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.