ATOSSA GENETICS INC
Form 10-K
March 30, 2015

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, 2014

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.)**

2345 Eastlake Ave. East, Suite 201

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. Yes x No ¨

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 ¨ No x

As of June 30, 2014, 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 $32,864,598. Shares of common stock held by each officer and director and by each person who is known to own 10% or more of the outstanding Common Stock have been excluded in that such persons may be deemed to be affiliates of the Company. This determination of affiliate status is not necessarily a conclusive determination for other purposes

The number of shares outstanding of the registrant's Common Stock, par value $0.001, as of March 27, 2015 was 25,396,124.

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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 maintain our clearances from the U.S. Food and Drug Administration, or FDA, and foreign regulatory bodies, and the CE Certificates of Conformity granted by our notified body, to sell, market and distribute our medical devices;
- whether we can achieve our revenue forecast and other financial projections for 2015;
- our ability to successfully launch and commercialize the FullCYTE Breast Aspirator in the United States and our ForeCYTE Breast Aspirator outside the United States;
- our ability to successfully continue selling and servicing Pharmacogenomics and NAF cytology testing in our laboratory;
- 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 launch and commercialize the FullCYTE Breast Aspirator in the United States and ForeCYTE Breast Aspirator and laboratory tests outside the United States;
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- our ability to engage third party suppliers to manufacture the ForeCYTE Breast Aspirator, FullCYTE Breast Aspirator, FullCYTE Microcatheter, other devices under development and their components at quantities and costs acceptable to us;

- our ability to satisfy ongoing FDA, European Union (EU) and foreign requirements for manufacturing, distributing, and promoting the FullCYTE Breast Aspirator, NAF cytology test and FullCYTE Microcatheter and to obtain regulatory approvals, clearances and CE Certificate of Conformity for our other products and services in development;

- our ability to successfully defend ongoing litigation, including 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 our laboratory tests, including the NAF cytology and Pharmacogenomics tests;

- our ability to establish and maintain intellectual property rights covering our products and services;

- the willingness of health insurance companies, including those who are members of the MultiPlan, FedMed and HealthSmart networks, and other third party payors to approve our products and services for coverage and reimbursement;

- our ability to establish and maintain an independent sales representative force, including with our current and future distributors and their sub-distributors, to market our current products and services and those that we may develop;

- 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 anticipated results as set forth in 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 activities conducted by the NRLBH. We were incorporated in Delaware in April 2009. Our principal executive offices are located at 2345 Eastlake Ave. East, Suite 201, 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 2015 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.

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PART I

ITEM 1. BUSINESS

Overview

We are a healthcare company focused on improving breast health through the development of a suite of laboratory services, medical devices and therapeutics. Our laboratory services are being developed and performed by our wholly owned subsidiary, The National Reference Laboratory for Breast Health, Inc. (the "NRLBH"). The NRLBH has developed and is currently marketing nipple aspirate fluid, or NAF, cytology tests and pharmacogenomics tests.

Our medical devices include the ForeCYTE Breast Aspirator for distribution outside the United States and the FullCYTE Breast Aspirator for the U.S. market. These devices are intended for the collection of NAF for cytological testing at a laboratory. The current version of the ForeCYTE Breast Aspirator is not cleared by the FDA for marketing in the United States; however, this device is CE-marked and is therefore being commercialized in the European Union and the countries of the European Free Trade Association (EFTA). The FullCYTE Breast Aspirator does not have a CE-mark, but it has been cleared by the FDA for the collection of NAF for cytological purposes. For this reason the FullCYTE device is being commercialized for the U.S. market. Other devices under development include intraductal 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. In March 2015, we launched the FullCYTE Breast Aspirator in the United States and the ForeCYTE Breast Aspirator in the EU and the countries of the EFTA, initially focusing on the Netherlands, Germany, Switzerland, and the United Kingdom.

The ForeCYTE Breast Aspirator will not be 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 that we plan to develop. For example, we plan to develop our patented intraductal microcatheters for the potential delivery of a pharmaceutical targeted to a condition called ductal carcinoma in-situ, or DCIS, which is the most common type of non-invasive breast cancer. 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 ductal hyperplasia or 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 in the United States.

Our 2015 objectives consist of the following:

(1) Launch and commercialize the FullCYTE Breast Aspirator in the United States: We began the launch of our FullCYTE Breast Aspirator in the United States in March 2015. We have engaged Thermo Fisher Scientific and Henry Schein Medical as our initial U.S. distributors and we plan to build our own specialty sales force.

(2) Launch and commercialize the ForeCYTE Breast Aspirator in the EU: We received CE Certificate of Conformity from our notified body for the ForeCYTE Breast Aspirator and Collection Kits in October 2014 and in March 2015 began the launch of this device in the EU and the countries of the European Free Trade Association (EFTA), focusing initially on the Netherlands, Germany, Switzerland, and the United Kingdom.

(3) Maximize total gross revenue from our products and services: We plan to grow our revenue by selling our products and promoting the tests currently being offered by the NRLBH, including NAF cytology tests and pharmacogenomics tests, and by developing and commercializing additional laboratory tests. We launched the pharmacogenomics test in October 2014 and processed and reported 527 tests through December 31, 2014.

(4) Begin one or more clinical studies using our devices and potential pharmaceutical therapy: We plan to develop a pharmaceutical to be delivered through our patented microcatheters, initially to treat DCIS. We also plan to develop a pharmaceutical to treat one or more conditions detected by the laboratory tests conducted on the NAF specimens collected with our breast aspirator devices. In this fashion, our devices and laboratory tests can be used as companion diagnostics to the therapies we plan to develop. We expect that these therapies and companion diagnostics will initially target DCIS, ductal hyperplasia, 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.

Many of our medical devices and the NRLBH's laboratory services, as well as the breast health companion diagnostics, are currently under development and, if required by the FDA, we must receive additional regulatory clearances and/or approvals prior to marketing and commercialization. The current regulatory status of our devices and the laboratory tests offered by the NRLBH is indicated in the table below.

Summary of Our Products and Services

Our products and services currently being offered and currently under development consist primarily of the following:

	Product or Service	Regulatory Status	Primary Market	Commercialization Status
Laboratory Tests Offered or Being Developed by NRLBH	Pharmacogenomics Test	Laboratory Developed Test (LDT); not FDA approved or cleared	United States	Launched October 2014
	NAF Cytology Test	LDT	United States	Launched December 2012
	NextCYTE Breast Cancer Test	LDT	United States	Validation Stage
	ArgusCYTE Breast Health Test	LDT	United States	Validation Stage
	Other Tests	Under Development	Various	N/A
Medical Devices	FullCYTE Breast Aspirator	FDA Cleared	United States	Launched March 2015
	ForeCYTE Breast Aspirator	CE Marked	EU and countries of EFTA	Launched March 2015
	FullCYTE Microcatheter to Collect Ductal Lavage Fluid for Cytology and/or Deliver Therapeutics	Additional FDA Clearance to be Sought	United States	Validation Stage
	Various Diagnostic Tools Including Microendoscopes	FDA Cleared; Additional Clearances may be Required	United States	Pre-launch; Evaluating Commercial Opportunities
Pharmaceuticals	Therapeutic to treat ductal hyperplasia, PED or high risk women	Pre-Clinical; Not approved by the FDA or any other foreign competent authorities	United States; Europe	Pre-clinical
	Therapeutic delivered via our microcatheter to treat DCIS	Pre-Clinical; Not approved by the FDA or any other foreign competent authorities	United States; Europe	Pre-clinical

*See below under the caption “Government Regulation” for information relating to the regulation of LDTs.

We have not yet established an ongoing source of revenue sufficient to cover our operating costs and allow us to continue as a going concern. Our ability to continue as a going concern is dependent on obtaining adequate capital to fund operating losses until we become profitable. We plan to obtain additional capital resources by: selling our equity securities; selling the FullCYTE Breast Aspirator in the United States and the ForeCYTE Breast Aspirator outside the United States; generating laboratory service revenue from our services 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. In 2013, substantially all of our revenue was from sales of the MASCT System and patient collection kits and from NAF cytology testing services performed by the NRLBH and substantially all of our revenue in 2014 was from pharmacogenomics testing performed by the NRLBH. As a result of the recall of the MASCT System and patient collection kits in October 2013, we did not generate revenue from October 2013 through the third quarter of 2014 when we launched and began generating revenue from the pharmacogenomics test offered by the NRLBH.

We will incur additional sales and marketing expenses as we commercialize the FullCYTE Breast Aspirator in the United States and the ForeCYTE Breast Aspirator in the EU and EFTA and as we continue to promote our pharmacogenomics test. We will need to revise our sales and marketing materials, continue hiring direct sales employees and engage new distributors. We also expect to continue to hire clinical consultants to assist in the sales of our NAF cytology tests. The FullCYTE Breast Aspirator may not gain adoption as quickly as the ForeCYTE Breast Aspirator and it may sell at lower margins. If so, our potential sales and revenues will be negatively impacted.

Our Capital Resources

As of December 31, 2014, we had cash and cash equivalents of $8,500,718. Additional potential capital resources as of the date of filing this report consist of the following:

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 approximately $11.3 million. 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, at our request, up to an aggregate of $25 million of shares of our common stock over the 30 month term of the new agreement, subject to certain conditions set forth therein. On December 23, 2013, we sold $1 million of common stock to Aspire under this new agreement and in 2015 prior to the filing of this report we sold $1.5 million to Aspire. Up to a total of $22.5 million remains available for sale to Aspire as of the date of filing this report.

On November 13, 2013, we filed a shelf registration statement with the SEC registering $40 million of our securities.

On January 29, 2014, we utilized the shelf registration statement and closed a public offering of approximately 5.8 million 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 of 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 Common Stock Purchase Agreements with Aspire Capital Fund, LLC

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 over the 30-month term of the agreement. Through March 27, 2015, we have sold the following shares to Aspire under the terms of our November 8, 2013 agreement with them: 500,000 shares with total proceeds to us of $1,000,000 in December 2013, and 832,066 shares with total proceeds to us of $1,539,367 from January 1, 2015 through March 27, 2015.

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 $2.00 per share. The second milestone event, which has not been satisfied, 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 are obligated to register the shares issued and issuable to Aspire 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 after November 8, 2013. 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. 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.

Reimbursement Organizations

As of the date of this report, we have contracts with the following third parties to facilitate the reimbursement process from insurers for the NRLBH laboratory tests: 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 with MultiPlan allows us to participate in the MultiPlan, PHCS and PHCS Savility Networks. FedMed 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. 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 will 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 ForeCYTE Breast Aspirator and FullCYTE Breast Aspirator

Overview of the Devices

The ForeCYTE Breast Aspirator is a CE marked medical device which 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 any testing laboratory for cytological analysis, including the NRLBH, our wholly-owned, CLIA-certified specialized cytology and molecular diagnostics laboratory in Seattle, Washington. The FullCYTE Breast Aspirator is FDA-cleared and is simpler in design as it contains four parts in a fully disposable, single-use aspirator. This device operates slightly differently than the ForeCYTE Breast Aspirator in that the NAF sample is captured via capillary tubes prior to being sent to any lab for analysis.

Clinical Development of the ForeCYTE Breast Aspirator Device

A clinical trial of the ForeCYTE Breast Aspirator device (formerly called 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 device. Thirty-one healthy, non-pregnant, pre-menopausal female volunteer subjects were tested with the ForeCYTE 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. No adverse events were reported in the study. Based on the results of the study, a premarket notification for the intended use of the device 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 device can be used for cytology testing.

On December 23, 2013, we submitted a new premarket notification 510(k) to the FDA for current version of the ForeCYTE Breast Aspirator. The current ForeCYTE Breast Aspirator has the same intended use and indications, and similar technological characteristics, and principles of operation as its predicate device. One of our studies shows that the current 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.

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, in the case of NAF collected with the current ForeCYTE device, 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 on samples collected with the ForeCYTE device 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.

Pharmacogenomics Testing

The NRLBH's pharmacogenomics test provides physicians with genetic information that can be used to guide therapeutic decisions, which may mitigate the incidence of costly adverse drug reactions and improve efficiencies.

On September 2, 2014, the NRLBH entered into a three-year rental agreement with Luminex Corporation ("Luminex"), which provides that the NRLBH acquires the right to use Luminex instruments, including accessories, peripherals and options (the "System") at no cost if the NRLBH purchases goods (the "Products") at agreed upon quantities and prices for the next three years. The minimum purchases of Products under the agreement are $452,408 per year. The title to the System remains with Luminex and the NRLBH is required to return the System to Luminex at the end of the rental agreement.

The NextCYTE Breast Cancer Test Under Development

The NextCYTE Breast Cancer Test, which is in the validation phase, 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's 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 current 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 EU for the intellectual property related to the software and have filed two patent applications in the United States covering certain aspects of the algorithm. We plan to complete a clinical trial and pursue any necessary approvals and/or clearances from the FDA. 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, in connection with the development of the NextCYTE test by the NRLBH, the NRLBH entered into an "OwnerChip Program Agreement" with Affymetrix, Inc, a manufacturer of GeneChip Systems, where Affymetrix agreed to loan a GeneChip System 3000Dx v.2 (the "Instrument") to NRLBH if NRBLH purchases and takes delivery of a minimum of thirty GeneChip Human Genome 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. In addition to the GeneChip Human Genome, the NRLBH must purchase a two year service contract for $51,600 to cover maintenance of the instrument during the contract period. The NRLBH placed an initial order for four 30-pack arrays during 2013 for $94,723. In September 2014, the NRLBH purchased six additional 30-pack arrays for $142,005. The NRLBH is obligated to purchase 20 additional 30-pack arrays during the two year contract term.

On September 1, 2014, the NRLBH entered into a three year agreement with TME Research LLC which requires TME to provide to the NRLBH 100 tissue specimens in connection with the development of the NextCYTE test. Fees payable to TME under the agreement includes $99,600 up front, $31,500 upon supplying the first 25 specimens and $31,500 at the time of final delivery of all specimens. The agreement is terminable with 60 days prior written notice or immediately upon a material breach. As of December 31, 2014, the Company has paid $131,000 in set-up fees, which were recorded as R&D expenses in the accompanying consolidated statement of operations.

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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 EU) 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 commercial launch of the NextCYTE test and receiving FDA approval. We must also pay a royalty of $50 and a service fee of $65 for each NextCYTE test performed. The NextCYTE test is still in the validation stage and no royalty or service fees have been paid as of December 31, 2014. The agreement terminates on the later of the ten year anniversary of the agreement or the expiration of the latest patents covering the software.

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.

The ArgusCYTE test is designed to identify 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 we are determining the regulatory pathway for this test in light of new proposed FDA guidelines regulating laboratory tests.

NAF Cytology Testing of Ductal Lavage Specimens Collected with Our FullCYTE 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, which we call the FullCYTE 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 2012, 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 microcatheters before commercialization.

In August 2011, we entered into an agreement with Lake Region Medical, formerly Accellent, to perform development work to reestablish 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. As of the date through December 31, 2014, we have incurred approximately $1.6 million in expenses for this development work. 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.

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 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.

The Market for our Leading Tests and Devices

United States Market for the FullCYTE Breast Aspirator

We expect that the FullCYTE 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; however, our NAF test and aspirator devices are not replacements for mammography.

Breast Cancer Survivors. The American Cancer Society, or ACS, has estimated that as of 2015, there were approximately 2.8 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.

European Market for the ForeCYTE Breast Aspirator

In the European markets, a significant number of women undergo additional and diagnostic mammograms; however, the rate at which additional and diagnostic mammograms are performed varies by region and by country. In Germany, over 130,000 women undergo additional and diagnostic mammograms and like in the United States, we believe that these women will be more likely to consider using the aspirator device and NAF cytology test as they will have an increased awareness of breast health issues.

United States Market for ArgusCYTE Test

The ACS has estimated that, as of 2015, there were more than 2.8 million breast cancer survivors, who we believe would be potential candidates for the ArgusCYTE test.

United States Market for NextCYTE Test

According to the NCI, approximately 232,340 women in the United States 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 FullCYTE Breast Aspirator in the United States

We commenced the launch of the FullCYTE Breast Aspirator in the United States in March 2015. As of the date of this report, we have engaged Thermo Fisher Scientific and Henry Schein Medical to distribute this device. We are also in the process of building our own direct sales force in several major U.S. cities. 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 medical device distributors do not sell the NRLBH laboratory tests; rather, the NRLBH has retained separate third party organizations for selling and marketing the NRLBH laboratory tests.

Our commercialization strategy is based on creating two main revenue sources: (i) product sales-based revenue from the sale of the FullCYTE Breast Aspirator 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.

In order to achieve this two-pronged revenue base, we manufacture, through medical device suppliers, the FullCYTE Breast Aspirator 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 FullCYTE Breast Aspirator.

We expect that the NRLBH will bill for the NAF cytology testing of FullCYTE specimens at the Medicare reimbursement rates of $190 per patient, and at approximately $405 for patients covered by private insurance. These amounts may be higher for specimens for which we perform additional IHC testing. Currently, Medicare and certain insurance carriers do not reimburse for the NAF collection procedure by our FullCYTE 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 FullCYTE 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 FullCYTE 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 FullCYTE devices in bulk to distributors and to clinics and physicians for the testing of their patients, and laboratory service revenue after our laboratory analyzes the results of these tests and renders a diagnosis.

Commercialization Strategy for the ForeCYTE Breast Aspirator

We received the CE Certificates of Conformity from our notified body for the ForeCYTE Breast Aspirator in October 2014. These certificates permitted us to affix the CE mark to the medical device before marketing and distributing this device in the EU Member States and certain other countries. We have engaged Rhenus Logistics in the Netherlands to provide logistics, distribution, billing and collection services in European and other potential markets for our ForeCYTE Breast Aspirator device.

In March 2015, we launched the ForeCYTE Breast Aspirator in the EU and the countries of the EFTA, focusing initially on the Netherlands, Germany, Switzerland, and the United Kingdom. We selected potential markets based on the following: a high degree of average patient education, strong healthcare spend per capita, forward thinking regarding breast health, an advanced healthcare infrastructure and whether a particular country or region could serve as a model for other countries to follow.

In March 2015 we accepted the first order for the ForeCYTE Breast Aspirator from the University Medical Center Utrecht, the Netherlands. This key scientific institution will perform several studies using the ForeCYTE platform.

We also intend to focus on physician and patient education in our target markets. Educational tools include, for example, academic publications, speaking engagements and attendance at key breast cancer conferences.

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 pharmacogenomics tests, cytology and molecular diagnostics testing and reading of results of collected NAF samples, NextCYTE tissue samples and ArgusCYTE blood samples and other laboratory tests. The NRLBH received accreditation from the College of American Pathologists (CAP), which is awarded to facilities that meet the highest standards of excellence in quality laboratory practices. 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.

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.

The NRLBH sells its laboratory services primarily through contracted sales and marketing groups. For example, on August 28, 2014, the NRLBH entered into a three year Laboratory Marketing Services Agreement with BioVentive, Inc. (“BioVentive”), which provides that BioVentive market and promote the NRLBH laboratory tests to licensed physicians practicing medicine for a fee. The NRLBH has entered into similar agreements with other organizations. The NRLBH also plans to build its own direct sales force in select major U.S. cities starting in 2015.

The NRLBH also provides reference laboratory testing services to other laboratories that refer pharmacogenomics tests to the NRLBH. These reference laboratory services are typically provided for a fixed fee. The referring laboratory is typically responsible for procuring the test requisition and specimen from the patient. The NRLBH performs the testing services at the request of the referring laboratory and also bills and collects from the patient and, where applicable, any third party payor such as an insurer, for the test.

Growth Strategy

We plan to market the FullCYTE Breast Aspirator in the United States and the ForeCYTE Breast Aspirator in select European and other countries, through a combination of our distributors and/or our own direct sales representatives. We plan to market our laboratory services through sales representatives of the NRLBH and through contracted parties. We also plan to develop additional laboratory tests.

Research and Development

We are conducting research and development on potential future indications for our devices and potential future laboratory tests. We are also researching potential pharmaceutical therapies to be used in conjunction with our devices and tests. Research and development costs are generally expensed as incurred. Our research and development expenses consist of costs incurred for internal and external research and development. These costs are also comprised of costs incurred to develop new technology and carry out clinical studies and includes salaries and benefits, reagents and supplies used in R&D laboratory work and rent expenses. Research and development expenses for the years ended December 31, 2014 and 2013 were $2,577,465 and $1,105,110, respectively.

Our Intraductal Treatment Research

Our Intraductal Treatment Research Program comprises our patented FullCYTE Microcatheters and pharmaceutical formulations for the intraductal treatment of breast pre-cancerous changes and/or 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 and/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.

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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 FullCYTE Breast Aspirator and laboratory testing to assist in the identification of women at high risk for breast cancer and/or woman with peripheral proliferative disease (PED), (2) provide a pharmaceutical treatment of those conditions, and (3) use our FullCYTE 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 FullCYTE Breast Aspirator and the NAF Collection Procedure

In the United States, 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 FullCYTE 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 FullCYTE Breast Aspirator supplies will contain materials to obtain, label, and ship the NAF samples, we expect the physician charge for collecting NAF samples to be below the average cost of a mammogram.

Billing for Laboratory Testing

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 for our pharmacogenomics 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 do not perform the requested tests and report test results if the billing information is incorrect or missing. If information is missing, we attempt to obtain any missing information and correct incomplete or erroneous billing information received from the healthcare provider.

