ATOSSA GENETICS INC
Form 10-Q
November 12, 2013

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15 (d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2013

OR

¨ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15 (d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission file number: 001-35610

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

Delaware	**26-4753208**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
1616 Eastlake Ave. East, Suite 510 Seattle, WA	**98102**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: (206) 325-6086

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 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 þ No ¨

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

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

Large accelerated filer ¨ Accelerated filer ¨ Non-accelerated filer ¨ Smaller reporting company þ

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

The number of shares of the registrant's common stock, $0.001 par value per share, outstanding at November 8, 2013 was 18,024,824.

ATOSSA GENETICS INC.
FORM 10-Q
QUARTERLY REPORT

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PART I. FINANCIAL INFORMATION

ITEM 1. CONSOLIDATED FINANCIAL STATEMENTS - UNAUDITED

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

	September 30, 2013 (Unaudited)	December 31, 2012 (Audited)
Assets		
Current Assets		
Cash and cash equivalents	$ 7,693,561	$ 1,725,197
Accounts receivable, net	299,338	141,665
Prepaid expense	559,386	122,633
Retainers (deposits)	43,160	-
Total Current Assets	8,595,445	1,989,495
Fixed Assets		
Furniture and equipment, net	443,272	159,967
Total Fixed Assets	443,272	159,967
Other Assets		
Security deposit	36,446	36,447
Intangible assets, net	4,407,058	4,640,224
Total Other Assets	4,443,504	4,676,671
Total Assets	$ 13,482,221	$ 6,826,133
Liabilities and Stockholders' Equity		
Current Liabilities		
Accounts payable	$ 31,131	$ 68,217
Accrued expenses	1,069,759	1,374,385
Deferred rent	60,753	-
Payroll liabilities	357,489	207,996
Contingent liabilities	402,840	-
Other current liabilities	20,300	-
Total Current Liabilities	1,942,272	1,650,598
Stockholders' Equity		
Preferred stock - $.001 par value; 10,000,000 shares authorized, 0 shares issued and outstanding	-	-
Common stock - $.001 par value; 75,000,000 shares authorized, 17,444,824 and 12,919,367 shares issued and outstanding	17,445	12,919
Additional paid-in capital	29,281,396	14,894,522
Accumulated deficit	(17,758,892)	(9,731,906)
Total Stockholders' Equity	11,539,949	5,175,535

Total Liabilities and Stockholders' Equity	$ 13,482,221	$ 6,826,133

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

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

	For the Three Months Ended September 30,		For The Nine Months Ended September 30,		From April 30, 2009 (Inception) Through September 30,
	2013	2012	2013	2012	2013
Revenue					
Diagnostic testing service	$ 72,187	$ 104,011	$ 361,905	$ 376,696	$ 837,307
Product sales	4,410	1,565	223,440	6,690	231,380
Total Revenue	76,597	105,576	585,345	383,386	1,068,687
Cost of Revenue					
Diagnostic testing service	25,938	9,000	75,893	29,985	111,638
Product sales	-	-	238,669	-	243,833
Total Cost of Revenue	25,938	9,000	314,562	29,985	355,471
Loss on reduction of inventory to LCM	-	6,077	-	29,884	121,910
Gross Profit	50,659	90,499	270,783	323,517	591,306
Selling expenses	373,418	87,704	965,383	281,971	1,605,259
Research and development expenses	321,111	548,108	731,258	1,508,944	4,288,644
General and administrative expenses	2,858,027	590,359	6,600,819	1,896,254	12,423,155
Total operating expenses	3,552,556	1,226,171	8,297,460	3,687,169	18,317,058
Operating Loss	(3,501,897)	(1,135,672)	(8,026,677)	(3,363,652)	(17,725,752)
Interest income	53	46	53	1,219	6,641
Interest expense	1	7,756	360	11,816	39,531
Net Loss before Income Taxes	(3,501,845)	(1,143,382)	(8,026,984)	(3,374,249)	(17,758,642)
Income Taxes	-	-	-	-	250
Net Loss	$ (3,501,845)	$ (1,143,382)	$ (8,026,984)	$ (3,374,249)	$ (17,758,892)
Loss per common share - basic and diluted	$ (0.22)	$ (0.10)	$ (0.55)	$ (0.30)	$ (1.95)
	15,830,033	11,256,867	14,697,221	11,256,867	9,127,656

