokeratin 5/6 (CK5/6) and EGFR (proteins expressed by basal cells). The incidence of each sub-type, and the treatment options available, are shown in the following table:

Molecular Subtype	Incidence	Treatment Options
Luminal 1, Basal Negative	60%	Tamoxifen, Raloxifene
Luminal 1, Basal Positive	6%	Tamoxifen, Raloxifene, EGFR inhibitors
Luminal 2, Basal Negative	6%	Tamoxifen, Raloxifene, Trastuzumab
Non-Luminal HER2+	6%	Trastuzumab
Core Basal Subgroup	9%	EGFR inhibitors
Five Negative Phenotype	7%	Non-receptor targeted chemotherapy

The six IHC molecular subtypes had very different five and 15 year survival rates.

These and other findings indicate that the six subtypes of breast cancer defined by the expression of five immunohistochemical markers have distinct biological characteristics that are associated with important differences in short-term and long-term outcomes. The application of these markers in the clinical setting could improve the targeting of adjuvant therapies to those women most likely to benefit.

These same markers have been studied in pre-cancerous changes and have been found useful in distinguishing future biological behavior of otherwise cytologically indistinct samples. For example, CK5/6 expression in usual ductal hyperplasia is associated with an increased risk of later development of cancer. Similarly, estrogen or progesterone receptor, HER2, and EGFR expression in a setting of hyperplasia are found in lesions that more frequently progress to breast cancer. In fact, ADH and usual ductal hyperplasia can be distinguished by IHC staining in cases where the cytology is indistinguishable. Thus, IHC testing on NAF samples with pre-cancerous changes can provide information about the possibility of future progression to breast cancer.

The Role of NAF Cytology and IHC in the Diagnosis and Treatment of Atypical Ductal Hyperplasia

In a study of women with normal mammograms who were undergoing breast reduction surgery, which was conducted at the Virginia Mason Medical Center in Seattle, Washington and published in *Plastic and Reconstructive Surgery* in October 2009, the incidence of ADH was found to be 4.4%. A separate study conducted in 2003 of 824 women found an incidence of ADH of 7.4% by biopsy. ADH can be definitively diagnosed only by NAF analysis or a breast tissue biopsy. In a study of approximately 2.5 million screening mammograms done between 1996 and 2005 and collected from mammography registries participating in the Breast Cancer Surveillance Consortium, the incidence of biopsy-proven ADH was 0.1%, suggesting that the use of biopsies in conjunction with screening mammography fails to detect ADH in over 97% of patients.

A comprehensive study of the predictive value of NAF cytology for identifying women at risk for breast cancer was conducted at the University of California at San Francisco over a 19-year period. This study, conducted by Margaret Wrensch and others at the University of California San Francisco, showed in two studies, the first with a sample size of 4,046 women and the second with a sample size of 3,627, that women with abnormal cytology in breast fluid obtained by nipple aspiration had an increased relative risk of breast cancer compared with women from whom fluid was not obtained and with women whose fluid had normal cytology. The nipple aspirate fluids were collected from women in the San Francisco Bay Area during the period from 1972 through 1991, the women were classified according to the most severe epithelial cytology observed in fluid specimens, and breast cancer incidence through March 1999 was determined. The groups were stratified into women with acellular, normal, hyperplasia, or atypical NAF cytology and the incidence of breast cancer determined in the two groups over an average of 21 and nine years follow-up, respectively. The incidence of hyperplasia by NAF cytology was 13.6% and the incidence of ADH was 1.6%. Breast cancer occurred in 3.7% of the women with acellular cytology and in 8.2% and 11.0% of the women with hyperplasia and atypia, respectively.

Drug therapy clinical trials for preventing breast cancer in high risk women are called chemoprevention trials. In a five-year chemoprevention study of over 19,700 women with ADH or other factors that placed them at a high risk for invasive breast cancer, the use of either tamoxifen or raloxifene, drugs that block or interfere with the actions of estrogen receptors, reduced the incidence of breast cancer by approximately 50%. A separate study of raloxifene versus placebo showed a 72% reduction in cancer incidence at four years and a 66% reduction at eight years in women at high risk for invasive breast cancer.

In a study of NAF specimens in 33 women at the start and six months after taking either tamoxifen or raloxifene, NAF cytology was unchanged in 85%, worsened in 4%, and improved in 11% while the biomarker PSA, which has been shown to be controlled by sex hormones and inversely associated with breast cancer, increased from abnormally low (37 ng/L) to within the normal range (112 ng/L) during treatment. United States patent 7,128,877, owned by the Company, covers the testing of NAF for the biomarker PSA. Other classes of drugs, including inhibitors of aromatase, an enzyme involved in making estrogen, are being tested or considered for testing in breast cancer chemoprevention trials. The Company believes that increased use of pharmaceutical treatments with chemopreventive agents in high risk women will lead to more NAF cytology studies to both diagnose ADH and follow the effects of treatment.

Finally, changes in diet and/or the use of dietary supplements are considered to have a possible impact on breast cancer occurrence and can potentially change the cytology or the presence of biomarkers in NAF. A study of the effect of dietary intervention in 71 women over a one-year period was conducted. The probability of obtaining a cellular NAF cytology increased with dietary fat intake, reaching over seven-fold increase for the highest to lowest quartile of fat intake. Furthermore, cellular NAF decreased with increasing plasma levels of dietary supplement antioxidants, lutein and alpha-carotene. The National Cancer Institute, or NCI, is currently sponsoring seven studies of the use of NAF sample collection and analysis of cytology and molecular biomarkers as study endpoints to monitor the efficacy of chemoprevention clinical trials using pharmaceuticals or dietary supplements. The Company believes the successful outcome of one or more of these studies could increase the use of NAF analysis.

Risk Stratification with Duct Cytology

Breast cancer risk stratification is becoming increasingly important as additional screening and prevention options are now available for women at different levels of risk. For example, use of screening breast MRI, tamoxifen chemoprevention, and genetic counseling and testing for hereditary breast cancer are appropriate for some women at increased susceptibility. The National Comprehensive Cancer Network, or NCCN, sets risk thresholds as: “Normal Risk,” defined as less than 15% lifetime risk; “Intermediate Risk,” as 15-20% lifetime risk; and “High Risk,” as greater than 20% lifetime risk.

The ForeCYTE Breast Health Test uses an established algorithm based on family history (including cousins with breast cancer and unaffected female relatives), personal medical data (including height (premenopausal) and BMI (postmenopausal) and use of hormone replacement therapy, and ductal cytology to provide estimates of BRCA1/2 mutation probability in addition to empiric age adjusted 10-year and lifetime breast cancer risk. In contrast, other algorithms use only atypia, hyperplasia, or lobular carcinoma in situ to increase the risk estimate in the model. Our model was developed using previously published data on the effects of familial and personal risk factors. Genetic risk is predicted assuming two autosomal-dominant loci — BRCA1/2 and a hypothetical low-penetrance dominant gene. The relative risk based on personal factors is used to adjust the calculated genetic absolute risk via a proportional hazard model. According to a peer-reviewed study published in *Oncology Genetics* in August 2009, this algorithm appeared the most consistently accurate for the prediction of breast cancer.

The Role of Ductal Lavage in Assessing Women at High Risk of Breast Cancer

Ductal lavage is a washing procedure that can remove fluid found in the individual breast ducts. The procedure involves inserting a small catheter into the ductal openings in the nipple and washing out cells from inside the duct. The cells are then analyzed to assess if they are normal or abnormal and the fluid can be tested for biomarkers of pre-cancerous and cancerous changes. We are conducting research using next-generation sequencing techniques to examine the genomic changes that occur in pre-cancerous hyperplasia and DCIS in the cells obtained from lavage fluid. Based on the generally accepted hypothesis that each of the five to seven breast ducts arises from a single cell during fetal development and is thus clonally distinct, breast cancer can be thought of as a “sick duct” disease. Knowing which duct is affected by precursors to breast cancer is the requisite diagnostic information to treating the condition with intraductal therapy. An October 2011 report from the Johns Hopkins Medical School demonstrated prevention of breast cancer in rats with intraductal but not systemic chemotherapy and the successful treatment of 17 women with breast cancer who subsequently received surgery.

Predicting Treatment and Recurrence Using Tumor Tissue Transcriptome Data

Gene expression is a measure of a gene's activity, which is determined by the number of times it is transcribed into mRNA and finally by the protein it encodes. A snapshot of a tissue's global gene activity (or expression) is captured by DNA microarray technology, by reverse transcription polymerase chain reaction, or RT-PCR, or by RNASeq, also called Whole Transcriptome Shotgun Sequencing, and is called a transcriptome. Lists of genes associated with prognoses, responses to various treatments or phenotypes, are called "gene profiles" or "gene signatures." The four major test platforms used for detecting gene profiles are immunohistochemistry (IHC), fluorescent in situ hybridization (FISH), quantitative reverse transcriptase polymerase chain reaction (qRT-PCR), and cDNA microarray (quantitative cDNA detection). While the former two platforms are semiquantitative and well established for detection of ER and HER2 status at low costs, the latter two are quantitative methods that require complex statistical methods to avoid false discovery. These two methodologies provide highly standardized and reproducible outcomes of uncertain prognostic value at this point. In addition, IHC has the advantage of directly measuring protein expression, not just mRNA copy numbers, and it provides a visualization of the difference of protein localization and modification, which gene profiling cannot.

Breast cancer is a complex disease characterized by a number of genetic and epigenetic abnormalities. Patients associated with similar clinical and pathological parameters may have very different tumor profiles at the molecular level and may respond differently to treatment. Genome-wide expression profiling of tumors has become an important tool to identify gene sets and gene signatures that can be used to predict clinical endpoints, such as survival and therapy response. A number of tumor classification algorithms based on gene expression profiles have been proposed using clinical data or known biological class labels to build predictive models for outcome: the 70-gene signature MammaPrint, the 16-gene signature of Oncotype Dx, and the Genomic Grade Index.

In a peer-reviewed publication in *PLoS One* in March 2011, a statistical framework to explore whether combination of the information from such sets may improve prediction of recurrence and breast cancer specific death in early-stage breast cancers was established. Microarray data from two clinically similar cohorts of breast cancer patients are used as training (n = 123) and test set (n = 81), respectively. Gene sets from eleven previously published gene signatures are included in the study.

Combining the predictive strength of multiple gene signatures improved prediction of breast cancer survival.

Monitoring Recurrence and Assisting Treatment Decisions from Analysis of Circulating Tumor Cells

Among women with early breast cancer, the presence of circulating tumor cells (cancer cells in the bloodstream, which are also called CTCs) increased the risk of cancer recurrence and shortened survival. Among women with metastatic breast cancer (cancer that has spread to other sites in the body), detection of cancer cells in the bloodstream has been linked with shorter time to cancer progression and shorter survival.

To evaluate the impact of CTCs among women with early breast cancer, researchers evaluated more than 2,000 patients. The test to detect CTCs was performed after surgery and before the start of chemotherapy. CTCs were detected in 21.5% of patients. Women with CTCs were more likely to have node-positive breast cancer than women without CTCs. Compared with women with no CTCs, women with one to four CTCs were almost twice as likely to experience cancer recurrence and death. The presence of five or more CTCs was linked with a fourfold increase in recurrence risk and a threefold increase in risk of death. These results suggest that detection of CTCs may provide information about recurrence risk and prognosis among women with early breast cancer.

CTCs may also be an indicator for therapeutic efficacy. During chemotherapy the continuous appearance of CTCs in blood would only occur if there was a persistent proliferation process. This may be halted with a successful therapy (stable disease) or might even be reduced (remission). There, the source of CTCs and their dissemination would have been removed, which is then associated with the disappearance of CTCs from blood.

ITEM 1A. RISK FACTORS

In addition to other information in this report, the following factors should be considered carefully in evaluating an investment in 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. 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.

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 did not begin the national launch of the ForeCYTE test until January 2013. 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 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 consolidated 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.

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

We expect to spend substantial amounts of capital to:

- 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, including our intraductal treatment program; and
- develop and commercialize the assets we recently acquired from Acueity Healthcare, Inc.

We also expect that we 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. As of December 31, 2012, we had cash and cash equivalents of $1.7 million. Although we received net proceeds of approximately $950,000 from the sale of shares of common stock to Aspire on March 27, 2013, we will need substantial additional capital to continue to operate our business.

Our purchase agreement with Aspire has a number of limitations on our ability to sell shares to them; for example, we must first have a registration statement covering the shares declared effective by the SEC and the registration statement must remain effective. Any sales of shares to Aspire will be limited by market conditions and the number of shares that we may be able to sell will be reduced if the volume of our common stock declines. We have not identified other sources for 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. 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 losses of approximately $9.7 million from our incorporation in April 2009 through December 31, 2012. We have received $483,342 in revenue as of December 31, 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 small quantities and because our 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 and to offer rebates of the purchase price to attract market awareness. This practice of selling our MASCT System substantially below its cost and offering rebates 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 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, including sales of shares of common stock to Aspire, 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 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 gai market acceptance for the MASCT System and our ForeCYTE and ArgusCYTE Tests, we will need to demonstrate to physicians and other healthca professionals the benefits of the MASCT System and its practical and economic application for their particular practice. Despite FDA clearance for th 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 and rebates to managed care payors and physicians and other referral services in response to competitive pressures and to promote early adoption.

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 and to promote early adoption, we will likely be increasingly required to offer discounted pricing arrangements and rebates 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 and rebates, 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 and rebates 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.

We have established the CLIA-certified National Reference Laboratory for Breast Health as a wholly-owned subsidiary and we rely on this physica facility in Seattle, Washington for the testing of patient samples. Our facility has received California, Florida, Maryland, Rhode Island, and Washington state laboratory licenses, and federal CLIA laboratory certification. However, our management team does not have significant prior experience with establishing and managing this type of laboratory facility. In addition, certain pieces of laboratory equipment required for the performance of our testing and analytical services may be difficult and costly to replace, and may require significant replacement lead-time. In the event that we are unable to maintain the laboratory facility in good working order, or if such laboratory or equipment is adversely affected by periodic malfunctions or man-made or natural disasters, then we may be unable to conduct business and meet potential customer demands for a significant period of time, which could negatively affect revenue and our long-term prospects.

The loss of the services of our Chief Executive Officer could adversely affect our business.

Our success is dependent in large part upon the ability to execute our business plan, manufacture the MASCT System, maintain our clinical and diagnosti laboratory, and attract and retain highly skilled professional, sales and marketing personnel. In particular, due to the relatively early stage of our business, our future success is highly dependent on the services of Steven C. Quay, our Chief Executive Officer and founder, who provides much of the necessary experience to execute our business plan. The loss of his services for any reason could impede our ability to achieve our objectives, such as the commercialization of the MASCT System and the development of a core of healthcare professionals who use the MASCT System, particularly initially, as w seek to build a reputation among physicians and clinicians.

We may experience difficulty in locating, attracting, and retaining experienced and qualified personnel, which could adversely affect our business.

We will need to attract, retain, and motivate experienced anatomic pathologists, cytologists, histotechnologists, skilled laboratory and information technology staff, experienced sales representatives, and other personnel, particularly in the Greater Seattle area as we expand our commercialization activities. These employees may not be available in this geographic region. In addition, competition for these employees is intense and recruiting and retaining skilled employees is difficult, particularly for a development-stage organization such as ours. If we are unable to attract and retain qualified personnel, revenue and earnings may be adversely affected.

We have limited prior experience with commercializing any products or services, and will need to establish a sophisticated sales and marketing effort in order to be successful.

We intend to build a network of national, regional, specialty distributors, each with a staff of independent sales representatives with experience in women's health products to target physicians and mammography clinics in the United States. Marketing our products to physicians and healthcare professionals will require us to educate such professionals on the comparative advantages of our products over other methods currently used for the detection and diagnosis of breast cancer. Experienced independent sales representatives may be difficult to locate and all sales representatives will need to undergo extensive training. We will need to incur significant costs to build, train, supervise and effectively deploy this independent sales force. We cannot be certain that we will be able to recruit sufficiently skilled sales representatives or that any new sales representatives will ultimately become productive. Independent sales representatives may carry competing products or products that provide a better financial return to them and therefore may not emphasize our products. If we are unable to recruit, train and retain qualified and productive independent sales personnel, our ability to successfully commercialize our products and services will be impaired.

Although we entered into a co-exclusive marketing agreement with Clarity in September 2012 for the supply and distribution of the MASCT System under the Clarity brand, and we launched the ForeCYTE Breast Health Test with Clarity in January 2013, Clarity and its distributors 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.

We use third-party suppliers for the production of the MASCT and Microcatheter Systems, which are currently manufactured in small quantities. If such suppliers are not capable of producing quantities of these systems sufficient for commercial sale when we are ready, we may not generate significant revenue or become profitable.

We rely on third-party suppliers for the continued manufacture and supply of the MASCT and Microcatheter Systems, including the NAF collection device and patient collection kits and for the laboratory instruments, equipment, consumable supplies, and other materials necessary to perform the specialized diagnostic tests. If our third-party suppliers cannot produce the MASCT or Microcatheter Systems in quantities sufficient for our commercial needs on acceptable terms when needed, we may be unable to commercialize the MASCT System and Microcatheter System and generate revenue from their sales as planned. In addition, if at any time after commercialization of our products, we are unable to secure essential equipment or supplies in a timely, reliable and cost-effective manner, we could experience disruptions in our services that could adversely affect anticipated results.

Currently Medicare and certain insurance carriers will not reimburse for the NAF collection procedure, which could slow or limit adoption of the MASCT System or prevent us from pricing the MASCT System at desired levels.

The Halo® Breast Pap Test, an NAF collection device similar to the MASCT System, is being marketed by Halo Healthcare, Inc. (formerly Neomatrix, LLC) of Irvine, California (Halo Healthcare, Inc. owns the registered trademark Halo®). Certain insurance carriers do not currently reimburse for the HALO System procedures. For example, in September 2010, United Healthcare published a policy statement indicating that it would not cover the costs of these procedures because it believes there is insufficient clinical evidence to support medical efficacy, based on its conclusion that there is inadequate clinical evidence that automated nipple aspiration either allows for better clinical decision-making or reduces breast cancer mortality. United Healthcare also recommended further studies to determine the efficacy of cytological examination of ductal fluid in detecting atypical cells to identify women at increased risk of breast cancer, as well as comparisons of the results to established methods of detecting and diagnosing breast cancer. Similarly, Medicare does not currently reimburse for the NAF collection procedure. Lack of Medicare or insurance coverage will require patients to bear the full costs of the NAF sample acquisition process used with the MASCT System. As a result, and particularly in light of healthcare reform and cost-containment initiatives being undertaken widely across the United States, physicians and other healthcare professionals may be slow to adopt the MASCT System and may not recommend its use in patients. We may be forced to reduce the price of the MASCT System components in response to low demand or to provide discounted pricing arrangements in order to secure sales, or may not be able to sell the product and services components of the MASCT System at acceptable margins, which would severely limit our ability to generate revenue.

We cannot ensure that we will have sufficient resources to develop and commercialize the medical devices we recently acquired from Acueity Healthcare, Inc.

In September 2012, we acquired the assets of Acueity Healthcare, Inc. The purchased assets included 35 issued patents (18 issued in the U.S. and 17 issued in foreign countries) and 41 patent applications (32 in the U.S. and 9 in foreign countries), six 510(k) FDA marketing authorizations related to the manufacturing, use, and sale of the Viaduct Miniscope and accessories, the Manoa Breast Biopsy system, the Excisor Bioptome, the Acueity Medical Light Source, the Viaduct Microendoscope and accessories, and cash in the amount of $400,000. The 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. We do not intend to begin to allocate human and financial resources to further develop and ultimately commercialize these medical devices until completion of the launch of our four diagnostic tests in the United States. We intend to complete the steps necessary to begin marketing and selling these tools, such as re-establishing the supply chain of component parts, securing manufacturers, performing test builds and commercial scale manufacturing in late 2013. 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, even if we devote resources to the development of these medical devices that we will ultimately be successful selling these tools.

Our intended business to sell predictive medical products may expose us to possible litigation and product liability claims.

Our business may expose us to potential product liability risks inherent in the testing, marketing and processing of predictive, or personalized medical products. Product liability risks may arise from, but are not limited to:

- the inability of the MASCT System or microcatheters to extract a sufficient NAF sample from the breast, which may lead to a NAF sample size that is inadequate for proper processing at our laboratory and insufficient for screening, which could lead to an inaccurate assessment of the health of the patient;
- failure by healthcare professionals to properly safeguard NAF samples collected using the MASCT System or microcatheters;
- the potential loss, mislabeling or misplacement of NAF sample shipments and test kits;
- the MASCT System and our microcatheters are manually operated devices, and, as a result, human error may result in improper collection of NAF or application of the device;
- inadequate cleaning of the collection pump between patients resulting in mixing of NAF samples from two patients or NAF samples attributed to the wrong patient;
- improper fitting of the MASCT System device to the breast; and
- inadequate cleaning of the breast prior to applying the MASCT System.

The ArgusCYTE Test must be run on fresh blood and improper storage conditions following drawing from the patient could lead to a missed diagnosis.

A successful product liability claim, or the costs and time commitment involved in defending against a product liability claim, could have a material adverse effect on our business. Any successful product liability claim may prevent us from obtaining adequate product liability insurance in the future on commercially desirable or reasonable terms. An inability to obtain sufficient insurance coverage at an acceptable cost, or otherwise, to protect against potential product liability claims could prevent or inhibit the commercialization of our products.

Our laboratory activities, including the analysis and reading of the NAF tests could expose us to possible litigation based on malpractice, data aggregation errors, or misdiagnoses.

Through a wholly-owned subsidiary, we operate a CLIA-certified laboratory to analyze patient samples and to report the results to referring healthcare professionals, researchers and potential collaborators worldwide. We or our subsidiary may be subject to claims by an affected patient, healthcare provider, researcher or collaborator if laboratory personnel make any of the following mistakes, by way of example:

- errors in the analysis of the tests;
- incorrect aggregation, categorization or labeling of data;
- improper, incorrect or inaccurate development of a computer database which categorizes, analyzes, or compares test data; or
- misinterpretation of the results of the test or collected data.

We maintain insurance to protect against such suits, but we cannot be certain that the insurance will be sufficient to cover potential damages, or that it will be cost-effective for us to maintain such a policy. Any adverse outcome against us could involve significant monetary judgments and could severely impact our financial resources and would be expected to impair our ability in the future to obtain malpractice, or other insurance, for our laboratory services.

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

Our commercial success will depend in part on our ability to obtain new patents and enforce existing patents, as well as our ability to maintain adequate protection of other intellectual property for our technologies and products in the United States and abroad. If we do not adequately protect our intellectual property, competitors may be able to use our technologies and erode or negate any competitive advantage we may otherwise have, which could adversely affect our business, negatively affect our position in the marketplace and limit our ability to commercialize our products. The laws of some foreign countries do not protect our proprietary rights to the same extent as the laws of the United States, and we may encounter significant problems in protecting our proprietary rights in these countries.

The patent positions of diagnostic, medical device, and pharmaceutical companies, including ours, involve complex legal and factual questions, and, therefore, validity and enforceability cannot be predicted with certainty, nor can we be certain that we are not infringing the patents of others. Our patents may be challenged, deemed unenforceable, invalidated or circumvented. In particular, on March 20, 2012, the U.S. Supreme Court issued a decision in*Mayo Collaborative Services, DBA Mayo Medical Laboratories, et al. v. Prometheus Laboratories, Inc.*, No. 10-1150, holding that several claims drawn to measuring drug metabolite levels from patient samples were not patentable subject matter. Although the Court's decision seems to impact diagnostics patents that merely apply a law of nature via a series of routine steps, the full impact of the *Prometheus* decision is not yet known. We will thus be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our proprietary technologies, existing products and any future products are covered by valid and enforceable patents or are effectively maintained as trade secrets, and we are willing and have the necessary resources to take enforcement action against such unauthorized use by third parties.

The degree of future protection for our proprietary rights is uncertain, and we cannot ensure that:

- we were the first to make the inventions covered by each of our patents and pending patent applications;
- we were the first to file patent applications for these inventions;
- others will not independently develop similar, or alternative technologies, or duplicate any of our technologies;
- any of our pending patent applications will result in issued patents;
- any of our issued patents will be valid or enforceable;
- any patents issued to us will provide a basis for commercially viable products, will provide us with any competitive advantages or will not be challenged by third parties;
- we will develop additional proprietary technologies or products that are patentable; or
- the patents of others will not have an adverse effect on our business.

We may be unable to adequately prevent disclosure of trade secrets and other proprietary information.

We rely on trade secrets to protect our proprietary know-how and technological advances, particularly where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. We rely in part on confidentiality agreements with our employees, consultants, outside scientific collaborators and other advisors to protect our trade secrets and other proprietary information. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover our trade secrets and proprietary information. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights. Failure to obtain, or maintain, trade secret protection could enable competitors to use our proprietary information to develop products that compete with our products or cause additional, material adverse effects upon our competitive business position.

Our current patent portfolio may not include all patent rights needed for the full development and commercialization of our products. We cannot be sure that patent rights we may need in the future will be available for license on commercially reasonable terms, or at all.

Although our patents may prevent others from making, using or selling similar products, they do not ensure that we will not infringe the patent rights of third parties. We may not be aware of all patents or patent applications that may impact our ability to make, use or sell our products or services. Furthermore, we may not be aware of published or granted conflicting patent rights. Any conflicts resulting from patent applications and patents of others could significantly reduce the coverage of our patents and limit our ability to obtain meaningful patent protection. If others obtain patents with conflicting claims, we may need to obtain licenses to these patents or to develop or obtain alternative technology.

We may be unable to obtain any licenses or other rights to patents, technology or know-how from third parties necessary to conduct our business as described in this prospectus and such licenses, if available at all, may not be available on commercially reasonable terms. For example, we are currently negotiating for a license to technology that we may use in our NextCYTE Test and others may seek licenses from us for other technology we use or intend to use. Any failure to obtain such licenses could delay or prevent us from developing or commercializing our proposed products and services, which would harm our business. For example, we may seek to develop our intraductal treatment program by licensing a pharmaceutical from a third party. We may not be able to secure such a license on acceptable terms. Litigation or patent interference proceedings need to be brought against third parties, as discussed below, to enforce any of our patents or other proprietary rights, or to determine the scope and validity or enforceability of the proprietary rights of such third parties.

Litigation regarding patents, patent applications and other proprietary rights may be expensive and time consuming. If we are involved in such litigation, we could be delayed in bringing product or service candidates to market and our ability to operate could be harmed.

Our commercial success will depend in part on our ability to manufacture, use and sell products and services without infringing patents or other proprietary rights of third parties. Third parties may challenge or infringe upon our, or our licensors', existing or future patents. Although we are not currently aware of any pending or actual litigation, or other proceedings, or third-party claims of intellectual property infringement related to the MASCT System, the Mammary Ductal Microcatheter System or other product candidates, the medical device and diagnostic industry is characterized by extensive litigation regarding patents and other intellectual property rights. Other parties may obtain patents in the future and allege that the use of our technologies infringes these patent claims or that it is employing their proprietary technology without authorization.

Legal proceedings involving our patents or patent applications, or those of others, could result in adverse decisions regarding the patentability of our inventions relating to our products or the enforceability, validity or scope of protection offered by our patents.

Even if we are successful in proceedings involving our intellectual property rights or those of others, we may incur substantial costs and divert management time and attention in pursuing these proceedings. If we are unable to avoid infringing the patent rights of others, we may be required to seek a license, defend an infringement action, or challenge the validity of the patents in court. Patent litigation is costly and time consuming and we may not have sufficient resources to bring enforcement actions to a successful conclusion. In addition, if we do not obtain a license, develop or obtain non-infringing technology, fail to defend an infringement action successfully or have infringed patents declared invalid, we may incur substantial monetary damages, encounter significant delays in bringing our product candidates to market, or be precluded from participating in the manufacture, use or sale of our products or product candidates or methods of treatment requiring licenses.

Risks Related to our Industry

Failure to adequately and timely address the FDA's warning letter received February 21, 2013, or other matters raised by the FDA, could adversely affect our business.

We received a Warning Letter ("Letter") from the FDA on February 21, 2013, regarding our MASCT System and MASCT System Collection Test (together, the "System"). The Letter arose from certain FDA findings during a July 2012 inspection, to which we responded in August 2012, explaining why we believed we are in compliance with applicable regulations and/or were implementing changes responsive to the findings of the FDA inspection. The FDA alleges in the Letter that following 510(k) clearance we changed the System in a manner that requires submission of an additional 510(k) notification to the FDA. Specifically, the FDA observes that the Instructions For Use (IFU) in the original 510(k) submission stated that the user must "Wash the collection membrane with fixative solution into the collection vial…" and the current IFU states "…apply one spray of Saccomanno's Fixative to the collection membrane…" and that "this change fixes the NAF specimen to the filter paper rather than washing it into a collection vial." At the time that the changes were made we determined that a new 510(k) was not required in accordance with the FDA's guidance document entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device."

The Letter also raises certain issues with respect to our marketing of the System and our compliance with FDA Good Manufacturing Practices (cGMP) regulations, among other matters. If the FDA does not agree with our position concerning clearance of the System, we may be required to submit and receive clearance of a new 510(k) notice for the current form of the System or revert to marketing the System using the prior NAF processing method.

We responded to the Letter on March 13, 2013, indicating the current actions taken and the timing of commitments we have made for future actions. The FDA could direct other compliance-verification activities or take other actions in connection with matters raised in the Letter, related to our response, and in connection with other matters that the FDA could identify in the future. Until these issues are resolved we may be subject to additional regulatory action by the FDA, and any such actions could disrupt our ongoing business and operations. Our business will be adversely affected if we cannot timely resolve the matters raised in the Letter, or other matters raised by the FDA, to the FDA's satisfaction or if we are not successful in continuing to market our existing System, reverting to marketing the System using the prior NAF processing method or obtaining an additional 510(k) clearance in a timely and cost-effective manner.

The manufacturing, marketing and sale of our products are subject to regulatory clearances or approvals and our business is subject to extensive regulatory requirements. If we fail to maintain regulatory clearances, or are unable to obtain, or experience significant delays in obtaining, FDA approvals or clearances for our future products or product enhancements, our ability to commercially manufacture, market and sell these products could suffer.

Our medical device products and operations are subject to extensive regulation by the FDA and various other federal and state governmental authorities. Government regulation of medical devices is meant to assure their safety and effectiveness, and includes regulation of, among other things: design, development, manufacture, testing, labeling, storage, marketing, distribution, promotion, record keeping, and approval or clearance.

Before a new medical device, or a new use of or claim for an existing device, can be marketed in the United States, it must first receive either a premarket clearance under Section 510(k) of the Federal Food, Drug, and Cosmetic Act (FDCA) or a PMA from the FDA, unless an exemption applies. Our devices generally require a 510(k) clearance before they can be marketed, which can be a lengthy and expensive process and we may not be able to obtain these approvals on a timely basis, if at all. A PMA generally requires extensive pre-clinical and clinical trials and can take two or more years to obtain. We may partner with a third party to pursue a PMA for our intraductal treatment program. However, if we cannot contract with a third party in a timely and efficient manner or if we cannot obtain a PMA for this program our operations would be adversely affected.

The FDA requires us and certain of our third-party suppliers to adhere to Quality System Regulations ("QSR"), which include production design controls, testing, quality control, and labeling, packaging, sterilization, and storage and documentation procedures. The FDA may at any time inspect our facilities to determine whether we have adequate compliance with the FDA's QSR and other regulatory requirements. Compliance with QSR for medical devices is difficult and costly. If our facilities or those of our suppliers fail to take satisfactory corrective action in response to an adverse QSR inspection, the FDA could take enforcement action. For example, the FDA has issued and could in the future issue warning letters or other communications to us. If we fail to satisfy or remediate the matters discussed in any such warning letters, including the warning letter we received on February 21, 2013, or communications, the FDA could take further enforcement action, including prohibiting the sale or marketing of the affected product. The FDA also strictly regulates labeling, advertising, promotion, and other types of information on products that are placed on the market. Medical devices may be promoted only for their intended use and in accordance with the provisions of the approved label. It is possible that federal or state enforcement authorities might take action if they consider our promotional or training materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under a variety of statutory authorities, including under the FDCA as well as laws prohibiting false claims for reimbursement. In addition, we may not be found compliant as a result of future changes in, or interpretations of, regulations by the FDA or other regulatory agencies.

Sales of our products outside the U.S. are subject to foreign regulatory requirements that vary from country to country. The time required to obtain approvals from foreign countries may be longer or shorter than that required for FDA approval, and requirements for foreign licensing may differ from FDA requirements. In any event, if we fail to obtain the necessary approvals to sell any of our products in a foreign country, or if any obtained approval is revoked or suspended, we will not be able to sell those products there.

The federal, state and foreign laws and regulations regarding the manufacture and sale of our products are subject to future changes, as are administrative interpretations and policies of regulatory agencies. If we fail to comply with applicable federal, state or foreign laws or regulations, we could be subject to enforcement actions. Enforcement actions could include product seizures, recalls, withdrawal of clearances or approvals, and civil and criminal penalties, which in each case would harm our business.

Our inadvertent or unintentional failure to comply with the complex government regulations concerning privacy of medical records could subject us to fines and adversely affect our reputation.

The federal privacy regulations, among other things, restrict our ability to use or disclose protected health information in the form of patient-identifiable laboratory data, without written patient authorization, for purposes other than payment, treatment, or healthcare operations (as defined under the Health Insurance Portability and Accountability Act, or HIPAA) except for disclosures for various public policy purposes and other permitted purposes outlined in the privacy regulations. The privacy regulations provide for significant fines and other penalties for wrongful use or disclosure of protected health information, including potential civil and criminal fines and penalties. Although the HIPAA statute and regulations do not expressly provide for a private right of damages, we could incur damages under state laws to private parties for the wrongful use or disclosure of confidential health information or other private personal information.

We intend to implement policies and practices that we believe will make us compliant with the privacy regulations. However, the documentation and process requirements of the privacy regulations are complex and subject to interpretation. Failure to comply with the privacy regulations could subject us to sanctions or penalties, loss of business, and negative publicity.