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 2014 was minus .75%.

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 FullCYTE Breast Aspirator NAF Collection Procedure

The NAF collection procedure of the FullCYTE 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.

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 2015 at approximately $190.

CPT Code for Pharmacogenomics Testing

The Medicare reimbursement rates for our pharmacogenomics test is expected to average approximately $1,103 per test during 2015; however this amount can change depending upon ongoing evaluation and decisions by CMS.

Laboratories typically set patient fee schedules for private payors at higher rates for the same procedure. For example, we bill private carriers approximately $1,700 for pharmacogenomics tests.

Non-U.S. Markets

Reimbursement for our devices outside the United States will vary from country to country. Our strategy is to launch our devices in areas with favorable reimbursement or a high potential for patient pay.

Intellectual Property

As of the date of this report, and based on a recent periodic review of our patent estate, we own 148 issued patents (45 in the United States and at least 103 in foreign countries), and 20 pending patent applications (10 in the United States and 10 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:

	United States			Foreign/PCT		
Description	Issued [1]	Expiration	Pending [1]	Issued [1]	Expiration	Pending [1]
ForeCYTE Breast Aspirator	6	2016-2031	5	12	2016-2031	8

FullCYTE Microcatheter /FullCYTE Breast Aspirator	19	2019-2031	5	53	2019-2031	4
NextCYTE Test	0	2031	1	0	2031	1
ArgusCYTE Test	1	2020	0	1	2031	0
Intraductal Treatment Program	12	2030	3	47	2030	1
Carbohydrate Biomarkers	2	2022	0	4	2022	0
Acueity Tools	13	2015-2024	0	2	2015-2024	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 stylized), ForeCYTE, FullCYTE, NextCYTE, ArgusCYTE, and Oxy-MASCT.

Competition to the FullCYTE and ForeCYTE Breast Aspirators

We believe that the FullCYTE Breast Aspirator will compete in the medical device product industry in the U.S. and EU 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 FullCYTE Breast Aspirator compared to the Neomatrix device include a lower acquisition cost and portability. The disadvantages of the FullCYTE 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 and FullCYTE Breast Aspirators, the technical expertise provided by our focus on diagnoses utilizing NAF, service-focused relationships with referring physicians, and our advanced technology. We have patent and other intellectual property protection on certain aspects of NAF collected with our devices and the transportation and processing of NAF collected with our devices.

Laboratories that could process NAF samples whether or not they were collected with one of our breast aspirator devices include thousands of local and regional pathology groups, national laboratories, hospital pathologists, and academic laboratories both in the United States, in Europe and elsewhere. The largest such competitors in the United States 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. In the EU, laboratories tend to be regional or national in nature and typically do not operate in multiple countries.

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. Turnaround 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.

Non-U.S. Laboratories. We will compete with laboratories serving physicians outside the U.S. As of the date of this report, we have not established laboratory operations outside the United States. NAF samples collected outside the United States with our devices or otherwise may not be sent to our U.S. laboratory for a number of reasons, including physician preference or requirements to use local laboratories and regulatory restrictions on shipping specimens across borders.

Diagnostic Tools Provided by Others. We do not promote our devices and tests as alternatives to other established diagnostic tests. We anticipate that our aspirator devices 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 aspirators as a screening tool for existing breast cancer, like mammography, rather than as an adjunctive procedure to mammography. As a result, our aspirators could be deemed to compete directly with mammography, an established procedure, which could impair market adoption of our aspirator devices.

The advantages of our aspirators 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 our aspirators compared to ultrasound, mammography, and MRI include the fact that we don't anticipate that our aspirators will be cleared by the FDA to detect or screen for cancer. The advantage of our aspirators 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 our aspirators 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 aspirators 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 and 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.

Competition to the Pharmacogenomics Test

Numerous laboratories provide pharmacogenomics tests similar to ours. Although we have trade secrets protecting to some degree our pharmacogenomics testing procedures, we do not have pending or issued patents covering this test. Accordingly, we expect competition in this area to develop and to grow as the test becomes more widely known and available.

Competition to the Acueity Tools

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.

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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 postmarket 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 FullCYTE Breast Aspirator is a Class II device. Class III devices are those for which insufficient information exists to assure safety and effectiveness solely through general or special controls, and include life-sustaining, life-supporting, or implantable devices, and devices not "substantially equivalent" to a device that is already legally marketed. Most Class I devices, including the laboratory staining kits and reagents we use, and some Class II devices are exempted by regulation from the 510(k) clearance requirement and can be marketed without prior authorization from the 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, 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) or PMA submission, as the case may be. For example, we expect that our intraductal 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 we 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;

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- 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 occur; 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 our medical devices, including the FullCYTE Breast Aspirator, and FullCYTE Microcatheter 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 recordkeeping. 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 our devices, 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. The 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. Among other things, we recalled the MASCT System and have not marketed it in the U.S. since that time.

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 its proposed corrective actions to address the FDA's observations and discussion points.

On December 5, 2014, we received EIRs (Establishment Inspection Reports) from the FDA Office of Compliance which indicated the FDA closed our inspections. This means that the observations that resulted from the inspections have been addressed; however, the FDA will continue to conduct additional inspections in the future, and may issue additional observations.

Federal Oversight of Laboratory Developed Tests

Clinical laboratory tests are regulated under CLIA, as well as by applicable state laws. Historically, most laboratory developed tests, or LDTs, were not subject to FDA regulations applicable to medical devices, although reagents, instruments, software or components provided by third parties and used to perform LDTs may be subject to regulation. The FDA defines the term “laboratory developed test” as an *in vitro* diagnostic test that is intended for clinical use and designed, manufactured and used within a single laboratory. We believe that the tests and services provided by NRLBH are LDTs. Until 2014, the FDA exercised enforcement discretion such that it did not enforce provisions of the Food, Drug and Cosmetic Act with respect to LDTs. In July 2014, due to the increased proliferation of LDTs for complex diagnostic testing, and concerns with several high-risk LDTs related to lack of evidentiary support for claims, erroneous results and falsification of data, the FDA issued guidance that, when finalized, would adopt a risk-based framework that would increase FDA oversight of LDTs. As part of this developing framework, FDA issued draft guidance in October 2014, informing manufacturers of LDTs of its intent to collect information from laboratories regarding their current LDTs and newly developed LDTs through a notification process. The FDA will use this information to classify LDTs and to prioritize enforcement of premarket review requirements for categories of LDTs based on risk, using a public process. Specifically, FDA plans to use advisory panels to provide recommendations to the agency on LDT risks, classification and prioritization of enforcement of applicable regulatory requirements on certain categories of LDTs, as appropriate.

We cannot predict the potential effect the FDA’s current and forthcoming guidance on LDTs will have on our solutions or materials used to perform our diagnostic services. While we qualify all materials used in our diagnostic services

according to CLIA regulations, we cannot be certain that the FDA might not promulgate rules or issue guidance documents that could affect our ability to purchase materials necessary for the performance of our diagnostic services. Should any of the reagents obtained by us from vendors and used in conducting our diagnostic services be affected by future regulatory actions, our business could be adversely affected by those actions, including increasing the cost of service or delaying, limiting or prohibiting the purchase of reagents necessary to perform the service.

We cannot provide any assurance that FDA regulation, including premarket review, will not be required in the future for our diagnostic services, whether through additional guidance or regulations issued by the FDA, new enforcement policies adopted by the FDA or new legislation enacted by Congress. Legislative proposals addressing oversight of LDTs were introduced in recent years and we expect that new legislative proposals will be introduced from time to time. It is possible that legislation could be enacted into law or regulations or guidance could be issued by the FDA which may result in new or increased regulatory requirements for us to continue to offer our diagnostic services or to develop and introduce new services.

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. In February 2015 the NRLBH received accreditation from the College of American Pathologists (CAP), which is awarded to facilities that meet the highest standards of excellence in quality laboratory practices.

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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 biohazardous 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's 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 were generated from Medicare billings although the majority of our billings for our pharmacogenomics test that we began offering in October 2014 is from Medicare billings. 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 recordkeeping 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 published draft guidelines indicating they intend to regulate LDTs. While these guidelines have not become law, it is probable that some form of premarket notification or approval process will become a requirement for certain LDTs. Premarket notification or approval of our future LDTs would be costly and delay our ability to commercialize such tests.

Regulation of Medical Devices and Laboratory Tests Outside the United States

In the EU and the European Free Trade Association countries, the ForeCYTE Breast Aspirator is marketed as a medical device.

The intended purpose for use of Atossa's ForeCYTE device is to collect NAF for cytological testing. The physician or researcher may choose to use the NAF and the resulting analysis for any clinical process as they deem appropriate. Before we can market a medical device in the European Union and the European Free Trade Association, we must comply with the Essential Requirements set forth in Annex I to the Directive 93/42/EEC of 14 June 1993 concerning medical devices, commonly known as the Medical Devices Directive. The Essential Requirements relate to the quality, safety and performance of the medical devices. Compliance with the Essential Requirements entitles a manufacturer to affix the Conformité Européenne mark, or CE mark, without which the products cannot be placed on the market in the European Union and the European Free Trade Association countries. To demonstrate compliance with the Essential Requirements and obtain the right to affix the CE mark, medical device manufacturers must undergo a conformity assessment procedure, which varies according to the type of medical device and its classification.

The Medical Devices Directive establishes a classification system placing devices into Class I, IIa, IIb, or III, depending on the risks and characteristics of the medical device. For certain types of low risk medical devices, the manufacturer may prepare a CE Declaration of Conformity based on a self-assessment of the conformity of its products with the Essential Requirements set forth in Annex I to the Medical Devices Directive. Other devices are subject to a conformity assessment procedure requiring the intervention of a "notified body," which is a private organization designated by the competent authorities of an EU Member State to conduct conformity assessments and verify the conformity of manufacturers and their medical devices with the Essential Requirements. The notified body issues a CE Certificate of Conformity following successful completion of a conformity assessment procedure conducted in relation to the medical device and its manufacturer and their conformity with the Essential Requirements. This Certificate entitles the manufacturer to affix the CE mark to its medical devices after having prepared and signed a related Declaration of Conformity.

The ForeCYTE Breast Aspirator is classified as a Class II medical device.

Our "notified body" in Europe is DQS Medizinprodukte GmbH (Frankfurt am Main, Germany).

The EU includes the following 28 Member States: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden and United Kingdom. Iceland, Norway and Liechtenstein which are part of the European Free Trade Association also apply the rules laid down in the Medical Devices Directive. The Swiss Confederation honors the CE marking also, with minor adaptations. This means that obtaining a CE Marking, provides access to a region that has over 520 million inhabitants.

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 filing this report, we employed four executive officers and 23 other full-time employees and three 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 for our Chief Executive Officer, commercial general and office premises liability insurance, and product errors and omissions liability insurance for our products and services.

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. Our FullCYTE Breast Aspirator does not utilize this membrane; rather, it incorporates a syringe to create vacuum and the specimen is collected in a vial for transportation to a cytology laboratory.

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

Proliferative epithelial disease (PED) in the breast includes a number of 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.

In December 2014, a study titled Proliferative Epithelial Disease Identified in Nipple Aspirate Fluid and Risk of Developing Breast Cancer: A Systematic Review was published by the peer-reviewed journal, *Current Medical Research and Opinion*. The objective of the study was to comprehensively review the published literature to characterize and summarize abnormal cytology detected by NAF and the association of PED-NAF with subsequent risk of developing breast cancer. Thirty articles were included in the study after full-text review, of which 16 were analyzed, containing data on 20,808 unique aspirations from over 17,378 subjects. Seven (44%) of the studies used the King cytological classification system. Among aspirations from women free of breast cancer, 51.5% contained fluid, in which over 27.7% had PED on cytology. In the two prospective studies of 7,850 cancer-free women, abnormal cytology by NAF carried a 2.1-fold higher risk (95% CI, 1.6-2.6; $p < 0.001$) of developing breast cancer, compared with women from whom no fluid could be obtained.

The study concluded that “PED-NAF among women free of breast cancer, compared with no fluid being obtained, has an independent risk of developing breast cancer comparable to the risk of a woman with a positive family history of breast cancer. These findings have implications for augmenting risk prediction and clinical decisions concerning breast cancer surveillance and chemoprevention. As with all reviews, heterogeneity across studies may have influenced the results. The limited literature calls for prospective studies on asymptomatic women with long-term follow up.” The study was sponsored and funded by Atossa and authored by John Hornberger, Adjunct Clinical Professor of Medicine , Department of Internal Medicine, Stanford University School of Medicine, Stanford, CA; Priyanka Kakad and Qianyi Li, Cedar Associates LLC, Menlo Park, CA; and Shu-Chih Chen and Steven C. Quay, Atossa. Shu-Chih Chen and Steven Quay have a financial interest in Atossa and receive compensation from Atossa. Shu-Chih Chen is a board member of Atossa while Steve Quay is Chairman, President and CEO of Atossa. Atossa markets devices for the collection of nipple aspirate. The uses described in the article have not been approved or cleared by the FDA for any Atossa product.

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 subtypes. 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, WA 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, the FullCYTE Breast Aspirator 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.

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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 most likely reflect 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 began operations in December 2008 focused on 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 System (now called the ForeCYTE Breast Aspirator), the FullCYTE Breast Aspirator and the FullCYTE Microcatheter, establishing our CLIA-certified laboratory, validating our laboratory developed tests, conducting research and development on the FullCYTE, ForeCYTE and NextCYTE tests, securing distribution partners and beginning the launch and commercialization of our products. We will require significant additional capital to achieve our business objectives, and the inability to obtain such financing on acceptable terms or at all could lead to closure of the business.

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

- execute our business plan and commercialization strategy, including growing revenue with our pharmacogenomics test sold primarily through third party sales and marketing groups;
- work with contract manufacturers to produce the ForeCYTE Breast Aspirator, FullCYTE Breast Aspirator, Acueity Tools and FullCYTE 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 and maintain regulatory clearances and CE Certificates of Conformity in a timely manner;
- sell our products and service at the prices currently expected; and
- attract and retain key personnel.

We may not continue as a going concern.

We have not yet established an ongoing source of revenue sufficient to cover operating costs and allow us to continue as a going concern. The report issued by our independent auditors also emphasized our ability 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.

If we do not raise additional capital, we anticipate liquidity issues in the next four to eight months.

For the year ended December 31, 2014, we generated $525,955 in net revenues from the sale of our products and services and we incurred a net loss of $14,657,925. Through December 31, 2014, we had an accumulated deficit of approximately $35,174,539. As of the date of filing this report, we expect that our existing resources will be sufficient to fund our planned operations for at least the next four to eight 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 ability to continue as a going concern is dependent on obtaining adequate capital to fund operating losses until we become profitable. We may not receive or maintain regulatory clearance or CE Certificates of Conformity for our medical devices and laboratory services, including the ForeCYTE Breast Aspirator and FullCYTE Breast Aspirator, 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 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.

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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:

- continue to market and sell our pharmacogenomics test, including the cost of retaining third party sales and marketing groups and hiring our own direct sales force;
- launch and commercialize the FullCYTE Breast Aspirator, ForeCYTE Breast Aspirator and additional laboratory tests, including the manufacture of the FullCYTE Breast Aspirator and ForeCYTE Breast Aspirator devices 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;
- commence clinical studies and drug formulations for therapeutics to treat the breast health conditions detected by our tests and devices; and
- develop and commercialize the assets we acquired from Acueity Healthcare, Inc.

We also expect that we may need to raise additional funds if we encounter delays or problems in the sale of our pharmacogenomics tests, our ForeCYTE and FullCYTE Breast Aspirators. As of December 31, 2014, we had cash and cash equivalents of $8,500,718. 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 emphasized in their report on our financial statements doubt as to our ability to continue as a "going concern," 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 $35,174,539 from our incorporation in April 2009 through December 31, 2014. 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 ForeCYTE Breast Aspirator has historically been substantially lower than its cost because it 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. We may not be able to sell our ForeCYTE Breast Aspirator, FullCYTE Breast Aspirator and NAF cytology test at the same price levels we achieved in 2013. Although we expect that the cost to manufacture our ForeCYTE Breast Aspirator 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.

The failure to successfully launch and commercialize our lead devices and laboratory tests will significantly and adversely affect our business.

Our products and services are new to the market. We launched our pharmacogenomics test in October 2014 and in March 2015 began the launch of the FullCYTE device in the U.S. and ForeCYTE device in the EU. We may not be successful in commercializing these and other planned products and services for a number of reasons, including:

- NAF collection devices, NAF ductal cytology test and other devices are not established in the practice of medicine and doctors and patients may not be receptive to their use, for example our FullCYTE Breast Aspirators and microcatheters were previously owned by other companies that were not successful in commercializing them;
- pharmacogenomics testing is in the very early stages of adoption and we will likely face competition from larger laboratories with greater resources which may lower our prices and limit our sales;

- reimbursement policies and practices for our devices and services can change;
- foreign doctors and patients may not utilize the NRLBH and we may not be successful establishing a foreign laboratory; and
- we may not maintain regulatory compliance in any of our markets.

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 may 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 sought but did not obtain 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 may pursue another FDA clearance for this device which we may not obtain 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 clinical data on NAF collected by multiple physicians and processed by multiple laboratories;
- although we had a pre-submission meeting with the FDA before submitting our prior 510(k) to them and we plan to have a further meeting with them prior to submitting an additional 510(k), any input from the FDA at these meetings is not binding on the FDA and the FDA can raise objections to our 510(k) submission that were not raised at a pre-submission meeting;
- 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 premarket 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. Any future 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. However, we may not be able to provide the information the FDA requires related to the laboratory processing of NAF samples collected with our devices; 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; and in September 2014 the FDA made a determination that the ForeCYTE Breast Aspirator was not substantially equivalent to its predicate device and by doing so did not clear the device for marketing in the U.S.; we do not know if we will be able to provide the FDA with data it will find acceptable with any new 510(k) we may submit.

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 may 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 could be more limited to "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. Similarly, the FullCYTE Breast Aspirator is cleared for the collection of NAF for cytology – which is potentially more limited that the clearance we received for the ForeCYTE device. As a result, our sales of the FullCYTE device could be more limited that the sales we experienced with the ForeCYTE device.

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.

Inspections by the FDA and other regulatory bodies could lead to adverse regulatory events.

We are subject to periodic inspections by the FDA and other regulatory bodies and by our notified body DQS. For example, 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. We received the Establishment Inspection Report for this inspection in December of 2014, which signified the closure of this inspection.

Our notified body conducted an audit of our facilities on March 3rd and 4th, 2015. This audit resulted in the issuance of three observations related to training, quality audits, and labeling. We will be providing response to these observations over the next ninety days. Once accepted, these items will be evaluated at the next regularly scheduled audit of our Quality Management System by the notified body. Failure to adequately and timely address these or any observations or other concerns raised now or in the future could result in a suspension of our CE mark or delay of the issuance of future CE marks that we may pursue until any and all observations have been adequately addressed with the notified body.

Future FDA inspections could result in the issuance by the FDA of Form 483 observations, warning letters, fines, penalties, delayed or denied 510(k) submissions and other regulatory actions, any of which would have a material adverse effect on our business. Inspections by foreign regulatory bodies could result in similar actions.

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 or CE Certificates of Conformity have been obtained. Medical devices may also be modified after regulatory clearance and CE Certificates of Conformity are obtained to such an extent that additional regulatory clearance or new or amended CE Certificates of Conformity are 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 were removed from the market and will not be re-introduced unless or until a new 510(k) is obtained. This recall is now officially closed.

The October 2013 recall significantly and adversely impacted our business and may 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;
- virtually all of our revenues prior to the fourth quarter of 2014 were generated from the ForeCYTE products and services; 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 in the U.S. 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.

Any future recall could 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 and notified body inspections or other regulatory actions.

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. The Company and other defendants filed motions to dismiss the amended complaint on May 30, 2014. The plaintiffs filed briefs in opposition to these motions on July 11, 2014. The Company replied to the opposition briefs on August 11, 2014. On October 6, 2014 the Court granted defendants' motion dismissing all claims against Atossa and all other defendants. The Court's order provided plaintiffs with a deadline of October 26, 2014 to file a motion for leave to amend their complaint and the plaintiffs did not file such a motion by that date. On October 30, 2014, the Court entered a final order of dismissal. On November 3, 2014, plaintiffs filed a notice of appeal with the Court and have appealed the Court's dismissal order to the U.S. Court of Appeals for the Ninth Circuit. 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 FullCYTE Breast Aspirator, ForeCYTE Breast Aspirator, pharmacogenomics and our NAF cytology and other tests, we will need to demonstrate to physicians and other healthcare professionals the benefits of these devices and tests including the clinical and economic application for their particular practice. 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 and we expect the reimbursement rate for our NAF cytology test will be lower than it was in 2013.

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, in both the United States, Europe and other markets, 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. Our FullCYTE Breast Aspirator may sell at lower prices that the ForeCYTE Breast Aspirator and the NAF cytology test service is expected to be lower on NAF samples collected with the FullCYTE Breast Aspirator than it was for the FullCYTE Breast Aspirator. 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 our medical devices, 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 FullCYTE Breast Aspirator and 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 Thermo Fisher Scientific and Henry Schein Medical to sell the FullCYTE Breast Aspirator, they may not achieve any level of commercial success from their efforts.

