ATOSSA GENETICS INC
Form S-1
January 28, 2013

As filed with the Securities and Exchange Commission on January 28, 2013

Registration Statement No. 333-

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM S-1

Registration Statement

Under

The Securities Act of 1933

ATOSSA GENETICS INC.

(Exact name of registrant as specified in its charter)

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

4105 E. Madison Street, Suite 320

Seattle, Washington 98112

Telephone: (206) 325-6086

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

Steven C. Quay

Chairman, Chief Executive Officer and President

4105 E. Madison Street, Suite 320

Seattle, Washington 98112

Telephone: (206) 325-6086

(Name, address, including zip code, and telephone

number, including area code, of agent for service)

_____

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

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

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

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

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

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

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

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

CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	**Amount to be**	**Proposed maximum**	**Proposed maximum**	**Amount of registration fee**

	registered		offering price per share		aggregate offering price		
Common Stock, par value $0.001 per share	8,021,340	(1)	$ 4.43	(2)	$ 35,534,537	$	4,847

(1) Represents 862,500 shares of Common Stock, par value $0.001 per share (the "***Common Stock***"), and 7,158,840 shares of Common Stock that are issuable upon exercise of outstanding warrants as of the date of this Registration Statement that are to be sold by the selling stockholders named herein. Pursuant to Rule 416(a) of the Securities Act of 1933, as amended, this Registration Statement also covers any additional shares of Common Stock which may become issuable to prevent dilution from stock splits, stock dividends and similar events.

(2) Pursuant to Rule 457(c), calculated on the basis of the average of the high and low prices per share of the registrant's Common Stock reported on the NASDAQ Capital Market on January 24, 2013.

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

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

PROSPECTUS (Subject to Completion)

dated January 25, 2013

ATOSSA GENETICS INC.

8,021,340 shares of Common Stock

This prospectus covers the sale of an aggregate of 8,021,340 shares (the "***Shares***") of our Common Stock, $0.001 par value per share (the "***Common Stock***"), 7,158,840 of which are issuable upon the exercise of warrants (the "***Warrants***") at exercise prices ranging from $1.25 to $5.00, by the selling stockholders identified in this prospectus (collectively with any holder's transferee, pledgee, donee or successor, the "***Selling Stockholders***").

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

The Company's Common Stock is traded on the NASDAQ Capital Market under the symbol "ATOS". On January 24, 2013, the closing sale price of our Common Stock on the NASDAQ Capital Market was $4.46 per share. Our principal executive offices are located at 4105 E. Madison Street, Suite 320, Seattle, Washington 98112 and our telephone number is (206) 325-6086.

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

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

The date of this prospectus is , 2013

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You should read this prospectus, any applicable prospectus supplement and the information incorporated by reference in this prospectus before making an investment in the securities of Atossa Genetics Inc. See "Where You Can Find Additional Information" on page 99 for more information. You should rely only on the information contained in or incorporated by reference in this prospectus or a prospectus supplement. The Company has not authorized anyone to provide you with different information. This document may be used only in jurisdictions where offers and sales of these securities are permitted. You should assume that information contained in this prospectus, or in any document incorporated by reference, is accurate only as of any date on the front cover of the applicable document. Our business, financial condition, results of operations and prospects may have changed since that date.

NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus and the documents incorporated by reference into it contain, in addition to historical information, certain information, assumptions and discussions that may constitute forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "***Securities Act***") and Section 21E of the Securities Exchange Act of 1934, as amended (the "***Exchange Act***"). We have made these statements in reliance on the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These statements are subject to certain risks and uncertainties, which could cause actual results to differ materially from those projected or anticipated. Although we believe our assumptions underlying our forward-looking statements are reasonable as of the date of this prospectus, we cannot assure you that the forward-looking statements set out in this prospectus will prove to be accurate. We typically identify these forward-looking statements by the use of forward-looking words such as "expect," "potential," "continue," "may," "will," "should," "could," "would," "seek," "intend," "plan," "estimate," "anticipate" or the negative versio words or other comparable words. Forward-looking statements contained in this prospectus include, but are not limited to, statements about:

- our ability to successfully sell our products and services at currently expected prices or otherwise at prices acceptable to us;
- our ability to successfully develop and commercialize new tests, tools and technologies currently in development and in the time frames currently expected;
- our ability to engage third-party suppliers to manufacture the MASCT or Microcatheter System and its components at quantities and costs acceptable to us;
- our ability to satisfy ongoing Food and Drug Administration requirements for the MASCT and Microcatheter System and to obtain regulatory approvals for our other products and services in development;
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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 Network, 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.

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

PROSPECTUS SUMMARY

This summary highlights some information from this prospectus. It may not contain all the information important to making an investment decision. You should read the following summary together with the more detailed information regarding our company and the securities being sold in this offering, including "Risk Factors" and other information incorporated by reference herein. Unless otherwise noted, (1) the term "Atossa Genetics" refers to Atossa Genetics Inc., a Delaware corporation, (2) the terms "Atossa," the "Company," "we," "us," and "our," refer to the ongoing business opera of Atossa and its wholly-owned subsidiary, whether conducted through Atossa Genetics or its subsidiary and (3) the term "Common Stock" refers to shares of Atossa Genetics Inc.'s Common Stock and the term "stockholder(s)" refers to the holders of Common Stock or securities exercisable for Common Stock.

Our Business

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

Additionally, we are conducting research on the treatment of these pre-cancerous cells 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 1,334 ForeCYTE samples and 41 ArgusCYTE samples as of September 30, 2012 and 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 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-gynocologists. As of December 31, 2011 and September 30, 2012, we have generated $1,500 and $384,886 in revenue, respectively, from the sale of our products and services. We incurred net operating losses of approximately $3.4 million, $1.1 million and $3.4 million for our nine months ended September 30, 2012 and our fiscal years ended December 31, 2010 and 2011, respectively. As of September 30, 2012, we had an accumulated deficit of approximately $8.0 million. We have not yet established an ongoing source of revenue sufficient to cover our operating costs and allow us to continue as a going concern. Our ability to continue as a going concern is dependent on obtaining adequate capital to fund operating losses until we become profitable. We plan to obtain additional capital resources by selling our equity securities, selling the MASCT System and generating laboratory service revenue from our tests, and making short-term borrowings 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.

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

ArgusCYTE The ArgusCYTE Breast Health Test, launched in December 2011, provides information to help inform breast cancer treatment options and to help monitor potential recurrence. It involves collecting a blood specimen from a patient using our patented, FDA 510(k)-Exempt blood collection tube and submitting it to our CLIA-certified laboratory (our ArgusCYTE Breast Health Test blood collection tube was registered with the FDA in 2011). It can monitor breast cancer distant recurrence by obtaining a "liquid biopsy" or blood sample, and analyzing it for the presence of circulating tumor cells, which can then be analyzed to determine the expression of Estrogen Receptor/Progesterone Receptor, or ER/PR, and Human Epidermal Growth Factor Receptor, or Her2, in those cells, a predictor of the cancer's sensitivity to existing treatment options. The presence of circulating tumor cells in the blood sample may serve as an early indicator of the recurrence of breast cancer and the data obtained from the ArgusCYTE sensitivity analysis may help physicians better select which treatment options to use with a particular patient. The ArgusCYTE test uses a proprietary blood collection tube to obtain a blood sample for shipment and analysis at our CLIA-certified laboratory. The supplier of the blood collection tube owns patents with respect to the tube, while we own patents concerning laboratory features utilized in the testing process. Because the ArgusCYTE test involves the collection of a blood sample to be analyzed for the presence of

circulating tumor cells, there is no comparable method relating to the analysis of traditional biopsy specimens that could be used to achieve results similar to or better than those provided by our ArgusCYTE test.

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

NextCYTE

The NextCYTE Breast Cancer Test, which is in the prevalidation phase and which we intend to launch in 2013, is designed to profile breast cancer specimens for prediction of treatment outcomes and distant recurrence in women newly diagnosed with breast cancer. It involves using surgery specimens and advanced genome sequencing techniques to quantify and analyze the entire tumor genetic transcriptome, which represents all genes that are being actively expressed within the tumor. Because our NextCYTE test analyzes traditional biopsy specimens using advanced genome sequencing techniques, we believe that other present methods of analyzing traditional biopsy specimens would not achieve results similar to or better than results provided by our NextCYTE test and we expect that physicians will be able to use the information provided by the NextCYTE test to better customize treatment options for women, based on the genetic composition of the individual tumor. We are currently conducting non-clinical trial research to verify the superiority of the technology regarding NextCYTE by profiling gene expression from breast cancer biopsy specimens obtained from commercial archival tissue banks, in which the five-year survival or death for the patients from whom the specimens are taken is known, and seeing if the algorithm can accurately predict the known outcome. The experiments are being conducted in a blinded fashion, without knowledge of the survival data, and we will not have knowledge of the outcome until the blind is broken (currently planned for February 2013). We own a pending PCT patent application on the NextCYTE technology to the use of full transcriptome analysis of 22,000 human genes in predicting breast cancer recurrence and have an option through February 2013 to license additional technology (specifically certain algorithms involving over 900 of these genes) to augment our existing technology from the University of Oslo in Norway. We do not believe this additional technology is essential to the operation or future development of the NextCYTE test, should we decide not to exercise this option.

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 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.

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

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 because it embodies all of the requisite assumptions (including trading volatility, estimated terms and risk-free rates) necessary to determine the fair value of the warrants. There are no future financial obligations from us to Acueity from the commercialization of the acquired assets.

The acquired patents and patent applications relate to intraductal diagnostic and therapeutic devices and methods of use. The microendoscopes are less than 0.9 mm outside diameter and can be inserted into a milk duct. This permits a physician to pass a microendoscope into the milk duct system of the breast and view the 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. 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 Acueity 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.

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, 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.

Intellectual Property and FDA Marketing Clearances

As of the date of this prospectus, 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 34 of the issued patents (18 issued in the U.S. and 16 issued in foreign countries) and 41 of the patent applications (32 in the U.S. and 9 in foreign countries).

Our Founder

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

Our Commercialization Strategy

The ForeCYTE Test provides us with two revenue sources:

(i) revenue from the sale of the MASCT System device and patient kits to physicians, breast health clinics, 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 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 priced at approximately $35 per kit, however, our sale prices to our distributors are significantly below these prices. 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.

Risk Factors

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

- we will need significant additional capital to execute our business strategy as currently contemplated;
- we have a history of operating losses and expect to incur losses for the foreseeable future and may never achieve profitability;
- The MASCT System and other risk assessment tools, diagnostic tests and tools and other predictive and personalized medicine products that we may develop may never achieve significant commercial market acceptance;
- we are dependent on the commercial success of the MASCT System and the ForeCYTE and ArgusCYTE Tests;
- we may not be successful in commercializing the MASCT System because physicians and clinicians may be slow to adopt our product and, even if commercialized, the fees we receive for our products and services may be significantly lower than currently expected;
- our ability to commercialize the MASCT System may be limited because Medicare and certain insurance carriers are not expected to provide reimbursement for the NAF sample collections which are necessary for our tests (even though Medicare and certain insurance carriers do provide reimbursement for the laboratory analysis of the collected NAF samples through our ForeCYTE and ArgusCYTE tests); and
- we may not be able to hire, train or maintain the independent sales representatives and build the distributorship arrangements necessary to market and sell the MASCT System and our services as planned.

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-gynocologists 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, 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.

MultiPlan Arrangement

In September 2012, we entered into an agreement with MultiPlan, Inc., or MultiPlan, a leading provider of healthcare cost management solutions, for diagnostic laboratory testing involving our tests. Approximately 20% of Americans are covered by MultiPlan. The agreement allows us to participate in the MultiPlan, PHCS and PHCS Savility Networks. Our agreement with MultiPlan will give MultiPlan's participating providers and their patients access to our tests, including the ForeCYTE and ArgusCYTE Breast Health Tests. We anticipate that the agreement with MultiPlan will help ensure that more doctors and their patients have access to the ForeCYTE and ArgusCYTE Breast Health Tests and that patients will receive insurance reimbursement for the laboratory costs associated with these tests.

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

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.

The Offering

This prospectus relates to the resale by the Selling Stockholders identified in this prospectus of up to 8,021,340 shares of Common Stock, 7,158,840 of which are issuable upon the exercise of Warrants. All of the Shares, when sold, will be sold by the Selling Stockholders. The Selling Stockholders may sell their Shares from time to time at market prices prevailing at the time of sale, at prices related to the prevailing market price, or at negotiated prices. We will not receive any proceeds from the sale of Shares by the Selling Stockholders, other than proceeds in the event that some or all of the Warrants held by the Selling Stockholders are exercised for cash.

Corporate Information

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

MASCT is our registered trademark and Oxy-MASCT and our name and logo are our trademarks. ForeCYTE, FullCYTE, NextCYTE, and ArgusCYTE are our service marks. This prospectus also includes additional trademarks, trade names and service marks of third parties, which are the property of their respective owners.

SUMMARY FINANCIAL DATA

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

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

ATOSSA GENETICS, INC.

(A DEVELOPMENT STAGE COMPANY)

CONSOLIDATED STATEMENTS OF OPERATIONS

(UNAUDITED)

	For The Three Months Ended September 30,		For The Nine Months Ended September 30,		From April 30, 2009 (Inception) Through September 30, 2012
	2012	2011	2012	2011	
Revenue					
Diagnostic Testing Service	$104,011	$-	$376,696	$-	$ 376,696
Product Sales	1,565	-	6,690	-	8,190
Total Revenue	105,576	-	383,386	-	384,886
Cost of Revenue					
Diagnostic Testing Service	(9,000)	-	(29,985)	-	(29,985)
Product Sales	-	-	-	-	(5,164)
Total Cost of Revenue	(9,000)	-	(29,985)	-	(35,149)
Loss on Reduction of Inventory to LCM	(6,077)	-	(29,884)	-	(121,910)
Gross Profit	90,499	-	323,517	-	227,827
Selling expenses	(87,704)	-	(281,971)	-	(455,026)
General and Administrative expenses	(1,138,467)	(1,274,189)	(3,405,198)	(2,231,906)	(7,766,497)
Total operating expenses	(1,226,171)	(1,274,189)	(3,687,169)	(2,231,906)	(8,221,523)
Operating Loss	(1,135,672)	(1,274,189)	(3,363,652)	(2,231,906)	(7,993,694)
Interest Income	46	2,267	1,219	3,428	6,588
Interest Expense	(7,756)	(758)	(11,816)	(8,388)	(38,947)
Net Loss before Income Taxes	(1,143,382)	(1,272,680)	(3,374,249)	(2,236,866)	(8,026,053)
Income Taxes	-	-	-	-	250
Net Loss	$(1,143,382)	$(1,272,680)	$(3,374,249)	$(2,236,866)	$ (8,026,303)
	$-0.10	$-0.11	$-0.30	$-0.27	$ (1.05)

Loss per common share - basic and diluted					
Weighted average shares outstanding, basic & diluted	11,256,867	11,256,867	11,256,867	8,394,219	7,657,400

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

ATOSSA GENETICS, INC.

(A DEVELOPMENT STAGE COMPANY)

CONSOLIDATED BALANCE SHEETS

	September 30, 2012 (Unaudited)	December 31, 2011 (Audited)
Assets		
Current Assets		
Cash and cash equivalents	$ 418,570	$ 1,910,821
Restricted cash	250,000	1,000,000
Accounts receivable	175,408	1,224
Prepaid expense	39,975	31,184
Rental deposits	1,500	2,200
Total Current Assets	885,453	2,945,429
Fixed Assets		
Furniture and Equipment, net	67,497	80,467
Total Fixed Assets	67,497	80,467
Other Assets		
Security deposit	36,446	5,157
Intangible assets, net	4,703,078	40,841
Total Other Assets	4,739,524	45,998
Total Assets	$ 5,692,474	$ 3,071,894
Liabilities and Stockholders' Equity		
Current Liabilities		
Line of Credit	$ 250,000	$ 1,000,000
Accounts payable	72,100	64,766
Accrued expenses	1,888,344	442,329
Note payable - related party	80,453	5,078
Total Current Liabilities	2,290,897	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, 12,119,367 shares issued and outstanding	12,119	11,257
Additional paid-in capital	11,415,761	6,200,520

Accumulated deficit	(8,026,303)	(4,652,056)
Total Stockholders' Equity (Deficit)	3,401,577	1,559,721
Total Liabilities and Stockholders' Equity	$ 5,692,474	$ 3,071,894

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

RISK FACTORS

A purchase of our shares of common stock is an investment in our securities and involves a high degree of risk. You should carefully consider the following information about these risks, together with the other information contained in this prospectus, before purchasing our securities. If any of the following risks actually occur, our business, financial condition and results of operations would likely suffer. In that case, the market price of the common stock could decline, and you may lose part or all of your investment in our company. 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 will require significant additional capital to achieve our business objectives, and the inability to obtain such financing on acceptable terms or at all could lead to closure of the business.

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

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

- attract and retain key personnel.

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

The report of our independent auditors contained in our financial statements explains that we have not yet established an ongoing source of revenue sufficient to cover operating costs and allow us to continue as a going concern. Our ability to continue as a going concern is dependent on obtaining adequate capital to fund operating losses until we become profitable. If we are unable to obtain adequate capital, we may be unable to expand our product offerings or geographic reach and we could be forced to cease operations.

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. We have not identified sources for such additional funding and cannot be certain that additional funding will be available on acceptable terms, or at all. If we are unable to raise additional capital in sufficient amounts or on acceptable terms, we may have to significantly delay, scale back or discontinue the commercialization of our products and services or our research and development activities. Furthermore, such lack of funds may inhibit our ability to respond to competitive pressures or unanticipated capital needs, or may force us to reduce operating expenses, which could significantly harm the business and development of operations. Because our independent auditors have expressed doubt as to our ability to continue as a "going concern," as reported in their report on our financial statements, our ability to raise capital may be severely hampered. Similarly, our ability to borrow any such capital may be more expensive and difficult to obtain until this "going concern" issue is eliminated.

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

We have a limited operating history and have incurred total net operating losses of approximately $8.0 million from our incorporation in April 2009 through September 30, 2012. We have received $384,886 in revenue as of September 30, 2012 and we do not expect that we will be in a position to generate significant revenue until we are able to launch our tests more broadly. Additionally, we will continue to incur further losses in connection with inventory costs for our medical test products, marketing and sales expenses in launching our products and services, research and development costs for additional tests, and the maintenance of our CLIA-certified laboratory. For example, the sales price of our MASCT System is currently substantially lower than its cost because the MASCT System is currently manufactured only in small quantities and because the Company's current marketing strategy is to attempt to quickly penetrate the market of the products and services offered by the Company by offering the MASCT System at a price substantially lower than its cost 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, 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 gain market acceptance for the MASCT System and our ForeCYTE and ArgusCYTE Tests, we will need to demonstrate to physicians and other healthcare professionals the benefits of the MASCT System and its practical and economic application for their particular practice. Despite FDA clearance for the MASCT System, many physicians and healthcare professionals may be hesitant to introduce new services, or techniques, into their practice for many reasons, including the learning curve associated with the adoption of such new services or techniques into already established procedures and the uncertainty of the applicability or reliability of the results of a new product. In addition, the availability of full or even partial payment for our products and tests, whether by third-party payors (e.g., insurance companies), or the patients themselves, will likely heavily influence physicians' decisions to recommend or use our products and services.