The HIPAA privacy regulations establish a “floor” of minimum protection for patients as to their medical information and do not supersede state laws that are more stringent. Therefore, we are required to comply with both HIPAA privacy regulations and various state privacy laws. The failure to do so could subject us to regulatory actions, including significant fines or penalties, and to private actions by patients, as well as to adverse publicity and possible loss of business. In addition, federal and state laws and judicial decisions provide individuals with various rights for violation of the privacy of their medical information by healthcare providers such as us.

Changes in regulations, policies, or payor mix may adversely affect reimbursement for laboratory services and could have a material adverse impact on our revenue and profitability.

Most of our services will be billed to a party other than the physician who ordered the test. Reimbursement levels for healthcare services are subject to continuous and often unexpected changes in policies. Changes in governmental and third-party reimbursement rates and policies may result from statutory and regulatory changes, retroactive rate adjustments, administrative rulings, competitive bidding initiatives, and other policy changes. Uncertainty also exists as to the coverage and reimbursement status of new services. Government payors and insurance companies have increased their efforts to control the cost, utilization, and delivery of healthcare services. For example, at least yearly, Congress has considered and enacted changes in the Medicare fee schedule in conjunction with budgetary legislation. Further reductions of reimbursement for Medicare services or changes in policy regarding coverage of tests may be implemented from time to time. The payment amounts under the Medicare fee schedules are often used as a reference for the payment amounts set by other third-party payors. As a result, a reduction in Medicare reimbursement rates could result in a corresponding reduction in the reimbursements we may receive from such third-party payors. Changes in test coverage policies of other third-party payors may also occur. Such reimbursement and coverage changes in the past have resulted in reduced prices, added costs and reduced accession volume, and have imposed more complex regulatory and administrative burdens. Further changes in federal, state, and local third-party payor laws, regulations, or policies may have a material adverse impact on our business.

Failure to participate as a provider with payors, or operating as a non-contracting provider, could have a material adverse effect on revenue.

The healthcare industry has experienced a trend of consolidation among healthcare insurers, resulting in fewer but larger insurers with significant bargaining power in negotiating fee arrangements with healthcare providers, including laboratories. Managed care providers often restrict their contracts to a small number of laboratories that may be used for tests ordered by physicians in the managed care provider's network. As of the date of this prospectus we do not have any managed care provider contracts and there can be no assurance any contracts will be established. If we do not have a contract with a managed care provider, we may be unable to gain those physicians as clients. In cases in which we will contract with a specified insurance company as a participating provider, we will be considered "in-network," and the reimbursement of third-party payments is governed by contractual relationships. Our in-network services will be primarily negotiated on a fee-for-service basis at a discount from our patient fee schedule, which could result in price erosion that would adversely affect revenue. Our failure to obtain managed care contracts, or participate in new managed care networks, could adversely affect revenue and profitability. In cases in which we do not have a contractual relationship with an insurance company, or are not an approved provider for a government program, we will have no contractual right to collect for services and such payors may refuse to reimburse us for services, which could lead to a decrease in accession volume and a corresponding decrease in revenue. As an out-of-network provider, reductions in reimbursement rates for non-participating providers could also adversely affect us. Third-party payors, with whom we do not participate as a contracted provider, may also require that we enter into contracts, which may have pricing and other terms that are materially less favorable than the terms under which we intend to operate. While accession volume may increase as a result of these contracts, revenue per accession may decrease.

Use of our laboratory services as a non-participating provider is also expected to result in greater co-payments for the patient, unless we elect to treat patients as if we were a participating provider in accordance with applicable law. Treating such patients as if we were a participating provider may adversely impact results of operations because we may be unable to collect patient co-payments and deductibles. In some states, applicable law prohibits us from treating these patients as if we were a participating provider. As a result, referring physicians may avoid use of our services, which could result in a decrease in accession volume and adversely affect revenue.

Changes in FDA policies regarding the "home brew" exception from FDA review for laboratory-developed tests and reagents could adversely affect our business and results of operations.

Laboratory diagnostic tests developed and validated by a laboratory for its own use, also known as laboratory developed tests, which are referred to as LDTs or "home brew" tests, are subject to regulation under the federal Food, Drug and Cosmetic Act, or FDCA. To date, the FDA has decided, as a matter of enforcement discretion, not to exercise its authority with respect to most "home brew" tests performed by high complexity laboratories certified under CLIA, which is the type of laboratory that we have established. In addition, manufacturers and suppliers of analyte specific reagents, or ASRs, which we may utilize in our LDTs, are required to register with the FDA, conform manufacturing operations to the FDA's Quality System Regulation, or QSR, and comply with certain reporting and other record keeping requirements. The FDA regularly considers the application of additional regulatory controls over the development and use of LDTs by laboratories. It is possible that the FDA will require premarket notification or approval for LDT diagnostic tests that we may develop and perform in the future. The FDA held public hearings in the third quarter of 2010 to discuss how it will oversee LDTs. No definitive recommendations or findings have yet come from these hearings, but it is likely that the FDA will impose additional or new regulations affecting LDTs, including requiring premarket notification or approval for these tests. Any premarket notification or approval requirements could restrict or delay our ability to provide specialized diagnostic services and may adversely affect our business. FDA regulation of LDTs, or increased regulation of the various medical devices used in laboratory-developed testing, could increase the regulatory burden and generate additional costs and delays in introducing new tests.

The failure to comply with complex federal and state laws and regulations related to submission of claims for services could result in significant monetary damages and penalties and exclusion from the Medicare and Medicaid programs.

We are subject to extensive federal and state laws and regulations relating to the submission of claims for payment for services, including those that relate to coverage of services under Medicare, Medicaid, and other governmental healthcare programs, the amounts that may be billed for services, and to whom claims for services may be submitted, such as billing Medicare as the secondary, rather than the primary, payor. The failure to comply with applicable laws and regulations, for example, enrollment in PECOS, the Medicare Provider Enrollment, Chain and Ownership System, could result in our inability to receive payment for our services or attempts by third-party payors, such as Medicare and Medicaid, to recover payments from us that we have already received. Submission of claims in violation of certain statutory or regulatory requirements can result in penalties, including civil money penalties of up to $10,000 for each item or service billed to Medicare in violation of the legal requirement, and exclusion from participation in Medicare and Medicaid. Government authorities may also assert that violations of laws and regulations related to submission of claims violate the federal False Claims Act or other laws related to fraud and abuse, including submission of claims for services that were not medically necessary. The Company will be generally dependent on independent physicians to determine when its services are medically necessary for a particular patient. Nevertheless, we could be adversely affected if it was determined that the services we provided were not medically necessary and not reimbursable, particularly if it were asserted that we contributed to the physician's referrals of unnecessary services. It is also possible that the government could attempt to hold us liable under fraud and abuse laws for improper claims submitted by us if it were found that we knowingly participated in the arrangement that resulted in submission of the improper claims.

Our business is subject to rapid technological innovation, and the development by third parties of new or improved diagnostic testing technologies or information technology systems could have a material adverse effect on our business.

The anatomic pathology industry is characterized by rapid changes in technology, frequent introductions of new diagnostic tests, and evolving industry standards and client demands for new diagnostic technologies. Advances in technology may result in the development of more point-of-care testing equipment that can be operated by physicians or other healthcare providers in their offices, or by patients themselves, without the services of freestanding laboratories and pathologists, thereby reducing demand for our services. In addition, advances in technology may result in the creation of enhanced diagnostic tools that enable other laboratories, hospitals, physicians, patients, or third parties to provide specialized laboratory services superior to ours, or that are more patient-friendly, efficient, or cost-effective. Our success depends in part upon our ability to acquire or license on favorable terms or develop new and improved technologies for early diagnosis before its competitors and to obtain appropriate reimbursement for diagnostic tests using these technologies. Introduction of prophylactic treatments or cures for breast cancer could substantially reduce or eliminate demand for our services.

Risks Related to the Securities Markets and Investment in our Securities

Our shares of common stock are listed on the NASDAQ Capital Market, but we cannot guarantee that we will be able to satisfy the continue listing standards going forward.

Although our shares of common stock are listed on the NASDAQ Capital Market, we cannot ensure that we will be able to satisfy the continued listin standards of the NASDAQ Capital Market going forward. If we cannot satisfy the continued listing standards going forward, NASDAQ may commen delisting procedures against us, which could result in our stock being removed from listing on the NASDAQ Capital Market. If our stock were to be deliste the market liquidity of our stock could be adversely affected and the market price of our stock could decrease. Delisting could also adversely affect our stockholders' ability to trade or obtain quotations on our shares because of lower trading volumes and transaction delays. These factors could contribute to lower prices and larger spreads in the bid and ask price for our common stock. You may also not be able to resell your shares at or above the price you paid for such shares or at all. In addition, class action litigation has often been instituted against companies whose securities have experienced periods of volatility in market price. Any such litigation brought against us could result in substantial costs and a diversion of management's attention and resources, which could hurt our business, operating results and financial condition.

The sale of our common stock to Aspire may cause substantial dilution to our existing stockholders and the sale, actual or anticipated, of the shares of common stock acquired by Aspire could cause the price of our common stock to decline.

We have the right to sell up to $30 million of our shares of common stock to Aspire, including the 83,333 shares sold to Aspire on March 27, 2013 and the 250,000 shares issued to Aspire as a commitment fee. We are obligated to register these shares with the SEC. Also, we have agreed to initially register 2,496,667 additional shares that we may sell to Aspire in the future. It is anticipated that these shares will be sold by Aspire over a period of up to approximately three years from the date of this report. Under the rules of the Nasdaq Capital Market, in no event may we issue more than 19.99% of our shares outstanding on March 27, 2013 under the purchase agreement (which is approximately 2,833,519 shares based on 14,174,686 shares of common stock outstanding on March 27, 2013), unless we obtain stockholder approval.

Any actual or anticipated sales of shares by Aspire may cause the trading price of our common stock to decline. Additional issuances of shares to Aspire may result in dilution to the interests of other holders of our common stock. The sale of a substantial number of shares of our common stock by Aspire, or anticipation of such sales, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect sales. However, we have the right to control the timing and amount of sales of our shares to Aspire Capital, and the purchase agreement may be terminated by us at any time at our discretion without any penalty or cost to us.

The trading price of our common stock has been, and is likely to continue to be, volatile.

Since shares of our common stock were sold in our IPO in November 2012 at a price of $5.00 per share, our stock price has ranged from $3.44 to $12.4 through March 26, 2013. In addition to the factors discussed in this report, the trading price of our common stock may fluctuate significantly in response to numerous factors, many of which are beyond our control, including:

- actual or anticipated growth rates and fluctuations in our revenue and other operating results;
- regulatory and FDA actions, including the warning letter we received from the FDA on February 21, 2013, and our responses to those actions;
- actions of securities analysts who initiate or maintain coverage of us, and changes in financial estimates by any securities analysts who follow our company, or our failure to meet these estimates or the expectations of investors;
- additional shares of our common stock being sold into the market by us or our existing stockholders or the anticipation of such sales; and
- media coverage of our business and financial performance.

In addition, the stock markets have experienced extreme price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many healthcare companies. Stock prices of many healthcare companies have fluctuated in a manner unrelated or disproportionate to the operating performance of those companies. As a result, an investment in our common stock may decrease in value.

Substantial shares of our common stock may be sold into the market when the "lock-up" ends or for other reasons which could cause the price of our common stock to decline.

The price of our common stock could decline if there are substantial sales of our common stock. For example, we sold 800,000 shares of common stock in our IPO, all of which are generally freely tradable. However, as of March 26, 2013, there are approximately an additional 13.3 million shares outstanding and a substantial amount of these will become available for trading when the existing lock-up expires on May 7, 2013. We are also in the process of registering for resale the shares of common stock issuable upon exercise of our outstanding warrants and certain shares of common stock issued in private placements. When those shares are registered for resale, additional shares of our common stock may be sold into the market. These and any other substantial sales of our common stock into the market could cause the price of our common stock to decline.

The ownership of our common stock is concentrated among a small number of stockholders, and if our principal stockholders, directors and officers choose to act together, they may be able to significantly influence management and operations, which may prevent us from taking actions that may be favorable to you.

Our ownership is concentrated among a small number of stockholders, including our founders, directors, officers and entities related to these persons. Our directors, officers and entities affiliated with them beneficially own approximately 35% of our outstanding voting securities. Accordingly, these stockholders, acting together, will have the ability to exert substantial influence over all matters requiring approval by our stockholders, including the election and removal of directors and any proposed merger, consolidation or sale of all or substantially all of our assets. This concentration of ownership could have the effect of delaying, deferring or preventing a change in control of the Company or impeding a merger or consolidation, takeover or other business combination that could be favorable to you.

If we are unable to implement and maintain effective internal control over financial reporting in the future, investors may lose confidence in the accuracy and completeness of our financial reports and the trading price of our common stock may be negatively affected.

We are required to maintain internal controls over financial reporting and to report any material weaknesses in such internal controls. If we identify material weaknesses in our internal control over financial reporting, if we are unable to comply with the requirements of the Sarbanes-Oxley Act in a timely manner or assert that our internal control over financial reporting is effective, or if our independent registered public accounting firm is unable to express, if required, an opinion as to the effectiveness of our internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our financial reports and the trading price of our common stock could be negatively affected, and we could become subject to investigations by the stock exchange on which our securities is listed, the Securities and Exchange Commission, or other regulatory authorities, which could require additional financial and management resources.

The requirements of being a public company may strain our resources and divert management's attention.

We are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended (Exchange Act), the Sarbanes-Oxley Act, the Dodd Frank Act, the listing requirements of the NASDAQ Capital Market, and other applicable securities rules and regulations. Compliance with these rules and regulations will increase our legal and financial compliance costs, make some activities more difficult, time-consuming, or costly, and increase demand on our systems and resources. As a result, management's attention may be diverted from other business concerns, which could harm our business and operating results. Although we have hired additional employees to comply with these requirements, we may need to hire more employees in the future, which will increase our costs and expenses.

In addition, complying with public disclosure rules makes our business more visible, which we believe may result in threatened or actual litigation, including by competitors and other third parties. If such claims are successful, our business and operating results could be harmed, and even if the claims do not result in litigation or are resolved in our favor, these claims, and the time and resources necessary to resolve them, could divert the resources of our management and harm our business and operating results.

Anti-takeover provisions in our charter documents and Delaware law could delay or prevent a change in control which could limit the market price of the our common stock and could prevent or frustrate attempts by the our stockholders to replace or remove current management and the current Board of Directors.

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could delay or prevent a change in control or changes in our Board of Directors that our stockholders might consider favorable. These provisions include the establishment of a staggered Board of Directors, which divides the board into three classes, with directors in each class serving staggered three-year terms. The existence of a staggered board can make it more difficult for a third party to effect a takeover of our company if the incumbent board does not support the transaction. For more information about these anti-takeover provisions as well as anti-takeover provisions under the Delaware General Corporation Law, please see "Description of Securities to be Registered — Anti-Takeover Devices." These and other provisions in our corporate documents and Delaware law might discourage, delay or prevent a change in control or changes in the Board of Directors of the Company. These provisions could also discourage proxy contests and make it more difficult for an investor and other stockholders to elect directors not nominated by our Board. Furthermore, the existence of these provisions, together with certain provisions of Delaware law, might hinder or delay an attempted takeover other than through negotiations with the Board of Directors.

We do not expect to pay dividends in the future, which means that investors may not be able to realize the value of their shares except through a sale.

We have never, and do not anticipate that we will, declare or pay a cash dividend. We expect to retain future earnings, if any, for our business and do not anticipate paying dividends on common stock at any time in the foreseeable future. Because we do not anticipate paying dividends in the future, the only opportunity for our stockholders to realize the creation of value in our common stock will likely be through a sale of those shares.

We are an "emerging growth company" and we cannot be certain if we will be able to maintain such status or if the reduced disclosure requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the Jumpstart our Business Startups Act of 2012, or JOBS Act, and we intend to adopt certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies" including, but not limited to, not being required to comply with the auditor attestation requirements of section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We may remain as an "emerging growth company" for up to five full fiscal years following our initial public offering. We would cease to be an emerging growth company, and therefore not be able to rely upon the above exemptions, if we have more than $1 billion in annual revenue in a fiscal year, we issue more than $1 billion of non-convertible debt over a three-year period, or we have more than $700 million in market value of our common stock held by non-affiliates as of any June 30 before the end of the five full fiscal years. Additionally, we cannot predict if investors will find our common stock less attractive because we will rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 2. PROPERTIES

We lease approximately 9,800 square feet of office and laboratory space in Seattle, Washington, which includes space rented from Sanders Properties, LLC, CompleGen, Inc., and the Fred Hutchinson Cancer Research Center. We believe that our current facilities will be adequate to meet our needs for the next 24 months. The information in this report under "PART II, ITEM 7. MANAGEMENT DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS – Commercial Lease Arrangements" is incorporated into this PART I, ITEM 2.

ITEM 3. LEGAL PROCEEDINGS

On June 30, 2011, Robert Kelly, our former President, filed a counterclaim against us in an arbitration proceeding, alleging breach of contract in connection with the termination of a consulting agreement between Mr. Kelly (dba Pitslayer LLC) and us that was entered into in July 2010 in connection with his resignation as President and a director. The consulting agreement was terminated by us in September 2010. Mr. Kelly seeks $450,000 in compensatory damages, which is the amount he claims would have been earned had the consulting agreement been fulfilled to completion.

On December 11, 2012, Mr. Kelly filed a complaint in the United States District Court, Western Division of Washington seeking compensatory damages, interest and attorneys' fees related to the termination of Mr. Kelly's consulting contract and the rescission of shares issued to him in July 2010 in connection with his resignation as President and a director. The specific amount of damages sought is to be proven at trial and is not specified.

On February 26, 2013, Mr. Victor Cononi filed a complaint in the United States District Court, Western Division of Washington seeking compensatory damages, interest and attorneys' fees related to the rescission of shares issued to him in July 2010 in connection with Mr. Kelly's resignation as President and a director. Mr. Cononi is the father of Mr. Kelly's paramour. The specific amount of damages sought is to be proven at trial and is not specified.

A hearing in the arbitration has been postponed pending certain procedures in the above Western Division action and may be delayed further to accommodate other third party civil and federal criminal proceedings alleging securities and wire fraud that have been brought against Mr. Kelly with respect to his prior employment and predating his service with the Company.

We are reasonably confident in our defenses to Mr. Kelly's and Mr. Cononi's claims. Consequently, no provision or liability has been recorded for these claims as of December 31, 2012. However, it is at least reasonably possible that our estimate of liability may change in the near term. Any payments by reason of an adverse determination in this matter will be charged to earnings in the period of determination.

ITEM 4. MINE SAFETY DISCLOSURE

Not Applicable.

PART II

ITEM 5. MARKET FOR THE REGISTRANT'S COMMON EQUITY, RELATED SHAREHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

Our common stock trades on The NASDAQ Capital Market under the symbol "ATOS". The following table sets forth, for the periods indicated, the intraday high and low prices of our common stock as reported by the NASDAQ from November 8, 2012, our first day of trading on NASDAQ, to December 31, 2012.

	High	Low
2012		
Fourth Quarter	$ 5.61	$ 3.44

On March 26, 2013, the closing price of our common stock was $11.30. As of March 26, 2013, there were approximately 230 shareholders of record of our common stock, one of which is Cede & Co., a nominee for Depository Trust Company, or DTC. All of the shares of common stock held by brokerage firms, banks and other financial institutions as nominees for beneficial owners are deposited into participant accounts at DTC, and are therefore considered to be held of record by Cede & Co. as one shareholder.

Certain Unregistered Sales of Securities

The Company sold the following securities during the period covered by this report which were not registered under the Act and not previously reported on a quarterly report on Form 10-Q or a current report or Form 8-K: On December 20, 2012, the Company issued an option to purchase 200,000 shares of its common stock to Christopher Destro as an inducement grant for the employment of Mr. Destro as the Company's Vice President of Sales and Marketing. The option is exercisable at $4.11 per share which was the fair market value of the Company's Common Stockon the date of grant. This transaction was exempt from registration under Section 4(a)(2) of the Securities Act, as a transaction by an issuer not involving any public offering.

Dividends

The Company has never declared or paid any cash dividends on our common stock. We currently intend to retain any future earnings to finance the growth and development of our business.

Issuer Purchases of Securities

We did not repurchase any of our equity securities during the fourth quarter of the year ended December 31, 2012.

Equity Compensation Plan Information

The information under the principal heading "Equity Compensation Plan Information" in our definitive Proxy Statement for the Annual Meeting of Stockholders to be held on or about May 6, 2013, to be filed with the SEC, is incorporated herein by reference.

Use of Proceeds

Our initial public offering of common stock was effected through a Registration Statement on Form S-1 (File No. 333-179500) that was declared effective by the SEC on November 7, 2012, which registered an aggregate of 800,000 shares of our common stock for aggregate gross proceeds of $4 million. All of the 800,000 shares of common stock registered under the Registration Statement were sold at a price to the public of $5.00 per share. The offering closed on November 14, 2012. The underwriters had an option, which was not exercised, to purchase an additional 120,000 shares of our common stock for 45 days from November 7, 2012. Dawson James Securities, Inc. acted as sole book-running manager for the offering.

Net proceeds received were approximately $3.0 million, after deduction of underwriting fees and estimated offering expenses. No offering expenses were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning ten percent or more of any class of our equity securities or to any other affiliates. We intend to use the proceeds as described in the final prospectus filed with the SEC pursuant to Rule 424(b) on November 9, 2012. There has been no material change in the planned use of proceeds from our initial public offering as described in the final prospectus dated November 7, 2012 filed with the SEC on November 9, 2012.

ITEM 6. SELECTED FINANCIAL DATA

Not applicable.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion of the financial condition and results of operations should be read in conjunction with the financial statements and the related notes included elsewhere in this report. This discussion contains forward-looking statements, which are based on assumptions about the future of the Company's business. The actual results could differ materially from those contained in the forward-looking statements. Please read "Forward-Looking Statements" included elsewhere in this report for additional information regarding forward-looking statements.

Company Overview

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 and ductal carcinoma in situ, or DCIS.

Our diagnostic tests consist of patented medical devices that can collect fluid and tissue 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 CLIA-certified laboratory, the National Reference Laboratory for Breast Health, which 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 and DCIS by using our patented microcatheters to deliver, directly into the milk ducts, pharmaceutical formulations that can be used to treat these conditions. By using this localized delivery method, patients are expected to receive high local concentrations of these drugs at the site of the pre-cancerous lesions or DCIS, potentially promoting efficacy of the treatment while limiting systemic exposure, which has the potential to lower the overall toxicity of these treatments.

Current Operations

We launched our commercial operations in late 2011 and in 2012 initiated and completed the field experience trial of our first two tests, the ForeCYTE test and the ArgusCYTE test. In January 2013, we announced the national launch of the ForeCYTE test through our distributor Clarity Women's Health, a division of Diagnostic Testing Services, LLC. As of December 31, 2012, have enrolled and sold MASCT System kits or provided ArgusCYTE collection kits to 37 doctors and clinics as providers of the ForeCYTE and/or ArgusCYTE tests and have received, processed, and reported the results to physicians from 1,664 ForeCYTE samples (representing 832 patients) and 41 ArgusCYTE samples. From inception (April 30, 2009) through December 31, 2012, we have generated $483,342 in revenue from the sale of our MASCT System and providing laboratory services. We incurred net operating losses of $5,079,851 and $3,442,269 for the twelve months ended December 31, 2012 and 2011, respectively. As of December 31, 2012, we had an accumulated deficit of approximately $9.7 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 ForeCYTE test kits and generating laboratory service revenue from our tests, and borrowing from stockholders or others 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.

Finally, the acquisition of the Acueity assets may become a complement to our current business at some point in the future. We are not currently allocating human or financial resources to these assets, with the exception of approximately $50,000 for patent maintenance fees and application prosecution expenses related to the Acueity asset purchase. 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 this asset purchase, would not delay the expected development of these diagnostic tools or that we will ultimately be successful selling these tools.

On March 27, 2013 we entered into a stock purchase agreement with Aspire Capital Fund, LLC, which provides that, upon the terms and subject to the conditions and limitations set forth therein, Aspire is committed to purchase up to an aggregate of $30 million of shares of our common stock over the three-year term of the agreement. Under the agreement, Aspire purchased $1,000,000 of our common stock on March 27, 2013 for $12 per share. Before we can sell any additional shares under the agreement, we must register the shares and have the registration statement declared effective by the SEC.

Revenue Sources

The commercialization of the ForeCYTE Test provides us with two revenue sources: (i) sales-based revenue from the sale of the MASCT System device and patient kits to distributors, physicians, breast health clinics, and mammography clinics and (ii) service, or use-based, revenue from the preparation and interpretation of the NAF samples sent to our laboratory for analysis. The commercialization of the ArgusCYTE test provides only laboratory service revenue.

Commencing in December 2011, we began to market 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 initially use regional specialty product distributors, with independent sale representatives specializing in Women's Health, to commercialize the ForeCYTE and ArgusCYTE Tests. As of December 31, 2012, we have entered an agreement with Clarity Women's Health, a division of Diagnostic Test Group LLC (DTG); however, we cannot be certain that we will be able to build distributor relationships, including our relationship with DTG, adequately to address the national market. In addition to Dr. Quay, in April 2012 we hired a board-certified pathologist part-time to assist in the interpretation of the NAF samples.

Commercial Lease Agreements

On September 29, 2010, the Company entered into a commercial lease agreement with CompleGen, Inc. for laboratory space located in Seattle, WA. The lease provides for monthly rent of $3,658 and a security deposit of $3,658. The lease terms are from September 29, 2010 through March 31, 2011, at which time the lease has converted to month to month unless two months' prior written notice of the intent to terminate the agreement is given. The monthly rent for the lease increased to $4,267 commencing January 2012. For the twelve months ended December 31, 2012, the Company incurred $46,529 of rent expense for the lease. The lease was terminated in December 2012, and the rental deposit was applied to the rent of the final month.

On March 4, 2011, the Company entered into a commercial lease agreement with Sanders Properties, LLC for office space located in Seattle, WA. The lease provides for monthly rent of $1,100 and a security deposit of $1,500. The lease terms are from April 1, 2011 through March 31, 2013. For the twelve months ended December 31, 2012, the Company incurred $13,200 of rent expense for the lease.

On July 9, 2011, the Company entered into a commercial lease agreement with Sanders Properties, LLC for additional office space located in Seattle, WA. The lease provides for monthly rent of $600 and a security deposit of $1,200. The lease terms are from July 11, 2011 through July 31, 2012. For the twelve months ended December 31, 2012, the Company incurred $4,200 of rent expense for the lease. This lease terminated on July 31, 2012 and was not renewed.

On September 27, 2011, the Company entered into another commercial lease agreement with Sanders Properties, LLC for additional office space located in Seattle, WA. The lease provides for monthly rent of $1,400 and a security deposit of $1,000. The lease terms are from October 1, 2011 to March 31, 2012. For the period of October 1, 2011 through March 31, 2012, the Company incurred $8,400 of rent expense for the lease. This lease terminated on March 31, 2012 and was not renewed.

On December 9, 2011, the Company entered into another commercial lease agreement with Fred Hutchinson Research Center for lab and office space located in Seattle, WA. The lease provides for monthly rent of $16,395 for the period from February 24, 2012 to August 31, 2012, $19,923 for the period from September 1, 2012 to August 31, 2013, and $20,548 for the period from September 1, 2013 to November 29, 2014. The security deposit of $32,789 was paid in March 2012 and recorded as Security Deposit on the consolidated balance sheet as of September 30, 2012. For the twelve months ended December 31, 2012, the Company incurred $208,581 of rent expense for the lease, which included leasing office management expenses.

We expect that these new facilities will be sufficient to meet our needs for the foreseeable future and we do not expect to need additional office and laboratory space for at least the next 24 months.

Legal Proceedings

On June 30, 2011, Robert Kelly, the Company's former President, filed a counterclaim against the Company in an arbitration proceeding, alleging breach of contract in connection with the termination of a consulting agreement between Mr. Kelly (dba Pitslayer LLC) and the Company that was entered into in July 2010 in connection with his resignation from the Company as President and a director. The consulting agreement was terminated by the Company in September 2010. Mr. Kelly seeks $450,000 in compensatory damages, which is the amount he claims would have been earned had the consulting agreement been fulfilled to completion.

On December 11, 2012, Mr. Kelly filed a complaint in the United States District Court, Western Division of Washington seeking compensatory damages, interest and attorneys' fees related to the termination of Mr. Kelly's consulting contract and the rescission of shares issued to him in July 2010 in connection with his resignation from the Company as President and a director. The specific amount of damages sought is to be proven at trial and is not specified.

On February 26, 2013, Mr. Victor Cononi filed a complaint in the United States District Court, Western Division of Washington seeking compensatory damages, interest and attorneys' fees related to the rescission of shares issued to him in July 2010 in connection with Mr. Kelly's resignation from the Company as President and a director. Mr. Cononi is the father of Mr. Kelly's paramour. The specific amount of damages sought is to be proven at trial and is not specified.

A hearing in the arbitration has been postponed pending certain procedures in the above Western Division action and may be delayed further to accommodate other third party civil and federal criminal proceedings alleging securities and wire fraud that have been brought against Mr. Kelly with respect to his prior employment and predating his service with the Company.

The Company is reasonably confident in its defenses to Mr. Kelly's and Mr. Cononi's claims. Consequently, no provision or liability has been recorded for these claims as of December 31, 2012. However, it is at least reasonably possible that the Company's estimate of liability may change in the near term. Any payments by reason of an adverse determination in this matter will be charged to earnings in the period of determination.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States, or GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses. On an ongoing basis, we evaluate these estimates and judgments, including those described below. We base our estimates on our historical experience and on various other assumptions that we believe to be reasonable under the circumstances. These estimates and assumptions form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results and experiences may differ materially from these estimates.

While our significant accounting policies are more fully described in Note 3 to our financial statements, we believe that the following accounting policies are the most critical to aid you in fully understanding and evaluating our reported financial results and affect the more significant judgments and estimates that we use in the preparation of our financial statements.

Revenue Recognition

Overview

We will recognize product and service revenue in accordance with GAAP when the following overall fundamental criteria are met: (i) persuasive evidence of an arrangement exists, (ii) delivery has occurred or the service has been performed, (iii) our price to the customer is fixed or determinable, and (iv) collection is reasonably assured.

Product Revenue

We recognize revenue for sales of the MASCT kits and devices upon receipt of cash as we have an insufficient sales history on which to determine the collectability. Shipping documents and the completion of any customer acceptance requirements, when applicable, will be used to verify product delivery. We will assess whether a price is fixed or determinable based upon the payment terms associated with the transaction and whether the sales price is subject to refund or adjustment. Once a history of sales and collectability has been established, we will recognize revenue on an accrual basis with an offsetting reserve for doubtful accounts based on the history during the initial sales period.

Service Revenue

We record revenue for diagnostic testing on an accrual basis at the Medicare allowed and invoiced amount. Amounts invoiced above the Medicare amount, namely non-Medicare, are not recognized on an accrual basis and instead are recognized on a cash basis as received. Diagnostic testing revenue at the Medicare rate is recognized upon completion of the test, communication of results to the patient's physician, and when collectability is reasonably assured. Customer purchase orders and/or contracts will generally be used to determine the existence of an arrangement. Once the Company has historical sales and can determine the proper amount to recognize as uncollectible, it will then begin to recognize the entire amount, both Medicare and non-Medicare billing on an accrual basis, with an offsetting allowance for doubtful accounts recorded based on history. We estimate we will utilize the diagnostic testing revenue history once it reaches 12 months of collection data to determine a proper allowance for doubtful accounts.

Inventory

The Company's inventories are stated at lower of cost or market. Cost is determined on a moving-average basis. Costs of inventories include purchase and related costs incurred in delivering the products to their present location and condition. Market value is determined by reference to selling prices after the balance sheet date or to management's estimates based on prevailing market conditions. Inherent in the lower of cost or market calculation are several significant judgments based on a review of the aging of the inventory, inventory movement of products, economic conditions, and replacement costs. Because the sales price of the MASCT System was substantially lower than its cost for the years ended December 31, 2012 and 2011, resulting in the net realizable value of the MASCT System being determined at zero as of the balance sheet dates through taking the average sales price subtracted by selling expenses per unit, $29,884 and $92,026 of loss on reduction of inventory to the lower of cost or market was assessed and recorded as of and for the years then ended, respectively. Additionally, management periodically evaluates the composition of its inventories at least quarterly to identify slow-moving and obsolete inventories to determine if valuation allowance is required. As of December 31, 2012 and 2011, management had identified no slow moving or obsolete inventory.

The Company provides, either directly or through distributors, the ForeCYTE testing specimen collection kits to doctors with our MASCT System for doctors to collect specimens that are returned to the Company for diagnostic analysis. These collection kits are considered part of the MASCT System. During the initial marketing phase, the Company has decided to distribute the kits to customers at no cost and bundle them with the MASCT System, and has not intended to deem the kits as a primary product line due to their nominal cost and value per unit. As a result, the kits are immediately expensed and recorded as selling expense upon purchasing of the kits. For the years ended December 31, 2012 and 2011, selling expense of $55,282 and $0 was recorded related to the ForeCYTE kits, respectively.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. Accordingly, actual results could differ from those estimates.

Intangible Assets

Intangible assets consist of intellectual property and software acquired. At least annually, we evaluate purchased intangibles for impairment whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of the asset and its eventual disposition are less than its carrying amount. Estimating future cash flows related to an intangible asset involves significant estimates and assumptions. If our assumptions are not correct, there could be an impairment loss or, in the case of a change in the estimated useful life of the asset, a change in amortization expense.

