ATOSSA GENETICS INC
Form 10-K
March 27, 2014

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

FORM 10-K

(Mark one)

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

For the fiscal year ended December 31, 2013

OR

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

For the transition period from: to

Commission File Number 001-35610

ATOSSA GENETICS INC.
(Exact name of registrant as specified in its charter)

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

1616 Eastlake Ave. East, Suite 510
Seattle, WA 98102
(Address of principal executive offices)
Registrant's telephone number, including area code: **(800) 351-3902**

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

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

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

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

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

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer or a non-accelerated filer, as defined in Rule 12b-2 of the Exchange Act.

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

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

As of June 28, 2013, the last business day of the registrant’s most recently completed second fiscal quarter, the aggregate market value of the voting and non-voting common equity held by non-affiliates was $54,125,110.

The number of shares outstanding of the registrant's Common Stock, par value $0.001, as of March 24, 2014 was 24,428,568.

Documents Incorporated by Reference

Portions of the registrant's Proxy Statement, which will be filed with the Securities and Exchange Commission (SEC) pursuant to Regulation 14A in connection with the registrant's 2014 Annual Meeting of Shareholders, expected to be held on or about May 5, 2014, are incorporated by reference in Part III of this Form 10-K.

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NOTE REGARDING FORWARD-LOOKING STATEMENTS

Statements made in this report on Form 10-K that are not statements of historical information are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the ***"Securities Act"***) and Section 21E of the Securities Exchange Act of 1934, as amended (the ***"Exchange Act"***). We have made these statements in reliance on the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These statements are subject to certain risks and uncertainties, which could cause actual results to differ materially from those projected or anticipated. Although we believe our assumptions underlying our forward-looking statements are reasonable as of the date of this report we cannot assure you that the forward-looking statements set out in this report will prove to be accurate. We typically identify these forward-looking statements by the use of forward-looking words such as "expect," "potential," "continue," "may," "will," "should," "could," "would," "seek," "intend," "plan," "estimate," "an negative version of those words or other comparable words. Forward-looking statements contained in this report include, but are not limited to, statements about:

- Whether we will obtain in a timely manner clearance from the Food and Drug Administration to sell, market and distribute our MASCT System, which we also refer to as the ForeCYTE Breast Aspirator;
- our ability to successfully re-launch our ForeCYTE Breast Aspirator and NAF cytology test;
- the estimated costs associated with our product recall;
- our ability to successfully sell our products and services at currently expected prices or otherwise at prices acceptable to us;
- our ability to successfully develop and commercialize new tests, tools and treatments currently in development and in the time frames currently expected;
- our ability to maintain our business relationships, including with our distributors, suppliers and customers, while we are undergoing the recall we commenced in October 2013 and while we seek additional regulatory clearance to market, sell and distribute our ForeCYTE Breast Aspirator and NAF cytology test;
- our ability to engage third-party suppliers to manufacture the ForeCYTE Breast Aspirator, Microcatheter System, other devices under development and their components at quantities and costs acceptable to us;
- our ability to satisfy ongoing FDA requirements for the ForeCYTE Breast Aspirator, NAF cytology test and Microcatheter System and to obtain regulatory approvals and/or clearances for our other products and services in development, including our ability to timely and adequately respond to and ultimately close-out the Warning Letter we received from the FDA on February 21, 2013, and the inspectional observations and discussion points we received March 14,2014 and any issues resulting therefrom;
- our ability to defend the securities class action law suit filed against us on October 10, 2013, and other similar complaints that may be brought in the future, in a timely manner and within the coverage, scope and limits of our insurance policies;
- the benefits and clinical accuracy of NAF cytology test 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;
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the willingness of health insurance companies, including those who are members of the MultiPlan, FedMed and HealthSmart networks, and other third-party payors to approve our products and services for coverage and reimbursement;

- our ability to establish and maintain an independent sales representative force, including with our current and future distributors and their sub-distributors, to market our products and services that we may develop, both regionally and nationally;
- our expectations regarding, and our ability to satisfy, federal, state and foreign regulatory requirements;
- the accuracy of our estimates of the size and characteristics of the markets that our products and services may address;
- our expectations as to future financial performance, expense levels and liquidity sources;
- our ability to attract and retain key personnel; and
- our ability to sell additional shares of our common stock to Aspire Capital under the terms of our purchase agreement with them.

These and other forward-looking statements made in this report are presented as of the date on which the statements are made. We have included important factors in the cautionary statements included in this report, particularly in the section titled "ITEM 1A. 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 report. 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.

CORPORATE INFORMATION

Our corporate website is located at *www.atossagenetics.com* and our laboratory website is located at *www.nrlbh.com*. Information contained on, or that can be accessed through, our websites is not a part of this report. We make available, free of charge through our website or upon written request, our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and other periodic SEC reports, along with amendments to all of those reports, as soon as reasonably practicable after we file the reports with the SEC.

Unless otherwise noted, the term "Atossa Genetics" refers to Atossa Genetics Inc., a Delaware corporation, the terms "Atossa," the "Company," "we," "us," and "our," refer to the ongoing business operations of Atossa and its wholly-owned subsidiary, The National Reference Laboratory for Breast Health, Inc. (the "NRLBH"), whether conducted through Atossa Genetics or its subsidiary; however unless the context otherwise indicates, references to "we," "our" or the "Company" as they relate to our laboratory tests generally refers to the NRLBH. We were incorporated in Delaware in April 2009. Our principal executive offices are located at 1616 Eastlake Ave. East, Suite 510, Seattle WA 98102, and our telephone number is (800) 351-3902.

MASCT is our registered trademark and Oxy-MASCT and our name and logo are our trademarks. ForeCYTE, FullCYTE, NextCYTE, ForeCYTE Breast Aspirator and ArgusCYTE are our service marks. This report also includes additional trademarks, trade names and service marks of third parties, which are the property of their respective owners. You are advised to read this Annual Report on Form 10-K in conjunction with other reports and documents that we file from time to time with the Securities and Exchange Commission (the "SEC"). In particular, please read our definitive proxy statement, which will be filed with the SEC in connection with our 2014 Annual meeting of Stockholders, our Quarterly Reports on 10-Q and any Current Reports on Form 8-K that we may file from time to time. You may obtain copies of these reports after the date of this annual report from the SEC at the SEC's Public Reference Room at 100 F Street, N.E. Washington, D.C. 20549. In addition the SEC maintains information for electronic filers (including Atossa) at its website www.sec.gov. The public may obtain information regarding the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. We make our periodic and current reports available on our internet website, free of charge, as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC.

PART I

ITEM 1. BUSINESS

Overview

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

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

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

Our strategy consists of the following:

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

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

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

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

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

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

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

The NRLBH has been certified pursuant to the Clinical Laboratory Improvement Amendments, or CLIA. CLIA certification is legally required to receive reimbursement from federal or state medical benefit programs, like Medicare and Medicaid, and is a practical requirement for most third-party insurance benefit programs. Our CLIA-certified laboratory, which is permitted to accept samples from all 50 states under its CLIA certification, its state licenses, or, in New York under recognized exemption provisions while its license application is pending, examines the NAF specimens by cytological analysis.

On April 30, 2013, we entered into a Distribution and Marketing Services Agreement with Millennium Medical Devices LLC, pursuant to which, once we receive any necessary FDA clearances, Millennium will market and distribute the ForeCYTE Breast Aspirator in New York City and Northern New Jersey. In May 2013, we entered into a distribution agreement with Fisher Healthcare, a division of Fisher Scientific Company, LLC, and in September 2013, we entered into a distribution agreement with McKesson Medical Surgical.

From our inception (April 30, 2009) through our recall in October, 2013, we have received, processed, and reported the results to physicians from approximately 2,808 NAF samples processed and reported with our NAF cytology test (representing 1,404 patients). From inception through December 31, 2013, we have generated $1,115,900 in product and service revenue. We incurred net losses of $10,784,708 for the year ended December 31, 2013 and $20,516,614 since inception. 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; if cleared by the FDA, selling the ForeCYTE Breast Aspirator and generating laboratory service revenue from our tests performed by the NRLBH; and borrowing from stockholders or others when needed. However, we cannot assure you that we will be successful in accomplishing any of these plans and, if we are unable to obtain adequate capital, we could be forced to cease operations.

Our Voluntary Product Recall

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

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

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

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

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

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

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

Follow-up FDA Inspection

On March 14, 2014, the FDA completed a follow up inspection at our Seattle facility. A Form 483 was provided to us at the conclusion of the inspection. In the FDA's most recent Form 483, five inspectional observations were identified regarding our quality management system. The FDA inspector also verbally identified five additional discussion points related to our product labeling prior to the recall of the MASCT System; sufficiency of the content of our pending 510(k) submission for the ForeCYTE Breast Aspirator; and other compliance issues. On March 26, 2014, we submitted a response to the FDA, which included our proposed corrective actions to address the FDA's observations and discussion points. Whether the FDA will accept our response is uncertain, particularly in light of the similar nature of certain of the current inspectional observations to previous inspectional observations. If the FDA does not agree with our proposed corrective actions, or accepts them but finds that we have not implemented them adequately, or if we otherwise are found to be out of compliance with applicable regulatory requirements at a later date, the FDA could initiate an enforcement action including additional warning letters, fines and penalties. The FDA also may not clear our pending 510(k) for the ForeCYTE Breast Aspirator or our other devices and services under development. Any of the foregoing would have a material adverse effect on our business.

Our Common Stock Purchase Agreements with Aspire Capital Fund, LLC

On March 27, 2013, we entered into a stock purchase agreement with Aspire Capital Fund, LLC, or Aspire. Pursuant to that agreement we have sold common stock to Aspire with aggregate gross proceeds to us of approximately $11.3 million. On November 8, 2013 we terminated that agreement and entered into a new stock purchase agreement with Aspire.

The November 8, 2013 stock purchase agreement with Aspire provides that, upon the terms and subject to the conditions and limitations set forth therein, Aspire is committed to purchase up to an aggregate of $25 million of shares of our common stock (this amount is in additional to the proceeds we received from sales to Aspire under the March 27, 2013 agreement with them) over the 30-month term of the agreement. Before we can sell any shares under the agreement, we were required to register the shares and have the registration statement declared effective by the SEC. Other terms and conditions of the agreement are described below.

Concurrent with entering into the purchase agreement, we also entered into a registration rights agreement with Aspire. The registration rights agreement provides that the Company will file one or more registration statements, as

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

As described in more detail below, generally under the purchase agreement we have two ways we can elect to sell shares of common stock to Aspire on any business day we select: (1) through a regular purchase of up to 150,000 shares (but not to exceed $500,000) at a known price based on the market price of our common stock prior to the time of each sale, and (2) through a volume-weighted average price ("VWAP") purchase of a number of shares up to 30% of the volume traded on the purchase date at a price equal to the lesser of the closing sale price or 95% of the VWAP for such purchase date. Additionally, there are two milestone stock sales to Aspire described below.

Under the purchase agreement we issued 375,000 shares of our common stock to Aspire in consideration for entering into the purchase agreement (the "Commitment Shares"). The SEC declared the initial registration statement effective on December 13, 2013. Accordingly, on any business day on which the closing sale price of our common stock equals or exceeds $0.25 per share, over the 30-month term of the purchase agreement, we have the right, in our sole discretion, to present Aspire with a purchase notice directing Aspire to purchase up to 150,000 shares of our common stock per business day; however, no sale pursuant to such purchase notice may exceed $500,000 per business day. The purchase price per share, which we call the "Regular Purchase Price," is the lower of (i) the lowest sale price for our common stock on the purchase date or (ii) the arithmetic average of the three lowest closing sale prices for our common stock during the 12 consecutive business days ending on the business day immediately preceding the purchase date. The applicable purchase price will be determined prior to delivery of any purchase notice.

In addition, on any date on which we have submitted a purchase notice to Aspire in the amount of 150,000 shares, we also have the right, in our sole discretion, to present Aspire with a volume-weighted average price purchase notice, or a "VWAP Purchase Notice" directing Aspire to purchase an amount of our common stock equal to a percentage (not to exceed 30%) of the aggregate shares of common stock traded on the next business day subject to a maximum number of shares determined by us. The purchase price per share pursuant to such VWAP Purchase Notice shall be generally the lower of (i) the closing sale price on the purchase date, and (ii) 95% of the VWAP of our common stock traded on the Nasdaq Capital Market on the purchase day.

In addition to the regular purchase and VWAP purchase describe above, we are also obligated to sell, and Aspire is obligated to purchase, $1 million of our common stock upon the occurrence each of two milestone events, for total potential proceeds to us of $2 million. The first event is the filing by us with the FDA of a premarket notification (510k) covering the collection, preparation, and processing of nipple aspirate fluid specimens in regard to our NAF cytology test and the Mammary Aspiration Specimen Cytology Test device which occurred on December 23, 2013. The purchase price for this milestone event was based on the lower of $2.00 per share or the Regular Purchase Price of $2.34 on December 23, 2013. The second milestone event is the clearance by the FDA of the foregoing 510(k) application and the purchase price for the shares sold upon the occurrence of this milestone event is the lower of $4.00 per share or the Regular Purchase Price on the date of the event.

We have the right to sell up to $25 million of our shares of common stock to Aspire Capital during the term of our agreement with them, $1,000,000 of which had been sold as of the date of this report. We are obligated to register these shares with the SEC and have initially registered the Commitment Shares issued to Aspire Capital plus an additional 3,825,000 shares which we may sell to Aspire Capital in the future. Under the rules of the NASDAQ Capital Market, in no event may we issue more than 19.99% of our shares outstanding (which is approximately 3,528,199 shares based on 17,649,824 shares outstanding prior to the signing of the purchase agreement and is referred to as the "Exchange Cap") under the purchase agreement unless we obtain stockholder approval or an exception pursuant to the rules of the NASDAQ Capital Market is obtained to issue more than 19.99%. This limitation shall not apply if, at any time the Exchange Cap is reached and at all times thereafter, the average price paid for all shares issued and sold under the purchase agreement is equal to or greater than $1.99, which was the closing sale price of our Common Stock on November 7, 2013. We are not required or permitted to issue any shares of common stock under the purchase agreement if such issuance would breach our obligations under the rules or regulations of the NASDAQ Capital Market.

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

The purchase agreement contains customary representations, warranties, covenants, closing conditions and indemnification and termination provisions. The purchase agreement may be terminated by us at any time, at our discretion, without any cost or penalty. Aspire has covenanted not to cause or engage in any manner whatsoever, any direct or indirect short selling or hedging of our common stock. We did not pay any additional amounts to reimburse or otherwise compensate Aspire in connection with the transaction other than the commitment shares. There are no limitations on use of proceeds, financial or business covenants, and restrictions on future financings, rights of first refusal, participation rights, penalties or liquidated damages in the purchase agreement.

Our gross proceeds will depend on the purchase prices and the frequency of sales of shares to Aspire; provided, however, that the maximum aggregate proceeds from sales of shares is $25 million. As of the date of this report, we have sold $1,000,000 of common stock to Aspire under the November 2013 agreement with them. In connection with the financing we completed on January 29, 2014, we agreed not to utilize the facility with Aspire for 120 days from that date (other than the potential milestone sale of $1 million of common stock to Aspire upon receipt of a 510(k) clearance for the ForeCYTE Breast Aspirator). The actual maximum proceeds we receive from sales of stock to Aspire will depend on the price of our stock at the time of sales to Aspire. Our delivery of purchase notices will be made subject to market conditions, in light of our anticipated capital needs from time to time and under the limitations contained in the purchase agreement. We expect to use proceeds from sales of shares for general corporate purposes and working capital requirements.

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

Summary of Our Laboratory Tests, Devices and Therapeutics under Development

Tests being developed by the NRLBH include the following:

- Cytology Tests: these are cytological tests performed on NAF samples sent to the NRLBH, including NAF samples collected with our devices such as the ForeCYTE Breast Aspirator and ductal lavage samples collected with our microcatheters (these devices are subject to additional FDA clearances and are not currently available for sale in the United States). NAF specimens collected with our devices may be sent to any cytology laboratory for analysis.

- NextCYTE Breast Cancer Test: a test being developed for women newly diagnosed by their physician as having breast cancer that is a qualitative in vitro diagnostic test service, performed in a single laboratory, using the gene expression profile of formalin-fixed, paraffin embedded breast cancer tissue samples to assess a patient's risk for distant metastasis, chemotherapy response and lymph node involvement. It uses the Affymetrix GeneChip 2.0 and proprietary software to quantify and analyze the tumor genetic transcriptome, which represents genes that are being actively expressed within the tumor. This test is in the early validation phase and, if we receive FDA regulatory clearance we anticipate launching it in the fourth quarter of 2014 or the first quarter of 2015.

- ArgusCYTE Breast Health Test: a blood sample test for breast cancer survivors which provides information on the presence of circulating tumor cells. We completed the development of this test and conducted a limited trial launch in 2012. We are completing enhancements to this test and after receiving any necessary additional FDA clearances we plan to re-launch it in the fourth quarter of 2014 or the first quarter of 2015.

Our Medical Devices Under Development: These include our ForeCYTE Breast Aspirator and our intra ductal microcatheters for ductal lavage and for the potential administration of a targeted therapeutic. The ForeCYTE Breast Aspirator device consists 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 a testing laboratory, including the NRLBH. Pending FDA clearance, we plan to re-launch the ForeCYTE Breast Aspirator in the fourth quarter of 2014. Our intra ductal microcatheters and being developed for surgeons to collect NAF specimens through a ductal lavage process from the individual breast ducts of women who are at a high risk of developing breast cancer. We plan that the specimens will be sent to the NRLBH for NAF cytology testing. We plan to complete additional validation studies and obtain regulatory clearance of our manufacturing procedures and processes for the microcatheters in 2014 and to launch the test in the fourth quarter of 2014.

Therapeutic Program and Companion Diagnostics: We are also developing our patented microcatheters for the delivery of pharmaceutical formulations directly into the milk ducts. We plan to initially target DCIS, a condition diagnosed in more than 65,000 patients each year. 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. This program has not been approved by the FDA. We plan to identify a partner for the clinical development of the pharmaceutical to be used with our device in mid-2014. We also plan to develop our medical devices and laboratory tests as companion diagnostics to pharmaceutical therapies to treat women at high risk of breast cancer and for the treatment of conditions known as proliferative epithelial disease (PED). These programs are in the early pre-clinical stage and will require testing and approval and/or clearance from the FDA prior to commercialization.

Our Diagnostic Tools

In 2012 we acquired the rights from Acueity to manufacture, use and sell a number of diagnostic tools, including: the Viaduct Miniscope and accessories, the Manoa Breast Biopsy system, the Excisor Bioptome, the Acueity Medical Light Source, the Viaduct Microendoscope and accessories. We also acquired cash in the amount of $400,000. The microendoscopes are less than 0.9 mm outside diameter and can be inserted into a milk duct. This permits a physician to pass a microendoscope into the milk duct system of the breast and view the duct system via fiberoptic video images. Abnormalities that are visualized can then be biopsied from inside the duct with the biopsy tools that are inserted adjacent to the microendoscope. Based on a recent periodic review of the Acueity patent estate, these tools are covered by 15 issued patents (13 U.S. patents, one U.K. patent and one German patent). We did not, however, acquire an inventory of these diagnostic tools, manufacturing capabilities or any personnel to market and sell the tools.

Following the launch of our four diagnostic tests in the United States, we will then begin to allocate human and financial resources to further develop and ultimately commercialize these medical devices. We intend to complete the steps necessary to begin marketing and selling these tools, such as re-establishment of the supply chain of component parts, securing manufacturers, performing test builds and commercial scale manufacturing, in 2015. This asset purchase is not expected to have an impact on the development and commercialization timetables of our existing product lines. We cannot, however, provide any assurances that delays related to the launch of our four diagnostic tests, independent of the asset purchase, would not delay the expected development of these diagnostic tools or that we will ultimately be successful selling these tools.

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

Therapeutic Programs under Development

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

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

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

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

We intend to build on these academic studies with a research program targeted initially as neoadjuvant therapy in DCIS and to begin preclinical studies during 2014. We may partner with a third party to provide the pharmaceutical for the program. However, we have not as of the date of this report contracted with such a partner nor have we begun the process of applying for FDA approval of our Intraductal Treatment Research Program.

Our National Launch Through Distributors

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.

On April 30, 2013, we entered into a Distribution and Marketing Services Agreement with Millennium Medical Devices LLC, pursuant to which Millennium will market and distribute our NAF cytology test kits in New York City and Northern New Jersey. In May 2013, we entered into a distribution agreement with Fisher Healthcare, a division of

Fisher Scientific Company, LLC, and in September 2013 we entered into a distribution agreement with McKesson Medical Surgical. Although we entered into distribution agreements with DTG, Fisher Healthcare, Millennium Healthcare and PSS Medical Surgical, they may not be successful in selling our products and we may not achieve any level of commercial success from their efforts. The current recall of the MASCT System may cause our distributors to terminate our agreements with them or otherwise cause them not to sell our ForeCYTE devices or other products.