Weighted average shares outstanding, basic & diluted			

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

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

	For the Nine Months Ended September 30, 2013	2012	For The Period From April 30, 2009 (Inception) to September 30, 2013
CASH FLOWS FROM OPERATING ACTIVITIES			
Net loss	$ (8,026,984)	$ (3,374,249)	$ (17,758,892)
Common shares issued for services	144,391	-	215,392
Compensation cost for stock options granted	1,187,717	96,251	1,479,981
Loss on reduction of inventory to LCM	-	29,884	121,910
Loan initiation fee accrued for notes payable	-	-	2,000
Depreciation and amortization	350,536	25,586	496,711
Contingent loss	402,840	-	402,840
Bad debt expense	228,841	-	228,841
Adjustments to reconcile net loss to net cash provided by operating activities:			
Increase in accounts receivable	(386,514)	(174,183)	(528,179)
Increase in inventory	-	(29,884)	(121,910)
Decrease (Increase) in prepaid expenses	71,439	(8,791)	(51,194)
Increase in security deposits	(43,160)	(30,589)	(79,608)
Decrease (Increase) in accounts payable	(37,086)	7,335	31,131
Decrease in accrued payroll	149,493	-	149,493
Increase in deferred rent	60,753	-	60,753
Decrease (Increase) in accrued expenses	(304,626)	1,491,014	1,322,756
Increase in other current liabilities	20,300	-	20,300
Net cash used in operating activities	(6,182,060)	(1,967,626)	(14,007,675)
CASH FLOWS FROM INVESTING ACTIVITIES			
Purchase of furniture & fixtures	(346,007)	-	(537,054)
Purchase of software	(54,667)	-	(135,133)
Net cash used in investing activities	(400,674)	-	(672,187)
CASH FLOWS FROM FINANCING ACTIVITIES			
Net proceeds from issuance of common stocks and warrants	12,551,098	400,000	22,375,423
Repayments of bank line of credit	-	(750,000)	-
Proceeds from (repayments of) loans from related parties	-	75,375	(2,000)
Cash released from commercial line of credit	-	750,000	-
Net cash provided by financing activities	12,551,098	475,375	22,373,423
NET INCREASE (DECREASE) IN CASH & CASH EQUIVALENTS	5,968,364	(1,492,251)	7,693,561
CASH & CASH EQUIVALENTS, BEGINNING BALANCE	1,725,197	1,910,821	-

CASH & CASH EQUIVALENTS, ENDING BALANCE	$ 7,693,561	$ 418,570	$ 7,693,561
SUPPLEMENTAL DISCLOSURES:			
Interest paid	$ 359	$ 13,892	$ 33,067
Income taxes paid	$ -	$ -	$ 250
NONCASH INVESTING AND FINANCING ACTIVITIES:			
Common stock and warrants issued for asset purchase	$ -	$ 4,674,853	$ 4,674,853
Options issued for previously accrued director compensation	$ -	$ 45,000	$ 45,000
Commitment shares distributed for capital contribution	$ 2,387,250	$ -	$ 2,387,250
Amortization of commitment shares issued for distributed shares	$ 1,879,058	$ -	$ 1,879,058

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

ATOSSA GENETICS INC.
(A DEVELOPMENT STAGE COMPANY)
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(UNAUDITED)

NOTE 1: NATURE OF OPERATIONS

The Company's operations began in December 2008 with the negotiations for the acquisition of the Mammary Aspirate Specimen Cytology Test System, or the MASCT System, patent rights and assignments and the FDA clearances for marketing, which acquisition was completed in January 2009. Atossa Genetics Inc. (the "Company") was incorporated on April 30, 2009 in the State of Delaware. The Company was formed to develop and market the MASCT System, which was cleared by the FDA in 2003 as a medical device that is intended for use in the collection of nipple aspirate fluid for laboratory cytological testing. The Company's fiscal year ends on December 31st.