We will likely be increasingly required to offer discounted pricing arrangements 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 physical 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 diagnostic 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 we 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 assets included six 510(k)-cleared medical devices, 35 issued patents (18 issued in the U.S. and 17 issued in foreign countries) and 41 patent applications (32 in the U.S. and 9 in foreign countries). The FDA-cleared, patented medical devices consist of microendoscopes, light sources, and biopsy tools. The 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. 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

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 continued 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 listing standards of the NASDAQ Capital Market going forward. If we cannot satisfy the continued listing standards going forward, NASDAQ may commence 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 delisted, 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 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 41% 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.

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.

USE OF PROCEEDS

The proceeds from the resale of the Shares under this prospectus are solely for the account of the Selling Stockholders. We may indirectly receive proceeds of up to $12,283,162 to the extent that any Selling Stockholders exercise warrants to purchase shares of Common Stock for cash and then resell those shares under this prospectus; however, we will not directly receive any proceeds from the sale of Shares under this prospectus.

DIVIDEND POLICY

The Company has not declared any dividends and does not anticipate that it will declare dividends in the foreseeable future, but rather intends to retain any future earnings for the development of the business. Payment of future cash dividends, if any, will be at the discretion of the Board of Directors of the Company after taking into account various factors, including the Company's financial condition, operating results, current and anticipated cash needs, outstanding indebtedness and plans for expansion and restrictions imposed by lenders, if any.

SELLING STOCKHOLDERS

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

- 862,500 shares of Common Stock issued in connection with our acquisition of the assets of Acueity;
- 325,000 shares issuable upon the exercise of warrants issued in connection with our acquisition of the assets of Acueity;
- 5,256,800 shares issuable upon the exercise of warrants issued in private offerings that occurred between April 2011 and June 2011; and
- 1,577,040 shares issuable upon the exercise of warrants issued to the placement agent in connection with the private offerings that occurred between April 2011 and June 2011.

Acquisition of Assets from Acueity

In September 2012, we acquired substantially all of the assets of Acueity. The acquisition was effected through an asset purchase in which we acquired 35 issued patents, 41 patent applications 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.

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

Private Placements

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

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

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

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

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

The April Warrants, May Warrants, June 10 Warrants, June 23 Warrants and the Dawson James Warrants became exercisable on June 23, 2011 and expire on June 23, 2016.

In connection with the April, May, June 10, June 23 and Dawson James Placements, we agreed to register the resale of the Common Stock underlying the warrants issued in such private placements.

The following table sets forth certain information regarding the Selling Stockholders and the shares of Common Stock beneficially owned by them, which information is available to us as of January 18, 2013. Selling Stockholders may offer Shares under this prospectus from time to time and may elect to sell none, some or all of the Shares set forth next to their name. As a result, we cannot estimate the number of shares of Common Stock that a Selling Stockholder will beneficially own after termination of sales under this prospectus. However, for the purposes of the table below, we have assumed that, after completion of the offering, none of the Shares covered by this prospectus will be held by the Selling Stockholders. In addition, a Selling Stockholder may have sold, transferred or otherwise disposed of all or a portion of that holder’s shares of Common Stock since the date on which they provided information for this table. We have not made independent inquiries about this. We are relying on written commitments from the Selling Stockholders to notify us of any changes in their beneficial ownership after the date they originally provided this information. See “Plan of Distribution” beginning on page 29.

Selling Stockholder (1)	# of Shares held before Offering	Total # of Shares covered by this Prospectus	# of Shares Offered	# of Shares Underlying Warrants	# of Shares beneficially owned after Offering	% of Shares beneficially owned after Offering(2)
Private Placement Selling Stockholders						
Adam Linn	40,000	20,000	—	20,000	20,000	*
Alan David Cohen	40,000	20,000	—	20,000	20,000	*
Albert Poliak	110,000	110,000	—	110,000	—	*
Allison M. Dwan, IRA	40,000	20,000	—	20,000	20,000	*
Ann M. Angle	120,000	60,000	—	60,000	60,000	*
Ashley W. Weatherford, IRA	40,000	20,000	—	20,000	20,000	*
Bengt Ling	40,000	20,000	—	20,000	20,000	*
Brenda Forwood	20,000	10,000	—	10,000	10,000	*
Bret Shapiro	116,796	116,796	—	116,796	—	*
Bruce Robinson	40,000	20,000	—	20,000	20,000	*

Selling Stockholder (1)	# of Shares held before Offering	Total # of Shares covered by this Prospectus	# of Shares Offered	# of Shares Underlying Warrants	# of Shares beneficially owned after Offering(2)	% of Shares beneficially owned after Offering (2)
Bruce Robinson, IRA	120,000	60,000	—	60,000	60,000	*
Bunkap Industries, Inc.	80,000	40,000	—	40,000	40,000	*
C.B. Brechin, IRA	40,000	20,000	—	20,000	20,000	*
Cadence Investments, II	320,000	160,000	—	160,000	160,000	1.2 %
Carolyn Amanda Clark-Sobrien	20,000	10,000	—	10,000	10,000	*
Charles and Sandra Curtis, JTWROS	80,000	40,000	—	40,000	40,000	*
Chris Sidhilail	64,000	32,000	—	32,000	32,000	*
Christina and Joseph Landsman	20,000	10,000	—	10,000	10,000	*
Christina and Joseph Landsman, JTWROS	20,000	10,000	—	10,000	10,000	*
Christopher P. Gutek	20,000	10,000	—	10,000	10,000	*
Connie Walker McComb	22,400	11,200	—	11,200	11,200	*
Connie Walker McComb, IRA	40,000	20,000	—	20,000	20,000	*
Constantine Hagepanos, IRA	40,000	20,000	—	20,000	20,000	*
Craig Lindberg	40,000	20,000	—	20,000	20,000	*
Daniel A. Hudson, IRA	40,000	20,000	—	20,000	20,000	*
Dave Bandell IRA	39,200	19,600	—	19,600	19,600	*
David and Lisa Mangold, JTWROS	80,000	40,000	—	40,000	40,000	*
David Hansen	80,000	40,000	—	40,000	40,000	*
Dawson James Securities, Inc.	533,006	533,006	—	533,006	—	*
Delta Securities, Ltd.	160,000	80,000	—	80,000	80,000	*
Denton Business, Inc.	160,000	80,000	—	80,000	80,000	*
Derek Mason, IRA	80,000	40,000	—	40,000	40,000	*
Dillon Finch	20,000	10,000	—	10,000	10,000	*
Donald R. Myrtue	40,000	20,000	—	20,000	20,000	*
Donald S. Darendinger Revoc Trust	40,000	20,000	—	20,000	20,000	*
Dr. Carl Eric Mayer Rev. Trust	60,000	30,000	—	30,000	30,000	*
Dram Investments LLP	200,000	100,000	—	100,000	100,000	*
Earl M. Harper	40,000	20,000	—	20,000	20,000	*

Selling Stockholder (1)	# of Shares held before Offering	Total # of Shares covered by this Prospectus	# of Shares Offered	# of Shares Underlying Warrants	# of Shares beneficially owned after Offering	% of Shares beneficially owned after Offering (2)
Eduardo and Maria C. Soto	160,000	80,000	—	80,000	80,000	*
Elmer Salovich Revocable Living Trust U/A 12/16/96	120,000	60,000	—	60,000	60,000	*
Estate of Nizar Noorali Lokhandwala	40,000	20,000		20,000	20,000	*
F. Larry Holcomb	40,000	20,000	—	20,000	20,000	*
F. Richard Stark	40,000	20,000	—	20,000	20,000	*
Flavia Milano	40,000	20,000	—	20,000	20,000	*
Francis and Jeffrey Chan, JTWROS	40,000	20,000	—	20,000	20,000	*
Francis Howard	40,000	20,000	—	20,000	20,000	*
Frank and Hope Patton	40,000	20,000	—	20,000	20,000	*
Frank Guy, IRA	40,000	20,000	—	20,000	20,000	*
Fred Militello, IRA	20,000	10,000	—	10,000	10,000	*
Frederick Reese Freyer	64,000	32,000	—	32,000	32,000	*
Gary W. and Sherry L. Rosenberry	40,000	20,000	—	20,000	20,000	*
George A. Long, III	80,000	40,000	—	40,000	40,000	*
George W. Duncan	80,000	40,000	—	40,000	40,000	*
Gerald and Seena Sperling	160,000	80,000	—	80,000	80,000	*
Gerald L. Woolam	80,000	40,000	—	40,000	40,000	*
Gilya Alchits	96,000	48,000	—	48,000	48,000	*
Gregory Harrison	80,000	40,000	—	40,000	40,000	*
Gurprett Ahluwalia, M.D.	80,000	40,000	—	40,000	40,000	*
Hopfenspirger 2011 Grat A	80,000	40,000	—	40,000	40,000	*
Howard and Arlene Berger	40,000	20,000	—	20,000	20,000	*
Howard Roth, IRA	40,000	20,000	—	20,000	20,000	*
Ines Bahl & Burkhard Koeder, JTWROS	60,000	30,000	—	30,000	30,000	*
Jack and Marcy Garson, JTWROS	320,000	160,000	—	160,000	160,000	1.2 %
James E. Anderson	80,000	40,000	—	40,000	40,000	*
James Harvey Walker	40,000	20,000	—	20,000	20,000	*
James Krag	40,000	20,000	—	20,000	20,000	*
James Narutowicz and Michael Narutowicz	40,000	20,000	—	20,000	20,000	*
James Street	24,000	12,000	—	12,000	12,000	*

Selling Stockholder (1)	# of Shares held before Offering	Total # of Shares covered by this Prospectus	# of Shares Offered	# of Shares Underlying Warrants	# of Shares beneficially owned after Offering	% of Shares beneficially owned after Offering (2)
James Street, IRA	46,000	28,000	—	28,000	28,000	*
James Williams, IRA	20,000	10,000	—	10,000	10,000	*
Jason Curtis	40,000	20,000	—	20,000	20,000	*
Jay R. Angle	200,000	100,000	—	100,000	100,000	*
Jay Scott Angle	40,000	20,000	—	20,000	20,000	*
JJB GA SF LLC	120,000	60,000	—	60,000	60,000	*
Joan Hopfenspirger	32,000	16,000	—	16,000	16,000	*
John Alessandro, IRA	40,000	20,000	—	20,000	20,000	*
John and Monic Suryan JTTEN	32,000	16,000	—	16,000	16,000	*
John Black	80,000	40,000	—	40,000	40,000	*
John Blum, Jr.	80,000	40,000	—	40,000	40,000	*
John D. Marks	40,000	20,000	—	20,000	20,000	*
John Majowsky	20,000	10,000	—	10,000	10,000	*
John Nash	20,000	10,000	—	10,000	10,000	*
John R. Rogers	40,000	20,000	—	20,000	20,000	*
John R. Rogers, IRA	40,000	20,000	—	20,000	20,000	*
John Sloan, IRA	40,000	20,000	—	20,000	20,000	*
John Weatherford, IRA	24,000	12,000	—	12,000	12,000	*
Jordan Family, LLC	88,000	44,000	—	44,000	44,000	*
Joseph E. Balagot	689,166	609,166	—	609,166	80,000	*
Joseph Thomas Watters III	80,000	40,000	—	40,000	40,000	*
Karen Cake, IRA	36,800	18,400	—	18,400	18,400	*
Kerston Coombs	20,000	10,000	—	10,000	10,000	*
Kevin Lydon, IRA	40,000	20,000	—	20,000	20,000	*
Lamar F. Callaway, IRA	40,000	20,000	—	20,000	20,000	*
Larry Hopfenspirger	280,000	140,000	—	140,000	140,000	1.1 %
Lawrence W. Lappin Jr.	40,000	20,000	—	20,000	20,000	*
Lilia Berezkina	20,000	10,000	—	10,000	10,000	*
Lynn R. Gordon	40,000	20,000	—	20,000	20,000	*
Margaret E. Crumbley	40,000	20,000	—	20,000	20,000	*
Mark Butt	120,000	60,000	—	60,000	60,000	*

Selling Stockholder (1)	# of Shares held before Offering	Total # of Shares covered by this Prospectus	# of Shares Offered	# of Shares Underlying Warrants	# of Shares beneficially owned after Offering	% of Shares beneficially owned after Offering (2)
Mark Ravich	60,000	30,000	—	30,000	30,000	*
Martin C. Yerg Jr., IRA	80,000	40,000	—	40,000	40,000	*
Mary Jo Brocato	20,000	10,000	—	10,000	10,000	*
Mary Majowsky	20,000	10,000	—	10,000	10,000	*
Melvyn Gober	60,000	30,000	—	30,000	30,000	*
Michael Brodherson	40,000	20,000	—	20,000	20,000	*
Michael Earl Greene, IRA	20,000	10,000	—	10,000	10,000	*
Michael McManus	40,000	20,000	—	20,000	20,000	*
Michael Pantelis	40,000	20,000	—	20,000	20,000	*
Monica Suryan, ROTH I.R.A.	32,000	16,000	—	16,000	16,000	*
Murray F. Brown	80,000	40,000	—	40,000	40,000	*
Nathan W. Levin	64,000	32,000	—	32,000	32,000	*
Nazim Lokhandwala	60,000	30,000	—	30,000	30,000	*
Nimah O'Reilly	160,000	80,000	—	80,000	80,000	*
Norman and Ona Lou McClain	40,000	20,000	—	20,000	20,000	*
Palmer, Arnold, IRA	80,000	40,000	—	40,000	40,000	*
Pamela J. Corson, IRA	20,000	10,000	—	10,000	10,000	*
Paul Bigler	20,000	10,000	—	10,000	10,000	*
Peter Kaplan	40,000	20,000	—	20,000	20,000	*
Peter Kaplan, IRA	80,000	40,000	—	40,000	40,000	*
Philip H. Stark	40,000	20,000	—	20,000	20,000	*
Polly Ristaino	20,000	10,000	—	10,000	10,000	*
Raffaele Santini, IRA	20,000	10,000	—	10,000	10,000	*
Randy Meeks	40,000	20,000	—	20,000	20,000	*
Raymond G. Tinney 1995 Inter Vivos Trust U/A 6/21/95	80,000	40,000	—	40,000	40,000	*
Raymond McGill	51,200	25,600	—	25,600	25,600	*
Reginald Davenport	20,000	10,000	—	10,000	10,000	*
Reuben Graber	400,000	200,000	—	200,000	200,000	1.5 %
Richard B. Curtis	40,000	20,000	—	20,000	20,000	*

Selling Stockholder (1)	# of Shares held before Offering	Total # of Shares covered by this Prospectus	# of Shares Offered	# of Shares Underlying Warrants	# of Shares beneficially owned after Offering	% of Shares beneficially owned after Offering (2)
Robert C. Brumder 1950 Trust dated 12/85/50	20,000	10,000	—	10,000	10,000	*
Robert D. Mathews and Elsie D. Mathews	20,000	10,000	—	10,000	10,000	*
Robert D. Young	40,000	20,000	—	20,000	20,000	*
Robert Stanger	20,000	10,000	—	10,000	10,000	*
Robert Webber	40,000	20,000	—	20,000	20,000	*
Robert Zelin	20,000	10,000	—	10,000	10,000	*
Robert Zens	100,000	50,000	—	50,000	50,000	*
Ronald Sauter, IRA	40,000	20,000	—	20,000	20,000	*
Serz and Sabuhi Khan, JTWROS	160,000	80,000	—	80,000	80,000	*
Sharon Eshel Gloster	40,000	20,000	—	20,000	20,000	*
Sheldon T. Fleck	120,000	60,000	—	60,000	60,000	*
Shipman & Goodwin LLP Profit Sharing Retirement Plan & Trust fboJames T. Betts	40,000	20,000	—	20,000	20,000	*
Smith Revocable Trust	40,000	20,000	—	20,000	20,000	*
Stephen Troutman	20,000	10,000	—	10,000	10,000	*
Stephenson Pension Trust	120,000	60,000	—	60,000	60,000	*
Steve Gersten	48,000	24,000	—	24,000	24,000	*
Steve Wilson	20,000	10,000	—	10,000	10,000	*
Steven Etra	480,000	240,000	—	240,000	240,000	1.9 %
Super Angel Capital LLC	80,000	40,000	—	40,000	40,000	*
Tammy Sue McClain, IRA	40,000	20,000	—	20,000	20,000	*
Terrence E. Troy	40,000	20,000	—	20,000	20,000	*
The Nigel F. Burrow Living Trust, Nigel Burrow Trustee	40,000	20,000	—	20,000	20,000	*
The Walter W. and Karin H. Gloyer Trust Dated 9/20/07	40,000	20,000	—	20,000	20,000	*
Thom Hands	110,000	110,000	—	110,000	—	*
Todd Loudin	40,000	20,000	—	20,000	20,000	*
Tom Curtis	178,072	178,072	—	178,072	—	*
Vibha Nayar and Arwan Kumar Nayar, JTWROS	40,000	20,000	—	20,000	20,000	*
Vincent P. Rose, Jr.	120,000	60,000	—	60,000	60,000	*
W.P. O'Reilly & Associates Ltd.	160,000	80,000	—	80,000	80,000	*
Wall J. Kent and Karol Kent	40,000	20,000	—	20,000	20,000	*
William Harold Earls	200,000	100,000	—	100,000	100,000	*

Selling Stockholder (1)	# of Shares held before Offering	Total # of Shares covered by this Prospectus	# of Shares Offered	# of Shares Underlying Warrants	# of Shares beneficially owned after Offering	% of Shares beneficially owned after Offering (2)
William S. Atkins and Sally S. Atkins as Trustees for the William S.Atkins Living Trust	20,000	10,000	—	10,000	10,000	*
Wrayswood, LLLP	40,000	20,000	—	20,000	20,000	*
Acueity Selling Stockholders						
Asset Management Partners, L.P.	16,117	16,117	16,117	—	—	—
James V. Babcock	149,938	149,938	99,216	50,722	—	—
Niyazi Beyhan	15,643	15,643	11,971	3,672	—	—
Bruce J. Carusi	10,567	10,567	8,150	2,417	—	—
Mallory Factor	122,160	122,160	94,214	27,946	—	—
James Fantaci	57,911	57,911	44,663	13,248	—	—
Dominick L. Gatto	9,026	9,026	9,026	—	—	—
Huddee Jacob Ho	21,482	21,482	16,436	5,046	—	—
Roberta Lee	236,684	236,684	181,648	55,036	—	—
Teresa Louie	1,415	1,415	1,090	325	—	—
Joyce Reitman	231	231	231	—	—	—
TCDT LLC	323,618	323,618	208,314	115,304	—	—
The Johnson Revocable Trust dated 6-23-2003	199,891	199,891	151,542	48,349	—	—
Thomas M. Tuggle	3,064	3,064	2,363	701	—	—
Lynda Won-Chung	9,114	9,114	6,880	2,234	—	—
Ron Yamamoto	10,000	10,000	10,000	—	—	—
Samuel Zuckswert	639	639	639	—	—	—

* Less than 1%.

(1) If required, information about other selling security holders, except for any future transferees, pledgees, donees or successors of Selling Stockholders named in the table above, will be set forth in a prospectus supplement or amendment to the registration statement of which this prospectus is a part. Additionally, post-effective amendments to the registration statement will be filed to disclose any material changes to the plan of distribution from the description contained in the final prospectus.