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

The Halo Breast Pap Test, an NAF collection device similar to our breast aspirators, 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 FullCYTE 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 FullCYTE Breast Aspirator. 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 FullCYTE Breast Aspirator and may not recommend their use in patients. We may be forced to reduce the price of the 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 aspirator devices 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 our breast aspirators 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 result;
- failure by healthcare professionals to properly safeguard NAF samples collected using our aspirators or microcatheters;
- the potential loss, mislabeling or misplacement of NAF sample shipments and test kits;
- the FullCYTE Breast Aspirator and 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 aspirator device to the breast; and

- cleaning of the breast prior to applying the 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 pharmacogenomics and NAF tests could expose us to possible litigation based on malpractice, data aggregation errors, or misdiagnoses.

The NRLBH analyzes patient samples and reports the results to referring healthcare professionals, researchers and potential collaborators. We or the NRLBH 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.

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 American 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 intraductal treatment program by licensing a pharmaceutical from a third party. We may not be able to secure such a license on acceptable terms. Litigation or patent interference proceedings need to be brought against third parties, as discussed below, to enforce any of our patents or other proprietary rights, or to determine the scope and validity or enforceability of the proprietary rights of such third parties.

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 on 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, or patents that may be issued 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

We have in the past and may in the future receive warning letters from the FDA; failure to adequately and timely address the FDA's warning letter or other matters raised by the FDA, could adversely affect our business.

We received a Warning Letter (the "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. 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 made for future actions. The issues raised in the Warning Letter ultimately led to a voluntary recall of the System and caused us to seek an additional 510(k) clearance for the System which we have not been successful in obtaining.

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 its proposed corrective actions to address the FDA's observations and discussion points. In December 2014, the Company received establishment inspection reports from the FDA which means that the FDA inspections have been closed.

Although we received an establishment inspection report closing out the FDA's prior inspections, we expect to be inspected by the FDA again in the future. Such inspections can lead to regulatory actions, including warning letters, Form 483 observations, fines and penalties, any of which will have a material adverse effect on our business.

The manufacturing, marketing and sale of our products are subject to regulatory clearances or approvals and the delivering by our notified body of CE Certificates of Conformity and our business is subject to extensive regulatory requirements. If we fail to maintain regulatory clearances or CE Certificates of Conformity, or are unable to obtain, or experience significant delays in obtaining FDA approvals or clearances and CE certificates of Conformity from our notified body 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 state and foreign 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, recordkeeping, and approval clearance or CE marking. 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 or CE Certificates of Conformity from our notified body 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.

Even after clearance, approval or CE Certificate of Conformity for our products is obtained, we are subject to extensive post-market regulation by the FDA, our notified body and foreign competent authorities. 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. Similar requirements are applicable in the EU and in other foreign jurisdictions. 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, or other communications, the FDA could take further enforcement action, including prohibiting the sale or marketing of the affected product. The FDA and the competent authorities in the EU also strictly regulate labeling, advertising,

promotion, and other types of information on products that are placed on the market. It is possible that 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 competent authorities.

Failure to comply with regulatory requirements such as QSR, may result in changes to labeling, restrictions on such products or manufacturing processes, suspension, variation, or withdrawal of the CE Certificates of Conformity, 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 administrative 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 occur, 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.

In the EU, we must comply with the EU Medical Device Vigilance System (MEDDEV 2.12/1 rev.8) which is intended to protect the health and safety of patients, users and others by establishing reporting procedures and reducing the likelihood of reoccurrence of incidents related to the use of a medical device. Under this system, incidents (which are defined as any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labeling or the instructions for use which, directly or indirectly, may lead to or may have led to the death of a patient, or user or other persons or to a serious deterioration in such person's state of health) must be reported by manufacturers through a Manufacturer's Incident Reports to competent authorities within periods of time specified in the MEDDEV 2.12/1 rev. 8. Such incidents are evaluated and, where appropriate, information is disseminated between the competent authorities of the EU Member States. The MEDDEV 2.12/1 rev. 8 is also intended to facilitate a direct, early and harmonized establishment of Field Safety Corrective Actions, or FSCAs, across the EU Member States in which the device is being marketed. A FSCA is an action taken by a manufacturer to reduce a risk of death or serious deterioration in the state of health associated with the use of a medical device that is already placed on the market. A FSCA may include device recall, modification, exchange, or destruction. FSCAs must be reported by the manufacturer or the manufacturer's European Authorized Representative, to its customers and/or the end users of the device through a Field Safety Notice. FSCAs must also be reported to the competent authorities of the EU Member States. Failure to comply with any of these requirements could significantly and adversely affect our business.

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

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

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

The HIPAA privacy regulations establish a "floor" of minimum protection for patients as to their medical information and do not supersede state laws that are more stringent. Therefore, we are required to comply with both HIPAA privacy regulations and various state privacy laws. The failure to do so could subject us to regulatory actions, including significant fines or penalties, and to private actions by patients, as well as to adverse publicity and possible

loss of business. In addition, federal and state laws and judicial decisions provide individuals with various rights for violation of the privacy of their medical information by healthcare providers such as us.

The collection and use of personal health data in the EU is governed by the provisions of Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data, commonly known as the Data Protection Directive. The Directive imposes a number of requirements including an obligation to seek the consent of individuals to whom the personal data relates, the information that must be provided to the individuals, notification of data processing obligations to the competent national data protection authorities of individual EU Member States and the security and confidentiality of the personal data. The Data Protection Directive also imposes strict rules on the transfer of personal data out of the EU to the U.S. Failure to comply with the requirements of the Data Protection Directive and the related national data protection laws of the EU Member States may result in fines and other administrative penalties and harm our business.

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 2015 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.

Legislative or 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. Similar changes and revisions can also occur in foreign countries.

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.

If the FDA were to begin regulating the test and services provided by the NRLBH, we could incur substantial costs and delays associated with trying to obtain premarket clearance or other approvals.

Clinical laboratory tests are regulated under CLIA, as well as by applicable state laws. Historically, most laboratory developed tests, or LDTs, were not subject to FDA regulations applicable to medical devices, although reagents, instruments, software or components provided by third parties and used to perform LDTs may be subject to regulation. The FDA defines the term "laboratory developed test" as an *in vitro* diagnostic test that is intended for clinical use and designed, manufactured and used within a single laboratory. We believe that the tests and services provided by the NRLBH are LDTs. Until 2014, the FDA exercised enforcement discretion such that it did not enforce provisions of the Food, Drug, and Cosmetic Act, or FDA Act, with respect to LDTs. In July 2014, due to the increased proliferation of LDTs for complex diagnostic testing and concerns with several high-risk LDTs related to lack of evidentiary support for claims, erroneous results and falsification of data, the FDA issued guidance that, when finalized, would adopt a risk-based framework that would increase FDA oversight of LDTs. As part of this developing framework, FDA issued draft guidance in October 2014, informing manufacturers of LDTs of its intent to collect information from laboratories regarding their current LDTs and newly developed LDTs through a notification process. The FDA will use this information to classify LDTs and to prioritize enforcement of premarket review requirements for categories of LDTs based on risk, using a public process. Specifically, the FDA plans to use advisory panels to provide recommendations to the agency on LDT risks, classification and prioritization of enforcement of applicable regulatory requirements on certain categories of LDTs, as appropriate.

We cannot provide any assurance that FDA regulation, including premarket review, will not be required in the future for our tests, whether through additional guidance or regulations issued by the FDA, new enforcement policies adopted by the FDA or new legislation enacted by Congress. It is possible that legislation will be enacted into law, regulations could be promulgated or guidance could be issued by the FDA which may result in increased regulatory burdens for us to continue to offer our tests or to develop and introduce new tests. We cannot predict the timing or content of future legislation enacted, regulations promulgated or guidance issued regarding LDTs, or how it will affect our business.

If FDA premarket review, including clearance or approval, is required for the NRLBH's NAF cytology test, pharmacogenomics test or any of our future tests (either alone or together with sample collection devices), products or services we may develop, or we decide to voluntarily pursue FDA clearance or approval, we may be forced to stop selling our tests while we work to obtain such FDA clearance or approval. Our business would be negatively affected until such review was completed and clearance to market or approval was obtained. The regulatory process may involve, among other things, successfully completing additional clinical studies and submitting premarket notification or filing a premarket approval application with the FDA. If premarket review is required by the FDA or if we decide to voluntarily pursue FDA premarket review of our tests, there can be no assurance that any tests, products or services we may develop in the future will be cleared or approved on a timely basis, if at all, nor can there be assurance that labeling claims will be consistent with our current claims or adequate to support continued adoption of our tests. If our tests are allowed to remain on the market but there is uncertainty in the marketplace about our tests, if we are required by the FDA to label them investigational, or if labeling claims the FDA allows us to make are limited, orders may decline. Ongoing compliance with FDA regulations would increase the cost of conducting our business, and subject us to heightened regulation by the FDA and penalties for failure to comply with these requirements.

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 price 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 $0.80. 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 March 27, 2015, we have the right to sell up to 2,492,934 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 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 $0.80 to $12.40 through March 27, 2015. 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 inspections and warning letters;

- 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.

If our common stock is delisted from the NASDAQ Capital Market, we may be subject to the risks relating to penny stocks.

If our common stock were to be delisted from trading on the NASDAQ Capital Market and the trading price of the common stock were below $5.00 per share on the date the common stock were delisted, trading in our common stock would also be subject to the requirements of certain rules promulgated under the Exchange Act. These rules require additional disclosure by broker-dealers in connection with any trades involving a stock defined as a “penny stock” and impose various sales practice requirements on broker-dealers who sell penny stocks to persons other than established customers and accredited investors, generally institutions. These additional requirements may discourage broker-dealers from effecting transactions in securities that are classified as penny stocks, which could severely limit the market price and liquidity of such securities and the ability of purchasers to sell such securities in the secondary market. A penny stock is defined generally as any non-exchange listed equity security that has a market price of less than $5.00 per share, subject to certain exceptions.

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 23% 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.

Our Stockholder Rights Agreement, the 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 Stockholder Rights Agreement we adopted in May 2014, 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, our Shareholder Rights Plan 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, 2014, we leased approximately 12,296 square feet of office and laboratory space in three locations in Seattle, Washington, which includes space rented from Sanders Properties, LLC, Eastlake Properties LLC, and the Legacy Groups. We believe that our current facilities will be adequate to meet our needs for the next 24 months. This information is incorporated in this report under "PART II, ITEM 7. MANAGEMENT DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS – Commercial Lease Arrangements".

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 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 us in September 2010.

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.

On November 3, 2014, the matters with Messrs. Kelly and Cononi were settled through mutual agreement of the parties. The parties agreed to mutual releases and to dismiss the arbitration and federal actions. The amount paid by the Company to settle this matter was not significant.

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. An amended complaint was filed on April 15, 2014. The Company and other defendants filed motions to dismiss the amended complaint on May 30, 2014. The plaintiffs filed briefs in opposition to these motions on July 11, 2014. The Company replied to the opposition briefs on August 11, 2014. On October 6, 2014 the Court granted defendants’ motion dismissing all claims against Atossa and all other defendants. The Court’s order provided plaintiffs with a deadline of October 26, 2014 to file a motion for leave to amend their complaint and the plaintiffs did not file such a motion by that date. On October 30, 2014, the Court entered a final order of dismissal. On November 3, 2014, plaintiffs filed a notice of appeal with the Court and have appealed the Court’s dismissal order to the U.S. Court of Appeals for the Ninth Circuit. On February 11, 2015, plaintiffs filed their opening appellate brief. Defendants’ answering brief is due April 13, 2015. A hearing for the appeal has not been set.

The Company believes this complaint is without merit and plan to defend ourselves vigorously; however failure to obtain a favorable resolution of the claims set forth in the complaint could have a material adverse effect on the Company’s 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, 2014. The costs associated with defending and resolving the complaint 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 NASDAQ.

	High	Low
2014		
First Quarter	$3.28	$1.68
Second Quarter	$1.90	$1.15
Third Quarter	$2.57	$1.68
Fourth Quarter	$2.10	$0.80

On March 27, 2015, the closing price of our common stock was $1.78. As of March 27, 2015, there were approximately 35 shareholders of record of our common stock, one of which is Cede & Co., a nominee for Depository Trust Company, or DTC and approximately 4,000 beneficial holders. 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, 2014.

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.

Overview

We are a healthcare company focused on improving breast health through the development of a suite of laboratory services, medical devices and therapeutics. Our laboratory services are being developed and conducted by our wholly-owned subsidiary, The National Reference Laboratory for Breast Health, Inc. (the "NRLBH"). The NRLBH has developed and is currently marketing nipple aspirate fluid, or NAF, cytology tests and pharmacogenomics tests.

Our medical devices include the ForeCYTE Breast Aspirator for distribution outside the United States and the FullCYTE Breast Aspirator for the U.S. market. These devices are intended for the collection of NAF for cytological testing at a laboratory. The current version of the ForeCYTE Breast Aspirator is not cleared by the FDA for marketing in the United States; however, this device is CE-marked and is therefore being commercialized in the EU and the countries of the European Free Trade Association (EFTA). The FullCYTE Breast Aspirator does not have a CE-mark, but it has been cleared by the FDA for the collection of NAF for cytological purposes. For this reason the FullCYTE device is being commercialized for the U.S. market. Other devices under development include intraductal 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. In March 2015, we launched the FullCYTE Breast Aspirator in the United States and the ForeCYTE Breast Aspirator in the EU and the countries of the EFTA, initially focusing on the Netherlands, Germany, Switzerland, and the United Kingdom.

The ForeCYTE Breast Aspirator will not be 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 that we plan to develop. For example, we plan to develop our patented intraductal microcatheters for the potential delivery of a pharmaceutical targeted to a condition called ductal carcinoma in-situ, or DCIS, which is the most common type of non-invasive breast cancer. 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 ductal hyperplasia or proliferative epithelial disease (PED). These programs are in the early pre-clinical stage and will require testing and are likely to require approval and/or clearance from the FDA prior to commercialization in the United States.

Our 2015 objectives consist of the following:

(1) Launch and commercialize the FullCYTE Breast Aspirator in the United States: We began the launch of our FullCYTE Breast Aspirator in the United States in March 2015. We have engaged Thermo Fisher Scientific and Henry Schein Medical as our initial U.S. distributors and we plan to build our own specialty sales force.

(2) Launch and commercialize the ForeCYTE Breast Aspirator in the EU: We received CE Certificate of Conformity from our notified body for the ForeCYTE Breast Aspirator and Collection Kits in October 2014 and in March 2015 began the launch of this device in the EU and the countries of the European Free Trade Association (EFTA), focusing initially on the Netherlands, Germany, Switzerland, and the United Kingdom.

(3) Maximize total gross revenue from our products and services: We plan to grow our revenue by selling our products and promoting the tests currently being offered by the NRLBH, including NAF cytology tests and pharmacogenomics tests, and by developing and commercializing additional laboratory tests. We launched the pharmacogenomics test in October 2014 and processed and reported 527 tests through December 31, 2014.

(4) Begin one or more clinical studies using our devices and potential pharmaceutical therapy: We plan to develop a pharmaceutical to be delivered through our patented microcatheters, initially to treat DCIS. We also plan to develop a pharmaceutical to treat one or more conditions detected by the laboratory tests conducted on the NAF specimens collected with our breast aspirator devices. In this fashion, our devices and laboratory tests can be used as companion diagnostics to the therapies we plan to develop. We expect that these therapies and companion diagnostics will initially target DCIS, ductal hyperplasia, 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.

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

Our Medical Devices

Our medical devices being commercialized and under development include our breast aspirators, intraductal microcatheters and various tools for breast surgeons.

Our ForeCYTE Breast Aspirator (formerly called the MASCT System) was launched in a “field experience” trial in the U.S. 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 premarket notification to the FDA for a 510(k) clearance for the ForeCYTE Breast Aspirator, and in September 2014 the FDA determined that the ForeCYTE Breast Aspirator is not substantially equivalent to its predicate device which means that as of the date of this report the device is not cleared by the FDA for marketing in the United States. We are currently evaluating the feedback we received from the FDA and the U.S. regulatory pathway for the ForeCYTE device in the United States.

The ForeCYTE Breast Aspirator device has received the CE Mark and we began the launch of this device in the EU and EFTA countries in March 2015, initially focusing on the Netherlands, Germany, Switzerland, and the United Kingdom. This device is being manufactured in Asia and we have contracted with Rhenus Logistics for logistical and other services in European and other markets.

The FullCYTE Breast Aspirator was launched in the United States in March 2015. This device is marketed in the U.S. by direct sales personnel as well as third party distributors, including Fisher Healthcare, a division of Thermo Fisher Scientific, and Henry Schein Medical.

Our intraductal microcatheters are being developed for the collection of ductal lavage fluid for cytology testing and for the potential administration of pharmaceutical therapeutics.

Our CLIA-Certified Laboratory – the NRLBH

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. The NRLBH is also accredited by the College of American Pathologists (CAP), which is awarded to facilities that meet the highest standards of excellence in quality laboratory practices.

The NRLBH is permitted to accept NAF and pharmacogenomics 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. The NRLBH markets and sells its tests primarily through third party sales and marketing organizations, such as BioVentive, Inc.

The NRLBH currently offers two tests: NAF cytology tests and pharmacogenomics tests. The pharmacogenomics tests were launched in October 2014. The NAF cytology testing was offered beginning in 2012.

Our Therapeutic Program 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 pharmaceutical formulations for the intraductal treatment of breast pre-cancerous changes and DCIS. The method uses our Mammary Ductal Microcatheter System 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. The method was invented by Dr. Susan Love, President of the Dr. Susan Love Research Foundation, and her colleagues, and acquired by us.

We have not yet established an ongoing source of revenue sufficient to cover our operating costs and allow us to continue as a going concern. Our ability to continue as a going concern is dependent on obtaining adequate capital to fund operating losses until we become profitable. We plan to obtain additional capital resources by: selling our equity securities; selling the FullCYTE Breast Aspirator in the United States and the ForeCYTE Breast Aspirator outside the U.S.; generating laboratory service revenue from our services 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. In 2013 and 2014, 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 did not generate revenue from October 2013 through the third quarter of 2014 when we launched and began generating revenue from the pharmacogenomics test offered by the NRLBH.

We will incur additional sales and marketing expenses as we commercialize the FullCYTE Breast Aspirator in the United States and the ForeCYTE Breast Aspirator outside the United States. We will need to revise our sales and marketing tools, continue hiring direct sales employees and engage new distributors. We also expect to continue to hire clinical consultants to assist in the sale of our NAF cytology tests. The FullCYTE Breast Aspirator may not gain adoption as quickly as the ForeCYTE Breast Aspirator and it may sell at lower margins. If so, our potential sales and revenues will be negatively impacted.

Revenue Sources

Our business provides us with two potential revenue sources: (i) sales-based revenue from the sale of our medical devices, such as our ForeCYTE Breast Aspirator and FullCYTE Breast Aspirator and patient kits to distributors, physicians, breast health clinics, and mammography clinics and (ii) service, or use-based, revenue from laboratory services performed by the NRLBH, such as preparation and interpretation of the NAF samples sent to our laboratory for analysis, pharmacogenomics tests and other tests that may be developed and commercialized by the NRLBH. Our main source of revenue beginning in October 2014 has been from pharmacogenomics testing and we anticipate generating additional revenue from other resources when we develop and launch new laboratory tests and/or when we further commercialize the FullCYTE Breast Aspirator in the United States and the ForeCYTE Breast Aspirator outside the United States. We plan to initially sell the breast aspirators and our laboratory services 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 March 4, 2011, we entered into a commercial lease agreement with Sanders Properties, LLC for office space located in Seattle, WA. The lease terminated on March 31, 2014 and provided 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. In July 2013, we entered into an agreement with ARE LLC (Alexandria) to lease additional office spaces under a separate lease agreement. The lease was from August 2013 through November 2014, and the gross rent was $4,800 per month.

On March 24, 2014, we entered into another commercial lease agreement with ARE LLC (Alexandria) which extends the term of the existing lab lease with Fred Hutchison Research Center which expires in November 2014 through November 30, 2016. The lease provided for monthly rent payments of $22,736 from December 2014 through November 2015 and $23,258 from December 2015 through November 2016. As of December 31, 2014 we incurred and recorded a security deposit of $25,000. For the year ended December 31, 2014, we incurred $340,938 of rent expenses for the lease, which included leasing office management expenses and the new agreement with ARE LLC.

On August 8, 2014, we entered into a new commercial lease agreement with the Legacy Group Inc., to lease office space in Seattle, WA in conjunction with expiration of the current office space lease with Fred Hutchinson Research Center on November 29, 2014. The lease provides for monthly rent payments of $16,695 from December 1, 2014 through June 30, 2015, $17,172 from July 1, 2015 through June 30, 2016 and $17,649 from July 1, 2016 through June 30, 2017. For the year ended December 31, 2014, we incurred $17,248 of rent expense for the lease.

We expect that these laboratory and office facilities will be sufficient to meet our needs for the foreseeable future and we do not expect to need additional space for at least the next 18 months.

Critical Accounting Policies and Estimates

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

While our significant accounting policies are more fully described in Note 3 to our financial statements, 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.

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.

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

Although the Company is not currently recognizing product revenue, the Company generally recognizes revenue for sales of our devices on an accrual basis. 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.