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

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

On October 4, 2013 the Company commenced the voluntary recall of the ForeCYTE Breast Health Test (also known as the MASCT System or ForeCYTE Test). As a result of this recall, this product is currently not being marketed or distributed in the U.S. The Company intends to obtain an additional FDA 510(k) clearance from the FDA for the ForeCYTE Test and to re-launch the test upon receiving regulatory clearance.

Development Stage Risk

From April 30, 2009 (inception) through September 30, 2013, the Company earned $1,068,687 in revenue from the sale of its products and laboratory services. The Company's activities have been accounted for as those of a "Development Stage Enterprise" as set forth in Accounting Standards Codification ("ASC") 915 "Development Stage Entities", which was previously Statement of Financial Accounting Standards No. 7 ("SFAS 7"). Among the disclosures required by ASC 915 are that the Company's financial statements be identified as those of a development stage company, and that the statements of operations, stockholders' equity and cash flows disclose activity since the date of the Company's inception.

Since its inception, the Company has been dependent upon the receipt of capital investment to fund its continuing activities. In addition to the normal risks associated with a new business venture, there can be no assurance that the Company's business plan will be successfully executed. The Company's ability to execute its business plan will depend

on its ability to obtain additional financing and achieve a profitable level of operations. There can be no assurance that sufficient financing will be obtained. Further, the Company cannot give any assurance that it will generate substantial revenue or that its business operations will prove to be profitable.

NOTE 2: GOING CONCERN

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

Management's Plan to Continue as a Going Concern

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

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

NOTE 3: SUMMARY OF ACCOUNTING POLICIES

Basis of Presentation:

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

Recently Issued Accounting Pronouncements:

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

Revenue Recognition:

Overview

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

Product Revenue

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

Service Revenue

The Company records revenue for diagnostic testing on an accrual basis at the Medicare allowed and invoiced amount. Amounts invoiced above the Medicare amount, namely non-Medicare, are not recognized on an accrual basis and instead are recognized on a cash basis as received. Diagnostic testing revenue at the Medicare rate is recognized upon completion of the test, communication of results to the patient's physician, and when collectability is reasonably assured. Customer purchase orders and/or contracts will generally be used to determine the existence of an arrangement. Once the Company has historical sales and can determine the proper amount to recognize as uncollectible, it will then begin to recognize the entire amount, both Medicare and non-Medicare billing on an accrual basis, with an offsetting allowance for doubtful accounts recorded based on history. The Company estimates it will utilize the diagnostic testing revenue history to determine a proper allowance for doubtful accounts beginning in 2014.

Cash and Cash Equivalents:

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

Use of Estimates:

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

Accounts Receivable:

Accounts receivable are recorded at net realizable value consisting of the carrying amount less allowance for doubtful accounts, as needed. The Company assesses the collectability of accounts receivable based primarily upon the creditworthiness of the customer as determined by credit checks and analysis, as well as the customer's payment history. Management reviews the composition of accounts receivable and analyzes historical bad debts, customer concentrations, customer credit worthiness, current economic trends, and changes in customer payment patterns to evaluate the adequacy of these reserves. The Company's allowance for doubtful accounts and bad debt expenses as of September 30, 2013 and December 31, 2012 was $228,841 and $0, respectively.

Inventories:

The Company's inventories are stated at lower of cost or market. Cost is determined on a moving-average basis. Costs of inventories include purchase and related costs incurred in delivering the products to their present location and condition. Market value is determined by reference to selling prices after the balance sheet date or to management's estimates based on prevailing market conditions. Inherent in the lower of cost or market calculation are several significant judgments based on a review of the aging of the inventory, inventory movement of products, economic conditions, and replacement costs. Because the sales price of the MASCT System was substantially lower than its cost for the period ended September 30, 2013 and December 31, 2012, resulting in the net realizable value of the MASCT System being determined at zero as of September 30, 2013 and December 31, 2012, through taking the average sales price subtracted by selling expenses per unit. The Company assessed and recorded $0 and $29,884 loss on reduction of inventory to the lower of cost or market for the nine months ended September 30, 2013 and for the year ended December 31, 2012, respectively. Additionally, management periodically evaluates the composition of its inventories at least quarterly to identify slow-moving and obsolete inventories to determine if any valuation allowance is required. As of September 30, 2013 and December 31, 2012, management had identified no slow moving or obsolete inventory.