(2) This number is based on 12,919,367 shares of Common Stock outstanding as of January 18, 2013 and assumes the sale of all Shares being offered by this prospectus.

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PLAN OF DISTRIBUTION

The Shares offered by this prospectus may be sold by the Selling Stockholders. Such sales may be made at fixed prices that may be changed, at market prices prevailing at the time of sale, at prices related to such prevailing market prices, or at negotiated prices, and may be made in the over-the-counter market or any exchange on which our Common Stock may then be listed, or otherwise. In addition, the Selling Stockholders may sell some or all of their Shares through:

- a block trade in which a broker-dealer may resell a portion of the block, as principal, in order to facilitate the transaction;
- purchases by a broker-dealer, as principal, and resale by the broker-dealer for its account;
- ordinary brokerage transactions and transactions in which a broker solicits purchasers;
- in negotiated transactions;
- in a combination of any of the above methods of sale; or
- any other method permitted under applicable law.

The Selling Stockholders may also engage in short sales against the box, puts and calls and other hedging transactions in the Shares or derivatives of the Shares and may sell or deliver the Shares in connection with these trades. For example, the Selling Stockholders may:

- enter into transactions involving short sales of our Common Stock by broker-dealers;
- sell our Common Stock short themselves and redeliver such Shares to close out their short positions;
- enter into option or other types of transactions that require the Selling Stockholder to deliver shares of Common Stock to a broker-dealer, who will then resell or transfer the Common Stock under this prospectus; or
-

loan or pledge shares of Common Stock to a broker-dealer, who may sell the loaned shares or, in the event of default, sell the pledged shares.

There is no assurance that any of the Selling Stockholders will sell any or all of the Shares offered by them.

The Selling Stockholders may negotiate and pay broker-dealers commissions, discounts or concessions for their services. Broker-dealers engaged by the Selling Stockholders may allow other broker-dealers to participate in resales. However, the Selling Stockholders and any broker-dealers involved in the sale or resale of our common stock may qualify as "underwriters" within the meaning of the Section 2(a)(11) of the Securities Act. In addition, the broker-dealers' commissions, discounts or concessions may qualify as underwriters' compensation under the Securities Act. If the Selling Stockholders qualify as "underwriters," they will be subject to the prospectus delivery requirements of the Securities Act.

In addition to selling their shares of Common Stock under this prospectus, the Selling Stockholders may:

- transfer their Common Stock in other ways not involving market makers or established trading markets, including, but not limited to, directly by gift, distribution, privately negotiated transactions in compliance with applicable law or other transfer; or

- sell their Common Stock under Rule 144 of the Securities Act rather than under this prospectus, if the transaction meets the requirements of Rule 144. Each Selling Stockholder will bear all expenses with respect to the offering of Common Stock by such Selling Stockholder.

Each Selling Stockholder will be subject to the applicable provisions of the Exchange Act and the associated rules and regulations under the Exchange Act, including Regulation M, which provisions may limit the timing of purchases and sales of shares of our Common Stock by the Selling Stockholders.

The Selling Stockholders may from time to time pledge or grant a security interest in some or all of the Shares owned by them and, if they default in the performance of their secured obligations, the pledges or secured parties may offer and sell the Shares from time to time under this prospectus after an amendment has been filed under Rule 424(b)(3) or other applicable provision of the Securities Act amending the list of Selling Stockholders to include the pledge, transferee or other successors in interest as "Selling Stockholders" under this prospectus.

The Selling Stockholders also may transfer the Shares in other circumstances, in which case the respective pledgees, donees, transferees or other successors in interest will be the selling beneficial owners for purposes of this prospectus and may sell the Shares from time to time under this prospectus after an amendment has been filed under Rule 424(b)(3) or other applicable provision of the Securities Act amending the list of Selling Stockholders to include the pledge, transferee or other successors in interest as "Selling Stockholders" under this prospectus.

We will make copies of this prospectus available to the Selling Stockholders and have informed them of the need to deliver copies of this prospectus to purchasers at or prior to the time of any sale of the Shares.

We will bear all costs, expenses and fees in connection with the registration of the Shares. The Selling Stockholders will bear all commissions and discounts, if any, attributable to the resale of the Shares. The Selling Stockholders may agree to indemnify any broker-dealer or agent that participates in transactions involving sales of the Shares against certain liabilities, including liabilities arising under the Securities Act.

We have agreed to indemnify the Selling Stockholders against liabilities, including liabilities under the Securities Act, the Exchange Act and state securities laws, relating to the registration of the Shares offered by this prospectus.

Certain of the Selling Stockholders entered into lock-up agreements in connection with our initial public offering. Those agreements generally prohibit exercise of the warrants held by the Selling Stockholders and sale of the shares underlying the warrants for a period of six months following November 7, 2012.

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 "Summary Financial Data" and the financial statements and the related notes included elsewhere in this prospectus. 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 prospectus for additional information regarding forward-looking statements used in this prospectus.

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 FDA-cleared and 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 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.

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.

Current Operations

We launched our commercial operations in late 2011 and, as of September 30, 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 638 ForeCYTE samples and 41 ArgusCYTE samples. From inception (April 30, 2009) through September 30, 2012, we have generated $384,886 in revenue from the sale of our MASCT System and providing laboratory services. We incurred net operating losses of $3,374,249 and $2,236,866 for the nine months ended September 30, 2012 and 2011, respectively. As of September 30, 2012, we had an accumulated deficit of approximately $8.0 million. We have not yet established an ongoing source of revenue sufficient to cover our operating costs and allow us to continue as a going concern. Our ability to continue as a going concern is dependent on obtaining adequate capital to fund operating losses until we become profitable. We plan to obtain additional capital resources by selling our equity securities, selling the MASCT System and generating laboratory service revenue from our tests, and making short-term borrowings from stockholders or other parties when needed. However, we cannot assure you that we will be successful in accomplishing any of these plans and, if we are unable to obtain adequate capital, we could be forced to cease operations.

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 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 September 30, 2012, we have entered an agreement with 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 nine months ended September 30, 2012, the Company incurred $38,403 of rent expense for the lease.

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 nine months ended September 30, 2012, the Company incurred $9,900 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 nine months ended September 30, 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 nine months ended September 30, 2012, the Company incurred $161,424 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.

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 included at the end of this prospectus, 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) the Company's 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 the occurrence of all of the following: (i) receipt of cash, (ii) confirmation of product delivery (shipping documents and the completion of any customer acceptance requirements, when applicable, will be used to verify product delivery), and (iii) assessment of 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 expect to recognize revenue upon delivery of goods from the supplier's or our warehouse or upon arrival of goods at the customer's designated location, depending on the shipping terms, with an offsetting reserve for doubtful accounts estimated based on the relevant collections history.

Service Revenue

We recognize revenue for our diagnostic testing on an accrual basis at the Medicare allowed and invoiced amount and upon satisfaction of the above four fundamental criteria. Amounts invoiced above the Medicare allowed reimbursement amount are recognized upon receipt of cash during the initial three- to six-month period as we have insufficient individual customer history on which to determine the collectability of amounts that are invoiced above the Medicare amount. 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 whether persuasive evidence of an arrangement exists. Once the Company has an appropriate history of sales and can determine the proper amount to recognize as uncollectible, it will then begin to recognize the entire amount, both Medicare allowed and non-Medicare billing, when all criteria of revenue recognition are met, with an offsetting allowance for doubtful accounts estimated based on collections history. We estimate it will take between three to six months of sales and collection history to establish reasonable assurance of collection and estimate of doubtful accounts, which is subject to change based on the sufficiency of the actual number of sales transactions for the period.

Cash and Cash Equivalents

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

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 nine months ended September 30, 2012 and for the year ended December 31, 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 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 valuation allowance is required. As of September 30, 2012 and December 31, 2011, management had identified no slow moving or obsolete inventory.

The Company provides 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 nine months ended September 30, 2012 and for the year ended December 31, 2011, selling expense of $36,741 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.

Research and Development Expenses

Research and development costs are generally expensed as incurred. Our 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.

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 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 CTO, 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 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 Stock Option and Incentive 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 Stock Option and Incentive 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 Stock Option and Incentive 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.

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 $96,251 for the nine months ended September 30, 2012.

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	
Date of grant	22-Jul-10		4-Apr-11		1-Sep-11		1-Sep-11		30-Apr-12	
Fair value of common stock on date of grant	$ 2.756	(B)	$ 0.906	(C)	$ 0.906	(C)	$ 0.906	(C)	$ 6.00	(D)
Exercise price of the options	$ 5.00		$ 1.25		$ 1.25		$ 1.25		$ 6.00	
Expected life of the options (years)	3.33		5.31		5.65		5.65		5.00	
Dividend yield	0.00	%	0.00	%	0.00	%	0.00	%	0.00	%
Expected volatility	58.59	%	54.12	%	53.90	%	53.90	%	62.46	%
Risk-free interest rate	1.03	%	2.26	%	1.08	%	1.08	%	0.89	%
Expected forfeiture per year (%)	0.00	%	0.00	%(A)			0.00	%	0.00	%
Weighted-average fair value of the options (per unit)	$ 0.6744		$ 0.3729		$ 0.3579		$ 0.3579		$ 3.0367	

(A) 0.00% for the first year after the grant date, and 2.50% 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 in the initial public 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.

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 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, the end results of which are described elsewhere in this prospectus in the summary of the Company's business and operations. However, the specific actions that took place between September 2011 and February 2012 that supported this increase in value were as follows. 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 (which is the technology that the Company is currently using 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 acquired the FullCYTE Microcatheter System from Hologics, reestablished the supply chain and began preparing for a commercial launch later in 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 intractuctal 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 studied the use of the FullCYTE microcatheter in six patients (which study is described in more detail on page 56) to establish the feasibility of performing next-generation tests on samples taken with the microcatheters. Additionally, the Company’s scientists invented and filed a patent application to the NextCYTE technology and the Company has negotiated a one-year option to acquire commercial rights to additional NextCYTE-related technology to augment its existing position and has started researching 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 five state licenses and has a pending application in New York State, the only remaining state 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 supported a valuation of $5.00 to $7.00 per share of the Company's common stock when the Company filed its initial Registration Statement on Form S-1 in February 2012.

Options issued and outstanding as of September 30, 2012 and their activities during the nine 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, 2011	608,000	$ 3.41	
Granted	19,757	6.00	
Expired	—	—	
Forfeited	—	—	
Outstanding as of September 30, 2012	627,757	3.49	5.51
Exercisable as of September 30, 2012	508,632	3.21	6.02
Vested and expected to vest[(1)]	624,049	3.50	5.49

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

As of September 30, 2012 and December 31, 2011, the aggregate intrinsic value of options outstanding, exercisable, and vested and expected to vest was $389,053 and $329,053, respectively.

A summary of the status of the Company's unvested shares as of September 30, 2012 and changes during the 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	19,757	60,000
Vested	(189,882)	(141,761)
Forfeited	—	—
Unvested as of September 30, 2012	119,125	$ 77,252

Results of Operations

Discussion of Three Months Ended September 30, 2012

For the three months ended September 30, 2012, we had total revenue of $105,576, consisting of $1,565 product revenue from sales of MASCT Systems and $104,011 diagnostic testing service revenue from our ForeCYTE and ArgusCYTE testing services performed. Total cost of revenue was $9,000, primarily attributable to cost of diagnostic testing services performed, which consisted of $9,000 in payments to doctors for their time administering the ForeCYTE testing service and $0 in shipping and packaging costs related to the delivery of test specimens from doctors to the Company. 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 three months ended September 30, 2012. Gross profit was $95,011 for the diagnostic testing service and $1,565 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 $6,077 for the three months ended September 30, 2012, primarily due to write-off of parts purchased during the three months 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, 2011 and September 30, 2012. Our MASCT System is currently sold at a price substantially lower than its cost because the MASCT System is currently manufactured by our suppliers only in sufficient quantities to be utilized in our field experience trial. Because the MASCT System is being manufactured in small quantities, the manufacturing cost allocated to each inventory unit is high. Total operating expenses were $1,226,171, consisting of G&A expenses of $1,138,467 and selling expenses of $87,704, which included $19,863 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 $67,493 in salaries and $0 in advertising.

The G&A expenses consisted primarily of $23,358 in salaries and bonus expense, $310,302 in legal expense, $49,579 in consulting expense, $34,475 in accounting expense, $5,133 in travel expense, $16,091 in professional fees, $26,774 in health insurance expense and $19,494 in business insurance. Also included in G&A expense is $548,108 in research and development expense, consisting primarily of $170,083 in salaries and bonus expense, $97,643 in rent expense, $1,684 in laboratory supplies, $20,882 in MASCT System development, $32,268 in MASCT Service development, $183,351 in ductal lavage product development, and $7,024 in circulating tumor cells service development.

Comparison of the Three Months Ended September 30, 2012 and 2011

Revenue and Cost of Goods Sold

For the three months ended September 30, 2012, we had total revenue of $105,576, consisting of $1,565 product revenue from sales of MASCT Systems and $104,011 diagnostic testing service revenue from our ForeCYTE and ArgusCYTE testing services performed. This compares to total revenue of $0 for the three months ended September 30, 2011. Total cost of revenue for the three months ended September 30, 2012 was $9,000 primarily attributable to cost of diagnostic testing services performed, which consisted of $9,000 in payments to doctors for their time administering the ForeCYTE testing service and $0 in shipping and packaging costs related to the delivery of test specimens from doctors to the Company. 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 three months ended September 30, 2012. For the three months ended September 30, 2011, total cost of revenue was $0. Gross profit for the three months ended September 30, 2012 was $95,011 for the diagnostic testing service and $1,565 for the product sales of MASCT System with no corresponding cost of goods sold. This compares to gross profit of $0 for the three months ended September 30, 2011. Loss on reduction of inventory to lower of cost or market was $6,077 for the three months ended September 30, 2012, primarily due to write-off of parts purchased during the quarter 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 September 30, 2012. Our MASCT System is currently sold at a price substantially lower than its cost because the MASCT System is currently manufactured by our suppliers only in sufficient quantities to be utilized in our field experience trial. Because the MASCT System is being manufactured in small quantities, the manufacturing cost allocated to each inventory unit is high. No loss on reduction of inventory to lower of cost or market was recorded for the three months ended September 30, 2011 due to no primary operating activities.

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 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 $1,226,171 for the three months ended September 30, 2012, consisting of G&A expenses of $1,138,467 and selling expenses of $87,704, which included $19,863 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 $70,361 in salaries and $0 in advertising. This compares to total operating expenses of $1,274,189 for the three months ended September 30, 2011, consisting of G&A expenses of $1,274,189 and selling expenses of $0. Total operating expenses decreased by $48,018 or 4% from $1,274,189 for the three months ended September 30, 2011 to $1,226,171 for the three months ended September 30, 2012 as the Company focused its efforts on our initial public offering and delayed any growth plans until post funding.

General and Administrative Expenses. G&A expenses for the three months ended September 30, 2012 were $1,138,467, a decrease of $135,722 or 11% from $1,274,189 for the three months ended September 30, 2011. G&A expenses for the three months ended September 30, 2012 primarily consisted of $23,358 in salaries and bonus expense, $310,302 in legal expense, $49,579 in consulting expense, $34,475 in accounting expense, $5,133 in travel expense, $16,091 in professional fees, $26,774 in health insurance expense and $19,494 in business insurance. Also included in G&A expense is $548,108 in research and development expense, consisting primarily of $170,083 in salaries and bonus expense, $97,643 in rent expense, $1,684 in laboratory supplies, $20,882 in MASCT System development, $32,268 in MASCT Service development, $183,351 in ductal lavage product development, and $7,024 in circulating tumor cells service development.

G&A expenses for the three months ended September 30, 2011 were $1,274,189, and mainly consisted of $334,451 in legal, $193,807 in compensation expenses, $31,112 in consulting expenses, $24,110 in travel expense, $20,934 accounting expense, and $9,724 in other professional fees. Also included in G&A expense is $575,446 of R&D expense, consisting primarily of $149,708 in salaries and bonus expense, $11,392 in rent expense, $78,480 in MASCT System development, $0 in Ductal Lavage service development, $102,338 in Ductal Lavage product development, $101,735 in circulating tumor cells service development, and $50,237 in Laboratory supplies.

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. We expect that our G&A expenses will continue to increase as we add additional full time 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.

Discussion of Nine Months Ended September 30, 2012

For the nine months ended September 30, 2012, we had total revenue of $383,386, consisting of $6,690 product revenue from sales of MASCT Systems and $376,696 diagnostic testing service revenue from our ForeCYTE and ArgusCYTE testing services performed. Total cost of revenue was $29,985, primarily attributable to cost of diagnostic testing services performed, which consisted of $27,470 in payments to doctors for their time administering the ForeCYTE testing service and $2,515 in shipping and packaging costs related to the delivery of test specimens from doctors to the Company. 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 nine months ended September 30, 2012. Gross profit was $346,711 for the diagnostic testing service and $6,690 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 nine months ended September 30, 2012, primarily due to write-off of parts purchased during the nine months 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, 2011 and September 30, 2012. Our MASCT System is currently sold at a price substantially lower than its cost because the MASCT System is currently manufactured by our suppliers only in sufficient quantities to be utilized in our field experience trial. Because the MASCT System is being manufactured in small quantities, the manufacturing cost allocated to each inventory unit is high. Total operating expenses were $3,687,169, consisting of G&A expenses of $3,405,198 and selling expenses of $281,971, which included $36,741 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 $196,326 in salaries and $48,557 in advertising.

The G&A expenses consisted primarily of $225,055 in salaries and bonus expense, $883,400 in legal expense, $151,245 in consulting expense, $102,640 in accounting expense, $25,541 in travel expense, $57,775 in payroll taxes, $64,118 in professional fees, $56,987 in health insurance expense and $53,584 in business insurance. Also included in G&A expense is $1,509,643 in research and development expense, consisting primarily of $488,536 in salaries and bonus expense, $198,058 in rent expense, $25,971 in laboratory supplies, $120,106 in MASCT System development, $489,778 in ductal lavage product development, $39,789 in ductal lavage service development and $30,797 in circulating tumor cells service development.

Comparison of the Nine Months Ended September 30, 2012 and 2011

Revenue and Cost of Goods Sold. For the nine months ended September 30, 2012, we had total revenue of $383,386, consisting of $6,690 product revenue from sales of MASCT Systems and $376,696 diagnostic testing service revenue from our ForeCYTE and ArgusCYTE testing services performed. This compares to total revenue of $0 for the nine months ended September 30, 2011. Total cost of revenue for the nine months ended September 30, 2012 was $29,985 primarily attributable to cost of diagnostic testing services performed, which consisted of $27,470 in payments to doctors for their time administering the ForeCYTE testing service and $2,515 in shipping and packaging costs related

to the delivery of test specimens from doctors to the Company. 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 nine months ended September 30, 2012. For the nine months ended September 30, 2011, total cost of revenue was $0. Gross profit for the nine months ended September 30, 2012 was $346,711 for the diagnostic testing service and $6,690 for the product sales of MASCT System with no corresponding cost of goods sold. This compares to gross profit of $0 for the nine months ended September 30, 2011. Loss on reduction of inventory to lower of cost or market was $29,884 for the nine months ended September 30, 2012, primarily due to write-off of parts purchased during the quarter 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 September 30, 2012. Our MASCT System is currently sold at a price substantially lower than its cost because the MASCT System is currently manufactured by our suppliers only in sufficient quantities to be utilized in our field experience trial. Because the MASCT System is being manufactured in small quantities, the manufacturing cost allocated to each inventory unit is high. No loss on reduction of inventory to lower of cost or market was recorded for the nine months ended September 30, 2011 due to no primary operating activities.