Reimbursement Organizations

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

Our agreements with reimbursement organizations will give their participating providers and their patients greater access to our tests, including our NAF cytology test once ForeCYTE Breast Aspirator is cleared by the FDA and becomes available. We anticipate that these agreements will help ensure that more doctors and their patients have access to our tests and that patients will receive insurance reimbursement for the laboratory costs associated with these tests.

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

The MASCT System and ForeCYTE Breast Aspirator

Overview of the Device

The product components of the MASCT System (now called the ForeCYTE Breast Aspirator) 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 any testing laboratory for cytological analysis, including the NRLBH, our wholly-owned, CLIA-certified specialized cytology and molecular diagnostics laboratory in Seattle, Washington.

Clinical Development of the Device

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 using the MASCT System. 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 for cytology testing.

On December 23, 2013, we submitted a new premarket notification 510(k) to FDA for the ForeCyte Breast Aspirator which is a modified version of our already FDA-cleared MASCT System. We have also prepared a study showing that the ForeCYTE Breast Aspirator device has been used clinically to collect 1,364 NAF specimens from 687 patients between January 2, 2013 and September 30, 2013. Eight specimens were unsatisfactory for cytological analysis according to licensed, trained cytotechnologists and this designation was confirmed by licensed pathologists. This yielded a performance of 99.4% for the collection of nipple aspirate fluid specimens by the ForeCYTE device for cytological testing. The ForeCYTE Breast Aspirator has the same intended use and indications, and similar technological characteristics, and principles of operation as its predicate device.

NAF cytology Testing

The NRLBH provides NAF cytology testing, which is an LDT consisting 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. The NAF samples collected with our devices may be sent to any laboratory for analysis. The NAF cytology test also involves one biomarker of sample integrity and has been validated to CLIA standards. NAF cytology testing may be performed by the NRLBH on NAF samples collected by means other than our devices, including, for example, NAF collected by a device being sold by Halo Healthcare, Inc.

The cytology and molecular diagnostics testing and analysis services are billed to federal and/or state health plans at the Medicare reimbursement rates which have historically been either $344 or $729 per patient, depending on the complexity of the analysis performed. We expect that the substantial majority of Medicare patients will be billed at the $344 rate and that we would perform the more complex tests, corresponding with a reimbursement rate of $729, for only those patients who have an initial test result that requires further analysis. 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 device 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 NAF cytology test.

The ArgusCYTE Breast Health Test

The ArgusCYTE test is being developed by the NRLBH to provide 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. We are currently seeking a new supplier of the blood tubes. The ArgusCYTE test consists of a two-step “Combination-of-Combinations-Principle” involving (1) cell isolation, whereby tumor cells are enriched by a three antibody-mix linked to magnetic particles and mRNA is isolated from the selected tumor cells, and (2) molecular biological detection and analysis, whereby the isolated mRNA is transcribed into cDNA and a multiplex PCR is carried out for the analysis of epithelial cell related transcripts and tumor associated gene expression. Due to the combination of different selection and tumor markers, both the heterogeneity of the tumor cells and possible individual or therapy-induced deviations in the expression patterns are taken into account.

As far as we know, the ArgusCYTE test is the only CLIA-certified circulating breast tumor cell test 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.

The NRLBH is currently developing an improved version of the ArgusCYTE Test and plans to reintroduce it to the market later in the fourth quarter of 2014 or the first quarter of 2015.

Ductal Lavage Cytology Testing and our Microcatheters

The NRLBH is also developing a cytology test on the ductal lavage fluid collected by physicians using our patented Mammary Duct Microcatheter System, invented by Dr. Susan Love, author, breast surgeon, and founder of the Dr.

Susan Love Research Foundation, Santa Monica, California. These microcatheters are designed to lavage, or irrigate, each of the five to seven breast ducts and to collect the lavage fluid. The collected fluid may then be analyzed by a laboratory, including the NRLBH, for 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, 25 U.S. issued patents and at least 76 issued foreign counterparts (in for example, 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 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 obligated 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; and for the collection of cells and/or fluid for cytological analysis. We plan to seek additional 510(k) clearances from the FDA for the micro catheters before commercialization.

This project is in the research and development phase, and we have 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.

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 research and commercialization. The agreement divided the development work into three phases with a fixed time and budget for each phase. In aggregate, the budget to complete all phases is approximately $713,000. The agreement also contains a fixed price schedule for manufacturing the microcatheter following commercial launch. The price schedule contains a volume-based reduction in the cost per microcatheter.

The NextCYTE Breast Cancer Test

The NextCYTE Breast Cancer Test, which is in the validation phase and which we intend to launch in the fourth quarter of 2014 or the first quarter of 2015 after receiving any necessary FDA clearance, is being developed by the NRLBH to profile breast cancer specimens for prediction of chemotherapy response, recurrence and lymph node involvement. It involves using surgery specimens and advanced genome sequencing techniques using the Affymetrix GeneChip 2.0 to quantify and analyze the tumor genetic transcriptome, which represents the genes that are being actively expressed within the tumor. Because our NextCYTE test analyzes traditional biopsy specimens using advanced genome sequencing techniques, we believe that other present methods of analyzing traditional biopsy specimens would not achieve results similar to or better than results provided by our NextCYTE test and we expect that physicians will be able to use the information provided by the NextCYTE test to better customize treatment options for women, based on the genetic composition of the individual tumor. The NextCYTE Breast Cancer Test is intended to use microarray-based genome-wide transcriptome data from surgical breast cancer biopsy specimens to predict a patient's 10-year survival probability and response to treatment. The algorithm was created from 2,400 unique genome-wide microarrays and validated against a separate sample of over 1,600 microarray data sets. A correct classification was obtained for over 85% of both estrogen receptor negative and positive tumors. We have an exclusive license outside the European Union for the intellectual property related to the software and have filed two patent applications in the United States covering certain aspects of the algorithm. This test is in the validation stage. We plan to complete a clinical trial and, if we receive the necessary clearances from the FDA, intend to launch this product in the fourth quarter of 2014 or the first quarter of 2015. The FDA could require clinical data before clearing or approving this test which would delay or prevent us from receiving regulatory clearance or approval.

In September 2013, we entered into an "OwnerChip Program Agreement" with Affymetrix, Inc, a manufacturer of GeneChip Systems, where Affymetrix has agreed to loan a GeneChip System 3000Dx v.2 to us if we purchase and take delivery of a minimum thirty GeneChip Human Gene U133 Plus 2.0 (30-pack) arrays at $21,590 per 30 pack for the next three years for a total purchase obligation of $647,700 with a minimum purchase of ten 30-pack arrays per contract year. At the end of the three year contract, upon fulfillment of the purchase commitment, the instrument title and ownership transfer to us at no additional cost. In addition to the GeneChip, we must purchase a two year service contract for $51,600 to cover maintenance of the instrument during the contract period. We placed an order for four 30-pack arrays for the year ended December 31, 2013 for $94,723. We are obligated to purchase 26 additional arrays during the three year contract term.

On June 10, 2013, we entered into an irrevocable license and service agreement with A5 Genetics KFT, Corporation, pursuant to which we received the world-wide (other than the European Union) exclusive license to the software used in the NextCYTE test. We have the right to prosecute patents related to this software, two of which we have filed in the United States. The patent applications have been assigned to us. We paid a one-time fee of $100,000 to A5 Genetics in 2013 and in March 2014 we completed software validation and paid an additional $100,000 to A5 Genetics. We are obligated to pay up to an additional $1.2 million to A5 Genetics upon the achievement of future milestones. We must also pay a royalty of $50 for each NextCYTE Test performed and $65 as a service fee for each NextCYTE Test performed. The agreement terminates on the later of the ten year anniversary of the agreement or the expiration of the latest to expire patent covering the software.

The Market

United States Market for the ForeCyte Breast Aspirator

The Company expects that the ForeCYTE Breast Aspirator will initially be adopted by physicians and other healthcare professionals for use in women who are undergoing other testing.

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. 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. We believe that physicians may consider prescribing the NAF cytology test to these women undergoing a diagnostic mammogram, because they will have an increased concern over breast health.

Breast Cancer Survivors. The American Cancer Society, or ACS, has estimated that as of 2012, there were approximately 2.9 million breast cancer survivors in the United States. The Company believes these women and their healthcare providers will have an increased concern over breast health and will consider taking the NAF cytology test.

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. We believe that women who are tested by their physicians as being at high risk for breast cancer will also consider the NAF cytology test because of their increased concern over breast health.

United States Market for ArgusCYTE Test

The American Cancer Society has estimated that, as of 2012, there were more than 2.9 million breast cancer survivors, who we believe would be potential candidates for the ArgusCYTE Test.

United States Market for NextCYTE Test

According to the National Cancer Institute, approximately 232,340 women are diagnosed with breast cancer each year and approximately $16.5 billion is spent each year in the United States on breast cancer treatment. Most of these women would be candidates for the NextCYTE Test.

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.

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.

Commercialization Strategy for the ForeCYTE Breast Aspirator

We plan to obtain FDA clearance for the ForeCYTE Breast Aspirator, our lead medical device, and then to re-launch it through a direct sales force and our distributors, including Fisher Healthcare and PSS McKesson. NAF samples collected with our devices may also be sent to any cytology laboratory for analysis. We also plan to perform cytology testing at our laboratory on NAF samples collected with our device or collected through other means and sent to our laboratory.

Our commercialization strategy is based on creating two main revenue sources: (i) product sales-based revenue from the sale of the ForeCYTE Breast Aspirator, including the NAF specimen collection kits, to physicians, breast health clinics, mammography clinics and distributors, and (ii) service-based revenue generated by the NRLBH for the preparation and interpretation of the NAF samples sent to the NRLBH. This is intended to result in revenue from both the sale and the use of the ForeCYTE Breast Aspirator.

In order to achieve its two-pronged revenue base, we manufacture, through medical device suppliers, the ForeCYTE Breast Aspirator components (i.e., the collection device and patient NAF specimen kits) and we will establish a network of direct sales representatives and distributors to call on physicians and breast health and mammography clinics to market and sell the ForeCYTE Breast Aspirator. The collection device is reusable when sanitized between patients. The kit contains the patient contact materials, 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.

If we re-launch the ForeCYTE Breast Aspirator, we may provide a cost-rebate to the physician to encourage early adoption. The cytology and molecular diagnostics testing and analysis services are billed to federal and/or state health plans at the Medicare reimbursement rates of either $344 or $729 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 Medicare patients will be billed at the $344 rate and that we would perform the more complex tests, corresponding with a reimbursement rate of $729, 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 ForeCYTE Breast Aspirator or for other NAF collection device systems similar to our device, 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 NAF cytology 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 ForeCYTE Breast Aspirator, which may result in physicians and other healthcare professionals not using our device or recommending its use in patients. If this were to occur, we may be forced to reduce the price of the device, provide discounted pricing arrangements to secure sales, or

we may not be able to sell the product and services components of the ForeCYTE Breast Aspirator at acceptable margins, all of which could limit our ability to generate revenue.

Our product- and service-based income plan is intended to provide revenue from multiple, different sources with different timing in the procedure cycle. We expect 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 ForeCYTE Breast Aspirator and its related laboratory diagnostic services, we will need to contract with distributors as well as hire sales representatives with technical knowledge in, for example, molecular diagnostics, mammography, obstetrics/gynecology office practices, and women's health clinics. As a result, we expect our 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 ForeCYTE Breast Aspirator 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.

Distributors

We have entered into U.S. distributorship arrangements with DTG, Millennium, Fisher and PSS McKesson. Our distributors may not, however, be successful in selling our products and we may not achieve any level of commercial success from their efforts. The current recall of the MASCT System may cause our distributors to terminate our agreements with them or otherwise cause them not to sell our ForeCYTE Breast Aspirator or other products.

The National Reference Laboratory for Breast Health

We have 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, NextCYTE tissue samples and ArgusCYTE blood samples. We believe that by maintaining our own clinical laboratory, we will be positioned to generate substantial additional service revenue through cytology and molecular diagnostic testing, in addition to the sale of the ForeCYTE Breast Aspirator pumps and specimen collection kits. The NRLBH may employ its own direct sales force, or contract with third parties, to sell the services and tests provided by the NRLBH.

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

Growth Strategy

We plan to market the ForeCYTE Breast Aspirator, if cleared by the FDA, nationally through our distributors and our own direct sales representatives. We plan to market our laboratory services through sales representatives of the NRLBH and through contracted parties.

Research and Development

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. It is comprised of costs incurred to develop new technology and carry out clinical studies and include salaries and benefits, reagents and supplies used in R&D laboratory work and rent expenses. Research and Development expenses for the year ended December 31, 2013 and 2012 were $1,105,110 and $1,974,013.

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

Other Research Programs Companion Diagnostics

We are researching the use of certain of our devices and laboratory services as companions to pharmaceutical therapies. For example, we are researching potential companion diagnostics that would (1) use our ForeCYTE Breast Aspirator and laboratory testing to assist in the identification of women at high risk for breast cancer and/or woman with peripheral epithelial disease (PED), (2) provide a pharmaceutical treatments of those conditions, and (3) use our ForeCYTE Breast Aspirator and laboratory testing to monitor treatment response. We must perform a significant amount of additional work prior to commercializing any companion diagnostics, including, for example, developing or otherwise procuring a pharmaceutical candidate alone or with partners, performing pre-clinical studies, developing a clinical trial protocol, successfully completing clinical trials and obtaining FDA approval. We may not be successful in completing any of these tasks or other steps necessary to successfully develop and launch any companion diagnostics.

Billing and Reimbursement

Billing for the ForeCYTE Breast Aspirator and the NAF Collection Procedure

Medicare and certain insurance carriers do not currently cover the cost of collecting the NAF sample. We intend to work with physicians and other interest groups to attempt to obtain coverage for the NAF collection procedures but this process can be lengthy, costly, and might not be successful. Failure to receive reimbursement for the collection process could limit the adoption and utilization of the ForeCYTE Breast Aspirator and our NAF cytology test. Because the process can be done by a nurse or physician's assistant, takes less than ten minutes, and the ForeCYTE Breast Aspirator supplies will contain materials to obtain, label, and ship the NAF samples, we expect the physician 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 NAF cytology test and from insurance carriers for the ArgusCYTE test. Billing for diagnostic services is generally complex. As a result, we rely on a third-party billing company to perform all of our billing and collection services. Laboratories must bill various payors, such as private insurance companies, managed care companies, governmental payors such as Medicare and Medicaid, physicians, hospitals, and employer groups, each of whom may have different billing requirements. We expect to be obligated to bill in the specific manner prescribed by the various payors. Additionally, the audit requirements that must be met to ensure compliance with applicable laws and regulations, as well as internal compliance policies and procedures, add further complexity to the billing process. Other factors that complicate billing include:

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

In general, we perform the requested tests and report test results even if the billing information is incorrect or missing. We will subsequently attempt to obtain any missing information and correct incomplete or erroneous billing

information received from the healthcare provider. Missing or incorrect information on requisitions adds complexity to and slows the billing process, creates backlogs of unbilled requisitions, and generally increases the aging of accounts receivable and the length of time to recognize revenue. When all issues relating to the missing or incorrect information are not resolved in a timely manner, the related receivables will be written off to the allowance for doubtful accounts.

Reimbursement

Depending on the billing arrangement and applicable law, the party that reimburses us for our services will be (i) a third party who provides coverage to the patient, such as an insurance company, managed care organization, or a governmental payor program such as Medicare; (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.

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

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

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

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

In billing Medicare, we are required to accept the lowest of: our actual charge, the fee schedule amount for the state or local geographical area, or a national limitation amount, as payment in full for covered tests performed on behalf of Medicare beneficiaries. Payment under the laboratory fee schedule has been limited by Congressional action such as freezes on the otherwise applicable annual Consumer Price Index, or CPI, update to the fee schedule amount. For example, the CPI update of the laboratory fee schedule for 2013 was minus 2.5%.

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

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

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

Reimbursement Strategy

CPT Code for ForeCYTE Breast Aspirator NAF Collection Procedure

The NAF collection procedure of the ForeCYTE Breast Aspirator 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 NAF 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 2013 at either $344 or $729, depending on the complexity of the test.

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

Intellectual Property

As of the date of this report, and based on a recent periodic review of our patent estate, we own 137 issued patents (45 in the United States and at least 92 in foreign countries), and 11 pending patent applications (9 in the United States and 2 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. Our patent estate consists primary of the following;

Description	United States Issued [1]	Expiration	Pending [1]	Foreign/PCT Issued [1]	Expiration	Pending
ForeCYTE Breast Aspirator	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
Acueity Tools	13	2015-2028	0	2	2015-2028	0

(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 ForeCYTE Breast Aspirator will compete in the medical device product industry with Halo Healthcare (formerly, 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 ForeCYTE Breast Aspirator compared to the Neomatrix device include a lower acquisition cost and portability. The disadvantages of the ForeCYTE Breast Aspirator 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 ForeCYTE Breast Aspirator, the technical expertise provided by our focus on diagnoses utilizing NAF, service-focused relationships with referring physicians, and our advanced technology. The 510(k) clearance we are seeking for the ForeCYTE Breast Aspirator does not prohibit the NAF specimens collected with our device from being sent to and processed by other laboratories. However, we do have patent and other intellectual property protection on certain aspects of NAF collected, transported and processed with our device.

Laboratories that could process NAF samples whether or not they were collected with the ForeCYTE Breast Aspirator 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 other than cytological assessment.

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.

Diagnostic Tools Provided by Others. We do not promote our devices and tests as alternatives to other established diagnostic tests. We anticipate that the ForeCYTE Breast Aspirator 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 and because we do not plan to promote our device and tests as alternatives to these established diagnostic tests. In addition, although we do not plan to promote our devices and tests as alternative to mammography, physicians and other medical professionals may view the ForeCYTE Breast Aspirator as a screening tool for existing breast cancer, like mammography, rather than as an adjunctive procedure to mammography. As a result, the ForeCYTE Breast Aspirator could be deemed to compete directly with mammography, an established procedure, which could impair market adoption of the ForeCYTE Breast Aspirator. The advantages of the ForeCYTE Breast Aspirator 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 ForeCYTE Breast Aspirator compared to ultrasound, mammography, and MRI include the fact that we don't anticipate that our ForeCYTE Breast Aspirator will be cleared by the FDA to detect cancer. The advantage of the ForeCYTE Breast Aspirator 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 ForeCYTE Breast Aspirator 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 ForeCYTE Breast Aspirator and the testing of collected NAF samples, we will 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.

Potential Competition for the Acueity tools includes Solos Endoscopy's Mammo View. Potential competition for our NextCYTE Test under development include: OncoType DX offered by Genomic Health, Inc., MammaPrint offered by Agendia, Inc., and tests run on the PAM50 system offered by NanoString, Inc.

Information Systems

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

Government Regulation

United States Medical Device Regulation

The Federal Food, Drug, and Cosmetic Act, or FDCA, and the FDA's implementing regulations, govern registration and listing, manufacturing, labeling, storage, advertising and promotion, sales and distribution, and post-market surveillance. Medical devices and their manufacturers are also subject to inspection by the FDA. The FDCA,

supplemented by other federal and state laws, also provides civil and criminal penalties for violations of its provisions. We manufacture and market a medical device that is regulated by the FDA, comparable state agencies and regulatory bodies in other countries. We also operate a clinical and diagnostic laboratory which uses reagents and test kits some of which are regulated medical devices.

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

Most Class I devices, including the laboratory staining kits and reagents we use, and some Class II devices are exempted by regulation from the 510(k) clearance requirement and can be marketed without prior authorization from FDA. Class I and Class II devices that have not been so exempted are eligible for marketing through the 510(k) clearance pathway. By contrast, devices placed in Class III generally require premarket approval, or PMA, approval prior to commercial marketing. To obtain 510(k) clearance for a medical device, an applicant must submit a premarket notification to the FDA demonstrating that the device is "substantially equivalent" to a predicate device legally marketed in the United States. A device is substantially equivalent if, with respect to the predicate device, it has the same intended use and (i) the same technological characteristics, or (ii) has different technological characteristics and the information submitted demonstrates that the device is as safe and effective as a legally marketed device and does not raise different questions of safety or effectiveness. A showing of substantial equivalence sometimes, but not always, requires clinical data. 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.

We expect that each of our devices under development will require clinical trials to support a 510(k) submission. We also expect that our intra ductal treatment program and any companion diagnostics that we develop will require a PMA prior to commercialization.