The Company outsources product manufacturing to outside manufacturer contactors. The ownership of the goods transfers from the manufacturer to the Company's customer at the time the products are shipped to the customers. As of September 30, 2013, there are no inventories on our books.

The Company provides, either directly or through distributors, the ForeCYTE testing specimen collection kits to doctors with our MASCT System for doctors to collect specimens that are returned to the NRLBH for diagnostic analysis. These collection kits are considered part of the MASCT System. The Company's direct sales personnel distributes the kits directly to physicians free of charge, or by offering a rebate to physicians. The Company has not intended to deem the kits as a primary product line due to their nominal cost and value per unit. As a result, the kits are immediately expensed and recorded as selling expense upon purchasing of the kits.

Property, plant, and equipment:

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

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

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

Intangible assets:

Intangible assets consist of intellectual property and software acquired in the Acueity asset purchase. At least annually, we evaluate purchased intangibles for impairment whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of the asset and its eventual disposition are less than its carrying amount. Estimating future cash flows related to an intangible asset involves significant estimates and assumptions. If our assumptions are not correct, there could be an impairment loss or, in the case of a change in the estimated useful life of the asset, a change in amortization expense. There was no impairment of intangible assets as of and for the nine months ended September 30, 2013 and year ended December 31, 2012, respectively.

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

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

Research and Development Expenses:

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

Share-Based Payments:

In December 2004, the Financial Accounting Standards Board, or the FASB, issued the Statement of Financial Accounting Standards, or SFAS, No. 123(R), "Share-Based Payment", which replaces SFAS No. 123 and supersedes APB Opinion No. 25. SFAS No. 123(R) is now included in the FASB's ASC Topic 718, "Compensation Stock Compensation." Under SFAS No. 123(R), companies are required to measure the compensation costs of share-based

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

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

NOTE 4: PREPAID EXPENSES

Prepaid expenses consisted of the following:

	September 30, 2013	December 31, 2012
Prepaid stock purchase agreement service fee	$ 508,442	$ -
Prepaid insurance	27,445	62,551
Prepaid hardware/software maintenance and support service fee	23,499	20,000
Prepaid payroll taxes	-	40,082
	$ 559,386	$ 122,633

NOTE 5: PROPERTY, PLANT, AND EQUIPMENT

Property, plant and equipment consisted of the following:

	September 30, 2013	December 31, 2012
Machinery and equipment	$ 269,771	$ 97,383
Leasehold improvements	93,665	93,665
Capitalized new product development costs	173,766	-
Less: Accumulated depreciation	(93,930)	(31,081)
Property, plant, and equipment, net	$ 443,272	$ 159,967

Depreciation expense for the nine months ended September 30, 2013 and 2012 was $62,849 and $12,970, respectively.

NOTE 6: INTANGIBLE ASSETS

Intangible assets consisted of the following:

	September 30, 2013	December 31, 2012
Patents	$ 4,704,853	$ 4,704,853
Software	105,133	50,466
Less: Accumulated amortization	(402,928)	(115,095)
	$ 4,407,058	$ 4,640,224

Intangible assets amounted to $4,407,058 and $4,640,224 as of September 30, 2013 and December 31, 2012, respectively, and consisted of patents and software acquired. The acquired software mainly consisted of $58,000 in laboratory software and $31,500 in the newly developed Company website. The amortization period for the purchased software is 3 years. Amortization expense related to software for the nine months ended September 30, 2013 and 2012 was $15,322 and $12,616, respectively.