Share-Based Payments

In December 2004, the Financial Accounting Standards Board, or the FASB, issued the Statement of Financial Accounting Standards, or SFAS, No. 123(R), "Share-Based Payment," which replaces SFAS No. 123 and supersedes APB Opinion No. 25. SFAS No. 123(R) is now included in the FASB's ASC Topic 718, "Compensation — Stock Compensation." Under SFAS No. 123(R), companies are required to measure the compensation costs of share-based compensation arrangements based on the grant-date fair value and recognize the costs in the financial statements over the period during which employees or independent contractors are required to provide services. Share-based compensation arrangements include stock options and warrants, restricted share plans, performance-based awards, share appreciation rights and employee share purchase plans. In March 2005, the SEC issued Staff Accounting Bulletin No. 107, or SAB 107, which expresses views of the staff regarding the interaction between SFAS No. 123(R) and certain SEC rules and regulations and provides the staff's views regarding the valuation of share-based payment arrangements for public companies. SFAS No. 123(R) permits public companies to adopt its requirements using one of two methods. On April 14, 2005, the SEC adopted a new rule amending the compliance dates for SFAS No. 123(R). Companies may elect to apply this statement either prospectively, or on a modified version of retrospective application under which financial statements for prior periods are adjusted on a basis consistent with the pro forma disclosures required for those periods under SFAS No. 123.

We have fully adopted the provisions of FASB ASC 718 and related interpretations as provided by SAB 107. As such, compensation cost is measured on the date of grant as the fair value of the share-based payments. Such compensation amounts, if any, are amortized over the respective vesting periods of the option grant.

The amended employment agreement with the Chief Executive Officer, entered into on July 22, 2010, granted options to purchase 250,000 shares (or 565,830 shares prior to the reverse stock-split on September 28, 2010) at a price of $5.00 per share, in consideration of his service to the Company. Of these options, 25% (or 62,500 shares) vested on December 31, 2010 with the remaining 75% (or 187,500 shares) to vest in equal quarterly installments over the next three years so long as the executive remains employed with the company. These options have five-year contractual terms.

The amended employment agreement with the Chief Scientific Officer, entered into on July 22, 2010, granted options to purchase 100,000 shares (or 226,332 shares prior to the reverse stock-split on September 28, 2010) at a price of $5.00 per share in consideration of her service to the Company. Of these options, 25% (or 25,000 shares) vested on December 31, 2010 with the remaining 75% (or 75,000 shares) to vest in equal quarterly installments over the next three years so long as the executive remains employed with the company. These options have five-year contractual terms.

On April 4, 2011, 45,000 non-qualified stock options were granted under the 2010 Stock Option and Incentive Plan (the "Plan") to Dr. Tim Hunkapiller for being a member of the Company's Scientific Advisory Board and consulting services to be provided to the Company, at an exercise price of $1.25 per share. These options have a ten-year contractual term and shall vest as follows:

(i) 11,250 option shares shall vest ninety (90) days after the date of grant;

(ii) 11,000 option shares shall vest one hundred and eighty (180) days after the date of grant;

(iii) 11,500 option shares shall vest two hundred and seventy (270) days after the date of grant; and

(iv) 11,250 option shares shall vest three hundred and sixty (360) days after the date of grant.

On September 1, 2011, 219,000 incentive stock options were granted under the Plan to employees and officers as part of their employment agreements, at an exercise price of $1.25 per share. These options have a ten-year contractual term and shall vest and become exercisable as follows:

(i) twenty-five percent (25%) of the underlying shares on the first anniversary of the date of grant; and

(ii) one-forty eighth (1/48) of the underlying shares monthly thereafter.

On September 1, 2011, 200,000 non-qualified stock options were granted under the Plan to non-employee directors for services to be provided to the Company, at an exercise price of $1.25 per share. These options have a ten-year contractual term and shall vest and become exercisable as follows:

(i) 80,000 option shares shall vest on September 1, 2011;

(ii) 30,000 option shares shall vest on December 1, 2011;

(iii) 30,000 option shares shall vest on March 1, 2012;

(iv) 30,000 option shares shall vest on June 1, 2012; and

(v) 30,000 option shares shall vest on September 1, 2012.

On April 30, 2012, 19,757 non-qualified stock options were granted under the Plan to non-employee directors for serving as directors of the Company, at an exercise price of $6.00 per share. These options have a ten-year contractual term and shall vest and become exercisable in full immediately as of the grant date.

On December 17, 2012, 228,000 incentive stock options were granted under the Plan to employees as part of their employment agreements, at an exercise price of $4.24 per share and on December 20, 2012, an option for 200,000 shares was granted outside of the Plan to an employee as part of his employment agreement, at an exercise price of $4.11 per share. These options have a ten-year contractual term. One-fourth of the options vest and become exercisable one year from the date of hire and one-sixteenth (1/16) quarterly thereafter over the following three years.

Results of Operations

Discussion of Twelve Months Ended December 31, 2012

For the twelve months ended December 31, 2012, we had total revenue of $481,842, consisting of $6,440 product revenue from sales of MASCT Systems and $475,402 diagnostic testing service revenue from our ForeCYTE and ArgusCYTE testing services performed. Total cost of revenue was $35,745, primarily attributable to cost of diagnostic testing services performed, which consisted of $35,745 in payments to doctors for their time administering the ForeCYTE testing service. Since the inventory of MASCT System was recorded at zero net realizable value as a result of the lower of cost or market analysis performed at December 31, 2011, no corresponding cost of goods sold was recorded for the sales of MASCT System for the twelve months ended December 31, 2012. Gross profit was $439,657 for the diagnostic testing service and $6,440 for the product sales of MASCT System with no corresponding cost of goods sold. Loss on reduction of inventory to lower of cost or market was $29,884 for the twelve months ended December 31, 2012, primarily due to write-off of parts purchased during the year for the assembly of MASCT System, which was determined at zero net realizable value as a result of lower of cost or market analysis performed at December 31, 2012. Our MASCT System is currently sold at a price substantially lower than its cost to encourage sales and because the MASCT System is currently manufactured by our suppliers only in small quantities. For these reasons, the manufacturing cost allocated to each inventory unit is high. For 2012, total operating expenses were $5,485,243, consisting of G&A expenses of $5,018,422 and selling expenses of $466,821, which included $55,282 of cost of ForeCYTE and ArgusCYTE testing specimen collection kits that were immediately expensed upon purchase during the quarter. During the initial marketing phase, the Company has decided to distribute the kits to customers at no cost and bundle them with the MASCT System and has not intended to deem the kits as a primary product line due to their nominal cost and value per unit. The selling expenses also included $266,698 in salaries and $114,822 in advertising.

The G&A expenses consisted primarily of $350,914 in salaries and bonus expense, $1,072,992 in legal expense, $229,838 in consulting expense, $232,291 in accounting expense, $40,868 in travel expense, $86,489 in payroll taxes, $166,614 in professional fees, $84,624 in health insurance expense and $113,400 in business insurance. Also included in G&A expense is $1,976,638 in research and development expense, consisting primarily of $645,901 in salaries and bonus expense, $246,950 in rent expense, $27,853 in laboratory supplies, $130,040 in MASCT System development, $244,203 in MASCT System service development, $489,778 in ductal lavage product development, $39,789 in ductal lavage service development and $34,649 in circulating tumor cells service development.

Comparison of the Twelve Months Ended December 31, 2012 and 2011

Revenue and Cost of Goods Sold. For the twelve months ended December 31, 2012, we had total revenue of $481,842, consisting of $6,440 product revenue from sales of MASCT Systems and $475,402 diagnostic testing service revenue from our ForeCYTE and ArgusCYTE testing services performed. This compares to total revenue of $1,500 for the twelve months ended December 31, 2011. Total cost of goods sold was $5,164 and consisted of $4,158 in direct costs related to the production of the MASCT systems which were sold, and $1,006 in costs of goods sold for items expensed when purchased. Since the inventory of MASCT System was recorded at zero net realizable value as a result of the lower of cost or market analysis performed at December 31, 2011, no corresponding cost of goods sold was recorded for the sales of MASCT System for the twelve months ended December 31, 2012. Gross profit for the twelve months ended December 31, 2012 was $416,213 for the diagnostic testing service and $6,440 for the product sales of MASCT System with no corresponding cost of goods sold. This compares to gross profit of ($95,690) for the twelve months ended December 31, 2011. Loss on reduction of inventory to lower of cost or market was $29,884 for the twelve months ended December 31, 2012, primarily due to write-off of parts purchased during the year for the assembly of MASCT System which was determined at zero net realizable value as a result of lower of cost or market analysis at December 31, 2011 and December 31, 2012. Our MASCT System is currently sold at a price substantially lower than its cost to encourage sales and because the MASCT System is currently manufactured by our suppliers only in small quantities. For these reasons, the manufacturing cost allocated to each inventory unit is high.

As discussed below, we expect that our R&D and G&A expenses will continue to increase in the foreseeable future, and that if we successfully launch the MASCT System and our related laboratory service offerings, we would also begin to incur sales and marketing expenses as we build a regional, and ultimately national, sales force. We may limit our fixed sales and marketing costs initially by using third party distributors and employing temporary workers or those who are compensated on a commission basis. However, we expect our expenditures to increase significantly in future periods.

Operating Expenses. Total operating expenses were $5,485,243 for the twelve months ended December 31, 2012, consisting of G&A expenses of $5,018,422 and selling expenses of $466,821, which included $55,282 of cost of ForeCYTE and ArgusCYTE testing specimen collection kits that were immediately expensed upon purchase during the year. During the initial marketing phase, the Company has decided to distribute the kits to customers at no cost and bundle them with the MASCT System and has not intended to deem the kits as a primary product line due to their nominal cost and value per unit. The selling expenses also included $266,698 in salaries and $114,822 in advertising. This compares to total operating expenses of $3,333,500 for the twelve months ended December 31, 2011, consisting of G&A expenses of $3,172,649 and selling expenses of $160,851. Total operating expenses increased by $2,151,743 or 65% from $3,333,500 for the twelve months ended December 31, 2011 to $5,485,243 for the twelve months ended December 31, 2012.

General and Administrative Expenses. G&A expenses for the twelve months ended December 31, 2012 were $5,018,422, an increase of $1,845,773 or 58% from $3,172,649 for the twelve months ended December 31, 2011. G&A expenses for the twelve months ended December 31, 2012 primarily consisted of $350,914 in salaries and bonus expense, $1,072,992 in legal expense, $229,838 in consulting expense, $232,291 in accounting expense, $40,868 in travel expense, $86,489 in payroll taxes, $166,614 in professional fees, $84,624 in health insurance expense and $113,400 in business insurance. Also included in G&A expense is $1,976,638 in research and development expense, consisting primarily of $645,901 in salaries and bonus expense, $246,950 in rent expense, $27,853 in laboratory supplies, $130,040 in MASCT System development, $244,203 in MASCT System service development, $489,778 in ductal lavage product development, $39,789 in ductal lavage service development and $34,649 in circulating tumor cells service development.

G&A expenses for the twelve months ended December 31, 2011 were $3,172,649. G&A expenses for the twelve months ended December 31, 2011 primarily consisted of $486,877 in salaries and bonus expense, $431,280 in legal expense, $124,189 in consulting expense, $75,651 in accounting expense, $73,454 in travel expense, $65,784 in payroll taxes, $57,218 in licenses & permits expenses, $56,133 in professional fees, $47,103 in health insurance expense, $26,973 in business insurance. Also included in general and administrative expense is $1,580,749 in research and development expense, consisting primarily of $589,861 in salaries & bonus expense, $45,199 in rent expense, $75,109 in laboratory supplies, $164,631 in MASCT system development, $265,120 in ductal lavage product development, $76,405 in ductal lavage service development, $135,234 in circulating tumor cell service development, and $103,225 in patent licenses acquisition.

The increase in expenses is attributed to the launch of the Company's MASCT System, ForeCYTE service and ArgusCYTE service and the related growth in expenses to hire additional staff, expand our operations, and invest additional funds in Research and Development, as well as professional fees related to our initial public offering and the filing of the Registration Statement on Form S-1. We expect that our G&A expenses will continue to increase as we add additional full time employees and incur additional costs as a publicly traded company. Additionally, G&A costs are expected to rise as we increase headcount to coordinate the production and manufacture of the MASCT System, and the expected increase in service revenues.

Liquidity and Capital Resources

We have a history of operating losses as we have focused our efforts on raising capital and building the MASCT System. The report of our independen auditors issued on our consolidated financial statements as of and for the years ended December 31, 2012 and 2011 expresses substantial doubt about our ability to continue as a going concern. In 2011, we were successful in raising net proceeds of $5.7 million through a private placement in order to fund the growth of our operations and product development. In November 2012 we were successful in our initial public offering and raising net proceeds of approximately $3.5 million. Our ability to continue as a going concern is dependent on our obtaining additional adequate capital to fund additional operating losses until we become profitable. If we are unable to obtain adequate capital, we could be forced to cease operations.

On March 27, 2013 we entered into a stock purchase agreement with Aspire Capital Fund, LLC, which provides that, upon the terms and subject to the conditions and limitations set forth therein, Aspire is committed to purchase up to an aggregate of $30 million of shares of our common stock over the three-year term of the agreement. Under the agreement, Aspire purchased $1,000,000 of our common stock on March 27, 2013 for $12 per share. Before we can sell any additional shares under the agreement, we must register the shares and have the registration statement declared effective by the SEC.

Cash Flows

For the twelve months ended December 31, 2012, we incurred a net loss of $5,079,851. Net cash used in operating activities was $3,899,964, net cash used in investing activities was $134,582 and net cash provided by financing activities was $3,848,922. During the twelve months ended December 31, 2012 we repaid $1,000,000 that we previously drew on our bank line of credit. For the twelve months ended December 31, 2011, we incurred a net loss of $3,442,269, net cash used in operating activities was $3,492,364, net cash used in investing actives was $136,931 and net cash provided by financing activities was $5,529,863.

Funding Requirements

We expect to incur substantial expenses and generate ongoing operating losses for the foreseeable future as we prepare for the scale-up manufacturing and ongoing launch of the MASCT System, complete the development of and launch the FullCYTE and NextCYTE Tests, and build and operate our plann diagnostics laboratory in the Fred Hutchinson Cancer Research Center. To fund our operations for at least the next 12 months under our current business plan we estimate that we would need between $4 million and $10 million of additional capital. We expect that our existing resources as of December 31, 2012, to be sufficient to fund our planned operations for at least the first four months of 2013. If we are unable to raise this amount of capital, however, we could be forced to curtail or cease operations. Our future capital uses and requirements depend on numerous forward-looking factors. These factors include the following:

- the time and expense needed to complete the manufacturing of the MASCT and Microcatheter Systems;
- the expense associated with building a network of independent sales representatives to market the MASCT System, ForeCYTE Test an ArgusCYTE Test; and
- the degree and speed of patient and physician acceptance of our products and the degree to which third-party payors approve the ForeCYTE and ArgusCYTE Tests for reimbursement.

As of December 31, 2012, we have generated $483,342 in revenue. We do not expect to generate significant revenue until we are able to manufacture and launch the MASCT System more broadly. We expect our continuing operating losses to result in increases in cash used in operations over at least the next year. Although we expect our existing resources as of December 31, 2012, to be sufficient to fund our planned operations for at least the first four months of 2013, we may require additional funds earlier than we currently expect to successfully commercialize the MASCT System. Because of the numerous risks and uncertainties associated with the development and commercialization of the MASCT System and our services, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated research and development activities and commercialization efforts.

Additional funding may not be available to us on acceptable terms or at all. In addition, the terms of any financing may adversely affect the holdings or the rights of our stockholders. For example, if we raise additional funds by issuing equity securities or by selling debt securities, if convertible, further dilution to our existing stockholders would result. To the extent our capital resources are insufficient to meet our future capital requirements, we will need to finance our future cash needs through public or private equity offerings, collaboration agreements, debt financings or licensing arrangements.

If adequate funds are not available, we may be required to terminate, significantly modify or delay our development programs, reduce our planned commercialization efforts, or obtain funds through collaborators that may require us to relinquish rights to our technologies or product candidates that we might otherwise seek to develop or commercialize independently. Further, we may elect to raise additional funds even before we need them if we believe the conditions for raising capital are favorable.

Off-Balance Sheet Arrangements

We do not currently have, nor have we ever had, any relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities, established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. In addition, we do not engage in trading activities involving non-exchange traded contracts.

Recent Accounting Pronouncements

The Company has adopted all recently issued accounting pronouncements that management believes to be applicable to the Company. The adoption of these accounting pronouncements, including those not yet effective, is not anticipated to have a material effect on the financial position or results of operations of the Company.

Jumpstart Our Business Startups Act of 2012

The JOBS Act permits an "emerging growth company" such as us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies. We have chosen to "opt out" of this provision and, as a result, we will comply with new or revised accounting standards as required when they are adopted. Our decision to opt out of the extended transition period under the JOBS Act is irrevocable.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The financial statements required by this item are set forth beginning on page 50 of this report and are incorporated herein by reference.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

(a) Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures

At the end of the period covered by this report, we carried out an evaluation, under the supervision and with the participation of our management, including our principal executive officer and principal accounting and financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures, as such term is defined under Rule 13a-15(e) promulgated under the Securities Exchange Act of 1934, as amended (the Exchange Act). Based on this evaluation, our principal executive officer and our principal accounting and financial officer concluded that our disclosure controls and procedures were effective as of December 31, 2012 to ensure that information to be disclosed by us in this Annual Report on Form 10-K was recorded, processed summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and Form 10-K.

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms and that such information is accumulated and communicated to our management, including our chief executive officer and principal accounting and financial officer, as appropriate, to allow for timely decisions regarding required disclosure. There were no changes in our internal controls over financial reporting during the year ended December 31, 2012 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

We intend to review and evaluate the design and effectiveness of our disclosure controls and procedures on an ongoing basis and to correct any material deficiencies that we may discover. Our goal is to ensure that our management has timely access to material information that could affect our business. While we believe the present design of our disclosure controls and procedures is effective to achieve our goal, future events affecting our business may cause us to modify our disclosure controls and procedures. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

(b) Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f). Under the supervision and with the participation of our management, including our principal executive officer and principal accounting and financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our evaluation under the framework in *Internal Control—Integrated Framework*, our management concluded that our internal control over financial reporting was effective as of December 31, 2012. Because we are a smaller reporting company, KCCW Accountancy Corp., our independent registered public accounting firm, is not required to attest to and or issue a report on the effectiveness of our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this Item with respect to executive officers, directors and corporate governance matters is incorporated by reference to the information set forth under the caption "Election of Directors," "Executive Officers" and "Corporate Governance" in the Company's Proxy Statement for the 2013 Annual Meeting of Shareholders.

The section entitled "Compliance Under Section 16(a) of the Securities Exchange Act of 1934" appearing in the Proxy Statement for the 2013 Annual Meeting of Shareholders sets forth the information concerning compliance by officers, directors and 10% shareholders of the company with Section 16 of the Exchange Act of 1934 and is incorporated herein by reference.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this Item is incorporated herein by reference to the information set forth under the caption "Executive Compensation" in the Proxy Statement for the 2013 Annual Meeting of Shareholders.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED SHAREHOLDER MATTERS

The information required by this Item is incorporated herein by reference to the information set forth under the caption "Security Ownership of Certain Beneficial Owners and Management and Related Shareholder Matters" in the Proxy Statement for the 2013 Annual Meeting of Shareholders.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this Item is incorporated herein by reference to the information set forth under the captions "Directors" and "Certain Relationships and Related Transactions" in the Proxy Statement for the 2013 Annual Meeting of Shareholders.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this Item is incorporated herein by reference to the information set forth under the caption "Principal Accountant Fees and Services" in the Proxy Statement for the 2013 Annual Meeting of Shareholders.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a)

1. Financial Statements

2. Financial Statement Schedules

All financial statement schedules are omitted because they are not required or the required information is included in the consolidated financial statements or notes thereto.

3. Exhibits

See the Exhibit Index set forth on page 75 of this report.

ATOSSA GENETICS, INC.
(A Development Stage Company)

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of:
Atossa Genetics, Inc.

We have audited the accompanying consolidated balance sheets of Atossa Genetics, Inc. (a development stage company) (the "Company") as of December 31, 2012 and 2011, and the related consolidated statements of operations, stockholders' equity, and cash flows for the years then ended and since inception (April 30, 2009). The Company's management is responsible for these consolidated financial statements. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Atossa Genetics, Inc. (a development stage company) as of December 31, 2012 and 2011, and the consolidated results of its operations and its cash flows for the years then ended and since inception (April 30, 2009) in conformity with accounting principles generally accepted in the United States of America.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As described in Note 2 of the consolidated financial statements, the Company has been in the development stage since its inception (April 30, 2009) and continues to incur net losses. The Company's viability is dependent upon its ability to obtain future financing and the success of its future operations. These matters raise substantial doubt about the Company's ability to continue as a going concern. Management's plan in regard to these matters is also described in Note 2 to the consolidated financial statements. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ KCCW Accountancy Corp.

Diamond Bar, California
March 27, 2013

KCCW Accountancy Corp.
22632 Golden Springs Dr. #230, Diamond Bar, CA 91765, USA
Tel: +1 909 348 7228 • Fax: +1 626 529 1580 • info@kccwcpa.com

ATOSSA GENETICS, INC.
(A DEVELOPMENT STAGE COMPANY)
CONSOLIDATED BALANCE SHEETS

	As of December 31,	
	2012	**2011**
Assets		
Current Assets		
Cash and cash equivalents	$ 1,725,197	$ 1,910,821
Restricted cash	-	1,000,000
Accounts receivable	141,665	1,224
Prepaid expense	122,633	31,184
Rental deposits	-	2,200
Total Current Assets	1,989,495	2,945,429
Fixed Assets		
Furniture and Equipment, net	159,967	80,467
Total Fixed Assets	159,967	80,467
Other Assets		
Security deposit	36,446	5,157
Intangible assets, net	4,640,224	40,841
Total Other Assets	4,676,670	45,998
Total Assets	$ 6,826,133	$ 3,071,894
Liabilities and Stockholders' Equity		
Current Liabilities		
Line of Credit	$ -	$ 1,000,000
Accounts payable	68,217	64,766
Accrued expenses	1,582,381	442,329
Note payable - related party	-	5,078
Total Current Liabilities	1,650,598	1,512,173
Stockholders' Equity		
Preferred stock - $.001 par value; 10,000,000 shares authorized, 0 shares issued and outstanding	-	-
Common stock - $.001 par value; 75,000,000 shares authorized, 12,919,367 and 11,256,867 shares issued and outstanding	12,919	11,257
Additional paid-in capital	14,894,522	6,200,520
Accumulated deficit	(9,731,906)	(4,652,056)
Total Stockholders' Equity	5,175,535	1,559,721
Total Liabilities and Stockholders' Equity	$ 6,826,133	$ 3,071,894

The accompanying notes are an integral part of these consolidated financial statements.

ATOSSA GENETICS, INC.
(A DEVELOPMENT STAGE COMPANY)
CONSOLIDATED STATEMENTS OF OPERATIONS

	For the Years Ended December 31,		From April 30, 2009 (Inception) Through December
	2012	2011	31, 2012
Revenue			
Diagnostic Testing Service	$ 475,402	$ -	$ 475,402
Product Sales	6,440	1,500	7,940
Total Revenue	481,842	1,500	483,342
Cost of Revenue			
Diagnostic Testing Service	(35,745)	-	(35,745)
Product Sales	-	(5,164)	(5,164)
Total Cost of Revenue	(35,745)	(5,164)	(40,909)
Loss on Reduction of Inventory to LCM	(29,884)	(92,026)	(121,910)
Gross Profit (Loss)	416,213	(95,690)	320,523
Selling expenses	(466,821)	(160,851)	(639,876)
General and Administrative expenses	(5,018,422)	(3,172,649)	(9,379,722)
Total operating expenses	(5,485,243)	(3,333,500)	(10,019,598)
Operating Loss	(5,069,030)	(3,429,190)	(9,699,073)
Interest Income	1,219	4,914	6,588
Interest Expense	(12,040)	(17,992)	(39,171)
Net Loss before Income Taxes	(5,079,851)	(3,442,269)	(9,731,656)
Income Taxes	-	-	250
Net Loss	$ (5,079,851)	$ (3,442,269)	$ (9,731,906)
Loss per common share - basic and diluted	$ (0.41)	$ (0.38)	$ (1.27)
Weighted average shares outstanding, basic & diluted	12,452,929	9,117,746	7,657,400

The accompanying notes are an integral part of these consolidated financial statements.

ATOSSA GENETICS, INC.
(A DEVELOPMENT STAGE COMPANY)
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

	Common Stock		Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Deficit	Equity
Balance at April 30, 2009, Founders' shares	3,976,465	$ 3,976	$ 50,024	$ -	$ 54,000
Issuance of shares for cash, July 28, 2009	39,765	40	500	-	540
Issuance of shares for cash, December 21, 2009	883,658	884	99,116	-	100,000
Net loss for the period ended December 31, 2009	-	-	-	(122,857)	(122,857)
Balance at December 31, 2009	4,899,888	4,900	149,640	(122,857)	31,683
Issuance of common shares for cash	901,354	901	101,099	-	102,000
Issuance of common shares for services	198,825	199	70,801	-	71,000
Compensation cost for stock options granted to executives	-	-	30,396	-	30,396
Net loss for the year ended December 31, 2010	-	-	-	(1,086,930)	(1,086,930)
Balance at December 31, 2010	6,000,067	6,000	351,936	(1,209,787)	(851,851)
Issuance of common shares for cash	5,256,800	5,257	5,708,528	-	5,713,785
Compensation cost for stock options granted to executives and employees	-	-	140,056	-	140,056
Net loss for the period ended December 31, 2011	-	-	-	(3,442,268)	(3,442,268)
Balance at December 31, 2011	11,256,867	11,257	6,200,520	(4,652,055)	1,559,721
Issuance of common shares for cash	800,000	800	3,453,200	-	3,454,000
Issuance of common shares for cash and asset purchase	862,500	863	4,311,637	-	4,312,500
Issuance of warrants for asset purchase	-	-	762,353	-	762,353
Compensation cost for stock options granted to executives and employees	-	-	166,812	-	166,812
Net loss for the period ended December 31, 2012	-	-	-	(5,079,851)	(5,079,851)
Balance at December 31, 2012	**12,919,367**	**$ 12,919**	**$ 14,894,522**	**$ (9,731,906)**	**$ 5,175,535**

The accompanying notes are an integral part of these consolidated financial statements.

ATOSSA GENETICS, INC.
(A DEVELOPMENT STAGE COMPANY)
CONSOLIDATED STATEMENTS OF CASH FLOWS

	For The Years Ended December 31,		For The Period From April 30, 2009 (Inception) to December 31, 2012
	2012	2011	
CASH FLOWS FROM OPERATING ACTIVITIES			
Net loss	$ (5,079,851)	$ (3,442,269)	$ (9,731,906)
Common shares issued for services	-	-	71,000
Compensation cost for stock options granted	121,812	140,056	292,264
Loss on reduction of inventory to LCM	29,884	92,026	121,910
Loan initiation fee accrued for notes payable	-	-	2,000
Depreciation and amortization	130,552	15,623	146,175
Adjustments to reconcile net loss to net cash provided by operating activities:			
Increase in accounts receivable	(140,441)	(1,224)	(141,665)
Increase in inventory	(29,884)	(92,026)	(121,910)
Increase in prepaid expenses	(91,449)	(31,184)	(122,633)
Increase in security deposits	(29,089)	(2,600)	(36,447)
Increase in accounts payable	3,451	64,765	68,217
Decrease in accrued payroll	-	(278,571)	-
Increase in accrued expenses	1,185,051	43,040	1,627,380
Net cash used in operating activities	(3,899,964)	(3,492,364)	(7,825,615)
CASH FLOWS FROM INVESTING ACTIVITIES			
Purchase of furniture & fixtures	(104,582)	(86,465)	(191,047)
Purchase of software	(30,000)	(50,466)	(80,466)
Net cash used in investing activities	(134,582)	(136,931)	(271,513)
CASH FLOWS FROM FINANCING ACTIVITIES			
Net proceeds from issuance of common stocks and warrants	3,854,000	5,713,785	9,824,325
(Repayments of) proceeds from bank line of credit	(1,000,000)	1,000,000	-
Repayments of loans from related parties	(5,078)	(183,922)	(2,000)
Cash released from (restricted for) commercial line of credit	1,000,000	(1,000,000)	-
Net cash provided by financing activities	3,848,922	5,529,863	9,822,325
NET INCREASE (DECREASE) IN CASH & CASH EQUIVALENTS	(185,624)	1,900,568	1,725,197
CASH & CASH EQUIVALENTS, BEGINNING BALANCE	1,910,821	10,253	-
CASH & CASH EQUIVALENTS, ENDING BALANCE	$ 1,725,197	$ 1,910,821	$ 1,725,197
SUPPLEMENTAL DISCLOSURES:			
Interest paid	$ 14,715	$ 17,992	$ 32,707
Income taxes paid	$ -	$ -	$ 250
NONCASH INVESTING AND FINANCING ACTIVITIES:			
Common stock and warrants issued for asset purchase	$ 4,674,853	$ -	$ 4,674,853
Options issued for previously accrued director compensation	$ 45,000	$ -	$ 45,000

The accompanying notes are an integral part of these consolidated financial statements.

NOTE 1: NATURE OF OPERATIONS

The Company's operations began in December 2008 with the negotiations for the acquisition of the Mammary Aspirate Specimen Cytology Test System, or the MASCT System, patent rights and assignments and the FDA clearance for marketing, which acquisition was completed in January 2009. Atossa Genetics Inc. (the "Company") was incorporated on April 30, 2009 in the State of Delaware. The Company was formed to develop and market the MASCT System, a cellular and molecular diagnostic risk assessment product for the detection of pre-cancerous changes that could lead to breast cancer. The Company's fiscal year ends on December 31st.

In December 2011 the Company established the National Reference Laboratory for Breast Health, or NRLBH, as a wholly-owned subsidiary. NRLBH is the Company's CLIA-certified laboratory where the ForeCYTE and ArgusCYTE test specimens are examined 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.

In September 2012, the Company acquired the assets of Acueity Healthcare, Inc. ("Acueity"). The purchased assets included 35 issued patents (18 issued in the U.S. and 17 issued in foreign countries) and 41 patent applications (32 in the U.S. and 9 in foreign countries), six 510(k) FDA marketing authorizations related to the manufacturing, use, and sale of the Viaduct Miniscope and accessories, the Manoa Breast Biopsy system, the Excisor Bioptome, the Acueity Medical Light Source, the Viaduct Microendoscope and accessories, and cash in the amount of $400,000. The microendoscopes are less than 0.9 mm outside diameter and can be inserted into a milk duct. This permits a physician to pass a microendoscope into the milk duct system of the breast and view the duct system via fiberoptic video images. Abnormalities that are visualized can then be biopsied from inside the duct with the biopsy tools that are inserted adjacent to the microendoscope. The patents relate to intraductal diagnostic and therapeutic devices and methods of use. The Company did not, however, acquire an inventory of these diagnostic tools, manufacturing capabilities or any personnel to market and sell the tools. The Company cannot provide any assurance that it will be successful commercializing these tools.

Development Stage Risk

From April 30, 2009 (inception) through December 31, 2012, the Company earned $483,342 in revenue from the sale of its MASCT System and laboratory services. The Company's activities have been accounted for as those of a "Development Stage Enterprise" as set forth in Accounting Standards Codification ("ASC") 915 "Development Stage Entities", which was previously Statement of Financial Accounting Standards No. 7 ("SFAS 7"). Among the disclosures required by ASC 915 are that the Company's financial statements be identified as those of a development stage company, and that the statements of operations, stockholders' equity and cash flows disclose activity since the date of the Company's inception.

Since its inception, the Company has been dependent upon the receipt of capital investment to fund its continuing activities. In addition to the normal risks associated with a new business venture, there can be no assurance that the Company's business plan will be successfully executed. The Company's ability to execute its business plan will depend on its ability to obtain additional financing and achieve a profitable level of operations. There can be no assurance that sufficient financing will be obtained. Further, the Company cannot give any assurance that it will generate substantial revenue or that its business operations will prove to be profitable.

NOTE 2: GOING CONCERN

The Company's consolidated financial statements are prepared using generally accepted accounting principles in the United States of America applicable to a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The Company has not yet established an ongoing source of revenue sufficient to cover its operating costs and allow it to continue as a going concern. The ability of the Company to continue as a going concern is dependent on the Company obtaining adequate capital to fund operating losses until it becomes profitable. If the Company is unable to obtain adequate capital, it could be forced to cease operations. The accompanying consolidated financial statements do not include any adjustments that might be necessary if the Company is unable to continue as a going concern.

Management's Plan to Continue as a Going Concern

In order to continue as a going concern, the Company will need, among other things, additional capital resources. Management's plans to obtain such resources for the Company include (1) obtaining capital from the sale of its equity securities, (2) sales of the MASCT System and laboratory service revenue, and (3) short-term borrowings from banks, stockholders or other related party(ies) when needed. However, management cannot provide any assurance that the Company will be successful in accomplishing any of its plans.

The ability of the Company to continue as a going concern is dependent upon its ability to successfully accomplish the plans described in the preceding paragraph and eventually to secure other sources of financing and attain profitable operations.

NOTE 3: SUMMARY OF ACCOUNTING POLICIES

Basis of Presentation:

The accompanying consolidated financial statements include the financial statements of Atossa Genetics Inc. and its wholly-owned subsidiary NRLBH. All significant intercompany account balances and transactions have been eliminated in consolidation. These consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America.

Recently Issued Accounting Pronouncements:

The Company has adopted all recently issued accounting pronouncements that management believes to be applicable to the Company. The adoption of these accounting pronouncements, including those not yet effective, is not anticipated to have a material effect on the financial position or results of operations of the Company.

Revenue Recognition:

Overview

The Company recognizes product and service revenue in accordance with GAAP when the following overall fundamental criteria are met: (i) persuasive evidence of an arrangement exists, (ii) delivery has occurred or the service has been performed, (iii) the Company's price to the customer is fixed or determinable and (iv) collection of the resulting accounts receivable is reasonably assured.