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; and
- criminal prosecution.

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

We received a Warning Letter ("Warning Letter") from the FDA on February 21, 2013, regarding our MASCT System and MASCT System Collection Test (together, the "System"). The Warning Letter arose from certain FDA findings during a July 2012 inspection. A Form FDA 483 was issued at the end of that inspection. We responded in August 2012, and explained why we believed we are in compliance with applicable regulations and/or were implementing changes responsive to the findings of the FDA inspection. FDA issued the Warning Letter after the agency reviewed our response to the inspection. The FDA alleged in the Warning Letter that following 510(k) clearance we changed the System in a manner that requires submission of an additional 510(k) notification to the FDA. Specifically, the FDA indicated that the Instructions For Use (IFU) in the original 510(k) submission stated that the user must "Wash the collection membrane with fixative solution into the collection vial…" and the current IFU states "…apply one spray of Saccomanno's Fixative to the collection membrane…" and that "this change fixes the NAF specimen to the filter paper rather than washing it into a collection vial." At the time that the changes were made we determined that a new 510(k) was not required in accordance with the FDA's guidance document entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device."

The Warning Letter also raised certain issues with respect to our marketing of the System and our compliance with FDA Good Manufacturing Practices (cGMP) regulations, among other matters.

We responded to the Warning Letter on March 13, 2013, and November 14, 2013, indicating the current actions taken and the timing of commitments we have made for future actions. We believe we have adequately addressed the issues raised in the Warning Letter. However, the FDA could disagree and direct other compliance-verification activities or take other actions in connection with matters raised in the Warning Letter, related to our response, and in connection with other matters that the FDA could identify in the future, including items that the FDA could identify in additional inspections of our facilities. For example, the FDA issued observations to us on form 483 and made verbal observations resulting from an inspection of our facility that concluded on March 14, 2014. Until these issues are resolved we may be subject to additional regulatory action by the FDA, and any such actions could disrupt our ongoing business and operations. Our business will be adversely affected if we cannot timely resolve the matters

raised in the Warning Letter, or other matters raised by the FDA, to the FDA's satisfaction.

We are reasonably confident in our responses to the FDA. Consequently, no provision or liability has been recorded as of December 31, 2013, as a result of the Warning Letter. However, it is at least reasonably possible that our estimate of related liability may change in the near term. Any payments by reason of an adverse determination in this matter will be charged to earnings in the period of determination.

CLIA and State Regulation

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

In addition to CLIA requirements, we and the NRLBH are subject to various state laws. CLIA provides that a state may adopt laboratory regulations that are more stringent than those under federal law, and a number of states, including Washington, where the NRLBH 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. On January 14, 2014, we applied for CAP certification.

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

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

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

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

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

of confidential health information or other private personal information.

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

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

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

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

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

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

Federal and State Fraud and Abuse Laws

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

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

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

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

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

Physician Referral Prohibitions

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

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

We estimate that less than 5% of our revenues in 2013 have been generated from Medicare billings. We may decide that to reduce the cost associated with complying with the above and other regulations, and to reduce the risk and potential costs of any non-compliant activities, in the future we may decide to stop billing Medicare for our services.

Discriminatory Billing Prohibition

In response to competitive pressures, we will be increasingly required to offer discounted pricing arrangements to managed care payors and physicians and other referral services. Discounts to referral sources raise issues under the Anti-Kickback Statute. Any discounted charge below the amount that Medicare or Medicaid would pay for a service

also raises issues under Medicare's discriminatory billing prohibition. The Medicare statute permits the government to exclude a laboratory from participation in federal healthcare programs if it charges Medicare or Medicaid "substantially in excess" of its usual charges in the absence of "good cause." In 2000, the OIG stated in informal correspondence that the prohibition was violated only if the laboratory's charge to Medicare was substantially more than the "median non-Medicare/ Medicaid charge." On September 15, 2003, the OIG issued a notice of proposed rulemaking addressing the statutory prohibition. Under the proposed rule, a provider's charge to Medicare or Medicaid would be considered "substantially in excess of [its] usual charges" if it was more than 120% of the provider's mean or median charge for the service. The proposed rule was withdrawn in June 2007. At that time, the OIG stated that it would continue to evaluate billing patterns of individuals and entities on a case-by-case basis.

Corporate Practice of Medicine

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

State Laboratory Licensure

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

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

Referrals after Becoming a Public Company

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

Other Regulatory Requirements

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

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

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

The FDA has conducted public hearings to discuss oversight of LDTs. While the outcome of those hearings is unknown, it is probable that some form of pre-market notification or approval process will become a requirement for

certain LDTs. Pre-market notification or approval of our future LDTs would be costly and delay our ability to commercialize such tests.

Compliance Program

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

Legal Proceedings

“See Part 1, Item 3. Legal Proceedings” in this report which is incorporated into this Part 1, Item 1 by this reference.

Employees

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

Insurance

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

Implications of being an Emerging Growth Company

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

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

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

Scientific and Industry Background

Breast Anatomy and Nipple Aspirate Fluid Collection

The female breast has two main components: milk-producing, or glandular, tissue (lobes and ducts) and connective/fatty tissue. The breast is divided into 5 to 8 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 ForeCYTE Breast Aspirator is 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

Proliferative epithelial disease (PED) in the breast includes a number conditions marked by an increase in the growth of epithelial cells. Those conditions include ductal hyperplasia and lobular hyperplasia. The presence of PED may lead to increased risk of 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, according to a study by Dupont *et al.* it produces up to a 4.3 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 Role of Immunohistochemistry (IHC) in the Molecular Classification of Breast Cancer and Pre-Cancerous Lesions

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

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

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

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

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

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

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

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

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

Drug therapy clinical trials for preventing breast cancer in high risk women are called chemoprevention trials. In a five-year chemoprevention study of over 19,700 women with ADH or other factors that placed them at a high risk for

invasive breast cancer, the use of either tamoxifen or raloxifene, drugs that block or interfere with the actions of estrogen receptors, reduced the incidence of breast cancer by approximately 50%. A separate study of raloxifene versus placebo showed a 72% reduction in cancer incidence at four years and a 66% reduction at eight years in women at high risk for invasive breast cancer.

In a study of NAF specimens in 33 women at the start and six months after taking either tamoxifen or raloxifene, NAF cytology was unchanged in 85%, worsened in 4%, and improved in 11% while the biomarker PSA, which has been shown to be controlled by sex hormones and inversely associated with breast cancer, increased from abnormally low (37 ng/L) to within the normal range (112 ng/L) during treatment. United States patent 7,128,877, owned by the Company, covers a sample collection device for collecting NAF, wherein the NAF is positive 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.

Our NAF cytology test and the ForeCYTE Breast Aspirator are not cleared or approved by the FDA as a risk assessment device.

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 was associated with a 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). Therefore, the source of CTCs and their dissemination would have been removed, which is then associated with the disappearance of CTCs from blood.

ITEM 1A. RISK FACTORS

In addition to other information in this report, the following factors should be considered carefully in evaluating an investment in our securities. If any of the following risks actually occur, our business, financial condition and results of operations would likely suffer. In that case, the market price of the common stock could decline, and you may lose part or all of your investment in our company. Additional risks of which we are not presently aware or that we currently believe are immaterial may also harm our business and results of operations.

Risks Relating to our Business

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

We are a development stage company, with operations beginning in December 2008 around acquiring the MASCT System patent rights and assignments and the FDA clearance for marketing the MASCT System, 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 intr-ductal Microcatheter Systems, establishing our CLIA-certified laboratory, validating our laboratory developed tests, conducting research and development on the FullCYTE and NextCYTE tests, securing distribution partners and beginning the commercialization of our products. We did not begin the national launch of the NAF cytology test until January 2013 and we subsequently recalled our lead medical device in October 2013. We will require significant additional capital to achieve our business objectives, and the inability to obtain such financing on acceptable terms or at all could lead to closure of the business.

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

- execute our business plan and commercialization strategy, including with respect to the assets we acquired from Acueity Healthcare, Inc.;
- work with contract manufacturers to produce the ForeCYTE Breast Aspirator, Acueity Tools 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;
- obtain regulatory clearances in a timely manner and maintain those clearances, including for our lead product the MASCT System which was recalled in October 2013 and for which we are seeking an additional regulatory clearance;
- sell our products and service at the prices currently expected; and
- attract and retain key personnel.

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

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

We anticipate liquidity issues in the next eight to twelve months.

For the year ended December 31, 2013, we generated $632,558 in revenue from the sale of our products and services and we incurred a net loss of $10,784,708. Through December 31, 2013, we had an accumulated deficit of approximately $20,516,614. As of the date of this report, we expect that our existing resources will be sufficient to fund our planned operations for at least the next eight to twelve months. 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 only source of revenue has historically been from our NAF cytology test and MASCT System, which was recalled commencing in October 2013 and will not be re-launched without an additional regulatory clearance. Our ability to continue as a going concern is dependent on obtaining adequate capital to fund operating losses until we become profitable. We may not achieve profitability from the sale of our products and services in the next eight to twelve months and other sources of capital may not be available when we need them or on acceptable terms. For example, we may not be able to raise capital by selling Common Stock to Aspire because our stock price may not be at the minimum $0.25 price per share required under our agreement with Aspire, or the Aspire registration statement may not remain effective. If we are unable to raise in a timely fashion the amount of capital we anticipate needing, from Aspire or otherwise, we would be forced to curtail or cease operations.

If we are not successful in obtaining, or are delayed in obtaining, a new 510(k) clearance from the FDA for our ForeCYTE Breast Aspirator, our operations will be significantly and adversely affected.

On October 4, 2013, we announced that we commenced a voluntary recall of our ForeCYTE Breast Health Test devices (also known as the Mammary Aspiration Specimen Cytology Test (MASCT)). We are currently seeking an additional 510(k) clearance from the FDA in order to market, sell or distribute the current version of this device which we call the ForeCYTE Breast Aspirator. We do not expect to generate revenue unless and until we obtain this clearance from the FDA. We may not obtain clearance from the FDA in a timely manner or at all for a number of reasons, including:

§ we may be required to submit additional clinical data that we do not have and cannot obtain in a timely manner;

§ the FDA may not agree with the scope or content of our proposed protocol and study design, including our identification and analysis of the devices and processes we are using as predicates;

§ the FDA may request that we submit additional information, data and studies, either prospectively or retrospectively, related to the collection and preparation of NAF samples, or the processing and analysis of NAF samples at our laboratory or at other laboratories, which we may not be able to obtain in a timely manner or at all. For example, in connection with a previous 510(k) that we submitted the FDA requested that we provide data on NAF processing by multiple third party laboratories and we were not able to provide that information;

§ although we had a pre-submission meeting with the FDA before submitting our 510(k) to them, any input from the FDA at that meeting is not binding on the FDA and the FDA can raise objections to our 510(k) submission that were not raised at the pre-submission meeting;

§ review by the FDA of our proposed 510(k) submission could be delayed because the FDA has up to 90 days to review the application, which time period is extended while we are responding to any FDA questions;

§ if we conclude that the FDA is likely not to clear our 510(k) submission for any reason we may decide to withdraw the submission and file a new 510(k) notification. For example, we previously filed a 510(k) for the MASCT System which we withdrew on the 89th day of its pendency because the FDA requested information that we could not provide in a timely fashion;

- § the FDA might conclude that we need to submit a pre-market application, or PMA, rather than a 510(k), which would require significantly more time and expense;

- § our responses to the warning letter we received from the FDA in February 2013, and the follow-up inspection by the FDA concluded on March 14, 2014 and any other inspection by the FDA as a follow-up to the warning letter, could raise questions by the FDA that could impact their review of our 510(k) submission;

- the FDA has indicated that the processing of NAF samples by our laboratory constitutes an in-vitro diagnostic testing service rather than a laboratory developed test and is subject to their regulatory authority. We have therefore included certain aspects of laboratory processing within the scope of our 510(k) submission; however, the FDA could require additional information, data and studies related to this processing by our laboratory or other laboratories which we may not be able to provide in a timely or cost effective manner;

- the FDA inspected our facilities in connection with the warning letter we received in February 2013 and concluded a re-inspection of our facilities on March 14, 2014. At the conclusion of the re-inspection the FDA raised issues verbally related to the sufficiency of the information in our pending 510(k) and they could make additional observations resulting from that inspection that could adversely impact our 510(k) submission; and

- in the letter we received from the FDA on February 28, 2014 the FDA indicated that certain data we provided in our 510(k) filing was not sufficient; we do not know if we will be able to provide the FDA with data they will find acceptable within the 180 days that we are required to provide additional information.

If we don't obtain the additional 510(k) clearance for the ForeCYTE Breast Aspirator in a timely manner for the above or any other reasons, our operations will be significantly and adversely affected.

The scope of any 510(k) clearance that we might receive from the FDA covering our ForeCYTE Breast Aspirator or any of our future products could be more limited than expected, potentially limiting our ability to market the test.

Even if we are successful in obtaining the 510(k) clearance for the ForeCYTE Breast Aspirator or any of our other product candidates in a timely manner, the scope of the clearance for our device could be more limited than expected and could limit our ability to market the device and our NAF cytology test. For example, the indication for use for our MASCT System that was cleared in 2003 states that the "MASCT device is intended for use in the collection of nipple aspirate fluid for laboratory cytological testing. The collected fluid can be used in the determination and/or differentiation of normal versus premalignant versus malignant cells." The new indication for use that we intend to clear with the FDA is potentially more limited in that it provides that the "ForeCYTE Breast Aspirator is intended for use in the collection, preparation, and processing of nipple aspirate fluid (NAF) specimens for cytological testing in a laboratory."This indication for use could be further limited while we pursue our additional 510(k) clearances.

Our business may be adversely affected if the manner in which our ForeCYTE Breast Aspirator and other product candidates may ultimately be marketed is narrower than the manner in which the MASCT System was cleared and marketed.

Our follow-up FDA inspection concluded on March 14, 2014 could lead to adverse regulatory events.

On March 14, 2014, the FDA completed a follow up inspection at our Seattle facility. A Form 483 was provided to us at the conclusion of the inspection. In the FDA's most recent Form 483, five inspectional observations were identified regarding our quality management system. The FDA inspector also verbally identified five additional discussion points related to our product labeling prior to the recall of the MASCT System; sufficiency of the content of our pending 510(k) submission for the ForeCYTE Breast Aspirator; and other compliance issues. On March 26, 2014, we submitted a response to the FDA, which included our proposed corrective actions to address the FDA's observations and discussion points. Whether the FDA will accept our response is uncertain, particularly in light of the similar nature of certain of the current inspectional observations to previous inspectional observations. If the FDA does not agree with our proposed corrective actions, or accepts them but finds that we have not implemented them adequately, or if we otherwise are found to be out of compliance with applicable regulatory requirements at a later date, the FDA could initiate an enforcement action including additional warning letters, fines and penalties. The FDA also may not clear our pending 510(k) for the ForeCYTE Breast Aspirator or our other devices and services under development. Any of the foregoing would have a material adverse effect on our business.

The voluntary recall and market withdrawal of the MASCT System, and any future recalls and/or product withdrawals, will significantly and adversely affect our business, prospects, financial condition and results of operations.

The manufacturing of medical devices involves an inherent risk that our products may prove to be defective and cause a health risk even after regulatory clearances have been obtained. Medical devices may also be modified after regulatory clearance is obtained to such an extent that additional regulatory clearance is necessary before the device can be further marketed. In these events, we may voluntarily implement a recall or market withdrawal or may be required to do so by a regulatory authority.

On October 4, 2013, we announced a nation-wide voluntary recall of the MASCT System device to address concerns raised by the FDA in a warning letter we received in February 2013 in which the FDA raised concerns about (1) the current instructions for use (IFU); (2) certain promotional claims used to market these devices; and (3) the need for FDA clearance for certain changes made to the Nipple Aspirate Fluid (NAF) specimen collection process identified in the current IFU. These devices are being removed from the market and will not be re-introduced unless or until a new 510(k) is obtained.

The October 2013 recall has significantly and adversely impacted our business and will continue to significantly and adversely impact our business in a number of ways, including:

§ the recall could damage our reputation with consumers, healthcare providers, distributors and other business partners;

§ we have estimated that the direct costs associated with the recall will be approximately $435,243. However, the direct and indirect costs could be higher than expected;

- virtually all of our revenues were generated from the ForeCYTE products and services. We do not expect to generate any significant revenue during the recall and while we are seeking additional regulatory clearance for the ForeCYTE Breast Aspirator; and

- on October 10, 2013 a securities class action suit was filed against us, certain of our officers and directors and others in U.S. and Federal District Court for the Western District of Washington. Additional complaints could be filed against us. We believe these suits are without merit and we will vigorously defend them; however, the defense will be costly and could consume significant management time and resources and the ultimate outcome cannot be predicted;

For the above and other reasons, we will also face risks and uncertainties if and when we re-launch ForeCYTE and our other products and services in the pipeline. We will need to incur additional expenses re-building our brand and awareness, developing new marketing strategies and materials, and re-engaging our partners and customers.

The ForeCYTE recall, and any future recall, could also harm our ability to market our other products and services in the pipeline, because of confusion over the scope of the recall, perceived risks or other concerns. A product recall also could lead to legal claims against us, regulatory agency inspections or other regulatory actions.

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:

- complete the recall of the MASCT System and pursue an additional 510(k) clearance for the device;

- launch and commercialize the ForeCYTE Breast Aspirator and ArgusCYTE Tests, including the manufacture of the ForeCYTE Breast Aspirator device in commercial quantities and building a direct sales force and 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 NextCYTE Test, intraductal treatment program and our companion diagnostic systems; 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 ForeCYTE device in commercial quantities, or the establishment of a larger sales force. As of December 31, 2013, we had cash and cash equivalents of $6,342,161. We will need substantial additional capital to continue to operate our business.

Our November 8, 2013 purchase agreement with Aspire has a number of limitations on our ability to sell shares to them; for example, the registration statement covering the shares must remain effective. Any sales of shares to Aspire will be limited by market conditions and the number of shares that we may be able to sell will be reduced if the volume of our Common Stock declines. We have not identified other sources for additional funding and cannot be certain that additional funding will be available on acceptable terms, or at all. If we are unable to raise additional capital in sufficient amounts or on acceptable terms, we may have to significantly delay, scale back or discontinue the commercialization of our products and services or our research and development activities. Furthermore, such lack of funds may inhibit our ability to respond to competitive pressures or unanticipated capital needs, or may force us to reduce operating expenses, which could significantly harm the business and development of operations. Because our independent auditors have expressed doubt as to our ability to continue as a "going concern," as reported in their report on our financial statements, our ability to raise capital may be severely hampered. Similarly, our ability to borrow any such capital may be more expensive and difficult to obtain until this "going concern" issue is eliminated.

We have a history of operating losses and we expect to continue to incur losses in the future.

We have a limited operating history and have incurred total net losses of approximately $20,516,614 from our incorporation in April 2009 through December 31, 2013. We have received $632,558 in revenue as of December 31, 2013, we do not expect to generate any revenues until we can obtain an additional regulatory clearance for our lead product, the ForeCYTE Breast Aspirator. 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 has historically been substantially lower than its cost because the MASCT System is currently manufactured only in small quantities and because our current marketing strategy is to attempt to quickly penetrate the market of the products and services offered by the Company by offering the ForeCYTE Breast Aspirator 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 ForeCYTE Breast Aspirator substantially below its cost and offering rebates negatively impacts our profitability. If and when we re-launch the ForeCYTE Breast Aspirator, we may not be able to sell our ForeCYTE Breast Aspirator and NAF cytology test and the same price levels we achieved in 2013. Although we expect that the cost to manufacture our ForeCYTE Breast Aspirator 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.

Our business may be affected by legal proceedings.

We have been in the past, and may become in the future, involved in legal proceedings. For example, on October 10, 2013, a securities class action complaint was filed against us, certain of our directors and officers and the underwriters from our initial public offering. This action was purportedly brought on behalf of a class of persons and entities who purchased our common stock between November 8, 2012 and October 4, 2013, inclusive. The complaint alleges that the defendants made false or misleading statements. Although we believe this complaint is without merit and plan to defend it vigorously, the costs associated with defending and resolving the complaint and ultimate outcome cannot be predicted.

You should carefully review and consider the various disclosures we make in our reports filed with the SEC regarding legal matters that may affect our business. Civil and criminal litigation is inherently unpredictable and outcomes can result in excessive verdicts, fines, penalties and/or injunctive relief that affect how we operate our business. Monitoring and defending against legal actions, whether or not meritorious, and considering stockholder demands, is time-consuming for our management and detracts from our ability to fully focus our internal resources on our business activities. In addition, legal fees and costs incurred in connection with such activities may be significant. We cannot predict with certainty the outcome of any legal proceedings in which we become involved and it is difficult to estimate

the possible costs to us stemming from these matters. Settlements and decisions adverse to our interests in legal actions could result in the payment of substantial amounts and could have a material adverse effect on our cash flow, results of operations and financial position.