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 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 $3,687,169 for the nine months ended September 30, 2012, consisting of G&A expenses of $3,405,198 and selling expenses of $281,971, which included $36,741 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 $196,326 in salaries and $48,557 in advertising. This compares to total operating expenses of $2,231,906 for the nine months ended September 30, 2011, consisting of G&A expenses of $2,231,906 and selling expenses of $0. Total operating expenses increased by $1,455,263 or 65% from $2,231,906 for the nine months ended September 30, 2011 to $3,687,169 for the nine months ended September 30, 2012.

General and Administrative Expenses. G&A expenses for the nine months ended September 30, 2012 were $3,405,198, an increase of $1,173,292 or 53% from $2,231,906 for the nine months ended September 30, 2011. G&A expenses for the nine months ended September 30, 2012 primarily consisted of $225,055 in salaries and bonus expense, $883,400 in legal expense, $151,245 in consulting expense, $102,640 in accounting expense, $25,541 in travel expense, $57,775 in payroll taxes, $64,118 in professional fees, $56,987 in health insurance expense and $53,584 in business insurance. Also included in G&A expense is $1,509,643 in research and development expense, consisting primarily of $488,536 in salaries and bonus expense, $198,058 in rent expense, $25,971 in laboratory supplies, $120,106 in MASCT System development, $489,778 in ductal lavage product development, $39,789 in ductal lavage service development and $30,797 in circulating tumor cells service development.

G&A expenses for the nine months ended September 30, 2011 were $2,231,906, and mainly consisted of $343,907 in legal expenses, $368,203 in compensation expenses, $79,232 in consulting expenses, $39,231 in travel expenses, $43,479 accounting expense, and $30,933 in other professional fees. Also included in G&A expense is $1,065,133 of R&D expense, consisting primarily of $437,178 in salaries and bonus expense, $37,573 in rent expense, $136,562 in MASCT System development, $38,810 in Ductal Lavage service development, $102,338 in Ductal Lavage product development and $84,055 in patent license 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. We expect that our G&A expenses will continue to increase as we add additional full time 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 independent auditors issued on our financial statements as of and for the year ended December 31, 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 $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.

Cash Flows

For the nine months ended September 30, 2012, we incurred a net loss of $3,374,249. Net cash used in operating activities was $1,967,626 and net cash provided by financing activities was $475,375. During the nine months ended September 30, 2012 we repaid $750,000 that we previously drew on our bank line of credit. For the nine months ended September 30, 2011, we incurred a net loss of $2,236,866, net cash used in operating activities was $2,453,767, net cash used in investing activies was $85,276 and net cash provided by financing activities was $5,534,785.

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 planned 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 $6 million of additional capital. We expect that the proceeds we received from our initial public offering, together with our existing resources as of the date of this prospectus, to be sufficient to fund our planned operations for at least the next 6 months. 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 and ArgusCYTE Test; and
- the degree 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 September 30, 2012, we have generated $384,886 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 the proceeds of our initial public offering, together with our existing resources as of the date of this prospectus, to be sufficient to fund our planned operations for at least the next 6 months, 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.

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	IIncidence	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.

BUSINESS

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 FDA-cleared and 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 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.

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.

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

ArgusCYTE

The ArgusCYTE Breast Health Test, launched in December 2011, provides information to help inform breast cancer treatment options and to help monitor potential recurrence. It involves collecting a blood specimen from a patient using our patented, FDA 510(k)-Exempt blood collection tube and submitting it to our CLIA-certified laboratory (our ArgusCYTE Breast Health Test blood collection tube was registered with the FDA in 2011). It can monitor breast cancer distant recurrence by obtaining a "liquid biopsy" or blood sample, and analyzing it for the presence of circulating tumor cells, which can then be analyzed to determine the expression of 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 and FDA-cleared Mammary Ductal Microcatheter System (our Microcatheter System received 510(k) clearances from the FDA in 1999 and 2000) and analyzing the samples by the same molecular and cellular biomarkers used in the ForeCYTE test described above. From these tests, we are able to ascertain which individual duct contains pre-malignant or malignant

changes, which may allow the physician to better target treatment to the specific duct with the pre-malignant changes or malignant changes and therefore avoid side effects associated with systemic treatment. Traditional biopsies, involving invasive procedures in which tissue is removed surgically, typically cut across the natural anatomy of the breast ductal system, making subsequent intraductal treatment difficult or, in certain cases, impossible. The present methods used by pathologists to analyze traditional biopsy specimens, i.e., microscopy and, when needed, immunohistochemistry, are the same methods used to analyze FullCYTE specimens and would be expected to achieve similar results for patients with similar medical conditions.

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. We are currently conducting non-clinical trial research to

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

Our Diagnostic Tools

In September 2012, we acquired the assets of Acueity Healthcare, Inc. The assets included six 510(k)-cleared medical devices, 35 issued patents (18 issued in the U.S. and 17 issued in foreign countries) and 41 patent applications (32 in the U.S. and 9 in foreign countries). The FDA-cleared, patented medical devices consist of microendoscopes, light sources, and biopsy tools. The microendoscopes are less than 0.9 mm outside diameter and can be inserted into a milk duct. This permits a physician to pass a microendoscope into the milk duct system of the breast and view the duct system via fiberoptic video images. Abnormalities that are visualized can then be biopsied from inside the duct with the biopsy tools that are inserted adjacent to the microendoscope. The patents relate to intraductal diagnostic and therapeutic devices and methods of use. We did not, however, acquire an inventory of these diagnostic tools, manufacturing capabilities or any personnel to market and sell the tools. Following the launch of our four diagnostic tests in the U.S., we will then begin to allocate human and financial resources to further develop and ultimately commercialize these medical devices. We intend to complete the steps necessary to begin marketing and selling these tools, such as re-establishment of the supply chain of component parts, securing manufacturers, performing test builds and commercial scale manufacturing, in late 2013. This asset purchase is not expected to have an impact on the development and commercialization timetables of our existing product lines. We cannot, however, provide any assurances that delays related to the launch of our four diagnostic tests, independent of the asset purchase, would not delay the expected development of these diagnostic tools or that we will ultimately be successful selling these tools.

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

Intraductal Treatment Research

Our Intraductal Treatment Research Program comprises our patented microcatheter-delivery technology and our patented pharmaceutical formulations for the intraductal treatment of breast pre-cancerous changes 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.

Intellectual Property and FDA Marketing Clearances

As of the date of this prospectus, 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 U.S. and 17 issued in foreign countries) and 41 of the patent applications (32 in the U.S. and 9 in foreign countries).

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 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 at approximately $35 per kit, however, our sale prices to our distributors are significantly below these prices. 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.

In September 2012, we entered into an agreement with MultiPlan, Inc. (“MultiPlan”), a leading provider of healthcare cost management solutions, for diagnostic laboratory testing involving our tests. Approximately 20% of Americans are covered by MultiPlan. Our agreement with MultiPlan will give MultiPlan’s participating providers and their patients access to our tests, including the ForeCYTE Breast Health 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 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.

In September 2012, we entered into an agreement with MultiPlan, a leading provider of healthcare cost management solutions, for diagnostic laboratory testing involving our tests. Approximately 20% of Americans are covered by MultiPlan. Our agreement with MultiPlan will give MultiPlan's participating providers and their patients access to our tests, including the ArgusCYTE Breast Health Test.

The FullCYTE Breast Health Test

The FullCYTE Breast Health Test uses our patented, FDA-cleared 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™ 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 uses surgical biopsy specimens that have been routinely processed into formalin-fixed, paraffin embedded tissue blocks to extract RNA and analyze the whole-genome mRNA expression profiles of the extracted RNA to predict breast cancer 10-year survival. The method combines eleven published gene signatures, including over 900 breast cancer-related genes. In a March 2011 publication of the technology, training (n=123) and test (n=81) cohorts of breast cancer patients were analyzed by the method and the resulting algorithm outperformed all individual gene signatures, including a 16-gene test and a 70-gene test, in predicting 10-year recurrence. Our scientists made inventions regarding this technology and have filed a PCT patent application related to the NextCYTE test to the use of full transcriptome analysis of 22,000 human genes in predicting breast cancer recurrence. We are conducting research to verify the superiority of the technology and have a one-year option to license additional technology (specifically certain algorithms involving over 900 of these genes) from the University of Oslo in Norway. In February 2012 we signed a term sheet with Inven2 AS for an option to acquire and commercialize intellectual property from the University of Oslo and a term sheet containing the principal terms of a definitive license agreement. The definitive agreement contains signing and milestone payments in an amount up to $50,000 in the aggregate (not including a potential milestone payment of $15,000 per country upon reaching a pre-determined performance milestone in each country in which the test is marketed), as well as royalties in the mid single digits on the service revenue from the NextCYTE test as a percent of net income and minimum annual royalties in the high tens of thousands for 2012 and between $100,000 and $200,000 for 2013 and after. If we exercise this option and license the technology, we would be required to pay the University of Oslo an up-front fee, milestone payments, and an annual royalty on the service revenue from the NextCYTE test as a percent of net income. We do not believe this additional technology is essential to the operation or future development of the NextCYTE test, should we decide not to exercise this option.

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, and preparing for the commercialization of our products.

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 represent 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 in 2010, there were more than 2.5 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, the 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 December 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 in 2010 there were more than 2.5 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, 210,000 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-gynocologists 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 MASCT System 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. The Company intends 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 be 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 do reimburse for the laboratory analysis of the NAF sample. We have received reimbursement from insurance carriers and Medicare for the ForeCYTE test and from insurance carriers for the ArgusCYTE test. Billing for diagnostic services is generally complex. As a result, the Company relies on a third-party billing company to perform all of its 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. The Company expects 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 the Company does 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, the Company performs the requested tests and reports test results even if the billing information is incorrect or missing. The Company 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 the Company for its 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, the Company’s 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 the Company provides, 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 the Company will provide, it 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 the Company's laboratory services will be reimbursed based on the physician fee schedule, changes to the physician fee schedule could result in a greater impact on the Company's revenue than changes to the Medicare laboratory fee schedule.

The Company expects to bill the Medicare program directly. Generally, it 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, the Company is required to rely on physicians to obtain an ABN from the patient. When the Company is not provided an ABN, it is generally unable to recover payment for a service for which Medicare has denied payment for lack of medical necessity.

In billing Medicare, the Company is required to accept the lowest of: its 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. The Company 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.

The Company's reimbursement rates also vary depending on whether it is considered an "in-network," or participating, provider. If it enters into a contract with an insurance company, the Company's reimbursement will be governed by its contractual relationship, and it will typically be reimbursed on a fee-for-service basis at a discount from the patient fee schedule. If the Company does not have a contract with an insurance company, it will be classified as "out-of-network," or as a non-participating provider. In such instances, it 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 prospectus, 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 U.S. 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 marks 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 the Company intends 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 the Company uses, 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.

The Company and its 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 the Company or any of its contract manufacturers or regulated suppliers is not in compliance with these requirements, it can shut down the Company's 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 the Company or its officers or other employees. Any such action by the FDA would have a material adverse effect on the Company's business.

CLIA and State Regulation

As a provider of cytology and molecular diagnostic services, the Company is required to hold certain federal, state and local licenses, certifications, and permits. Under CLIA, it is required to hold a certificate applicable to the type of work it performs 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 its CLIA certificates, which it is required to renew every two years, the Company 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, the Company is 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

The Company is 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 the Company.

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. The Company is 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 the Company's 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, the Company could incur damages under state laws to private parties for the wrongful use or disclosure of confidential health information or other private personal information.

The Company has implemented policies and practices that it believes brings it 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 the Company 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, the Company is required to comply with both HIPAA privacy regulations and various state privacy laws. The failure to do so could subject it 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 the Company.

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. The Company has employed what it considers 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 the Company 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. The Company has outsourced to a third-party vendor the handling of its 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. The Company intends to obtain NPIs for its laboratory facilities and pathologists so that it can report NPIs to Medicare, Medicaid, and other

health plans.

The healthcare information of the Company's 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, the Company 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

The Company's 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 the Company intends to employ or engage, particularly in terms of the degree of control that the Company exercises or has 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 the Company, from practicing medicine and employing or engaging physicians to practice medicine. These requirements are generally imposed by state law in the states in which the Company operates, 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 the Company even if it does 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. The Company believes that it operates in material compliance with these requirements. However, failure to comply can lead to action against the Company and the licensed healthcare professionals that it employs, 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 the Company's business, and other material adverse consequences.

State Laboratory Licensure

The Company is certified by CLIA and has been licensed in the states of California, Florida, Maryland, Rhode Island, and Washington. The Company is in the process of obtaining a license to accept testing samples from New York, which requires out-of-state laboratories to hold a state license, and is 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 the Company 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.

The Company 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. The Company intends to follow instructions from the state regulators as how to comply with such requirements.

Referrals after Becoming a Public Company

Now that the Company's stock is publicly traded, it is not able to accept referrals from physicians who own, directly or indirectly, shares of its stock unless it complies 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

The Company's 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. The Company uses 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 the Company's.

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 the Company's future LDTs would be costly and delay the ability of the Company 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. The Company seeks to conduct its business in compliance with all statutes and regulations applicable to its operations. To this end, it has established a compliance program that reviews for regulatory compliance procedures, policies, and facilities throughout its business.

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) and the Company. 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. The specific amount of damages sought is to be proven at trial and not specified.

A hearing in the arbitration was set for March 2013 but 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 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 claims. Consequently, no provision or liability has been recorded for Mr. Kelly's claims as of September 30, 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.

Employees

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

Property

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, as described elsewhere in this prospectus. We believe that our current facilities will be adequate to meet our needs for the next 24 months.

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.

MANAGEMENT

The following table sets forth information regarding the members of the Board of Directors of the Company and its executive officers as of the date of this prospectus:

Executive Officers and Directors

Name	Age	Position(s)
Steven C. Quay, M.D., Ph.D.	62	Chairman of the Board of Directors, Chief Executive Officer and President
Kyle Guse	49	Chief Financial Officer, General Counsel and Secretary
Shu-Chih Chen, Ph.D.	51	Director, Chief Scientific Officer
John Barnhart	56	Director
Stephen Galli, M.D.	65	Director
Alexander Cross, Ph.D.	80	Director
H. Lawrence Remmel	60	Director

The Company's bylaws provide that the number of directors authorized to serve on the Board of Directors of the Company may be established, from time to time, by action of the Board of Directors of the Company. Vacancies in the existing Board of Directors of the Company are filled by a majority vote of the remaining directors on the Board of Directors of the Company. Our Board of Directors is divided into three classes and directors serve for a three-year term until the third annual meeting following their election and until their respective successors have been elected and qualified or until death, resignation or removal. Dr. Quay and Mr. Barnhart are Class I directors (whose terms will expire on the date of the 2013 annual meeting), Dr. Cross and Dr. Galli are Class II directors (whose terms will expire on the date of the 2014 annual meeting), and Dr. Chen and Mr. Remmel are Class III directors (whose terms will expire on the date of the 2015 annual meeting). The Company's executive officers are appointed by and serve at the discretion of the Board of Directors of the Company.

Dr. Quay is the Chief Executive Officer and Chairman of the Board of Directors of the Company. Dr. Shu-Chih Chen is the Chief Scientific Officer and a director. Drs. Quay and Chen are husband and wife. They currently beneficially own a substantial minority of the outstanding voting securities of the Company.

Steven C. Quay, M.D., Ph.D. Dr. Quay has served as Chief Executive Officer and Chairman of the Board of Directors of the Company since the Company was incorporated in April 2009. Prior to his work at the Company, Dr. Quay served as Chairman of the Board, President and Chief Executive Officer of MDRNA, Inc., a biotechnology company focused on the development and commercialization of RNAi-based therapeutic products, from August 2000 to May 2008, and as its Chief Scientific Officer until November 30, 2008 (MDRNA, Inc. was formerly known as

Nastech Pharmaceutical Company Inc. and is currently known as Marina Biotech, Inc.). From December 2008 to April 2009, Dr. Quay was involved in acquiring the Company's assets and preparing the Company's business plan. Dr. Quay is certified in Anatomic Pathology with the American Board of Pathology, completed both an internship and residency in anatomic pathology at the Massachusetts General Hospital, a Harvard Medical School teaching hospital, is a former faculty member of the Department of Pathology, Stanford University School of Medicine, and is a named inventor on 14 U.S. and foreign patents covering the MASCT System. He oversaw the clinical testing and regulatory filing of the MASCT device with the FDA that led to its ultimate marketing clearance. Including the patents for the MASCT System, Dr. Quay has a total of 76 U.S. patents, 108 pending patent applications and is a named inventor on patents covering five pharmaceutical products that have been approved by the FDA. Dr. Quay received an M.D. in 1977 and a Ph.D. in 1975 from the University of Michigan Medical School. He also received his B.A. degree in biology, chemistry and mathematics from Western Michigan University in 1971. Dr. Quay is a member of the American Society of Investigative Pathology, the Association of Molecular Pathology, the Society for Laboratory Automation and Screening and the Association of Pathology Informatics. He was selected to serve on the Company's Board of Directors because of his role as the founder of the Company and the inventor of the MASCT System, as well as his qualifications as a physician and the principal researcher overseeing the clinical and regulatory development of the MASCT System.

Kyle Guse, Esq., CPA. Mr. Guse has served as Chief Financial Officer, General Counsel and Secretary since January 2013. His experience includes more than 20 years of counseling life sciences and other rapid growth companies through all aspects of finance, corporate governance, securities laws and commercialization. Mr. Guse has practiced law at several of the largest international law firms, including from January 2012 through January 2013 as a partner at Baker Botts LLP and, prior to that, from October 2007 to January 2012, as a partner at McDermott Will & Emery LLP. Before working at McDermott Will & Emery, Mr. Guse previously served as a partner at Heller Ehrman LLP. Mr. Guse began his career as an accountant at Deloitte & Touche and he is a licensed Certified Public Accountant in the state of California. Mr. Guse earned a B.S. in Business Administration and an M.B.A. from California State University, Sacramento, and a J.D. from Santa Clara University School of Law.

Shu-Chih Chen, Ph.D. Dr. Chen has served as Chief Scientific Officer and director of the Company since the Company was incorporated in April 2009. Prior to joining the Company, Dr. Chen served as President of Ensisheim beginning in 2008, was founder and President of SC2Q Consulting Company from 2006 to 2008, and served as Head, Cell Biology, Nastech Pharmaceuticals Company, Inc. from 2002 to 2006. During 1995 and 1996, she was an Associate Professor at National Yang Ming University, Taipei, Taiwan, and served as the principal investigator of an NIH RO1 grant studying tumor suppression by gap junction protein connexin 43 at the Department of Molecular Medicine at Northwest Hospital before working in the research department at Nastech Pharmaceutical Company. She is named as an inventor on four patent applications related to cancer therapeutics. Dr. Chen received her Ph.D. degree in microbiology and public health from Michigan State University in 1992 and has published extensively on Molecular Oncology. She received her B.S. degree in medical technology from National Yang Ming University, Taipei, Taiwan in 1984. Dr. Chen was selected to serve on the Company's Board of Directors because of her qualifications in medical technology and as a professor and researcher in the field of cancer therapeutics.