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Patents amounted to $4,704,853 and $4,704,853 as of September 30, 2013 and December 31, 2012, respectively, and mainly consisted of patents acquired from Acueity on September 30, 2012 in an asset purchase transaction (see Note 13). Patent assets are amortized based on their determined useful life, and tested annually for impairment. The amortization period was from 9 to 14 years. Amortization expense related to patents was $272,511 and $0 for the nine months ended September 30, 2013 and 2012, respectively.

Future estimated amortization expenses as of September 30, 2013 for the five succeeding years is as follows:

As of September 30,	Amounts
2014	$ 393,073
2015	381,331
2016	378,781
2017	363,902
2018	363,028
Thereafter	2,526,943
	$ 4,407,058

NOTE 7: PAYROLL LIABILITIES:

Payroll liabilities consisted of the following:

	September 30, 2013	December 31, 2012
Accrued bonus payable	$ 297,290	$ 189,131
Accrued payroll liabilities	40,318	-
Accrued payroll tax liabilities	19,881	18,865
	$ 357,489	$ 207,996

NOTE 8: STOCKHOLDERS' EQUITY

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

Reverse Stock-Split

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

Prior Issuances of Common Stock at Inception

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

Private Placements and Warrants

On April 28, May 31, June 10, and June 23, 2011, pursuant to Securities Purchase Agreements with various investors (the “Investors”), the Company issued 5,256,800 shares of the Company’s common stock and 5,256,800 warrants (the “Investor Warrants”), each of which entitles the investors to purchase the Company’s common stock, exercisable for 1.60 per share, for aggregate gross proceeds of $6,571,000 (the “Private Placement”).

Placement Agent Fees

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

Warrants

The Warrants, including the Investor Warrants and the Placement Agent Warrants, are exercisable at any time commencing after June 23, 2011 which is the date that the Company completed a "significant private financing" under the terms of the Warrants (the "Initial Exercise Date"). The Warrants shall expire and no longer be exercisable on the fifth anniversary of the Initial Exercise Date (the "Expiration Date"). The Warrants may be exercised for cash or, at the option of the holder, may be exercised on a cashless basis; however if a registration statement is in effect for the resale of the common stock issuable upon exercise of the Warrants then the Warrants cannot be exercised on a cashless basis. As of September 30, 2013 such a registration statement was in effect and, therefore, the Warrants cannot be exercised on a cashless basis.

As of September 30, 2013, 4,775,550 warrants are outstanding including 325,000 warrants issued in the Acueity transation described below and substantially all of the Placement Agents Warrants have been exercised. There are no redemption features embodied in the Warrants and they have met the conditions provided in current accounting standards for equity classification.

Fair Value Considerations

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

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

Fair Value Hierarchy Level	April-June2011	December 2011	
	Investor Warrants	Placement Agent Warrants	Placement Agent Warrants

Indexed shares			5,256,800		788,520			788,520	
Exercise price		$	1.60	$	1.60		$	1.25	
Significant assumptions:									
Stock price	3	$	0.906	$	0.906		$	0.906	
Remaining term	3		6 years		6 years			6 years	
Risk free rate	2		2.49	%	1.12	%		1.12	%
Expected volatility	3		53.55	%	54.21	%		54.21	%

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

(1) There were no Level 1 inputs.

(2) Level 2 inputs include:

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

(3) Level 3 inputs include:

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

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

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

Asset Purchase and Warrants

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

Warrants

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

Fair Value Considerations

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

free rates) necessary to fair value these instruments.

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

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

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

(1) There were no Level 1 inputs.

(2) Level 2 inputs include:

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

(3) Level 3 inputs include:

Stock price- The Company’s common stock was not publicly traded at the time the Acueity Warrants were issued. Therefore, the stock price was determined at the offering price of the then contemplated initial public offering, for which the registration statement on Form S-1 (File No. 333-179500) was subsequently declared effective by the Securities and Exchange Commission on November 7, 2012, and a prospectus was subsequently filed pursuant to Rule 424(b)(4) on November 9, 2012 (see Note 14).