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 raise additional capital by issuing equity securities, including sales of shares of Common Stock to Aspire, the value of the then outstanding common stock may be reduced. 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 gain market acceptance for the ForeCYTE Breast Aspirator and our NAF cytology and other tests, we will need to demonstrate to physicians and other healthcare professionals the benefits of the ForeCYTE Breast Aspirator and its practical and economic application for their particular practice. Even if we obtain FDA clearance for the ForeCYTE Breast Aspirator, many physicians and healthcare professionals may be hesitant to introduce new services, or techniques, into their practice for many reasons, including lack of time and resources to administer the test, 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. If and when we re-launch the ForeCYTE Breast Aspirator and the NAF cytology test service, it may be at prices lower than we experienced in 2013 and payors may pay at a rate lower than we experienced in 2013. We may come under increased price pressure because of reputational issues created by our recall, lower Medicare reimbursement rates, increased competition and other market conditions.

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 ForeCYTE Breast Aspirator, maintain our 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 ForeCYTE Breast Aspirator, 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, and 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. 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 as well as our own direct 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 distribution agreements with Clarity, Fisher Healthcare, Millennium Healthcare and PSS Medical Surgical, they may not be successful in selling our products and we may not achieve any level of commercial success from their efforts. The current recall of the MASCT System may cause our distributors to terminate our agreements with them or otherwise cause them not to sell our ForeCYTE devices or other products.

We use third-party suppliers for the production of the ForeCYTE device 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 ForeCYTE Breast Aspirator 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 ForeCYTE Breast Aspirator or Microcatheter Systems in quantities sufficient for our commercial needs on acceptable terms when needed, we may be unable to commercialize the ForeCYTE Breast Aspirator 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 ForeCYTE Breast Aspirator or prevent us from pricing the device at desired levels.

The Halo Breast Pap Test, an NAF collection device similar to the ForeCYTE Breast Aspirator, is being marketed by Halo Healthcare, Inc. (formerly Neomatrix, LLC), or Halo, of Irvine, California. 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. We believe that insurance carriers are not generally reimbursing healthcare providers for the NAF collection procedure using our ForeCYTE device.

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 ForeCYTE Breast Aspirator and may not recommend its use in patients. We may be forced to reduce the price of the ForeCYTE Breast Aspirator 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 ForeCYTE Breast Aspirator 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 acquired from Acueity Healthcare, Inc.

In September 2012, we acquired the assets of Acueity Healthcare, Inc., including intellectual property rights for 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. 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. 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 products and services 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 personalized medical products. Product liability risks may arise from, but are not limited to:

- the inability of the ForeCYTE Breast Aspirator 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, which could lead to an inaccurate test results;
- failure by healthcare professionals to properly safeguard NAF samples collected using the ForeCYTE Breast Aspirator or microcatheters;
- the potential loss, mislabeling or misplacement of NAF sample shipments and test kits;
- ForeCYTE Breast Aspirator 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 ForeCYTE Breast Aspirator device to the breast; and
- cleaning of the breast prior to applying the ForeCYTE Breast Aspirator.

Additionally, 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. We or our subsidiary may be subject to claims by an affected patient, healthcare provider, researcher or collaborator if laboratory personnel make mistakes, including 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.

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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.

We cannot be certain that the claims in our granted patents and pending patent applications will be considered patentable by the United States Patent and Trademark Office, or the USPTO, courts in the United States, or by patent offices and courts in foreign countries. Furthermore, the laws of some foreign countries do not protect intellectual property rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property abroad.

The strength of patents in the diagnostic, medical device, and pharmaceutical fields involves complex legal and scientific questions and can be uncertain. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our products or services in the United States or in foreign countries. Even if such patents do successfully issue, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. Any successful opposition to our patents could deprive us of exclusive rights necessary for the successful commercialization of our products and services. Furthermore, even if they are unchallenged, our patents may not adequately protect our intellectual property, provide exclusivity for our products and services, or prevent others from designing around our claims. If the breadth or strength of protection provided by the patents we hold with respect to our products and services is threatened, it could dissuade companies from collaborating with us to develop, or threaten our ability to commercialize, our products and services. In addition, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after it is filed. Various extensions may be available; however the life of a patent, and the protection it affords, is limited. Without patent protection for our products and services, we may be open to competition. Further, if we encounter delays in our development efforts, including our clinical trials, the period of time during which we could market our products and services under patent protection would be reduced.

For U.S. patent applications in which patent claims are entitled to a priority date before March 16, 2013, an interference proceeding can be provoked by a third party, or instituted by the USPTO to determine who was the first to invent any of the subject matter covered by those patent claims. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our participation in an interference proceeding may fail and, even if successful, may result in substantial costs and distract our management and other employees.

For U.S. patent applications containing a claim not entitled to priority before March 16, 2013, there is greater level of uncertainty in the patent law. In September 2011, the Leahy-Smith America Invents Act, or the American Invents Act (AIA), was signed into law. The AIA includes a number of significant changes to U.S. patent law, including provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. The USPTO is currently developing regulations and procedures to govern administration of the AIA, and many of the substantive changes to patent law associated with the AIA, and in particular, the “first to file” provisions, were enacted on March 16, 2013. This will require us to be cognizant going forward of the time from invention to filing of a patent application. It is not clear what other, if any, impact the AIA will have on the operation of our business. Moreover, the AIA and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

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.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent process. Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on any issued patents and/or applications are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patents and/or applications. We have systems in place to remind us to pay these fees, and we employ an outside firm and rely on our outside counsel to pay these fees. While an inadvertent lapse may sometimes be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to enter the market earlier than should otherwise have been the case, which would have a material adverse effect on our business.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our products and services.

As is the case with other diagnostic, medical device and pharmaceutical companies, our success is heavily dependent on intellectual property, particularly on obtaining and enforcing patents. Obtaining and enforcing patents in the diagnostic, medical device and pharmaceutical industries involve both technological and legal complexity, and is therefore costly, time-consuming and inherently uncertain. In addition, the United States has recently enacted and is currently implementing wide-ranging patent reform legislation. Further, recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. 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. The full impact of the *Prometheus* decision on diagnostic claims is uncertain. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents once obtained. Depending on decisions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on our products and services in all countries throughout the world would be prohibitively expensive. In addition, the laws of some foreign countries do not protect intellectual property rights in the same manner and to the same extent as laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States. Competitors may use our

technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection but enforcement of such patent protection is not as strong as that in the United States. These products may compete with our products and services, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing with our products and services.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products and services in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop.

Our current patent portfolio may not include all patent rights needed for the full development and commercialization of our products and services. 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.

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 report and such licenses, if available at all, may not be available on commercially reasonable terms. Others may seek licenses from us for other technology we use or intend to use. Any failure to obtain such licenses could delay or prevent us from developing or commercializing our proposed products and services, which would harm our business. For example, we may seek to develop our intra-ductal 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.

Third-party claims alleging intellectual property infringement may prevent or delay our drug discovery and development efforts.

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties, including the intellectual property rights of competitors. There is a substantial amount of litigation, both within and outside the United States, involving patents and other intellectual property rights in the diagnostic, medical device and pharmaceutical fields, as well as administrative proceedings for challenging patents, including interference and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in various foreign jurisdictions. Recently, the America Invents Act (AIA) introduced new procedures including inter partes review and post grant review. The implementation of these procedures brings uncertainty to the possibility of challenges to our patents in the future, including those patents perceived by our competitors as blocking entry into the market for their products and services, and the outcome of such challenges. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing our products and services. As the diagnostic, medical device and pharmaceutical industries expand and more patents are issued, the risk increases that our activities related to our products may give rise to claims of infringement of the patent rights of others.

We cannot assure you that our current or future products and services will not infringe existing or future patents. We may not be aware of patents that have already issued that a third party might assert are infringed by one of our current or future products or services. Nevertheless, we are not aware of any issued patents that will prevent us from marketing our products and services.

Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents of which we are currently unaware with claims to materials, formulations, methods of manufacture,

or methods for treatment related to the use or manufacture of our products. Because patent applications can take many years to issue and may be confidential for eighteen (18) months or more after filing, there may be currently pending third-party patent applications which may later result in issued patents that our products may infringe, or which such third parties claim are infringed by our products and services.

Parties making claims against us for infringement or misappropriation of their intellectual property rights may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our products and services. Defense of these claims, regardless of their merit, would involve substantial expenses and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us by a third party, we may have to (i) pay substantial damages, including treble damages and attorneys' fees if we are found to have willfully infringed the third party's patents; (ii) obtain one or more licenses from the third party; (iii) pay royalties to the third party; or (iv) redesign any infringing products. Redesigning any infringing products may be impossible or require substantial time and monetary expenditure. Further, we cannot predict whether any required license would be available at all or whether it would be available on commercially reasonable terms. In the event that we could not obtain a license, we may be unable to further develop and commercialize our products, which could harm our business significantly. Even if we were able to obtain a license, the rights may be nonexclusive, which may give our competitors access to the same intellectual property.

In addition to infringement claims against us, if third parties have prepared and filed patent applications in the United States that also claim technology related to our products and services, we may have to participate in interference proceedings in the USPTO to determine the priority of invention. Third parties may also attempt to initiate reexamination, post grant review or inter partes review of our patents in the USPTO. We may also become involved in similar proceedings in the patent offices in other jurisdictions regarding our intellectual property rights with respect to our products and technology.

We may be involved in proceedings to protect or enforce our patents or the patents of our licensors, which could be expensive, time-consuming and unsuccessful.

Third parties may infringe, misappropriate or otherwise violate our patents, patents that may issue to us in the future. To counter infringement or unauthorized use, we may be required to file infringement claims. Infringement claims can be expensive and time-consuming. Further, we may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States.

In addition, if we initiated legal proceedings against a third party to enforce a patent, the defendant could counterclaim that our patents are invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover our products and services. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection for our products and services. Such a loss of patent protection could have a material adverse impact on our business.

Litigation proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Finally, we may not be able to prevent, alone or with the support of our licensors, misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the United States.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.

We have received confidential and proprietary information from third parties. In addition, we employ individuals who were previously employed at other diagnostic, medical device or pharmaceutical companies. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise improperly used or disclosed confidential information of these third parties or our employees' former employers. Further, we may be subject to ownership disputes in the future arising, for example, from conflicting obligations of consultants or others who are involved in developing our products. We may also be subject to claims that former employees, consultants, independent contractors, collaborators or other third parties have an ownership interest in our patents or other intellectual property. Litigation may be necessary to defend against these and other claims challenging our right to and use of confidential and proprietary information. If we fail in defending any such claims, in addition to paying monetary damages, we may lose our rights therein. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against these claims, litigation could result in substantial cost and be a distraction to our management and employees.

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

We rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable or that we elect not to patent, processes for which patents are difficult to enforce, and any other elements of our discovery and development processes that involve proprietary know-how, information or technology that is not

covered by patents. However, trade secrets can be difficult to protect. We require all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology, to enter into confidentiality agreements. However, we cannot be certain that all such confidentiality agreements have been duly executed, that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Misappropriation or unauthorized disclosure of our trade secrets could impair our competitive position and may have a material adverse effect on our business. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret.

Risks Related to our Industry

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

We received a Warning Letter ("Warning Letter") from the FDA on February 21, 2013, regarding our MASCT System and MASCT System Collection Test (together, the "System"). The Warning Letter arose from certain FDA findings during a July 2012 inspection. A Form FDA 483 was issued at the end of that inspection. We responded in August 2012, and explained why we believed we are in compliance with applicable regulations and/or were implementing changes responsive to the findings of the FDA inspection. FDA issued the Warning Letter after the agency reviewed our response to the inspection. The FDA alleged in the Warning Letter that following 510(k) clearance we changed the System in a manner that requires submission of an additional 510(k) notification to the FDA. Specifically, the FDA indicated that the Instructions For Use (IFU) in the original 510(k) submission stated that the user must "Wash the collection membrane with fixative solution into the collection vial…" and the current IFU states "…apply one spray of Saccomanno's Fixative to the collection membrane…" and that "this change fixes the NAF specimen to the filter paper rather than washing it into a collection vial." At the time that the changes were made we determined and documented that the changes could not significantly affect the safety or effectiveness of the System and this determined that a new 510(k) was not required in accordance with the FDA's guidance document entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device."

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

We responded to the Warning Letter on March 13, 2013, and November 14, 2013 indicating the current actions taken and the timing of commitments we have made for future actions. The FDA could direct other compliance-verification activities or take other enforcement actions in connection with matters raised in the Warning Letter, related to our response, and in connection with other matters that the FDA could identify in the future, including, for example, additional issues identified in follow-up inspections of our facilities. Until these issues are resolved we may be subject to additional regulatory action by the FDA, and any such actions could disrupt our ongoing business and operations. For example, on October 4, 2013, we initiated a voluntary recall of the System and we are seeking an additional 510(k) clearance prior to re-launching the System. Our business will be adversely affected if we cannot timely resolve the matters raised in the Warning Letter, or other matters raised by the FDA, to the FDA's satisfaction or if we are not successful in obtaining an additional 510(k) clearance in a timely and cost-effective manner.

On March 14, 2014, the FDA completed a follow up inspection at our Seattle facility. A Form 483 was provided to us at the conclusion of the inspection. In the FDA's most recent Form 483, five inspectional observations were identified regarding our quality management system. The FDA inspector also verbally identified five additional discussion points related to our product labeling prior to the recall of the MASCT System; sufficiency of the content of our pending 510(k) submission for the ForeCYTE Breast Aspirator; and other compliance issues. On March 26, 2014, we submitted a response to the FDA, which included our proposed corrective actions to address the FDA's observations and discussion points. Whether the FDA will accept our response is uncertain, particularly in light of the similar nature of certain of the current inspectional observations to previous inspectional observations. If the FDA does not agree with our proposed corrective actions, or accepts them but finds that we have not implemented them adequately, or if we otherwise are found to be out of compliance with applicable regulatory requirements at a later date, the FDA could initiate an enforcement action including additional warning letters, fines and penalties. The FDA also may not clear our pending 510(k) for the ForeCYTE Breast Aspirator or our other devices and services under development. Any of the foregoing would have a material adverse effect on our business.

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

Our medical device products and operations are subject to extensive regulation by the FDA and various other federal and state governmental authorities. Government regulation of medical devices is meant to assure their safety and effectiveness, and includes regulation of, among other things: design, development, manufacture, testing, labeling, storage, marketing, distribution, promotion, record keeping, and approval or clearance. Any pharmaceutical therapies that we develop internally or with third parties including those that may use our devices and lab services as companions, will require clinical trials and FDA approvals of a PMA prior to commercialization.

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

a PMA for these programs our operations would be adversely affected. We are also pursing an additional 510(k) clearance for our ForeCYTE Breast Aspirator, and failure to obtain this clearance would adversely affect our business. We submitted a new 510(k) to FDA on December 23, 2013 for the ForeCYTE Breast Aspirator which is a modified version of MASCT system. On February 28, 2014, we received a request from the FDA for additional information and we have until August 20, 2014 to provide any necessary information. The FDA may not accept any additional information we submit to them and they may request further information that may be difficult or time consuming to provide.

Even after clearance or approval for our products is obtained, we are subject to extensive post-market regulation by the FDA. Our failure to meet strict regulatory requirements could require us to pay fines, incur other costs or even close our facilities.

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

Failure to comply with regulatory requirements such as QSR, may result in changes to labeling, restrictions on such products or manufacturing processes, withdrawal of the products from the market, voluntary or mandatory recalls, a requirement to repair, replace or refund the cost of any medical device we manufacture or distribute, fines, suspension of regulatory approvals, product seizures, injunctions or the imposition of civil or criminal penalties which would adversely affect our business, operating results and prospects.

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

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

If our products, or malfunction of our products, cause or contribute to a death or a serious injury, we will be subject to medical device reporting regulations, which can result in voluntary corrective actions or agency enforcement actions.

Under the FDA's medical device reporting, or MDR, regulations, we are required to report to the FDA any incident in which our product may have caused or contributed to a death or serious injury or in which our product malfunctioned and, if the malfunction were to recur, would likely cause or contribute to death or serious injury. Repeated product malfunctions may result in a voluntary or involuntary product recall, which could divert managerial and financial resources, impair our ability to manufacture our products in a cost-effective and timely manner, and have an adverse effect on our reputation, results of operations and financial condition.

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.

If we fail to comply with CLIA and other complex federal, state, local and foreign laws and regulations that apply to our business, we could suffer severe consequences that could materially and adversely affect our operating

results and financial condition.

We are subject to the CLIA, a federal law that regulates clinical laboratories that perform testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention, or treatment of disease. CLIA regulations mandate specific standards in the areas of personnel qualifications, administration, and participation in proficiency testing, patient test management, quality control, quality assurance, and inspections. Moreover, we expect a CLIA inspection of our laboratory in 2014 and inspectors may make random inspections of our laboratory. Failure to pass an inspection or to otherwise maintain our CLIA license would have a material adverse effect on our operations.

We are also required to maintain a license to conduct testing in Washington. Washington laws establish standards for day-to-day operation of our clinical reference laboratory, including the training and skills required of personnel and quality control. In addition, our clinical reference laboratory is required to be licensed by a number of states, including New York State. New York law mandates proficiency testing for laboratories licensed under New York state law, regardless of whether or not such laboratories are located in New York. Our application for such a license from New York State is currently pending and we operate based on a waiver by New York State of the obligations to have the license. If we are unable to obtain the necessary approvals or if New York State does not extend our waiver, our business could suffer. Moreover, several other states require that we hold licenses to test specimens from patients in those states and failure to maintain those licenses would adversely affect our business. Other states may have similar requirements or may adopt similar requirements in the future. Finally, we may be subject to regulation in foreign jurisdictions as we seek to expand international distribution of our products, which may require review of our products in order to offer our services or may have other limitations such as prohibitions on the export of tissue necessary for us to perform our tests that may limit our ability to distribute outside of the United States.

Any sanction imposed under CLIA, its implementing regulations, or state or foreign laws or regulations governing licensure, or our failure to renew a CLIA certificate, a state or foreign license, or accreditation, could have a material adverse effect on our business. Most CLIA deficiencies are not classified as “condition-level” deficiencies, and there are no adverse effects upon the laboratory operations as long as the deficiencies are corrected. Remediations of these deficiencies are routine matters, with corrections occurring within several hours or weeks. More serious CLIA deficiencies could rise to the level of “condition-level” deficiencies, and CMS has the authority to impose a wide range of sanctions, including revocation of the CLIA certification along with a bar on the ownership or operation of a CLIA certified laboratory by any owners or operators of the deficient laboratory. There is an administrative hearing procedure that can be pursued by the laboratory in the event of imposition of such sanctions, during which the sanctions are stayed, but the process can take a number of years to complete. If we were to lose our CLIA certification or CAP accreditation, we would not be able to operate our clinical reference laboratory and conduct our molecular tests, which would result in material harm to our business and results of operations.

Our operations are subject to other extensive federal, state, local and foreign laws and regulations, all of which are subject to change. These laws and regulations currently include, among others:

- HIPAA, which established comprehensive federal standards with respect to the privacy and security of protected health information and requirements for the use of certain standardized electronic transactions, particularly with respect to our online portal, Interactive Cancer Explorer;
- amendments to HIPAA under the Health Information Technology for Economic and Clinical Health Act, which strengthen and expand HIPAA privacy and security compliance requirements, increase penalties for violators, extend enforcement authority to state attorneys general, and impose requirements for breach notification;
- the federal Anti-Kickback Statute, which prohibits knowingly and willfully offering, paying, soliciting, or receiving remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing, arranging for, or recommending of an item or service that is reimbursable, in whole or in part, by a federal health care program;
- the federal Stark physician self-referral law, which prohibits a physician from making a referral for certain designated health services covered by the Medicare program, including laboratory and pathology services, if the physician or an immediate family member has a financial relationship with the entity providing the designated health services, unless the financial relationship falls within an applicable exception to the prohibition;
- the federal False Claims Act, which imposes liability on any person or entity that, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment to the federal government;
- the federal Civil Monetary Penalties Law, which prohibits, among other things, the offering or transfer of remuneration to a Medicare or state health care program beneficiary if the person knows or should know it is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of services reimbursable by Medicare or a state health care program, unless an exception applies;
- other federal and state fraud and abuse laws, such as anti-kickback laws, prohibitions on self-referral, fee-splitting restrictions, prohibitions on the provision of products at no or discounted cost to induce physician or patient adoption, and false claims acts, which may extend to services reimbursable by any third-party payor, including private insurers;
- the prohibition on reassignment of Medicare claims, which, subject to certain exceptions, precludes the reassignment of Medicare claims to any other party;
- the rules regarding billing for diagnostic tests reimbursable by the Medicare program, which prohibit a physician or other supplier from marking up the price of the technical component or professional component of a diagnostic test ordered by the physician or other supplier and supervised or performed by a physician who does not "share a practice" with the billing physician or supplier;

- state laws that prohibit other specified practices, such as billing physicians for testing that they order; waiving coinsurance, copayments, deductibles, and other amounts owed by patients; billing a state Medicaid program at a price that is higher than what is charged to one or more other payors; and
- similar foreign laws and regulations that apply to us in the countries in which we operate.