Product Revenue

The Company recognizes revenue for sales of the MASCT kits and devices upon receipt of cash as the company has an insufficient sales history on which to determine the collectability. Shipping documents and the completion of any customer acceptance requirements, when applicable, will be used to verify product delivery. The Company will assess whether a price is fixed or determinable based upon the payment terms associated with the transaction and whether the sales price is subject to refund or adjustment. Once a history of sales and collectability has been established, the company will recognize revenue on an accrual basis with an offsetting reserve for doubtful accounts based on the history during the initial sales period.

Service Revenue

The Company records revenue for diagnostic testing on an accrual basis at the Medicare allowed and invoiced amount. Amounts invoiced above the Medicare amount, namely non-Medicare, are not recognized on an accrual basis and instead are recognized on a cash basis as received. Diagnostic testing revenue at the Medicare rate is recognized upon completion of the test, communication of results to the patient's physician, and when collectability is reasonably assured. Customer purchase orders and/or contracts will generally be used to determine the existence of an arrangement. Once the Company has historical sales and can determine the proper amount to recognize as uncollectible, it will then begin to recognize the entire amount, both Medicare and non-Medicare billing on an accrual basis, with an offsetting allowance for doubtful accounts recorded based on history. The Company estimates it will utilize the diagnostic testing revenue history once it reaches 12 months of collection data to determine a proper allowance for doubtful accounts.

Cash and Cash Equivalents:

Cash and cash equivalents include cash and all highly liquid instruments with original maturities of three months or less.

As of December 31, 2012 and 2011, $0 and $1,000,000 of cash was restricted as collateral for a commercial line of credit obtained from JPMorgan Chase Bank in September 2011 (see Note 8), respectively. These amounts were designated as restricted cash under current assets on our consolidated balance sheets.

Use of Estimates:

The preparation of consolidated financial statements in conformity with generally accepted accounting principles in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenue and expenses during the reporting period. Accordingly, actual results could differ from those estimates.

Accounts Receivable:

Accounts receivable are recorded at net realizable value consisting of the carrying amount less allowance for doubtful accounts, as needed. We assess the collectability of accounts receivable based primarily upon the creditworthiness of the customer as determined by credit checks and analysis, as well as the customer's payment history. Management reviews the composition of accounts receivable and analyzes historical bad debts, customer concentrations, customer credit worthiness, current economic trends, and changes in customer payment patterns to evaluate the adequacy of these reserves. As of December 31, 2012 and 2011, no allowance for doubtful accounts was assessed or recorded.

Inventories:

The Company's inventories are stated at lower of cost or market. Cost is determined on a moving-average basis. Costs of inventories include purchase and related costs incurred in delivering the products to their present location and condition. Market value is determined by reference to selling prices after the balance sheet date or to management's estimates based on prevailing market conditions. Inherent in the lower of cost or market calculation are several significant judgments based on a review of the aging of the inventory, inventory movement of products, economic conditions, and replacement costs. Because the sales price of the MASCT System was substantially lower than its cost for the years ended December 31, 2012 and 2011, resulting in the net realizable value of the MASCT System being determined at zero as of the balance sheet dates through taking the average sales price subtracted by selling expenses per unit, a $29,884 and $92,026 loss on reduction of inventory to the lower of cost or market was assessed and recorded as of and for the period and for the year then ended, respectively. Additionally, management periodically evaluates the composition of its inventories at least quarterly to identify slow-moving and obsolete inventories to determine if any valuation allowance is required. As of December 31, 2012 and December 31, 2011, management had identified no slow moving or obsolete inventory.

The Company provides, either directly or through distributors, the ForeCYTE testing specimen collection kits to doctors with our MASCT System for doctors to collect specimens that are returned to the Company for diagnostic analysis. These collection kits are considered part of the MASCT System. During the initial marketing phase, the Company has decided to distribute the kits to customers at no cost and bundle them with the MASCT System, and has not intended to deem the kits as a primary product line due to their nominal cost and value per unit. As a result, the kits are immediately expensed and recorded as selling expense upon purchasing of the kits. For the years ended December 31, 2012 and 2011, selling expense of $55,282 and $0 was recorded related to the ForeCYTE kits, respectively.

Property, plant, and equipment:

Property, plant and equipment are stated at cost less accumulated depreciation. Expenditures for maintenance and repairs are charged to earnings as incurred; additions, renewals and betterments are capitalized. When property, plant and equipment are retired or otherwise disposed of, the related cost and accumulated depreciation are removed from the respective accounts, and any gain or loss is included in operations.

Depreciation is computed using the straight-line method over the estimated useful lives of the assets as follows:

	Useful Life (in years)
Machinery and equipment	5
Leasehold improvements	2.083

Intangible assets:

Intangible assets consist of intellectual property and software acquired in the Acueity asset purchase. At least annually, we evaluate purchased intangibles for impairment whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of the asset and its eventual disposition are less than its carrying amount. Estimating future cash flows related to an intangible asset involves significant estimates and assumptions. If our assumptions are not correct, there could be an impairment loss or, in the case of a change in the estimated useful life of the asset, a change in amortization expense. There was no impairment of intangible assets as of and for the years ended December 31, 2012 and 2011.

Amortization is computed using the straight-line method over the estimated useful lives of the assets as follows:

	Useful Life (in years)
Patents	9-14
Software	3

Research and Development Expenses:

Research and development costs are generally expensed as incurred. The Company's research and development expenses consist of costs incurred for internal and external research and development.

Share Based Payments:

In December 2004, the Financial Accounting Standards Board, or the FASB, issued the Statement of Financial Accounting Standards, or SFAS, No. 123(R), "Share-Based Payment", which replaces SFAS No. 123 and supersedes APB Opinion No. 25. SFAS No. 123(R) is now included in the FASB's ASC Topic 718, "Compensation – Stock Compensation." Under SFAS No. 123(R), companies are required to measure the compensation costs of share-based compensation arrangements based on the grant-date fair value and recognize the costs in the financial statements over the period during which employees or independent contractors are required to provide services. Share-based compensation arrangements include stock options and warrants, restricted share plans, performance-based awards, share appreciation rights and employee share purchase plans. In March 2005, the SEC issued Staff Accounting Bulletin No. 107, or SAB 107, which expresses views of the staff regarding the interaction between SFAS No. 123(R) and certain SEC rules and regulations and provides the staff's views regarding the valuation of share-based payment arrangements for public companies. SFAS No. 123(R) permits public companies to adopt its requirements using one of two methods. On April 14, 2005, the SEC adopted a new rule amending the compliance dates for SFAS No. 123(R). Companies may elect to apply this statement either prospectively, or on a modified version of retrospective application under which financial statements for prior periods are adjusted on a basis consistent with the pro forma disclosures required for those periods under SFAS No. 123.

The Company has fully adopted the provisions of FASB ASC 718 and related interpretations as provided by SAB 107. As such, compensation cost is measured on the date of grant as the fair value of the share-based payments. Such compensation amounts, if any, are amortized over the respective vesting periods of the option grant.

NOTE 4: PREPAID EXPENSES

Prepaid expenses consisted of the following:

	December 31, 2012	December 31, 2011
Prepaid insurances	$ 62,551	$ 14,146
Prepaid payroll taxes	40,082	-
Prepaid hardware/software maintenance and support service fee	-	12,850
Prepaid media relations service fee	20,000	-
Prepaid rent	-	4,188
	$ 122,633	$ 31,184

NOTE 5: RENTAL DEPOSITS

Rental deposits amounted to $0 and $2,200 as of December 31, 2012 and 2011, respectively, mainly consisted of the security deposits for office leases. The rental deposits of $2,200 as of December 31, 2011 consisted of two office leases, and the lease terms were from July 11, 2011 to July 31, 2012 and from October 1, 2011 to March 31, 2012 (see Note 13). Both were terminated on July 31, 2012 and March 31, 2012, respectively and were not renewed, and the security deposits have been received in full amount as of December 31, 2012.

NOTE 6: PROPERTY, PLANT, AND EQUIPMENT

Property, plant and equipment consisted of the following:

	December 31, 2012	December 31, 2011
Machinery and equipment	$ 97,383	$ 86,465
Leasehold improvements	93,664	-
Less: Accumulated depreciation	(31,080)	(5,998)
Property, plant, and equipment, net	$ 159,967	$ 80,467

Depreciation expense for the years ended December 31, 2012 and 2011 was $25,082 and $3,920, respectively.

NOTE 7: INTANGIBLE ASSETS

Intangible assets consisted of the following:

	December 31, 2012	December 31, 2011
Patents	$ 4,704,853	$ -
Software	50,466	50,466
Less: Accumulated amortization	(115,095)	(9,625)
	$ 4,640,224	$ 40,841

Intangible assets amounted to $4,640,224 and $40,841 as of December 31, 2012 and December 31, 2011, respectively, mainly consisted of patents and software acquired. The acquired software in the amount of $50,466 is for the purpose of managing laboratory results pursuant to a software installation agreement that was entered into on June 8, 2011. Amortization expense related to software for the years ended December 31, 2012 and 2011 was $17,090 and $9,625, respectively.

Patents amounted to $4,704,853 and $0 as of December 31, 2012 and 2011, respectively, and mainly consisted of patents acquired from Acueity on September 30, 2012 in an asset purchase transaction (see Note 15). Amortization expense related to patents was $88,650 and $0 for the years ended December 31, 2012 and December 31, 2011, respectively.

Future estimated amortization expenses as of December 31, 2012 for the five succeeding years is as follows:

As of December 31,	Amounts
2013	$ 374,415
2014	364,790
2015	357,593
2016	357,593
2017	357,593
Thereafter	2,828,240
	$ 4,640,224

NOTE 8: LINE OF CREDIT

In June 2011, the Company entered into a commercial line of credit agreement with JPMorgan Chase Bank. The term of the loan started from June 28, 2011 with maturity date on June 28, 2012. On July 23, 2012, the Company entered into a business loan extension agreement with JPMorgan Chase Bank to extend the loan for three months from the original maturity date. The line of credit agreement provides for borrowings up to $1,000,000. The adjustable interest rate is a rate per annum equal to the sum of an index, which is the LIBOR Rate plus 1.914 percentage point(s). The outstanding balance of the line of credit was $0 and $1,000,000 as of December 31, 2012 and 2011, respectively. The adjustable annual interest rate for the line of credit was 2.7618% and 2.2070% as of December 31, 2012 and 2011, respectively. On October 22, 2012, the Company paid off the line of credit in full amount.

As of December 31, 2012 and 2011, $0 and $1,000,000 of cash was restricted as collateral for the commercial line of credit, respectively.

NOTE 9: ACCRUED EXPENSES

Accrued expenses consisted of the following:

	December 31, 2012	December 31, 2011
Accrued expenses	$ 1,374,384	$ 201,113
Accrued bonus payable	189,131	153,830
Accrued payroll tax liabilities	18,866	87,386
Accrued interest	-	-
	$ 1,582,381	$ 442,329

NOTE 10: STOCKHOLDERS' EQUITY

The Company is authorized to issue a total of 85,000,000 shares of stock consisting of 75,000,000 shares of Common Stock, par value $0.001 per share, and 10,000,000 shares of Preferred Stock, par value $0.001 per share.

Reverse Stock-Split

On September 28, 2010, the Board of Directors approved a 1-for-2.26332 reverse share split for all issued and outstanding shares of Common Stock, with no change to the par value of the Common Stock.

Prior Issuances of Common Stock

On April 30, 2009 (inception), the Company issued 1,767,316 shares (or 4,000,000 shares prior to the reverse stock-split on September 28, 2010) to Ensisheim Partners LLC, a related party to the Company through common ownership, for cash in the amount of $24,000, or $0.014 per share (or $0.006 per share prior to the reverse stock-split on September 28, 2010); 1,325,487 shares (or 3,000,000 shares prior to the reverse stock-split on September 28, 2010) to Manistee Ventures LLC, a related party to the Company through common ownership, for cash in the amount of $18,000, or $0.014 per share (or $0.006 per share prior to the reverse stock-split on September 28, 2010); and 883,662 shares (or 2,000,000 shares prior to the reverse stock-split on September 28, 2010) to the Chairman, CEO and President of the Company at that time for cash in the amount of $12,000, or $0.014 per share (or $0.006 per share prior to the reverse stock-split on September 28, 2010).

On July 28, 2009, the Company issued 39,765 shares (or 90,000 shares prior to the reverse stock-split on September 28, 2010) to a director of the Company for cash in the amount of $540, or $0.014 per share (or $0.006 per share prior to the reverse stock-split on September 28, 2010).

On December 28, 2009, the Company issued 883,658 shares (or 2,000,000 shares prior to the reverse stock-split on September 28, 2010) to Ensisheim Partners LLC for cash in the amount of $100,000, or $0.11 per share (or $0.05 per share prior to the reverse stock-split on September 28, 2010).

On January 21, 2010, the Company issued 866,007 shares (or 1,960,000 shares prior to the reverse stock-split on September 28, 2010) to forty-four (44) investors for cash in the amount of $98,000, or $0.11 per share (or $0.05 per share prior to the reverse stock-split on September 28, 2010).

On January 21, 2010, the Company issued 132,549 shares (or 300,000 shares prior to the reverse stock-split on September 28, 2010) to a servicer for effecting transactions intended to cause the Company to become a public company and to have its securities traded in the United States. The shares were issued at a value of $15,000, or $0.11 per share (or $0.05 per share prior to the reverse stock-split on September 28, 2010), the same price as the issuance of the 866,007 shares (or 1,960,000 shares prior to the reverse stock-split on September 28, 2010) for cash on the same date.

On January 21, 2010, the Company issued an additional 53,020 shares (or 120,000 shares prior to the reverse stock-split on September 28, 2010) to a shareholder who acquired 13,255 shares (or 30,000 shares prior to the reverse stock-split on September 28, 2010) for cash on the same date as one of the forty-four (44) investors. Those shares were issued to the shareholder for services to be performed, including investor relations, media relations, and corporate communications. Those shares were issued at a value of $6,000, or $0.11 per share (or $0.05 per share prior to the reverse stock-split on September 28, 2010), the same price as the issuance of the 866,007 shares (or 1,960,000 shares prior to the reverse stock-split on September 28, 2010) for cash on the same date.

On January 23, 2010, the Company issued 35,346 shares (or 80,000 shares prior to the reverse stock-split on September 28, 2010) to an investor for cash in the amount of $4,000, or $0.11 per share (or $0.05 per share prior to the reverse stock-split on September 28, 2010).

On April 27, 2010, the Company issued 13,256 shares (or 30,000 shares prior to the reverse stock-split on September 28, 2010) to a service provider for website development services pursuant to an original agreement between the Company and the website developer executed on December 14, 2009 (the "measurement date"), where it was agreed at that time that, at the Company's option, $50,000 would be paid or 13,256 shares (or 30,000 shares of common stock prior to the reverse stock-split on September 28, 2010) would be issued to the developer in exchange for his services.

On September 30, 2012, the Company issued 862,500 shares to the shareholders of Acueity as part of the consideration for the asset purchase (see Note 15). The shares were valued at $5.00 per share, the offering price of the then contemplated initial public offering, for which the registration statement on Form S-1 (File No. 333-179500) was subsequently declared effective by the Securities and Exchange Commission on November 7, 2012, and a prospectus was subsequently filed pursuant to Rule 424(b)(4) on November 9, 2012 (see Note 16), or $4,312,500 in total.

On November 7, 2012, the Company's registration statement on Form S-1 (File No. 333-179500) was declared effective by the Securities and Exchange Commission for the Company's initial public offering. On November 9, 2012, pursuant to Rule 424(b)(4), the Company filed a prospectus for the initial public offering of 800,000 shares of its common stock with the offering price of $5.00 per share. As a result of the initial public offering, the Company received net proceeds of $3,454,000 after deducting underwriting discounts and commissions of approximately $546,000.

Private Placements and Warrants

On April 28, May 31, June 10, and June 23, 2011, pursuant to Securities Purchase Agreements with various investors (the "Investors"), the Company issued 5,256,800 shares of the Company's common stock and 5,256,800 warrants (the "Investor Warrants"), each of which entitles the investors to purchase the Company's common stock at $1.25 per share, for aggregate gross proceeds of $6,571,000 (the "Private Placement").

Placement Agent Fees

In connection with the Private Placement, the Company paid Dawson James Securities, Inc. (the "Placement Agent"), a cash fee equal to 10% of the gross proceeds from sale of the common stocks and warrants, plus 3% non-accountable expense allowance, an aggregate of $857,230 (the "Placement Agent Fee"). In addition, the Company entered into Warrant Agreements with the placement agent pursuant to which the Placement Agent received 788,520 warrants, Collectively, each of which entitles the Placement Agent to purchase one share of the Company's common stock at $1.60 per share, plus an additional 788,520 warrants (the "Placement Agent Warrants"), each of which entitles the placement agent to purchase the Company's common stock at $1.25 per share. The cash payment of $857,230 Placement Agent Fee and the $495,876 aggregated initial fair value of the Placement Agent Warrants (see *Fair Value Considerations* below) were directly attributable to an actual offering and were charged through additional paid-in capital in accordance with the SEC Staff Accounting Bulletin (SAB) Topic 5A.

Warrants

The Warrants, including the Investor Warrants and the Placement Agent Warrants, are exercisable at any time commencing after June 23, 2011 which is the date that the Company completed a "significant private financing" under the terms of the Warrants (the "Initial Exercise Date"). The Warrants shall expire and no longer be exercisable on the fifth anniversary of the Initial Exercise Date (the "Expiration Date"). The Company may at any time during the term of this Warrant reduce the then current Exercise Price to any amount and for any period of time deemed appropriate by the Board of Directors of the Company. The Warrants may be exercised for cash or, at the option of the Investor, may be exercised on a cashless basis; however if a registration statement is in effect for the resale of the common stock issuable upon exercise of the Warrants then the Warrants cannot be exercised on a cashless basis. There are no redemption features embodied in the Warrants and they have met the conditions provided in current accounting standards for equity classification.

Fair Value Considerations

The Company's accounting for the issuance of warrants to the Investors and the Placement Agent required the estimation of fair values of the financial instruments. The development of fair values of financial instruments requires the selection of appropriate methodologies and the estimation of often subjective assumptions. The Company selected the valuation techniques based upon consideration of the types of assumptions that market participants would likely consider in exchanging the financial instruments in market transactions. The warrants were valued 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 fair value these instruments.

The Investor Warrants and the Placement Agent Warrants were initially valued at $1,808,025 or $0.344 per warrant, $228,712 or $0.290 per warrant, and $267,164 or $0.339 per warrant, respectively. The following tables reflect assumptions used to determine the fair value of the Warrants:

	Fair Value Hierarchy Level	April-June 2011	December 2011	
		Investor Warrants	Placement Agent Warrants	Placement Agent Warrants
Indexed shares		5,256,800	788,520	788,520
Exercise price		$ 1.60	$ 1.60	$ 1.25
Significant assumptions:				
Stock price	3	$ 0.906	$ 0.906	$ 0.906
Remaining term	3	6 years	6 years	6 years
Risk free rate	2	2.49%	1.12%	1.12%
Expected volatility	3	53.55%	54.21%	54.21%

Fair value hierarchy of the above assumptions can be categorized as follows:

(1) There were no Level 1 inputs.

(2) Level 2 inputs include:

Risk-free rate- The risk-free rate of return reflects the interest rate for United States Treasury Note with similar time-to-maturity to that of the warrants.

(3) Level 3 inputs include:

Stock price- The Company's common stock was not publicly traded at the time the Warrants were issued. Therefore, the stock price was determined implicitly from an iterative process in order for the combined fair value of the common stock and the warrants to equal the amount of proceeds received in the Private Placement, based upon the assumption that the Private Placement was the result of an arm's length transaction.

Remaining term- The Company does not have a history to develop the expected term for its warrants. Accordingly, the Company expected that the Initial Exercise Date to occur within one year from the date of issuance plus the contractual term in the calculations.

Expected volatility- We did not have a historical trading history sufficient to develop an internal volatility rate for use in the model. As a result, as required by ASC 718-10-30, the Company has accounted for the warrants using the calculated value method. The Company identified seven public entities in the similar industry for which share price information was available, and considered the historical volatilities of those public entities' share prices in calculating the expected volatility appropriate to the Company.

Asset Purchase and Warrants

On September 30, 2012, pursuant to the asset purchase agreement with Acueity, the Company issued 862,500 shares of common stock and 325,000 warrants ("Acueity Warrants") to the shareholders of Acueity, each of which entitles the recipients to subscribe for and purchase from the Company one share of the Company's common stock at $5.00 per share (the "Exercise Price"), subject to a six-month lock up agreement.

Warrants

The Acueity Warrants are exercisable at any time commencing after September 30, 2012 (the "Issuance Date") and shall expire and no longer be exercisable on the fifth anniversary of the Issuance Date (the "Expiration Date"). The Company may at any time during the term of the Acueity Warrants reduce the then current Exercise Price to any amount and for any period of time deemed appropriate by the Board of Directors of the Company. The Acueity Warrants do not have a cashless exercise provision. There are no redemption features embodied in the Acueity Warrants and they have met the conditions provided in current accounting standards for equity classification.

Fair Value Considerations

The Company's accounting for the issuance of the Acueity Warrants required the estimation of fair values of the financial instruments. The development of fair values of financial instruments requires the selection of appropriate methodologies and the estimation of often subjective assumptions. The Company selected the valuation techniques based upon consideration of the types of assumptions that market participants would likely consider in exchanging the financial instruments in market transactions. The warrants were valued 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 fair value these instruments.

The Acueity Warrants were valued at $762,353 or $2.3457 per warrant. The following tables reflect assumptions used to determine the fair value of the Warrants:

	Fair Value Hierarchy Level	September 2012 Acueity Warrants
Indexed shares		325,000
Exercise price		$ 5.00
Significant assumptions:		
Stock price	3	$ 5.00
Remaining term	3	5 years
Risk free rate	2	0.62%
Expected volatility	3	56.54%

Fair value hierarchy of the above assumptions can be categorized as follows:

(1) There were no Level 1 inputs.

(2) Level 2 inputs include:

Risk-free rate- The risk-free rate of return reflects the interest rate for United States Treasury Note with similar time-to-maturity to that of the warrants.

(3) Level 3 inputs include:

Stock price- The Company's common stock was not publicly traded at the time the Acueity Warrants were issued. Therefore, the stock price was determined at the offering price of the then contemplated initial public offering, for which the registration statement on Form S-1 (File No. 333-179500) was subsequently declared effective by the Securities and Exchange Commission on November 7, 2012, and a prospectus was subsequently filed pursuant to Rule 424(b)(4) on November 9, 2012 (see Note 16).

Remaining term- The Company does not have a history to develop the expected term for its warrants. Accordingly, the Company expected that the Initial Exercise Date to occur within one year from the date of issuance plus the contractual term in the calculations.

Expected volatility- We did not have a historical trading history sufficient to develop an internal volatility rate for use in the model. As a result, as required by ASC 718-10-30, the Company has accounted for the warrants using the calculated value method. The Company identified seven public entities in the similar industry for which share price information was available, and considered the historical volatilities of those public entities' share prices in calculating the expected volatility appropriate to the Company.

Stock Option and Incentive Plan

On September 28, 2010, the Board of Directors approved the adoption of the 2010 Stock Option and Incentive Plan, or the 2010 Plan, subject to stockholder approval, to provide for the grant of equity-based awards to employees, officers, non-employee directors and other key persons providing services to the Company. Awards of incentive options may be granted under the 2010 Plan until September 2020. No other awards may be granted under the 2010 Plan after the date that is 10 years from the date of stockholder approval. An aggregate of 1,000,000 shares (or 2,263,320 shares prior to the reverse stock-split on September 28, 2010) are reserved for issuance in connection with awards granted under the 2010 Plan, such number of shares to be subject to adjustment as provided in the plan and in any award agreements entered into by the Company under the plan, and upon the exercise or conversion of any awards granted under the plan.

On April 4, 2011, 45,000 non-qualified stock options were granted under the 2010 Plan to Dr. Tim Hunkapiller for being a member of the Company's Scientific Advisory Board and consulting services to be provided to the Company.

On September 1, 2011, 219,000 incentive stock options were granted under the 2010 Plan to employees and officers and 200,000 non-qualified stock options were granted under the Plan to non-employee directors, respectively, for their employment with and services to be provided to the Company (see Note 14).

On April 30, 2012, 19,757 non-qualified stock options were granted under the 2010 Plan to members of the Board of Directors for their services provided to the Company.

On December 17, 2012, 228,000 incentive stock options were granted under the 2010 Plan to employees for their employment with and services to be provided to the Company (see Note 14).

On December 20, 2012, 200,000 inducement stock options were granted outside of the 2010 Plan to an employee for his employment with and services to be provided to the Company (see Note 14).

NOTE 11: INCOME TAXES

The Company accounts for income taxes as outlined in ASC 740, "Income Taxes", which was previously Statement of Financial Accounting Standards No. 109, "Accounting for Income Taxes" ("SFAS 109"). Under the asset and liability method of SFAS 109, deferred income tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between the financial reporting and tax bases of assets and liabilities and are measured using enacted tax rates in effect for the year in which those temporary differences are expected to be recovered or settled. A valuation allowance is provided for the amount of deferred tax assets that, based on available evidence, are not expected to be realized.

As a result of the Company's cumulative losses, management has concluded that a full valuation allowance against the Company's net deferred tax assets is appropriate. No income tax liabilities existed as of December 31, 2012 and 2011 due to the Company's continuing operating losses.

NOTE 12: CONCENTRATION OF CREDIT RISK

Financial instruments that potentially subject the Company to concentration of credit risk consist principally of cash deposits. Accounts at each institution are insured by the Federal Deposit Insurance Corporation ("FDIC") up to $250,000. At December 31, 2012 and 2011, the Company had $1,475,197 and $2,660,821 in excess of the FDIC insured limit, respectively.

NOTE 13: COMMITMENTS AND CONTINGENCIES

Lease Commitments

On September 29, 2010, the Company entered into a commercial lease agreement with CompleGen, Inc. for laboratory space located in Seattle, WA. The lease provides for monthly rent of $3,658 and a security deposit of $3,658. The lease terms are from September 29, 2010 through March 31, 2011, at which time the lease has converted to month to month unless two months' prior written notice of the intent to terminate the agreement is given. The monthly rent for the lease increased to $4,267 commencing January 2012. For the year ended December 31, 2012, the Company incurred $46,529 of rent expense for the lease. The lease was terminated in December 2012, and the rental deposit was applied to the rent of the final month.

On March 4, 2011, the Company entered into a commercial lease agreement with Sanders Properties, LLC for office space located in Seattle, WA. The lease provides for monthly rent of $1,100 and a security deposit of $1,500. The lease terms are from April 1, 2011 through March 31, 2013. For the year ended December 31, 2012, the Company incurred $13,200 of rent expense for the lease.

On July 9, 2011, the Company entered into a commercial lease agreement with Sanders Properties, LLC for additional office space located in Seattle, WA. The lease provides for monthly rent of $600 and a security deposit of $1,200. The lease terms are from July 11, 2011 through July 31, 2012. For the year ended December 31, 2012, the Company incurred $4,200 of rent expense for the lease. This lease terminated on July 31, 2012 and was not renewed.

On September 27, 2011, the Company entered into another commercial lease agreement with Sanders Properties, LLC for additional office space located in Seattle, WA. The lease provides for monthly rent of $1,400 and a security deposit of $1,000. The lease terms are from October 1, 2011 to March 31, 2012. For the period of October 1, 2011 through March 31, 2012, the Company incurred $8,400 of rent expense for the lease. This lease terminated on March 31, 2012 and was not renewed.

On December 9, 2011, the Company entered into another commercial lease agreement with Fred Hutchinson Research Center for lab and office space located in Seattle, WA. The lease provides for monthly rent of $16,395 for the period from February 24, 2012 to August 31, 2012, $19,923 for the period from September 1, 2012 to August 31, 2013, and $20,548 for the period from September 1, 2013 to November 29, 2014. The security deposit of $32,789 was paid in March 2012 and recorded as Security Deposit on the consolidated balance sheet as of December 31, 2012. For the year ended December 31, 2012, the Company incurred $208,581 of rent expense for the lease, which included leasing office management expenses.

The future minimum lease payments due subsequent to December 31, 2012 under all non-cancelable operating leases for the next five years are as follows:

As of December 31,	**Amount**
2013	$ 262,159
2014	246,808
2015	-
2016	-
2017	-
Thereafter	-
Total minimum lease payments	**$ 508,967**

Contingencies

On June 30, 2011, Robert Kelly, the Company's former President, filed a counterclaim against the Company in an arbitration proceeding, alleging breach of contract in connection with the termination of a consulting agreement between Mr. Kelly (dba Pitslayer LLC) and the Company that was entered into in July 2010 in connection with his resignation from the Company as President and a director. The consulting agreement was terminated by the Company in September 2010. Mr. Kelly seeks $450,000 in compensatory damages, which is the amount he claims would have been earned had the consulting agreement been fulfilled to completion.

On December 11, 2012, Mr. Kelly filed a complaint in the United States District Court, Western Division of Washington seeking compensatory damages, interest and attorneys' fees related to the termination of Mr. Kelly's consulting contract and the rescission of shares issued to him in July 2010 in connection with his resignation from the Company as President and a director. The specific amount of damages sought is to be proven at trial and is not specified.

On February 26, 2013, Mr. Victor Cononi filed a complaint in the United States District Court, Western Division of Washington seeking compensatory damages, interest and attorneys' fees related to the rescission of shares issued to him in July 2010 in connection with Mr. Kelly's resignation from the Company as President and a director. Mr. Cononi is the father of Mr. Kelly's paramour. The specific amount of damages sought is to be proven at trial and is not specified.

A hearing in the arbitration has been postponed pending certain procedures in the above Western Division action and may be delayed further to accommodate other third party civil and federal criminal proceedings alleging securities and wire fraud that have been brought against Mr. Kelly with respect to his prior employment and predating his service with the Company.

The Company is reasonably confident in its defenses to Mr. Kelly's and Mr. Cononi's claims. Consequently, no provision or liability has been recorded for these claims as of December 31, 2012. However, it is at least reasonably possible that the Company's estimate of liability may change in the near term. Any payments by reason of an adverse determination in this matter will be charged to earnings in the period of determination.

NOTE 14: RELATED PARTY TRANSACTIONS

Loans from Officer

On May 26, 2009, the Company borrowed $5,000 from its Chairman of the Board and Chief Executive Officer as a short-term, unsecured loan via verbal agreement and did not bear any interest. Commencing June 30, 2010, the loan was converted into a written Promissory Note bearing an annual interest rate of 10%, with a maturity date of December 31, 2010. This note was repaid in full on May 16, 2011 including approximately $439 of accrued interest.

On June 30, 2010, the Company borrowed an additional $100,000 from its Chairman of the Board and Chief Executive Officer pursuant to a promissory note. The loan under the note was funded to the Company on July 12, 2010. The note bears a 10% interest rate per annum and carries a $4,000 loan origination fee which is accreted to the loan balance throughout the life of the loan. The $4,000 loan origination fee was fully accreted to the loan balance as of March 31, 2011 and December 31, 2010, and recorded as interest expense for the year ended December 31, 2010. This note (including the $4,000 origination fee) was repaid in full on May 19, 2011 including approximately $8,959 in accrued interest.

On November 3, 2010, the Company entered into a line of credit agreement for borrowing up to $500,000 from its Chairman of the Board and Chief Executive Officer pursuant to a promissory note. The note bears a 10% interest rate per annum. An aggregate of $140,000 was funded to the Company under the line of credit as of March 31, 2011 which was repaid on May 31, 2011, including approximately $6,093 in accrued interest. As of December 31, 2011, the unpaid principal balance drawn from the line of credit was $5,078, which was fully repaid on March 31, 2012.

On July 30, 2012, the Company entered into a line of credit agreement for borrowing up to $500,000 from its Chairman of the Board and Chief Executive Officer pursuant to a promissory note. The note bears a 12% interest rate per annum. An aggregate of $79,300 was funded to the Company under the line of credit as of December 31, 2012. The principal balance of $79,300 and interest of $1,440 was fully repaid on October 11, 2012.

Exclusive License Agreement

On July 27, 2009, the Company entered into an exclusive license agreement with Ensisheim Partners LLC ("Ensisheim"), an entity solely owned by the Chairman and Chief Executive Officer of the Company and the Chief Scientific Officer of the Company, who is also the Company's Chairman and CEO's wife. Pursuant to that agreement, Ensisheim granted the Company an exclusive, worldwide, perpetual, irrevocable, royalty-bearing, license to the MASCT System, with the right to grant and authorize sublicenses. The license agreement provided that the Company would pay Ensisheim a royalty equal to 2% of net sales revenue, with a minimum royalty of $12,500 per fiscal quarter during the term of the agreement, which would have increased to a minimum royalty of $25,000 per fiscal quarter beginning in the quarter in which the first commercial sale of a licensed product would have taken place. From inception through December 31, 2010, the Company had incurred $16,250 in patent-related expenses under the license agreement with Ensisheim, and $0 subsequent to December 31, 2010.

On June 17, 2010, the Company and Ensisheim entered into an Assignment Agreement, whereby Ensisheim assigned to the Company all rights to the patents and patent applications underlying the MASCT System. Pursuant to the assignment, the Company will have all responsibility for prosecution, maintenance, and enforcement and will indemnify Ensisheim from any and all claims against the patent estate. Ensisheim retained no residual rights with respect to the patents and patent applications. In conjunction with the assignment, the Company terminated the exclusive license agreement between the Company and Ensisheim dated July 27, 2009. As a result of the termination, the Company has no further obligations with respect to royalty payments to Ensisheim due under the old licensing agreement. As a result, the $12,500 of patent royalty payable to Ensisheim recorded as accrued royalty payable at December 31, 2009 has been reversed through royalty expense during the second quarter of 2010.

Commercial Lease Agreement

On December 24, 2009, the Company entered into a commercial lease agreement with Ensisheim for office space located in Seattle, Washington. The lease provided for annual rent of $13,200, plus applicable sales tax. From inception through December 31, 2009, the Company incurred $248 of rent expense for the lease with security deposit of $1,100. For the period of January 1, 2010 through June 30, 2010, the Company incurred $6,600 of rent expense for the lease. On July 15, 2010 the Company and Ensisheim terminated the lease, effective July 1, 2010 and the Company commenced use of the facility rent free until April 1, 2011 when the commercial lease agreement the Company entered into with Sanders Properties, LLC became effective (see Note 13). The $1,100 security deposit paid to Ensisheim was received as of December 31, 2012.