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

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

As of September 30, 2013, the Company has granted warrants to purchase 58,500 shares of common stock to the placement agent in connection with the financing facility with Aspire Capital. The warrants are exercisable at $5.80 or $5.70 per share and expire in 2017. An expense of $72,549 has been recognized during 2013 for issuance of these warrants.

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On September 28, 2010, the Board of Directors approved the adoption of the 2010 Stock Option and Incentive Plan, or the 2010 Plan, subject to stockholder approval, to provide for the grant of equity-based awards to employees, officers, non-employee directors and other key persons providing services to the Company. Awards of incentive options may be granted under the 2010 Plan until September 2020. No other awards may be granted under the 2010 Plan after the date that is 10 years from the date of stockholder approval. An aggregate of 1,000,000 shares (or 2,263,320 shares prior to the reverse stock-split on September 28, 2010) were initially reserved for issuance in connection with awards granted under the 2010 Plan, such number of shares to be subject to adjustment as provided in the plan and in any award agreements entered into by the Company under the plan, and upon the exercise or conversion of any awards granted under the plan. On January 1, 2012, 450,275 shares were added to the 2010 Plan and on January 1, 2013, 500,000 shares were added to the 2010 Plan, as provided under the terms of the 2010 Plan.

The Company granted options to purchase 122,740 and 857,394 shares of common stock to employees during the three months and nine months ended September 30, 2013, respectively. The Company issued zero and 5,546 shares of common stocks in connection with the exercise of employee's stock options during the three months and nine months ended September 30, 2013. As of September 30, 2013, there are 471,624 options available for grant under the 2010 Plan.

NOTE 9: INCOME TAXES

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

As a result of the Company's cumulative losses, management has concluded that a full valuation allowance against the Company's net deferred tax assets is appropriate. No income tax liabilities existed as of September 30, 2013 and December 31, 2012 due to the Company's continuing operating losses.

NOTE 10: CONCENTRATION OF CREDIT RISK

Financial instruments that potentially subject the Company to concentration of credit risk consist principally of cash deposits. Accounts at each institution are insured by the Federal Deposit Insurance Corporation ("FDIC") up to $250,000. At September 30, 2013 and December 31, 2012, the Company had $7,443,561 and $1,475,197 in excess of the FDIC insured limit, respectively.

NOTE 11: COMMITMENTS AND CONTINGENCIES

Lease Commitments

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

On March 4, 2011, the Company entered into a commercial lease agreement with Sanders Properties, LLC for office space located in Seattle, WA. The lease provides for monthly rent of $1,100 and a security deposit of $1,500. The lease terms are from April 1, 2011 through March 31, 2014. For the nine months ended September 30, 2013, the Company incurred $8,800 of rent expense for the lease.

On December 9, 2011, the Company entered into another commercial lease agreement with Fred Hutchinson Research Center for lab and office space located in Seattle, WA. The lease provides for monthly rent of $16,395 for the period from February 24, 2012 to August 31, 2012, $19,923 for the period from September 1, 2012 to August 31, 2013, and $20,548 for the period from September 1, 2013 to November 29, 2014. The security deposit of $32,789 was paid in March 2012 and recorded as Security Deposit on the consolidated balance sheet as of December 31, 2012. For the nine months ended September 30, 2013, the Company incurred $233,260 of rent expense for the lease, which included leasing office management expenses.

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

The future minimum lease payments due subsequent to September 30, 2013 under all non-cancelable operating leases for the next five years are as follows:

As of September 30,	Amount
2014	$ 380,767
2015	62,451
2016	-
2017	-
2018	-
Thereafter	-
Total minimum lease payments	$ 443,218

Affymetrix Purchase Commitment

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

Contingencies

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

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

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

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

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The Company is reasonably confident in its defenses to Mr. Kelly's and Mr. Cononi's claims. Consequently, no provision or liability has been recorded for these claims as of September 30, 2013. However, it is at least reasonably possible that the Company's estimate of liability may change in the near term. Any payments by reason of an adverse determination in this matter will be charged to earnings in the period of determination.