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. Patient requisition forms 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.

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. The Company's allowance for doubtful accounts as of December 31, 2014 and 2013 was $564,456 and $354,861, respectively. Bad debt expense is included in general and administrative expense on the Company's consolidated statements of operations. Bad debt expense was $209,288 and $354,861 for the years ended December 31, 2014 and 2013, respectively.

Intangible Assets

Intangible assets consist of intellectual property and software acquired. Intangibles are reviewed at least annually for impairment or whenever events or changes in circumstances indicate that the carrying value of the assets might 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.

We have evaluated and reprioritized our research and development pipeline based on recent business strategies, and as a result have delayed plans to develop and invest further in Acueity patents and technologies for at least the next year. Because of these changed business plans related to the Acueity assets, we have re-evaluated the assets for potential impairment. We have concluded that these assets are partially impaired and have recorded asset impairment charges of $2,352,626 for the year ended December 31, 2014 to adjust the carrying value of these intangible assets to their estimated fair values as of December 31, 2014.

We determined the fair values of the Acueity intangibles using an income approach. When available and appropriate, we use comparative market multiples to corroborate discounted cash flow results. For purposes of the income approach, fair value is determined based on the present value of estimated future cash flows to be generated from development of products using the patented technology acquired in the Acueity transaction based on our current plans, discounted at an appropriate risk-adjusted rate. We use our internal forecasts to estimate future cash flows and include an estimate of long-term future growth rates based on our most recent views of the outlook of the business. We use discount rates that are commensurate with the risk and uncertainty inherent in the business and in our internally developed forecasts. Discount rates used in valuations for these intangible assets ranged from 18% to 21%.

Share-Based Payments

We follow the provisions of the Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 718, *Compensation Stock Compensation* ("ASC 718"), which requires the measurement and recognition of compensation expense for all share-based payment awards made to employees, non-employee directors, and consultants, including employee stock options. Stock compensation expense based on the grant date's fair value was estimated in accordance with the provisions of ASC 718 and is recognized as an expense over the requisite service period.

The fair value of each option grant is estimated using the Black-Scholes option-pricing model, which requires assumptions regarding the expected volatility of our stock options, the expected life of the options, an expectation regarding future dividends on our common stock, and estimation of an appropriate risk-free interest rate. Our expected common stock price volatility assumption is based upon the volatility of a basket of companies that we consider comparable to us given that our own stock has not been traded for a sufficient period to establish a volatility assumption based on our own historical data as our stock began trading in November 2012. As additional data becomes available regarding our own stock price volatility, we plan to incorporate that data in our volatility assumption. The expected life assumption for stock option grants was based upon the simplified method provided for under ASC 718-10, which averages the contractual term of the options of ten years with the average vesting term of four years. The dividend yield assumption of zero is based upon the fact that we have never paid cash dividends and presently have no intention of paying cash dividends in the future. The risk-free interest rate used for each grant was based upon prevailing short-term interest rates over the expected life of the options.

We have estimated an annualized forfeiture rate of 10.0% for options granted. We will record additional expense if the actual forfeitures are lower than estimated and will record a recovery of prior expense if the actual forfeiture rates are higher than estimated.

Results of Operations

Comparison of Years Ended December 31, 2014 and 2013

Revenue and Cost of Revenue: For the year ended December 31, 2014, we had total net revenue of $525,954, consisting of mainly pharmacogenomics testing. This represents a decrease of $106,604, or 17%, from the total revenue of $632,558 from our ForeCYTE device and laboratory testing in the year ended December 31, 2013. We ceased generating any revenue from October 2013 through October 2014 due to our product recall. Substantially all of our revenue for the year ended December 31, 2014 was recognized during the fourth quarter of 2014 when we launched the new pharmacogenomics testing in our laboratory. In March 2015, we began the launch of the FullCYTE

Breast Aspirator in the U.S. and the ForeCYTE Breast Aspirator in the EU, focusing initially on the Netherlands, Germany, Switzerland, and the United Kingdom.

Total cost of revenue for the year ended December 31, 2014 was $340,658 and consisted of costs relating to pharmacogenomics testing services; compared to $345,519 for the year ended December 2013, consisting of $105,764 in ForeCYTE laboratory costs and $239,755 in ForeCYTE product costs. 2013 cost of revenue also includes $149,946 in loss on reduction of inventory to lower of cost market and obsolete inventory due to the recall of MASCT Systems. Gross profit for the year ended December 31, 2014 was $185,296 which was entirely attributable to pharmacogenomics testing, as compared to a gross profit of $137,093 for the year ended December 31, 2013, consisting of $303,354 for the NAF cytology testing offset by $166,261 loss for the product sales of MASCT.

Operating Expenses: Total operating expenses were $14,827,713 for the year ended December 31, 2014, consisting of general and administrative (G&A) expenses of $8,625,917, R&D expenses of $2,577,465, selling expenses of $1,271,705, and a $2,352,626 expense for impairment of intangibles, collectively representing an increase of $3,905,977, or 36%, from $10,921,736 for the year ended December 31, 2013, which consisted of G&A expenses of $8,558,835, R&D expenses of $1,105,110, and selling expenses of $1,257,791.

Selling Expenses: Selling expenses for the year ended December 31, 2014 were $1,271,705, an increase of $13,914, or 1%, from $1,257,791 for the year ended December 31, 2013. Selling expenses for the year ended December 31, 2014 consisted primarily of $216,391 in selling and marketing professional fees, $409,625 in compensation expenses, and $610,774 in advertisement and were comparable with prior year's expenses. We expect that our selling expenses will increase in the foreseeable future, as we build a sales force in the United States and outside the United States to support the launch and commercialization of the ForeCYTE and FullCYTE Breast Aspirators and our laboratory service offerings. Selling expenses may also increase as we market and sell the services offered by the NRLBH, including NAF cytology tests, pharmacogenomics tests and potentially other tests.

General and Administrative Expenses: G&A expenses for the year ended December 31, 2014 were $8,625,917, an increase of $67,082, or 0.8% from $8,558,835 for the same period in 2013. G&A expenses consists primarily of personnel and related benefit costs, facilities, professional services, insurance, and public company related expenses. The increase was primarily attributable to a $1,773,876 increase in personnel costs and legal expenses in 2014 attributed to ongoing regulatory fees and shareholders' litigation, offset by a reduction in expenses associated with our 2013 product recall for approximately $449,610, $975,068 in professional fees, and $291,484 in advertising.

We expect our G&A expenses to grow as we hire additional administrative and manufacturing personnel to prepare for and execute on the launch of the ForeCYTE Breast Aspirator and FullCYTE Breast Aspirator, pharmacogenomics testing and our other products and services under development and as we incur additional costs associated with being a publicly traded company.

Research and Development Expenses: R&D expenses for the year ended December 31, 2014 were $2,577,465, an increase of $1,472,355, or 133%, from the year ended December 31, 2013. The increase in R&D expenses in 2014 is attributed to additional R&D expenditures on the development of our new products and tests in the pipeline, including the NextCYTE test, FullCYTE Microcatheters and FullCYTE Breast Aspirator. We expect that our R&D expenses will continue to increase throughout 2015 as we add additional full time employees and incur additional costs to continue the development of our products and services under development, including the development of a potential pharmaceutical and conducting one or more clinical studies.

Impairment of Intangible Assets: During the year ended December 31, 2014, we recorded an impairment charge of $2,352,626 for certain intangible assets purchased in the Acueity transaction in 2012. As a result of changes in our plans to develop and invest further in the Acueity assets, we determined that the assets were impaired and wrote them down to the estimated fair value as of December 31, 2014. No impairments of intangible assets were recorded during the year ended December 31, 2013.

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 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 incurred net losses and negative operating cash flows since inception. For the year ended December 31, 2014, the Company recorded a net loss of approximately $14.6 million and used approximately $10.5 million of cash in operating activities. As of December 31, 2014, the Company had approximately $8.5 million in cash and cash equivalents and working capital of approximately $6.9 million. 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. The Company can give no assurances that any additional capital that it is able to obtain, if any, will be sufficient to meet its needs, or that any such financing will be obtainable on acceptable terms. If the Company is unable to obtain adequate capital, it could be forced to cease operations or substantially curtail is commercial activities. These conditions raise substantial doubt as to the Company's ability to continue as a going concern. The accompanying consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts and classification of liabilities should the Company be unable to continue as a going concern.

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 and in 2015 prior to the filing of this report we sold $1.5 million to Aspire. Up to a total of $22.5 million remains available for sale to Aspire as of the date of filing this report.

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 of 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

As of December 31, 2014, we had cash and cash equivalents of $8,500,718.

Net Cash Flows from Operating Activities: Net cash used in operating activities was approximately $10,555,450 for the year ended December 31, 2014, compared with $8,830,044 for the year ended December 31, 2013. The increase in cash used in operating activities of $1,725,406 resulted primarily from an increase in R&D activities related to our new product developments, additional salaries to support the operations, and legal expenses related to the recall and ongoing litigation.

Net Cash Flows from Investing Activities: Net cash used in investing activities was $343,257 for the year ended December 31, 2014, compared with $489,815 for the year ended December 31, 2013. The decrease was primarily attributable to the reduction in purchases of fixed asset equipment in 2014 as compared to 2013.

Net Cash Flows from Financing Activities: Net cash provided by financing activities was $13,057,264 for the year ended December 31, 2014, compared with $13,936,823 for the year ended December 31, 2013. In both years, we recognized substantial financing cash flows from the sale of our common stock and warrants. The decrease in financing activities is primarily attributable to warrants that were exercised in 2013 compared to no warrant exercises in 2014.

Funding Requirements

We expect to incur substantial expenses and generate ongoing operating losses for the foreseeable future as we continue to launch the ForeCYTE Breast Aspirator outside the United States and the FullCYTE Breast Aspirator in the United States, continue to launch our laboratory tests including the pharmacogenomics and NAF cytology tests, complete the development of and potentially launch the ArgusCYTE test, NextCYTE test, and potentially other devices in the pipeline, and start the development of our planned therapeutic programs including related clinical studies. We expect that our existing resources as of December 31, 2014 will be sufficient to fund our planned operations for at least the first four to eight months of 2015. In addition to our cash and cash equivalents at December 31, 2014 of approximately $8.5 million, additional potential sources of capital include utilizing our Common Stock Purchase Agreement with Aspire Capital, selling securities that are registered on our Form S-3 registration statement

and seeking to raise capital through sales of securities to third parties and existing stockholders. 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, which include the following:

- the time and expense needed to continue the launch and commercialization of the ForeCYTE and FullCYTE Breast Aspirators;
- the expense associated with building a network of independent sales representatives to market the ForeCYTE and FullCYTE Breast Aspirators, pharmacogenomics tests, NAF cytology tests, 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.

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

In May 2014, the Financial Accounting Standards Board (the “FASB”) issued Accounting Standards Update (“ASU”) No. 2014-09, *Revenue from Contracts with Customers: Topic 606* (“ASU 2014-09”), to supersede nearly all existing revenue recognition guidance under U.S. GAAP. The core principle of ASU 2014-09 is to recognize revenues when promised goods or services are transferred to customers in an amount that reflects the consideration that is expected to be received for those goods or services. ASU 2014-09 defines a five step process to achieve this core principle and, in doing so, it is possible more judgment and estimates may be required within the revenue recognition process than required under existing GAAP including identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation. ASU 2014-09 is effective in the first quarter of 2017 using either of two methods: (i) retrospective to each prior reporting period presented with the option to elect certain practical expedients as defined within ASU 2014-09; or (ii) retrospective with the cumulative effect of initially applying ASU 2014-09 recognized at the date of initial application and providing certain additional disclosures as defined per ASU 2014-09. We are currently evaluating the impact of our pending adoption of ASU 2014-09 on our consolidated financial statements.

In June 2014, FASB issued ASU No. 2014-10, *Elimination of Development Stage Entity Requirements.* This ASU eliminates the concept of Development Stage Entities (DSE's) from U.S. GAAP and is intended to result in cost-savings for certain entities, such as start-ups or research and development entities. As a result of these changes, the financial statements of developing entities no longer need to meet the inception-to-date income, cash flow and equity information; the requirement to label financial statements as those of a developing company was eliminated; and certain disclosures related to the nature of the entities development stage activities were eliminated. We adopted ASU 2014-10 during the year ended December 31, 2014. Given that the Company has been generating revenues from pharmacogenomic testing beginning in October 2014, the Company is not considered a development stage entity.

In August 29, 2014, FASB issued ASU No. 2014-15, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*. This ASU requires management to determine whether substantial doubt exists regarding the entity's going concern presumption, which generally refers to an entity's ability to meet its obligations as they become due. If substantial doubt exists but is not alleviated by management's plan, the footnotes must specifically state that "there is substantial doubt about the entity's ability to continue as a going concern within one year after the financial statements are issued". In addition, if substantial doubt exists, regardless of whether such doubt was alleviated, entities must disclose (a) principal conditions or events that raise substantial doubt about the entity's ability to continue as a going concern (before consideration of management's plans, if any); (b) management's evaluation of the significance of those conditions or events in relation to the entity's ability to meet its obligations; and (c) management's plans that are intended to mitigate the conditions or events that raise substantial doubt, or that did alleviate substantial doubt, about the entity's ability to continue as a going concern. If substantial doubt has not been alleviated, these disclosures should become more extensive in subsequent reporting periods as additional information becomes available. In the period that substantial doubt no longer exists (before or after considering management's plans), management should disclose how the principal conditions and events that originally gave rise to substantial doubt have been resolved. The ASU applies prospectively to all entities for annual periods ending after December 15, 2016, and to annual and interim periods thereafter. Early adoption is permitted. We have yet adopted the provisions of ASU No. 2014-15.

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 79 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

Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures

At the end of the period covered by this report, we carried out an evaluation, under the supervision and with the participation of our management, including our principal executive officer and principal accounting and financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures, as such term is defined under Rule 13a-15(e) promulgated under the 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, 2014 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, 2014 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.

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, 2014. Because we are a smaller reporting company, BDO USA LLP, 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

DIRECTORS:

The Certificate of Incorporation of the Company provides that the Board is to be divided into three classes as nearly equal in number as reasonably possible, with directors in each class serving three-year terms. The total Board size is currently fixed at six directors. Currently, the Class I directors (whose terms expire at the 2016 annual meeting of stockholders) are Steven C. Quay, M.D., Ph.D., and Gregory L. Weaver. The Class II directors (whose terms expire at the 2017 annual meeting of stockholders) are Stephen J. Galli, M.D., and Richard I. Steinhart. The Class III directors (whose terms expire at the 2015 annual meeting of stockholders) are Shu-Chih Chen, Ph.D., and H. Lawrence Remmel, Esq. Directors elected at an annual meeting will hold office until the next annual meeting of stockholders and until their successors are elected and qualified, unless they resign or their seats become vacant due to death, removal, or other cause in accordance with the Bylaws of the Company.

The following table sets forth the following information for the Company's directors: the year each was first elected a director of the Company; their respective ages as of the date of filing of this report; the positions currently held with the Company; the year their current term will expire and their current class.

Nominee/Director Name and Year First Became a Director	Age	Position(s) with the Company	Year Current Term Expires	Current Director Class
Shu-Chih Chen, Ph.D. (2009)	53	Director	2015	III
H. Lawrence Remmel, Esq. (2012)	63	Director	2015	III
Steven C. Quay, M.D., Ph.D. (2009)	64	Chairman of the Board of Directors, President and Chief Executive Officer	2016	I
Gregory L. Weaver (2013)	58	Director	2016	I
Stephen J. Galli, M.D. (2011)	68	Director	2017	II
Richard I. Steinhart (2014)	57	Director	2017	II

Shu-Chih Chen, Ph.D. Dr. Chen served as Chief Scientific Officer of the Company since the Company was incorporated in April 2009 through August 2014. Dr. Chen has served as a director of the Company since April 2009.Prior to joining the Company, Dr. Chen served as President of Ensisheim beginning in 2008, was founder and President of SC2Q Consulting Company from 2006 to 2008, and served as Head, Cell Biology, Nastech Pharmaceutical Company, Inc. from 2002 to 2006. During 1995 and 1996, she was an Associate Professor at National Yang Ming University, Taipei, Taiwan, and served as the principal investigator of an NIH RO1 grant studying tumor suppression by gap junction protein connexin 43 at the Department of Molecular Medicine at Northwest Hospital before working in the research department at Nastech Pharmaceutical Company. She is named as an inventor on four patent applications related to cancer therapeutics. Dr. Chen received her Ph.D. degree in microbiology and public health from Michigan State University in 1992 and has published extensively on Molecular Oncology. She received her B.S. degree in medical technology from National Yang Ming University, Taipei, Taiwan in 1984. Dr. Chen was selected to serve on the Company's Board of Directors because of her role as a founder of the Company and her qualifications in medical technology and as a professor and researcher in the field of cancer therapeutics.

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

Steven C. Quay, M.D., Ph.D. Dr. Quay has served as Chief Executive Officer, President and Chairman of the Board of Directors of the Company since the Company was incorporated in April 2009. Prior to his work at the Company, Dr. Quay served as Chairman of the Board, President and Chief Executive Officer of MDRNA, Inc., a biotechnology company focused on the development and commercialization of RNAi-based therapeutic products, from August 2000 to May 2008, and as its Chief Scientific Officer until November 30, 2008 (MDRNA, Inc. was formerly known as Nastech Pharmaceutical Company Inc. and is currently known as Marina Biotech, Inc.). From December 2008 to April 2009, Dr. Quay was involved in acquiring the Company's assets and preparing the Company's business plan. Dr. Quay is certified in Anatomic Pathology with the American Board of Pathology, completed both an internship and residency in anatomic pathology at Massachusetts General Hospital, a Harvard Medical School teaching hospital, is a former faculty member of the Department of Pathology, Stanford University School of Medicine, and is a named inventor on 14 U.S. and foreign patents covering the ForeCYTE Breast Aspirator. Including the patents for the ForeCYTE Breast Aspirator, Dr. Quay is a named inventor on 76 U.S. patents, 108 pending patent applications and is a named inventor on patents covering five pharmaceutical products that have been approved by the U.S. Food and Drug Administration. Dr. Quay received an M.D. in 1977 and a Ph.D. in 1975 from the University of Michigan Medical School. He also received his B.A. degree in biology, chemistry and mathematics from Western Michigan University in 1971. Dr. Quay is a member of the American Society of Investigative Pathology, the Association of Molecular Pathology, the Society for Laboratory Automation and Screening and the Association of Pathology Informatics. He was selected to serve on the Company's Board of Directors because of his role as a founder of the Company and the inventor of the ForeCYTE Breast Aspirator, as well as his qualifications as a physician and the principal researcher overseeing the clinical and regulatory development of the ForeCYTE Breast Aspirator.

Gregory L. Weaver. Mr. Weaver has served as a director of the Company since October 2013. Mr. Weaver currently serves as Global Chief Financial Officer of Oryzon Genomics, an epigenetics company. From August 2013 to October 2014, Mr. Weaver served as Chief Financial Officer, Senior Vice President, Treasurer and Corporate Secretary of Fibrocell Science, Inc., an autologous cellular therapeutic company. From June 2011 to July 2013, Mr. Weaver served as Chief Financial Officer and Senior Vice President of Celsion Corp., an oncology drug development company. From February 2009 to August 2010, Mr. Weaver served as Chief Financial Officer and Senior Vice President of Poniard Pharmaceuticals, Inc., a drug development company. From April 2007 to December 2008, Mr. Weaver served as Chief Financial Officer of Talyst, Inc., an information technology services company. Mr. Weaver received his B.S. degree from Trinity University and his M.B.A. degree from Boston College. Mr. Weaver has been selected to serve on

the Company’s Board of Directors because of his qualifications as a business executive and audit committee financial expert, and his current and prior experience as a Chief Financial Officer, director and committee member of public companies.

Stephen J. Galli, M.D. Dr. Galli has served as a director of the Company since July 2011. Dr. Galli is Chair of the Department of Pathology, Professor of Pathology and of Microbiology & Immunology and the Mary Hewitt Loveless, M.D., Professor, Stanford University School of Medicine, Stanford, California, and has served in these capacities since February 1999. Before joining Stanford, he was on the faculty of Harvard Medical School. He holds 13 U.S. patents and has over 340 publications. He is past president of the American Society for Investigative Pathology and was president of the Collegium Internationale Allergologicum. From 2010-2014. In addition to receiving awards for his research, he was recently recognized with the 2010 Stanford University President's Award for Excellence through Diversity for his recruitment and support of women and underrepresented minorities at Stanford University. He received his B.A. degree in biology, magna cum laude, from Harvard College in 1968 and his M.D. degree from Harvard Medical School in 1973 and completed a residency in anatomic pathology at the Massachusetts General Hospital in 1977. Dr. Galli has been selected to serve on the Company's Board of Directors because of his qualifications as a professor and physician, and his specialized expertise as a pathologist.