Executive Compensation

On May 19, 2010, the Company entered into employment agreements with three executives, including its Chief Executive Officer, its former President, and its Chief Scientific Officer. The annual base salaries under each agreement were calculated based on combined consideration of the success of capital raise and the operating results of the Company, and capped at $360,000, $350,000, and $250,000, respectively for the three executives.

On July 22, 2010, in connection with the resignation and departure of Robert L. Kelly, the President and a director, the Company entered into a consulting agreement with a limited liability company controlled by Mr. Kelly. Under the agreement, the Company was to receive consulting services relating to capital raising and investor relations. The agreement was terminated by the Company in September 2010, through which time a total of $30,000 consulting expense had been paid.

On July 22, 2010, the Company restated and amended the employment agreements with its CEO and CSO. The agreements modified the base annual salary amounts to $250,000 and $200,000, respectively, effective retroactively to May 19, 2010. For the year ended December 31, 2011, the total amount of salaries and bonuses of the CEO and CSO was $693,048, of which $492,095 was recorded to research and development expense. For the year ended December 31, 2012, salaries and bonuses of CEO and CSO amounted to $322,590 and $243,554, of which $161,295 and $243,554 were recorded to research and development expense, respectively.

Share-Based Compensation

The amended employment agreement with the CEO, entered into on July 22, 2010, granted options to purchase 250,000 shares (or 565,830 shares prior to the reverse stock-split on September 28, 2010) at a price of $5.00 per share, in consideration of his service to the Company. Of these options, 25% (or 62,500 shares) vested on December 31, 2010 with the remaining 75% (or 187,500 shares) to vest in equal quarterly installments over the next three years so long as the executive remains employed with the company. These options have five-year contractual terms.

The amended employment agreement with the CSO, entered into on July 22, 2010, granted options to purchase 100,000 shares (or 226,332 shares prior to the reverse stock-split on September 28, 2010) at a price of $5.00 per share in consideration of her service to the Company. Of these options, 25% (or 25,000 shares) vested on December 31, 2010 with the remaining 75% (or 75,000 shares) to vest in equal quarterly installments over the next three years so long as the executive remains employed with the company. These options have five-year contractual terms.

On April 4, 2011, 45,000 non-qualified stock options were granted under the 2010 Plan to Dr. Tim Hunkapiller for being a member of the Company's Scientific Advisory Board and consulting services to be provided to the Company, at an exercise price of $1.25 per share. These options have a ten-year contractual term and shall vest as follows:

(i) 11,250 option shares shall vest ninety (90) days after the date of grant;
(ii) 11,000 option shares shall vest one hundred and eighty (180) days after the date of grant;
(iii) 11,500 option shares shall vest two hundred and seventy (270) days after the date of grant;
(iv) 11,250 option shares shall vest three hundred and sixty (360) days after the date of grant.

On September 1, 2011, 219,000 incentive stock options were granted under the 2010 Plan to employees and officers as part of their employment agreements, at an exercise price of $1.25 per share. These options have a ten-year contractual term and shall vest and become exercisable as follows:

(i) twenty-five percent (25%) of the underlying shares on the first anniversary of the date of grant; and
(ii) one-forty eighth (1/48) of the underlying shares monthly thereafter.

On September 1, 2011, 200,000 non-qualified stock options were granted under the 2010 Plan to non-employee directors for services to be provided to the Company, at an exercise price of $1.25 per share. These options have a ten-year contractual term and shall vest and become exercisable as follows:

(i) 80,000 option shares shall vest on September 1, 2011;
(ii) 30,000 options shares shall vest on December 1, 2011;
(iii) 30,000 options shares shall vest on March 1, 2012;
(iv) 30,000 options shares shall vest on June 1, 2012;
(v) 30,000 options shares shall vest on September 1, 2012.

On April 30, 2012, 19,757 non-qualified stock options were granted under the 2010 Plan to non-employee directors for serving as directors of the Company, at an exercise price of $6.00 per share. These options have a ten-year contractual term and shall vest and become exercisable in full immediately as of the grant date.

On December 17, 2012, 228,000 non-qualified stock options were granted under the 2010 Plan to employees as part of their employment agreements, at an exercise price of $4.24 per share. On December 20, 2012, 200,000 non-qualified stock options were granted outside of the 2010 Plan, but governed in all respects by the 2010 Plan, to an employee as part of his employment agreement, at an exercise price of $4.11 per share. These options each have a ten-year contractual term and shall vest and become exercisable as follows:

(i) twenty-five percent (25%) of the underlying shares on the first anniversary of the date employment commence; and
(ii) one-sixteenth (1/16) of the underlying shares quarterly thereafter.

In accordance with the guidance provided in ASC Topic 718, Stock Compensation (formerly SFAS 123R), the compensation costs associated with these options are recognized, based on the grant-date fair values of these options, over the requisite service period, or vesting period. Accordingly, the Company recognized a compensation expense of $121,812 and $140,056 for the years ended December 31, 2012 and 2011, respectively.

The Company estimated the fair value of these options using the Black-Scholes-Merton option pricing model based on the following weighted-average assumptions:

	CEO & CSO	Dr. Hunkapiller	Employees & Officers	Non-employee Directors	Non-employee Directors	Employees	Employee
Date of grant	22-Jul-10	4-Apr-11	1-Sep-11	1-Sep-11	30-Apr-12	17-Dec-12	20-Dec-12
Fair value of common stock on date of grant	$ 2.7560(B)	$ 0.9060(C)	$ 0.9060(C)	$ 0.9060(C)	$ 6.00(D)	$ 4.24(E)	$ 4.11(E)
Exercise price of the options	$ 5.00	$ 1.25	$ 1.25	$ 1.25	$ 6.00	$ 4.24	$ 4.11
Expected life of the options (years)	3.33	5.31	5.65	5.65	5.00	5.74-6.10	6.11
Dividend yield	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
Expected volatility	58.59%	54.12%	53.90%	53.90%	62.46%	42.44-44.58%	42.44%
Risk-free interest rate	1.03%	2.26%	1.08%	1.08%	0.89%	0.91-0.99%	0.99%
Expected forfeiture per year (%)	0.00%	0.00%	(A)	0.00%	0.00%	0.00-10.00%	0.00%
Weighted-average fair value of the options (per unit)	$ 0.6744	$ 0.3729	$ 0.3579	$ 0.3579	$ 3.0367	$ 1.7426-1.7887	$ 1.7842

(A) 0.00% for the first year after the grant date, and 96.35% for every three months thereafter.
(B) The fair value of the Company's common stock was derived implicitly from the public offering filed in March 2010 at $3.00 per share and from the terms of an underwritten offering contemplated in July 2010 at $6.00 per Unit that was filed in October 2010, with $2.756 per share being allocated to common stock using an iterative approach in order for the combined fair value of the common stock and warrants to equal the amount of consideration to be received for the offering.
(C) The fair value of the Company's common stock was derived implicitly from the Private Placement during April through June 2011 at $1.25 per Unit, wherein one Unit was comprised of one share of common stock and one warrant to purchase one share of common stock at an exercise price of $1.60 per share.
(D) The fair value of the Company's common stock was derived implicitly from the public offering filed in February 2012 at $6.00 per share.
(E) The fair values of the Company's common stock were derived from the closing prices on the NASDAQ Capital Market as of the dates of grant.

In October 2010, the Company filed a Registration Statement on Form S-1 with the SEC. However, the market for early stage investments in medical technology transactions had deteriorated between mid-2010 and early 2011. In addition, the Company's ability to negotiate with potential investors was limited. The Company's cash position had also diminished since the summer of 2010 and the founders of the Company were unable to finance the Company at the level needed for growth. The withdrawal of the Registration Statement in February 2011 further weakened the impression of the Company in the market. The fair value of the Company's common stock decreased from $2.756 in 2010 to $0.906 in 2011 primarily because the grants in 2011 relied on the arm's-length negotiation of the private placement financing (for illiquid stock) as opposed to relying on an anticipated initial public offering (of publicly-traded stock), as was the case in 2010. The private placement transactions were between the company and over 200 accredited investors and ascribed a value of $0.906 to the Company's common stock.

Fair value hierarchy of the above assumptions can be categorized as follows:

(1) There were no Level 1 inputs.

(2) Level 2 inputs include:

Risk-free rate- The risk-free rate of return reflects the interest rate for United States Treasury Note with similar time-to-maturity to that of the options.

(3) Level 3 inputs include:

Expected lives- The expected lives of options granted were derived from the output of the option valuation model and represented the period of time that options granted are expected to be outstanding.

Expected forfeitures per year- The expected forfeitures are estimated at the dates of grant and will be revised in subsequent periods pursuant to actual forfeitures, if significantly different from the previous estimates.

Expected volatility- We did not have a historical trading history sufficient to develop an internal volatility rate for use in the model. As a result, as required by ASC 718-10-30, the Company has accounted for the options using the calculated value method. The Company identified five to seven public entities in the similar industry for which share price information was available, and considered the historical volatilities of those public entities' share prices in calculating the expected volatility appropriate to the Company.

The estimates of fair value from the model are theoretical values of stock options and changes in the assumptions used in the model could result in materially different fair value estimates. The actual value of the stock options will depend on the market value of the Company's common stock when the stock options are exercised.

Notwithstanding that the fair market value of the Company's common stock in September 2011 was $0.906 per share, the Company filed a Registration Statement on Form S-1 in February 2012 to offer shares of its common stock at $5.00 to $7.00 per share. This increase in share value is justified by the accomplishments achieved by the Company between September 2011 and February 2012. Specifically, the MASCT System manufacturing had been completed, supplies for the Field Experience Trial were completed and the Company had established an FDA-compliant inventory and warehousing facility. Further, the National Reference Laboratory for Breast Health, the Company's wholly-owned subsidiary, was established as a Delaware corporation, was equipped and staffed, and the protocols and procedures needed to be a CLIA-registered facility were put in place. Moreover, the ForeCYTE test, which involves cytopathology and five biomarkers of hyperplasia and one biomarker of sample integrity, was completed, tested, and validated to CLIA standards. Computer hardware and software was acquired, set up, made operational, and the ForeCYTE report template, with unique reporting information for the requesting physician and a patient letter template, were created. The company explored and identified a technology for the ArgusCYTE test, negotiated a supply agreement with the supplier, and tested and validated the test. An ArgusCYTE report template was also established and a new reporting scheme invented and a patent application filed.

Further, the Company negotiated the acquisition of the FullCYTE Microcatheter System from Hologics, reestablished the supply chain and began preparing for a commercial launch later in 2012 or early 2013. In doing so, the Company increased its U.S. patent portfolio from 5 to 31 and its total portfolio of patents and applications to over 120. The Hologic patent estate also contains the key patents that permit microcatheter-based intraductal treatment of cancer and pre-cancer. The Company also prepared marketing documents for the launch of the ForeCYTE and ArgusCYTE tests, which occurred in December 2011. The Company launched a clinical trial of the FullCYTE microcatheter to establish the feasibility of performing Next Generation Sequencing on the samples obtained with the microcatheter, negotiated the acquisition of the NextCYTE technology, and is conducting a study of the utility of the technology in providing superior information in the setting of cancer diagnosis and treatment selection.

The Company also established third-party relationships to perform the reimbursement billing in anticipation of the commercial launch and to permit electronic remittance of testing revenue. The Company launched a Field Test Experience limited launch of both the ForeCYTE and ArgusCYTE tests on schedule in December 2011 and has seen significant market acceptance of both tests from the doctors and clinics using the tests. The Company passed a CLIA inspection and became CLIA-certified, has obtained several state licenses and has pending applications in all remaining states where licensure is required. Finally, the Board of Directors and scientific advisory board were each strengthened with the addition of key new executives and scientists.

The Board of Directors considered each of the foregoing achievements, and considered input from the Company's investment bankers, in determining that the value of the Company supports a valuation of $5.00 to $7.00 per share of the Company's common stock.

Options issued and outstanding as of December 31, 2012 and their activities during the twelve months then ended are as follows:

	Number of Underlying Shares	Weighted-Average Exercise Price Per Share	Weighted-Average Contractual Life Remaining in Years
Outstanding as of January 1, 2012	608,000	$ 3.41	
Granted	447,757	4.26	
Expired	-	-	
Forfeited	(3,621)	1.25	
Outstanding as of December 31, 2012	1,051,636	3.78	7.12
Exercisable as of December 31, 2012	531,095	3.28	5.64
Vested and expected to vest (1)	1,048,845	3.78	7.12

(1) Includes vested shares and unvested shares after a forfeiture rate is applied.

As of December 31, 2012 and 2011, the aggregate intrinsic value of options outstanding was $1,150,416 and $329,053, respectively.

A summary of the status of the Company's unvested shares as of December 31, 2012 and changes during the twelve month period then ended is presented below:

Unvested Shares	Shares	Weighted-Average Grant-Date Fair Value
Unvested as of January 1, 2012	**289,250**	**$ 159,013**
Granted	**447,757**	**822,659**
Vested	**(212,345)**	**(156,724)**
Forfeited	**(3,621)**	**(1,296)**
Unvested as of December 31, 2012	**520,541**	**$ 823,652**

NOTE 15: ASSET PURCHASE

On September 30, 2012, the Company entered into an asset purchase agreement with Acueity Healthcare, Inc ("Acueity") to acquire substantially all of the assets of Acueity. Through the asset purchase, the Company acquired 35 issued patents (18 issued in the U.S. and 17 issued in foreign countries), 41 patent applications (32 in the U.S. and 9 in foreign countries), six 510(k) FDA marketing authorizations related to the manufacturing, use, and sale of the Viaduct Miniscope and accessories, the Manoa Breast Biopsy system, the Excisor Bioptome, the Acueity Medical Light Source, the Viaduct Microendoscope and accessories, and cash in the amount of $400,000; no liabilities were assumed in the transaction. In consideration for the assets, the Company issued 862,500 shares of common stock, valued at $5.00 per share, the offering price listed on the prospectus filed pursuant to Rule 424(b)(4) on November 9, 2012, and warrants to purchase up to 325,000 shares of common stock at an exercise price of $5.00 per share, to the shareholders of Acueity, 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 (see Note 10). There are no future financial obligations from the Company to Acueity from the commercialization of the acquired assets.

NOTE 16: SUBSEQUENT EVENTS

Management has evaluated subsequent events through March 27, 2013, the date which the consolidated financial statements were available to be issued. All subsequent events requiring recognition as of December 31, 2012 have been incorporated into these consolidated financial statements and there are no subsequent events that require disclosure in accordance with FASB ASC Topic 855, "Subsequent Events".

Recent Share and Option Issuances

The Company has issued the following securities pursuant to exemptions from registration under the Securities Act of 1933, as amended (the "Act"):

1. On January 4, 2013, the Company granted 500,000 stock options (405,000 of which were not registered under the Act) to Kyle Guse in connection with his employment as Chief Financial Officer, General Counsel and Secretary. The options have an exercise price of $4.11 per share, the fair market value of the Company's Common Stock on the date of grant, and vest 25% at the end of the first year of employment and one-sixteenth (1/16) quarterly over the following three years.

2. On January 13, 2013, the Company issued a warrant to purchase 60,000 shares of Common Stock to a consultant as compensation for services to the Company. The warrant has an exercise price of $4.24 per share which was the fair market value of the Company's Common Stock on the date of grant. The warrant has a net-exercise feature and it vests monthly over one year so long as the consultant continues to provide services to the Company.

3. On January 24, 2013, the Company issued 32,186 shares of Common Stock to consultants as compensation for the performance of services to the Company. The aggregate value of shares issued was $143,550, or $4.46 per share, the fair market value of the Company's Common Stock on the date of issuance.

4. On February 25, 2013 the Company issued 1,081,782 shares of Common Stock and on February 28, 2013 the Company issued 139,971 shares of Common Stock each upon exercise of outstanding warrants. These warrants were exercised on a "net" basis without additional consideration received by the Company. These warrants were originally issued in 2011 in connection with the Company's private placement to accredited investors pursuant to Rule 506 of Regulation D under the Act. The shares issued upon exercise of the warrants remain subject to the six-month lock-up agreements between the holders of the shares and Dawson James Securities, Inc. that were entered into in connection with the Company's initial public offering.

The above securities were issued and sold pursuant to an exemption from registration under Section 4(a)(2) of the Act as transactions by an issuer not involving any public offering.

As of the date of filing this report, management was still in the process of determining the fair value of the 500,000 stock options and the 60,000 warrants issued as described above, in accordance with FASB ASC Topic 718.

FDA Warning Letter

On February 21, 2013, the Company received a Warning Letter ("Letter") from the FDA regarding its Mammary Aspirate Specimen Cytology Test (MASCT) System and MASCT System Collection Test (together, the "System"). The Letter arises from certain FDA findings during a July 2012 inspection, to which the Company responded in August 2012, explaining why the Company believed it was in compliance with applicable regulations and/or was implementing changes responsive to the findings of the FDA inspection. FDA alleges in the Letter that following 510(k) clearance the Company changed the System in a manner that requires submission of an additional 510(k) notification to the FDA. Specifically, the FDA observes that the Instructions For Use (IFU) in the original 510(k) submission stated that the user must "Wash the collection membrane with fixative solution into the collection vial…" and the current IFU states "…apply one spray of Saccomanno's Fixative to the collection membrane…" and that "this change fixes the NAF specimen to the filter paper rather than washing it into a collection vial." At the time that the changes were made the Company determined that a new 510(k) was not required in accordance with the FDA's guidance document entitled, "Deciding When to Submit a 510(k) for a Change to an Existing Device." The Letter also raises certain issues with respect to the Company's marketing of the System and the Company's compliance with FDA Good Manufacturing Practices (cGMP) regulations, among other matters. The Company responded to the Letter on March 13, 2013.

The Company is reasonably confident in its responses to the FDA. Consequently, no provision or liability has been recorded as of December 31, 2012 as a result of the Letter. However, it is at least reasonably possible that the Company's estimate of related liability may change in the near term. Any payments by reason of an adverse determination in this matter will be charged to earnings in the period of determination.

Contract with Reimbursement Organization

On March 7, 2013, NRLBH entered into a contractual agreement with FedMed, Inc., which has proprietary Preferred Provider Organization (PPO) networks in the U.S. for diagnostic laboratory testing. The agreement will give FedMed's participating providers and its clients' members greater access to the Company's tests.

Common Stock Purchase Agreement with Aspire Capital Fund, LLC

On March 27, 2013 the Company entered into a stock purchase agreement with Aspire Capital Fund, LLC, which provides that, upon the terms and subject to the conditions and limitations set forth therein, Aspire is committed to purchase up to an aggregate of $30 million of shares of the Company's common stock over the three-year term of the agreement. Under the agreement, on March 27, 2013, Aspire purchased 83,333 shares of our common stock at $12.00 per share, with gross proceeds to the Company of $1,000,000. Before we can sell any additional shares under the agreement, we must register the shares with the SEC and have the registration statement declared effective and remain effective.

SIGNATURES

Pursuant to the requirements Section 13 or 15(d) of the Securities Exchange Act of 1934, the issuer, a corporation organized and existing under the laws of the State of California, has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized in the City of Seattle, State o Washington, on the 27 day of March, 2013.

Atossa Genetics Inc.

By: /s/ Steven C. Quay

Steven C. Quay, M.D., Ph.D.
Chairman, Chief Executive Officer and President

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints Steven C. Quay and Kyle Guse and each of them acting individually, as his true and lawful attorneys-in-fact and agents, each with full power of substitution, for him in any and all capacities, to sign any and all amendments to this report on Form 10-K and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, with full power of each to act alone, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully for all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or his or their substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this Annual Report on Form 10-K has been signed by the following persons in the capacities and on the dates indicated

Signature	Office(s)	Date
/s/ Steven C. Quay **Steven C. Quay, M.D., Ph.D.**	Chairman, Chief Executive Officer and President (Principal Executive Officer)	March 27, 2013
/s/ Kyle Guse **Kyle Guse**	Chief Financial Officer, General Counsel and Secretary (Principal Financial and Accounting Officer)	March 27, 2013
/s/ John Barnhart **John Barnhart**	Director	March 27, 2013
/s/ Shu-Chih Chen **Shu-Chih Chen, Ph.D.**	Director	March 27, 2013
/s/ Alexander Cross **Alexander Cross, Ph.D.**	Director	March 27, 2013
/s/ Stephen J. Galli **Stephen J. Galli, M.D.**	Director	March 27, 2013
/s/ H. Lawrence Remmel **H. Lawrence Remmel**	Director	March 27, 2013

EXHIBIT INDEX

Exhibit No.	Description	Incorporated by Reference Herein	
		Form	Date
2.1††	Agreement and Plan of Reorganization, dated September 30, 2012, by and among the Company, Acueity Healthcare, Inc., and Ted Lachowicz, as Stockholder Representative	Registration Statement on Form S-1, as Exhibit 2.1	October 4, 2012
3.1	Certificate of Incorporation of Atossa Genetics Inc.	Registration Statement on Form S-1, as Exhibit 3.2	June 11, 2012
3.2	Bylaws of Atossa Genetics Inc.	Registration Statement on Form S-1, as Exhibit 3.4	June 11, 2012
3.3	Amendment to Bylaws of Atossa Genetics Inc.	Current Report on Form 8-K, as Exhibit 3.1	December 20, 2012
4.1	Specimen common stock certificate	Registration Statement on Form S-1, as Exhibit 4.1	May 21, 2012
4.2	Form of Warrant from 2011 private placement	Registration Statement on Form S-1, as Exhibit 4.2	October 4, 2012
4.3	Form of Placement Agent Warrant from 2011 private placement	Registration Statement on Form S-1, as Exhibit 4.3	October 4, 2012
4.4	Form of Warrant dated September 30, 2012	Registration Statement on Form S-1, as Exhibit 4.4	October 4, 2012
4.5	Registration Rights Agreement, dated as of March 27, 2013, by and between the Company and Aspire Capital Fund, LLC.	Filed herewith	
10.1	Exclusive Patent License Agreement with Ensisheim Partners, LLC, dated July 27, 2009	Registration Statement on Form S-1, as Exhibit 10.1	February 14, 2012
10.2	Termination of Exclusive Patent License Agreement, dated June 17, 2010	Registration Statement on Form S-1, as Exhibit 10.2	February 14, 2012
10.3#	Restated and Amended Employment Agreement with Steven Quay	Registration Statement on Form S-1, as Exhibit 10.3	February 14, 2012
10.4#	Restated and Amended Employment Agreement with Shu-Chih Chen	Registration Statement on Form S-1, as Exhibit 10.4	February 14, 2012
10.5	Form of Indemnification Agreement	Registration Statement on Form S-1, as Exhibit 10.5	May 21, 2012
10.6#	Atossa Genetics Inc. 2010 Stock Option and Incentive Plan, as amended	Registration Statement on Form S-1, as Exhibit 10.6	June 11, 2012

10.7#	Form of Incentive Stock Option Agreement	Registration Statement on Form S-1, as Exhibit 10.7	June 11, 2012
10.8#	Form of Non-Qualified Stock Option Agreement for Employees	Registration Statement on Form S-1, as Exhibit 10.8	June 11, 2012
10.9#	Form of Non-Qualified Stock Option Agreement for Non-Employee Directors	Registration Statement on Form S-1, as Exhibit 10.9	June 11, 2012
10.10	Form of Subscription Agreement	Registration Statement on Form S-1, as Exhibit 10.10	February 14, 2012
10.11	Sublease Agreement with CompleGen, Inc. dated September 29, 2010	Registration Statement on Form S-1, as Exhibit 10.11	February 14, 2012
10.12	Patent Assignment Agreement by and between the Company and Ensisheim Partners, LLC	Registration Statement on Form S-1, as Exhibit 10.12	April 6, 2012
10.13#	Form of Restricted Stock Award Agreement	Registration Statement on Form S-1, as Exhibit 10.13	June 11, 2012
10.14	Form of Lock-Up Agreement	Registration Statement on Form S-1, as Exhibit 10.14	April 6, 2012
10.15	Business Consultant Agreement with Edward Sauter	Registration Statement on Form S-1, as Exhibit 10.16	February 14, 2012
10.16	Prototype Development Proposal and Terms and Conditions, between the Company and HLB, LLC	Registration Statement on Form S-1, as Exhibit 10.17	February 14, 2012
10.17	Office Lease with Sander Properties, LLC, dated March 4, 2011	Registration Statement on Form S-1, as Exhibit 10.20	April 6, 2012
10.18	Office Lease with Sander Properties, LLC, dated July 8, 2011	Registration Statement on Form S-1, as Exhibit 10.21	April 6, 2012
10.19	Office Lease with Sander Properties, LLC, dated September 20, 2011	Registration Statement on Form S-1, as Exhibit 10.22	April 6, 2012
10.20	Sublease with Fred Hutchinson Cancer Research Center, dated December 9, 2011	Registration Statement on Form S-1, as Exhibit 10.23	April 6, 2012

10.21	Promissory Note — Line of Credit, effective November 3, 2010, by and between the Company and Steven C. Quay	Registration Statement on Form S-1, as Exhibit 10.24	May 21, 2012
10.22†	Term Sheet for License Agreement between the Company and Inven2 AS	Registration Statement on Form S-1, as Exhibit 10.25	June 25, 2012
10.23†	Agreement between the Company and Accellent Inc., dated August 8, 2011	Registration Statement on Form S-1, as Exhibit 10.26	June 25, 2012
10.24†	Supply Agreement between the Company and Biomarker LLC, dated June 24, 2011	Registration Statement on Form S-1, as Exhibit 10.27	June 18, 2012
10.25†	Purchase Agreement between the Company and Hologic Inc., dated May 11, 2011	Registration Statement on Form S-1, as Exhibit 10.28	June 25, 2012
10.26	Agreement between the Company and Biomarker LLC, dated June 22, 2012	Registration Statement on Form S-1, as Exhibit 10.29	June 25, 2012
10.27	Form of Investor Lock-Up Agreement	Registration Statement on Form S-1, as Exhibit 10.30	August 30, 2012
10.28†	Supply and Distribution Agreement, dated as of September 21, 2012, between the Company and Diagnostics Test Group LLC	Registration Statement on Form S-1, as Exhibit 10.31	October 4, 2012
10.29	Employment Agreement between the Company and Kyle Guse dated January 4, 2013#	Registration Statement on Form S-1, as Exhibit 10.31	January 28, 2013
10.30	Common Stock Purchase Agreement, dated as of March 27, 2013, by and between the Company and Aspire Capital Fund, LLC.	Filed herewith	
21.1	List of Subsidiaries.	Registration Statement on Form S-1, as Exhibit 21.1	October 4, 2012
23.1	Consent of KCCW Accountancy Corp.	Filed herewith	
24.1	Powers of Attorney	Filed herewith on the signature page	
31.1	Certification pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934 of Steven C. Quay	Filed herewith	
31.2	Certification pursuant to Rule 13a-14(a) under the Securities Exchange Act of Kyle Guse	Filed herewith	
32.1	Certification pursuant to 18 U.S.C. Section 1350 of Steven C. Quay	Filed herewith	
32.2	Certification pursuant to 18 U.S.C. Section 1350 of Kyle Guse	Filed herewith	
101.INS	XBRL Instance Document (1)		
101.SCH	XBRL Taxonomy Extension Schema Document (1)		
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document (1)		
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document (1)		
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document (1)		
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document (1)		

# Indicates management contract or compensatory plan, contract or agreement.

† Confidential treatment has been requested for portions of this exhibit. These portions have been omitted from the Registration Statement and submitted separately to the Securities and Exchange Commission.

†† Schedules and exhibits omitted pursuant to Item 601 of Regulation S-K.

(1) Pursuant to applicable securities laws and regulations, we are deemed to have complied with the reporting obligation relating to the submission of interactive data files in such exhibits and are not subject to liability under any anti-fraud provisions of the federal securities laws as long as we have made a good faith attempt to comply with the submission requirements and promptly amend the interactive data files after becoming aware that the interactive data files fail to comply with the submission requirements. In accordance with Rule 406T of Regulation S-T, the information in these exhibits is furnished and deemed not filed or a part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, is deemed not filed for purposes of Section 18 of the Exchange Act of 1934, and otherwise is not subject to liability under these sections and shall not be incorporated by reference into any registration statement or other document filed under the Securities Act of 1933, as amended, except as expressly set forth by specific reference in such filing.

Execution Copy

REGISTRATION RIGHTS AGREEMENT

REGISTRATION RIGHTS AGREEMENT (this "**Agreement**"), dated as of March 27, 2013, by and between **ATOSSA GENETICS, INC**, a Delaware corporation (the "**Company**"), and **ASPIRE CAPITAL FUND, LLC**, an Illinois limited liability company (together with its permitted assigns, the "**Buyer**"). Capitalized terms used herein and not otherwise defined herein shall have the respective meanings set forth in the Common Stock Purchase Agreement by and between the parties hereto, dated as of the date hereof (as amended, restated, supplemented or otherwise modified from time to time, the "**Purchase Agreement**").

WHEREAS:

A. Upon the terms and subject to the conditions of the Purchase Agreement, the Company has agreed to issue to the Buyer, and the Buyer has agreed to purchase, (i) up to Thirty Million Dollars ($30,000,000) of the Company's common stock, par value $0.001 per share (the "**Common Stock**") (the "**Purchase Shares**"), and (ii) such number of shares of Common Stock as is required pursuant to Section 4(e) of the Purchase Agreement (the **"Commitment Shares"**), in an at the market offering; and

B. To induce the Buyer to enter into the Purchase Agreement, the Company has agreed to provide certain registration rights under the Securities Act of 1933, as amended, and the rules and regulations thereunder, or any similar successor statute (collectively, the "**1933 Act**"), and applicable state securities laws.

NOW, THEREFORE, in consideration of the promises and the mutual covenants contained herein and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Company and the Buyer hereby agree as follows:

1. DEFINITIONS.

As used in this Agreement, the following terms shall have the following meanings:

a. "**Person**" means any person or entity including any corporation, a limited liability company, an association, a partnership, an organization, a business, an individual, a governmental or political subdivision thereof or a governmental agency.

b. "**Register**," "**registered**," and "**registration**" refer to a registration effected by preparing and filing one or more registration statements of the Company in compliance with the 1933 Act and pursuant to Rule 415 under the 1933 Act or any successor rule providing for offering securities on a continuous basis ("**Rule 415**"), and the declaration or ordering of effectiveness of such registration statement(s) by the U.S. Securities and Exchange Commission (the "**SEC**").

c. "**Registrable Securities**" means (i) all of the Commitment Shares, (ii) all of the Initial Purchase Shares, and (iii) such number of Additional Purchase Shares as reasonably determined by the Company, which may from time to time be, issued or issuable to the Buyer upon purchases of the Available Amount under the Purchase Agreement, and any shares of capital stock issued or issuable with respect to the Purchase Shares, the Commitment Shares or the Purchase Agreement as a result of any stock split, stock dividend, recapitalization, exchange or similar event, without regard to any limitation on purchases under the Purchase Agreement.

d. "**Registration Statement**" means a registration statement of the Company covering only the sale of the Registrable Securities.

2. REGISTRATION.

a. Mandatory Registration The Company shall within Ten (10) Business Days from the date hereof file with the SEC the Registratio Statement. The Registration Statement shall register the Registrable Securities. The Buyer and its counsel shall have a reasonable opportunity to review an comment upon such Registration Statement or any amendment to such Registration Statement and any related prospectus prior to its filing with the SEC. Buye shall furnish all information reasonably requested by the Company for inclusion therein. The Company shall use its commercially reasonable efforts to have the Registration Statement or any amendment declared effective by the SEC as soon as practicable. Subject to Section 3(e), the Company shall use commerciall reasonable efforts to keep the Registration Statement effective pursuant to Rule 415 promulgated under the 1933 Act and available for sales of all of the Registrable Securities at all times until the earlier of (i) the date as of which the Buyer may sell all of the Registrable Securities without restriction pursuant t Rule 144 promulgated under the 1933 Act (or successor thereto) or (ii) the date on which the Buyer shall have sold all the Registrable Securities and n Available Amount remains under the Purchase Agreement (the "**Registration Period**"). The Registration Statement (including any amendments o supplements thereto and prospectuses contained therein) shall not contain any untrue statement of a material fact or omit to state a material fact required to be stated therein, or necessary to make the statements therein, in light of the circumstances under which they were made, not misleading.

b. Rule 424 Prospectus. The Company shall, as required by applicable securities regulations, from time to time file with the SEC, pursuant t Rule 424 promulgated under the 1933 Act, a prospectus and prospectus supplements, if any, to be used in connection with sales of the Registrable Securities under the Registration Statement. The Buyer and its counsel shall have two (2) Business Days to review and comment upon such prospectus prior to its filin with the SEC. The Buyer shall use its commercially reasonable efforts to comment upon such prospectus within one (1) Business Day from the date the Buye receives the final version of such prospectus.

c. Sufficient Number of Shares Registered In the event the number of shares available under the Registration Statement is insufficient t cover the Registrable Securities, the Company shall, to the extent necessary and permissible, amend the Registration Statement or file a new registratio statement (a "**New Registration Statement**"), so as to cover all of such Registrable Securities as soon as practicable, but in any event not later than ten (10) Business Days after the necessity therefor arises. The Company shall use its commercially reasonable efforts to have such amendment and/or New Registration Statement become effective as soon as reasonably practicable following the filing thereof.