Our failure to comply could lead to civil or criminal penalties, exclusion from participation in government health care programs, or prohibitions or restrictions on our laboratory's ability to conduct commercial activities. We believe that we are in material compliance with all statutory and regulatory requirements, but there is a risk that one or more government agencies could take a contrary position. These laws and regulations are complex and are subject to interpretation by the courts and by government agencies. If one or more such agencies alleges that we may be in violation of any of these requirements, regardless of the outcome, it could damage our reputation and adversely affect important business relationships with third parties, including managed care organizations and other commercial third-party payors.

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 report 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.

U.S. Legislative or FDA regulatory reforms may make it more difficult and costly for us to obtain regulatory approval of our product candidates and to manufacture, market and distribute our products after approval is obtained.

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the regulatory approval, manufacture and marketing of regulated products or the reimbursement thereof. In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of future products. In addition, FDA regulations and guidance are often revised or reinterpreted by the agency in ways that may significantly affect our business and our products. It is impossible to predict whether legislative changes will be enacted or FDA regulations, guidance or interpretations changed, and what the impact of such changes, if any, may be.

For example, the FDA may change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions which may prevent or delay approval or clearance of our products under development or impact our ability to modify our currently cleared products on a timely basis. For example, in 2011, the FDA initiated a review of the premarket clearance process in response to internal and external concerns regarding the 510(k) program, announcing 25 action items designed to make the process more rigorous and transparent. In addition, as part of the Food and Drug Administration Safety and Innovation Act of 2012, or the FDASIA, Congress enacted several reforms entitled the Medical Device Regulatory Improvements and additional miscellaneous provisions which will further affect medical device regulation both pre- and post-approval. The FDA has implemented, and continues to implement, these reforms, which could impose additional regulatory requirements upon us and delay our ability to obtain new 510(k) clearances, increase the costs of compliance or restrict our ability to maintain our current clearances. For example, the FDA recently issued guidance documents intended to explain the procedures and criteria the FDA will use in assessing whether a 510(k) submission meets a minimum threshold of acceptability and should be accepted for review. Under the "Refuse to Accept" guidance, the FDA conducts an early review against specific acceptance criteria to inform 510(k) submitters if the submission is administratively complete, or if not, to identify the missing element(s). Submitters are given the opportunity to provide the FDA with the identified information, but if the information is not provided within a defined time, the submission will not be accepted for FDA review. Any change in the laws or regulations that govern the clearance and approval processes relating to our current and future products could make it more difficult and costly to obtain clearance or approval for new products, or to produce, market and distribute existing products. Significant delays in receiving clearance or approval, or the failure to receive clearance or approval for our new products would have an adverse effect on our ability to expand our business.

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. For example, the FDA has indicated to us that the manner in which

our laboratory processed of NAF samples prior to our October 2013 recall constitutes an in-vitro diagnostic test service that is subject to their regulatory authority and we may therefore be required to obtain a 510(k) clearance covering our laboratory processing. The FDA may also choose to exercise regulatory authority over our laboratory because it is wholly-owned by us and as a medical device manufacturer we are subject to FDA regulation. 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.

Healthcare policy changes, including recently enacted legislation reforming the United States healthcare system, may have a material adverse effect on our financial condition and results of operations

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, collectively, the PPACA, enacted in March 2010, makes changes that are expected to significantly impact the pharmaceutical and medical device industries and clinical laboratories. Beginning in 2013, each medical device manufacturer will have to pay an excise tax in an amount equal to 2.3% of the price for which such manufacturer sells its medical devices. We expect that the new tax may apply to some or all of our diagnostic products. The PPACA also mandates a reduction in payments for clinical laboratory services paid under the Medicare Clinical Laboratory Fee Schedule of 1.75% for the years 2011 through 2015 and a productivity adjustment to the Clinical Laboratory Fee Schedule. These or any future proposed or mandated reductions in payments may apply to some or all of the clinical laboratory tests that our diagnostics customers use our technology to deliver to Medicare beneficiaries, and may indirectly reduce demand for our diagnostic products.

Other significant measures contained in the PPACA include coordination and promotion of research on comparative clinical effectiveness of different technologies and procedures, initiatives to revise Medicare payment methodologies,

such as bundling of payments across the continuum of care by providers and physicians, and initiatives to promote quality indicators in payment methodologies. The PPACA also includes significant new fraud and abuse measures, including required disclosures of financial arrangements with physician customers, lower thresholds for violations and increasing potential penalties for such violations. In addition, the PPACA establishes an Independent Payment Advisory Board, or IPAB, to reduce the per capita rate of growth in Medicare spending. The IPAB has broad discretion to propose policies to reduce health care expenditures, which may have a negative impact on payment rates for services, including our tests. The IPAB proposals may impact payments for clinical laboratory services that our future diagnostics customers use our technology to deliver beginning in 2016 and for hospital services beginning in 2020, and may indirectly reduce demand for our diagnostic products.

In addition to the PPACA, the effect of which cannot presently be quantified, various healthcare reform proposals have also emerged from federal and state governments. Changes in healthcare policy, such as the creation of broad test utilization limits for diagnostic products in general or requirements that Medicare patients pay for portions of clinical laboratory tests or services received, could substantially impact the sales of our tests, increase costs and divert management's attention from our business. Such co-payments by Medicare beneficiaries for laboratory services were discussed as possible cost savings for the Medicare program as part of the debt ceiling budget discussions in mid-2011 and may be enacted in the future. In addition, sales of our tests outside of the United States will subject us to foreign regulatory requirements, which may also change over time.

We cannot predict whether future healthcare initiatives will be implemented at the federal or state level or in countries outside of the United States in which we may do business, or the effect any future legislation or regulation will have on us. The taxes imposed by the new federal legislation and the expansion in government's effect on the United States healthcare industry may result in decreased profits to us, lower reimbursements by payors for our products or reduced medical procedure volumes, all of which may adversely affect our business, financial condition and results of operations.

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. For example, if the closing bid prices of our common stock is less than $1.00 for 30 consecutive trading days, we will be delisted. The closing price of our common stock has been as low as $1.77 during the 30 trading days prior to March 19, 2014. 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 sale of a substantial number of shares of our common stock into the market may cause substantial dilution to our existing stockholders and the sale, actual or anticipated, of a substantial number of shares of common stock could cause the price of our common stock to decline.

As of the date of this report, we have the right to sell up to $24 million of our shares of common stock to Aspire. We are obligated to register these shares with the SEC and maintain the effectiveness of the registration statement. It is anticipated that these shares will be sold by Aspire over a period of up to approximately 30 months from the date the date we entered into the agreement with Aspire, which was November 8, 2013. Under the rules of the Nasdaq Capital Market, we generally may not issue more than 19.99% of our shares outstanding on November 8, 2013 under the purchase agreement (which is approximately 3,528,199 shares based on 17,649,824 shares of common stock outstanding on November 8, 2013), unless we obtain stockholder approval.

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

Additionally, sales of common stock by the investors in our 2011 private placement, including shares of common stock issuable upon exercise of warrants that were issued to them in 2011, as well as sales of common stock by investors upon exercise of warrants we issued in the public offering we completed in January 2014, could cause the price of our common stock to decline.

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

Since shares of our common stock were sold in our IPO in November 2012 at a price of $5.00 per share, our stock price has ranged from $1.74 to $12.40 through March 20, 2014. In addition to the factors discussed in this report, the trading price of our common stock may fluctuate significantly in response to numerous factors, many of which are beyond our control, including:

- actual or anticipated growth rates and fluctuations in our revenue and other operating results;
- regulatory and FDA actions, including their response to our 510(k) notification we filed for the ForeCYTE Breast Aspirator Test, the Warning Letter we received from the FDA on February 21, 2013;
- actions of securities analysts who initiate or maintain coverage of us, and changes in financial estimates by any securities analysts who follow our company, or our failure to meet these estimates or the expectations of investors;
- any ongoing litigation that we are currently involved in or litigation that we may become involved in in the future;
- additional shares of our common stock being sold into the market by us or our existing stockholders or the anticipation of such sales; and
- media coverage of our business and financial performance.

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

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 31.1% of our outstanding voting securities. Accordingly, these stockholders, acting together, will have the ability to exert substantial influence over all matters requiring approval by our stockholders, including the election and removal of directors and any proposed merger, consolidation or sale of all or substantially all of our assets. This concentration of ownership could have the effect of delaying, deferring or preventing a change in control of the Company or impeding a merger or consolidation, takeover or other business combination that could be favorable to you.

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

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

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

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

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

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

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could delay or prevent a change in control or changes in our Board of Directors that our stockholders might consider favorable. These provisions include the establishment of a staggered Board of Directors, which divides the board into

three classes, with directors in each class serving staggered three-year terms. The existence of a staggered board can make it more difficult for a third party to effect a takeover of our company if the incumbent board does not support the transaction. These and other provisions in our corporate documents and Delaware law might discourage, delay or prevent a change in control or changes in the Board of Directors of the Company. These provisions could also discourage proxy contests and make it more difficult for an investor and other stockholders to elect directors not nominated by our Board. Furthermore, the existence of these provisions, together with certain provisions of Delaware law, might hinder or delay an attempted takeover other than through negotiations with the Board of Directors.

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

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

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

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

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 2. PROPERTIES

As of December 31, 2013, we leased approximately 10,700 square feet of office and laboratory space in Seattle, Washington, which includes space rented from Sanders Properties, LLC, and the Fred Hutchinson Cancer Research Center. We believe that our current facilities will be adequate to meet our needs for the next 24 months. The information in this report under "PART II, ITEM 7. MANAGEMENT DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS Commercial Lease Arrangements" is incorporated into this PART I, ITEM 2.

ITEM 3. LEGAL PROCEEDINGS

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

On December 11, 2012, Mr. Kelly filed a complaint in the United States District Court, Western Division of Washington seeking compensatory damages, interest and attorneys' fees related to the termination of Mr. Kelly's consulting contract and the rescission of shares issued to him in July 2010 in connection with his resignation as President and a director. The specific amount of damages sought is to be proven at trial and is not specified. On July 8, 2013 the court granted the Company's motion to compel arbitration of these claims and therefore this action was stayed pending resolution of the arbitration of the claims; however, Mr. Kelly has not initiated arbitration of those claims.

On February 26, 2013, Mr. Victor Cononi filed a complaint in the United States District Court, Western Division of Washington seeking compensatory damages, interest and attorneys' fees related to the rescission of shares issued to him in July 2010 in connection with Mr. Kelly's resignation as President and a director. Mr. Cononi is the father of Mr. Kelly's paramour. The specific amount of damages sought is to be proven at trial and is not specified. In August 2013, the court granted the Company's motion to compel arbitration of these claims and therefore this action was stayed pending resolution of the arbitration of the claims; however, Mr. Cononi has not initiated arbitration of those claims.

A hearing in the arbitration has been held in abeyance to accommodate other third party civil and federal criminal proceedings alleging securities and wire fraud that have been brought against Mr. Kelly with respect to his prior employment and predating his service with us. On March 11, 2014, a press release was issued by the FBI stating that Mr. Kelly had pled guilty in Manhattan federal court to securities and wire fraud charges related to his employment as CEO of Wwebnet. Mr. Kelly also agreed to forfeit $2,111,600 and, separately, pay $2,111,600 in restitution. The sentencing hearing is scheduled for July 17, 2014.

We are reasonably confident in our defenses to Mr. Kelly's and Mr. Cononi's claims. Consequently, no provision or liability has been recorded for these claims as of December 31, 2013. However, it is at least reasonably possible that our estimate of liability may change in the near term. Any payments by reason of an adverse determination in this matter will be charged to earnings in the period of determination.

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

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

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

ITEM 4. MINE SAFETY DISCLOSURE

Not applicable.

PART II

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

Market Information

Our common stock, par value $0.001 per share, began trading on The NASDAQ Capital Market under the symbol "ATOS" on November 8, 2012. The following table sets forth, for the periods indicated, the intraday high and low prices of our common stock as reported by the NASDAQ.

	High	Low
2012		
Fourth Quarter	$ 5.61	$ 3.44
2013		
First Quarter	$ 12.40	$ 3.77
Second Quarter	$ 9.87	$ 4.11
Third Quarter	$ 7.75	$ 4.22
Fourth Quarter	$ 5.82	$ 1.74

On March 24, 2014, the closing price of our common stock was $1.79. As of March 24, 2014, there were approximately 42 shareholders of record of our common stock, one of which is Cede & Co., a nominee for Depository Trust Company, or DTC. All of the shares of common stock held by brokerage firms, banks and other financial institutions as nominees for beneficial owners are deposited into participant accounts at DTC, and are therefore considered to be held of record by Cede & Co. as one shareholder.

Certain Unregistered Sales of Securities

None

Dividends

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

Issuer Purchases of Securities

We did not repurchase any of our equity securities during the fourth quarter of the year ended December 31, 2013.

Equity Compensation Plan Information

The information under the principal heading "Equity Compensation Plan Information" in our definitive Proxy Statement for the Annual Meeting of Stockholders to be held on or about May 5, 2014, to be filed with the SEC, is incorporated herein by reference.

Use of Proceeds

Not applicable.

ITEM 6. SELECTED FINANCIAL DATA

Not applicable.

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

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

Company Overview

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

Our medical devices under development include the ForeCYTE Breast Aspirator (510(k) pending, not for sale in the United States.) intended for the collection of NAF for cytological testing at a laboratory, intra ductal microcatheters for the collection of ductal lavage fluid and for the potential administration of a targeted therapeutic, and various tools for potential use by breast surgeons. Our ForeCYTE Breast Aspirator (previously called the MASCT System) was launched nationally in early 2013 and was recalled in October 2013. It will not be re-launched in the United States unless and until we receive additional regulatory clearance from the FDA.

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

Our strategy consists of the following:

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

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

(3) Develop Pharmaceutical Therapies to be used as Companions with our Devices and Laboratory Services: We plan to develop our patented microcatheters to deliver pharmaceuticals to initially treat DCIS. We also plan to develop our devices and laboratory services for use as companion diagnostics. For example, we intend to use our devices to collect specimens of NAF, test the NAF specimens in our laboratory, provide pharmaceutical treatment options for the breast health conditions detected by our tests and then use our medical devices to monitor treatment

response. We expect that these companion diagnostic systems will initially target PED and/or high risk women and will require lengthy and costly clinical trials that we will undertake only with input and direction from the FDA.

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

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

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

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

The NRLBH has been certified pursuant to the Clinical Laboratory Improvement Amendments, or CLIA. CLIA certification is legally required to receive reimbursement from federal or state medical benefit programs, like Medicare and Medicaid, and is a practical requirement for most third-party insurance benefit programs. Our CLIA-certified laboratory, which is permitted to accept samples from all 50 states under its CLIA certification, its state licenses, or, in New York under recognized exemption provisions while its license application is pending, examines the specimens by cytological analysis.

On April 30, 2013, we entered into a Distribution and Marketing Services Agreement with Millennium Medical Devices LLC, pursuant to which, once we receive any necessary FDA clearances, Millennium will market and distribute the ForeCYTE Breast Aspirator in New York City and Northern New Jersey. In May 2013, we entered into a distribution agreement with Fisher Healthcare, a division of Fisher Scientific Company, LLC, and in September 2013, we entered into a distribution agreement with McKesson Medical Surgical.

From our inception (April 30, 2009) through our recall in October, 2013, we have received, processed, and reported the results to physicians from approximately 3,041 NAF samples processed and reported with our NAF cytology test (representing 1,404 patients). From inception through December 31, 2013, we have generated $1,115,900 in product and service revenue. We incurred net losses of $10,784,708 for the year ended December 31, 2013 and $20,516,614 since inception. 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, if cleared by the FDA selling the ForeCYTE Breast Aspirator and generating laboratory service revenue from our NAF cytology tests, and borrowing from stockholders or others when needed. However, we cannot assure you that we will be successful in accomplishing any of these plans and, if we are unable to obtain adequate capital, we could be forced to cease operations.

Revenue Sources

The commercialization of the MASCT System and NAF cytology test has provided us with two revenue sources: (i) sales-based revenue from the sale of the MASCT System device and patient kits to distributors, physicians, breast health clinics, and mammography clinics and (ii) service, or use-based, revenue from the preparation and interpretation of the NAF samples sent to our laboratory for analysis. However, as a result of the recall of the MASCT System in October 2013, our product revenue and service revenue have ceased. We do not anticipate generating revenue until and unless we receive an additional 510(k) clearance from the FDA for our ForeCYTE Breast Aspirator and re-launch the device. If and when ForeCYTE is re-launched, we plan to initially sell the ForeCYTE Breast Aspirator through regional and national specialty product distributors, with independent sales representatives specializing in women's Health, and through our own direct sale force.

Commercial Lease Agreements

On September 29, 2010, we entered into a commercial lease agreement with CompleGen, Inc. for laboratory space located in Seattle, WA. The monthly rent for the lease was $4,267 in 2012 and the lease was terminated in December 2012.

On March 4, 2011, we entered into a commercial lease agreement with Sanders Properties, LLC for office space located in Seattle, WA. The lease terminates on March 31, 2014 and provides for monthly rent of $1,100 and a security deposit of $1,500. On March 20, 2014, the Company entered into a new agreement with Sanders properties which extends the terms of the lease through March 31, 2015 with a monthly rent of $1,150.

On December 9, 2011, we 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. For the twelve month December 31, 2013, we incurred $264,569 of rent expenses for this lease which included leasing office management expenses.

In July 2013, we entered into an agreement with ARE LLC (Alexandria) to lease additional office spaces in our existing building under a separate lease agreement. The lease is from August 2013 through November 2014, and the gross rent is $ 4,800 per month.

We expect that these laboratory facilities will be sufficient to meet our needs for the foreseeable future and we do not expect to need additional laboratory space for at least the next 24 months. However, upon termination of the lease for the office space, we may need to secure additional office space. Additional office space is readily available in our local market and we believe we can rent additional office space on acceptable terms if necessary.

On March 24, 2014, the Company entered into another commercial lease agreement with ARE LLC (Alexandria) which extends the term of the existing lease with Fred Hutchison Research Center which expires in November 2014 through November 30, 2016. The lease provides for monthly rent payments of $22,736 from December 2014 through November 2015 and $23,258 from December 2015 through November 2016. The Company will incur 3.7% in tenant share of operating expenses and $25,000 in security deposit.

Legal Proceedings

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

On December 11, 2012, Mr. Kelly filed a complaint in the United States District Court, Western Division of Washington seeking compensatory damages, interest and attorneys' fees related to the termination of Mr. Kelly's consulting contract and the rescission of shares issued to him in July 2010 in connection with his resignation from the Company as President and a director. The specific amount of damages sought is to be proven at trial and is not specified. On July 8, 2013, the court granted the Company's motion to compel arbitration of these claims and therefore this action was stayed pending resolution of the arbitration of the claims; however, Mr. Kelly has not initiated arbitration of those claims.

On February 26, 2013, Mr. Victor Cononi filed a complaint in the United States District Court, Western Division of Washington seeking compensatory damages, interest and attorneys' fees related to the rescission of shares issued to him in July 2010 in connection with Mr. Kelly's resignation from the Company as President and a director. The specific amount of damages sought is to be proven at trial and is not specified. In August 2013, the court granted the Company's motion to compel arbitration of these claims and therefore this action was stayed pending resolution of the arbitration of the claims; however, Mr. Cononi has not initiated arbitration of those claims.

A hearing in the arbitration has been held in abeyance to accommodate other third party civil and federal criminal proceedings alleging securities and wire fraud that have been brought against Mr. Kelly with respect to his prior employment and predating his service with the Company. On March 11, 2014 a press release was issued by the FBI stating that Mr. Kelly had pled guilty in Manhattan federal court to securities and wire fraud charges related to his employment as CEO of Wwebnet. Mr. Kelly also agreed to forfeit $2,111,600 and, separately, pay $2,111,600 in restitution. The sentencing hearing is scheduled for July 17, 2014.