John Barnhart. Mr. Barnhart has served as a director of the Company since July 2009. He is the founder and has been the Managing Director of the Visconti Group, a management consulting group in Seattle, Washington, since November 2003. He held prior executive positions at The Walt Disney Company, Sony Pictures Entertainment, and Walt Disney Imagineering. He received a B.S. degree in engineering from California State University, Long Beach in 1983. Mr. Barnhart was selected to serve on the Company's Board of Directors because of his understanding and experience with development and marketing of consumer-oriented products and services.

Stephen J. Galli, M.D. Dr. Galli has served as a director of the Company since July 2011. Dr. Galli is Chair of the Department of Pathology, Professor of Pathology and of Microbiology & Immunology and the Mary Hewitt Loveless, M.D., Professor, Stanford University School of Medicine, Stanford, California, and has served in these capacities since February 1999. Before joining Stanford, he was on the faculty of Harvard Medical School. He holds 13 U.S. patents and has over 340 publications. He is past president of the American Society for Investigative Pathology and current president of the Collegium Internationale Allergologicum. In addition to receiving awards for his research, he was recently recognized with the 2010 Stanford University President's Award for Excellence Through Diversity for his recruitment and support of women and underrepresented minorities at Stanford University. He received his B.A. degree in biology, magna cum laude, from Harvard College in 1968 and his M.D. degree from Harvard Medical School in 1973 and completed a residency in anatomic pathology at the Massachusetts General Hospital in 1977. Dr.

Galli has been selected to serve on the Company's Board of Directors because of his qualifications as a professor and physician, and his specialized expertise as a pathologist.

Alexander D. Cross, Ph.D. Dr. Cross has served as a director of the Company since July 2011. Dr. Cross has served on the board and as a member of the Audit, Compensation, and Nominating and Governance Committees of a number of public companies, including Marina Biotech, Inc. (formerly MDRNA, Inc. and, before that, Nastech Pharmaceutical Company Inc. from July 2005 through May 2009). Dr. Cross also served as Chairman of the Board and CEO of CytoPharm, Inc., a company engaged in the development of light-activated drugs for the treatment of various diseases, until August 2006. Dr. Cross has been a consultant in the fields of pharmaceuticals and biotechnology since January 1986 and has served as a principal of NDA Partners, LLC, a consulting firm that provides strategic advisory services for the development of medical products, since 2003. Previously, Dr. Cross served as President and CEO of Zoecon Corporation, a biotechnology company, from April 1983 to December 1985, and Executive Vice President and Chief Operating Officer from 1979 to 1983. Dr. Cross also previously held several corporate management positions at Syntex Corporation from 1961 through 1979. Dr. Cross holds 109 issued U.S. patents and is the author of 90 peer-reviewed publications. Dr. Cross received his B.Sc., Ph.D. and D.Sc. degrees from the University of Nottingham, England, and is a Fellow of the Royal Society of Chemistry. Dr. Cross has been selected to serve on the Company's Board of Directors because of his qualifications as a scientist, business executive and audit committee financial expert, and his prior experience as a director and committee member of public companies.

H. Lawrence Remmel, Esq. Mr. Remmel served as a director of the Company since February 2012. He is currently a partner of the law firm Pryor Cashman LLP, located in New York City, where he chairs the Banking and Finance practice group. Mr. Remmel joined Pryor Cashman in 1988. His practice includes corporate and banking financings, issues relating to the Investment Company Act of 1940, and intellectual property and licensing issues, in particular in the biotechnology and biocosmeceutical areas. He was an associate of the law firm Reboul, MacMurray, Hewitt, Maynard & Kristol from 1984 to 1988, and began his legal career at Carter, Ledyard & Milburn, where he was an associate from 1979 to 1984. He was admitted to the New York bar in 1980 and is a member of the New York State Bar Association. He received his J.D. from the Washington & Lee University School of Law in 1979 and his B.A. from Princeton University in 1975. Mr. Remmel has been selected to serve on the Company's Board of Directors because of his substantial experience as a corporate attorney advising biotechnology companies and his familiarity with the fiduciary duties and the regulatory requirements affecting publicly traded companies.

Scientific Advisory Board

The Company has established a Scientific Advisory Board to provide strategic resources to the Company's management and its Board of Directors. It is intended that the Company's scientific advisory board has knowledge in breast cancer, NAF, breast cancer biomarkers, and Next Generation Sequencing technologies. The Company expects to expand the size of the advisory board in the future. The members of the Scientific Advisory Board work individually with the Company to advise the Company on matters of research interest to the Company and which are within the expertise of the advisor. Accordingly, the Scientific Advisory Board does not meet as a full board and the Company does not anticipate having a need for such meetings in the future. The initial Scientific Advisory Board currently consists of:

Dr. Edward Sauter, M.D., Ph.D. Dr. Sauter is the Associate Dean for Research and Professor of Surgery at the University of North Dakota School of Medicine & Health Sciences and has served in this position since Fall 2008. He received his M.D. from the Louisiana State School of Medicine and his Ph.D. from the University of Pennsylvania. He completed his general surgery residency at the Ochsner Clinic, in New Orleans, Louisiana. Dr. Sauter also completed a Surgical Oncology Fellowship at Fox Chase Cancer Center in Philadelphia, Pennsylvania. Dr. Sauter was Vice-Chair for Research in the Department of Surgery and Professor at the University of Missouri-Columbia from 2002 to 2008. He also completed his MHA while at the University of Missouri. Dr. Sauter is widely recognized for his research and clinical experience in breast cancer. Among his many accomplishments, Dr. Sauter and a team of researchers pioneered noninvasive and minimally invasive techniques to predict breast cancer risk using NAF. Dr. Sauter is the co-author of over 100 peer-reviewed publications on breast cancer, the majority of which pertain to cytology and molecular diagnostic biomarkers in NAF.

Dr. Sauter and the Company entered into a consulting agreement on February 18, 2010 which provides a $5,000 signing fee and $1,000 per month for up to four hours per month of Dr. Sauter's time. The agreement also provides reasonable travel expenses in connection with his work for the Company. This is the only compensation received for being a member of the Scientific Advisory Board.

Dr. Timothy Hunkapiller, Ph.D.

Dr. Hunkapiller has been a pioneering presence in computational biotechnology since its infancy 30 years ago and is co-inventor of the largest selling analytical research instrument in the world: the Perkin Elmer/Applied Biosystems DNA sequencer. Through his Seattle, Washington-based company, DiscoveryBiosciences, he provides technical consulting and commercialization services to both established and upcoming biotech companies.

Dr. Hunkapiller earned a Ph.D. from California Institute of Technology and was Research Assistant Professor in the Department of Molecular Biotechnology at the University of Washington from 1992 until 1999. As a scientist, Dr. Hunkapiller's research focus included molecular immunology, evolution, computational genetics and comparative genomics. He is considered a leading expert on the genetics, genomic organization and functional diversity of the immune system. For the last 20 years, he has also been involved in bioinformatics, algorithm and database development and experimental process optimization.

While at Caltech, Dr. Hunkapiller originated the model for the automated, fluorescent DNA sequencer. The manifestation of this idea in products such as the ABI 3700™ and the MD Megabase™ sequencers catalyzed and enabled the completion of the first drafts of the Human Genome and helped to revolutionize the field of genomics. He continues to work with Applied Biosystems today on improving the throughput and quality of data from these instruments and their associated chemistry.

Dr. Hunkapiller has been an advisor to a number of biotechnology companies as well as technology companies servicing the biotechnology and pharmaceutical industry. These efforts range from helping with SNP association studies for target discovery in breast cancer to the application of novel computer technologies in intelligently searching very large, unstructured text sources to improve intellectual property analysis.

In April 2011, Dr. Hunkapiller received options to purchase up to 45,000 shares of our common stock at an exercise price of $1.25 per share, the then fair market value. This is the only compensation received for being a member of the Scientific Advisory Board.

DIRECTOR COMPENSATION

The non-employee directors of the Company receive the following:

- upon joining the Board, an initial director compensation fee of $50,000, paid in shares of the Company's common stock and that vests ratably over one year from the date of grant;
- an annual director retainer of $50,000, paid in shares of the Company's common stock and that vests ratably over one year from the date of grant; and
- a fee of $2,000 for the chairperson for each Board or committee meeting attended in person, a fee of $1,500 for the members for each Board or committee meeting attended in person, a fee of $1,500 for the chairperson for each Board or committee meeting attended via telephone and a fee of $1,000 for the members for each Board or committee meeting attended via telephone.

In addition to the above, annual compensation for service on the Audit Committee is $12,000 for the Chair and $8,000 for each member, paid in fully vested shares of the Company's common stock or options, payable quarterly in arrears; and annual compensation for service on the Compensation Committee and Nominating/Governance Committee is $10,000 for the Chair and $6,000 for each member, paid in fully vested shares of the Company's common stock or options, payable quarterly in arrears.

The employee directors receive no compensation for their board service. Pursuant to the policies of Pryor Cashman, the law firm of which Mr. Remmel is a partner, the compensation Mr. Remmel receives for his services as a director (other than expense reimbursement) is paid to the firm directly. All directors receive reimbursement for reasonable travel expenses. The following table sets forth information regarding compensation earned by our non-employee directors during the fiscal year ended December 31, 2011:

Name	Fees Earned or Paid in Cash ($)	Option Awards ($)(1)	Total ($)
John Barnhart (2)	$ 28,000	$42,948	$70,948
Stephen Galli, M.D. (3)	$ 20,000	$14,316	$34,316
Alexander Cross, Ph.D. (4)	$ 22,500	$14,316	$36,816
H. Lawrence Remmel, Esq. (5)	—	—	—

(1) This column reflects the aggregate grant date fair value of equity awards granted in the applicable year and calculated in accordance with FASB ASC 718, excluding the effect of estimated forfeitures. Assumptions used in the

calculations for these amounts are included elsewhere in this prospectus.

(2) Fees earned or paid in cash consists of (a) $4,000 in meeting attendance fees; (b) $8,000 paid in fully vested options, payable quarterly in arrears, for service as a member of the Audit Committee; (c) $6,000 paid in fully vested options, payable quarterly in arrears, for service as a member of the Compensation Committee; and (d) $10,000 paid in fully vested options, payable quarterly in arrears, for service as chairperson of the Nominating/Governance Committee. During the fiscal year ended December 31, 2011, in lieu of an annual director retainer of $50,000 paid in shares of the Company's common stock for each of the years 2009, 2010 and 2011, Mr. Barnhart was granted options to purchase 120,000 shares of our common stock at an exercise price per share of $1.25. 80,000 options were fully vested on September 1, 2011, 10,000 options were fully vested on December 1, 2011 and 10,000 options vested on each of March 1, 2012, June 1, 2012 and September 1, 2012.

(3) Fees earned or paid in cash consists of (a) $2,000 in meeting attendance fees; (b) $8,000 paid in fully vested options, payable quarterly in arrears, for service as a member of the Audit Committee; and (c) $10,000 paid in fully vested options, payable quarterly in arrears, for service as chairperson of the Nominating/Governance Committee. During the fiscal year ended December 31, 2011, in lieu of an annual director grant of $50,000 paid in shares of the Company's common stock for 2011, Dr. Galli was granted options to purchase 40,000 shares of our common stock at an exercise price per share of $1.25. 10,000 options were fully vested on December 1, 2011 and 10,000 options vested on each of March 1, 2012, June 1, 2012 and September 1, 2012.

(4) Fees earned or paid in cash consists of (a) $4,500 in meeting attendance fees; (b) $12,000 paid in fully vested options, payable quarterly in arrears, for service as chairperson of the Audit Committee; and (c) $6,000 paid in fully vested options, payable quarterly in arrears, for service as a member of the Compensation Committee. During the fiscal year ended December 31, 2011, in lieu of an annual director grant of $50,000 paid in shares of the Company's common stock for 2011, Dr. Cross was granted options to purchase 40,000 shares of our common stock at an exercise price per share of $1.25. 10,000 options were fully vested on December 1, 2011 and 10,000 options vested on each of March 1, 2012, June 1, 2012 and September 1, 2012.

(5) Mr. Remmel was appointed to our Board of Directors on February 8, 2012 and thus did not receive compensation for service as a director during the fiscal year ended December 31, 2011.

Director Independence

The Board of Directors of the Company has reviewed the materiality of any relationship that each of our directors has with the Company, either directly or indirectly. Based on this review, the Board of Directors of the Company has determined that John Barnhart, Stephen J. Galli, M.D., Alexander Cross, Ph.D. and Lawrence Remmel, Esq. are "independent directors" as defined under the applicable rules of the NASDAQ Capital Market.

Committees of the Board of Directors of the Company

The Board of Directors of the Company has established an Audit Committee, a Compensation Committee and a Nominating and Governance Committee. The composition and function of each of these committees is described below.

Audit Committee

The Audit Committee is comprised of Dr. Cross (chair), Mr. Barnhart and Mr. Remmel. The Board of Directors of the Company has determined that Dr. Cross is an "Audit Committee Financial Expert," as defined by the rules of the SEC. The Audit Committee is authorized to:

- approve and retain the independent registered public accounting firm to conduct the annual audit of the Company's financial statements;
- review the proposed scope and results of the annual audit;
- review and pre-approve audit and non-audit fees and services;
- review proposed changes in the Company's financial and accounting standards and principles;
- review the Company's policies and procedures with respect to its internal accounting, auditing and financial controls;
- review and approve transactions between the Company and its directors, officers and affiliates; and
- establish procedures for complaints received by the Company regarding accounting matters.

The Company believes that the composition of its Audit Committee meets the independence requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and the NASDAQ Capital Market.

Compensation Committee

The Compensation Committee is comprised of Mr. Barnhart (chair), Dr. Cross, and Dr. Galli. All members of the Compensation Committee qualify as independent directors under the current definition promulgated by the NASDAQ Capital Market. The Compensation Committee is authorized to:

- review and recommend the compensation arrangements for management, or approve such arrangements, if directed by the board;
- establish and review general compensation policies with the objective to attract and retain superior talent, to reward individual performance and to achieve corporate goals;
- administer stock incentive and purchase plans; and
- review and recommend to the board the compensation paid to non-employee directors for their service on the Board of Directors.

Nominating and Governance Committee

The Nominating and Governance Committee is comprised of Dr. Galli (chair), Mr. Barnhart, and Mr. Remmel. All members of the Nominating and Governance Committee qualify as independent directors under the current definition promulgated by the NASDAQ Capital Market. The Nominating and Governance Committee is authorized to:

- identify and nominate candidates for election to the Board of Directors of the Company;
- establish policies under which stockholders may recommend a candidate for consideration for nomination as a director;
- annually review and evaluate the performance, operations, size and composition of the Board; and
- periodically assess and review the Company's Corporate Governance Guidelines and recommend any changes deemed appropriate to the Board for its consideration.

Compensation Committee Interlocks and Insider Participation

No member of our Compensation Committee has at any time been an employee of ours. None of our executive officers serves as a member of the Board of Directors or Compensation Committee of any other entity that has one or more executive officers serving as a member of our Board of Directors or Compensation Committee.

Code of Ethics

The Company has adopted a Code of Ethical Conduct that applies to all its employees, officers and directors, including those officers responsible for financial reporting. The Code of Ethical Conduct is available on the Company's website. The Company expects that any amendments to the code, or any waivers of its requirements, will be disclosed on its website.

Limitation of Directors' and Officers' Liability and Indemnification

The Delaware General Corporation Law authorizes corporations to limit or eliminate, subject to specified conditions, the personal liability of directors to corporations and their stockholders for monetary damages for breach of their fiduciary duties. The Company's certificate of incorporation and amended and restated bylaws limit the liability of its directors to the fullest extent permitted by Delaware law.

The Company has obtained director and officer liability insurance to cover liabilities the Company's directors and officers may incur in connection with their services to the Company. The Company's certificate of incorporation and amended and restated bylaws also provide that it will indemnify and advance expenses to any of its directors and officers who, by reason of the fact that he or she is an officer or director, is involved in a legal proceeding of any nature. The Company will repay certain expenses incurred by a director or officer in connection with any civil, criminal, administrative or investigative action or proceeding, including actions by the Company or in its name. Such indemnifiable expenses include, to the maximum extent permitted by law, attorney's fees, judgments, fines, settlement amounts and other expenses reasonably incurred in connection with legal proceedings. A director or officer will not receive indemnification if he or she is found not to have acted in good faith and in a manner he or she reasonably believed to be in, or not opposed to, the Company's best interest.

Such limitation of liability and indemnification does not affect the availability of equitable remedies. In addition, the Company has been advised that in the opinion of the SEC, indemnification for liabilities arising under the Securities Act of 1933, as amended, or the Securities Act, is against public policy as expressed in the Securities Act and is therefore unenforceable.

There is no pending litigation or proceeding involving any of the Company's directors, officers, employees or agents in which indemnification will be required or permitted. The Company is not aware of any threatened litigation or proceeding that may result in a claim for such indemnification.

EXECUTIVE COMPENSATION

Remuneration of Officers

The Company did not accrue or pay any remuneration or compensation to any officer, director or employee in 2009. In 2010, the Company accrued salary payments to Dr. Steven C. Quay and Dr. Shu-Chih Chen commencing as of May 19, 2010, which is the date that the employment agreement for each of Dr. Quay and Dr. Chen, repectively, became effective, in the amounts and on the terms as defined below. In July 2011, the Company paid accrued salary amounts of $154,762 and $123,810 to Drs. Quay and Chen, respectively. The accrued salary amounts were calculated on a pro rated basis for the period served during fiscal 2010 (i.e., May 19, 2010 through December 31, 2010) for each of Dr. Quay and Dr. Chen, on the basis of an annual salary of $250,000 for Dr. Quay and $200,000 for Dr. Chen, respectively.

The Company's Compensation Committee is responsible for reviewing and evaluating key executive employee base salaries, setting goals and objectives for executive bonuses and administering benefit plans. The Compensation Committee provides advice and recommendations to the Board of Directors of the Company on such matters. See "Committees of the Board of Directors — Compensation Committee" for further details on the role of the Compensation Committee.

Summary Compensation Table

The following table sets forth the compensation earned by the Company's Chief Executive Officer, Chief Scientific Officer and Chief Financial Officer (collectively, the "Named Executive Officers") for fiscal 2011:

Name and Position	Year	Salary	Bonus	Option Awards (1)	Total
Steven C. Quay, M.D., Ph.D. President and Chief Executive Officer	2011	$250,000	$61,905	$ —	$311,905
Christopher Benjamin (2) Chief Financial Officer	2011	$38,968	$—	$ —	$38,968
Shu-Chi Chen, Ph.D. Chief Scientific Officer	2011	$200,000	$37,143	$ —	$237,143

(1) This column reflects the aggregate grant date fair value of equity awards granted in the applicable year and calculated in accordance with FASB ASC 718, excluding the effect of estimated forfeitures. Assumptions used in the calculations for these amounts are included elsewhere in this prospectus.

(2) Mr. Benjamin serves as a part-time employee and is compensated pursuant to a consulting agreement, as described below.