Richard I. Steinhart. Mr. Steinhart has served as a director of the Company since March 2014. From April 2006 to December 2013, Mr. Steinhart was an executive at MELA Sciences, Inc., most recently serving as its Chief Financial Officer, Senior Vice President, Treasurer and Secretary. From 1992 to 2006, Mr. Steinhart was Managing Director at Forest St. Capital/SAE Ventures. Earlier, he served as Vice President and Chief Financial Officer at Emisphere Technologies from 1991 to 1992 and as General Partner and Chief Financial Officer of CW Group Inc. Mr. Steinhart is a Member of the Board of Directors of Actinium Pharmaceuticals where he is Chairman of the Audit Committee and a member of the Compensation Committee. From 2004 to 2012, Mr. Steinhart was a Member of the Board of Directors of Manhattan Pharmaceuticals and was Chairman of the Audit Committee. Mr. Steinhart received his B.B.A. and M.B.A. degrees from Pace University. Mr. Steinhart has been selected to serve on the Company's Board of Directors because of his qualifications as a business executive and audit committee financial expert, and his prior experience as a Chief Financial Officer, director and committee member of public companies.

EXECUTIVE OFFICERS AND KEY EMPLOYEES:

The names of our executive officers and key employees and their ages as of March 24, 2015 are as follows:

Name	Age	Position
Executive Officers:		
Steven C. Quay, M.D., Ph.D.	64	Chairman of the Board, President and Chief Executive Officer
Kyle Guse, Esq., CPA	51	Chief Financial Officer, General Counsel and Secretary
John E. Sawyer	60	Senior Vice President, Global Regulatory Affairs and Quality Assurance
Christopher S. Destro	45	Senior Vice President, Sales and Marketing
Key Employees:		
Scott Youmans	48	Senior Vice President, Operations
Jelle W. Kylstra, M.D., MBA	54	Vice President, Clinical Research and Development
Pieter Van der Poel	52	Vice President of European Operations

Michael Kalnoski, M.D., FCAP	55	Medical Director

63

Steven C. Quay, M.D., Ph.D. Dr. Quay has served as Chief Executive Officer, President and Chairman of the Board of Directors of the Company since the Company was incorporated in April 2009. Prior to his work at the Company, Dr. Quay served as Chairman of the Board, President and Chief Executive Officer of MDRNA, Inc., a biotechnology company focused on the development and commercialization of RNAi-based therapeutic products, from August 2000 to May 2008, and as its Chief Scientific Officer until November 30, 2008 (MDRNA, Inc. was formerly known as Nastech Pharmaceutical Company, Inc. and is currently known as Marina Biotech, Inc.). From December 2008 to April 2009, Dr. Quay was involved in acquiring the Company's assets and preparing the Company's business plan. Dr. Quay is certified in Anatomic Pathology with the American Board of Pathology, completed both an internship and residency in anatomic pathology at Massachusetts General Hospital, a Harvard Medical School teaching hospital, is a former faculty member of the Department of Pathology, Stanford University School of Medicine, and is a named inventor on 14 U.S. and foreign patents covering the ForeCYTE Breast Aspirator. Including the patents for the ForeCYTE Breast Aspirator, Dr. Quay is a named inventor on 76 U.S. patents, 108 pending patent applications and is a named inventor on patents covering five pharmaceutical products that have been approved by the U.S. Food and Drug Administration. Dr. Quay received an M.D. in 1977 and a Ph.D. in 1975 from the University of Michigan Medical School. He also received his B.A. degree in biology, chemistry and mathematics from Western Michigan University in 1971. Dr. Quay is a member of the American Society of Investigative Pathology, the Association of Molecular Pathology, the Society for Laboratory Automation and Screening and the Association of Pathology Informatics. He was selected to serve on the Company's Board of Directors because of his role as a founder of the Company and the inventor of the ForeCYTE Breast Aspirator, as well as his qualifications as a physician and the principal researcher overseeing the clinical and regulatory development of the ForeCYTE Breast Aspirator.

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

John E. Sawyer. Mr. Sawyer has served the Company as Senior Vice President, Global Regulatory Affairs and Quality Assurance since June 2014. Prior to joining Atossa Genetics, Mr. Sawyer owned his own consulting firm, Realistic Quality Solutions LLC, located in Snohomish, Washington from June 2010 until present. From April 2009 to June 2010, he was the Vice-President of Quality Assurance & Regulatory Affairs for Cardiac Science. He also served as the Vice-President, Quality Assurance & Regulatory Affairs for Welch-Allyn from May 2003 to April 2009. He has served in other leadership positions with Fujifilm Medical Systems and GE OEC Medical Systems. He is also affiliated with the Association of the Advancement of Medical Instrumentation (AAMI) where he teaches various quality management training courses, published articles and participated in various quality management webinars. Mr. Sawyer holds an MBA and a B.S. in business administration from Tampa College in Tampa, Florida.

Christopher Destro. Mr. Destro has served the Company as Vice President of Sales and Marketing since December 2012. Prior to joining Atossa, Mr. Destro served as Vice President of Sales at Magellan Biosciences from January 2011 to December 2014. Mr Destro has over 18 years of successful sales and client management expertise within the clinical sector of diagnostic biotechnology. From January 2007 to July 2011, Mr. Destro served in increasingly responsible positions including Director of Sales, North America, for three divisions of Magellan Biosciences, where he managed sales of automated blood culture and susceptibility instrumentation for Trek Diagnostics, automated immunochemistry for Dynex and a blood-lead care platform for point of care testing. In July 2011, Magellan was acquired by Thermo Fisher Scientific, where Mr. Destro became a commercial leader of the Microbiology Division. Prior to joining Magellan, Mr. Destro served as Americas Sales Director for Biotrace International from 2000 to 2006, where he managed sales of core pathogen diagnostic (ELISA) products while leading 17 distributors for the United States, Canada, Mexico and Latin America. Mr. Destro holds a B.S. degree in microbiology from The Ohio State University.

Scott Youman Mr. Youmans has served as the Senior Vice president of Operations since September 2014. Prior to that, Mr. Youmans was the Director of Engineering at Impel Neuropharma from February to September 2014. He consulted for Bayer Interventional from December 2013 to February 2014. Before that he was VP of Engineering at Pathway Medical Technologies from September 2000 to November 2013 when Pathway was acquired by Bayer Interventional. Mr. Youmans brings 20 years of medical device development and manufacturing experience in both U.S. and international markets. Throughout his 20 year career, he has focused on developing, manufacturing and commercializing complex, innovative medical technologies in a wide variety of clinical applications including: targeted drug delivery, peripheral vascular atherectomy, coronary atherectomy, thrombectomy, biopsy tools, and beating heart support. He brings experience in rapid product iteration, design controls, continuous improvement, supply chain development and management, product life-cycle management, project management, pre-clinical studies, clinical studies and clinical field support. Prior to joining Atossa Genetics, Mr. Youmans directed the development of the Precision Olfactory Device at Impel Neuropharma from February to September 2014. From 2000 to 2013, Mr. Youmans led the development of Pathway Medical's Jetstream Atherectomy System and held increasingly responsible roles, including VP of Engineering since 2003. Mr. Youmans holds a Bachelor of Science degree in Manufacturing Engineering Technology from Western Washington University.

Jelle W. Kylstra, M.D., MBA. Dr. Kylstra has served as Vice President of Clinical Research and Development since May 2014. Prior to joining Atossa, Dr. Kylstra served as Vice President, Global Clinical Affairs at Spectrum Pharmaceuticals from 2010 to May 2014, providing worldwide Medical Affairs team leadership in developing Radio-immuno Therapy (Zevalin), histone deacetylase inhibitors (Beleodaq), pralatrexate (Folotyn), liposomal vincristine (Marqibo) and hematopoetic stimulating factors (LAPS-GCSF). Prior to joining Spectrum, Dr. Kylstra served in clinical development roles of increasing responsibility at AngioDynamics Inc., Light Sciences Corp., Dendreon Corp., PathoGenesis Corp., Zeneca Pharmaceuticals (including oncology therapeutics for breast cancer) and Procter & Gamble Pharmaceuticals. In 1990 Dr. Kylstra received an MBA from Northwestern University, J.L. Kellogg Graduate School of Management, and prior to that he received a Medical Doctor (MD) degree from the University of Amsterdam. Dr. Kylstra is a member of the American Society of Clinical Oncology (ASCO), the Academy of Pharmaceutical Physicians and Investigators (APPI), and the American Association for Cancer Research (AACR).

Pieter Van der Poel. Mr. Van der Poel has served as Vice President of European Commercial Operations in since December 2014. Prior to joining Atossa, Mr. Van der Poel served as Senior Marketing Director at FEI in Netherlands from January to December 2014. He brings over 20 years of global medical device market and business development experience for leading medical companies, including Philips Medical Systems, Hewlett-Packard Medical (now Philips Healthcare) and GE Healthcare. Throughout his career, he has focused on leading development and the marketing of diagnostic imaging, automated blood analysis systems, retinal cameras, blood separation systems for blood transfusion services, and digital image analysis tools. In addition, Mr. Van der Poel brings global marketing experience and expertise gained at high technology companies such as Alstom Power and U.S.-based FEI Company. He brings broad experience in change management, corporate strategy, up and downstream marketing and continuous process improvement gained while at GE Healthcare in Milwaukee. Mr. Van der Poel holds a Bachelor of Business Administration from Nyenrode Business University in the Netherlands and an MBA from the University of Michigan - Ann Arbor.

Michael Kalnoski, M.D., FCAP. Dr. Kalnoski has served as Medical Director since April, 2012. Prior to that, Dr. Kalnoski served as Director of FISH Laboratory and Cytopathology at Puget Sound Institute of Pathology from 2002 to 2012. Dr. Kalnoski has also served as the medical director of multiple Pacific Northwest regional hospitals and large reference laboratories (Quest Diagnostics) in Washington and Alaska. Dr. Kalnoski attended Saint Louis University School of Medicine, where he earned his M.D. He completed his residency at the University of Washington in clinical and anatomic pathology and a fellowship in hematology and is board certified in all three. He also received post-graduate training (MBA) at Saint Louis University and San Francisco State University; post-graduate training in cell and molecular biology at the University of California, Los Angeles (UCLA) and earned a B.A. in chemistry from the University of Washington. He has extensive experience in genomics and analyzing single nucleotide polymorphisms (SNPs) in evaluating patient conditions. He is a member of the College of American Pathology (CAP) and recently received an achievement award for his efforts in laboratory inspections.

CORPORATE GOVERNANCE

Director Independence

We believe that the Company benefits from having a strong and independent Board. For a director to be considered independent, the Board must determine that the director does not have any direct or indirect material relationship with the Company that would affect his or her exercise of independent judgment. On an annual basis, the Board reviews the independence of all directors under guidelines established by NASDAQ and in light of each director's affiliations with the Company and members of management, as well as significant holdings of Company securities. This review considers all known relevant facts and circumstances in making an independence determination. Based on this review, the Board has made an affirmative determination that all directors, other than Drs. Quay and Chen, are independent. It was determined that Dr. Quay lacks independence because of his status as the Company's President and Chief Executive Officer and that Dr. Chen lacks independence because of her marriage to Dr. Quay.

Corporate Code of Business Conduct and Ethics

We believe that our Board and committees, led by a group of strong and independent directors, provide the necessary leadership, wisdom and experience that the Company needs in making sound business decisions. We have adopted a Code of Business Conduct and Ethics that applies to all of our officers and employees, including our President and Chief Executive Officer, our Chief Financial Officer and other employees who perform financial or accounting functions. The Code of Business Conduct and Ethics sets forth the basic principles that guide the business conduct of our employees. Our Corporate Code of Business Conduct and Ethics helps clarify the operating standards and ethics that we expect of all of our officers, directors and employees in making and implementing those decisions. Waivers of our Corporate Code of Business Conduct and Ethics may only be granted by the Board or the Audit Committee and will be publicly announced promptly on our website. In furthering our commitment to these principles, we invite you to review our Corporate Code of Business Conduct and Ethics located on our website at *www.atossagenetics.com* .

Stockholder Communications

Generally, stockholders who have questions or concerns regarding the Company should contact our Investor Relations representative at (800) 351-3902. However, any stockholders who wish to address questions regarding the business or affairs of the Company directly with the Board, or any individual director, should direct his or her questions in writing to the Chairman of the Board, Atossa Genetics Inc., 2345 Eastlake Ave. E, Suite 201, Seattle, WA 98102. Upon receipt of any such communications, the correspondence will be directed to the appropriate person, including individual directors.

Audit Committee

Our Board of Directors has appointed an Audit Committee, comprised of Messrs. Steinhart (Chairman), Weaver and Remmel. The Audit Committee selects the Company's independent registered public accounting firm, approves its compensation, oversees and evaluates the performance of the independent registered public accounting firm, oversees the accounting and financial reporting policies and internal control systems of the Company, reviews the Company's interim and annual financial statements, independent registered public accounting firm reports and management letters, and performs other duties, as specified in the Audit Committee Charter, a copy of which is available on the Company's website at *www.atossagenetics.com.* Additionally, the Audit Committee is involved in the oversight of the Company's risk management through its review of policies relating to risk assessment and management. The Audit Committee met four times in fiscal 2014. All members of the Audit Committee satisfy the current independence standards promulgated by NASDAQ and the SEC and the Board has determined that Richard Steinhart qualifies as an "audit committee financial expert," as the SEC has defined that term in Item 407 of Regulation S-K.

Equity Compensation Plan Information

The following table sets forth certain information, as of December 31, 2014, regarding the Company's 2010 Stock Option and Incentive Plan, as well as other stock options and warrants previously issued by the Company as compensation for services.

Plan category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights		Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights	**Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in First Column)** [1]
Equity compensation plans approved by security holders	2,270,634		$ 3.06	439,388
Equity compensation plans not approved by security holders	1,405,000	[2]	$ 2.55	—
Total	3,675,634		$ 2.86	439,388

(1) Excludes shares that may be added after December 31, 2014 pursuant to the "evergreen" feature under the 2010 Stock Option and Incentive Plan. For example, on January 1, 2015, 983,362 shares were automatically added to the 2010 Stock Option and Incentive Plan under the evergreen feature.

(2) Represents options granted to new employees as inducements for employment which were not required to be approved by security holders. The options are subject to the 2010 Stock Option and Incentive Plan, but were granted outside of such plan. Excludes warrants granted and outstanding in connection with financing agreements.

SECTION 16(A) BENEFICIAL OWNERSHIP REPORTING COMPLIANCE

Section 16(a) of the Exchange Act requires our executive officers and directors, and persons who own more than 10% of a registered class of our equity securities, to file reports of beneficial ownership and changes in beneficial ownership with the SEC. Executive officers, directors and greater-than-10% stockholders are required by SEC regulations to furnish us with copies of all reports filed under Section 16(a). To the Company's knowledge, based solely on the review of copies of the reports filed with the SEC, all reports required to be filed by our executive

officers, directors and greater-than-10% stockholders were timely filed in fiscal 2014.

ITEM 11. EXECUTIVE COMPENSATION

Remuneration of Officers

Our Compensation Committee is responsible for reviewing and evaluating key executive employee base salaries, setting goals and objectives for executive bonuses and administering benefit plans. The Compensation Committee provides advice and recommendations to our Board of Directors on such matters.

Summary Compensation Table

The following table sets forth the compensation earned by our President and Chief Executive Officer, Chief Financial Officer, Chief Scientific Officer, Senior Vice President of Global Regulatory Affairs and Quality Assurance, and Senior Vice president of Sales and Marketing (collectively, the " ***Named Executive Officers*** "), for fiscal years 2013 and 2014:

Name and Position	Year	Salary	Option Award (1)	Nonequity Incentive Plan Compensation	All Other Compensation (6)	Total
Steven C. Quay, M.D., Ph.D. President and Chief Executive Officer (2)	2014	$500,000	$ 129,138	$ 225,000	$ 10,400	$864,538
	2013	$259,250	$ -	$ 171,271	$ -	$430,521
Kyle Guse (3) Chief Financial Officer, General Counsel and Secretary	2014	$350,000	$ 236,190	$ 149,625	$ 10,400	$746,215
	2013	$225,000	$ 846,099	$ 181,117	$ -	$1,252,216
Shu-Chih Chen, Ph.D. Chief Scientific Officer (4)	2014	$224,268	$ 64,569	$ 87,500	$ 10,400	$386,737
	2013	$207,400	$ -	$ 105,872	$ -	$313,272
John Sawyer Senior Vice President of Regulatory Affairs and Quality Assurance (5)	2014	$163,334	$ 119,259	$ 43,288	$ -	$325,881
	2013	$-	$ -	$ -	$ -	$-
Christopher Destro	2014	$205,000	$ 70,702	$ 46,638	$ 10,400	$332,740

Senior Vice President of Sales and Marketing [6]						
	2013	$180,000	$ -	$ 58,590	$ -	$238,590

(1) The value of the option awards has been computed in accordance with FASB ASC 718, excluding the effect of estimated forfeitures. Assumptions used in the calculations for these amounts are included in notes to our financial statements included in this report. Additional information about the terms of each option award is below under PART III Item 11 “Executive Compensation – Outstanding Equity Awards at Fiscal Year End.”

(2) “Nonequity Incentive Plan Compensation” for 2013 consists of the following: the cash bonus of $51,850 payable to Dr. Quay for services in 2013 which was paid in March 2014; and the cash bonus of $72,590 payable to Dr. Quay for services in 2012 was paid in March 2013 in the form of a fully-vested option to purchase 44,194 shares of common stock at an exercise price of $6.57 per share, which had an aggregate fair market value of $119,421 on the date of grant.

(3) “Nonequity Incentive Plan Compensation” for 2013 included a fully-vested option granted in June 2013 to purchase 60,000 shares of common stock exercisable at $4.31 per share, which Mr. Guse received in lieu of a cash relocation and hiring bonus payable to him in connection with his hiring, which had an aggregate fair market value of $95,616 at the time of grant.

(4) Dr. Chen served as Chief Scientific Officer of the Company through August 2014. Her salary and bonus for 2014 reflect a pro-rata adjustment for service during her employment. Disclosure is included for her because, but for the fact that she was not serving as an executive officer on December 31, 2014 she would have been identified as a Named Executive Officer. The cash bonus of $34,221 payable to Dr. Chen for service in 2012 was paid on March 11, 2013 in the form of a fully-vested option to purchase 26,516 shares of common stock at an exercise price of $6.57 per share, which had an aggregate fair market value of $71,651 on the date of grant.

(5) Mr. Sawyer was hired as our Senior Vice President of Global Regulatory Affairs and Quality Assurance in June 2014.

(6) Amounts represent 401(k) match paid by the Company on behalf of the Named Executive Officer.

Outstanding Equity Awards at Fiscal Year-End

The following table shows information regarding our outstanding equity awards at December 31, 2014 for the Named Executive Officers, all of which are subject to the terms and conditions of the 2010 Stock Option and Incentive Plan which is described below:

Name	Grant Date	Number of Securities Underlying Unexercised Options (#) Exercisable		Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price	Option Expiration Date
Steven C. Quay, M.D., Ph.D., President and Chief Executive Officer [1]	7/22/2010	250,000	(1)	—	$ 5.00	7/22/2015
	3/11/2013	44,194	(2)	—	$ 6.57	3/11/2023
	5/6/2014	31,250	(3)	218,750	$ 1.22	5/06/2024
Kyle Guse [2] Chief Financial Officer, General Counsel and Secretary	1/4/2013	218,749	(4)	281,251	$ 4.11	1/04/2023
	6/4/2013	60,000	(2)	—	$ 4.31	6/04/2023
	1/8/2014	26,250	(3)	113,750	$ 2.20	1/08/2024
	5/6/2014	25,000	(3)	175,000	$ 1.22	5/06/2024
Shu-Chih Chen, Ph.D., Chief Scientific Officer [3]	7/22/2010	100,000	(1)	—	$ 5.00	7/22/2015
	3/11/2013	26,516	(2)	—	$ 6.57	3/11/2023
	5/6/2014	15,632	(3)	109,368	$ 1.22	5/06/2024
John Sawyer, Senior Vice President of Regulatory Affairs and Quality Assurance[4]	6/2/2014		(4)	200,000	$ 1.41	6/02/2024
Christopher Destro, Senior Vice President of Sales and Marketing [5]	12/20/2012	100,000	(4)	100,000	$ 4.11	12/20/2022
	1/8/2014	9,375	(3)	40,625	$ 2.20	1/08/2024
	5/6/2014	5,632	(3)	39,368	$ 1.22	5/06/2024

(1) One quarter of the shares of common stock underlying the option vested on December 31, 2010, and the remaining 75% vested in equal quarterly installments over the next three years so that the options were fully vested on December 31, 2013.

(2) Option was granted in lieu of a cash bonus payable to the executive. The option was fully vested on the date of grant. See PART III Item 11 “Executive Compensation” above.

(3) Option vests quarterly over four years from the date of grant.

(4)

One quarter of the shares of common stock underlying the option vested on the first anniversary of employment and the remaining 75% vest in equal quarterly installments over the next three years.

Employment Agreements

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

The Company has entered into an employment agreement with Dr. Quay to act as the Company's Chief Executive Officer. The agreement provides for an initial base salary of $250,000, which was subsequently increased to $500,000 for 2014 and $520,000 for 2015, with an annual target bonus of up to 50% of Dr. Quay's then-current base salary, payable upon the achievement of performance goals to be established annually by the Compensation Committee.

Under his employment agreement, Dr. Quay received an option to purchase up to 250,000 shares of common stock at an exercise price of $5.00 per share, the fair market value of the common stock on the date of grant, as determined by the Board of Directors. One-quarter of the shares of common stock underlying the option, or 62,500 shares, vested on December 31, 2010, and the remaining 75%, or 187,500 shares, vested in equal quarterly installments over the next three years. The options were fully vested as of December 31, 2013.