The Company is reasonably confident in its defenses to Mr. Kelly's and Mr. Cononi's claims. Consequently, no provision or liability has been recorded for these claims as of June 30, 2013. 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.

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

On February 14, 2014, the Court appointed plaintiffs Miko Levi, Bandar Almosa and Gregory Harrison (collectively, the "Levi Group") as lead plaintiffs, and approved their selection of co-lead counsel and liaison counsel. The Court also

amended the caption of the case to read In re Atossa Genetics, Inc. Securities Litigation. No. 2:13-cv-01836-RSM. The Court ordered lead plaintiffs to file an amended class action complaint by April 15, 2014.

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

Critical Accounting Policies

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

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

Revenue Recognition

Overview

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 on an accrual basis for sales to distributors when the above four criteria are met. For sales of MASCT kits and devices sold directly to physicians, the revenue is typically recognized upon receipt of cash as the Company has an insufficient history on which to determine 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. For sales directly to physicians, 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 are generally 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 to determine a proper allowance for doubtful accounts beginning in 2014.

Cost of Revenue

Cost of revenue consists of cost of diagnostic testing services and cost of product sales. Cost of diagnostic testing services primarily includes direct cost of material, direct labor, equipment, and shipping to process the patient samples (including pathology, quality control analysis, and shipping charges to transport tissue sample) in our laboratory. Costs associated with performing the Company's tests are recorded as tests are processed. Costs recorded for tissue sample processing and shipping charges represent the cost of all the tests processed during the period regardless of whether revenue was recognized with respect to that test. Cost of product sales primarily includes the manufacturing cost of our MASCT System for sales to distributors, which is recorded upon transfer of ownership of the goods.

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. 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. During the course of our recall commenced in October 2013, we have recalled a substantial number of MASCT Systems. Based on management's assessment of those devices and the pending FDA clearance, management decided to establish 100% allowance for valuation reserve on all MASCT Systems, and recorded $149,946 of losses on obsolete inventory as of and for the year ended December 31, 2013. During 2012 and prior, because the sales price of the MASCT System was substantially lower than its cost, 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 of loss on reduction of inventory to the lower of cost or market was assessed and recorded for the year ended December 31, 2012. The Company outsources product manufacturing to outside manufacturer contactors. The ownership of the goods transfers from the manufacturer to the Company's customer at the time the products are shipped to the customers. As of December 31, 2013 and 2012, inventories amounted to $0 after netting of the above valuation allowances.

The Company provides, either directly or through distributors, the NAF cytology testing specimen collection kits to doctors with our MASCT System for doctors to collect specimens that are returned to the NRLBH or other laboratories for diagnostic analysis. These collection kits are considered part of the MASCT System. During the initial marketing phase, we decided to distribute the kits to customers at no cost and bundle them with the MASCT pumps, and have not intended to deem the collection kits as a primary product line due to their nominal cost and value per unit. As a result, the kits are immediately expensed and recorded as selling expense upon purchasing of the kits. For the years ended December 31, 2013 and 2012, selling expense of $126,507 and $55,282 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.

Accounts Receivable:

Accounts receivable are recorded at net realizable value consisting of the carrying amount less allowance for doubtful accounts, as needed. The Company assesses the collectability of accounts receivable based primarily upon the creditworthiness of the customer as determined by credit checks and analysis, as well as the customer's payment history. Management reviews the composition of accounts receivable and analyzes historical bad debts, customer concentrations, customer credit worthiness, current economic trends, and changes in customer payment patterns to evaluate the adequacy of these reserves. As of December 31, 2013 and 2012, $354,860 and $0 in allowance for doubtful accounts and bad debt expense were assessed or recorded, respectively.

Property, plant, and equipment:

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

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

	Useful Life (in years)

Machinery and equipment	5
Leasehold improvements	2.083

The Company applies the provisions of FASB ASC Topic 360 (ASC 360), “Property, Plant, and Equipment” which addresses financial accounting and reporting for the impairment or disposal of long-lived assets. The Company periodically evaluates the carrying value of long-lived assets to be held and used in accordance with ASC 360, at least on an annual basis. ASC 360 requires the impairment losses to be recorded on long-lived assets used in operations when indicators of impairment are present and the undiscounted cash flows estimated to be generated by those assets are less than the assets’ carrying amounts. In that event, a loss is recognized based on the amount by which the carrying amount exceeds the fair market value of the long-lived assets. Loss on long-lived assets to be disposed of is determined in a similar manner, except that fair market values are reduced for the cost of disposal. For the years ended December 31, 2013 and 2012, $158,292 and $0 was assessed and recorded as impairment on long-life assets, respectively

Intangible Assets

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

Share-Based Payments

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

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.

Results of Operations

Comparison of Years Ended December 31, 2013 and 2012

Revenue and Cost of Goods Sold. For the year ended December 31, 2013, we had total revenue of $632,558, consisting of $223,440 product revenue from sales of MASCT Systems and $409,118 diagnostic testing service revenue from our NAF cytology testing services performed. This represents an increase of $150,716, or 31% from the total revenue of $481,842 for the year ended December 31, 2012. The growth in revenue is mainly due to $205,590 in product sales to Millennium for the initial purchase of 10,000 ForeCYTE kits. Substantially all of our revenue in 2013 was recognized during the period prior to the recall of the MASCT System which commenced in October 2013.

Total cost of revenue in 2013 was $345,519 and consisted of $239,755 in costs related to the production of the MASCT systems; and $105,764 in costs for diagnostic testing. Loss on reduction of inventory to lower of cost market and obsolete inventory was $149,946 due to the recall of MASCT Systems in October 2013. In 2013, we started allocating the direct laboratory costs (direct labor, material, and shipping) associated with processing patient samples from R&D to the cost of diagnostic services; the new presentation contributes to the total increase in diagnostic testing cost of service compared to 2012. The allocation is evaluated on an annual basis and is adjusted as needed. Gross profit for the twelve months ended December 31, 2013 was $137,093, consisting of $303,354 for the diagnostic testing service offset by $166,261 loss for the product sales of MASCT (including $149,946 loss on obsolete inventory) as compared to gross profit of $416,213 for the twelve months ended December 31, 2012, consisting of $439,657 in diagnostic testing offset by $23,444 loss for the product sales (including $29,884 loss on reduction of inventory to the lower of cost or market).

In December 2013, we terminated our contract with the our existing third party manufacturer and purchased the entire excess inventory of parts and finished goods; we established a reserve of $149,946 in obsolete inventory for the twelve months ended December 31, 2013, given uncertainties around whether that inventory would be salable if and when our pending 510(k) is cleared by the FDA. Our MASCT System is not being marketed because of our voluntary recall. We have chosen a new contract manufacturer which will start production of the new ForeCYTE Breast

Aspirator if and when we receive FDA clearance.

Because we have recalled the MASCT System, we do not expect to generate any significant revenue unless and until we receive FDA clearance and relaunch the device. We expect to receive FDA clearance in the fourth quarter of 2014, although clearance could be significantly delayed for a number of reasons, including if the FDA requests that we submit additional information that we cannot provide in a timely or cost effective manner, or at all.

Operating Expenses. Total operating expenses were $10,921,736 for the twelve months ended December 31, 2013, consisting of G&A expenses of $8,558,835, R&D expenses of $1,105,110, and selling expenses of $1,257,791, representing an increase of $5,436,493, or 99% from $5,485,243 in the same period in 2012, consisting of G&A expenses of $3,044,409, R&D expenses of $1,974,013, and selling expenses of $466,821. The increase in operating expenses are mainly due to our growth and commercialization of the MASCT System. We expect that our G&A and selling expenses will continue to increase in the foreseeable future, and that if we successfully relaunch the ForeCYTE Breast Aspirator and our related laboratory service offerings, we would also begin to incur additional sales and marketing expenses as we continue building a regional, and ultimately national, sales force.

Selling Expenses. Selling expenses for the year ended December 31, 2013 were $1,257,791, an increase of $790,970, or 169% from $466,821 in the same period in 2012. Our selling expenses consisted of $560,111 in personnel expenses, $570,092 in advertising and marketing, and $126,507 in cost of ForeCYTE specimen collection kits that were provided complimentary to the physicians as promotional kits. We distribute the kits to customers at no cost and bundle them with the MASCT System and we do not intended to deem the kits as a primary product line due to their nominal cost and value per unit. Selling expenses for the twelve months ended December 31, 2012 consisted of $264,322 in personnel expenses, $144,841 in advertising and marketing, and $55,281 in kits promotional. We expect that selling expenses will increase when and if we receive clearance from the FDA for the ForeCYTE Breast Aspirator and re-launch that device. We also expect selling expense to increase as we launch our other devices and tests in the pipeline.

General and Administrative Expenses. G&A expenses for the twelve months ended December 31, 2013 were $8,558,835, an increase of $5,514,426, or 181% from $3,044,409 for the twelve months ended December 31, 2012. G&A expenses for the twelve months ended December 31, 2013 primarily consisted of $2,219,685 in salaries and bonus expense, $3,202,036 in regulatory, legal and other professional services, $163,623 in travel expense, $185,123 in payroll taxes, $418,860 insurance expense, $435,243 in recall expenses, and $354,860 in bad debt expenses, $170,960 in employee benefits and health insurance, $121,201 in rent expense, $472,934 in depreciation and amortization, $158,292 in impairment loss on fixed assets, and $258,912 in office expenses (office supplies, website and internet services, postage and delivery, telephone, and printing). G&A expenses for the twelve months ended December 31, 2012 consisted of $340,516 in personnel expenses, $1,754,483 in legal and other professional services, $113,399 in insurance expenses, and $86,488 in payroll taxes. The increase in G&A expenses year over year is mainly due to hiring additional staff and outside professional services to support the launch of the Company's MASCT System, ForeCYTE service and the related growth to expand our operations.

Research and Development Expenses. R&D expenses for the twelve month ended December 31, 2013 were $1,105,110, a decrease of $868,903, or 44% from $1,974,013 in the same period in 2012. The decrease in R&D expenses is attributed to the completion of the development of the MASCT System for the national launch in 2013. We expect that our R&D expenses will increase as we continue the development of our products, tests and therapeutic programs in our pipeline.

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 consolidated financial statements as of and for the years ended December 31, 2013 and 2012 expresses substantial doubt about our ability to continue as a going concern. In 2011, we were successful in raising net proceeds of $5.7 million through a private placement in order to fund the growth of our operations and product development. In November 2012, we were successful in our initial public offering and raising net proceeds of approximately $3.5 million.

On March 27, 2013, we entered into a stock purchase agreement with Aspire Capital Fund, LLC, and pursuant to that agreement we sold common stock to Aspire from March 2013 through October 2013 for a total aggregate purchase price of $11,303,745. On November 8, 2013, we terminated this stock purchase agreement and entered into a new agreement with Aspire which provides that we may sell common stock to Aspire under the terms and subject to the conditions and limitations set forth therein. Under the new agreement, Aspire is committed to purchase up to an aggregate of $25 million of shares of our common stock over the 30 month term of the new agreement. On December 23, 2013, we sold $1 million of common stock to Aspire under this new agreement so that up to a total of $24 million remains available for sale to them as of the date of this report. However, in connection with our January 2014 public offering we agreed not to utilize the financing arrangement with Aspire for 120 days following completion of that offering.

On January 29, 2014, we closed a public offering of 5,834,234 units at the price of $2.40 per unit, with each unit consisting of one share of common stock and a warrant to purchase 0.20 a share of common stock, for gross proceeds of approximately $14.0 million. The warrants are exercisable at $3.00 per share and are callable by us if and when the trading price of our common stock is $6.00 per share over a defined period and subject to a daily volume minimum.

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 twelve months ended December 31, 2013, we incurred a net loss of $10,784,708. Net cash used in operating activities was $8,830,044, net cash used in investing activities was $489,815 and net cash provided by financing activities was $13,936,823. For the twelve months ended December 31, 2012, we incurred a net loss of $5,079,851, net cash used in operating activities was $3,899,964, net cash used in investing actives was $134,582 and net cash provided by financing activities was $3,848,922.

Funding Requirements

We expect to incur substantial expenses and generate ongoing operating losses for the foreseeable future as we prepare to relaunch the ForeCYTE Breast Aspirator, complete the development of and launch the ArgusCYTE test and NextCYTE test, other devices in the pipeline and start the development of our planned therapeutic programs. We expect that our existing resources as of December 31, 2013 will be sufficient to fund our planned operations for at least the first six months of 2014 and with the proceeds from our public offering completing in January 2014 we expect that we have sufficient capital resources for the remainder of 2014. If we are unable to raise additional capital when needed, however, we could be forced to curtail or cease operations. Our future capital uses and requirements depend on numerous factors. These factors include the following:

- § the time and expense needed to relaunch the ForeCYTE Breast Aspirator;
- § the expense associated with building a network of independent sales representatives to market the ForeCYTE Breast Aspirator, and NAF cytology tests, NextCYTE test, ArgusCYTE test and our planned therapeutic programs; and
- § the degree and speed of patient and physician acceptance of our products and the degree to which third-party payors approve the tests for reimbursement.

For the year ended December 31, 2013, we have generated $632,558 in revenue mainly recognized in the first three quarters of 2013. We do not expect to generate significant revenue until we receive FDA clearance to market the ForeCYTE Breast Aspirator. We expect our continuing operating losses to result in increases in cash used in operations over at least the next year. Although we expect our existing resources as of December 31, 2013, in addition to funds received from our public offering completed in January 2014 to be sufficient to fund our planned operations through 2014, we may require additional funds earlier than we currently expect to successfully commercialize the new ForeCYTE Breast Aspirator. Because of the numerous risks and uncertainties associated with the development and commercialization of the ForeCYTE Breast Aspirator and our other devices, tests and therapeutics in the pipeline, 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

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

Jumpstart Our Business Startups Act of 2012

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

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The financial statements required by this item are set forth beginning on page 68 of this report and are incorporated herein by reference.

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

None.

ITEM 9A. CONTROLS AND PROCEDURES

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

At the end of the period covered by this report, we carried out an evaluation, under the supervision and with the participation of our management, including our principal executive officer and principal accounting and financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures, as such term is defined under Rule 13a-15(e) promulgated under Exchange Act. Based on this evaluation, our principal executive officer and our principal accounting and financial officer concluded that our disclosure controls and procedures were effective as of December 31, 2013 to ensure that information to be disclosed by us in this Annual Report on Form 10-K was recorded, processed summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and Form 10-K.

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms and that such information is accumulated and communicated to our management, including our chief executive officer and principal accounting and financial officer, as appropriate, to allow for timely decisions regarding required disclosure. There were no changes in our internal controls over financial reporting during the year ended December 31, 2013 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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

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

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f). Under the supervision and with the participation of our management, including our principal executive officer and principal accounting and financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our evaluation under the framework in *Internal Control Integrated Framework* , our management concluded that our internal control over financial reporting was effective as of December 31, 2013. Because we are a smaller reporting company, KCCW Accountancy Corp., our independent registered public accounting firm, is not required to attest to and or issue a report on the effectiveness of our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this Item with respect to executive officers, directors and corporate governance matters is incorporated by reference to the information set forth under the caption "Election of Directors," “Executive Officers” and “Corporate Governance” in the Company's Proxy Statement for the 2014 Annual Meeting of Shareholders.

The section entitled "Compliance Under Section 16(a) of the Securities Exchange Act of 1934" appearing in the Proxy Statement for the 2014 Annual Meeting of Shareholders sets forth the information concerning compliance by officers, directors and 10% shareholders of the company with Section 16 of the Exchange Act of 1934 and is incorporated herein by reference.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this Item is incorporated herein by reference to the information set forth under the caption "Executive Compensation" in the Proxy Statement for the 2014 Annual Meeting of Shareholders.

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

The information required by this Item is incorporated herein by reference to the information set forth under the caption "Security Ownership of Certain Beneficial Owners and Management and Related Shareholder Matters" in the Proxy Statement for the 2014 Annual Meeting of Shareholders.

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

The information required by this Item is incorporated herein by reference to the information set forth under the captions "Directors" and "Certain Relationships and Related Transactions" in the Proxy Statement for the 2014 Annual Meeting of Shareholders.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this Item is incorporated herein by reference to the information set forth under the caption "Principal Accountant Fees and Services" in the Proxy Statement for the 2014 Annual Meeting of Shareholders.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a)

1. Financial Statements

2. Financial Statement Schedules

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

3. Exhibits

See the Exhibit Index set forth on page 85 of this report.

ATOSSA GENETICS, INC.
(A Development Stage Company)

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Audited Consolidated Financial Statements:

Audit · **T**ax · **C**onsulting · **F**inancial **A**dvisory
Registered with Public Company Accounting Oversight Board (PCAOB)

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited the accompanying consolidated balance sheets of Atossa Genetics Inc. (a development stage company) (the "Company") as of December 31, 2013 and 2012, and the related consolidated statements of operations, stockholders' equity, and cash flows for the years then ended and since inception (April 30, 2009). The Company's management is responsible for these consolidated financial statements. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

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

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Atossa Genetics, Inc. (a development stage company) as of December 31, 2013 and 2012, and the consolidated results of its operations and its cash flows for the years then ended and since inception (April 30, 2009) in conformity with accounting principles generally accepted in the United States of America.

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

KCCW Accountancy Corp.

Diamond Bar, California
March 26, 2014

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

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

	As of December 31, 2013	2012
Assets		
Current assets		
Cash and cash equivalents	$ 6,342,161	$ 1,725,197
Accounts receivable, net	139,072	141,666
Prepaid expenses	932,588	122,633
Total current assets	7,413,821	1,989,496
Fixed assets		
Furniture and equipment, net	163,147	159,967
Total fixed assets	163,147	159,967
Other assets		
Security deposit	36,446	36,446
Intangible assets, net	4,395,633	4,640,224
Total other assets	4,432,079	4,676,670
Total assets	$ 12,009,047	$ 6,826,133
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 9,634	$ 68,217
Accrued expenses	637,986	1,342,358
Deferred rent	48,157	-
Payroll liabilities	476,477	207,997
Contingent liabilities	211,493	-
Other current liabilities	23,649	32,026
Total current liabilities	1,407,396	1,650,598
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, 18,574,334 and 12,919,367 shares issued and outstanding	18,574	12,919
Additional paid-in capital	31,099,691	14,894,522
Accumulated deficit	(20,516,614)	(9,731,906)
Total stockholders' equity	10,601,651	5,175,535
Total liabilities and stockholders' equity	$ 12,009,047	$ 6,826,133

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

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

	For the Years Ended December 31, 2013	2012	From April 30, 2009 (Inception) Through December 31, 2013
Revenue			
Diagnostic testing service	$ 409,118	$ 475,402	$ 884,520
Product sales	223,440	6,440	231,380
Total revenue	632,558	481,842	1,115,900
Cost of revenue			
Diagnostic testing service	105,764	35,745	141,509
Product sales	239,755	-	244,919
Total cost of revenue	345,519	35,745	386,428
Loss on obsolete inventory & LCM	149,946	29,884	271,856
Gross profit	137,093	416,213	457,616
Selling expenses	1,257,791	466,821	1,897,667
Research and development expenses	1,105,110	1,974,013	4,662,496
General and administrative expenses	8,558,835	3,044,409	14,381,171
Total operating expenses	10,921,736	5,485,243	20,941,334
Operating loss	(10,784,643)	(5,069,030)	(20,483,718)
Interest income	295	1,219	6,883
Interest expense	360	12,040	39,531
Net loss before Income taxes	(10,784,708)	(5,079,851)	(20,516,366)
Income taxes	-	-	248
Net loss	$ (10,784,708)	$ (5,079,851)	$ (20,516,614)
Loss per common share - basic and diluted	$ (0.70)	$ (0.41)	$ (2.14)
Weighted average shares outstanding, basic & diluted	15,484,414	12,452,929	9,595,967

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

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

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

Compensation cost for stock options granted to executives and employees					
Net loss for the period ended December 31, 2012	-	-	-	(5,079,851)	(5,079,851)
Balance at December 31, 2012	12,919,367	$ 12,919	$ 14,894,522	$ (9,731,906)	$ 5,175,535
Issuance of common shares for cash	2,733,333	2,733	12,301,012	-	12,303,745
Issuance of common shares for services	66,696	67	180,185	-	180,252
Issuance of common shares for capital raising fees , net	625,000	625	651,336	-	651,961
Issuance of Common shares for warrants	2,224,392	2,224	1,618,958	-	1,621,182
Issuance of Common shares for exercise employees options	5,546	6	9,918	-	9,924
Compensation cost for stock options granted to executives and employees	-	-	1,443,760	-	1,443,760
Net loss for the period ended December 31, 2013	-	-	-	(10,784,708)	(10,784,708)
Balance at December 31, 2013	18,574,334	$ 18,574	$ 31,099,691	$ (20,516,614)	$ 10,601,651