On October 10, 2013, a putative securities class action complaint was filed in the United States District Court for the Western District of Washington against us, certain of our directors and officers and the underwriters of our November 2012 initial public offering. The complaint alleges that all defendants violated Sections 11 and 12(a)(2), and that we and certain of our directors and officers violated Section 15, of the Securities Act by making false and misleading statements and omissions in the offering's registration statement, and that we and certain of our directors and officers violated Sections 10(b) and 20A of the Exchange Act and SEC Rule 10b-5 promulgated thereunder by making false and misleading statements and omissions in the registration statement and in certain of our subsequent press releases and SEC filings with respect to our NAF specimen collection process, our ForeCYTE Breast Health Test and our MASCT device. This action seeks, on behalf of persons who purchased our common stock between November 8, 2012 and October 4, 2013, inclusive, damages of an unspecific amount. We believe this complaint is without merit and plan to defend ourselves vigorously. Failure by us to obtain a favorable resolution of the claims set forth in the complaint could have a material adverse effect on our business, results of operations and financial condition. Currently, the amount of such material adverse effect cannot be reasonably estimated, and no provision or liability has been recorded for these claims as of September 30, 2013. The costs associated with defending and resolving the complaint and ultimate outcome cannot be predicted. These matters are subject to inherent uncertainties and the actual cost, as well as the distraction from the conduct of our business, will depend upon many unknown factors and management's view of these may change in the future.

FDA Warning Letter

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

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

To ensure that the 510(k) includes the information that FDA feels is appropriate, we have requested a pre-submission meeting with the FDA. This meeting is scheduled to be held on November 14, 2013. Once we understand what types of data FDA is seeking, we intend to submit the 510(k) shortly after the meeting. Once filed we hope that the FDA will complete their review of our submission within 90 days; but of course we cannot predict if they will ask us for additional information or otherwise complete their review within the 90 days.

The Company has recorded a loss contingency as of September 30, 2013 of $402,840 related to the estimated costs of the recall, including the estimated costs of pursuing the additional 510(k) clearance. The recall and 510(k) process may take longer than expected and we may incur costs that we have not anticipated. Accordingly, the actual amount of the loss contingency may be higher than we currently expect.

NOTE 12: RELATED PARTY TRANSACTIONS

Loans from Officer

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

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

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

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

Exclusive License Agreement

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

On June 17, 2010, the Company and Ensisheim entered into an Assignment Agreement, whereby Ensisheim assigned to the Company all rights to the patents and patent applications underlying the MASCT System. Pursuant to the assignment, the Company will have all responsibility for prosecution, maintenance, and enforcement and will indemnify Ensisheim from any and all claims against the patent estate. Ensisheim retained no residual rights with

respect to the patents and patent applications. In conjunction with the assignment, the Company terminated the exclusive license agreement between the Company and Ensisheim dated July 27, 2009. As a result of the termination, the Company has no further obligations with respect to royalty payments to Ensisheim due under the old licensing agreement. As a result, the $12,500 of patent royalty payable to Ensisheim recorded as accrued royalty payable at December 31, 2009 has been reversed through royalty expense during the second quarter of 2010.

Commercial Lease Agreement

On December 24, 2009, the Company entered into a commercial lease agreement with Ensisheim for office space located in Seattle, Washington. The lease provided for annual rent of $13,200, plus applicable sales tax. From inception through December 31, 2009, the Company incurred $248 of rent expense for the lease with security deposit of $1,100. For the period of January 1, 2010 through June 30, 2010, the Company incurred $6,600 of rent expense for the lease. On July 15, 2010 the Company and Ensisheim terminated the lease, effective July 1, 2010 and the Company commenced use of the facility rent free until April 1, 2011 when the commercial lease agreement the Company entered into with Sanders Properties, LLC became effective (see Note 11). The $1,100 security deposit paid to Ensisheim was received as of December 31, 2012.

Executive Compensation

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

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

On July 22, 2010, the Company restated and amended the employment agreements with its CEO and CSO. The agreements modified the base annual salary amounts to $250,000 and $200,000, respectively, effective retroactively to May 19, 2010. For the nine months ended September 30, 2012, salaries and bonuses of CEO and CSO amounted to $269,438 and $200,550, of which $134,719 and $200,550 were recorded to research and development expense, respectively. For the nine months ended September 30, 2013, salaries and bonuses of CEO and CSO amounted to $258,635 and $191,908, of which $129,316 and $191,908 were recorded to research and development expense, respectively.