3. RELATED OBLIGATIONS.

With respect to the Registration Statement and whenever any Registrable Securities are to be registered pursuant to Sections 2(a) and (c), including on any New Registration Statement, the Company shall use its commercially reasonable efforts to effect the registration of the Registrable Securities in accordance with the intended method of disposition thereof and, pursuant thereto, the Company shall have the following obligations:

a. The Company shall prepare and file with the SEC such amendments (including post-effective amendments) and supplements to any Registration Statement and the prospectus used in connection with such Registration Statement, as may be necessary to keep the Registration Statement or any New Registration Statement effective at all times during the Registration Period, subject to Section 3(e) hereof and, during such period, comply with the provisions of the 1933 Act with respect to the disposition of all Registrable Securities of the Company covered by the Registration Statement or any New Registration Statement until such time as all of such Registrable Securities shall have been disposed of in accordance with the intended methods of disposition by the seller or sellers thereof as set forth in such Registration Statement. Should the Company file a post-effective amendment to the Registration Statement or a New Registration Statement, the Company will use its commercially reasonable efforts to have such filing declared effective by the SEC within Twenty (20) consecutive Business Days as of the date of filing, which such period shall be extended for an additional Thirty (30) Business Days if the Company receives a comment letter from the SEC in connection therewith.

b. The Company shall submit to the Buyer for review and comment any disclosure in the Registration Statement or any New Registration Statement and all amendments and supplements thereto (other than prospectus supplements that consist only of a copy of a filed Form 10-Q or a Current Report on Form 8-K) containing information provided by the Buyer for inclusion in such document and any descriptions or disclosure regarding the Buyer, the Purchase Agreement, including the transaction contemplated thereby, or this Agreement at least two (2) Business Days prior to their filing with the SEC, and not file any document in a form to which Buyer reasonably and timely objects. Upon request of the Buyer, the Company shall provide to the Buyer all disclosure in the Registration Statement or any New Registration Statement and all amendments and supplements thereto (other than prospectus supplements that consist only of a copy of a filed Form 10-Q or Current Report on Form 8-K) at least two (2) Business Days prior to their filing with the SEC, and not file any document in a form to which Buyer reasonably and timely objects, which consent shall not be unreasonably withheld, conditioned or delayed. The Buyer shall use its commercially reasonable efforts to comment upon the Registration Statement or any New Registration Statement and any amendments or supplements thereto within one (1) Business Day from the date the Buyer receives the final version thereof. The Company shall furnish to the Buyer, without charge, any correspondence from the SEC or the staff of the SEC to the Company or its representatives relating to the Registration Statement or any New Registration Statement.

c. Upon request of the Buyer, the Company shall furnish to the Buyer, (i) promptly after the same is prepared and filed with the SEC, at least one copy of the Registration Statement and any amendment(s) thereto, including financial statements and schedules, all documents incorporated therein by reference and all exhibits, (ii) upon the effectiveness of a Registration Statement, a copy of the prospectus included in such Registration Statement and all amendments and supplements thereto (or such other number of copies as the Buyer may reasonably request) and (iii) such other documents, including copies of any preliminary or final prospectus, as the Buyer may reasonably request from time to time in order to facilitate the disposition of the Registrable Securities owned by the Buyer.

d. The Company shall use commercially reasonable efforts to (i) register and qualify, unless an exemption from registration and qualification is available, the Registrable Securities covered by a Registration Statement under such other securities or "blue sky" laws of such jurisdictions in the United States as the Buyer reasonably requests, (ii) prepare and file in those jurisdictions, such amendments (including post-effective amendments) and supplements to such registrations and qualifications as may be necessary to maintain the effectiveness thereof during the Registration Period, (iii) take such other actions as may be necessary to maintain such registrations and qualifications in effect at all times during the Registration Period, and (iv) take all other actions reasonably necessary or advisable to qualify the Registrable Securities for sale in such jurisdictions; provided, however, that the Company shall not be required in connection therewith or as a condition thereto to (x) qualify to do business in any jurisdiction where it would not otherwise be required to qualify but for this Section 3(d), (y) subject itself to general taxation in any such jurisdiction, or (z) file a general consent to service of process in any such jurisdiction. The Company shall promptly notify the Buyer who holds Registrable Securities of the receipt by the Company of any notification with respect to the suspension of the registration or qualification of any of the Registrable Securities for sale under the securities or "blue sky" laws of any jurisdiction in the United States or its receipt of actual notice of the initiation or threat of any proceeding for such purpose.

e. As promptly as practicable after becoming aware of such event or facts, the Company shall notify the Buyer in writing if the Company has determined that the prospectus included in any Registration Statement, as then in effect, includes an untrue statement of a material fact or omits to state a material fact required to be stated therein or necessary to make the statements therein, in light of the circumstances under which they were made, not misleading, and promptly prepare a prospectus supplement or amendment to such Registration Statement to correct such untrue statement or omission, and, upon the Buyer's request, deliver a copy of such prospectus supplement or amendment to the Buyer. In providing this notice to the Buyer, the Company shall not include any other information about the facts underlying the Company's determination and shall not in any way communicate any material nonpublic information about the Company or the Common Stock to the Buyer. The Company shall also promptly notify the Buyer in writing (i) when a prospectus or any prospectus supplement or post-effective amendment has been filed, and when a Registration Statement or any post-effective amendment has become effective (notification of such effectiveness shall be delivered to the Buyer by facsimile or e-mail on the same day of such effectiveness), (ii) of any request by the SEC for amendments or supplements to any Registration Statement or related prospectus or related information, and (iii) of the Company's reasonable determination that a post-effective amendment to a Registration Statement would be appropriate.

f. The Company shall use its commercially reasonable efforts to prevent the issuance of any stop order or other suspension of effectiveness of any Registration Statement, or the suspension of the qualification of any Registrable Securities for sale in any jurisdiction and, if such an order or suspension is issued, to obtain the withdrawal of such order or suspension at the earliest practical time and to notify the Buyer of the issuance of such order and the resolution thereof or its receipt of actual notice of the initiation or threat of any proceeding for such purpose.

g. The Company shall (i) cause all the Registrable Securities to be listed on each securities exchange on which securities of the same class or series issued by the Company are then listed, if any, if the listing of such Registrable Securities is then permitted under the rules of such exchange, or (ii) secure designation and quotation of all the Registrable Securities if the Principal Market (as such term is defined in the Purchase Agreement) is an automated quotation system. The Company shall pay all fees and expenses in connection with satisfying its obligation under this Section.

h. The Company shall cooperate with the Buyer to facilitate the timely preparation and delivery of certificates (not bearing any restrictive legend) representing the Registrable Securities to be offered pursuant to any Registration Statement and enable such certificates to be in such denominations or amounts as the Buyer may reasonably request and registered in such names as the Buyer may request.

i. The Company shall at all times provide a transfer agent and registrar with respect to its Common Stock.

j. If reasonably requested by the Buyer, the Company shall (i) promptly incorporate in a prospectus supplement or post-effective amendment to the Registration Statement such information as the Buyer believes should be included therein relating to the sale and distribution of Registrable Securities including, without limitation, information with respect to the number of Registrable Securities being sold, the purchase price being paid therefor and any other terms of the offering of the Registrable Securities; (ii) make all required filings of such prospectus supplement or post-effective amendment promptly after being notified of the matters to be incorporated in such prospectus supplement or post-effective amendment; and (iii) supplement or make amendments to any Registration Statement.

k. The Company shall use its commercially reasonable efforts to cause the Registrable Securities covered by any Registration Statement to be registered with or approved by such other governmental agencies or authorities in the United States as may be necessary to consummate the disposition of such Registrable Securities.

l. Within one (1) Business Day after any Registration Statement is ordered effective by the SEC, either the Company or Company counsel shall deliver to the Transfer Agent for such Registrable Securities (with copies to the Buyer) confirmation that such Registration Statement has been declared effective by the SEC in the form attached hereto as Exhibit A. Thereafter, if reasonably requested by the Buyer at any time, the Company shall deliver to the Buyer a written confirmation of whether or not the effectiveness of such Registration Statement has lapsed at any time for any reason (including, without limitation, the issuance of a stop order) and whether or not the Registration Statement is currently effective and available to the Buyer for sale of all of the Registrable Securities.

m. The Company agrees to take all other reasonable actions as necessary and requested by the Buyer to expedite and facilitate disposition by the Buyer of Registrable Securities pursuant to any Registration Statement.

4. OBLIGATIONS OF THE BUYER.

a. The Buyer has furnished to the Company in Exhibit B hereto such information regarding itself, the Registrable Securities held by it and the intended method of disposition of the Registrable Securities held by it as required to effect the registration of such Registrable Securities and shall execute such documents in connection with such registration as the Company may reasonably request. The Company shall notify the Buyer in writing of any other information the Company reasonably requires from the Buyer in connection with any Registration Statement hereunder. The Buyer will as promptly as practicable notify the Company of any material change in the information set forth in Exhibit B, other than changes in its ownership of the Common Stock.

b. The Buyer agrees to cooperate with the Company as reasonably requested by the Company in connection with the preparation and filing of any amendments and supplements to any Registration Statement hereunder.

c. The Buyer agrees that, upon receipt of any notice from the Company of the happening of any event or existence of facts of the kind described in Section 3(f) or any notice of the kind described in the first sentence of 3(e), the Buyer will immediately discontinue disposition of Registrable Securities pursuant to any registration statement(s) covering such Registrable Securities until the Buyer's receipt (which may be accomplished through electronic delivery) of the copies of the filed supplemented or amended prospectus contemplated by Section 3(f) or the first sentence of 3(e). In addition, upon receipt of any notice from the Company of the kind described in the first sentence of Section 3(e), the Buyer will immediately discontinue purchases or sales of any securities of the Company unless such purchases or sales are in compliance with applicable U.S. securities laws. Notwithstanding anything to the contrary the Company shall cause its Transfer Agent to deliver as promptly as practicable shares of Common Stock without any restrictive legend in accordance with the terms of the Purchase Agreement in connection with any sale of Registrable Securities with respect to which the Buyer has received a Purchase Notice or VWAP Purchase Notice (both as defined in the Purchase Agreement) prior to the Buyer's receipt of a notice from the Company of the happening of any event of the kind described in Section 3(f) or the first sentence of 3(e) and for which the Buyer has not yet settled.

5. EXPENSES OF REGISTRATION.

All reasonable expenses of the Company, other than sales or brokerage commissions, incurred in connection with registrations, filings or qualifications pursuant to Sections 2 and 3, including, without limitation, all registration, listing and qualifications fees, printers and accounting fees, and fees and disbursements of counsel for the Company, shall be paid by the Company.

6. INDEMNIFICATION.

a. To the fullest extent permitted by law, the Company will, and hereby does, indemnify, hold harmless and defend the Buyer, each Person, if any, who controls the Buyer, the members, the directors, officers, partners, employees, agents, representatives of the Buyer and each Person, if any, who controls the Buyer within the meaning of the 1933 Act or the Securities Exchange Act of 1934, as amended (the "**1934 Act**") (each, an "**Indemnified Person**"), against any losses, claims, damages, liabilities, judgments, fines, penalties, charges, costs, reasonable attorneys' fees, amounts paid in settlement (with the consent of the Company, such consent not to be unreasonably withheld) or reasonable expenses, (collectively, "**Claims**") reasonably incurred in investigating, preparing or defending any action, claim, suit, inquiry, proceeding, investigation or appeal taken from the foregoing by or before any court or governmental, administrative or other regulatory agency or body or the SEC, whether pending or threatened, whether or not an indemnified party is or may be a party thereto ("**Indemnified Damages**"), to which any of them may become subject insofar as such Claims (or actions or proceedings, whether commenced or threatened, in respect thereof) arise out of or are based upon: (i) any untrue statement or alleged untrue statement of a material fact in the Registration Statement, any New Registration Statement or any post-effective amendment thereto or in any filing made in connection with the qualification of the offering under the securities or other "blue sky" laws of any jurisdiction in which Registrable Securities are offered ("**Blue Sky Filing**"), or the omission or alleged omission to state a material fact required to be stated therein or necessary to make the statements therein not misleading, (ii) any untrue statement or alleged untrue statement of a material fact contained in the final prospectus (as amended or supplemented, if the Company files any amendment thereof or supplement thereto with the SEC) or the omission or alleged omission to state therein any material fact necessary to make the statements made therein, in light of the circumstances under which the statements therein were made, not misleading, or (iii) any violation or alleged violation by the Company of the 1933 Act, the 1934 Act, any other law, including, without limitation, any state securities law, or any rule or regulation thereunder relating to the offer or sale of the Registrable Securities pursuant to the Registration Statement or any New Registration Statement (the matters in the foregoing clauses (i) through (iii) being, collectively "**Violations**"). The Company shall reimburse each Indemnified Person promptly as such expenses are incurred and are due and payable, for any reasonable legal fees or other reasonable expenses incurred by them in connection with investigating or defending any such Claim. Notwithstanding anything to the contrary contained herein, the indemnification agreement contained in this Section 6(a): (A) shall not apply to a Claim by an Indemnified Person arising out of or based upon a Violation which occurs in reliance upon and in conformity with information furnished in writing to the Company by such Indemnified Person expressly for use in connection with the preparation of the Registration Statement, any New Registration Statement or any such amendment thereof or supplement thereto, if such prospectus was timely made available by the Company; (B) with respect to any superseded prospectus, shall not inure to the benefit of any such person from whom the person asserting any such Claim purchased the Registrable Securities that are the subject thereof (or to the benefit of any other Indemnified Person) if the untrue statement or omission of material fact contained in the superseded prospectus was corrected in the revised prospectus, as then amended or supplemented, if such revised prospectus was timely made available by the Company pursuant to Section 3(c) or Section 3(e), and the Buyer was promptly advised in writing not to use the incorrect prospectus prior to the use giving rise to a violation; (C) shall not be available to the extent such Claim is based on a failure of the Buyer to deliver, or to cause to be delivered, the prospectus made available by the Company, if such prospectus was theretofore made available by the Company pursuant to Section 3(c) or Section 3(e); and (D) shall not apply to amounts paid in settlement of any Claim if such settlement is effected without the prior written consent of the Company, which consent shall not be unreasonably withheld. Such indemnity shall remain in full force and effect and shall survive the transfer of the Registrable Securities by the Buyer pursuant to Section 9.

b. In connection with the Registration Statement or any New Registration Statement, the Buyer agrees to indemnify, hold harmless and defend, to the same extent and in the same manner as is set forth in Section 6(a), the Company, each of its directors, each of its officers who signs the Registration Statement or any New Registration Statement, each Person, if any, who controls the Company within the meaning of the 1933 Act or the 1934 Act (collectively and together with an Indemnified Person, an "**Indemnified Party**"), against any Claim or Indemnified Damages to which any of them may become subject, under the 1933 Act, the 1934 Act or otherwise, insofar as such Claim or Indemnified Damages arise out of or are based upon any Violation, in each case to the extent, and only to the extent, that such Violation occurs in reliance upon and in conformity with written information about the Buyer set forth on Exhibit B attached hereto or updated from time to time in writing by the Buyer and furnished to the Company by the Buyer expressly for use in in the Registration Statement or any New Registration Statement or from the failure of the Buyer to deliver or to cause to be delivered the prospectus made available by the Company, if such prospectus was timely made available by the Company pursuant to Section 3(c) or Section 3(e); and, subject to Section 6(d), the Buyer will reimburse any legal or other expenses reasonably incurred by them in connection with investigating or defending any such Claim; provided, however, that the indemnity agreement contained in this Section 6(b) and the agreement with respect to contribution contained in Section 7 shall not apply to amounts paid in settlement of any Claim if such settlement is effected without the prior written consent of the Buyer, which consent shall not be unreasonably withheld; provided, further, however, that the Buyer shall be liable under this Section 6(b) for only that amount of a Claim or Indemnified Damages as does not exceed the net proceeds to the Buyer as a result of the sale of Registrable Securities pursuant to such registration statement. Such indemnity shall remain in full force and effect and shall survive the transfer of the Registrable Securities by the Buyer pursuant to Section 9.

c. Promptly after receipt by an Indemnified Person or Indemnified Party under this Section 6 of notice of the commencement of any action or proceeding (including any governmental action or proceeding) involving a Claim, such Indemnified Person or Indemnified Party shall, if a Claim in respec thereof is to be made against any indemnifying party under this Section 6, deliver to the indemnifying party a written notice of the commencement thereof, and the indemnifying party shall have the right to participate in, and, to the extent the indemnifying party so desires, jointly with any other indemnifying party similarly noticed, to assume control of the defense thereof with counsel mutually satisfactory to the indemnifying party and the Indemnified Person or the Indemnified Party, as the case may be, and upon such notice, the indemnifying party shall not be liable to the Indemnified Person or Indemnified Party for any legal or other expenses subsequently incurred by the Indemnified Person or Party in connection with the defense thereof; provided, however, that an Indemnified Person or Indemnified Party shall have the right to retain its own counsel with the fees and expenses to be paid by the indemnifying party, if, in the reasonable opinion of counsel retained by the indemnifying party, the representation by such counsel of the Indemnified Person or Indemnified Party and the indemnifying party would be inappropriate due to actual or potential differing interests between such Indemnified Person or Indemnified Party and any other party represented by such counsel in such proceeding. The Indemnified Party or Indemnified Person shall cooperate with the indemnifying party in connection with any negotiation or defense of any such action or claim by the indemnifying party and shall furnish to the indemnifying party all information reasonably available to the Indemnified Party or Indemnified Person which relates to such action or claim. The indemnifying party shall keep the Indemnified Party or Indemnified Person fully apprised as to the status of the defense or any settlement negotiations with respect thereto. No indemnifying party shall be liable for any settlement of any action, claim or proceeding effected without its written consent, provided, however, that the indemnifying party shall not unreasonably withhold, delay or condition its consent. No indemnifying party shall, without the consent of the Indemnified Party or Indemnified Person, consent to entry of any judgment or enter into any settlement or other compromise which does not include as an unconditional term thereof the giving by the claimant or plaintiff to such Indemnified Party or Indemnified Person of a release from all liability in respect to such claim or litigation. Following indemnification as provided for hereunder, the indemnifying party shall be subrogated to all rights of the Indemnified Party or Indemnified Person with respect to all third parties, firms or corporations relating to the matter for which indemnification has been made. The failure to deliver written notice to the indemnifying party within a reasonable time of the commencement of any such action shall not relieve such indemnifying party of any liability to the Indemnified Person or Indemnified Party under this Section 6, except to the extent that the indemnifying party is prejudiced in its ability to defend such action.

d. The indemnification required by this Section 6 shall be made by periodic payments of the amount thereof during the course of the investigation or defense, as and when bills are received or Indemnified Damages are incurred.

e. The indemnity agreements contained herein shall be in addition to (i) any cause of action or similar right of the Indemnified Party or Indemnified Person against the indemnifying party or others, and (ii) any liabilities the indemnifying party may be subject to pursuant to the law.

7. CONTRIBUTION.

To the extent any indemnification by an indemnifying party is prohibited or limited by law, the indemnifying party agrees to make the maximum contribution with respect to any amounts for which it would otherwise be liable under Section 6 to the fullest extent permitted by law; provided, however, that: (i) no seller of Registrable Securities guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the 1933 Act) shall be entitled to contribution from any seller of Registrable Securities who was not guilty of fraudulent misrepresentation; and (ii) contribution by any seller of Registrable Securities shall be limited in amount to the net amount of proceeds received by such seller from the sale of such Registrable Securities.

8. REPORTS AND DISCLOSURE UNDER THE SECURITIES ACTS.

With a view to making available to the Buyer the benefits of Rule 144 promulgated under the 1933 Act or any other similar rule or regulation of the SEC that may at any time permit the Buyer to sell securities of the Company to the public without registration ("**Rule 144**"), the Company agrees, at the Company's sole expense, to:

a. make and keep public information available, as those terms are understood and defined in Rule 144;

b. file with the SEC in a timely manner all reports and other documents required of the Company under the 1933 Act and the 1934 Act so long as the Company remains subject to such requirements and the filing of such reports and other documents is required to satisfy the current public information requirements of Rule 144; and

c. furnish to the Buyer so long as the Buyer owns Registrable Securities, as promptly as practicable at Buyer's request, (i) a written statement by the Company that it has complied in all material respects with the requirements of Rule 144(c)(1)(i) and (ii), and (ii) such other information, if any, as may be reasonably requested to permit the Buyer to sell such securities pursuant to Rule 144 without registration.

d. take such additional action as is requested by the Buyer to enable the Buyer to sell the Registrable Securities pursuant to Rule 144 including, without limitation, delivering all such legal opinions, consents, certificates, resolutions and instructions to the Company's Transfer Agent as may be reasonably requested from time to time by the Buyer and otherwise fully cooperate with the Buyer and the Buyer's broker to effect such sale of securities pursuant to Rule 144.

The Company agrees that damages may be an inadequate remedy for any breach of the terms and provisions of this Section 8 and that Investor shall whether or not it is pursuing any remedies at law, be entitled to seek, at its sole cost and expense, equitable relief in the form of a preliminary or permanent injunctions, upon any breach or threatened breach of any such terms or provisions.

9. ASSIGNMENT OF REGISTRATION RIGHTS.

The Company shall not assign this Agreement or any rights or obligations hereunder without the prior written consent of the Buyer. The Buyer may not assign its rights under this Agreement without the written consent of the Company.

10. AMENDMENT OF REGISTRATION RIGHTS.

Provisions of this Agreement may be amended and the observance thereof may be waived (either generally or in a particular instance and either retroactively or prospectively) only with the written consent of the Company and the Buyer.

11. MISCELLANEOUS.

a. Any notices, consents, waivers or other communications required or permitted to be given under the terms of this Agreement must be in writing and will be deemed to have been delivered: (i) upon receipt, when delivered personally; (ii) upon receipt, when sent by facsimile (provided confirmation of transmission is mechanically or electronically generated and kept on file by the sending party); or (iii) one (1) Business Day after deposit with a nationally recognized overnight delivery service, in each case properly addressed to the party to receive the same. The addresses and facsimile numbers for such communications shall be:

If to the Company:

Atossa Genetics, Inc.
1616 Eastlake Ave. East, Suite 510
Seattle, Washington 98102
Telephone: 800 351-3902
Facsimile: 206 430-1288
Attention: Kyle Guse
Chief Financial Officer and General Counsel

With a copy (which shall not constitute notice) to:

Ropes & Gray LLP
Three Embarcadero Center
San Francisco, CA 94111
Telephone: (415) 315-6395
Facsimile: (415) 315-6026
Attention: Ryan A. Murr, Esq.

If to the Buyer:

Aspire Capital Fund, LLC
155 North Wacker Drive, Suite 1600
Chicago, IL 60606
Telephone: 312-658-0400
Facsimile: 312-658-4005
Attention: Steven G. Martin

With a copy (which shall not constitute notice) to:

O'Melveny & Myers LLP
1625 Eye Street, NW
Washington, DC 20006
Telephone: 202-383-5418
Facsimile: 202-383-5414
Attention: Martin P. Dunn, Esq.

or at such other address and/or facsimile number and/or to the attention of such other person as the recipient party has specified by written notice given to each other party. Written confirmation of receipt (A) given by the recipient of such notice, consent, waiver or other communication, (B) mechanically or electronically generated by the sender's facsimile machine containing the time, date, recipient facsimile number and an image of the first page of such transmission or (C) provided by a nationally recognized overnight delivery service, shall be rebuttable evidence of personal service, receipt by facsimile or receipt from a nationally recognized overnight delivery service in accordance with clause (i), (ii) or (iii) above, respectively. Any party to this Agreement may give any notice or other communication hereunder using any other means (including messenger service, ordinary mail or electronic mail), but no such notice or other communication shall be deemed to have been duly given unless it actually is received by the party for whom it is intended.

b. No failure or delay in the exercise of any power, right or privilege hereunder shall operate as a waiver thereof, nor shall any single or partial exercise of any such power, right or privilege preclude other or further exercise thereof or of any other right, power or privilege.

c. The corporate laws of the State of Delaware shall govern all issues concerning the relative rights of the Company and its stockholders. All other questions concerning the construction, validity, enforcement and interpretation of this Agreement shall be governed by the internal laws of the State of Illinois, without giving effect to any choice of law or conflict of law provision or rule (whether of the State of Illinois or any other jurisdictions) that would cause the application of the laws of any jurisdictions other than the State of Illinois. Each party hereby irrevocably submits to the exclusive jurisdiction of the state and federal courts sitting in the City of Chicago for the adjudication of any dispute hereunder or in connection herewith or with any transaction contemplated hereby or discussed herein, and hereby irrevocably waives, and agrees not to assert in any suit, action or proceeding, any claim that it is not personally subject to the jurisdiction of any such court, that such suit, action or proceeding is brought in an inconvenient forum or that the venue of such suit, action or proceeding is improper. Each party hereby irrevocably waives personal service of process and consents to process being served in any such suit, action or proceeding by mailing a copy thereof to such party at the address for such notices to it under this Agreement and agrees that such service shall constitute good and sufficient service of process and notice thereof. Nothing contained herein shall be deemed to limit in any way any right to serve process in any manner permitted by law. If any provision of this Agreement shall be invalid or unenforceable in any jurisdiction, such invalidity or unenforceability shall not affect the validity or enforceability of the remainder of this Agreement in that jurisdiction or the validity or enforceability of any provision of this Agreement in any other jurisdiction. **EACH PARTY HEREBY IRREVOCABLY WAIVES ANY RIGHT IT MAY HAVE, AND AGREES NOT TO REQUEST, A JURY T FOR THE ADJUDICATION OF ANY DISPUTE HEREUNDER OR IN CONNECTION HEREWITH OR ARISING OUT AGREEMENT OR ANY TRANSACTION CONTEMPLATED HEREBY.**

d. This Agreement, the Purchase Agreement and the other Transaction Documents constitute the entire understanding among the parties hereto with respect to the subject matter hereof and thereof. There are no restrictions, promises, warranties or undertakings, other than those set forth or referred to herein and therein. This Agreement, the Purchase Agreement and the other Transaction Documents supersede all other prior oral or written agreements between the Buyer, the Company, their affiliates and persons acting on their behalf with respect to the subject matter hereof and thereof.

e. Subject to the requirements of Section 9, this Agreement shall inure to the benefit of and be binding upon the permitted successors and assigns of each of the parties hereto.

f. The headings in this Agreement are for convenience of reference and shall not form part of, or affect the interpretation of, this Agreement.

g. This Agreement may be executed in two or more identical counterparts, all of which shall be considered one and the same agreement and shall become effective when counterparts have been signed by each party and delivered to the other party; provided that a facsimile or pdf (or other electronic reproduction of a) signature shall be considered due execution and shall be binding upon the signatory thereto with the same force and effect as if the signature were an original, not a facsimile or pdf (or other electronic reproduction of a) signature.

h. Each party shall do and perform, or cause to be done and performed, all such further acts and things, and shall execute and deliver all such other agreements, certificates, instruments and documents as the other party may reasonably request in order to carry out the intent and accomplish the purposes of this Agreement and the consummation of the transactions contemplated hereby.

i. The language used in this Agreement will be deemed to be the language chosen by the parties to express their mutual intent and no rules of strict construction will be applied against any party.

j. This Agreement is intended for the benefit of the parties hereto and their respective permitted successors and assigns, and is not for the benefit of, nor may any provision hereof be enforced by, any other Person.

* * * * *

IN WITNESS WHEREOF, the parties have caused this Registration Rights Agreement to be duly executed as of day and year first above written.

THE COMPANY:

ATOSSA GENETICS, INC.

By: /s/ Steven C. Quay
Name: Steven C. Quay
Title: Chairman, Chief Executive Officer and President

BUYER:

ASPIRE CAPITAL FUND, LLC
BY: ASPIRE CAPITAL PARTNERS, LLC
BY: CHRISKO INVESTORS, INC.

By: /s/ Christos Komissopoulos
Name: Christos Komissopoulos
Title: President

EXHIBIT A

FORM OF NOTICE OF EFFECTIVENESS OF REGISTRATION STATEMENT

April __, 2013

VStock Transfer
77 Spruce Street , Suite 201
Cedarhurst, New York
Attention: Chief Executive Officer

RE: ATOSSA GENETICS, INC.

Ladies and Gentlemen:

We refer to that certain Common Stock Purchase Agreement, dated as of March 27, 2013 (the **"Purchase Agreement"**), entered into by and between **ATOSSA GENETICS, INC**, a Delaware corporation (the **"Company"**) and **Aspire Capital Fund, LLC** (the **"Buyer"**) pursuant to which the Company has agreed to issue to the Buyer shares of the Company's Common Stock, par value $0.001 per share (the **"Common Stock"**), in an amount up to Thirty Million Dollars ($30,000,000), in accordance with the terms of the Purchase Agreement. In connection with the transactions contemplated by the Purchase Agreement, the Company has registered with the U.S. Securities and Exchange Commission (the **SEC**") the sale by the Buyer of following shares of Common Stock:

(1) up to 2,833,519 shares of Common Stock to be issued upon purchase from the Company by the Buyer from time to time (the **"Purchase Shares."**).

(2) 250,000 shares of Common Stock which have been issued to the Buyer as a commitment fee (the **"Commitment Shares"**).

In connection with the transactions contemplated by the Purchase Agreement, the Company has filed a Registration Statement (File No. 333-_____) (the **"Registration Statement"**) with the SEC relating to the sale by the Buyer of the Purchase Shares and the Commitment Shares. Accordingly, we advise you that (i) the SEC has entered an order declaring the Registration Statement effective under the 1933 Act at _____ P.M. on _____, 20__ and (ii) the Company has no knowledge, after telephonic inquiry of a member of the SEC's staff, that any stop order suspending its effectiveness has been issued or that any proceedings for that purpose are pending before, or threatened by, the SEC and (iii) the Purchase Shares and the Commitment Shares are available for sale under the 1933 Act pursuant to the Registration Statement and may be issued without any restrictive legend.

Very truly yours,

By:_____

CC: Aspire Capital Fund, LLC

EXHIBIT B

Information About The Buyer Furnished To The Company By The Buyer
Expressly For Use In Connection With The Registration Statement and Prospectus

As of the date of the Purchase Agreement, Aspire Capital beneficially owned no shares of common stock of the Company. Steven G. Martin, Erik J. Brow and Christos Komissopoulos, the principals of Aspire Capital, are deemed to be beneficial owners of all of the shares of common stock owned by Aspire Capital. Messrs. Martin, Brown and Komissopoulos have shared voting and investment power over the shares being offered under the prospectus filed with the SEC in connection with the transactions contemplated under the Purchase Agreement. Aspire Capital is not a licensed broker dealer or an affiliate of a licensed broker dealer.

Plan of Distribution

The common stock may be sold or distributed from time to time by the selling stockholder directly to one or more purchasers or through brokers, dealers, or underwriters who may act solely as agents at market prices prevailing at the time of sale, at prices related to the prevailing market prices, at negotiated prices, or at fixed prices, which may be changed. The sale of the common stock offered by this prospectus may be effected in one or more of the following methods:

- ordinary brokers' transactions;
- transactions involving cross or block trades;
- through brokers, dealers, or underwriters who may act solely as agents;
- "at the market" into an existing market for the common stock;
- in other ways not involving market makers or established business markets, including direct sales to purchasers or sales effected through agents;
- in privately negotiated transactions; or
- any combination of the foregoing.

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

The selling stockholder may also sell shares of common stock under Rule 144 promulgated under the Securities Act, if available, rather than under this prospectus. In addition, the selling stockholder may transfer the shares of common stock by other means not described in this prospectus.

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

The selling stockholder and its affiliates have agreed not to engage in any direct or indirect short selling or hedging of our common stock during the term of the Purchase Agreement.

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

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

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

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

Execution Copy

COMMON STOCK PURCHASE AGREEMENT

COMMON STOCK PURCHASE AGREEMENT (the "**Agreement**"), dated as of March 27, 2013 by and between **ATOSSA GENETICS INC.**, a Delaware corporation (the "**Company**"), and **ASPIRE CAPITAL FUND, LLC**, an Illinois limited liability company (the "**Buyer**"). Capitalized terms used herein and not otherwise defined herein are defined in Section 10 hereof.

WHEREAS:

Subject to the terms and conditions set forth in this Agreement, the Company wishes to sell to the Buyer, and the Buyer wishes to buy from the Company, up to Thirty Million Dollars ($30,000,000) of the Company's common stock, par value $0.001 per share (the "**Common Stock**"). The shares of Common Stock to be purchased hereunder are referred to herein as the "**Purchase Shares**."

NOW THEREFORE, the Company and the Buyer hereby agree as follows:

1. PURCHASE OF COMMON STOCK.

Subject to the terms and conditions set forth in this Agreement, the Company has the right to sell to the Buyer, and the Buyer has the obligation to purchase from the Company, Purchase Shares as follows:

(a) Initial Purchase; Commencement of Purchases of Common Stock. Immediately upon the execution of this Agreement, the Buyer shall purchase from the Company 83,333 Purchase Shares and upon receipt of such Purchase Shares pay to the Company as the purchase price therefor, via wire transfer One Million Dollars ($1,000,000) (such purchase the "**Initial Purchase**" and such Purchase Shares are referred to herein as "**Initial Purchase Shares**"). Upon issuance and payment therefor as provided herein, such Initial Purchase Shares shall be validly issued and fully paid and non-assessable. The Initial Purchase Shares shall be issued to the Buyer bearing the restrictive legend set forth in Section 4(e). Thereafter, the purchase and sale of Purchase Shares hereunder shall occur from time to time upon written notices by the Company to the Buyer on the terms and conditions as set forth herein following the satisfaction of the conditions (the "**Commencement**") as set forth in Sections 6 and 7 below (the date of satisfaction of such conditions, the "**Commencement Date**").

(b) The Company's Right to Require Regular Purchases. Subject to the terms and conditions of this Agreement, on any given Business Day after the Commencement Date, the Company shall have the right but not the obligation to direct the Buyer by its delivery to the Buyer of a Purchase Notice from time to time, and the Buyer thereupon shall have the obligation, to buy the number of Purchase Shares specified in such notice, up to a maximum of 100,000 Purchase Shares, on such Business Day (as long as such notice is delivered on or before 5:00 p.m. Eastern time on such Business Day) (each such purchase, a "**Regular Purchase**") at the Purchase Price on the Purchase Date; however, in no event shall the Purchase Amount of a Regular Purchase exceed Four Hundred Thousand Dollars ($400,000) per Business Day. The Company may deliver additional Purchase Notices to the Buyer from time to time so long as the most recent purchase has been completed. The share amounts in the first sentence of this Section 1(b) shall be appropriately adjusted for any reorganization, recapitalization, non-cash dividend, stock split, reverse stock split, or other similar transaction.