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

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

Employment Agreement with Kyle Guse

The Company has entered into an employment agreement with Mr. Guse to act as the Company’s Chief Financial Officer, General Counsel and Secretary. The agreement provides for an initial base salary of $225,000, which has been increased to $350,000 for 2014 and $364,000 for 2015 and an annual target bonus of up to 45% of Mr. Guse’s then-current base salary, payable upon the achievement of performance goals to be established annually by the Compensation Committee.

The goals for fiscal 2014 included successful completion of a capital raising transaction with gross proceeds of at least $15 million, maintaining capital resources, facilitate expansion into one or more foreign markets, maintain GAAP and SEC compliance and contribute to achievement of corporate goals. In March 2015, the Compensation Committee reviewed the performance of Mr. Guse for 2014 against these goals and determined that his bonus for 2014 would be $149,625.

Under his employment agreement, on January 4, 2014, Mr. Guse received an option to purchase up to 500,000 shares of common stock at an exercise price of $4.11 per share, the fair market value of the common stock on the date of

grant, as determined by the Board of Directors. One-quarter of the shares of common stock underlying the option, or 125,000 shares, vested on January 4, 2014, and the remaining 75%, or 375,000 shares, vest in equal quarterly installments over the next three years, so long as Mr. Guse remains employed with the Company. In lieu of a cash signing and relocation bonus payable to Mr. Guse under the terms of his employment agreement, on June 4, 2013 he received a fully-vested option to purchase 60,000 shares of common stock exercisable at $4.31 per share, the fair value of the Company's common stock on the date of grant.

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

Mr. Guse has also agreed that, for the period commencing on the date of his employment agreement with the Company and during the term of his employment and for a period of six months following voluntary termination of his employment with the Company that he will not compete with the Company in the United States.

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

The Company has entered into an employment agreement with Dr. Chen to act as the Company's Chief Scientific Officer. The agreement provides for an initial base salary of $200,000, which was subsequently increased to $207,400, per year in 2013 and $350,000 in 2014 with an annual target bonus of up to 40% of Dr. Chen's then-current base salary, payable upon the achievement of performance goals to be established annually by the Compensation Committee. Dr. Chen's employment agreement was terminated in August 2014 in connection with her retirement as the Chief Scientific Officer of the Company.

The goals for fiscal 2014 included contribute to and maintain quality, create intellectual property value, submission of at least two manuscripts and/or abstracts for publication, and build infrastructure to support corporate goals. In March 2015, the Compensation Committee reviewed the performance of Dr. Chen for 2014 against these goals and determined that her bonus for 2014 would be $87,500.

Under her employment agreement, Dr. Chen received an option to purchase up to 100,000 shares of common stock at an exercise price of $5.00 per share, the fair market value of the common stock on the date of grant, as determined by the Board of Directors. One quarter of the shares of common stock underlying the option, or 25,000 shares, vested on December 31, 2010, and the remaining 75%, or 75,000 shares, vest in equal quarterly installments over the next three years. The options were fully vested as of December 31, 2013. In lieu of receiving a cash bonus for her 2012 services, on March 11, 2013, Dr. Chen received a fully-vested option to purchase 26,516 shares at $6.57 per share, the fair market value of the Company's common stock on the date of grant.

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

Dr. Chen has also agreed that, for the period commencing on the date of her employment agreement with the Company and during the term of her employment and for a period of 12 months following voluntary termination of her employment with the Company that she will not compete with the Company in the United States. The employment agreement also contains provisions relating to confidential information and assignment of inventions, which require Dr. Chen to refrain from disclosing any proprietary information and to assign to the Company any inventions that directly concern the ForeCYTE Breast Aspirator, or future products, research, or development, or that result from work she performs for the Company or using its facilities.

Employment Agreement with Christopher Destro

In connection with the hiring of Mr. Destro, the Company entered into an offer letter agreement which provides for an initial base salary of $180,000, which was increased to $205,000 in 2014 and $209,100 in 2015 with a bonus of up to 35%. Mr. Destro was also granted an option to purchase 200,000 shares of common stock at $4.10 per share, the fair market value of the common stock on the date of grant, as determined by the Board of Directors. One-quarter of the shares of common stock underlying the option vest one year from commencement of employment and the remaining 75% vest in equal quarterly installments over the next three years, so long as Mr. Destro remains employed with the Company. The offer letter agreement provides that Mr. Destro will be offered employment benefits similar to other members of management and that he is terminable at will. His options will accelerate upon a change of control.

Employment Agreement with John Sawyer

In connection with the hiring of Mr. Sawyer, the Company entered into an offer letter agreement which provides for an initial base salary of $280,000, which was increased to $291,200 in 2015 with a bonus of up to 30%. Mr. Sawyer was also granted an option to purchase 200,000 shares of common stock at $1.41 per share exercisable, the fair market value of the common stock on the date of grant, as determined by the Board of Directors. One-quarter of the shares of common stock underlying the option vest one year from commencement of employment and the remaining 75% vest in equal quarterly installments over the next three years, so long as Mr. Sawyer remains employed with the Company. The offer letter agreement provides that Mr. Sawyer will be offered employment benefits similar to other members of management and that he is terminable at will. His options will accelerate upon a change of control.

Severance Benefits and Change in Control Arrangements

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

Dr. Steven Quay

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

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

Kyle Guse

Pursuant to his employment agreement, if (i) the Company terminates the employment of Mr. Guse without cause, or (ii) Mr. Guse terminates his employment for good reason, then Mr. Guse will be entitled to receive all accrued but unpaid compensation including pro-rated bonus, plus a severance payment equal to 12 months of base salary. In addition, upon such event, the vesting of 50% of shares of common stock underlying unvested options then held by Mr. Guse will accelerate, and the options will remain exercisable for the remainder of their terms. The cash severance payment is required to be paid in substantially equal installments over a period of six months beginning on the

Company's first payroll date that occurs following the 30th day after the effective date of termination of Mr. Guse's employment, subject to certain conditions. The Company will not be required, however, to pay any severance pay for any period following the termination date if Mr. Guse materially violates certain provisions of his employment agreement and the violation is not cured within 30 days following receipt of written notice from the Company containing a description of the violation and a demand for immediate cure.

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

Dr. Shu-Chih Chen

Dr. Chen's employment agreement was terminated in August 2014 in connection with her retirement as the Chief Scientific Officer of the Company.

Messrs. Sawyer and Destro

The options granted to Messrs. Sawyer and Destro generally accelerate and become exercisable upon a change of control.

2010 Stock Option and Incentive Plan

The Company's 2010 Stock Option and Incentive Plan, or the 2010 Plan, provides for the grant of equity-based awards to employees, officers, non-employee directors and other key persons providing services to the Company. Awards of incentive options may be granted under the 2010 Plan until September 2020. No other awards may be granted under the 2010 Plan after the date that is 10 years from the date of stockholder approval.

Plan Administration. The 2010 Plan may be administered by the full Board or the Compensation Committee. It is the current intention of the Company that the 2010 Plan be administered by the Compensation Committee. The Compensation Committee has full power to select, from among the individuals eligible for awards, the individuals to whom awards will be granted, to make any combination of awards to participants, and to determine the specific terms and conditions of each award, subject to the provisions of the 2010 Plan. The Compensation Committee may delegate to our Chief Executive Officer the authority to grant stock options to employees who are not subject to the reporting and other provisions of Section 16 of the Exchange Act and not subject to Section 162(m) of the Code, subject to certain limitations and guidelines.

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

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

Stock Options. The 2010 Plan permits the granting of (i) options to purchase common stock intended to qualify as incentive stock options under Section 422 of the Code, and (ii) options that do not so qualify. Options granted under

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

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

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

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

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

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

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

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

similar events.

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

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

Other Benefits

The Company offers health, dental, disability, 401(k) matching up to 4% of salary (which became available in 2014) and life insurance to its full-time employees. Employees who elect Company-offered coverage pay a portion of health and dental premiums, while the Company pays all disability and life insurance premiums.

REPORT OF THE AUDIT COMMITTEE

The Audit Committee evaluates auditor performance, manages relations with the Company's independent registered public accounting firm, and evaluates policies and procedures relating to internal control systems. The Audit Committee operates under a written Audit Committee Charter that has been adopted by the Board, a copy of which is available on the Company's website at *www.atossagenetics.com*. All members of the Audit Committee currently meet the independence and qualification standards for Audit Committee membership set forth in the listing standards provided by NASDAQ and the SEC.

No member of the Audit Committee is a professional accountant or auditor. The members' functions are not intended to duplicate or to certify the activities of management and the independent registered public accounting firm. The Audit Committee serves a board-level oversight role in which it provides advice, counsel and direction to management and the auditors on the basis of the information it receives, discussions with management and the auditors, and the experience of the Audit Committee's members in business, financial and accounting matters. The Audit Committee oversees the Company's financial reporting process on behalf of the Board. The Company's management has the primary responsibility for the financial statements and reporting process, including the Company's system of internal controls. In fulfilling its oversight responsibilities, the Audit Committee reviewed with management the audited financial statements included in the Annual Report on Form 10-K for the fiscal year ended December 31, 2014. This review included a discussion of the quality and the acceptability of the Company's financial reporting, including the nature and extent of disclosures in the financial statements and the accompanying notes. The Audit Committee also reviewed the progress and results of the testing of the design and effectiveness of its internal controls over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act of 2002. The Audit Committee also reviewed with the Company's independent registered public accounting firm, which is responsible for expressing an opinion on the conformity of the audited financial statements with accounting principles generally accepted in the United States of America, their judgments as to the quality and the acceptability of the Company's financial reporting and such other matters as are required to be discussed with the Committee under generally accepted auditing standards, including Statement on Auditing Standards No. 61, as amended (AICPA, *Professional Standards*, Vol. 1. AU section 380), as adopted by the Public Company Accounting Oversight Board in Rule 3200T. The Audit Committee has received the written disclosures and the letter from the independent registered public accounting firm required by the Public Company Accounting Oversight Board. The Audit Committee discussed with the independent registered public accounting firm their independence from management and the Company, including the matters required by the applicable rules of the Public Company Accounting Oversight Board.

In addition to the matters specified above, the Audit Committee discussed with the Company's independent registered public accounting firm the overall scope, plans and estimated costs of their audit. The Committee met with the independent registered public accounting firm periodically, with and without management present, to discuss the results of the independent registered public accounting firm's examinations, the overall quality of the Company's financial reporting and the independent registered public accounting firm's reviews of the quarterly financial statements, and drafts of the quarterly and annual reports.

In reliance on the reviews and discussions referred to above, the Audit Committee recommended to the Board of Directors that the Company's audited financial statements should be included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2014.

Submitted by the Audit Committee of the Board of Directors

Richard I. Steinhart (Chairman)

Gregory L. Weaver

H. Lawrence Remmel, Esq.

DIRECTOR COMPENSATION

Non-employee director compensation is generally reviewed and set annually at the Board meeting held in connection with the Annual Stockholder Meeting. The non-employee directors of the Company received the following for service on the Board from May 2014 through May 2015:

- upon joining the Board, an initial fee of $50,000 in cash;
- an annual cash of $35,000 for each board member; and
- an annual option grant of 15,000 for each member, vesting quarterly over one year.

In lieu of the above annual option grant, Dr. Chen's outstanding options granted to her during her service as Chief Scientific Officer continue to vest and be exercisable during her services as a member of the Board.

In addition to the above, annual compensation for service on the Audit Committee is $15,000 for the Chair and $7,500 for each member, paid in cash quarterly. Annual compensation for service on the Compensation Committee and Nominating/Governance Committee is $10,000 for the Chair and $5,000 for each member, paid in cash quarterly.

The employee directors receive no compensation for their board service. Pursuant to the policies of Pryor Cashman, the law firm of which Mr. Remmel is a partner, the compensation Mr. Remmel receives for his services as a director (other than expense reimbursement) is paid to the firm directly. All directors receive reimbursement for reasonable travel expenses. The following table sets forth information regarding compensation earned by our non-employee directors during the fiscal year ended December 31, 2014:

Name	**Fees Earned or Paid in Cash**	**Option Awards [(1)]**	**Total**

Shu-Chih Chen, Ph.D. [2]	$ 13,125	$ —	$13,125
Stephen Galli, M.D.	$ 37,833	$ 6,860	$44,693
H. Lawrence Remmel, Esq.	$ 36,667	$ 6,860	$43,527
Gregory L. Weaver	$ 75,500	$ 6,860	$82,360
Richard Steinhart	$ 73,667	$ 6,860	$80,527

(1) The value of the awards has been computed in accordance with FASB ASC 718, excluding the effect of estimated forfeitures. Assumptions used in the calculations for these amounts are included in notes to our financial statements included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2014.

Option awards consist of 2014 annual option grants, to purchase 15,000 shares of common stock with an exercise price of $1.22, which was the fair value of our common shares at the time of grant. Options vest quarterly over a year.

(2) Dr. Chen retired as the Chief Scientific Officer in August 2014. The options granted to her as an executive officer continue to vest and be exercisable during her service as a member of the Board of Directors. See PART III Item 11 “Executive Compensation.”

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

BENEFICIAL OWNERS AND MANAGEMENT

Based on information available to us and filings with the SEC, the following table sets forth certain information regarding the beneficial ownership (as defined by Rule 13d-3 under the Securities Exchange Act of 1934) of our outstanding common stock for (i) each of our directors, (ii) each of our "named executive officers," as defined in Executive Compensation below, (iii) all of our directors and executive officers as a group, and (iv) persons known to us to beneficially hold more than 5% of our outstanding common stock. The following information is presented as of February 28, 2015 or such other date as may be reflected below.

Beneficial ownership and percentage ownership are determined in accordance with the rules of the SEC and include voting or investment power with respect to shares of stock. This information does not necessarily indicate beneficial ownership for any other purpose. Under these rules, shares of common stock issuable under stock options or warrants that are exercisable within 60 days of February 28, 2015 are deemed outstanding for the purpose of computing the percentage ownership of the person holding the options or warrant(s), but are not deemed outstanding for the purpose of computing the percentage ownership of any other person.

Unless otherwise indicated below, the address of each person listed on the table is c/o Atossa Genetics Inc., 2345 Eastlake Ave. East, Suite 201, Seattle, Washington 98102.

	Shares Beneficially Owned		
Name of Beneficial Owner	**Number**	**Percent of Class [1]**	
Steven C. Quay, M.D., Ph.D. [2]	5,087,927	20.4	%
Shu-Chih Chen, Ph.D. [3]	4,418,275	17.9	
Gregory L. Weaver [4]	78,440		*
Stephen J. Galli, M.D. [5]	154,911		*
Richard I Steinhart [6]	27,734		*
H. Lawrence Remmel, Esq. [7]	4,000		*
Kyle Guse, Esq., CPA, Esq. [8]	422,499		*
Chris Destro [9]	136,569		*
John Sawyer [10]	-		*
All current executive officers and directors as a group (9 persons)	6,062,040	23.6	%

* Less than one percent.

(1) Based on 24,564,058 shares of common stock issued and outstanding as of February 28, 2015.

(2) Consists of (i) 478,543 shares of common stock directly owned by Dr. Quay, (ii) 4,268,315 shares of common stock owned by Ensisheim, and (iii) 341,069 shares of common stock issuable upon the exercise of stock options held by Dr. Quay and exercisable within 60 days after February 28, 2015. Drs. Quay and Chen share voting and investment power over the securities held by Ensisheim. Ensisheim is solely owned and controlled by Drs. Quay and Chen, and, as a result, Drs. Quay and Chen are deemed to be beneficial owners of the shares held by this entity.

(3) Consists of (i) 4,268,315 shares of common stock owned by Ensisheim, and (ii) 149,960 shares of common stock issuable upon the exercise of stock options held by Dr. Chen and exercisable within 60 days after February 28, 2015. Drs. Quay and Chen share voting and investment power over the securities held by Ensisheim. Ensisheim is solely owned and controlled by Drs. Quay and Chen, and, as a result, Drs. Quay and Chen are deemed to be beneficial owners of the shares held by this entity.

(4) Consists of 68,440 shares of common stock issuable upon the exercise of stock options held by Mr. Weaver and exercisable within 60 days of February 28, 2015 and 34,510 shares of Common Stock held by Mr. Weaver.

(5) Consists of (i) 17,674 shares of common stock held by Dr. Galli, and (ii) 137,237 shares of common stock issuable upon the exercise of stock options held by Dr. Galli and exercisable within 60 days of February 28, 2015.

(6) Consists of 27,734 shares of common stock issuable upon the exercise of stock options held by Mr. Steinhart and exercisable within 60 days of February 28, 2015.

(7) Consists of 2,000 shares of Common Stock held by Mr. Remmel and 2,000 shares of Common Stock held by Mr. Remmel's spouse. Mr. Remmel disclaims beneficial ownership of the 2,000 shares of Common Stock held by his spouse.

(8) Consists of 422,499 shares of common stock issuable upon the exercise of stock options held by Mr. Guse and exercisable within 60 days of February 28, 2015.

(9) Consists of 136,569 shares of common stock issuable upon the exercise of stock options held by Mr. Destro and exercisable within 60 days of February 28, 2015.

(10) No shares of common stock issuable upon the exercise of stock options held by Mr. Sawyer within 60 days of February 28, 2015.

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

Transactions with Related Parties

Other than compensation arrangements described the captions "Executive Compensation" and "Director Compensation," we are not a party to any transactions between us and certain "related parties," which are generally considered to be our

directors and executive officers, nominees for director, holders of 5% or more of our outstanding common stock and members of their immediate families.

Related-Party Transaction Review and Approval

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

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The following is a summary of the fees billed to the Company by BDO and KCCW for professional services rendered for fiscal years ended December 31, 2014 and 2013. These fees are for work invoiced in the fiscal years indicated.

	2014		**2013**	
Audit Fees:				
Consists of fees billed for audit of our annual financial statements and the review of the financial statements included in our quarterly reports on Form 10-Q, and services that are normally provided by KCCW in connection with statutory and regulatory filings or engagements for that fiscal year.	$	25,000	$	71,000
Consists of fees billed for audit of our annual financial statements and the review of the financial statements included in our quarterly reports on Form 10-Q, and services that are normally provided by BDO in connection with statutory and regulatory filings or engagements for that fiscal year.	$	115,000		—
Other Fees:				
Audit-Related Fees Consists of fees billed for services rendered in connection with our	$	13,600	$	37,129

Forms S-1, Form S-3 and Form S-8, accounting research and services on transaction and proposed transaction related matters, and out-of-pocket expenses related to the audit that paid to KCCW.				
Tax Fees	$	—		—
All Other Fees	$	—		—
Total Other Fees	$	13,600	$	37,129
Total All Fees	$	153,600	$	108,129

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 100 of this report.

ATOSSA GENETICS, INC.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Audited Consolidated Financial Statements:

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders

Atossa Genetics, Inc.

Seattle, Washington

We have audited the accompanying consolidated balance sheet of Atossa Genetics, Inc. (the "Company") as of December 31, 2014, and the related consolidated statements of operations, stockholders' equity, and cash flows for the year then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit 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 audit 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 the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Atossa Genetics, Inc. at December 31, 2014, and the results of its operations and its cash flows for the year then ended**,** 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 to the consolidated financial statements, the Company has suffered recurring losses from operations and has an accumulated deficit that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty. Our opinion is not modified with respect to this matter.

/s/ BDO USA, LLP

Seattle, Washington

March 30, 2015

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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 sheet of Atossa Genetics Inc. (the "Company") as of December 31, 2013, and the related consolidated statements of operations, stockholders' equity, and cash flows for the year then ended. 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 audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit 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 audit 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 audit 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. as of December 31, 2013, and the consolidated results of its operations and its cash flows for the year then ended 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 to the consolidated financial statements, the Company has suffered recurring losses from operations and has an accumulated deficit that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2 to the consolidated financial statements. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ KCCW Accountancy Corp.

Diamond Bar, California

March 26, 2014

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ATOSSA GENETICS, INC.