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

ATOSSA GENETICS, INC.
(A DEVELOPMENT STAGE COMPANY)
CONSOLIDATED STATEMENT OF CASHFLOW

	2013	2012	For The Period From April 30, 2009 (Inception) to December 31, 2013
CASH FLOWS FROM OPERATING ACTIVITIES			
Net loss	$ (10,784,708)	$ (5,079,851)	$ (20,516,614)
Common shares issued for services	178,280	-	249,280
Compensation cost for stock options granted	1,443,760	121,812	1,736,024
Loss on reduction on obsolete inventory and LCM	149,946	29,884	271,856
Impairment loss on long-life assets	158,292	-	158,292
Loan initiation fee accrued for notes payable	-	-	2,000
Depreciation and amortization	472,934	130,552	619,109
Contingent Loss	211,493	-	211,493
Bad debt expenses	354,861	-	354,861
Adjustments to reconcile net loss to net cash provided by operating activities:			
Increase in accounts receivable	(352,267)	(140,441)	(493,932)
Increase in inventory	(149,946)	(29,884)	(271,856)
Increase in prepaid expenses	(57,994)	(91,449)	(180,627)
Increase in security deposits	-	(29,089)	(36,447)
Decrease (increase) in accounts payable	(58,583)	3,451	9,634
Increase (decrease) in payroll liabilities	268,480	(33,219)	268,480
Increase in deferred rent	48,157	-	48,157
Decrease (increase) in accrued expenses	(704,372)	1,198,860	923,008
Decrease (increase) in other current liabilities	(8,377)	19,410	(8,377)
Net cash used in operating activities	(8,830,044)	(3,899,964)	(16,655,659)
CASH FLOWS FROM INVESTING ACTIVITIES			
Purchase of furniture & fixtures	(244,442)	(104,582)	(435,489)
Purchase of intangible assets	(245,373)	(30,000)	(325,839)
Net cash used in investing activities	(489,815)	(134,582)	(761,328)
CASH FLOWS FROM FINANCING ACTIVITIES			
Net proceeds from issuance of common stocks and warrants	13,936,823	3,854,000	23,761,148
Repayments from bank line of credit	-	(1,000,000)	-
Repayments of loans from related parties	-	(5,078)	(2,000)
Cash released from commercial line of credit	-	1,000,000	-
Net cash provided by financing activities	13,936,823	3,848,922	23,759,148
NET INCREASE (DECREASE) IN CASH & CASH EQUIVALENTS	4,616,964	(185,624)	6,342,161

CASH & CASH EQUIVALENTS, BEGINNING BALANCE	1,725,197	1,910,821	-
CASH & CASH EQUIVALENTS, ENDING BALANCE	$ 6,342,161	$ 1,725,197	$ 6,342,161
SUPPLEMENTAL DISCLOSURES:			
Interest paid	$ 360	$ 14,715	$ 33,067
Income taxes paid	$ -	$ -	$ 248
NONCASH INVESTING AND FINANCING ACTIVITIES:			
Common stock and warrants issued for asset purchase	$ -	$ 4,674,853	$ 4,674,853
Options issued for previously accrued director compensation	$ -	$ 45,000	$ 45,000
Commitment shares issued for shares distributed for capital contribution	$ 3,137,500	$ -	$ 3,137,500
Amortization of commitment shares issued for shares distributed for capital contribution	$ 2,485,540	$ -	$ 2,485,540

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

NOTE 1: NATURE OF OPERATIONS

The Company's operations began in December 2008 with the negotiations for the acquisition of the Mammary Aspirate Specimen Cytology Test System, or the MASCT System, patent rights and assignments and the FDA clearance for marketing, which acquisition was completed in January 2009. Atossa Genetics Inc. (the "Company") was incorporated on April 30, 2009 in the State of Delaware. The Company was formed to develop and market the MASCT System, which is a medical device that collects specimens of nipple aspirate fluid (NAF). The Company's fiscal year ends on December 31st.

In December 2011, the Company established the National Reference Laboratory for Breast Health, Inc., or NRLBH, as a wholly-owned subsidiary. NRLBH is the Company's CLIA-certified laboratory which performs our NAF cytology test on NAF specimens including those collected with the MASCT System. The current version of the MASCT System is called the ForeCYTE Breast Aspirator. The NRLBH is developing other tests such as the ArgusCYTE test on blood sample from breast cancer survivors to detect circulating tumor cells.

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

Development Stage Risk

From April 30, 2009 (inception) through December 31, 2013, the Company earned $1,115,900 in revenue from the sale of its MASCT System and laboratory services. The Company's activities have been accounted for as those of a "Development Stage Enterprise" as set forth in Accounting Standards Codification ("ASC") 915 "Development Stage Entities", which was previously Statement of Financial Accounting Standards No. 7 ("SFAS 7"). Among the disclosures required by ASC 915 are that the Company's financial statements be identified as those of a development stage company, and that the statements of operations, stockholders' equity and cash flows disclose activity since the date of the Company's inception.

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

NOTE 2: GOING CONCERN

The Company's consolidated financial statements are prepared using generally accepted accounting principles in the United States of America applicable to a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The Company has not yet established an ongoing source of revenue sufficient to cover its operating costs and allow it to continue as a going concern. The ability of the Company to continue as a going concern is dependent on the Company obtaining adequate capital to fund operating losses until

it becomes profitable. If the Company is unable to obtain adequate capital, it could be forced to cease operations. The accompanying consolidated financial statements do not include any adjustments that might be necessary if the Company is unable to continue as a going concern.

Management's Plan to Continue as a Going Concern

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

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

NOTE 3: SUMMARY OF ACCOUNTING POLICIES

Basis of Presentation:

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

Recently Issued Accounting Pronouncements:

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

Revenue Recognition:

Overview

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

Product Revenue

The Company recognizes revenue for sales of the MASCT kits and devices on an accrual basis for sales to distributors when the above four criteria are met. For sales of MASCT kits and devices sold directly to physicians, the revenue is typically recognized upon receipt of cash as the Company has an insufficient history which to determine 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. For sales directly to physicians, 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 are generally 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.

Cost of Revenue:

Cost of revenue consists of cost of diagnostic testing services and cost of product sales. Cost of diagnostic testing services primarily includes direct cost of material, direct labor, equipment, and shipping to process the patient samples

(including pathology, quality control analysis, and shipping charges to transport tissue sample) in our laboratory. Costs associated with performing the Company's tests are recorded as tests are processed. Costs recorded for tissue sample processing and shipping charges represent the cost of all the tests processed during the period regardless of whether revenue was recognized with respect to that test. Cost of product sales primarily includes manufacturing cost of our MASCT System for sales to distributors, which is recorded upon transfer of ownership of the goods.

Cash and Cash Equivalents:

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

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. The Company assesses the collectability of accounts receivable based primarily upon the creditworthiness of the customer as determined by credit checks and analysis, as well as the customer's payment history. Management reviews the composition of accounts receivable and analyzes historical bad debts, customer concentrations, customer credit worthiness, current economic trends, and changes in customer payment patterns to evaluate the adequacy of these reserves. As of December 31, 2013 and 2012, $354,860 and $0 in allowance for doubtful accounts and bad debt expense were assessed or recorded, respectively.

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. 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. During the course of our recall commenced in October 2013, we have recalled a substantial number of MASCT Systems. Based on management's assessment of those devices and the pending FDA clearance, management decided to establish 100% allowance for valuation reserve on all MASCT Systems, and recorded $149,946 of losses on obsolete inventory as of and for the year ended December 31, 2013. During 2012 and prior, because the sales price of the MASCT System was substantially lower than its cost, 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 of loss on reduction of inventory to the lower of cost or market was assessed and recorded for the year ended December 31, 2012. The Company outsources product manufacturing to outside manufacturer contactors. The ownership of the goods transfers from the manufacturer to the Company's customer at the time the products are shipped to the customers. As of December 31, 2013 and 2012, inventories amounted to $0 after netting of the above valuation allowances.

The Company provides, either directly or through distributors, the NAF specimen collection kits to doctors with our MASCT System for doctors to collect specimens that are returned to the CNRLBH or other laboratories for diagnostic analysis. These collection kits are considered part of the MASCT System. During the initial marketing phase, the Company distributed the kits to customers free of charge and bundle them with the MASCT System, and has not intended to deem the kits as a primary product line due to their nominal cost and value per unit. As a result, the kits are immediately expensed and recorded as selling expense upon purchasing of the kits. For the years ended December 31, 2013 and 2012, selling expense of $126,507 and $55,282 was recorded related to the ForeCYTE kits, respectively.

Property, plant, and equipment:

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

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

	Useful Life (in years)

Machinery and equipment	5
Leasehold improvements	2.083

The Company applies the provisions of FASB ASC Topic 360 (ASC 360), “Property, Plant, and Equipment” which addresses financial accounting and reporting for the impairment or disposal of long-lived assets. The Company periodically evaluates the carrying value of long-lived assets to be held and used in accordance with ASC 360, at least on an annual basis. ASC 360 requires the impairment losses to be recorded on long-lived assets used in operations when indicators of impairment are present and the undiscounted cash flows estimated to be generated by those assets are less than the assets’ carrying amounts. In that event, a loss is recognized based on the amount by which the carrying amount exceeds the fair market value of the long-lived assets. Loss on long-lived assets to be disposed of is determined in a similar manner, except that fair market values are reduced for the cost of disposal. For the years ended December 31, 2013 and 2012, $158,292 and $0 was assessed and recorded as impairment on long-life assets.

Intangible assets:

Intangible assets consist of intellectual property and software acquired. At least annually, we evaluate purchased intangibles for impairment whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of the asset and its eventual disposition are less than its carrying amount. Estimating future cash flows related to an intangible asset involves significant estimates and assumptions. If our assumptions are not correct, there could be an impairment loss or, in the case of a change in the estimated useful life of the asset, a change in amortization expense. There was no impairment of intangible assets as of and for the years ended December 31, 2013 and 2012.

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

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

Research and Development Expenses:

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

Share Based Payments:

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

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

NOTE 4: PREPAID EXPENSES

Prepaid expenses consisted of the following:

	December 31, 2013	December 31, 2012
Prepaid stock purchase agreement service fee	$ 651,961	$ -
Prepaid hardware/software	131,204	-
Prepaid insurance	112,517	62,551
Retainer and security deposits	36,906	-
Prepaid payroll taxes	-	40,082
Prepaid media relations service fee	-	20,000
	$ 932,588	$ 122,633

NOTE 5: PROPERTY, PLANT, AND EQUIPMENT

Property, plant and equipment consisted of the following:

	December 31, 2013	December 31, 2012
Machinery and equipment	$ 326,824	$ 97,383
Leasehold improvements	93,665	93,664

Capitalized new product development cost		15,000		-
Less: Accumulated depreciation		(114,050)		(31,080)
Less: Allowance for loss on impairment of assets		(158,292)		-
Property, plant, and equipment, net	$	163,147	$	159,967

Depreciation expense for the years ended December 31, 2013 and 2012 was $82,970 and $25,082, respectively. As a result of the October 2013 recall of the MASCT System and the pending FDA clearance, we have established $158,292 as an allowance for impairment of fixed assets on the molds used in production of the MASCT System devices.

NOTE 6: INTANGIBLE ASSETS

Intangible assets consisted of the following:

	December 31, 2013	December 31, 2012
Patents	$ 4,794,853	$ 4,704,853
Software	105,839	50,466
Less: Accumulated amortization	(505,059)	(115,095)
	$ 4,395,633	$ 4,640,224

Intangible assets amounted to $4,395,633 and $4,640,224 as of December 31, 2013 and December 31, 2012, respectively, mainly consisted of patents and software acquired. The acquired software mainly included $58,000 of laboratory software and $31,500 of the Company's website. Amortization expense related to software for the years ended December 31, 2013 and 2012 was $24,308 and $17,090, respectively.

Patents amounted to $4,794,853 and $4,704,853 as of December 31, 2013 and 2012, respectively and mainly consisted of patents acquired from Acueity in September 2012 and from Doctor Love in 2013. Patents - are amortized based on their determined useful life, and tested annually for impairment. Amortization expense related to patents was $365,656 and $88,650 for the years ended December 31, 2013 and December 31, 2012, respectively.

Future estimated amortization expenses as of December 31, 2013 for the five succeeding years are as follows:

As of December 31,	Amounts
2014	$ 400,784
2015	392,212
2016	384,951
2017	373,990
2018	373,990
Thereafter	2,469,706
	$ 4,395,633

NOTE 7: PAYROLL LIABILITIES:

Payroll liabilities consisted of the following:

	December 31, 2013	December 31, 2012
Accrued bonus payable	$ 408,362	$ 189,132
Accrued payroll liabilities	48,232	-
Accrued payroll tax liabilities	19,883	18,865
	$ 476,477	$ 207,997

NOTE 8: STOCKHOLDERS' EQUITY

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

Reverse Stock-Split

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

Prior Issuances of Common Stock at Inception

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).

Private Placements and Warrants

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

Placement Agent Fees

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

Warrants

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

As of December 31, 2013, 4,751,550 warrants are outstanding including 325,000 warrants issued in the Acueity transaction described below at a weighted average exercise price of $1.92 per share and substantially all of the Placement Agents Warrants have been exercised. 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 %

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

(1) There were no Level 1 inputs.

(2) Level 2 inputs include:

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

(3) Level 3 inputs include:

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

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

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

Asset Purchase and Warrants

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

Warrants

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

Fair Value Considerations

The Company's accounting for the issuance of the Acueity Warrants required the estimation of fair values of the financial instruments. The development of fair values of financial instruments requires the selection of appropriate methodologies and the estimation of often subjective assumptions. The Company selected the valuation techniques based upon consideration of the types of assumptions that market participants would likely consider in exchanging the financial instruments in market transactions. The warrants were valued using a Black-Scholes-Merton Valuation Technique because it embodies all of the requisite assumptions (including trading volatility, estimated terms and risk

free rates) necessary to fair value these instruments.

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

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

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

(1) There were no Level 1 inputs.

(2) Level 2 inputs include:

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

(3) Level 3 inputs include:

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

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.

As of December 31, 2013, the Company has granted warrants to purchase 67,000 shares of common stock to the placement agent in connection with the financing facility with Aspire Capital. The warrants are exercisable at prices ranging from $2.12 to $12.43 per share and expire in 2017. An expense of $83,897 has been recognized during 2013 for issuance of these warrants.

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 January 1, 2012, 450,275 shares were added to the 2010 Plan and on January 1, 2013, 500,000 shares were added to the 2010 Plan, as provided under the terms of the 2010 Plan.

The Company granted options and restricted stock to purchase 964,094 shares of common stock to employees and directors during the twelve months ended December 31, 2013. The Company issued 5,546 shares of common stocks in connection with the exercise of employee's stock options during 2013. As of December 31, 2013, there are 411,046 options and restricted stock available for grant under the 2010 Plan.

NOTE 9: INCOME TAXES

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

As a result of the Company's cumulative losses, management has concluded that a full valuation allowance against the Company's net deferred tax assets is appropriate. No income tax liabilities existed as of December 31, 2013 and 2012 due to the Company's continuing operating losses.

NOTE 10: CONCENTRATION OF CREDIT RISK

Financial instruments that potentially subject the Company to concentration of credit risk consist principally of cash deposits. Accounts at each institution are insured by the Federal Deposit Insurance Corporation ("FDIC") up to $250,000. At December 31, 2013 and 2012, the Company had $6,092,161 and $1,475,197 in excess of the FDIC insured limit, respectively.

NOTE 11: COMMITMENTS AND CONTINGENCIES

Lease Commitments

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

On March 4, 2011, the Company entered into a commercial lease agreement with Sanders Properties, LLC for office space located in Seattle, WA. The lease provides for monthly rent of $1,100 and a security deposit of $1,500. The lease terms are from April 1, 2011 through March 31, 2013. For the year ended December 31, 2013, the Company incurred $12,100 of rent expense for the lease. On March 20, 2014, the Company entered into a new agreement with Sanders properties which extends the terms of the lease through March 31, 2015 with a monthly rent of $1,150.

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

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

On December 9, 2011, the Company entered into another commercial lease agreement with Fred Hutchinson Research Center for lab and office space located in Seattle, WA. The lease provides for monthly rent of $16,395 for the period from February 24, 2012 to August 31, 2012, $19,923 for the period from September 1, 2012 to August 31, 2013, and $20,548 for the period from September 1, 2013 to November 29, 2014. The security deposit of $32,789 was paid in March 2012. In July 2013, the Company entered into an agreement with ARE LLC (Alexandria) to lease additional office spaces in our existing building under a separate lease agreement. The lease is from August 2013 through November 2014, and the gross rent is $ 4,800 per month. For the year ended December 31, 2013, the Company incurred $288,569 of rent expense for the lease, which included leasing office management expenses.

On March 24, 2014, the Company entered into another commercial lease agreement with ARE LLC (Alexandria) which extends the term of the existing lease with Fred Hutchison Research Center which expires in November 2014 through November 30, 2016. The lease provides for monthly rent payments of $22,736 from December 2014 through November 2015 and $23,258 from December 2015 through November 2016. The Company will incur 3.7% in tenant share of operating expenses and $25,000 in security deposit.

The future minimum lease payments due subsequent to December 31, 2013 under all non-cancelable operating leases for the next five years are as follows:

As of December 31,	Amount
2014	386,252
2015	355,758
2016	330,390
2017	-
2018	-
Thereafter	-
Total minimum lease payments	$ 1,072,400

Affymetrix Purchase Commitment

In September 2013, the Company entered into an "OwnerChip Program Agreement" with Affymetrix, Inc, a manufacturer of GeneChip Systems, where Affymetrix has agreed to loan a GeneChip System 3000Dx v.2 ("instrument") to us if we purchase and take delivery of a minimum thirty GeneChip Human Gene U133 Plus 2.0 (30-pack) arrays at $21,590 per 30 pack for the next three years for a total purchase obligation of $647,700 with a minimum purchase of ten 30-pack arrays per contract year. At the end of the three year contract, upon fulfillment of the purchase commitment, the instrument title and ownership transfer to the Company at no additional cost. In addition to the GeneChip Human Gene, we must purchase a two year service contract for $51,600 to cover maintenance of the instrument during the contract period. We placed an order for four 30-pack arrays during the year ended December 31, 2013 for $94,723. We are obligated to purchase 26 additional arrays during the three year contract term.

A5 Software Development Commitment

On June 10, 2013 the Company entered into an irrevocable license and service agreement with A5 Genetics KFT, Corporation, pursuant to which the Company received the world-wide (other than the European Union) exclusive license to the software used in the NextCYTE test. The Company has the right to prosecute patents related to this software, two of which the Company has filed in the United States. The patent applications have been assigned to us. The Company paid a one-time fee of $100,000 to A5 Genetics in 2013 and in March 2014 the Company completed software validation and paid an additional $100,000 to A5 Genetics. The Company is obligated to pay up to an additional $1.2 million to A5 Genetics upon the achievement of future milestones. The Company must also pay a royalty of $50 for each NextCYTE Test performed and $65 as a service fee for each NextCYTE Test performed. The agreement terminates on the later of the ten year anniversary of the agreement or the expiration of the latest to expire patent covering the software.

Contingencies

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

On December 11, 2012, Mr. Kelly filed a complaint in the United States District Court, Western Division of Washington seeking compensatory damages, interest and attorneys' fees related to the termination of Mr. Kelly's consulting contract and the rescission of shares issued to him in July 2010 in connection with his resignation from the

Company as President and a director. The specific amount of damages sought is to be proven at trial and is not specified. On July 8, 2013, the court granted the Company's motion to compel arbitration of these claims and therefore this action was stayed pending resolution of the arbitration of the claims; however, Mr. Kelly has not initiated arbitration of those claims.

On February 26, 2013, Mr. Victor Cononi filed a complaint in the United States District Court, Western Division of Washington seeking compensatory damages, interest and attorneys' fees related to the rescission of shares issued to him in July 2010 in connection with Mr. Kelly's resignation from the Company as President and a director. Mr. Cononi is the father of Mr. Kelly's paramour. The specific amount of damages sought is to be proven at trial and is not specified. . In August 2013, the court granted the Company's motion to compel arbitration of these claims and therefore this action was stayed pending resolution of the arbitration of the claims; however, Mr. Cononi has not initiated arbitration of those claims.