Outstanding Equity Awards at Fiscal Year-End

The following table shows information regarding our outstanding equity awards at December 31, 2011 for the Named Executive Officers:

Name	**Number of Securities Underlying Unexercised Options (#) Exercisable**	**Number of Securities Underlying Unexercised Options (#) Unexercisable**	**Option Exercise Price ($)**	**Option Expiration Date**
Steven C. Quay, M.D., Ph.D.	125,000	125,000	$ 5.00	7/22/2015
Christopher Benjamin	—	—	—	—
Shu Chi Chen, Ph.D.	50,000	50,000	$ 5.00	7/22/2015

Employment Agreements

Employment Agreement with Steven Quay, M.D., Ph.D.

The Company has entered into an employment agreement with Dr. Quay to act as the Company's Chief Executive Officer. The agreement provides for an initial base salary of $250,000 per year and an annual target bonus of up to 40% of Dr. Quay's then-current base salary, payable upon the achievement of performance goals to be established annually by the Compensation Committee. The goals for fiscal 2011 included the MASCT System manufacturing scale-up and launch, filling additional key senior management positions in marketing and sales, finance, and laboratory management, establishing laboratory registration and certification, and launching the ForeCYTE Test.

Under the employment agreement, Dr. Quay received an option to purchase up to 250,000 shares of common stock at an exercise price of $5.00 per share, the fair market value of the common stock on the date of grant, as determined by the Board of Directors. One-quarter of the shares of common stock underlying the option, or 62,500 shares, vested on December 31, 2010, and the remaining 75%, or 187,500 shares, vest in equal quarterly installments over the next three years, so long as Dr. Quay remains employed with the Company.

During the employment term, the Company will make available to Dr. Quay employee benefits provided to other key employees and officers of the Company. To the extent these benefits are based on length of service with the Company,

Dr. Quay will receive full credit for prior service with the Company. Participation in health, hospitalization, disability, dental and other insurance plans that the Company may have in effect for other executives, all of which shall be paid for by the Company with contribution by Dr. Quay as set for the other executives, as and if appropriate.

Dr. Quay will be entitled to six weeks of paid vacation per year for each full year of employment, pro-rated for each partial year. Vacation time not taken during a calendar year will not be accrued to the next calendar year.

Dr. Quay has also agreed that, for the period commencing on the date of his employment agreement with the Company and during the term of his employment and for a period of 12 months following voluntary termination of his employment with the Company that he will not compete with the Company in the United States. The employment agreement also contains provisions relating to confidential information and assignment of inventions, which require Dr. Quay to refrain from disclosing any proprietary information and to assign to the Company any inventions which directly concern the MASCT System, Oxy-MASCT System, or future products, research, or development, or which result from work they perform for the Company or using its facilities.

Consulting Agreement with Christopher Benjamin

The Company has entered into an agreement with Christopher Benjamin to act as the Company's interim Chief Financial Officer. The agreement provides a monthly retainer fee of $2,250 for up to 25 hours of work per month and $100 per hour beyond that level. The agreement may be terminated by the Company upon 30 days' written notice.

Employment Agreement with Shu-Chih Chen, Ph.D.

The Company has entered into an employment agreement with Dr. Chen to act as the Company's Chief Scientific Officer. The agreement provides for an initial base salary of $200,000 per year and an annual target bonus of up to 30% of Dr. Chen's then-current base salary, payable upon the achievement of performance goals to be established annually by the Compensation Committee. The goals for fiscal 2011 included filling additional key positions in research and development as well as laboratory management, and establishing laboratory registration and certification.

Under the employment agreement, Dr. Chen received an option to purchase up to 100,000 shares of common stock at an exercise price of $5.00 per share, the fair market value of the common stock on the date of grant, as determined by the Board of Directors. One quarter of the shares of common stock underlying the option, or 25,000 shares, vested on December 31, 2010, and the remaining 75%, or 75,000 shares, vest in equal quarterly installments over the next three years, so long as Dr. Chen remains employed with the Company.

During the employment term, the Company will make available to Dr. Chen employee benefits provided to other key employees and officers of the Company. To the extent these benefits are based on length of service with the Company, Dr. Chen will receive full credit for prior service with the Company. Participation in health, hospitalization, disability, dental and other insurance plans that the Company may have in effect for other executives, all of which shall be paid for by the Company with contribution by Dr. Chen as set for the other executives, as and if appropriate.

Dr. Chen will be entitled to six weeks of paid vacation per year for each full year of employment, pro rated for each partial year. Vacation time not taken during a calendar year will not be accrued to the next calendar year.

Dr. Chen has also agreed that, for the period commencing on the date of her employment agreement with the Company and during the term of her employment and for a period of 12 months following voluntary termination of her employment with the Company that she will not compete with the Company in the United States. The employment agreement also contains provisions relating to confidential information and assignment of inventions, which require Dr. Chen to refrain from disclosing any proprietary information and to assign to the Company any inventions that

directly concern the MASCT System, Oxy-MASCT System, or future products, research, or development, or that result from work she performs for the Company or using its facilities.

Severance Benefits and Change in Control Arrangements

The Company has agreed to provide the severance benefits and change in control arrangements described below to its named executive officers.

Dr. Steven Quay

Pursuant to his employment agreement, if (i) the Company terminates the employment of Dr. Quay without cause, or (ii) Dr. Quay terminates his employment for good reason, then Dr. Quay will be entitled to receive all accrued but unpaid compensation, plus a severance payment equal to 12 months of base salary. In addition, upon such event, the vesting of all shares of common stock underlying options then held by Dr. Quay will accelerate, and the options will remain exercisable for the remainder of their terms. The cash severance payment is required to be paid in substantially equal installments over a period of six months beginning on the Company's first payroll date that occurs following the 30th day after the effective date of termination of Dr. Quay's employment, subject to certain conditions. The Company will not be required, however, to pay any severance pay for any period following the termination date if Dr. Quay materially violates certain provisions of his employment agreement and the violation is not cured within 30 days following receipt of written notice from the Company containing a description of the violation and a demand for immediate cure.

In addition, under the terms of his employment agreement, in the event of a "change in control" of the Company (as defined in the employment agreement) during Dr. Quay's employment term, Dr. Quay will be entitled to receive a one-time payment equal to 2.9 times his base salary, and the vesting of all outstanding equity awards then held by Dr. Quay will accelerate such that they are fully vested as of the date of the change in control.

Dr. Shu-Chih Chen

Pursuant to her employment agreement, if (i) the Company terminates the employment of Dr. Chen without cause, or (ii) Dr. Chen terminates her employment for good reason, then Dr. Chen will be entitled to receive all accrued but unpaid compensation, plus a severance payment equal to 12 months of base salary. In addition, upon such event, the vesting of all shares of common stock underlying options then held by Dr. Chen will accelerate, and the options will remain exercisable for the remainder of their terms. The cash severance payment is required to be paid in substantially equal installments over a period of six months beginning on the Company's first payroll date that occurs following the 30th day after the effective date of termination of Dr. Chen's employment, subject to certain conditions. The Company will not be required, however, to pay any severance pay for any period following the termination date if Dr. Chen materially violates certain provisions of her employment agreement and the violation is not cured within 30 days following receipt of written notice from the Company containing a description of the violation and a demand for immediate cure.

In addition, under the terms of her employment agreement, in the event of a "change in control" of the Company (as defined in the employment agreement) during Dr. Chen's employment term, Dr. Chen will be entitled to receive a one-time payment equal to 2.9 times her base salary, and the vesting of all outstanding equity awards then held by Dr. Chen will accelerate such that they are fully vested as of the date of the change in control.

2010 Stock Option and Incentive Plan

The Company's 2010 Stock Option and Incentive Plan, or the 2010 Plan, provides 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.

Plan Administration. The 2010 Plan may be administered by the full board or the Compensation Committee. It is the current intention of the Company that the 2010 Plan be administered by the Compensation Committee. The Compensation Committee has full power to select, from among the individuals eligible for awards, the individuals to whom awards will be granted, to make any combination of awards to participants, and to determine the specific terms and conditions of each award, subject to the provisions of the 2010 Plan. The Compensation Committee may delegate

to our Chief Executive Officer the authority to grant stock options to employees who are not subject to the reporting and other provisions of Section 16 of the Exchange Act and not subject to Section 162(m) of the Code, subject to certain limitations and guidelines.

Eligibility. Persons eligible to participate in the 2010 Plan will be those full or part-time officers, employees, non-employee directors and other key persons (including consultants and prospective officers) of the Company and its subsidiaries as selected from time to time by the Compensation Committee in its discretion.

Plan Limits. Initially, the total number of shares of common stock available for issuance under the 2010 Plan is 1,000,000 shares (or 2,263,320 shares prior to the reverse stock-split on September 28, 2010). As of January 1, 2012 and each January 1 thereafter, the number of shares of common stock reserved and available for issuance under the 2010 Plan will be cumulatively increased by 4% of the number of shares of common stock issued and outstanding on the immediately preceding December 31. Subject to these overall limitations, the maximum aggregate number of shares of Stock that may be issued in the form of incentive stock options or stock appreciation rights to any one individual will not exceed 50% of the initial 2010 Plan limit of 1,000,000, cumulatively increased on January 1, 2012 and each January 1 thereafter by the lesser of (i) the 4% annual increase applicable to the 2010 Plan for such year or (ii) 500,000 shares.

Stock Options. The 2010 Plan permits the granting of (i) options to purchase common stock intended to qualify as incentive stock options under Section 422 of the Code and (ii) options that do not so qualify. Options granted under the 2010 Plan will be non-qualified options if they fail to qualify as incentive options or exceed the annual limit on incentive stock options. Incentive stock options may only be granted to employees of the Company and its subsidiaries. Non-qualified options may be granted to any persons eligible to receive incentive options and to non-employee directors and key persons. The option exercise price of each option will be determined by the Compensation Committee but may not be less than 100% of the fair market value of the common stock on the date of grant. Fair market value for this purpose will be the last reported sale price of the shares of common stock on the NASDAQ Capital Market on the date of grant. The exercise price of an option may not be reduced after the date of the option grant, other than to appropriately reflect changes in our capital structure.

The term of each option will be fixed by the Compensation Committee and may not exceed 10 years from the date of grant. The Compensation Committee will determine at what time or times each option may be exercised. Options may be made exercisable in installments and the exercisability of options may be accelerated by the Compensation Committee. In general, unless otherwise permitted by the Compensation Committee, no option granted under the 2010 Plan is transferable by the optionee other than by will or by the laws of descent and distribution, and options may be exercised during the optionee's lifetime only by the optionee, or by the optionee's legal representative or guardian in the case of the optionee's incapacity.

Upon exercise of options, the option exercise price must be paid in full either in cash, by certified or bank check or other instrument acceptable to the Compensation Committee or by delivery (or attestation to the ownership) of shares of common stock that are beneficially owned by the optionee for at least six months or were purchased in the open market. Subject to applicable law, the exercise price may also be delivered to the Company by a broker pursuant to irrevocable instructions to the broker from the optionee. In addition, the Compensation Committee may permit non-qualified options to be exercised using a net exercise feature which reduces the number of shares issued to the optionee by the number of shares with a fair market value equal to the exercise price.

To qualify as incentive options, options must meet additional federal tax requirements, including a $100,000 limit on the value of shares subject to incentive options that first become exercisable by a participant in any one calendar year.

Stock Appreciation Rights. The Compensation Committee may award stock appreciation rights subject to such conditions and restrictions as the Compensation Committee may determine. Stock appreciation rights entitle the recipient to shares of common stock equal to the value of the appreciation in the stock price over the exercise price. The exercise price is the fair market value of the common stock on the date of grant. The term of a stock appreciation right will be fixed by the Compensation Committee and may not exceed 10 years.

Restricted Stock. The Compensation Committee may award shares of common stock to participants subject to such conditions and restrictions as the Compensation Committee may determine. These conditions and restrictions may include the achievement of certain performance goals and/or continued employment with us through a specified restricted period.

Restricted Stock Shares. The Compensation Committee may award restricted stock shares to any participants. Restricted stock shares are generally payable in the form of shares of common stock, although restricted stock shares granted to the chief executive officer may be settled in cash. These shares may be subject to such conditions and restrictions as the Compensation Committee may determine. These conditions and restrictions may include the achievement of certain performance goals (as summarized above) and/or continued employment with the Company through a specified vesting period. In the Compensation Committee's sole discretion, it may permit a participant to make an advance election to receive a portion of his or her future cash compensation otherwise due in the form of a restricted stock unit award, subject to the participant's compliance with the procedures established by the Compensation Committee and requirements of Section 409A of the Code. During the deferral period, the deferred stock awards may be credited with dividend equivalent rights.

Adjustments for Stock Dividends, Stock Splits, Etc. The 2010 Plan requires the Compensation Committee to make appropriate adjustments to the number of shares of common stock that are subject to the 2010 Plan, to certain limits in the 2010 Plan, and to any outstanding awards to reflect stock dividends, stock splits, extraordinary cash dividends and similar events.

Tax Withholding. Participants in the 2010 Plan are responsible for the payment of any federal, state or local taxes that the Company is required by law to withhold upon the exercise of options or stock appreciation rights or vesting of other awards. Subject to approval by the Compensation Committee, participants may elect to have the minimum tax withholding obligations satisfied by authorizing the Company to withhold shares of common stock to be issued pursuant to the exercise or vesting.

Amendments and Termination. The Board of Directors of the Company may at any time amend or discontinue the 2010 Plan and the Compensation Committee may at any time amend or cancel any outstanding award for the purpose of satisfying changes in the law or for any other lawful purpose. However, no such action may adversely affect any rights under any outstanding award without the holder's consent. To the extent required under the NASDAQ Capital Market rules, any amendments that materially change the terms of the 2010 Plan will be subject to approval by our stockholders. Without approval by our stockholders, the Compensation Committee may not reduce the exercise price of options or stock appreciation rights or effect repricing through cancellation or re-grants, including any cancellation in exchange for cash. Amendments shall also be subject to approval by our stockholders if and to the extent determined by the Compensation Committee to be required by the Code to preserve the qualified status of incentive options or to ensure that compensation earned under the 2010 Plan qualifies as performance-based compensation under Section 162(m) of the Code.

Other Benefits

The Company offers health, dental, disability, and life insurance to its full-time employees. All employees pay a portion of health, dental, and disability insurance premiums and pay all life insurance premiums.

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CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

Dr. Quay is the President, Chief Executive Officer and Chairman of the Board of Directors of the Company. Dr. Chen is the Chief Scientific Officer and a director of the Company. Drs. Quay and Chen are husband and wife. Drs. Quay and Chen are significant minority stockholders. Ensisheim Partners, LLC, which holds 35.3% of the outstanding common stock of the Company prior to this offering, is wholly owned by Drs. Quay and Chen, and they are the beneficial owners of the shares of the Company's stock owned by that entity.

Ensisheim was the original owner of the patents covering the MASCT System, which were acquired by the Company in June 2010. Ensisheim has no further interest or right to the U.S. patents and foreign counterparts that cover the manufacture, use, and sale of the MASCT System, the pending patent applications for improvements, or the FDA marketing authorization for the MASCT System that was transferred to the Company. Ensisheim did not receive any monetary compensation in connection with the transfer and assignment to the Company of the patents, patent applications and FDA marketing authorization but received shares of common stock of the Company in consideration for its contribution of these assets. Ensisheim holds patents and patent applications for inventions created by the owners in fields unrelated to the Company's business and provides a corporate structure for consulting activities of the owners in fields unrelated to the Company's business. Drs. Quay and Chen currently devote substantially all of their professional efforts to the business of the Company.

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 an oral 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 in 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 bore interest at a rate of 10% per annum and carried a $4,000 loan origination fee, which accreted to the loan balance over 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 for borrowing up to $500,000 from its Chairman of the Board and Chief Executive Officer pursuant to a promissory note. The note bore interest at a rate of 10% per

annum. An aggregate of $140,000 was funded to the Company under the line of credit through 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 $10,000. The note is payable in full on or before December 31, 2011 for the outstanding balance borrowed. 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, as well as $823 in interest.

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. As of December 31, 2009, a total of $12,500 was payable to Ensisheim under the minimum royalty provisions. From inception through December 31, 2010, the Company had incurred $16,250 in patent-related expenses under the license agreement with Ensisheim. The $16,250 in patent-related expenses relates to legal fees in connection with filing and prosecuting the related patent applications and has been paid in full by the Company.

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. Ensisheim did not receive further cash or equity consideration under the Assignment Agreement other than the shares of common stock it had already received in April 2009 as a result of its contribution of intellectual property rights and FDA marketing authorization for the MASCT System. Neither the Chief Executive Officer nor the Chief Technology Officer of the Company received consideration under the Assignment Agreement. However, since Ensisheim has at all times held a substantial equity position in the Company, the potential increased profits of the Company as a result of the removal of this royalty payment obligation may provide more potential economic value to Ensisheim than the royalty payment would have provided.

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. As of December 31, 2009, the security deposit for the lease amounted to $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. The $1,100 security deposit paid to Ensisheim remained outstanding and was recorded as Due from Related Party as of June 30, 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 amended and restated the employment agreements with its Chief Executive Officer and Chief Scientific Officer. The agreements modified the annual base salary amounts to $250,000 and $200,000, respectively, effective retroactively to May 19, 2010. These salaries were accrued and amounted to $391,071 and $278,571 as of March 31, 2011 and December 31, 2010, respectively, and paid in full in April 2011. For the twelve-month periods ended December 31, 2011 and 2010, salaries and bonuses of the Chief Executive Officer and Chief Scientific Officer amounted to $693,048 and $377,620, of which $492,095 and $0 was recorded to research and development expense, respectively. For the nine months ended September 30, 2012, salaries and bonuses of the CEO and CSO amounted to $269,438 and $200,550, of which $134,719 and $200,550 were recorded to research and development expense, respectively.

Share-Based Compensation

The amended and restated employment agreement with the Chief Executive Officer 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 (or $2.64 per share prior to the reverse stock split on September 28, 2010), 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 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 (or $2.64 per share prior to the reverse stock split on September 28, 2010) 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 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 vest ninety (90) days after the date of grant;

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

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

(iv) 11,250 option shares 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 Stock Option and Incentive 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 Stock Option and Incentive 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 vest on September 1, 2011;

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

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

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

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

On April 30, 2012, 19,757 non-qualified stock options were granted under the 2010 Stock Option and Incentive 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 term and shall vest and become exercisable in full immediately as of the grant date.

Sales of Unregistered Securities

In connection with the formation of the Company, the Company sold securities, which were not registered under the Securities Act, to certain related parties. The Company issued 4,899,888 shares of its common stock pursuant to an exemption from registration under Section 4(a)(2) of the Securities Act, as a transaction by an issuer not involving any public offering to the following related parties:

	Shares	Date	Consideration
Steven Quay	883,658	April 30, 2009	$ 12,000
Ensisheim Partners LLC	1,767,316	April 30, 2009	(1)
Ensisheim Partners LLC	883,658	December 28, 2009	$ 100,000
Manistee Ventures, Inc.	1,325,487	April 30, 2009	$ 18,000
John Barnhart	39,765	July 28, 2009	$ 540

(1) The 1,767,316 shares of common stock issued to Ensisheim Partners LLC at the Company's inception were issued in consideration for $24,000 in cash and this entity's contribution to the Company of intellectual property rights and FDA marketing authorization for the MASCT System.