CONSOLIDATED BALANCE SHEETS

	As of December 31, 2014	2013
Assets		
Current assets		
Cash and cash equivalents	$8,500,718	$6,342,161
Accounts receivable, net	297,958	139,072
Prepaid expenses	247,207	280,627
Inventory, net	39,788	-
Total current assets	9,085,671	6,761,860
Furniture and equipment, net	357,532	163,147
Intangible assets, net	1,920,645	4,395,633
Deferred financing costs	351,961	651,961
Other assets	48,193	36,446
Total assets	$11,764,002	$12,009,047
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$594,357	$248,142
Accrued expenses	444,861	295,310
Deferred rent	-	48,157
Payroll liabilities	1,056,705	580,645
Product recall liabilities	-	211,493
Short-term lease obligations	76,025	9,681
Other current liabilities	42,228	8,148
Total current liabilities	2,214,176	1,401,576
Deferred rent, net of current portion	2,483	-
Long-term lease obligations	49,216	5,820
Total liabilities	2,265,875	1,407,396
Commitments and contingencies (note 12)		
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, 24,564,058 and 18,574,334 shares issued and outstanding at December 31, 2014 and December 31, 2013, respectively	24,564	18,574

Additional paid-in capital	44,648,103	31,099,691
Accumulated deficit	(35,174,540)	(20,516,614)
Total stockholders' equity	9,498,127	10,601,651
Total liabilities and stockholders' equity	$11,764,002	$12,009,047

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

ATOSSA GENETICS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

	For the Years Ended December 31,	
	2014	**2013**
Revenue		
Diagnostic testing service	$ 525,954	$ 409,118
Product sales	-	223,440
Total revenue	525,954	632,558
Cost of revenue		
Diagnostic testing service	340,658	105,764
Product sales	-	239,755
Total cost of revenue	340,658	345,519
Loss on obsolete inventory	-	149,946
Gross profit	185,296	137,093
Selling expenses	1,271,705	1,257,791
Research and development expenses	2,577,465	1,105,110
General and administrative expenses	8,625,917	8,558,835
Impairment of intangible assets	2,352,626	-
Total operating expenses	14,827,713	10,921,736
Operating loss	(14,642,417)	(10,784,643)
Interest income	260	295
Interest expense	(15,769)	(360)
Net loss before income taxes	(14,657,926)	(10,784,708)
Income taxes	-	-
Net loss	$ (14,657,926)	$ (10,784,708)
Loss per common share - basic and diluted	$ (0.61)	$ (0.70)
Weighted average shares outstanding, basic & diluted	24,038,578	15,484,414

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

ATOSSA GENETICS, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

	Common Stock		Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Deficit	Equity
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 exercise of warrants	2,224,392	2,224	1,618,958	-	1,621,182
Stock option exercises	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	-	-	-	(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
Issuance of common shares for cash	5,834,234	5,834	13,996,328	-	14,002,162
Issuance of common shares for services	22,728	23	(23)	-	-
Issuance of common shares for capital raising fees, net	-	-	(1,378,417)	-	(1,378,417)
Issuance of common shares for exercise of warrants	20,000	20	31,980	-	32,000
Stock option exercises	112,762	113	199,887		200,000
Compensation cost for stock options granted to executives and employees	-	-	698,657	-	698,657
Net loss	-	-	-	(14,657,926)	(14,657,926)
Balance at December 31, 2014	24,564,058	$24,564	$ 44,648,103	$(35,174,540)	$9,498,127

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

ATOSSA GENETICS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

	For the Year Ended December 31,	
	2014	**2013**
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (14,657,926)	$ (10,784,708)
Adjustments to reconcile net loss to net cash used in operating activities:		
Common shares issued for services	-	178,280
Compensation cost for stock options granted	698,657	1,443,760
Loss on reduction on obsolete inventory	-	149,946
Impairment of long-lived assets	2,352,626	158,292
Depreciation and amortization	564,456	472,934
Bad debt expenses	209,288	354,861
Changes in operating assets and liabilities:		
Accounts receivable	(368,174)	(352,267)
Inventory	(39,788)	(149,946)
Prepaid expenses	(51,581)	(57,994)
Security deposits	(11,747)	-
Accounts payable	346,215	(58,583)
Payroll liabilities	476,060	268,480
Deferred rent	(45,674)	48,157
Product recall liabilities	(211,493)	211,493
Accrued expenses	149,551	(704,372)
Other current liabilities	34,080	(8,377)
Net cash used in operating activities	(10,555,450)	(8,830,044)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchases of furniture and equipment	(146,058)	(244,442)
Purchases of intangible assets	(197,199)	(245,373)
Net cash used in investing activities	(343,257)	(489,815)
CASH FLOWS FROM FINANCING ACTIVITIES		
Net proceeds from issuance of common stock and warrants	13,155,745	13,936,823
Payments on capital lease obligations	(98,481)	-
	13,057,264	13,936,823
NET INCREASE IN CASH AND CASH EQUIVALENTS	2,158,557	4,616,964
CASH AND CASH EQUIVALENTS, BEGINNING OF YEAR	6,342,161	1,725,197
CASH AND CASH EQUIVALENTS, ENDING OF YEAR	$ 8,500,718	$ 6,342,161
SUPPLEMENTAL DISCLOSURES:		
Interest paid	$ 15,769	$ 360
NONCASH INVESTING AND FINANCING ACTIVITIES:		

Reclassification of furniture and equipment to prepaid expenses	$ 15,000	$ -
Furniture and fixtures acquired through capital lease	$ 206,702	$ -
Common stock issued as commitment fee under stock purchase agreement	$ -	$ 2,387,250

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

NOTE 1: NATURE OF OPERATIONS

Atossa Genetics Inc. (the "Company") was incorporated on April 30, 2009 in the State of Delaware. 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. 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 31.

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 the Company's 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 providing other test services, including the pharmacogenomics test, and is developing other tests such as the ArgusCYTE test on blood samples 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 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.

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 incurred net losses and negative operating cash flows since inception. For the year ended December 31, 2014, the Company recorded a net loss of approximately $14.7 million and used approximately $10.5 million of cash in operating activities. As of December 31, 2014, the Company had approximately $8.5 million in cash and cash equivalents and working capital of approximately $6.9 million. 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. The Company can give no assurances that any additional capital that it is able to obtain, if any, will be sufficient to meet its needs, or that any such financing will be obtainable on acceptable terms. If the Company is unable to obtain adequate capital, it could be forced to cease operations or substantially curtail is commercial activities. These conditions raise substantial doubt as to the Company's ability to continue as a going concern. The accompanying consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts and classification of liabilities should the Company be 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 during 2015, (2) sales of the ForeCYTE and FullCYTE Breast Aspirators and laboratory service revenue beginning in early 2015, and (3) short-term borrowings from banks, stockholders or other related party(ies), if 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 have been prepared pursuant to the rules of the Securities and Exchange Commission ("SEC") and in accordance with U.S. generally accepted accounting principles ("GAAP"). 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.

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 expenses during the reporting period. Actual results could differ from those estimates.

Recently Issued Accounting Pronouncements:

In May 2014, the Financial Accounting Standards Board (the “FASB”) issued Accounting Standards Update (“ASU”) No. 2014-09, *Revenue from Contracts with Customers: Topic 606* (“ASU 2014-09”), to supersede nearly all existing revenue recognition guidance under U.S. GAAP. The core principle of ASU 2014-09 is to recognize revenues when promised goods or services are transferred to customers in an amount that reflects the consideration that is expected to be received for those goods or services. ASU 2014-09 defines a five step process to achieve this core principle and, in doing so, it is possible more judgment and estimates may be required within the revenue recognition process than required under existing GAAP including identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation. ASU 2014-09 is effective for the Company in the first quarter of 2017 using either of two methods: (i) retrospective to each prior reporting period presented with the option to elect certain practical expedients as defined within ASU 2014-09; or (ii) retrospective with the cumulative effect of initially applying ASU 2014-09 recognized at the date of initial application and providing certain additional disclosures as defined per ASU 2014-09. The Company is currently evaluating the impact of its pending adoption of ASU 2014-09 on its consolidated financial statements.

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In June 2014, FASB issued ASU 2014-10, *Elimination of Development Stage Entity Requirements.* This ASU eliminates the concept of Development Stage Entities (DSE's) from U.S. GAAP and is intended to result in cost-savings for certain entities, such as start-ups or research and development entities. As a result of these changes, the financial statements of developing entities no longer need to meet the inception-to-date income cash flow and equity information; developing companies do not have to label their financial statements as "development stage"; and certain disclosures related to the nature of the entity's development stage activities are no longer required. The Company adopted the provisions of this ASU during the year ended December 31, 2014.

In August, 2014, FASB issued ASU 2014-15, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern.* This ASU requires the management to determine whether substantial doubt exists regarding the entity's going concern presumption, which generally refers to an entity's ability to meet its obligations as they become due. If substantial doubt exists but is not alleviated by management's plan, the footnotes must specifically state that "there is substantial doubt about the entity's ability to continue as a going concern within one year after the financial statements are issued." In addition, if substantial doubt exists, regardless of whether such doubt was alleviated, entities must disclose (a) principal conditions or events that raise substantial doubt about the entity's ability to continue as a going concern (before consideration of management's plans, if any); (b) management's evaluation of the significance of those conditions or events in relation to the entity's ability to meet its obligations; and (c) management's plans that are intended to mitigate the conditions or events that raise substantial doubt, or that did alleviate substantial doubt, about the entity's ability to continue as a going concern. If substantial doubt has not been alleviated, these disclosures should become more extensive in subsequent reporting periods as additional information becomes available. In the period that substantial doubt no longer exists (before or after considering management's plans), management should disclose how the principal conditions and events that originally gave rise to substantial doubt have been resolved. The ASU applies prospectively to all entities for annual periods ending after December 15, 2016, and to annual and interim periods thereafter. Early adoption is permitted. The Company has not yet adopted the provisions of ASU 2014-15.

Reclassifications:

The prior period deferred financing costs have been reclassified to conform to the current year presentation. The reclassification had no impact on previously reported net loss or accumulated deficit.

Certain prior period accrued expenses and current liabilities have been reclassified as accounts payable, payroll liabilities, and lease obligations to conform to the current year presentation. The reclassification had no impact on previously reported net loss or accumulated deficit.

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

During 2013, the Company recognized revenue for sales of the MASCT kits and devices on an accrual basis for sales to distributors when the above four criteria were met. For sales of MASCT kits and devices sold directly to physicians, the revenue was typically recognized upon receipt of cash as the Company had an insufficient history on which to determine collectability. Shipping documents and the completion of any customer acceptance requirements, when applicable, were used to verify product delivery.

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 a proper allowance for doubtful accounts based on the diagnostic testing revenue collection history.

Cost of Revenue

Cost of revenue consists of the costs of diagnostic testing services and costs of product sales. Costs of diagnostic testing services primarily include direct costs 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 the Company's 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 for 2013 primarily included the manufacturing cost of the MASCT System for sales to distributors, which was recorded upon transfer of ownership of the goods.

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Cash and Cash Equivalents

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

Inventory

The Company's inventories consist of laboratory supply inventory and product inventory. Inventories are stated at lower of cost or market. Cost is determined on a moving-average basis. Costs of inventories include purchases 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 the Company's recall which commenced in October 2013, the Company recalled all of the MASCT Systems. Based on management's assessment of those devices and the pending FDA clearance, the Company recorded $149,946 of losses on obsolete inventory for the year ended December 31, 2013 as a result of reducing the carrying value of the MASCT systems inventory to zero. As of December 31, 2014 and 2013, inventories amounted to $39,788 and $0, respectively.

Accounts Receivable

Accounts receivable are recorded at net realizable value consisting of the carrying amount less an 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. The Company's allowance for doubtful accounts as of December 31, 2014 and 2013 was $564,149 and $354,861, respectively. Bad debt expense is included in general and administrative expense on the Company's consolidated statements of operations. Bad debt expense and was $209,288 and $354,861 for the years ended December 31, 2014 and 2013, respectively.

Furniture and Equipment

Furniture 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 furniture 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	3 - 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, 2014 and 2013, $0 and $158,292 was recorded as impairment of property and equipment, respectively.

Intangible Assets

Intangible assets consist of intellectual property and software acquired. Intangibles are reviewed at least annually for impairment or whenever events or changes in circumstances indicate that the carrying value of the assets might 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.

The Company has evaluated and reprioritized its research and development pipeline based on recent business strategies, and as a result has delayed plans to develop and invest further in Acueity patents and technologies for at least the next year. Because of these changed business plans related to the Acueity assets, the Company has re-evaluated the assets for potential impairment. The Company has concluded that these assets are partially impaired and has recorded asset impairment charges of $2,352,626 for the year ended December 31, 2014 to adjust the carrying value of these intangible assets to their estimated fair values as of December 31, 2014.

The Company determined the fair values of the Acueity intangibles using an income approach. When available and appropriate, the Company uses comparative market multiples to corroborate discounted cash flow results. For purposes of the income approach, fair value is determined based on the present value of estimated future cash flows to be generated from development of products using the patented technology acquired in the Acueity transaction based on our current plans, discounted at an appropriate risk-adjusted rate. The Company uses its internal forecasts to estimate future cash flows and include an estimate of long-term future growth rates based on its most recent views of the outlook of the business. The Company uses discount rates that are commensurate with the risk and uncertainty inherent in the business and in its internally developed forecasts. Discount rates used in the Company’s valuations for these intangible assets ranged from 18% to 21%.

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

	Useful Life (in years)
Patents	7 - 12
Software	3

Share-Based Payments

The Company follows the provisions of ASC Topic 718, *Compensation - Stock Compensation* ("ASC 718"), which requires the measurement and recognition of compensation expense for all share-based payment awards made to employees, non-employee directors, and consultants, including employee stock options. Stock compensation expense based on the grant date fair value estimated in accordance with the provisions of ASC 718 is recognized as an expense over the requisite service period.

The fair value of each option grant is estimated using the Black-Scholes option-pricing model, which requires assumptions regarding the expected volatility of the stock options, the expected life of the options, an expectation regarding future dividends on the Company's common stock, and estimation of an appropriate risk-free interest rate. The Company's expected common stock price volatility assumption is based upon the volatility of a basket of companies that it considers comparable to the Company given that the Company's own stock has not been traded for a sufficient period to establish a volatility assumption based on its own historical data as our stock began trading in November 2012. As there becomes additional data regarding the Company's own stock price volatility, it plans to incorporate that data in its volatility assumption. The expected life assumption for stock options grants was based upon the simplified method provided for under ASC 718-10, which averages the contractual term of the options of ten years with the average vesting term of four years. The dividend yield assumption of zero is based upon the fact that the Company has never paid cash dividends and presently has no intention of paying cash dividends in the future. The risk-free interest rate used for each grant was based upon prevailing short-term interest rates over the expected life of the options.

The Company has estimated an annualized forfeiture rate of 10.0% for options granted. The Company will record additional expense if the actual forfeitures are lower than estimated and will record a recovery of prior expense if the actual forfeiture rates are higher than estimated.

NOTE 4: PREPAID EXPENSES

Prepaid expenses consisted of the following:

	December 31, 2014	**December 31, 2013**
Prepaid insurance	$ 87,633	$ 112,517
Tradeshow and other marketing events	50,000	-
Prepaid hardware and software	38,268	131,204
Retainer and security deposits	25,000	36,906

Lab supplies	14,976	-
Other	31,330	-
Total prepaid expenses	$ 247,207	$ 280,627

NOTE 5: FURNITURE AND EQUIPMENT

Furniture and equipment consisted of the following:

	December 31, 2014	**December 31, 2013**
Machinery and equipment	$522,813	$168,532
Leasehold improvements	93,665	93,665
Capitalized new product development cost	-	15,000
Furniture and equipment	616,478	277,197
Less: accumulated depreciation	(258,946)	(114,050)
Total furniture and equipment, net	$357,532	$163,147

As of December 31, 2014, assets under capital lease of $206,702 are included in machinery and equipment. Depreciation expense for the years ended December 31, 2014 and 2013 was $144,896 and $82,970, respectively.

NOTE 6: INTANGIBLE ASSETS

Intangible assets consisted of the following:

	December 31, 2014	December 31, 2013
Patents	$ 1,630,000	$ 4,794,853
Capitalized license costs	200,000	-
Software	203,038	105,839
Intangible assets	2,033,038	4,900,692
Less: accumulated amortization	(112,393)	(505,059)
Total intangible assets, net	$ 1,920,645	$ 4,395,633

Intangible assets amounted to $1,920,645 and $4,395,633 as of December 31, 2014 and December 31, 2013, respectively, and consisted of patents, capitalized license costs and software acquired. The acquired software mainly consisted of $58,000 in laboratory software, $31,500 in the newly developed Company website and $72,200 in internal use SAP Business One ERP system which is under development. The amortization period for the purchased software is three years. Amortization expense related to software for the years ended December 31, 2014 and 2013 was $28,903 and $24,308, respectively.

Patents amounted to $1,630,000 and $4,794,853 as of December 31, 2014 and 2013, respectively, and mainly consisted of patents acquired from Acueity on September 30, 2012 in an asset purchase transaction. Patent assets are amortized based on their determined useful life, and tested annually for impairment. As discussed in Note 2, the Company has evaluated and reprioritized its research and development pipeline based on recent business strategies, and as a result has delayed plans to develop and invest further in Acueity patents for at least the next year. Because of these changed business plans related to the Acueity assets, the Company has re-evaluated the assets for potential impairment. The Company has concluded that these assets are partially impaired and the Company has recorded asset impairment charges of $2,352,626 during the year ended December 31, 2014.

The amortization period of intangible assets is from 7 to 12 years. Amortization expense related to intangible assets was $373,990 and $365,656 for years ended December 31, 2014 and 2013, respectively.

Capitalized license costs consist of fees paid to A5 Genetics KFT, Corporation, pursuant to which the Company received the world-wide (other than the European Union) exclusive license to use the software in the NextCYTE test. Amortization expense related to license costs was $16,667 for the year ended December 31, 2014.

Future estimated amortization expenses as of December 31, 2014 for the five succeeding years and thereafter is as follows:

As of December 31,	Amounts
2015	$213,776
2016	224,804
2017	193,443
2018	169,015
2019	169,015
Thereafter	950,592
	$1,920,645

NOTE 7: PAYROLL LIABILITIES:

Payroll liabilities consisted of the following:

	December 31, 2014	December 31, 2013
Accrued bonus payable	$ 752,828	$ 408,362
Accrued payroll liabilities	109,653	152,400
Accrued payroll tax liabilities	194,224	19,883
Total payroll liabilities	$ 1,056,705	$ 580,645

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. The Company has designated 750,000 shares of Series-A Junior Participating Preferred Stock, par value $0.001 per share through the filing of a certificate of designation with the Delaware Secretary of State.

On May 19, 2014, the Company adopted a stockholder rights agreement which provides that all stockholders of record on May 26, 2014 received a non-taxable distribution of one preferred stock purchase right for each share of the Company's common stock held by such stockholder. Each right is attached to and trades with the associated share of common stock. The rights will become exercisable only if one of the following occurs: (1) a person becomes an "Acquiring Person" by acquiring beneficial ownership of 15% or more of the Company's common stock (or, in the case of a person who beneficially owned 15% or more of the Company's common stock on the date the stockholder rights agreement was executed, by acquiring beneficial ownership of additional shares representing 2.0% of the Company's common stock then outstanding (excluding compensatory arrangements)), or (2) a person commences a tender offer that, if consummated, would result in such person becoming an Acquiring Person. If a person becomes an Acquiring Person, each right will entitle the holder, other than the Acquiring Person and certain related parties, to purchase a number of shares of the Company's common stock with a market value that equals twice the exercise price of the right. The initial exercise price of each right is $15.00, so each holder (other than the Acquiring Person and certain related parties) exercising a right would be entitled to receive $30.00 worth of the Company's common stock. If the Company is acquired in a merger or similar business combination transaction at any time after a person has become an Acquiring Person, each holder of a right (other than the Acquiring Person and certain related parties) will be entitled to purchase a similar amount of stock of the acquiring entity.

2014 Public Offering of Common Stock and Warrants

On January 29, 2014, the Company closed a public offering of 5,834,234 units at the price of $2.40 per unit for total gross proceeds of approximately $14.0 million (the "2014 Public Offering"). Each unit consists of one share of common stock and a warrant to purchase 0.20 of a share of common stock (the "2014 Investor Warrants"). The 2014 Investor Warrants are exercisable at $3.00 per share and callable by the Company if our stock trades above $6.00 per share if certain conditions are met.

Placement Agent Fees

In connection with the 2014 Public Offering, the Company paid Dawson James Securities, Inc. (the "Placement Agent"), a cash fee equal to 7% of the gross proceeds from sale of the units, which resulted in a payment to the Placement Agent of an aggregate of $980,151 (the "Placement Agent Fee"). In addition, the Company entered into Warrant Agreements with the Placement Agent pursuant to which the Placement Agent received a warrant to purchase 175,027 shares of common stock, or 3% of the aggregate number of shares sold in the offering (the "2014 Placement Agent Warrants" and together with the 2014 Investor Warrants, the "2014 Warrants"). The 2014 Placement Agent Warrant entitles the Placement Agent to purchase 175,027 shares of the Company's common stock at $3.00 per share. The cash payment of $980,151 for 2014 Placement Agent Fee and the $121,707 aggregated initial fair value of the 2014 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 2014 Warrants are exercisable at any time commencing after January 29, 2014 (the "Initial Exercise Date"). Subject to the call right described above, the 2014 Warrants shall expire and no longer be exercisable on the fifth anniversary of the Initial Exercise Date (the "Expiration Date"). The 2014 Warrants cannot be exercised on a cashless basis. There are no redemption features embodied in the 2014 Warrants and they have met the conditions for equity classification.

Fair Value Consideration

The Company's accounting for the issuance of the 2014 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 2014 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 assess the fair value of these instruments.