(c) VWAP Purchases. Subject to the terms and conditions of this Agreement, in addition to purchases of Purchase Shares as described in Section 1(b) above, with one Business Day's prior written notice (as long as such notice is delivered on or before 5:00 p.m. Eastern time on the Business Day immediately preceding the VWAP Purchase Date), the Company shall also have the right but not the obligation to direct Buyer by the Company's delivery to Buyer of a VWAP Purchase Notice from time to time, and Buyer thereupon shall have the obligation, to buy the VWAP Purchase Share Percentage of the trading volume of the Common Stock on the VWAP Purchase Date up to the VWAP Purchase Share Volume Maximum on the VWAP Purchase Date (each such purchase, a "**VWAP Purchase**") at the VWAP Purchase Price. The Company may deliver a VWAP Purchase Notice to the Buyer on or before 5:0 p.m. Eastern time on a date on which (i) the Company also submitted a Purchase Notice for a Regular Purchase of at least 100,000 Purchase Shares to the Buyer and (ii) the Closing Sale Price is higher than $2.00. A VWAP Purchase shall automatically be deemed completed at such time on the VWAP Purchase Date that the Sale Price falls below the VWAP Minimum Price Threshold; in such circumstance, the VWAP Purchase Amount shall be calculated using (i) the VWAP Purchase Share Percentage of the aggregate shares traded on the Principal Market for such portion of the VWAP Purchase Date prior to the time that the Sale Price fell below the VWAP Minimum Price Threshold and (ii) a VWAP Purchase Price calculated using the volume weighted average price of Common Stock sold during such portion of the VWAP Purchase Date prior to the time that the Sale Price fell below the VWAP Minimum Price Threshold. Each VWAP Purchase Notice must be accompanied by instructions to the Company's Transfer Agent to immediately issue to the Buyer an amount of Common Stock equal to the VWAP Purchase Share Estimate, a good faith estimate by the Company of the number of Purchase Shares that the Buyer shall have the obligation to buy pursuant to the VWAP Purchase Notice. In no event shall the Buyer, pursuant to any VWAP Purchase, purchase a number of Purchase Shares that exceeds the VWAP Purchase Share Estimate issued on the VWAP Purchase Date in connection with such VWAP Purchase Notice; however, the Buyer will immediately return to the Company any amount of Common Stock issued pursuant to the VWAP Purchase Share Estimate that exceeds the number of Purchase Shares the Buyer actually purchases in connection with such VWAP Purchase. Upon completion of each VWAP Purchase Date, the Buyer shall submit to the Company a confirmation of the VWAP Purchase in form and substance reasonably acceptable to the Company. The Company may deliver additional VWAP Purchase Notices to the Buyer from time to time so long as the most recent purchase has been completed. The Company may, by written notice to the Buyer, in its sole discretion at any time after the date of this Agreement, irrevocably terminate this Section 1(c) and its right to direct the Buyer to make VWAP Purchases.

(d) Payment for Purchase Shares. For each Regular Purchase, the Buyer shall pay to the Company an amount equal to the Purchase Amount as full payment for such Purchase Shares via wire transfer of immediately available funds on the same Business Day that the Buyer receives such Purchase Shares. For each VWAP Purchase, the Buyer shall pay to the Company an amount equal to the VWAP Purchase Amount as full payment for such Purchase Shares via wire transfer of immediately available funds on the third Business Day following the VWAP Purchase Date. All payments made under this Agreement shall be made in lawful money of the United States of America via wire transfer of immediately available funds to such account as the Company may from time to time designate by written notice in accordance with the provisions of this Agreement. Whenever any amount expressed to be due by the terms of this Agreement is due on any day that is not a Business Day, the same shall instead be due on the next succeeding day that is a Business Day.

(e) Purchase Price Floor. The Company and the Buyer shall not effect any sales under this Agreement on any Purchase Date where the Closing Sal Price is less than the Floor Price. "**Floor Price**" means $2.00 per share of Common Stock, which shall be appropriately adjusted for any reorganization recapitalization, non-cash dividend, stock split, reverse stock split or other similar transaction.

(f) Records of Purchases. The Buyer and the Company shall each maintain records showing the remaining Available Amount at any given time and the dates and purchase amounts for each purchase, or shall use such other method reasonably satisfactory to the Buyer and the Company to reconcile the remaining Available Amount.

(g) Taxes. The Company shall pay any and all transfer, stamp or similar taxes that may be payable with respect to the issuance and delivery of any shares of Common Stock to the Buyer made under this Agreement.

(h) Compliance with Principal Market Rules Notwithstanding anything in this Agreement to the contrary, and in addition to the limitations set forth in Section 1(e), the total number of shares of Common Stock that may be issued under this Agreement, including the Commitment Shares (as defined in Sectio 4(e) hereof), shall be limited to 2,833,519 shares of Common Stock (the "**Exchange Cap**"), which equals 19.99% of the Company's outstanding shares of Common Stock as of the date hereof, unless stockholder approval is obtained to issue more than such 19.99%. The foregoing limitation shall not apply i stockholder approval has not been obtained and at any time the Exchange Cap is reached and at all times thereafter the average price paid for all shares issued under this Agreement is equal to or greater than $9.55 (the "**Minimum Price**"), a price equal to the Closing Sale Price on the date hereof (in such circumstance, for purposes of the Principal Market, the transaction contemplated hereby would not be "below market" and the Exchange Cap would no apply). Notwithstanding the foregoing, the Company shall not be required or permitted to issue, and the Buyer shall not be required to purchase, any shares o Common Stock under this Agreement if such issuance would violate the rules or regulations of the Principal Market.

(i) Beneficial Ownership Limitation The Company shall not issue, and the Buyer shall not purchase any shares of Common Stock under thi Agreement, if such shares proposed to be issued and sold, when aggregated with all other shares of Common Stock then owned beneficially (as calculated pursuant to Section 13(d) of the Exchange Act and Rule 13d-3 promulgated thereunder) by the Buyer and its affiliates would result in the beneficial ownership by the Buyer and its affiliates of more than 19.99% of the then issued and outstanding shares of Common Stock of the Company.

2. BUYER'S REPRESENTATIONS AND WARRANTIES.

The Buyer represents and warrants to the Company that as of the date hereof and as of the Commencement Date:

(a) Investment Purpose. The Buyer is entering into this Agreement and acquiring the Commitment Shares and the Purchase Shares (the Purchas Shares and the Commitment Shares are collectively referred to herein as the "**Securities**"), for its own account for investment only and not with a view towards, or for resale in connection with, the public sale or distribution thereof; provided however, by making the representations herein, the Buyer does not agree to hold any of the Securities for any minimum or other specific term.

(b) Accredited Investor Status. The Buyer is an "accredited investor" as that term is defined in Rule 501(a)(3) of Regulation D of the 1933 Act.

(c) Reliance on Exemptions. The Buyer understands that the Securities are being offered and sold to it in reliance on specific exemptions from the registration requirements of United States federal and state securities laws and that the Company is relying in part upon the truth and accuracy of, and the Buyer's compliance with, the representations, warranties, agreements, acknowledgments and understandings of the Buyer set forth herein in order to determine the availability of such exemptions and the eligibility of the Buyer to acquire the Securities.

(d) Information. The Buyer has been furnished with all materials relating to the business, finances and operations of the Company and materials relating to the offer and sale of the Securities that have been reasonably requested by the Buyer, including, without limitation, the SEC Documents (as defined in Section 3(f) hereof). The Buyer understands that its investment in the Securities involves a high degree of risk. The Buyer (i) is able to bear the economic risk of an investment in the Securities including a total loss, (ii) has such knowledge and experience in financial and business matters that it is capable of evaluating the merits and risks of the proposed investment in the Securities and (iii) has had an opportunity to ask questions of and receive answers from the officers of the Company concerning the financial condition and business of the Company and other matters related to an investment in the Securities. Neither such inquiries nor any other due diligence investigations conducted by the Buyer or its representatives shall modify, amend or affect the Buyer's right to rely on the Company's representations and warranties contained in Section 3 below. The Buyer has sought such accounting, legal and tax advice as it has considered necessary to make an informed investment decision with respect to its acquisition of the Securities.

(e) No Governmental Review. The Buyer understands that no United States federal or state agency or any other government or governmental agency has passed on or made any recommendation or endorsement of the Securities or the fairness or suitability of the investment in the Securities nor have such authorities passed upon or endorsed the merits of the offering of the Securities.

(f) Transfer or Sale. The Buyer understands that except as provided in the Registration Rights Agreement (as defined in Section 4(a) hereof): (i) the Securities have not been and are not being registered under the 1933 Act or any state securities laws, and may not be offered for sale, sold, assigned or transferred unless (A) subsequently registered thereunder or (B) an exemption exists permitting such Securities to be sold, assigned or transferred without such registration; (ii) any sale of the Securities made in reliance on Rule 144 may be made only in accordance with the terms of Rule 144 and further, if Rule 144 is not applicable, any resale of the Securities under circumstances in which the seller (or the person through whom the sale is made) may be deemed to be an underwriter (as that term is defined in the 1933 Act) may require compliance with some other exemption under the 1933 Act or the rules and regulations of the SEC thereunder; and (iii) neither the Company nor any other person is under any obligation to register the Securities under the 1933 Act or any state securities laws or to comply with the terms and conditions of any exemption thereunder.

(g) Organization. The Buyer is a limited liability company duly organized and validly existing in good standing under the laws of the jurisdiction in which it is organized, and has the requisite organizational power and authority to own its properties and to carry on its business as now being conducted.

(h) Validity; Enforcement. This Agreement has been duly and validly authorized, executed and delivered on behalf of the Buyer and is a valid and binding agreement of the Buyer enforceable against the Buyer in accordance with its terms, subject as to enforceability to (i) general principles of equity and to applicable bankruptcy, insolvency, reorganization, moratorium, liquidation and other similar laws relating to, or affecting generally, the enforcement of applicable creditors' rights and remedies and (ii) public policy underlying any law, rule or regulation (including any federal or state securities law, rule or regulation) with regards to indemnification, contribution or exculpation. The execution and delivery of the Transaction Documents by the Buyer and the consummation by it of the transactions contemplated hereby and thereby do not conflict with the Buyer's certificate of organization or operating agreement or similar documents, and do not require further consent or authorization by the Buyer, its managers or its members.

(i) Residency. The Buyer is a resident of the State of Illinois.

(j) No Prior Short Selling The Buyer represents and warrants to the Company that at no time prior to the date of this Agreement has any of the Buyer, its agents, representatives or affiliates engaged in or effected, in any manner whatsoever, directly or indirectly, any (i) "short sale" (as such term is defined in Section 242.200 of Regulation SHO of the Securities Exchange Act of 1934, as amended (the "**1934 Act**")) of the Common Stock or (ii) hedging transaction, which establishes a net short position with respect to the Common Stock.

3. REPRESENTATIONS AND WARRANTIES OF THE COMPANY.

The Company represents and warrants to the Buyer that as of the date hereof and as of the Commencement Date:

(a) Organization and Qualification. The Company and its "Subsidiaries" (which for purposes of this Agreement means any entity in which the Company, directly or indirectly, owns more than 50% of the voting stock or capital stock or other similar equity interests) are corporations or limited liability companies duly organized and validly existing in good standing under the laws of the jurisdiction in which they are incorporated or organized, and have the requisite corporate or organizational power and authority to own their properties and to carry on their business as now being conducted. Each of the Company and its Subsidiaries is duly qualified as a foreign corporation or limited liability company to do business and is in good standing in every jurisdiction in which its ownership of property or the nature of the business conducted by it makes such qualification necessary, except to the extent that the failure to be so qualified or be in good standing could not reasonably be expected to have a Material Adverse Effect. As used in this Agreement, "**Material Adverse Effect**" means any material adverse effect on any of: (i) the business, properties, assets, operations, results of operations or financial condition of the Company and its Subsidiaries, if any, taken as a whole, or (ii) the authority or ability of the Company to perform its obligations under the Transaction Documents (as defined in Section 3(b) hereof). The Company has no material Subsidiaries except as set forth on Schedule 3(a).

(b) Authorization; Enforcement; Validity. (i) The Company has the requisite corporate power and authority to enter into and perform its obligations under this Agreement, the Registration Rights Agreement and each of the other agreements entered into by the parties on the Commencement Date and attached hereto as exhibits to this Agreement (collectively, the "**Transaction Documents**"), and to issue the Securities in accordance with the terms hereof and thereof, (ii) the execution and delivery of the Transaction Documents by the Company and the consummation by it of the transactions contemplated hereby and thereby, including without limitation, the issuance of the Commitment Shares and the reservation for issuance and the issuance of the Purchase Shares issuable under this Agreement, have been duly authorized by the Company's Board of Directors or duly authorized committee thereof, do not conflict with the Company's Certificate of Incorporation or Bylaws, and do not require further consent or authorization by the Company, its Board of Directors or its stockholders, (iii) this Agreement has been, and each other Transaction Document shall be on the Commencement Date, duly executed and delivered by the Company and (iv) this Agreement constitutes, and each other Transaction Document upon its execution on behalf of the Company, shall constitute, the valid and binding obligations of the Company enforceable against the Company in accordance with their terms, except as such enforceability may be limited by (y) general principles of equity or applicable bankruptcy, insolvency, reorganization, moratorium, liquidation or similar laws relating to, or affecting generally, the enforcement of creditors' rights and remedies and (z) public policy underlying any law, rule or regulation (including any federal or states securities law, rule or regulation) with regards to indemnification, contribution or exculpation. The Board of Directors of the Company or duly authorized committee thereof has approved the resolutions (the "**Signing Resolutions**") substantially in the form as set forth as **Exhibit B-1** attached hereto to authorize this Agreement and the transactions contemplated hereby. The Signing Resolutions are valid, in full force and effect and have not been modified or supplemented in any material respect other than by the resolutions set forth in **Exhibit B-2** attached hereto regarding the registration statement referred to in Section 4 hereof. The Company has delivered to the Buyer a true and correct copy of the Signing Resolutions as approved by the Board of Directors of the Company.

(c) Capitalization. As of the date hereof, the authorized capital stock of the Company consists of (i) 75,000,000 shares of Common Stock, of which as of the date hereof 14,174,686 shares are issued and outstanding, no shares are held as treasury shares, 2,555,274 shares are reserved for future issuance pursuant to the Company's equity incentive plan(s) and pursuant to options grants outside the Company's equity incentive plan(s), of which approximately 1,027,517 shares remain available for future option grants or stock awards, and 5,671,800 shares are issuable and reserved for issuance pursuant to securities (other than stock options or equity based awards issued pursuant to the Company's stock incentive plans) exercisable or exchangeable for, or convertible into, shares of Common Stock pursuant to warrants outstanding, and (ii) 10,000,000 shares of preferred stock, par value $0.001 per share, of which as of the date hereof no shares are designated, issued or outstanding. All of such outstanding shares have been, or upon issuance will be, validly issued and are fully paid and non-assessable. Except as disclosed in this Section 3(c) or Schedule 3(c), (i) no shares of the Company's capital stock are subject to preemptive rights or any other similar rights or any liens or encumbrances suffered or permitted by the Company, (ii) there are no outstanding debt securities of the Company or any of its Subsidiaries, (iii) there are no outstanding options, warrants, scrip, rights to subscribe to, calls or commitments of any character whatsoever relating to, or securities or rights convertible into, any shares of capital stock of the Company or any of its Subsidiaries, or contracts, commitments, understandings or arrangements by which the Company or any of its Subsidiaries is or may become bound to issue additional shares of capital stock of the Company or any of its Subsidiaries or options, warrants, scrip, rights to subscribe to, calls or commitments of any character whatsoever relating to, or securities or rights convertible into, any shares of capital stock of the Company or any of its Subsidiaries, (iv) there are no material agreements or arrangements under which the Company or any of its Subsidiaries is obligated to register the sale of any of their securities under the 1933 Act (except the Registration Rights Agreement and except such rights that have been satisfied), (v) there are no outstanding securities or instruments of the Company or any of its Subsidiaries which contain any redemption or similar provisions, and there are no contracts, commitments, understandings or arrangements by which the Company or any of its Subsidiaries is or may become bound to redeem a security of the Company or any of its Subsidiaries, (vi) there are no securities or instruments containing anti-dilution or similar provisions that will be triggered by the issuance of the Securities as described in this Agreement and (vii) the Company does not have any stock appreciation rights or "phantom stock" plans or agreements or any similar plan or agreement. The Company has furnished or made available to the Buyer true and correct copies of the Company's Certificate of Incorporation, as amended and as in effect on the date hereof (the "**Certificate of Incorporation**"), and the Company's Bylaws, as amended and as in effect on the date hereof (the "**Bylaws**").

(d) Issuance of Securities. The Commitment Shares and Initial Purchase Shares have been duly authorized and, upon issuance in accordance with th terms hereof, the Commitment Shares and Initial Purchase Shares shall be (i) validly issued, fully paid and non-assessable and (ii) free from all taxes, liens an charges with respect to the issuance thereof. 2,500,186 shares of Common Stock have been duly authorized and reserved for issuance upon future purchase under this Agreement. Upon issuance and payment therefore in accordance with the terms and conditions of this Agreement, the Purchase Shares shall be validly issued, fully paid and non-assessable and free from all taxes, liens and charges with respect to the issue thereof, with the holders being entitled to all rights accorded to a holder of Common Stock.

(e) No Conflicts. Except as disclosed in Schedule 3(e), the execution, delivery and performance of the Transaction Documents by the Company an the consummation by the Company of the transactions contemplated hereby and thereby (including, without limitation, the reservation for issuance and issuance of the Purchase Shares) will not (i) result in a violation of the Certificate of Incorporation, any Certificate of Designations, Preferences and Rights of an outstanding series of preferred stock of the Company or the Bylaws or (ii) constitute a default (or an event which with notice or lapse of time or both would become a default) under, or give to others any rights of termination, amendment, acceleration or cancellation of, any agreement, indenture or instrument to which the Company or any of its Subsidiaries is a party, or result, to the Company's knowledge, in a violation of any law, rule, regulation, order, judgment or decree (including federal and state securities laws and regulations and the rules and regulations of the Principal Market applicable to the Company or any of its Subsidiaries) or by which any property or asset of the Company or any of its Subsidiaries is bound or affected, except in the case of defaults, terminations amendments, accelerations, cancellations and violations under clause (ii), which could not reasonably be expected to result in a Material Adverse Effect. Except as disclosed in Schedule 3(e), neither the Company nor its Subsidiaries is in violation of any term of or in default under its Certificate of Incorporation any Certificate of Designation, Preferences and Rights of any outstanding series of preferred stock of the Company or Bylaws or their organizational charter or bylaws, respectively. Except as disclosed in Schedule 3(e), neither the Company nor any of its Subsidiaries is in violation of any term of or is in default under any material contract, agreement, mortgage, indebtedness, indenture, instrument, judgment, decree or order or any statute, rule or regulation applicable to the Company or its Subsidiaries, except for possible violations, defaults, terminations or amendments that could not reasonably be expected to have a Material Adverse Effect. The business of the Company and its Subsidiaries is not being conducted, and shall not be conducted, in violation of any law, ordinance, or regulation of any governmental entity, except for possible violations, the sanctions for which either individually or in the aggregate could not reasonably be expected to have a Material Adverse Effect. Except as specifically contemplated by this Agreement, reporting obligations under the 1934 Act or as required under the 1933 Act or applicable state securities laws or the filing of a Listing of Additional Shares Notification Form with the Principal Market, the Company is not required to obtain any consent, authorization or order of, or make any filing or registration with, any court or governmental agency or any regulatory or self-regulatory agency in order for it to execute, deliver or perform any of its obligations under or contemplated by the Transaction Documents in accordance with the terms hereof or thereof. Except for reporting obligations under the 1934 Act, all consents, authorizations, orders, filings and registrations which the Company is required to obtain pursuant to the preceding sentence shall be obtained or effected on or prior to the Commencement Date. The Company is not subject to any notices or actions from or to the Principal Market, other than routine matters incident to listing on the Principal Market and not involving a violation of the rules of the Principal Market. To the Company's knowledge, the Principal Market has not commenced any delisting proceedings against the Company.

(f) SEC Documents; Financial Statements Except as disclosed in Schedule 3(f), since November 7, 2012, the Company has filed all reports schedules, forms, statements and other documents required to be filed by it with the SEC pursuant to the reporting requirements of the 1934 Act (all of the foregoing filed prior to the date hereof and all exhibits included therein and financial statements and schedules thereto and documents incorporated by reference therein being hereinafter referred to as the "**SEC Documents**"). As of their respective dates (except as they have been correctly amended), the SEC Documents complied in all material respects with the requirements of the 1934 Act and the rules and regulations of the SEC promulgated thereunder applicable to the SEC Documents, and none of the SEC Documents, at the time they were filed with the SEC (except as they may have been properly amended) contained any untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary in order to make the statements therein, in light of the circumstances under which they were made, not misleading. As of their respective dates (except as they have been properly amended), the financial statements of the Company included in the SEC Documents complied as to form in all material respects with applicable accounting requirements and the published rules and regulations of the SEC with respect thereto. Such financial statements have been prepared in accordance with generally accepted accounting principles, consistently applied, during the periods involved (except (i) as may be otherwise indicated in such financial statements or the notes thereto or (ii) in the case of unaudited interim statements, to the extent they may exclude footnotes or may be condensed or summary statements) and fairly present in all material respects the financial position of the Company as of the dates thereof and the results of its operations and cash flows for the periods then ended (subject, in the case of unaudited statements, to normal year-end audit adjustments). Except for routine correspondence, such as comment letters and notices of effectiveness in connection with previously filed registration statements or periodic reports publicly available on EDGAR, to the Company's knowledge, the Company or any of its Subsidiaries are not presently the subject of any inquiry, investigation or action by the SEC.

(g) Absence of Certain Changes Except as disclosed in Schedule 3(g), since December 31, 2012, there has been no material adverse change in the business, properties, operations, financial condition or results of operations of the Company or its Subsidiaries taken as a whole. For purposes of this Agreement, neither a decrease in cash or cash equivalents nor losses incurred in the ordinary course of the Company's business shall be deemed or considered a material adverse change. The Company has not taken any steps, and does not currently expect to take any steps, to seek protection pursuant to any Bankruptcy Law nor does the Company or any of its Subsidiaries have any knowledge or reason to believe that its creditors intend to initiate involuntary bankruptcy or insolvency proceedings. The Company is financially solvent and is generally able to pay its debts as they become due**.**

(h) Absence of Litigation To the Company's knowledge, there is no action, suit, proceeding, inquiry or investigation before or by any court, public board, government agency, self-regulatory organization or body pending or, to the knowledge of the Company or any of its Subsidiaries, threatened against the Company, the Common Stock or any of the Company's Subsidiaries or any of the Company's or the Company's Subsidiaries' officers or directors in their capacities as such, which could reasonably be expected to have a Material Adverse Effect (each, an "**Action**"). A description of each such Action, if any, is set forth in Schedule 3(h).

(i) Acknowledgment Regarding Buyer's Status. The Company acknowledges and agrees that the Buyer is acting solely in the capacity of arm's length purchaser with respect to the Transaction Documents and the transactions contemplated hereby and thereby. The Company further acknowledges that the Buyer is not acting as a financial advisor or fiduciary of the Company (or in any similar capacity) with respect to the Transaction Documents and the transactions contemplated hereby and thereby and any advice given by the Buyer or any of its representatives or agents in connection with the Transaction Documents and the transactions contemplated hereby and thereby is merely incidental to the Buyer's purchase of the Securities. The Company further represents to the Buyer that the Company's decision to enter into the Transaction Documents has been based solely on the independent evaluation by the Company and its representatives and advisors.

(j) Intellectual Property Rights. To the Company's knowledge, the Company and its Subsidiaries own or possess adequate rights or licenses to use all material trademarks, trade names, service marks, service mark registrations, service names, patents, patent rights, copyrights, inventions, licenses, approvals, governmental authorizations, trade secrets and other intellectual property rights (collectively, "**Intellectual Property**") necessary to conduct their respective businesses as now conducted, except as set forth in Schedule 3(j) or to the extent that the failure to own, possess, license or otherwise hold adequate rights to use Intellectual Property would not, individually or in the aggregate, have a Material Adverse Effect. Except as disclosed in Schedule 3(j), to the Company's knowledge, none of the Company's active and registered Intellectual Property have expired or terminated, or, by the terms and conditions thereof, will expire or terminate within two years from the date of this Agreement. The Company and its Subsidiaries do not have any knowledge of any infringement by the Company or its Subsidiaries of any Intellectual Property of others, or of any such development of similar or identical trade secrets or technical information by others with respect to the Company's or its Subsidiaries' Intellectual Property and, except as set forth on Schedule 3(j), there is no claim, action or proceeding being made or brought against, or to the Company's knowledge, being threatened against, the Company or its Subsidiaries regarding Intellectual Property which could reasonably be expected to have a Material Adverse Effect.

(k) Environmental Laws. To the Company's knowledge, the Company and its Subsidiaries (i) are in material compliance with any and all applicable foreign, federal, state and local laws and regulations relating to the protection of the environment or human health and safety and with respect to hazardous or toxic substances or wastes, pollutants or contaminants ("**Environmental Laws**"), (ii) have received all material permits, licenses or other approvals required of them under applicable Environmental Laws to conduct their respective businesses and (iii) are in material compliance with all terms and conditions of any such permit, license or approval, except where, in each of the three foregoing clauses, the failure to so comply or receive such approvals could not reasonably be expected to have, individually or in the aggregate, a Material Adverse Effect.

(l) Title. The Company and its Subsidiaries have good and marketable title to all personal property owned by them that is material to the business of the Company and its Subsidiaries, free and clear of all liens, encumbrances and defects except such as are described in Schedule 3(l) or such as do not materially affect the value of such property and do not interfere with the use made and proposed to be made of such property by the Company and any of its Subsidiaries or could not reasonably be expected to have, individually or in the aggregate, a Material Adverse Effect. Any real property and facilities held under lease by the Company and any of its Subsidiaries, to the Company's knowledge, are held by them under valid, subsisting and enforceable leases with such exceptions as are not material and do not interfere with the use made and proposed to be made of such property and buildings by the Company and its Subsidiaries.

(m) Insurance. The Company and each of its Subsidiaries are insured by insurers of recognized financial responsibility against such losses and risks and in such amounts as management of the Company believes to be reasonable and customary in the businesses in which the Company and its Subsidiaries are engaged. To the Company's knowledge, since March 1, 2011, neither the Company nor any such Subsidiary has been refused any insurance coverage sought or applied for and neither the Company nor any such Subsidiary, to the Company's knowledge, will be unable to renew its existing insurance coverage as and when such coverage expires or to obtain similar coverage from similar insurers as may be necessary to continue its business at a cost that would not reasonably be expected to have a Material Adverse Effect.

(n) Regulatory Permits. The Company and its Subsidiaries possess all material certificates, authorizations and permits issued by the appropriate federal, state or foreign regulatory authorities necessary to conduct their respective businesses as currently conducted, and neither the Company nor any such Subsidiary has received any written notice of proceedings relating to the revocation or modification of any such material certificate, authorization or permit.

(o) Tax Status. The Company and each of its Subsidiaries has made or filed all federal and state income and all other material tax returns, reports and declarations required by any jurisdiction to which it is subject (unless and only to the extent that the Company and each of its Subsidiaries has set aside on its books reserves reasonably adequate for the payment of all unpaid and unreported taxes or filed valid extensions) and has paid all taxes and other governmental assessments and charges that are material in amount, shown or determined to be due on such returns, reports and declarations, except those being contested in good faith and has set aside on its books reserves reasonably adequate for the payment of all taxes for periods subsequent to the periods to which such returns, reports or declarations apply. To the Company's knowledge, there are no unpaid taxes in any material amount claimed to be due by the taxing authority of any jurisdiction.

(p) Transactions With Affiliates. Except as set forth on Schedule 3(p), and other than the grant or exercise of stock options or any other equity securities offered pursuant to duly adopted stock or incentive compensation plans as disclosed on Schedule 3(c), none of the officers, directors or employees of the Company is presently a party to any transaction with the Company or any of its Subsidiaries (other than for services as employees, officers and directors and reimbursement for expenses incurred on behalf of the Company), including any contract, agreement or other arrangement providing for the furnishing of services to or by, providing for rental of real or personal property to or from, or otherwise requiring payments to or from any officer, director or such employee or, to the knowledge of the Company, any corporation, partnership, trust or other entity in which any officer, director, or any such employee has a material interest or is an officer, director, trustee or general partner.

(q) Application of Takeover Protections. The Company and its board of directors have taken or will take prior to the Commencement Date al necessary action, if any, in order to render inapplicable any control share acquisition, business combination, poison pill (including any distribution under a rights agreement) or other similar anti-takeover provision under the Certificate of Incorporation or the laws of the state of its incorporation which is or could become applicable to the Buyer as a result of the transactions contemplated by this Agreement, including, without limitation, the Company's issuance of the Securities and the Buyer's ownership of the Securities.

4. COVENANTS.

(a) Filing of Form 8-K and Registration Statement The Company agrees that it shall, within the time required under the 1934 Act, file a Curren Report on Form 8-K (or provide substantially equivalent disclosure in the Company's Annual Report on Form 10-K to be filed within that time period) disclosing this Agreement and the transaction contemplated hereby. The Company shall also file within ten (10) Business Days from the date hereof a new registration statement, or a pre-effective amendment to the Company's registration statement on Form S-1 (File No. 333-186248), covering the sale of the Securities by the Buyer in accordance with the terms of the Registration Rights Agreement between the Company and the Buyer, dated as of the date hereof ("**Registration Rights Agreement**").

(b) Blue Sky. The Company shall take such action, if any, as is reasonably necessary in order to obtain an exemption for or to qualify (i) the initial sale of the Securities to the Buyer under this Agreement and (ii) any subsequent sale of the Securities by the Buyer, in each case, under applicable securities or "Blue Sky" laws of the states of the United States in such states as is reasonably requested by the Buyer from time to time, and shall provide evidence of any such action so taken to the Buyer at its written request.

(c) Listing. The Company shall promptly secure the listing of all of the Securities upon each national securities exchange and automated quotation system that requires an application by the Company for listing, if any, upon which shares of Common Stock are then listed (subject to official notice of issuance) and shall maintain such listing, so long as any other shares of Common Stock shall be so listed. The Company shall use its commercially reasonable efforts to maintain the Common Stock's listing on the Principal Market in accordance with the requirements of the Registration Rights Agreement. Neither the Company nor any of its Subsidiaries shall take any action that would be reasonably expected to result in the delisting or suspension of the Common Stock on the Principal Market, unless the Common Stock is immediately thereafter traded on the New York Stock Exchange, the NYSE MKT, the Nasdaq Global Sele Market, the Nasdaq Global Market, the Nasdaq Capital Market, the OTC Bulletin Board, or the OTCQB or OTCQX market places of the OTC Markets. Company shall pay all fees and expenses in connection with satisfying its obligations under this Section.

(d) Limitation on Short Sales and Hedging Transactions The Buyer agrees that beginning on the date of this Agreement and ending on the date of termination of this Agreement as provided in Section 11(k), the Buyer and its agents, representatives and affiliates shall not in any manner whatsoever enter into or effect, directly or indirectly, any (i) "short sale" (as such term is defined in Section 242.200 of Regulation SHO of the 1934 Act) of the Common Stock or (ii) hedging transaction, which establishes a net short position with respect to the Common Stock.

(e) Issuance of Commitment Shares and Initial Purchase Shares Immediately upon the execution of this Agreement, the Company shall issue to the Buyer as consideration for the Buyer entering into this Agreement 250,000 shares of Common Stock (the "**Commitment Shares**") and, pursuant to Section 1(a), the Buyer shall purchase the Initial Purchase Shares. The Commitment Shares and Initial Purchase Shares shall be issued in certificated form an (subject to Section 5 hereof) shall bear the following restrictive legend:

THE SECURITIES REPRESENTED BY THIS CERTIFICATE HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED, OR APPLICABLE STATE SECURITIES LAWS. THE SECURITIES HAVE BEEN ACQUIRED FOR INVESTMENT AND MAY NOT BE OFFERED FOR SALE, SOLD, TRANSFERRED OR ASSIGNED IN THE ABSENCE OF AN EFFECTIVE REGISTRATION STATEMENT FOR THE SECURITIES UNDER THE SECURITIES ACT OF 1933, AS AMENDED, OR APPLICABLE STATE SECURITIES LAWS, UNLESS SOLD PURSUANT TO: (1) RULE 144 UNDER THE SECURITIES ACT OF 1933, AS AMENDED, OR (2) AN OPINION OF HOLDER'S COUNSEL, IN A CUSTOMARY FORM, THAT REGISTRATION IS NOT REQUIRED UNDER SAID ACT OR APPLICABLE STATE SECURITIES LAWS.

(f) Due Diligence. The Buyer shall have the right, from time to time as the Buyer may reasonably deem appropriate, to perform reasonable due diligence on the Company during normal business hours and subject to reasonable prior notice to the Company. The Company and its officers and employees shall provide information and reasonably cooperate with the Buyer in connection with any reasonable request by the Buyer related to the Buyer's due diligence of the Company, including, but not limited to, any such request made by the Buyer in connection with (i) the filing of the registration statement described in Section 4(a) hereof and (ii) the Commencement; provided, however, that at no time is the Company required to disclose material nonpublic information to the Buyer or breach any obligation of confidentiality or non-disclosure to a third party or make any disclosure that could cause a waiver of attorney-client privilege. Each party hereto agrees not to disclose any Confidential Information of the other party to any third party and shall not use the Confidential Information of such other party for any purpose other than in connection with, or in furtherance of, the transactions contemplated hereby. Each party hereto acknowledges that the Confidential Information shall remain the property of the disclosing party and agrees that it shall take all reasonable measures to protect the secrecy of any Confidential Information disclosed by the other party. All disclosures of Confidential Information shall be subject to the terms and conditions of the Non-Disclosure Agreement dated March 25, 2013 between the Company and the Buyer.