Indemnification Agreements

The Company has entered into indemnification agreements with each of its directors and certain of its executive officers. These agreements require the Company to indemnify these individuals to the fullest extent permitted under Delaware law against liabilities that may arise by reason of their service to the Company, and to advance expenses incurred as a result of any proceeding against them as to which they could be indemnified.

Related Party Transaction Policies

Related party transactions that the Company is required to disclose publicly under the federal securities laws will require prior approval of the Company's independent directors without the participation of any director who may have a direct or indirect interest in the transaction in question. Related parties include directors, nominees for director, principal stockholders, executive officers and members of their immediate families. For these purposes, a "transaction" will include all financial transactions, arrangements or relationships, ranging from extending credit to the provision of goods and services for value and will include any transaction with a company in which a director, executive officer immediate family member of a director or executive officer, or principal stockholder (that is, any person who beneficially owns five percent or more of any class of the Company's voting securities) has an interest by virtue of a 10% or greater equity interest. The Company's policies and procedures regarding related party transactions are not expected to be a part of a formal written policy, but rather, will represent a course of practice determined to be appropriate by the Board of Directors of the Company.

PRINCIPAL STOCKHOLDERS

The following table sets forth information as of January 18, 2013 regarding the beneficial ownership of our common stock by each of our executive officers and directors, individually and as a group and by each person who beneficially owns in excess of five percent of the common stock after giving effect to any exercise of warrants or options held by that person within 60 days after January 18, 2013. Unless indicated otherwise, the address for the beneficial holders is c/o Atossa Genetics Inc., 4105 East Madison Street, Suite 320, Seattle, Washington.

		Percentage of Common Stock Beneficially Owned			
Name of Beneficial Owner	**Shares Beneficially Owned**	**Before Offering (1)**		**After Offering (2)**	
Steven C. Quay, M.D., Ph.D. (3)	5,047,623	38.5	%	23.9	%
Shu-Chih Chen, Ph.D. (4)	4,350,580	33.5	%	20.7	%
John Barnhart (5)	185,342	1.4	%	*	
Kyle Guse	—	—		—	
Stephen Galli, M.D. (6)	63,601	*		*	
Alexander D. Cross, Ph.D. (7)	134,293	1.0	%	*	
H. Lawrence Remmel, Esq. (8)	2,000	*		*	
All Current Officers and Directors as a Group (7 persons)	5,507,859	41.1	%	25.7	%

* Less than 1%

(1) Based on 12,919,367 shares of common stock issued and outstanding as of January 18, 2013.

(2) Assumes the sale of all 8,021,340 shares of Common Stock offered pursuant to this prospectus.

(3) Consists of (i) 584,543 shares of common stock directly owned by Dr. Quay, (ii) 4,275,580 shares of common stock owned by Ensisheim and (iii) 187,500 shares of common stock issuable upon the exercise of stock options held by Dr. Quay and exercisable within 60 days after January 18, 2013. Drs. Quay and Chen share voting and investment power over the securities held by Ensisheim. Ensisheim is solely owned and controlled by Drs. Quay and Chen, and, as a result, Drs. Quay and Chen are deemed to be beneficial owners of the shares held by this entity.

(4) Consists of (i) 4,275,580 shares of common stock owned by Ensisheim and (ii) 75,000 shares of common stock issuable upon the exercise of stock options held by Dr. Chen and exercisable within 60 days after January 18, 2013. Drs. Quay and Chen share voting and investment power over the securities held by Ensisheim. Ensisheim is solely owned and controlled by Drs. Quay and Chen, and, as a result, Drs. Quay and Chen are deemed to be beneficial owners of the shares held by this entity.

(5) Consists of (i) 39,765 shares of common stock held by Mr. Barnhart (ii) 17,674 shares of common stock held by certain family members and for which Mr. Barnhart is the beneficial owner and (iii) 127,903 shares of common stock issuable upon the exercise of stock options held by Mr. Barnhart and exercisable within 60 days of January 18, 2013.

(6)

Consists of 17,674 shares of common stock held by Dr. Galli and 45,927 shares of common stock issuable upon the exercise of stock options held by Dr. Galli and exercisable within 60 days of January 18, 2013.

(7) Consists of 88,366 shares of common stock held by the Alexander D. Cross Family Trust (Mr. Alexander D. Cross has sole voting and investment power over the securities held by the trust and as such, is deemed to be the beneficial owner of the shares held by this entity) and 45,927 shares of common stock issuable upon the exercise of stock options held by Dr. Cross and exercisable within 60 days of January 18, 2013.

(8) Consists of 2,000 shares of common stock held by Mr. Remmel.

DESCRIPTION OF SECURITIES TO BE REGISTERED

Our authorized capital stock consists of 75,000,000 shares of Common Stock, $0.001 par value per share, and 10,000,000 shares of preferred stock, $0.001 par value per share.

As of the date of this prospectus, there were approximately 225 record holders of the Company's common stock. The number of shares of our Common Stock outstanding as of the date of this prospectus is 12,919,367, which excludes 922,757 shares issuable upon the exercise of options outstanding as of the date of this prospectus under our 2010 Stock Option and Incentive Plan, or 2010 Plan, as well as 1,027,517 shares of common stock reserved for future issuance under our 2010 Plan, and 605,000 shares issuable upon exercise of options granted outside of our 2010 plan as inducement grants. The 2010 Plan contains an evergreen feature by which the initial 2010 Plan limit of 1,000,000 will increase on each January 1 by the lesser of (i) the 4% annual increase applicable to the 2010 Plan for such year or (ii) 500,000 shares. The 12,919,367 shares of Common Stock outstanding as of the date of this prospectus also excludes 6,833,840 shares of common stock underlying outstanding warrants with a weighted-average exercise price of $1.56 per share and 325,000 shares of common stock issuable upon the exercise of warrants with an exercise price of $5.00 per share issued in connection with our acquisition of substantially all the assets of Acueity Healthcare, Inc.

Common Stock

Holders of Common Stock are entitled to receive ratably dividends out of funds legally available, if and when declared from time to time by our Board of Directors. The Company has never paid any cash dividends on its Common Stock and the Company's Board of Directors does not anticipate that it will pay cash dividends in the foreseeable future. The future payment of dividends, if any, on the Company's Common Stock is within the discretion of the Board of Directors and will depend upon earnings, capital requirements, financial condition and other relevant factors. Holders of Common Stock are entitled to one vote for each share held on each matter to be voted on by stockholders. There is no cumulative voting in the election of directors. In the event of liquidation, dissolution or winding up of the affairs of the Company, holders of Common Stock are to share in all assets remaining after the payment of liabilities and any preferential distributions payable to preferred stockholders, if any. The holders of Common Stock have no preemptive or conversion rights and are not subject to further calls or assessments. There are no redemption or sinking fund provisions applicable to the Common Stock. The rights of the holders of the Common Stock are subject to any rights that may be fixed for holders of preferred stock, if any. All of the outstanding shares of Common Stock are fully paid and non-assessable.

Certificate of Incorporation

Under our Certificate of Incorporation, as amended, our Board of Directors, without further action by our stockholders, currently has the authority to issue up to 10,000,000 shares of preferred stock and to fix the rights (including voting rights), preferences and privileges of these “blank check” preferred shares. Such preferred stock may have rights, including economic rights, senior to our Common Stock. As a result, the issuance of the preferred stock could have a material adverse effect on the price of our Common Stock and could make it more difficult for a third party to acquire a majority of our outstanding Common Stock.

Anti-Takeover Devices

Our certificate of incorporation and bylaws include a number of provisions that may have the effect of delaying, deferring or preventing another party from acquiring control of us and encouraging persons considering unsolicited tender offers or other unilateral takeover proposals to negotiate with our Board of Directors rather than pursue non-negotiated takeover attempts. These provisions include the items described below.

Board Composition and Filling Vacancies. In accordance with the Company’s certificate of incorporation, our Board of Directors is divided into three classes serving staggered three-year terms, with one class being elected each year. The Company’s certificate of incorporation also provides that directors may only be removed from office for cause and only by the affirmative vote of holders of 75% or more of the outstanding shares of capital stock then entitled to vote at an election of directors. Furthermore, any vacancy on the Company’s Board of Directors, however occurring, including any vacancy resulting from an increase in the size of the board, may only be filled by the affirmative vote of a majority of our directors then in office even if less than a quorum. The classification of directors, together with the limitations on removal of directors and treatment of vacancies, has the effect of making it more difficult for stockholders to change the composition of our Board of Directors.

Undesignated Preferred Stock. The Company's certificate of incorporation authorizes "blank-check" preferred stock, which means that the Board of Directors of the Company has the authority to designate one or more series of preferred stock without stockholder approval. These series of preferred stock may have superior rights, preferences and privileges over our common stock, including dividend rights, voting rights and liquidation preferences. The ability of the Board of Directors of the Company to issue shares of the Company's preferred stock without stockholder approval could deter takeover offers and make it more difficult or costly for a third party to acquire the Company without the consent of the Board of Directors of the Company.

Section 203 of the Delaware General Corporation Law. In addition, the Company's certificate of incorporation does not opt out of Section 203 of the Delaware General Corporation Law, which protects a corporation against an unapproved takeover by prohibiting a company from engaging in any business combination with any interested stockholder (defined as a stockholder owning more than 15% of the outstanding shares) for a period of three years from the time such stockholder became a 15% holder unless approved by the Board of Directors of the Company.

Transfer Agent and Registrar

We have appointed VStock Transfer, LLC, 77 Spruce Street, Suite 201, Cedarhurst, New York 11516 (Telephone: (212) 828-8436; Facsimile (646) 536-3179) as the Company's transfer agent and registrar.

Listing

Our Common Stock is listed on the NASDAQ Capital Market under the symbol "ATOS". Our Common Stock began trading on the NASDAQ Capital Market on November 8, 2012 and, since that time through January 18, 2013, the high sales price has been $5.61 per share and the low price has been $3.44 per share.

DISCLOSURE OF COMMISSION POSITION ON INDEMNIFICATION
FOR SECURITIES ACT LIABILITIES

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers, and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable.

LEGAL MATTERS

Certain legal matters relating to the validity of the Common Stock offered by this prospectus will be passed upon for us by Ropes & Gray LLP, San Francisco, California.

EXPERTS

KCCW Accountancy Corp., an independent PCAOB registered public accounting firm, has audited the Company's balance sheets as of December 31, 2010 and 2011 and the related statements of operations, stockholders' equity, and cash flows, which are included in this prospectus. The financial statements are included in reliance on the report of KCCW Accountancy Corp., given their authority as experts in accounting and auditing.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

The Company is required to file annual, quarterly and special reports, proxy statements and other information with the SEC. You may read and copy any document filed by the Company at the SEC's Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the public reference room. The Company's filings with the SEC are also available to the public at the SEC's Internet web site at *http://www.sec.gov*.

The Company has filed a registration statement, of which this prospectus is a part, covering the securities offered hereby. As allowed by SEC rules, this prospectus does not include all of the information contained in the registration statement and the included exhibits, financial statements and schedules. You are referred to the registration statement, the included exhibits, financial statements and schedules for further information. This prospectus is qualified in its entirety by such other information.

ATOSSA GENETICS, INC.

(A Development Stage Company)

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

September 30, 2012

Unaudited Consolidated Financial Statements:

ATOSSA GENETICS, INC.

(A DEVELOPMENT STAGE COMPANY)

CONSOLIDATED BALANCE SHEETS

	September 30, 2012 (Unaudited)	**December 31, 2011 (Audited)**
Assets		
Current Assets		
Cash and cash equivalents	$418,570	$1,910,821
Restricted cash	250,000	1,000,000
Accounts receivable	175,408	1,224
Prepaid expense	39,975	31,184
Rental deposits	1,500	2,200
Total Current Assets	885,453	2,945,429
Fixed Assets		
Furniture and Equipment, net	67,497	80,467
Total Fixed Assets	67,497	80,467
Other Assets		
Security deposit	36,446	5,157
Intangible assets, net	4,703,078	40,841
Total Other Assets	4,739,524	45,998
Total Assets	$5,692,474	$3,071,894
Liabilities and Stockholders' Equity		
Current Liabilities		
Line of Credit	$250,000	$1,000,000
Accounts payable	72,100	64,766
Accrued expenses	1,888,344	442,329
Note payable - related party	80,453	5,078
Total Current Liabilities	2,290,897	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, 12,119,367 shares issued and outstanding	12,119	11,257

Additional paid-in capital	11,415,761	6,200,520
Accumulated deficit	(8,026,303)	(4,652,056)
Total Stockholders' Equity (Deficit)	3,401,577	1,559,721
Total Liabilities and Stockholders' Equity	$5,692,474	$3,071,894

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

ATOSSA GENETICS, INC.

(A DEVELOPMENT STAGE COMPANY)

CONSOLIDATED STATEMENTS OF OPERATIONS

(UNAUDITED)

	For The Three Months Ended September 30,		For The Nine Months Ended September 30,		From April 30, 2009 (Inception) Through September 30, 2012
	2012	2011	2012	2011	
Revenue					
Diagnostic Testing Service	$ 104,011	$ -	$ 376,696	$ -	$ 376,696
Product Sales	1,565	-	6,690	-	8,190
Total Revenue	105,576	-	383,386	-	384,886
Cost of Revenue					
Diagnostic Testing Service	(9,000)	-	(29,985)	-	(29,985)
Product Sales	-	-	-	-	(5,164)
Total Cost of Revenue	(9,000)	-	(29,985)	-	(35,149)
Loss on Reduction of Inventory to LCM	(6,077)	-	(29,884)	-	(121,910)
Gross Profit	90,499	-	323,517	-	227,827
Selling expenses	(87,704)	-	(281,971)	-	(455,026)
General and Administrative expenses	(1,138,467)	(1,274,189)	(3,405,198)	(2,231,906)	(7,766,497)
Total operating expenses	(1,226,171)	(1,274,189)	(3,687,169)	(2,231,906)	(8,221,523)
Operating Loss	(1,135,672)	(1,274,189)	(3,363,652)	(2,231,906)	(7,993,694)
Interest Income	46	2,267	1,219	3,428	6,588
Interest Expense	(7,756)	(758)	(11,816)	(8,388)	(38,947)
Net Loss before Income Taxes	(1,143,382)	(1,272,680)	(3,374,249)	(2,236,866)	(8,026,053)
Income Taxes	-	-	-	-	250
Net Loss	$ (1,143,382)	$ (1,272,680)	$ (3,374,249)	$ (2,236,866)	$ (8,026,303)

Loss per common share - basic and diluted	$ (0.10)	$ (0.11)	$ (0.30)	$ (0.27)	$ (1.05)
Weighted average shares outstanding, basic & diluted	11,256,867	11,256,867	11,256,867	8,394,219	7,657,400

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

ATOSSA GENETICS, INC.

(A DEVELOPMENT STAGE COMPANY)

CONSOLIDATED STATEMENTS OF CASH FLOWS

(UNAUDITED)

	For The Nine Months Ended September 30, 2012	For The Nine Months Ended September 30, 2011	For The Period From April 30, 2009 (Inception) to September 30, 2012
CASH FLOWS FROM OPERATING ACTIVITIES			
Net loss	$ (3,374,249)	$ (2,236,866)	$ (8,026,303)
Common shares issued for services	-	-	71,000
Compensation cost for stock options granted	96,251	111,288	266,703
Loss on reduction of inventory to LCM	29,884	-	121,910
Loan initiation fee accrued for notes payable	-	-	2,000
Depreciation and amortization	25,586	6,420	41,208
Adjustments to reconcile net loss to net cash provided by operating activities:			
Increase in accounts receivable	(174,183)	-	(175,407)
Increase in inventory	(29,884)	-	(121,910)
Increase in prepaid expenses	(8,791)	(41,946)	(39,975)
Increase in security deposits	(30,589)	(2,200)	(37,946)
Increase (decrease) in accounts payable	7,335	(1,500)	72,101
Decrease in accrued payroll	-	(278,571)	-
Increase (decrease) in accrued expenses	1,491,014	(10,392)	1,933,342
Net cash used in operating activities	(1,967,626)	(2,453,767)	(5,893,277)
CASH FLOWS FROM INVESTING ACTIVITIES			
Purchase of furniture & fixtures	-	(35,776)	(86,465)
Purchase of software	-	(49,500)	(50,466)
Net cash used in investing activities	-	(85,276)	(136,931)
CASH FLOWS FROM FINANCING ACTIVITIES			
Net proceeds from issuance of common stocks and warrants	400,000	5,713,785	6,370,325
(Repayments of) Proceeds from bank line of credit	(750,000)	1,000,000	250,000
Proceeds from (repayments of) loans from related parties	75,375	(179,000)	78,453
Cash released from (restricted for) commercial line of credit	750,000	(1,000,000)	(250,000)
Net cash provided by financing activities	475,375	5,534,785	6,448,778
NET INCREASE (DECREASE) IN CASH & CASH EQUIVALENTS	(1,492,251)	2,995,742	418,570
	1,910,821	10,253	-

CASH & CASH EQUIVALENTS, BEGINNING BALANCE			
CASH & CASH EQUIVALENTS, ENDING BALANCE	$ 418,570	$ 3,005,994.2	$ 418,570
SUPPLEMENTAL DISCLOSURES:			
Interest paid	$ 13,892	$ 5,389	$ 19,281
Income taxes paid	$ -	$ -	$ 250
NONCASH INVESTING AND FINANCING ACTIVITIES:			
Common stock and warrants issued for assets purchase	$ 4,674,853	$ -	$ -
Options issued for previously accrued director compensation	$ 45,000	$ -	$ -

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

ATOSSA GENETICS INC.

(A DEVELOPMENT STAGE COMPANY)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

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 assets included six 510(k)-cleared medical devices, 35 issued patents (18 issued in the U.S. and 17 issued in foreign countries) and 41 patent applications (32 in the U.S. and 9 in foreign countries). The FDA-cleared, patented medical devices consist of microendoscopes, light sources, and biopsy tools. The microendoscopes are less than 0.9 mm outside diameter and can be inserted into a milk duct. This permits a physician to pass a microendoscope into the milk duct system of the breast and view the duct system via fiberoptic video images. Abnormalities that are visualized can then be biopsied from inside the duct with the biopsy tools that are inserted adjacent to the microendoscope. The patents relate to intraductal diagnostic and therapeutic devices and methods of use. 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 September 30, 2012, the Company earned $384,886 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.

ATOSSA GENETICS INC.

(A DEVELOPMENT STAGE COMPANY)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

NOTE 2: GOING CONCERN

The Company's 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 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

The unaudited consolidated financial statements of Atossa Genetics Inc. have been prepared in accordance with U.S. generally accepted accounting principles for interim financial information. Accordingly, they do not include all the information and footnotes required by accounting principles generally accepted in the United States of America for annual financial statements. However, the information included in these interim consolidated financial statements reflects all adjustments (consisting solely of normal recurring adjustments) which are, in the opinion of management, necessary for the fair presentation of the consolidated financial position and the results of operations. Results shown for interim periods are not necessarily indicative of the results to be obtained for a full year. The consolidated balance sheet information as of December 31, 2011 was derived from the Company's audited consolidated financial statements. These interim consolidated financial statements should be read in conjunction with that report. Certain comparative amounts have been reclassified to conform to the current period's presentation.

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.

ATOSSA GENETICS INC.

(A DEVELOPMENT STAGE COMPANY)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

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 September 30, 2012 and December 31, 2011, $250,000 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). 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.