A hearing in the arbitration has been held in abeyance to accommodate other third party civil and federal criminal proceedings alleging securities and wire fraud that have been brought against Mr. Kelly with respect to his prior employment and predating his service with the Company. On March 11, 2014 a press release was issued by the FBI stating that Mr. Kelly had pled guilty in Manhattan federal court to securities and wire fraud charges related to his employment as CEO of Wwebnet. Mr. Kelly also agreed to forfeit $2,111,600 and, separately, pay $2,111,600 in restitution. The sentencing hearing is scheduled for July 17, 2014.

The Company is reasonably confident in its defenses to Mr. Kelly's and Mr. Cononi's claims. Consequently, no provision or liability has been recorded for these claims as of December 31, 2013. 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.

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

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

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

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FDA Warning Letter

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

On October 4, 2013, the Company initiated a voluntary recall of the system to address FDA's concerns regarding the modifications identified in the Warning Letter. As a result of this recall, this product is currently not being marketed or distributed in the U.S. The Company submitted a new premarket notification or 510(k) application for submission to the FDA on December 23, 2013 that covers the collection, preparation, and processing of NAF specimens at our laboratory and includes the spray method of fixing specimens to the collection membrane.

We hope that the FDA will complete their review of our submission within 90 days; but of course we cannot predict if they will ask us for additional information or otherwise complete their review within the 90 days. We received a letter from the FDA on February 28, 2014 requesting additional information and we have up to 180 days to respond.

On March 14, 2014, the FDA completed a follow up inspection at our Seattle facility. A Form 483 was provided to us at the conclusion of the inspection. In the FDA's most recent Form 483, five inspectional observations were identified regarding our quality management system. The FDA inspector also verbally identified five additional discussion points related to our product labeling prior to the recall of the MASCT System; sufficiency of the content of our pending 510(k) submission for the ForeCYTE Breast Aspirator; and other compliance issues. On March 26, 2014, we submitted a response to the FDA, which included our proposed corrective actions to address the FDA's observations and discussion points. Whether the FDA will accept our response is uncertain, particularly in light of the similar nature of certain of the current inspectional observations to previous inspectional observations. If the FDA does not agree with our proposed corrective actions, or accepts them but finds that we have not implemented them adequately, or if we otherwise are found to be out of compliance with applicable regulatory requirements at a later date, the FDA could initiate an enforcement action including additional warning letters, fines and penalties. The FDA also may not clear our pending 510(k) for the ForeCYTE Breast Aspirator or our other devices and services under development. Any of the foregoing would have a material adverse effect on our business.

The Company has recorded a loss contingency for the year ended December 31, 2013 of $211,493 and have incurred $223,750 in actual expenses related to the costs of the recall, including the estimated costs of pursuing the additional 510(k) clearance. The recall and 510(k) process may take longer than expected and we may incur costs that we have not anticipated. Accordingly, the actual amount of the loss contingency may be higher than we currently expect.

NOTE 12: RELATED PARTY TRANSACTIONS

Loans from Officers

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

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

Exclusive License Agreement

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

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

Executive Compensation

On May 19, 2010, the Company entered into employment agreements with its Chief Executive Officer, 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, and $250,000, respectively for the two executives.

On July 22, 2010, the Company restated and amended the employment agreements with its CEO and CSO. The agreements modified the base annual salary amounts to $250,000 and $200,000, respectively, effective retroactively to May 19, 2010. For the year ended December 31, 2013, salaries and bonuses of CEO and CSO amounted to $359,250 and $267,400, of which $137,044 and $221,932 were recorded to research and development expense, respectively. Compensation expense due to options granted to CEO and CSO amounted $41,692 and $16,677, respectively, for the year ended December 31, 2013, all recorded in general and administration expense. For the year ended December 31, 2012, the total amount of salaries and bonuses of the CEO and CSO was $322,590 and $243,554, of which $161,554 and $243,554 was recorded to research and development expense, respectively. Compensation expense due to options granted to CEO and CSO amounted $42,151 and $16,861, respectively, for the year ended December 31, 2012, all recorded in general and administration expense

Share-Based Compensation

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

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

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

2010 through December 2012	Employees	Employees & Officers	Directors	CEO & CSO
Date of Grant	December 2012	September 2011	September 2011-April 2012	July 2010
Fair value of common stock on date of grant	$4.11-$4.24(D)	$ 0.9060 (B)	$0.9060 (B) -$6.00(C)	$ 2.7560 (A)

Exercise price of the options	$4.11 - $4.24	$	1.25		$1.25-$6.00	$	5.00	
Expected life of the options (years)	5.74 - 6.11		5.65		5.00 5.65		3.33	
Dividend yield	0.00%		0.00	%	0.00%		0.00	%
Expected volatility	42.44 44.58%		53.90	%	53.90-62.46%		58.59	%
Risk-free interest rate	0.91-0.99%		1.08	%	0.89 1.08%		1.03	%
Expected forfeiture per year (%)	10.00%		10.00	%	0.00%		0.00	%
Weighted average fair value of the options per unit	$1.7426-$1.7842	$	0.3579		$0.3579-$3.0367	$	0.6744	

Year Ended December 2013	Employees	Employees & Officers	Directors	CEO & CSO
Date of Grant	January - December 2013	January - June 2013	May & October 2013	March 2013
Fair value of common stock on date of grant(E)	$2.05 - $5.19(D)	$4.11 - $4.58(D)	$2.04 - $6.59 (D)	$ 6.57 (D)
Exercise price of the options	$2.05 - $5.19	$4.11 - $4.58	$2.04 - $6.59	$ 6.57
Expected life of the options (years)	6.09 - 6.11	5.00 6.11	5.00 5.31	5.00
Dividend yield	0.00%	0.00%	0.00%	0.00 %
Expected volatility	40.73 41.81%	40.96 - 41.05%	41.06-41.53%	47.09 %
Risk-free interest rate	1.73 -1.97%	1.03-1.36%	0.73 - 1.49%	1.13 %
Expected forfeiture per year (%)	10.00%	10.00%	10.00%	0.00 %
Weighted average fair value of the options per unit	$0.878 - $2.18	$1.69 - $1.89	$0.790 - $2.49	$ 2.70

(A) The fair value of the Company's common stock was derived implicitly from the public offering filed in March 2010 at $3.00 per share and from the terms of an underwritten offering contemplated in July 2010 at $6.00 per Unit that was filed in October 2010, with $2.756 per share being allocated to common stock using an iterative approach in order for the combined fair value of the common stock and warrants to equal the amount of consideration to be received for the offering.

(B) 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.

(C) 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.

(D) The fair values of the Company's common stock were derived from the closing prices on the NASDAQ Capital Market as of the dates of grant.

In 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 $140,056 and $1,443,760 for the years ended December 31, 2013 and 2012, respectively.

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) Level 1 inputs include:

Stock price- The fair values of the Company's common stock after the commencement of being publicly traded in November 2012 were derived from the closing prices on the NASDAQ Capital Market as of the dates of grant.

(2) Level 2 inputs include:

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

(3) Level 3 inputs include:

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

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

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

Stock price- The fair values of the Company's common stock prior to the commencement of being publicly traded in November 2012 were derived implicitly from the contemplated public offerings and private placements prior to the grant dates.

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.

Fair value of the Company's common stock determined at $6.00 per share for the April 2012 option grants

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 NAF cytology test, which involves cytopathology and five biomarkers of hyperplasia and one biomarker of sample integrity, was completed, tested, and validated to CLIA standards. Computer hardware and software was acquired, set up, made operational, and the ForeCYTE report template, with unique reporting information for the requesting physician and a patient letter template, were created. The company explored and identified a technology for the ArgusCYTE test, negotiated a supply agreement with the supplier, and tested and validated the test. An ArgusCYTE report template was also established and a new reporting scheme invented and a patent application filed.

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

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

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

Options issued and outstanding as of December 31, 2013 and their activities during the twelve months then ended are as follows:

	Number of Underlying Shares	Weighted-Average Exercise Price Per Share	Weighted-Average Contractual Life Remaining in Years

Outstanding as of January 1, 2013	1,052,137	$	3.79	
Granted	1,507,584		4.86	
Expired	(1,625)		6.00	
Forfeited	(269,831)		4.40	
Exercised	(5,546)		1.79	
Outstanding as of December 31, 2013	2,282,719		4.43	7.89
Exercisable as of December 31, 2013	1,063,612		4.49	6.34
Vested and expected to vest [(1)]	2,125,932		4.43	7.79

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

As of December 31, 2013 and 2012, the aggregate intrinsic value of options outstanding was $3,656,782 and $1,150,416, respectively.

Issuance of Restricted Common Stock for Director's Compensation

On October 10, 2013, the Company issued 24,510 shares of restricted stock with a grant date value of $50,000 or $2.04 per share to a new board member. The restriction will be removed quarterly for a proportional number of granted shares over the first year of service on the board, and the grant date value of such shares will be expensed in the quarter the restriction is removed. For the year ended December 31, 2013, $11,248 was recorded through the Company's general and administration expense.

NOTE 13: 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 all of Acueity's U.S. and foreign patents related to the manufacturing, use, and sale of the Viaduct Miniscope and accessories, the Manoa Breast Biopsy system, the Excisor Bioptome, the Acueity Medical Light Source, the Viaduct Microendoscope and accessories, and cash in the amount of $400,000; no liabilities were assumed in the transaction. In consideration for the assets, the Company issued 862,500 shares of common stock, valued at $5.00 per share, the offering price listed on the prospectus filed pursuant to Rule 424(b)(4) on November 9, 2012, and warrants to purchase up to 325,000 shares of common stock at an exercise price of $5.00 per share, to the shareholders of Acueity, subject to a six-month lock up agreement. The warrants, which have a five-year term, do not have a cashless exercise provision. The warrants were valued at $2.3457 per warrant, using a Black-Scholes-Merton Valuation Technique because it embodies all of the requisite assumptions (including trading volatility, estimated terms and risk-free rates) necessary to determine the fair value of the warrants (see Note 8). There are no future financial obligations from the Company to Acueity from the commercialization of the acquired assets.

NOTE 14: SUBSEQUENT EVENTS

On January 29, 2014, the Company closed a public offering of 5,834,234 units at the price of $2.40 per unit for the total gross proceed of approximately $14.0 million. Each unit consists of one share of common stock and a warrant to purchase 0.20 of a share of common stock. The warrants are exercisable at $3.00 per share and callable by the Company at $6.00 per share if certain conditions are met. As of the date of this filing, management has been in the process of assessing the fair value of the warrants issued in this public offering.

On March 24, 2014, the Company entered into another commercial lease agreement with ARE LLC (Alexandria) which extends the term of the existing lease with Fred Hutchison Research Center which expires in November 2014 through November 30, 2016. The lease provides for monthly rent payments of $22,736 from December 2014 through November 2015 and $23,258 from December 2015 through November 2016. The Company will incur 3.7% in tenant share of operating expenses and $25,000 in security deposit.

On March 20, 2014, the Company entered into a new agreement with Sanders properties which extends the terms of the lease through March 31, 2015 with a monthly rent of $1,150.

Management has evaluated subsequent events through March 26, 2014, the date which the consolidated financial statements were available to be issued. All subsequent events requiring recognition as of December 31, 2013 have been incorporated into these consolidated financial statements, and besides the disclosures herein, there are no subsequent events that require disclosure in accordance with FASB ASC Topic 855, "Subsequent Events".

SIGNATURES

Pursuant to the requirements Section 13 or 15(d) of the Securities Exchange Act of 1934, the issuer, a corporation organized and existing under the laws of the State of Delaware, has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized in the City of Seattle, State of Washington, on the 27th day of March, 2014.

Atossa Genetics Inc.

By: /s/ Steven C. Quay
Steven C. Quay, M.D., Ph.D.
Chairman, Chief Executive Officer and President

POWER OF ATTORNEY

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

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

Signature	Office(s)	Date
/s/ Steven C. Quay **Steven C. Quay, M.D., Ph.D.**	Chairman, Chief Executive Officer and President (Principal Executive Officer)	March 27, 2014
/s/ Kyle Guse **Kyle Guse**	Chief Financial Officer, General Counsel and Secretary (Principal Financial and Accounting Officer)	March 27, 2014
/s/ Richard I. Steinhart Richard I. Steinhart	Director	March 27, 2014
/s/ Shu-Chih Chen **Shu-Chih Chen, Ph.D.**	Director	March 27, 2014
/s/ Gregory Weaver **Gregory Weaver**	Director	March 27, 2014
/s/ Stephen J. Galli **Stephen J. Galli, M.D.**	Director	March 27, 2014

/s/ H. Lawrence Remmel **H. Lawrence Remmel**	Director	March 27, 2014

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EXHIBIT INDEX

Exhibit No.	Description	Incorporated by Reference Herein Form	Date
2.1	Agreement and Plan of Reorganization, dated September 30, 2012, by and among the Company, Acueity Healthcare, Inc., and Ted Lachowicz, as Stockholder Representative	Registration Statement on Form S-1, as Exhibit 2.1	October 4, 2012
3.1	Certificate of Incorporation of Atossa Genetics Inc.	Registration Statement on Form S-1, as Exhibit 3.2	June 11, 2012
3.2	Bylaws of Atossa Genetics Inc.	Registration Statement on Form S-1, as Exhibit 3.4	June 11, 2012
3.3	Amendment to Bylaws of Atossa Genetics Inc.	Current Report on Form 8-K, as Exhibit 3.1	December 20, 2012
4.1	Specimen common stock certificate	Registration Statement on Form S-1, as Exhibit 4.1	May 21, 2012
4.2	Form of Warrant from 2011 private placement	Registration Statement on Form S-1, as Exhibit 4.2	October 4, 2012
4.3	Form of Placement Agent Warrant from 2011 private placement	Registration Statement on Form S-1, as Exhibit 4.3	October 4, 2012
4.4	Form of Warrant dated September 30, 2012	Registration Statement on Form S-1, as Exhibit 4.4	October 4, 2012
4.5	Registration Rights Agreement, dated as of March 27, 2013, by and between the Company and Aspire Capital Fund, LLC.	Registration Statement on Form S-1, as Exhibit 4.5	April 5, 2013
4.6	Registration Rights Agreement, dated as of November 8, 2013, by and between the Company and Aspire Capital Fund, LLC.	Quarterly Report on Form 10-Q, as Exhibit 4.1	November 12, 2013
4.7	Form of Warrant Agreement from January 2014 Public Offering	Current Report on Form 8-K, as Exhibit 4.1	January 20, 2014
4.8	Form of Warrant issued to Dawson James Securities Inc. in	Current Report on Form 8-K, as Exhibit 4.2	January 20, 2014

January 2014

10.1	Exclusive Patent License Agreement with Ensisheim Partners, LLC, dated July 27, 2009	Registration Statement on Form S-1, as Exhibit 10.1	February 14, 2012
10.2	Termination of Exclusive Patent License Agreement, dated June 17, 2010	Registration Statement on Form S-1, as Exhibit 10.2	February 14, 2012
10.3#	Restated and Amended Employment Agreement with Steven Quay	Registration Statement on Form S-1, as Exhibit 10.3	February 14, 2012
10.4#	Restated and Amended Employment Agreement with Shu-Chih Chen	Registration Statement on Form S-1, as Exhibit 10.4	February 14, 2012
10.5	Form of Indemnification Agreement	Registration Statement on Form S-1, as Exhibit 10.5	May 21, 2012

10.6#	Atossa Genetics Inc. 2010 Stock Option and Incentive Plan, as amended	Registration Statement on Form S-1, as Exhibit 10.6	June 11, 2012
10.7#	Form of Incentive Stock Option Agreement	Registration Statement on Form S-1, as Exhibit 10.7	June 11, 2012
10.8#	Form of Non-Qualified Stock Option Agreement for Employees	Registration Statement on Form S-1, as Exhibit 10.8	June 11, 2012
10.9#	Form of Non-Qualified Stock Option Agreement for Non-Employee Directors	Registration Statement on Form S-1, as Exhibit 10.9	June 11, 2012
10.10	Form of Subscription Agreement	Registration Statement on Form S-1, as Exhibit 10.10	February 14, 2012
10.11	Sublease Agreement with CompleGen, Inc. dated September 29, 2010	Registration Statement on Form S-1, as Exhibit 10.11	February 14, 2012
10.12	Patent Assignment Agreement by and between the Company and Ensisheim Partners, LLC	Registration Statement on Form S-1, as Exhibit 10.12	April 6, 2012
10.13#	Form of Restricted Stock Award Agreement	Registration Statement on Form S-1, as Exhibit 10.13	June 11, 2012
10.14	Form of Lock-Up Agreement	Registration Statement on Form S-1, as Exhibit 10.14	April 6, 2012
10.15	Business Consultant Agreement with Edward Sauter	Registration Statement on Form S-1, as Exhibit 10.16	February 14, 2012
10.16	Prototype Development Proposal and Terms and Conditions, between the Company and HLB, LLC	Registration Statement on Form S-1, as Exhibit 10.17	February 14, 2012
10.17	Office Lease with Sander Properties, LLC, dated March 4, 2011	Registration Statement on Form S-1, as Exhibit 10.20	April 6, 2012
10.18	Office Lease with Sander Properties, LLC, dated July 8, 2011	Registration Statement on Form S-1, as Exhibit 10.21	April 6, 2012
10.19	Office Lease with Sander Properties, LLC, dated September 20, 2011	Registration Statement on Form S-1, as Exhibit 10.22	April 6, 2012
10.20	Sublease with Fred Hutchinson Cancer Research Center, dated December 9, 2011	Registration Statement on Form S-1, as Exhibit 10.23	April 6, 2012
10.21			May 21, 2012

	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	
10.22	Term Sheet for License Agreement between the Company and Inven2 AS	Registration Statement on Form S-1, as Exhibit 10.25	June 25, 2012
10.23	Agreement between the Company and Accellent Inc., dated August 8, 2011	Registration Statement on Form S-1, as Exhibit 10.26	June 25, 2012
10.24	Supply Agreement between the Company and Biomarker LLC, dated June 24, 2011	Registration Statement on Form S-1, as Exhibit 10.27	June 18, 2012
10.25	Purchase Agreement between the Company and Hologic Inc., dated May 11, 2011	Registration Statement on Form S-1, as Exhibit 10.28	June 25, 2012

10.26	Agreement between the Company and Biomarker LLC, dated June 22, 2012	Registration Statement on Form S-1, as Exhibit 10.29	June 25, 2012
10.27	Form of Investor Lock-Up Agreement	Registration Statement on Form S-1, as Exhibit 10.30	August 30, 2012
10.28	Supply and Distribution Agreement, dated as of September 21, 2012, between the Company and Diagnostics Test Group LLC	Registration Statement on Form S-1, as Exhibit 10.31	October 4, 2012
10.29	Employment Agreement between the Company and Kyle Guse dated January 4, 2013#	Registration Statement on Form S-1, as Exhibit 10.31	January 28, 2013
10.30	Common Stock Purchase Agreement, dated as of March 27, 2013, by and between the Company and Aspire Capital Fund, LLC.	Annual Report on Form 10-K	March 28, 2013
10.31	OwnerChip Program Agreement dated September 1, 2013, between the National Reference Laboratory for Breast Health, Inc. and Affymetrix, Inc.	Quarterly Report on Form 10-Q, as Exhibit 10.1	November 12, 2013
10.32	License and Services Agreement dated June 10, 2013, between Atossa Genetics and A5 Genetics KFT.	Filed Herewith	
10.33	Office space Lease dated July 18, 2013 between Alexandria (ARE) and the Company.	Filed Herewith	
10.34	Common Stock Purchase Agreement, dated as of November 8, 2013, by and between the Company and Aspire Capital Fund, LLC.	Quarterly Report on Form 10-Q, as Exhibit 10.2	November 12, 2013
10.35	Lab and Office space Lease Agreement dated March 24, 2014 between Alexandria (ARE) and the Company.	Filed Herewith	
21.1	List of Subsidiaries.	Registration Statement on Form S-1, as Exhibit 21.1	October 4, 2012
23.1	Consent of KCCW Accountancy Corp	Filed herewith	
24.1	Powers of Attorney	Filed herewith on the signature page	
31.1		Filed herewith	

	Certification pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934 of Steven C. Quay	
31.2	Certification pursuant to Rule 13a-14(a) under the Securities Exchange Act of Kyle Guse	Filed herewith
32.1	Certification pursuant to 18 U.S.C. Section 1350 of Steven C. Quay	Filed herewith
32.2	Certification pursuant to 18 U.S.C. Section 1350 of Kyle Guse	Filed herewith
101.INS	XBRL Instance Document (1)	
101.SCH	XBRL Taxonomy Extension Schema Document (1)	
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document (1)	
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document (1)	
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document (1)	
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document (1)	

#	Indicates management contract or compensatory plan, contract or agreement.
	Confidential treatment has been granted for portions of this exhibit.
	Schedules and exhibits omitted pursuant to Item 601 of Regulation S-K.

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