5. TRANSFER AGENT INSTRUCTIONS.

Immediately upon the execution of this Agreement, the Company shall deliver to the Transfer Agent a letter in the form as set forth as **Exhibit D** attached hereto with respect to the issuance of the Commitment Shares and the Initial Purchase Shares.On the Commencement Date, the Company shall cause any restrictive legend on the Commitment Shares and the Initial Purchase Shares to be removed upon surrender of the originally issued certificate(s) for such shares. All of the Purchase Shares to be issued under this Agreement shall be issued without any restrictive legend unless the Buyer expressly consents otherwise. The Company shall issue irrevocable instructions to the Transfer Agent, and any subsequent transfer agent, to issue Common Stock in the name of the Buyer for the Purchase Shares (the '**Irrevocable Transfer Agent Instructions"**). The Company warrants to the Buyer that no instruction other than the Irrevocable Transfer Agent Instructions referred to in this Section 5, will be given by the Company to the Transfer Agent with respect to the Purchase Shares and that the Commitment Sharesand the Purchase Shares shall otherwise be freely transferable on the books and records of the Company as and to the extent provided in this Agreement and the Registration Rights Agreement, subject to the provisions of Section 4(e) in the case of the Commitment Shares and the Initial Purchase Shares.

6. CONDITIONS TO THE COMPANY'S RIGHT TO COMMENCE SALES OF SHARES OF COMMON STOCK UNDI AGREEMENT.

The right of the Company hereunder to commence sales of the Purchase Shares (other than the Initial Purchase Shares) is subject to the satisfactio of each of the following conditions on or before the Commencement Date (the date that the Company may begin sales of Purchase Shares):

(a) The Buyer shall have executed each of the Transaction Documents and delivered the same to the Company;

(b) The representations and warranties of the Buyer shall be true and correct as of the Commencement Date as though made at that time (except for representations and warranties that speak as of a specific date, which shall be true and correct in all material respects as of such specific date) and the Buyer shall have performed, satisfied and complied in all material respects with the covenants and agreements required by this Agreement to be performed, satisfied or complied with by the Buyer at or prior to the Commencement Date; and

(c) A registration statement covering the sale of the Securities shall have been declared effective under the 1933 Act by the SEC and no stop order with respect to the registration statement shall be pending or threatened by the SEC.

7. CONDITIONS TO THE BUYER'S OBLIGATION TO MAKE PURCHASES OF SHARES OF COMMON STOCK.

The obligation of the Buyer to buy Purchase Shares (other than the Initial Purchase Shares) under this Agreement is subject to the satisfaction of each of the following conditions on or before the Commencement Date (the date that the Company may begin sales of Purchase Shares other than the Initia Purchase Shares) and once such conditions have been initially satisfied, there shall not be any ongoing obligation to satisfy such conditions after the Commencement has occurred:

(a) The Company shall have executed each of the Transaction Documents and delivered the same to the Buyer;

(b) The Company shall have issued to the Buyer the Commitment Sharesand, in the event that the Buyer shall have surrendered the originally issued certificate(s), shall have removed the restrictive transfer legend from the certificate representing the Commitment Shares and Initial Purchase Shares;

(c) The Common Stock shall be authorized for quotation on the Principal Market, trading in the Common Stock shall not have been within the last 36 days suspended by the SEC or the Principal Market and the Securities shall be approved for listing upon the Principal Market;

(d) The Buyer shall have received the opinion of the Company's legal counsel dated as of the Commencement Date in customary form and substance;

(e) The representations and warranties of the Company shall be true and correct in all material respects (except to the extent that any of such representations and warranties is already qualified as to materiality in Section 3 above, in which case, such representations and warranties shall be true and correct without further qualification) as of the date of this Agreement and as of the Commencement Date as though made at that time (except for representations and warranties that speak as of a specific date, which shall be true and correct in all material respects as of such specific date) and the Company shall have performed, satisfied and complied in all material respects with the covenants, agreements and conditions required by the Transaction Documents to be performed, satisfied or complied with by the Company at or prior to the Commencement Date. The Buyer shall have received a certificate, executed by the CEO, President or CFO of the Company, dated as of the Commencement Date, to the foregoing effect in the form attached hereto as **Exhibit A**;

(f) The Board of Directors of the Company or a duly authorized committee thereof shall have adopted resolutions substantially in the form attached hereto as **Exhibit B-1** which shall be in full force and effect without any amendment or supplement thereto as of the Commencement Date;

(g) As of the Commencement Date, the Company shall have reserved out of its authorized and unissued Common Stock, solely for the purpose of effecting purchases of Purchase Shares hereunder, 2,500,186 shares of Common Stock;

(h) The Irrevocable Transfer Agent Instructions, in form acceptable to the Buyer shall have been signed by the Company and the Buyer and have been delivered to the Transfer Agent;

(i) The Company shall have delivered to the Buyer a certificate evidencing the incorporation and good standing of the Company in the State of Delaware issued by the Secretary of State of the State of Delaware as of a date within ten (10) Business Days of the Commencement Date;

(j) The Company shall have delivered to the Buyer a certified copy of the Certificate of Incorporation, as certified by the Secretary of State of the State of Delaware within ten (10) Business Days of the Commencement Date;

(k) The Company shall have delivered to the Buyer a secretary's certificate executed by the Secretary of the Company, dated as of the Commencement Date, in the form attached hereto as **Exhibit C**;

(l) A registration statement covering the sale of (i) all of the Commitment Shares, (ii) all of the Initial Purchase Shares and (iii) such number of additional Purchase Shares as reasonably determined by the Company shall have been declared effective under the 1933 Act by the SEC and no stop order with respect thereto shall be pending or threatened by the SEC. The Company shall have prepared and delivered to the Buyer a final and complete form of prospectus, dated and current as of the Commencement Date, to be used by the Buyer in connection with any sales of any Securities, and to be filed by the Company one (1) Business Day after the Commencement Date pursuant to Rule 424(b). The Company shall have made all filings under all applicable federal and state securities laws necessary to consummate the issuance of the Commitment Shares and the Purchase Shares pursuant to this Agreement in compliance with such laws;

(m) No Event of Default hasoccurred and is continuing, or any event which, after notice and/or lapse of time, would become an Event of Default has occurred;

(n) On or prior to the Commencement Date, the Company shall take all necessary action, if any, and such actions as reasonably requested by the Buyer, in order to render inapplicable any control share acquisition, business combination, stockholder rights plan or poison pill (including any distribution under a rights agreement) or other similar anti-takeover provision under the Certificate of Incorporation or the laws of the state of its incorporation, other than Section 203 of the Delaware General Corporation Law, that is or could become applicable to the Buyer as a result of the transactions contemplated by this Agreement including, without limitation, the Company's issuance of the Securities and the Buyer's ownership of the Securities; and

(o) The Company shall have provided the Buyer with the information reasonably requested by the Buyer in connection with its due diligence requests made prior to, or in connection with, the Commencement, in accordance with the terms of Section 4(f) hereof.

8. INDEMNIFICATION.

In consideration of the Buyer's execution and delivery of the Transaction Documents and acquiring the Securities hereunder and in addition to all of the Company's other obligations under the Transaction Documents, the Company shall defend, protect, indemnify and hold harmless the Buyer and all of its affiliates, members, officers, directors, and employees, and any of the foregoing person's agents or other representatives (including, without limitation, those retained in connection with the transactions contemplated by this Agreement) (collectively, the "**Indemnitees**") from and against any and all actions, causes of action, suits, claims, losses, costs, penalties, fees, liabilities and damages, and expenses in connection therewith (irrespective of whether any such Indemnitee is a party to the action for which indemnification hereunder is sought), and including reasonable attorneys' fees and disbursements (the "**Indemnified Liabilities**"), incurred by any Indemnitee as a result of, or arising out of, or relating to (a) any misrepresentation or breach of any representation or warranty made by the Company in the Transaction Documents or any other certificate, instrument or document contemplated hereby or thereby, (b) any breach of any covenant, agreement or obligation of the Company contained in the Transaction Documents or any other certificate, instrument or document contemplated hereby or thereby, or (c) any cause of action, suit or claim brought or made against such Indemnitee and arising out of or resulting from the execution, delivery, performance or enforcement of the Transaction Documents or any other certificate, instrument or document contemplated hereby or thereby, other than with respect to Indemnified Liabilities which directly and primarily result from (A) a breach of any of the Buyer's representations and warranties, covenants or agreements contained in this Agreement, or (B) the gross negligence, bad faith or willful misconduct of the Buyer or any other Indemnitee. To the extent that the foregoing undertaking by the Company may be unenforceable for any reason, the Company shall make the maximum contribution to the payment and satisfaction of each of the Indemnified Liabilities which is permissible under applicable law.

9. EVENTS OF DEFAULT.

An "**Event of Default**" shall be deemed to have occurred at any time as any of the following events occurs:

(a) during any period in which the effectiveness of any registration statement is required to be maintained pursuant to the terms of the Registration Rights Agreement, the effectiveness of such registration statement lapses for any reason (including, without limitation, the issuance of a stop order) or is unavailable to the Buyer for the sale of all of the Registrable Securities (as defined in the Registration Rights Agreement), and such lapse or unavailability continues for a period of ten (10) consecutive Business Days or for more than an aggregate of thirty (30) Business Days in any 365-day period, which is not in connection with a post-effective amendment to any such registration statement or the filing of a new registration statement; provided, however, that in connection with any post-effective amendment to such registration statement or filing of a new registration statement that is required to be declared effective by the SEC, such lapse or unavailability may continue for a period of no more than Twenty (20) consecutive Business Days, which such period shall be extended for up to an additional Thirty (30) Business Days if the Company receives a comment letter from the SEC in connection therewith;

(b) the suspension from trading or failure of the Common Stock to be listed on a Principal Market for a period of three (3) consecutive Business Days;

(c) the delisting of the Common Stock from the Principal Market, and the Common Stock is not immediately thereafter trading on the New York Stock Exchange, the NYSE MKT, the Nasdaq Global Select Market, the Nasdaq Global Market, the Nasdaq Capital Market, the OTC Bulletin Board, or the OTCQB or OTCQX market places of the OTC Markets;

(d) the failure for any reason by the Transfer Agent to issue Purchase Shares to the Buyer within five (5) Business Days after the applicable Purchase Date that the Buyer is entitled to receive;

(e) the breach of any representation, warranty, covenant or other term or condition under any Transaction Document if such breach could reasonably be expected to have a Material Adverse Effect and except, in the case of a breach of a covenant which is reasonably curable, only if such breach continues uncured for a period of at least five (5) Business Days;

(f) if any Person commences a proceeding against the Company pursuant to or within the meaning of any Bankruptcy Law;

(g) if the Company pursuant to or within the meaning of any Bankruptcy Law; (A) commences a voluntary case, (B) consents to the entry of an order for relief against it in an involuntary case, (C) consents to the appointment of a Custodian of it or for all or substantially all of its property, (D) makes a general assignment for the benefit of its creditors or (E) becomes insolvent; or

(h) a court of competent jurisdiction enters an order or decree under any Bankruptcy Law that (A) is for relief against the Company in an involuntary case, (B) appoints a Custodian of the Company or for all or substantially all of its property, or (C) orders the liquidation of the Company or any Subsidiary.

(i) if at any time after the Commencement Date, the Exchange Cap is reached unless and until stockholder approval is obtained pursuant to Section 1(h) hereof. The Exchange Cap shall be deemed to be reached at such time if, upon submission of a Purchase Notice or VWAP Purchase Notice under this Agreement, the issuance of such shares of Common Stock would exceed that number of shares of Common Stock which the Company may issue under this Agreement without breaching the Company's obligations under the rules or regulations of the Principal Market.

In addition to any other rights and remedies under applicable law and this Agreement, including the Buyer termination rights under Section 11(k) hereof, so long as an Event of Default has occurred and is continuing, or if any event which, after notice and/or lapse of time, would become an Event of Default, has occurred and is continuing, or so long as the Closing Sale Price is below the Floor Price, the Company may not require and the Buyer shall not be obligated or permitted to purchase any shares of Common Stock under this Agreement. If pursuant to or within the meaning of any Bankruptcy Law, the Company commences a voluntary case or any Person commences a proceeding against the Company, a Custodian is appointed for the Company or for all or substantially all of its property, or the Company makes a general assignment for the benefit of its creditors, (any of which would be an Event of Default as described in Sections 9(f), 9(g) and 9(h) hereof) this Agreement shall automatically terminate without any liability or payment to the Company without further action or notice by any Person. No such termination of this Agreement under Section 11(k)(i) shall affect the Company's or the Buyer's obligations under this Agreement with respect to pending purchases and the Company and the Buyer shall complete their respective obligations with respect to any pending purchases under this Agreement.

10. CERTAIN DEFINED TERMS.

For purposes of this Agreement, the following terms shall have the following meanings:

(a) "**1933 Act**" means the Securities Act of 1933, as amended.

(b) "**Available Amount**" means initially Thirty Million Dollars ($30,000,000) in the aggregate which amount shall be reduced by the Initial Purchase and the Purchase Amount each time the Buyer purchases shares of Common Stock pursuant to Section 1 hereof.

(c) "**Bankruptcy Law**" means Title 11, U.S. Code, or any similar federal or state law for the relief of debtors.

(d) "**Business Day**" means any day on which the Principal Market is open for trading during normal trading hours (i.e., 9:30 a.m. to 4:00 p.m. Eastern Time), including any day on which the Principal Market is open for trading for a period of time less than the customary time.

(e) "**Closing Sale Price**" means the last closing trade price for the Common Stock on the Principal Market as reported by the Principal Market.

(f) "**Confidential Information**" means any information disclosed by either party to the other party, either directly or indirectly, in writing, orally or by inspection of tangible objects (including, without limitation, documents, protocols, development plans, commercialization plans, samples, compounds and clinical and pre-clinical trial results). Confidential Information may also include information disclosed to a disclosing party by third parties. Confidential Information shall not, however, include any information which (i) was publicly known and made generally available in the public domain prior to the time of disclosure by the disclosing party; (ii) becomes publicly known and made generally available after disclosure by the disclosing party to the receiving party through no action or inaction of the receiving party; (iii) is already in the possession of the receiving party at the time of disclosure by the disclosing party as shown by the receiving party's files and records immediately prior to the time of disclosure; (iv) is obtained by the receiving party from a third party without a breach of such third party's obligations of confidentiality; (v) is independently developed by the receiving party without use of or reference to the disclosing party's Confidential Information, as shown by documents and other competent evidence in the receiving party's possession; or (vi) is required by law to be disclosed by the receiving party, provided that the receiving party gives the disclosing party prompt written notice of such requirement prior to such disclosure and assistance in obtaining an order protecting the information from public disclosure.

(g) "**Custodian**" means any receiver, trustee, assignee, liquidator or similar official under any Bankruptcy Law.

(h) "**Maturity Date**" means the date that is thirty-six (36) months from the Commencement Date.

(i) "**Person**" means an individual or entity including any limited liability company, a partnership, a joint venture, a corporation, a trust, an unincorporated organization and a government or any department or agency thereof.

(j) "**Principal Market**" means the Nasdaq Capital Market; provided however, that in the event the Company's Common Stock is ever listed or traded on the New York Stock Exchange, the NYSE MKT, the Nasdaq Global Select Market, the Nasdaq Global Market, the OTC Bulletin Board, or either one the OTCQB or the OTCQX market places of the OTC Markets, then the "Principal Market" shall mean such other market or exchange on which t Company's Common Stock is then listed or traded.

(k) "**Purchase Amount**" means, with respect to any particular purchase made hereunder, the portion of the Available Amount to be purchased by the Buyer pursuant to Section 1 hereof as set forth in a valid Purchase Notice or VWAP Purchase Notice which the Company delivers to the Buyer.

(l) "**Purchase Date**" means with respect to any Regular Purchase made hereunder, the Business Day of receipt by the Buyer of a valid Purchase Notice that the Buyer is to buy Purchase Shares pursuant to Section 1(b) hereof.

(m) "**Purchase Notice**" shall mean an irrevocable written notice from the Company to the Buyer directing the Buyer to buy Purchase Shares pursuant to Section 1(b) hereof as specified by the Company therein at the applicable Purchase Price on the Purchase Date.

(n) "**Purchase Price**" means the lesser of (i) the lowest Sale Price of the Common Stock on the Purchase Date or (ii) the arithmetic average of th three (3) lowest Closing Sale Prices for the Common Stock during the twelve (12) consecutive Business Days ending on the Business Day immediate preceding such Purchase Date (to be appropriately adjusted for any reorganization, recapitalization, non-cash dividend, stock split, reverse stock split or other similar transaction).

(o) "**Sale Price**" means any trade price for the shares of Common Stock on the Principal Market during normal trading hours, as reported by the Principal Market.

(p) "**SEC**" means the United States Securities and Exchange Commission.

(q) "**Transfer Agent**" means the transfer agent of the Company as set forth in Section 11(f) hereof or such other person who is then serving as the transfer agent for the Company in respect of the Common Stock.

(r) "**VWAP Minimum Price Threshold**" means, with respect to any particular VWAP Purchase Notice, the Sale Price on the VWAP Purchas Date equal to the greater of (i) 90% of the Closing Sale Price on the Business Day immediately preceding the VWAP Purchase Date or (ii) such higher pric as set forth by the Company in the VWAP Purchase Notice.

(s) "**VWAP Purchase Amount**" means, with respect to any particular VWAP Purchase Notice, the portion of the Available Amount to be purchased by the Buyer pursuant to Section 1(c) hereof as set forth in a valid VWAP Purchase Notice which requires the Buyer to buy the VWAP Purchas Share Percentage of the aggregate shares traded on the Principal Market during normal trading hours on the VWAP Purchase Date up to the VWA Purchase Share Volume Maximum, subject to the VWAP Minimum Price Threshold.

(t) "**VWAP Purchase Date**" means, with respect to any VWAP Purchase made hereunder, the Business Day following the receipt by the Buyer o a valid VWAP Purchase Notice that the Buyer is to buy Purchase Shares pursuant to Section 1(c) hereof.

(u) "**VWAP Purchase Notice**" shall mean an irrevocable written notice from the Company to the Buyer directing the Buyer to buy Purchase Share on the VWAP Purchase Date pursuant to Section 1(c) hereof as specified by the Company therein at the applicable VWAP Purchase Price with th applicable VWAP Purchase Share Percentage specified therein.

(v) "**VWAP Purchase Share Percentage**" means, with respect to any particular VWAP Purchase Notice pursuant to Section 1(c) hereof, the percentage set forth in the VWAP Purchase Notice which the Buyer will be required to buy as a specified percentage of the aggregate shares traded on the Principal Market during normal trading hours up to the VWAP Purchase Share Volume Maximum on the VWAP Purchase Date subject to Section 1(c hereof but in no event shall this percentage exceed thirty percent (30%) of such VWAP Purchase Date's share trading volume of the Common Stock on the Principal Market during normal trading hours.

(w) "**VWAP Purchase Price**" means the lesser of (i) the Closing Sale Price on the VWAP Purchase Date; or (ii) ninety-five percent (95%) o volume weighted average price for the Common Stock traded on the Principal Market during normal trading hours on (A) the VWAP Purchase Date if th aggregate shares traded on the Principal Market on the VWAP Purchase Date have not exceeded the VWAP Purchase Share Volume Maximum, or (B) th portion of the VWAP Purchase Date until such time as the sooner to occur of (1) the time at which the aggregate shares traded on the Principal Market ha exceeded the VWAP Purchase Share Volume Maximum, or (2) the time at which the sale price of Common Stock falls below the VWAP Minimum Pric Threshold (to be appropriately adjusted for any reorganization, recapitalization, non-cash dividend, stock split, reverse stock split or other similar transaction).

(x) "**VWAP Purchase Share Estimate**" means the number of shares of Common Stock that the Company has in its sole discretion irrevocably instructed its Transfer Agent to issue to the Buyer via the Depository Trust Company ("**DTC**") Fast Automated Securities Transfer Program in connection with a VWAP Purchase Notice pursuant to Section 1(c) hereof and issued to the Buyer's or its designee's balance account with DTC through its Depos Withdrawal At Custodian (DWAC) system on the VWAP Purchase Date (to be appropriately adjusted for any reorganization, recapitalization, non-cas dividend, stock split, reverse stock split or other similar transaction).

(y) "**VWAP Purchase Share Volume Maximum**" means a number of shares of Common Stock traded on the Principal Market during norma trading hours on the VWAP Purchase Date equal to: (i) the VWAP Purchase Share Estimate, divided by (ii) the VWAP Purchase Share Percentage (to b appropriately adjusted for any reorganization, recapitalization, non-cash dividend, stock split, reverse stock split or other similar transaction).

11. MISCELLANEOUS.

(a) Governing Law; Jurisdiction; Jury Trial The laws of the State of Delaware shall govern all issues concerning the relative rights of the Company and its stockholders. All other questions concerning the construction, validity, enforcement and interpretation of this Agreement and the other Transaction Documents shall be governed by the internal laws of the State of Illinois, without giving effect to any choice of law or conflict of law provision or rule (whether of the State of Illinois or any other jurisdictions) that would cause the application of the laws of any jurisdictions other than the State of Illinois. Each party hereby irrevocably submits to the exclusive jurisdiction of the state and federal courts sitting in the City of Chicago, for the adjudication of any dispute hereunder or under the other Transaction Documents or in connection herewith or therewith, or with any transaction contemplated hereby or discussed herein, and hereby irrevocably waives, and agrees not to assert in any suit, action or proceeding, any claim that it is not personally subject to the jurisdiction of any such court, that such suit, action or proceeding is brought in an inconvenient forum or that the venue of such suit, action or proceeding is improper. Each party hereby irrevocably waives personal service of process and consents to process being served in any such suit, action or proceeding by mailing a copy thereof to such party at the address for such notices to it under this Agreement and agrees that such service shall constitute good and sufficient service of process and notice thereof. Nothing contained herein shall be deemed to limit in any way any right to serve process in any manner permitted by law. **EACH PARTY HEREBY IRREVOCABLY WAIVES ANY RIGHT IT MAY HAVE, AND AGREES NOT TO REQUEST, A JURY TRIAL FOR ADJUDICATION OF ANY DISPUTE HEREUNDER OR IN CONNECTION HEREWITH OR ARISING OUT OF THIS AGREEM ANY TRANSACTION CONTEMPLATED HEREBY.**

(b) Counterparts. This Agreement may be executed in two or more identical counterparts, all of which shall be considered one and the same agreement and shall become effective when counterparts have been signed by each party and delivered to the other party; provided that a facsimile or pdf (or other electronic reproduction) signature shall be considered due execution and shall be binding upon the signatory thereto with the same force and effect as if the signature were an original, not a facsimile or pdf (or other electronic reproduction) signature.

(c) Headings. The headings of this Agreement are for convenience of reference and shall not form part of, or affect the interpretation of, this Agreement.

(d) Severability. If any provision of this Agreement shall be invalid or unenforceable in any jurisdiction, such invalidity or unenforceability shall not affect the validity or enforceability of the remainder of this Agreement in that jurisdiction or the validity or enforceability of any provision of this Agreement in any other jurisdiction.

(e) Entire Agreement. This Agreement and the Registration Rights Agreement supersede all other prior oral or written agreements between the Buyer, the Company, their affiliates and persons acting on their behalf with respect to the matters discussed herein, and this Agreement, the other Transaction Documents and the instruments referenced herein contain the entire understanding of the parties with respect to the matters covered herein and therein and, except as specifically set forth herein or therein, neither the Company nor the Buyer makes any representation, warranty, covenant or undertaking with respect to such matters. The Company acknowledges and agrees that is has not relied on, in any manner whatsoever, any representations or statements, written or oral, other than as expressly set forth in this Agreement.

(f) Notices. Any notices, consents or other communications required or permitted to be given under the terms of this Agreement must be in writing and will be deemed to have been delivered: (i) upon receipt when delivered personally; (ii) upon receipt when sent by facsimile (provided confirmation of transmission is mechanically or electronically generated and kept on file by the sending party); or (iii) one (1) Business Day after timely deposit with a nationally recognized overnight delivery service, in each case properly addressed to the party to receive the same. The addresses and facsimile numbers for such communications shall be:

If to the Company:

Atossa Genetics, Inc.
1616 Eastlake Ave., East, Suite 510
Seattle, Washington 98102
Telephone: 800 351-3902
Facsimile: 206 430-1288
Attention: Kyle Guse
Chief Financial Officer and General Counsel

With a copy (which shall not constitute notice) to:

Ropes & Gray LLP
Three Embarcadero Center
San Francisco, CA 94111
Telephone: (415) 315-6395
Facsimile: (415) 315-6026
Attention: Ryan A. Murr, Esq.

If to the Buyer:

Aspire Capital Fund, LLC
155 North Wacker Drive, Suite 1600
Chicago, IL 60606
Telephone: 312-658-0400
Facsimile: 312-658-4005
Attention: Steven G. Martin

With a copy to (which shall not constitute delivery to the Buyer):

O'Melveny & Myers LLP
1625 Eye Street, NW
Washington, DC 20006
Telephone: 202-383-5418
Facsimile: 202-383-5414
Attention: Martin P. Dunn, Esq.

If to the Transfer Agent:

VStock Transfer
77 Spruce Street , Suite 201
Cedarhurst, New York
Telephone: 212 828-8436
Facsimile: 646 536-3179
Attention: Chief Executive Officer

or at such other address and/or facsimile number and/or to the attention of such other person as the recipient party has specified by written notice given to each other party one (1) Business Day prior to the effectiveness of such change. Written confirmation of receipt (A) given by the recipient of such notice, consent or other communication, (B) mechanically or electronically generated by the sender's facsimile machine containing the time, date, and recipient facsimile number or (C) provided by a nationally recognized overnight delivery service, shall be rebuttable evidence of receipt in accordance with clause (i), (ii) or (iii) above, respectively.

(g) Successors and Assigns. This Agreement shall be binding upon and inure to the benefit of the parties and their respective successors and assigns. The Company shall not assign this Agreement or any rights or obligations hereunder without the prior written consent of the Buyer, including by merger or consolidation. The Buyer may not assign its rights or obligations under this Agreement.

(h) No Third Party Beneficiaries This Agreement is intended for the benefit of the parties hereto and their respective permitted successors and assigns, and is not for the benefit of, nor may any provision hereof be enforced by, any other person.

(i) Publicity. The Buyer shall have the right to approve before issuance any press release, SEC filing or any other public disclosure made by or on behalf of the Company whatsoever with respect to, in any manner, the Buyer, its purchases hereunder or any aspect of this Agreement or the transactions contemplated hereby; provided, however, that the Company shall be entitled, without the prior approval of the Buyer, to make any press release or other public disclosure (including any filings with the SEC) with respect to such transactions as is required by applicable law and regulations so long as the Company and its counsel consult with the Buyer in connection with any such press release or other public disclosure at least one (1) Business Day prior to its release. The Buyer must be provided with a copy thereof at least one (1) Business Day prior to any release or use by the Company thereof.

(j) Further Assurances. Each party shall do and perform, or cause to be done and performed, all such further acts and things, and shall execute and deliver all such other agreements, certificates, instruments and documents, as the other party may reasonably request in order to carry out the intent and accomplish the purposes of this Agreement and the consummation of the transactions contemplated hereby.

(k) Termination. This Agreement may be terminated only as follows:

(i) By the Buyer any time an Event of Default exists without any liability or payment to the Company. However, if pursuant to or within the meaning of any Bankruptcy Law, the Company commences a voluntary case or any Person commences a proceeding against the Company, a Custodian is appointed for the Company or for all or substantially all of its property, or the Company makes a general assignment for the benefit of its creditors, (any of which would be an Event of Default as described in Sections 9(f), 9(g) and 9(h) hereof) this Agreement shall automatically terminate without any liability or payment to the Company without further action or notice by any Person. No such termination of this Agreement under this Section 11(k)(i) shall affect the Company's or the Buyer's obligations under this Agreement with respect to pending purchases and the Company and the Buyer shall complete their respective obligations with respect to any pending purchases under this Agreement.

(ii) In the event that the Commencement shall not have occurred the Company shall have the option to terminate this Agreement for any reason or for no reason without any liability whatsoever of either party to the other party under this Agreement except as set forth in Section 11(k)(viii) hereof.

(iii) In the event that the Commencement shall not have occurred on or before June 1, 2013, due to the failure to satisfy any of the conditions set forth in Sections 6 and 7 above with respect to the Commencement, either party shall have the option to terminate this Agreement at the close of business on such date or thereafter without liability of either party to any other party; provided, however, that the right to terminate this Agreement under this Section 11(k)(iii) shall not be available to either party if such failure to satisfy any of the conditions set forth in Sections 6 and 7 is the result of a breach of this Agreement by such party or the failure of any representation or warranty of such party included in this Agreement to be true and correct in all material respects.

(iv) At any time after the Commencement Date, the Company shall have the option to terminate this Agreement for any reason or for no reason by delivering notice (a "**Company Termination Notice**") to the Buyer electing to terminate this Agreement without any liability whatsoever of either party to the other party under this Agreement except as set forth in Section 11(k)(viii) hereof. The Company Termination Notice shall not be effective until one (1) Business Day after it has been received by the Buyer.

(v) This Agreement shall automatically terminate on the date that the Company sells and the Buyer purchases the full Available Amount as provided herein, without any action or notice on the part of any party and without any liability whatsoever of any party to any other party under this Agreement except as set forth in Section 11(k)(viii) hereof.

(vi) If by the Maturity Date for any reason or for no reason the full Available Amount under this Agreement has not been purchased as provided for in Section 1 of this Agreement, this Agreement shall automatically terminate on the Maturity Date, without any action or notice on the part of any party and without any liability whatsoever of any party to any other party under this Agreement except as set forth in Section 11(k)(viii) hereof.

(vii) Except as set forth in Sections 11(k)(i) (in respect of an Event of Default under Sections 9(f), 9(g) and 9(h)), 11(k)(v) and 11(k)(vi), any termination of this Agreement pursuant to this Section 11(k) shall be effected by written notice from the Company to the Buyer, or the Buyer to the Company, as the case may be, setting forth the basis for the termination hereof.

(viii) The representations and warranties of the Company and the Buyer contained in Sections 2, 3 and 5 hereof, the indemnification provisions set forth in Section 8 hereof and the agreements and covenants set forth in Sections 4(e) and 11, shall survive the Commencement and any termination of this Agreement. No termination of this Agreement shall affect the Company's or the Buyer's rights or obligations (A) under the Registration Rights Agreement which shall survive any such termination in accordance with its terms or (B) under this Agreement with respect to pending purchases and the Company and the Buyer shall complete their respective obligations with respect to any pending purchases under this Agreement.

(l) No Financial Advisor, Placement Agent, Broker or Finder. Other than Dawson James Securities, Inc., the Company represents and warrants to the Buyer that it has not engaged any financial advisor, placement agent, broker or finder in connection with the transactions contemplated hereby. The Buyer represents and warrants to the Company that it has not engaged any financial advisor, placement agent, broker or finder in connection with the transactions contemplated hereby. Each party shall be responsible for the payment of any fees or commissions, if any, of any financial advisor, placement agent, broker or finder engaged by such party relating to or arising out of the transactions contemplated hereby. Each party shall pay, and hold the other party harmless against, any liability, loss or expense (including, without limitation, attorneys' fees and out of pocket expenses) arising in connection with any such claim.

(m) No Strict Construction. The language used in this Agreement will be deemed to be the language chosen by the parties to express their mutual intent, and no rules of strict construction will be applied against any party.

(n) Failure or Indulgence Not Waiver. No failure or delay in the exercise of any power, right or privilege hereunder shall operate as a waiver thereof, nor shall any single or partial exercise of any such power, right or privilege preclude other or further exercise thereof or of any other right, power or privilege.

* * * * *

IN WITNESS WHEREOF, the Buyer and the Company have caused this Common Stock Purchase Agreement to be duly executed as of the date first written above.

THE COMPANY:

ATOSSA GENETICS, INC.

By: /s/ Steven C. Quay
Name: Steven C. Quay
Title: Chairman, Chief Executive Officer and President

BUYER:

ASPIRE CAPITAL FUND, LLC
BY: ASPIRE CAPITAL PARTNERS, LLC
BY: CHRISKO INVESTORS, INC.

By: /s/ Christos Komissopoulos
Name: Christos Komissopoulos
Title: President

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to incorporation by reference in the Registration Statement on Form S-8 (File No. 333-185625) of Atossa Genetics Inc. (a developmer stage company) of our report dated March 27, 2013 relating to the consolidated financial statements as of and for the years ended December 31, 2012 and 2011 and since its inception (April 30, 2009), which appears in this Annual Report on Form 10-K.

/s/ KCCW Accountancy Corp.

Diamond Bar, California
March 27, 2013

Exhibit 31.1

CERTIFICATION PURSUANT TO RULE 13a-14(a)
OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED
AS ADOPTED PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Steven C. Quay, certify that:

1. I have reviewed this Annual Report of Atossa Genetics Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent function):

(a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 27, 2013

/s/Steven C. Quay
Steven C. Quay
Chief Executive Officer and President
(Principal executive officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO RULE 13a-14(a)
OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED
AS ADOPTED PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Kyle Guse, certify that:

1. I have reviewed this Annual Report of Atossa Genetics Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent function):

(a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 27, 2013

/s/Kyle Guse
Kyle Guse
Chief Financial Officer, General Counsel and Secretary
(Principal financial and accounting officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Atossa Genetics Inc. (the "Company") on Form 10-K for the period ending December 31, 2012 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Steven C. Quay, Chief Executive Officer and President of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 27, 2013

/s/ Steven C. Quay
Steven C. Quay
Chief Executive Officer and President
(Principal executive officer)

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Atossa Genetics Inc. (the "Company") on Form 10-K for the period ending December 31, 2012 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Kyle Guse, Chief Financial Officer, General Counsel and Secretary of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 27, 2013

/s/ Kyle Guse

Kyle Guse
Chief Financial Officer, General Counsel and Secretary
(Principal financial and accounting officer)