ATOSSA GENETICS INC.

(A DEVELOPMENT STAGE COMPANY)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

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 nine months ended September 30, 2012 and for the year ended December 31, 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 September 30, 2012 and December 31, 2011, management had identified no slow moving or obsolete inventory.

The Company provides 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 nine months ended September 30, 2012 and for the year ended December 31, 2011, selling expense of $36,741 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

Intangible assets:

For intangible assets subject to amortization, an impairment loss is recognized if the carrying amount of the intangible asset is not recoverable and exceeds fair value. The carrying amount of the intangible asset is considered not recoverable if it exceeds the sum of the undiscounted cash flows expected to result from the use of the asset. Intangible assets as of September 30, 2012 and December 31, 2011 were mainly software acquired for the purpose of managing laboratory results and patents acquired (see Note 7).

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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:

	September 30, 2012	December 31, 2011
Prepaid payroll taxes	$ 36,083	$ -
Prepaid insurances	2,472	14,146
Prepaid hardware/software maintenance and support service fee	1,420	12,850
Prepaid rent	-	4,188
	$ 39,975	$ 31,184

NOTE 5: RENTAL DEPOSITS

Rental deposits amounted to $1,500 and $2,200 as of September 30, 2012 and December 31, 2011, respectively, mainly consisted of the security deposits for office leases. The rental deposit in the amount of $1,500 as of September 30, 2012 consisted of one office lease with the lease term from April 1, 2011 to March 31, 2013 (see Note 13). The rental deposit of $2,200 as of December 31, 2011 consisted of two office leases separate from the one as of September 30, 2012, 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 September 30, 2012.

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NOTE 6: PROPERTY, PLANT, AND EQUIPMENT

Property, plant and equipment consisted of the following:

	September 30, 2012	December 31, 2011
Machinery and equipment	$ 86,465	$ 86,465
Less: Accumulated depreciation	(18,968)	(5,998)
Property, plant, and equipment, net	$ 67,497	$ 80,467

Depreciation expense for the nine months ended September 30, 2012 and 2011 was $12,970 and $3,920, respectively.

NOTE 7: INTANGIBLE ASSET

Intangible assets consisted of the following:

	September 30, 2012	December 31, 2011
Software	$ 50,466	$ 50,466
Patents	4,674,853	-
Less: Accumulated amortization	(22,241)	(9,625)
	$ 4,703,078	40,841

Intangible asset amounted to $4,703,078 and $40,841 as of September 30, 2012 and December 31, 2011, respectively, mainly consisted of patents acquired related to the asset purchase of Acueity in September 2012 and software previously acquired for the purpose of managing laboratory results. The acquired software in the amount of $50,466

for the purpose of managing laboratory results pursuant to a software installation agreement was entered into on June 8, 2011. The amortization period for the purchased software is 3 years. Amortization expense for the nine months ended September 30, 2012 and 2011 was $12,616 and $5,500, respectively.

Patents

Patents amounted to $4,674,853 and $0 as of September 30, 2012 and December 31, 2011, respectively, and mainly consisted of patents acquired from Acueity on September 30, 2012 in an asset purchase transaction (see Note 15). Patents will be amortized based on their determined useful life, and tested annually for impairment. The amortization period is from 9 to 14 years. Amortization expense related to patents was $0 for the nine months ended September 30, 2012 and 2011, respectively.

Future estimated amortization expenses as of September 30, 2012 for the five succeeding years is as follows:

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As of September 30,	Amounts
2013	$376,841
2014	371,341
2015	360,100
2016	360,019
2017	360,019
Thereafter	2,874,758
	$4,703,078

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 $250,000 and $1,000,000 as of September 30, 2012 and December 31, 2011, respectively. The adjustable annual interest rate for the line of credit was 2.9138% and 2.2070% as of September 30, 2012 and December 31, 2011, respectively. On October 22, 2012, the Company paid off the line of credit in full amount.

As of September 30, 2012 and December 31, 2011, $250,000 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:

	September 30, 2012	December 31, 2011
Accrued expenses	$ 1,744,555	$ 201,113
Accrued bonus payable	135,239	153,830
Accrued payroll tax liabilities	7,951	87,386
Accrued interest	599	-
	$ 1,888,344	$ 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.

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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).

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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 web site 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.

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 (the "Placement Agent Warrants"), 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 the earliest of the following to occur (the "Initial Exercise Date"):

(a) Six (6) months from the closing of the Company Initial Public Offering (initial public offering of the Company's Common Stock registered under the Securities Act),

(b) The closing of a "fundamental transaction" (in case of any reclassification, capital reorganization, exchange of shares, liquidation, recapitalization or change of the Common Stock, or in case of any consolidation or merger of the Company with or into another corporation or entity, or in case of any sale, lease or conveyance to another corporation or entity of all or substantially all of the assets of the Company), or

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(c) Closing of a "significant private financing" (sale of the Company's securities primarily for capital raising purposes in a transaction or series of related transactions that is exempt from registration under the Securities Act and in which the Company issues securities representing at least 20% of the then outstanding capital stock of the Company, calculated assuming the conversion or exercise of all outstanding options, warrants and other securities convertible into or exercisable for capital stock of the Company).

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. 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:

	April-June 2011	December 2011

	Fair Value Hierarchy Level	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 %

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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.

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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.

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- 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 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 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 Plan to members of the Board of Directors for their services provided to the Company.

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 September 30, 2012 and December 31, 2011 due to the Company’s continuing operating losses.

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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 September 30, 2012 and December 31, 2011, the Company had $418,570 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 nine months ended September 30, 2012, the Company incurred $38,403 of rent expense for the lease.

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 nine months ended September 30, 2012, the Company incurred $9,900 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 nine months ended September 30, 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 nine months ended September 30, 2012, the Company incurred $161,424 of rent expense for the lease, which included leasing office management expenses.

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The future minimum lease payments due subsequent to September 30, 2012 under all non-cancelable operating leases for the next five years are as follows:

As of September 30,	Amount
2013	$246,296
2014	246,575
2015	41,096
2016	-
2017	-
Thereafter	-
Total minimum lease payments	$533,967

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) and the Company. 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. A hearing in the arbitration is currently set for March 2013 but may be delayed to accommodate the other civil and criminal proceedings.

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. The specific amount of damages sought is to be proven at trial and not specified.

The Company is reasonably confident in its defenses to Mr. Kelly's claims. Consequently, no provision or liability has been recorded for Mr. Kelly's claims as of September 30, 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.

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(UNAUDITED)

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 September 30, 2012, and the accrued interest was $1,153 as of September 30, 2012. The principal balance of $79,300 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 Technology 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.

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 September 30, 2012.

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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 Technology 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 CTO. 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 CTO was $693,048, of which $492,095 was recorded to research and development expense. For the nine months ended September 30, 2012, salaries and bonuses of CEO and CTO amounted to $269,438 and $200,550, of which $134,719 and $200,550 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 CTO, 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 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.

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On September 1, 2011, 219,000 incentive stock options were granted under the 2010 Stock Option and Incentive 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 Stock Option and Incentive 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 Stock Option and Incentive 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.

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 $96,251 for the nine months ended September 30, 2012.

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 & CTO		Dr. Hunkapiller		Employees & Officers		Non-employee Directors		Non-employee Directors	
Date of grant	22-Jul-10		4-Apr-11		1-Sep-11		1-Sep-11		30-Apr-12	
Fair value of common stock on date of grant	$ 2.756	(B)	$ 0.906	(C)	$ 0.906	(C)	$ 0.906	(C)	$ 6.00	(D)
Exercise price of the options	$ 5.00		$ 1.25		$ 1.25		$ 1.25		$ 6.00	
Expected life of the options (years)	3.33		5.31		5.65		5.65		5.00	
Dividend yield	0.00	%	0.00	%	0.00	%	0.00	%	0.00	%
Expected volatility	58.59	%	54.12	%	53.90	%	53.90	%	62.46	%
Risk-free interest rate	1.03	%	2.26	%	1.08	%	1.08	%	0.89	%
Expected forfeiture per year (%)	0.00	%	0.00	%		(A)	0.00	%	0.00	%
Weighted-average fair value of the options (per unit)	$ 0.6744		$ 0.3729		$ 0.3579		$ 0.3579		$ 3.0367	

(A) 0.00% for the first year after the grant date, and 2.50% 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 in 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.

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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.

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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 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.

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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 September 30, 2012 and their activities during the nine 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	19,757	6.00	
Expired	-	-	
Forfeited	-	-	
Outstanding as of September 30, 2012	627,757	3.49	5.51
Exercisable as of September 30, 2012	508,632	3.21	6.02
Vested and expected to vest [1]	624,049	3.50	5.49

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

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As of September 30, 2012 and December 31, 2011, the aggregate intrinsic value of options outstanding, exercisable, and vested and expected to vest was $389,053 and $329,053, respectively.

A summary of the status of the Company's unvested shares as of September 30, 2012 and changes during the 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	19,757	60,000
Vested	(189,882)	(141,761)
Forfeited	-	-
Unvested as of September 30, 2012	119,125	$ 77,252

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 six 510(k) FDA cleared patents, 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 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 (see Note 16), 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

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 $3,455,000 after deducting underwriting discounts and commissions of approximately $545,000.

Management has evaluated subsequent events through December 14, 2012, the date which the consolidated financial statements were available to be issued. All subsequent events requiring recognition as of September 30, 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".

Up to 8,021,340 Shares of Common Stock

ATOSSA GENETICS INC.

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 13. Other Expenses of Issuance and Distribution.

The following table sets forth the costs and expenses, payable by the Company in connection with the registration and sale of the Common Stock being registered. All amounts are estimates except the SEC registration fee.

	Amount to be paid
SEC registration fee	$ 4,847
Printing expense	2,000
Legal fees and expenses	25,000
Accounting fees and expenses	5,000
Transfer Agent Fees	1,000
Miscellaneous Fees	2,153
Total	$ 40,000

Item 14. Indemnification of Directors and Officers.

Section 145 of the Delaware General Corporation Law, or the DGCL, authorizes a corporation to indemnify its directors and officers against liabilities arising out of actions, suits and proceedings to which they are made or threatened to be made a party by reason of the fact that they have served or are currently serving as a director or officer to a corporation. The indemnity may cover expenses (including attorneys' fees) judgments, fines and amounts paid in settlement actually and reasonably incurred by the director or officer in connection with any such action, suit or proceeding. Section 145 permits corporations to pay expenses (including attorneys' fees) incurred by directors and officers in advance of the final disposition of such action, suit or proceeding. In addition, Section 145 provides that a corporation has the power to purchase and maintain insurance on behalf of its directors and officers against any liability asserted against them and incurred by them in their capacity as a director or officer, or arising out of their status as such, whether or not the corporation would have the power to indemnify the director or officer against such liability under Section 145.

We have adopted provisions in our certificate of incorporation and bylaws that limit or eliminate the personal liability of our directors to the fullest extent permitted by the DGCL, as it now exists or may in the future be amended. Consequently, a director will not be personally liable to us or our stockholders for monetary damages or breach of fiduciary duty as a director, except for liability for:

- any breach of the director's duty of loyalty to us or our stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- any unlawful payments related to dividends or unlawful stock purchases, redemptions or other distributions; or
- any transaction from which the director derived an improper personal benefit.

These limitations of liability do not alter director liability under the federal securities laws and do not affect the availability of equitable remedies such as an injunction or rescission.

In addition, our bylaws provide that:

- we will indemnify our directors, officers and, in the discretion of our Board of Directors, certain employees to the fullest extent permitted by the DGCL, as it now exists or may in the future be amended; and
- we will advance reasonable expenses, including attorneys' fees, to our directors and, in the discretion of our Board of Directors, to our officers and certain employees, in connection with legal proceedings relating to their service for or on behalf of us, subject to limited exceptions.

We have entered into indemnification agreements with each of our directors and certain of our executive officers. These agreements provide that we will indemnify each of these directors and executive officers to the fullest extent permitted by Delaware law. We will advance expenses, including attorneys' fees, judgments, fines and settlement amounts, to each indemnified director, executive officer or affiliate in connection with any proceeding in which indemnification is available and we will indemnify our directors and officers for any action or proceeding arising out of that person's services as an officer or director brought on behalf of the Company or in furtherance of our rights.

We maintain general liability insurance that covers certain liabilities of our directors and officers arising out of claims based on acts or omissions in their capacities as directors or officers, including liabilities under the Securities Act.

Item 15. Recent Sales of Unregistered Securities

The Company has sold the following securities within the past three years which were not registered under the Securities Act of 1933:

Pursuant to an exemption from registration under Section 4(a)(2) of the Securities Act of 1933, as amended, as a transaction by an issuer not involving any public offering as founder shares in connection with the formation of the Company, the Company issued 4,899,888 shares of its Common Stock as follows:

	Shares	Date	Consideration
Steven Quay	883,662	April 30, 2009	$ 12,000
Ensisheim Partners LLC	1,767,316	April 30, 2009	(1)
Ensisheim Partners LLC	883,658	December 28, 2009	$ 100,000
Manistee Ventures, Inc.	1,325,487	April 30, 2009	$ 18,000
John Barnhart	39,765	July 28, 2009	$ 540

(1) The 1,767,316 shares of common stock issued to Ensisheim Partners LLC at the Company's inception were issued in consideration for $24,000 in cash and this entity's contribution to the Company of intellectual property rights and FDA marketing authorization for the MASCT System.

In January 2010, pursuant to an exemption from registration under Rule 504 pursuant to the Securities Act, the Company issued an aggregate of 901,354 shares of its common stock to 45 investors for aggregate cash proceeds of $102,000. Of these 45 investors, 13 are accredited investors and 4 are citizens and residents of Taiwan, Republic of China.

In January 2010, the Company issued 185,569 shares in consideration for services performed by two consultants, with an aggregate value of $21,000. This offering was exempt from registration under Rule 504 under the Securities Act.

On April 23, 2010, the Company issued 13,256 shares of common stock for services performed by a consultant with an aggregate value of $50,000. This offering was exempt from registration under Section 4(a)(2) of the Securities Act, as a transaction by an issuer not involving any public offering.

Between April 2011 and June 2011, the Company issued a total of 5,256,800 shares of the Company's common stock and warrants to purchase up to an additional 5,256,800 shares of common stock at a price of $1.25 per share, for aggregate gross proceeds of $6,571,000 (the "***Private Placement***"). All purchasers in the Private Placement were accredited investors, as defined under Regulation D under the Securities Act, and this offering was exempt from registration under Rule 506 under the Securities Act. In connection with the completion of the Private Placement, the Company issued common stock warrants to Dawson James Securities ("***Dawson James***"), the placement agent for the Private Placement, representing the right to purchase up to 788,520 shares of common stock at a price of $1.25 per share, plus the right to purchase up to 788,520 additional shares of common stock at a price of $1.60 per share. The issuance of the warrants to Dawson James was exempt from registration under Section 4(a)(2) of the Securities Act, as a transaction by an issuer not involving a public offering.

On September 30, 2012, in connection with its acquisition of substantially all of the assets of Acueity Healthcare, Inc. ("***Acueity***"), the Company issued to the stockholders of Acueity 862,500 shares of common stock 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 shares and warrants were issued as consideration for the assets acquired from Acueity: 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. The issuance of the shares and the warrants was exempt from registration under Section 4(a)(2) of the Securities Act, as a transaction by an issuer not involving a public offering. The Common Stock was valued at $5.00 per share and the warrants were valued at $2.3457 per warrant.

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 on 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.

On January 4, 2013, the Company issued options to purchase 500,000 shares of its common stock, exercisable at $4.11 per share which was the fair market value on the date of grant, to Kyle Guse as an inducement grant for the employment of Mr. Guse as the Company's Chief Financial Officer, General Counsel and Secretary. 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.

Item 16. Exhibits and Financial Statement Schedules.

See Exhibit Index set forth on page 104 to this Registration Statement.

Item 17. Undertakings.

The undersigned registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933;

(ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20 percent change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement.

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;

(2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(4) That, for the purpose of determining liability under the Securities Act of 1933 to any purchaser: each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A, shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness; *provided, however*, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use.

Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers, and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Seattle, State of Washington, on January 28, 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 constitutes and appoints Steven C. Quay, M.D., Ph.D. as attorney-in-fact, with power of substitution, in any and all capacities, to sign any and all amendments and post-effective amendments to this registration statement, and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that said attorney-in-fact, or his substitute or substitutes, may do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Act of 1933, this registration statement 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)	January 28, 2013
/s/ Kyle Guse **Kyle Guse**	Chief Financial Officer, General Counsel and Secretary (Principal Financial and Accounting Officer)	January 28, 2013
/s/ John Barnhart **John Barnhart**	Director	January 28, 2013

/s/ Shu-Chih Chen **Shu-Chih Chen, Ph.D.**	Director	January 28, 2013
/s/ Alexander Cross **Alexander Cross, Ph.D.**	Director	January 28, 2013
/s/ Stephen J. Galli **Stephen J. Galli, M.D.**	Director	January 28, 2013
/s/ H. Lawrence Remmel **H. Lawrence Remmel**	Director	January 28, 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
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
5.1	Opinion of Ropes & Gray LLP	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	Agreement with Christopher Benjamin	Registration Statement on Form S-1, as Exhibit 10.15	February 14, 2012
10.16	Business Consultant Agreement with Edward Sauter	Registration Statement on Form S-1, as Exhibit 10.16	February 14, 2012
10.17	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
10.18	Commercial Lease Agreement with Ensisheim Partners LLC, dated December 24, 2009	Registration Statement on Form S-1, as Exhibit 10.18	April 6, 2012
10.19	Termination of Lease Obligation with Ensisheim Partners LLC, dated July 21, 2010	Registration Statement on Form S-1, as Exhibit 10.19	April 6, 2012
10.20	Office Lease with Sander Properties, LLC, dated March 4, 2011	Registration Statement on Form S-1, as Exhibit 10.20	April 6, 2012
10.21	Office Lease with Sander Properties, LLC, dated July 8, 2011	Registration Statement on Form S-1, as Exhibit 10.21	April 6, 2012
10.22	Office Lease with Sander Properties, LLC, dated September 20, 2011	Registration Statement on Form S-1, as Exhibit 10.22	April 6, 2012

10.23	Sublease with Fred Hutchinson Cancer Research Center, dated December 9, 2011	Registration Statement on Form S-1, as Exhibit 10.23	April 6, 2012

10.24	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
10.25†	Term Sheet for License Agreement between the Company and Inven2 AS	Registration Statement on Form S-1, as Exhibit 10.25	June 25, 2012
10.26†	Agreement between the Company and Accellent Inc., dated August 8, 2011	Registration Statement on Form S-1, as Exhibit 10.26	June 25, 2012
10.27†	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
10.28†	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
10.29	Agreement between the Company and Biomarker LLC, dated June 22, 2012	Registration Statement on Form S-1, as Exhibit 10.29	June 25, 2012
10.30	Form of Investor Lock-Up Agreement	Registration Statement on Form S-1, as Exhibit 10.30	August 30, 2012
10.31†	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
10.31	Employment Agreement between the Company and Kyle Guse dated January 4, 2013#	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	
23.2	Consent of Ropes & Gray LLP	Filed as part of Exhibit 5.1	
24.1	Powers of Attorney	Included on the signature page in Part II	

# 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.