The 2014 Investor Warrants and the 2014 Placement Agent Warrants were valued at $834,986 or $0.72 per warrant, and $121,707 or $0.70 per warrant, respectively. The following tables reflect assumptions used to determine the fair value of the 2014 Warrants:

	Fair Value Hierarchy Level	January 29, 2014 2014 Investor Warrants		Placement Agent Warrants	
Indexed shares		1,166,849		175,027	
Exercise price		$3.00		$3.00	
Significant assumptions:					
Stock price	1	$2.50		$2.47	
Remaining term	3	5 years		5 years	
Risk free rate	2	1.45	%	1.42	%
Expected volatility	3	37.96	%	37.95	%

Outstanding Warrants

As of December 31, 2014, warrants to purchase 6,033,426 shares of common stock were outstanding including:

	Outstanding Warrants to purchase shares	Exercise price	Expiration date
2011 private placement	4,252,050	$ 1.25 - 1.60	June 23, 2016
Acueity warrants	325,000	5.00	September 30, 2017
2014 public offering	1,166,849	3.00	January 29, 2019
Placement agent fees for Company's offerings	242,027	2.12 – 12.43	March - November, 2018
Outside consulting	47,500	$ 4.24	January 14, 2018

NOTE 9: NET LOSS PER SHARE

Basic net loss per common share is computed by dividing net loss attributable to common stockholders by the weighted average number of common shares outstanding. Diluted net loss per common share is computed by dividing net loss attributable to common stockholders by the weighted average number of common shares that would have been outstanding during the period assuming the issuance of common shares for all potential dilutive common shares outstanding. Potential common shares consist of shares issuable upon the exercise of stock options and warrants. Because the inclusion of potential common shares would be anti-dilutive for all periods presented, diluted net loss per common share is the same as basic net loss per common share.

The following table sets forth the number of potential common shares excluded from the calculation of net loss per diluted share for the years ended December 31, 2014 and 2013:

	Year Ended December 31,	
	2014	2013
Options to purchase common stock	3,675,634	2,282,719
Warrants to purchase common stock	6,033,426	4,751,550
Restricted stock units	-	-
Total	9,709,060	7,034,269

NOTE 10: INCOME TAXES

The Company accounts for income taxes using the asset and liability method, under which 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.

The Company did not record an income tax benefit for its losses incurred in 2014 or 2013 due to uncertainty regarding utilization of its net operating loss carryforwards and due to its history of losses. The benefit for income taxes differs from the benefit computed by applying the federal statutory rate to loss before income taxes as follows:

	Year Ended December 31,	
	2014	2013
Expected federal income tax benefit	$(4,983,700)	$(3,774,648)
Share-based compensation	36,100	-
Other permanent items	9,000	4,363
Effect of change in valuation allowance	4,938,600	3,770,285
Actual federal income tax benefit	$-	$-

The components of net deferred tax assets are as follows:

	As of December 31,	
	2014	2013
Deferred tax assets, current:		
Allowance for doubtful accounts	$191,900	$120,700
Deferred rent	900	16,400
Accrued vacation	30,400	16,400
Accrued bonuses	228,100	-
Obsolete inventory	48,400	51,000
Valuation allowance, current	(499,700)	(204,500)
Net deferred tax asset, current	-	-
Deferred tax assets, long term:		
Fixed assets, net	-	8,900
Intangible assets, net	841,800	29,000
Allowance for loss on fixed assets	53,800	53,800
Contribution, carryforward	300	-
Share-based compensation	732,400	546,600
Net operating loss carryforwards	9,772,300	6,144,800
Valuation allowance, long term	(11,397,400)	(6,783,100)
Deferred tax asset, long term	3,200	-
Deferred tax liabilities		
Fixed assets, net	(3,200)	-
Net deferred tax asset, long term	-	-
Net deferred tax asset	$-	$-

The Company has incurred net operating losses from inception. At December 31, 2014, the Company had domestic federal net operating loss carryforwards of approximately $28,700,000 which are available to reduce future taxable income. These federal net operating loss carryforwards, expire at various dates beginning in 2029 through 2034. The Company recorded a valuation allowance against all of its net deferred tax assets of $11,897,100 and $6,987,600 as of December 31, 2014 and 2013, respectively.

Based on an assessment of all available evidence including, but not limited to the Company’s limited operating history in its core business and lack of profitability, uncertainties of the commercial viability of its technology, the impact of government regulation and healthcare reform initiatives, and other risks normally associated with biotechnology companies, the Company has concluded that it is more likely than not that these net operating loss carryforwards and credits will not be realized and, as a result, a full valuation allowance has been recorded against the Company’s

deferred income tax assets.

The Company files income tax returns in the U.S. The Company is subject to tax examinations for the 2011 tax year and beyond. The Company has no unrecognized tax positions and does not believe there will be any material changes in its unrecognized tax positions over the next 12 months. The Company has not incurred any interest or penalties related to unrecognized tax positions. In the event that the Company is assessed interest or penalties at some point in the future, they will be classified in the financial statements as general and administrative expense.

NOTE 11: 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. As of December 31, 2014 and 2013, the Company had $ 8,250,718 and $6,092,161 in excess of the FDIC insured limit, respectively.

NOTE 12: COMMITMENTS AND CONTINGENCIES

Lease Commitments

The future minimum lease payments due subsequent to December 31, 2014 under all non-cancelable operating and capital leases for the next five years are as follows:

Year Ending December 31,	Operating Leases Amount	Capital Leases Amount
2015	$ 499,267	$ 76,025
2016	478,210	49,216
2017	119,333	-
2018	13,439	-
2019	13,439	-
Total minimum lease payments	$ 1,123,688	$ 125,241

The total rent expense for 2014 and 2013, respectively, is as follows:

Year Ending December 31,	2014	2013
Research and development expenses	$227,996	$214,301
General and administrative expenses	149,174	121,201
Total rent expense	$377,170	$335,502

Affymetrix Purchase Commitment

In connection with the development of the NextCYTE test by the NRLBH, the NRLBH entered into an "OwnerChip Program Agreement" with Affymetrix, Inc. ("Affymetrix"), a manufacturer of GeneChip Systems, where Affymetrix has agreed to loan a GeneChip System 3000Dx v.2 ("instrument") to the Company if it purchases and takes delivery of a minimum thirty GeneChip Human Genome 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 NRLBH at no additional cost. Because the Company takes ownership of the equipment at the completion of the three-year contract, the Company determined that the arrangement represents a capital lease for the

equipment. The Company recorded $206,702 as a capital lease for the equipment and began amortizing the equipment on a straight line basis over five years. In addition to the GeneChip Human Genome, the NRLBH must purchase a two year service contract for $51,600 to cover maintenance of the instrument during the contract period. The NRLBH placed an initial order for four 30-pack arrays during 2013 for $94,723. In September 2014, the NRLBH purchased six additional 30-pack arrays for $142,005.

The future minimum payments for the Affymetrix capital lease are as follows:

Year Ending December 31,	**Amount**
2015	$70,204
2016	49,216
Total minimum lease payments	$119,420

A5 Software Development Commitment

On June 10, 2013 the Company entered into an irrevocable license and service agreement with A5 Genetics KFT, Corporation ("A5 Genetics"), 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 the Company. 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 receiving the regulatory clearance for NextCYTE test. The Company must also pay a royalty of $50 for each NextCYTE test performed and a service fee of $65 for each NextCYTE test performed. The NextCYTE test is still in validation stage and no royalty or service fees have been paid as of December 31, 2014. The agreement terminates on the later of June 10, 2023 or the expiration of the latest patents covering the software.

Luminex Reagent Rental Agreement and Assay License Agreement

On September 2, 2014, in connection with the development of a pharmacogenomics test by the NRLBH, the NRLBH entered into a three-year rental agreement with Luminex Corporation (Luminex), which provides that the NRLBH acquires the right to use Luminex instruments, including accessories, peripherals and options (the "System") at no cost if the NRLBH purchases goods (the "Products") at agreed upon quantities and prices for the next three years. The minimum purchases of Products under the agreement are $452,408 per year. The title to the System remains with Luminex and the NRLBH is required to return the System to Luminex at the end of the three-year rental agreement.

BioVentive Laboratory Marketing Service Agreement

On August 28, 2014, NRLBH entered into a three year Laboratory Marketing Services Agreement with BioVentive, Inc. (“BioVentive”), which provides that BioVentive market and promote the NRLBH laboratory tests to licensed physicians practicing medicine for a fee. The agreement may be terminated prior to the end of the three year term by either party for material breach that is not cured and the NRLBH may terminate if BioVentive fails to meet certain minimums or if the NRLBH undergoes a change of control. If the agreement is terminated by the NRLBH for any reason other than for cause (which includes a material uncured breach by BioVentive or if BioVentive fails to meet certain minimums), the NRLBH is required to pay BioVentive a termination fee equal to approximately three months of fees otherwise payable to BioVentive.

Targeted Medical Education (TME) Master Service Agreement

On September 1, 2014, the NRLBH entered into a three year agreement with TME Research LLC (TME) which requires TME to provide to the NRLBH 100 tissue specimens in connection with the development of the NextCYTE test. Fees payable to TME under the agreement includes $99,600 up front, $31,500 upon supplying the first 25 specimens and $31,500 at the time of final delivery of all specimens. The agreement is terminable with 60 days prior written notice or immediately upon a material breach. As of December 31, 2014, the Company has paid $131,000 in set-up fees, which were recorded as R&D expenses in the accompanying consolidated statement of operations.

Litigation and 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.

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.

On November 3, 2014, the matters with Messrs. Kelly and Cononi were settled through mutual agreement of the parties. The parties agreed to mutual releases and to dismiss the arbitration and federal actions. The amount paid by the Company to settle this matter was not significant.

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 the Company's directors and officers and the underwriters of the Company November 2012 initial public offering. The complaint alleges that all defendants violated Sections 11 and 12(a)(2), and that the Company and certain of its 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. An amended complaint was filed on April 15, 2014. The Company and other defendants filed motions to dismiss the amended complaint on May 30, 2014. The plaintiffs filed briefs in opposition to these motions on July 11, 2014. The Company replied to the opposition brief on August 11, 2014. On October 6, 2014 the Court granted defendants' motion dismissing all claims against Atossa and all other defendants. The Court's order provided plaintiffs with a deadline of October 26, 2014 to file a motion for leave to amend their complaint and the plaintiffs did not file such a motion by that date. On October 30, 2014, the Court entered a final order of dismissal. On November 3, 2014, plaintiffs filed a notice of appeal with the Court and have appealed the Court's dismissal order to the U.S. Court of Appeals for the Ninth Circuit. On February 11, 2015, plaintiffs filed their opening appellate brief. Defendants' answering brief is due April 13, 2015. A hearing for the appeal has not been set.

The Company believes this lawsuit is without merit and plans to defend itself vigorously; however, failure by the Company to obtain a favorable resolution of the claims set forth in the complaint could have a material adverse effect on the Company's 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, 2014. 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 the Company's business, will depend upon many unknown factors and management's view of these may change in the future.

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 the 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 United States. The Company submitted a new premarket notification, or 510(k) application, with the FDA on December 23, 2013 that covered the collection, preparation, and processing of NAF specimens and includes the spray method of fixing specimens to the collection membrane and in September 2014 the FDA rendered a decision that the ForeCYTE Breast Aspirator is not "substantially equivalent" to its predicate device. The ForeCYTE Breast Aspirator is therefore not cleared by the FDA for marketing in the United States. We cannot market or distribute the ForeCYTE Breast Aspirator within the United States until we receive clearance for this device from the FDA.

On March 14, 2014, the FDA completed a follow-up inspection at the Company's Seattle facility. A Form 483 was provided to the Company at the conclusion of the inspection. In the FDA's most recent Form 483, five inspectional observations were identified regarding the Company's quality management system. The FDA investigator also orally identified five additional discussion points related to the Company's product labeling prior to the recall of the MASCT System; sufficiency of the content of the Company's pending 510(k) submission for the ForeCYTE Breast Aspirator; and other compliance issues. On March 26, 2014, the Company submitted a response to the FDA, which included its proposed corrective actions to address the FDA's observations and discussion points. On December 5, 2014, we received EIRs (Establishment Inspection Reports) from the FDA Office of Compliance which means the FDA closed our inspections. This means that the observations that resulted from the inspections have been addressed; however, the FDA will conduct additional inspections and may issue additional observations.

NOTE 13: STOCK BASED COMPENSATION

Stock Options 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, 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 were initially 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, 516,774 shares were added to the 2010 Plan, and on January 1, 2014, 742,973 shares were added to the 2010 plan as provided under the terms of the 2010 Plan.

The Company granted options to purchase 2,426,669 shares of common stock to employees and directors and issued 160,000 shares of common stock in connection with the exercise of directors stock options during the year ended December 31, 2014. There are 439,388 options available for grant under the 2010 Plan as of December 31, 2014, and as a result of the evergreen provision contained in the 2010 Plan, there are 1,422,750 options available for grant under the 2010 Plan as of January 1, 2015.

Compensation costs associated with the Company’s stock 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 stock based compensation expense of $698,657 and $1,443,760 for the years ended December 31, 2014 and 2013, respectively.

	Year Ended December 31,	
	2014	**2013**
General and administrative	$556,288	$1,168,455
Research and development	46,783	174,553
Selling	95,586	100,752
Total stock compensation expense	$698,657	$1,443,760

The following table presents information concerning stock option grants for the year ended December 31, 2014:

	Employees	Executives & Officers	Directors
Fair value of common stock on date of grant	$0.96 - 2.20	$0.96 - 2.20	$1.22 - 2.20
Exercise price of the options	$0.96 - 2.20	$0.96- 2.20	$1.22-2.20
Expected life of the options (years)	6.06- 6.11	6.06 - 6.11	5.09 – 5.31
Dividend yield	0.00 %	0.00 %	0.00 %
Expected volatility	38.83- 41.72 %	38.83 - 41.70 %	38.64 - 38.68 %
Risk-free interest rate	1.75 - 2.11 %	1.75 - 2.11 %	1.53 – 1.75 %
Expected forfeiture per year (%)	10.00 %	10.00 %	10.00 %
Weighted average fair value of the options per unit	$0.64	$0.56	$0.70

Options issued and outstanding as of December 31, 2014 and their activities during the year then ended are as follows:

	Number of Underlying Shares	**Weighted-Average Exercise Price Per Share**	**Weighted-Average Contractual Life Remaining in Years**	**Aggregate Intrinsic Value**
Outstanding as of January 1, 2014	2,282,719	$ 4.43		$ 282,063
Granted	2,426,669	1.45		
Forfeited	(873,754)	4.29		21,540
Exercised	(160,000)	1.25		69,388
Outstanding as of December 31, 2014	3,675,634	2.86	8.11	$ 344,000
Exercisable as of December 31, 2014	1,391,749	4.34	6.31	$ 37,878
Vested and expected to vest (1)	3,380,169	$ 2.95	8.01	$ 301,945

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

At December 31, 2014, there were 2,283,885 unvested options outstanding and the related unrecognized total compensation cost associated with these options was $1,506,667. This expense is expected to be recognized over a weighted-average period of 2.84 years.

Issuance of Restricted Common Stock and Stock Options for Directors' and Executives' 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. On March 1, 2014, the Company agreed to issue 22,728 shares of restricted stock with a grant date value of $50,000 or $2.20 per share to a new board member. These share issuances were canceled in May 2014 in connection with a new compensation plan adopted by the Board of Directors for independent members of the Board and the grants were each replaced with $35,000 in cash payment.

On May 6, 2014, options to purchase a total of 15,000 shares of common stock, with exercise prices of $1.22 per share, which was the fair market value on the date of grant, were also granted under the 2010 Plan to each of our four non-employee directors for service on the Board during the year following our 2014 annual meeting of stockholders. On that date, options to purchase 665,000 shares of stock, exercisable at $1.22 per share, which was the fair market value on the date of grant, were granted to senior officers under the 2010 Plan. The options granted to non- employee directors vest quarterly over one year and options granted to the senior officers vest quarterly over four years.

In May 2014, 200,000 stock options were granted outside the 2010 Plan to the Vice President of Clinical Research and Development. The options have an exercise price of $1.25, which was the fair market value on the date of grant, and vest 25% at the end of the first year and vest quarterly thereafter over the following three years.

In June 2014, 200,000 stock options were granted outside the 2010 Plan to the Senior Vice President of Global Regulatory Affairs and Quality Assurance. The options have an exercise price of $1.41, which is the fair market value on the date of grant, and vest 25% at the end of the first year and vest quarterly thereafter over the following three years.

In September 2014, 200,000 stock options were granted outside the 2010 Plan to the Senior Vice President of Operations as an inducement grant material to hiring a new employee in this position. The options have an exercise price of $1.86, which was the fair market value on the date of grant, and vest 25% at the end of the first year and vest quarterly thereafter over the following three years.

In December 2014, 200,000 stock options were granted outside the 2010 Plan to the Vice President of European Commercial Operations as an inducement grant material to hiring a new employee in this position. The options have an exercise price of $.96 per share, which was the fair market value on the date of grant, and vest 25% at the end of the first year and vest quarterly thereafter over the following three years.

NOTE 14: SUBSEQUENT EVENTS

All subsequent events requiring recognition as of December 31, 2014 have been incorporated into these consolidated financial statements and there are no subsequent events that require disclosure in accordance with FASB ASC Topic 855, “Subsequent Events”, except as follows:

Subsequent to January 1, 2015, and through March 27, 2015 the Company has sold a total of 832,066 shares of Common Stock to Aspire Capital Fund LLC under the stock purchase agreement dated November 8, 2013 with aggregate gross proceeds to the Company of $1,539,367.

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 30th day of March, 2015.

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 30, 2015
/s/ Kyle Guse **Kyle Guse**	Chief Financial Officer, General Counsel and Secretary (Principal Financial and Accounting Officer)	March 30, 2015

/s/ Richard I. Steinhart Richard I. Steinhart	Director	March 30, 2015
/s/ Shu-Chih Chen **Shu-Chih Chen, Ph.D.**	Director	March 30, 2015
/s/ Gregory Weaver **Gregory Weaver**	Director	March 30, 2015
/s/ Stephen J. Galli **Stephen J. Galli, M.D.**	Director	March 30, 2015
/s/ H. Lawrence Remmel **H. Lawrence Remmel**	Director	March 30, 2015

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			January 20, 2014

	Form of Warrant Agreement from January 2014 Public Offering	Current Report on Form 8-K, as Exhibit 4.1	
4.8	Form of Warrant issued to Dawson James Securities Inc. in January 2014	Current Report on Form 8-K, as Exhibit 4.2	January 20, 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

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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	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
10.12#	Form of Restricted Stock Award Agreement	Registration Statement on Form S-1, as Exhibit 10.13	June 11, 2012
10.13	Business Consultant Agreement with Edward Sauter	Registration Statement on Form S-1, as Exhibit 10.16	February 14, 2012
10.14	Office Lease with Sander Properties, LLC, dated March 4, 2011	Registration Statement on Form S-1, as Exhibit 10.20	April 6, 2012
10.15	Office Lease with Sander Properties, LLC, dated July 8, 2011	Registration Statement on Form S-1, as Exhibit 10.21	April 6, 2012
10.16	Office Lease with Sander Properties, LLC, dated September 20, 2011	Registration Statement on Form S-1, as Exhibit 10.22	April 6, 2012
10.17	Sublease with Fred Hutchinson Cancer Research Center, dated December 9, 2011	Registration Statement on Form S-1, as Exhibit 10.23	April 6, 2012
10.18†	Agreement between the Company and Accellent Inc., dated August 8, 2011	Registration Statement on Form S-1, as Exhibit 10.26	June 25, 2012
10.19†	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

10.20	Agreement between the Company and Biomarker LLC, dated June 22, 2012	Registration Statement on Form S-1, as Exhibit 10.29	June 25, 2012
10.21#	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
10.22	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
10.23	Office space Lease dated July 18, 2013 between Alexandria (ARE) and the Company.	Annual Report on Form 10-K, as Exhibit 10.33	March 27, 2014
10.24	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
10.25	Lab and Office space Lease Agreement dated March 24, 2014 between Alexandria (ARE) and the Company.	Annual Report on Form 10-K, as Exhibit 10.33	March 27, 2014
10.26#	Offer Letter Agreement with Peter Carbonaro dated May 23, 2013.	Quarterly Report on Form 10-Q, as Exhibit 10.1	May 14, 2014
10.27#	Offer Letter Agreement with Chris Destro dated May 23, 2013.	Quarterly Report on Form 10-Q, as Exhibit 10.2	May 14, 2014
10.28	Office Space Assignment and Assumption of Lease and Consent to Assignment dated August 8, 2014 between Legacy Group, Inc. and the Company.	Quarterly Report on Form 10-Q, as Exhibit 10.1	August 12, 2014
10.29	TME Master Service Agreement dated September 1, 2014 between Targeted Medical Education (TME) and NRLBH	Quarterly Report on Form 10-Q, as Exhibit 10.2	November 12, 2014

10.30#	Offer Letter Agreement with John Sawyer dated May 23, 2014.	Filed herewith
23.1	Consent of BDO USA LLP	Filed herewith
23.2	Consent of KCCW	Filed herewith
24.1	Powers of Attorney	Filed herewith on the signature page
31.1	Certification pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934 of Steven C. Quay	Filed herewith
31.2	Certification pursuant to Rule 13a-14(a) under the Securities Exchange Act of Kyle Guse	Filed herewith
32.1	Certification pursuant to 18 U.S.C. Section 1350 of Steven C. Quay	Filed herewith
32.2	Certification pursuant to 18 U.S.C. Section 1350 of Kyle Guse	Filed herewith
101.INS	XBRL Instance Document	
101.SCH	XBRL Taxonomy Extension Schema Document	
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document	
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document	
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document	
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document	

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#Indicates management contract or compensatory plan, contract or agreement.
††Schedules and exhibits omitted pursuant to Item 601 of Regulation S-K.