Share-Based Compensation

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(ii) one-sixteenth (1/16) of the underlying shares quarterly thereafter.

In accordance with the guidance provided in ASC Topic 718, Stock Compensation (formerly SFAS 123R), the compensation costs associated with these options are recognized, based on the grant-date fair values of these options, over the requisite service period, or vesting period. Accordingly, the Company recognized a compensation expense of $1,187,716 and $96,251 for the nine months ended September 30, 2013 and 2012, respectively.

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

2010 through December 2012	Employee	Employee & Officers	Directors		CEO & CSO
Date of Grant	December 2012	September 2011	April 2012	September 2011	July 2010
Fair value of common stock on date of grant	$4.11-$4.24(D)	$0.9060(B)	$0.9060 (B &C)		$2.7560(A)
Exercise price of the options	$4.11 - $4.24	$1.25	$1.25-$6.00		$5.00
Expected life of the options (years)	5.74 - 6.11	5.65	5.00 5.65		3.33
Dividend yield	0.00%	0.00%	0.00%		0.00%
Expected volatility	42.44 44.58%	53.90%	53.90-62.46%		58.59%
Risk-free interest rate	0.91-0.99%	1.08%	0.89 1.08%		1.03%
Expected forfeiture per year (%)	10.00%	10.00%	0.00%		0.00%
Weighted average fair value of the options per unit	$1.7426-$1.7842	$0.3579	$0.3579-$3.0367		$0.6744

Year To Date September 2013	Employee	Employee & Officers	Directors	CEO & CSO
Date of Grant	January - August 2013	January - June 2013	May 2013	March 2013
Fair value of common stock on date of grant(E)	$3.95 - $5.19(D)	$4.11 - $4.58(D)	$6.59 (D)	$6.57 (D)
Exercise price of the options	$3.95 - $5.19	$4.11 - $4.58	$6.59	$6.57
Expected life of the options (years)	6.09 - 6.11	5.00 6.11	5.00 5.31	5.00
Dividend yield	0.00%	0.00%	0.00%	0.00%
Expected volatility	40.73 - 40.92%	40.96 - 41.05%	41.06-41.09%	47.09%
Risk-free interest rate	1.73 -1.97%	1.03-1.36%	0.73 - 0.84%	1.13%
Expected forfeiture per year (%)	10.00%	10.00%	10.00%	0.00%
Weighted average fair value of the options per unit	$1.35 - $2.18	$1.69 - $1.89	$2.41 - $2.49	$2.70

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

(B) The fair value of the Company's common stock was derived implicitly from the Private Placement during April through June 2011 at $1.25 per Unit, wherein one Unit was comprised of one share of common stock and one warrant to purchase one share of common stock at an exercise price of $1.60 per share.

(C) The fair value of the Company's common stock was derived implicitly from the public offering filed in February 2012 at $6.00 per share.

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

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

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

(1) There were no Level 1 inputs.

(2) Level 2 inputs include:

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

(3) Level 3 inputs include:

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

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

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

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

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

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

superior information in the setting of cancer diagnosis and treatment selection.

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

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

Options issued and outstanding as of September 30, 2013 and their activities during the nine months then ended are as follows:

	Number of Underlying Shares	Weighted-Average Exercise Price Per Share	Weighted-Average Contractual Life Remaining in Years
Outstanding as of January 1, 2013	1,052,137	$ 3.79	
Granted	1,425,394	5.02	
Expired	(3,812)	4.99	
Forfeited	(221,522)	4.21	
Exercised	(5,546)	1.79	
Outstanding as of September 30, 2013	2,246,651	4.53	8.87
Exercisable as of September 30, 2013	1,044,549	4.54	8.21
Vested and expected to vest (1)	2,090,475	4.54	8.83

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

As of September 30, 2013 and December 31, 2012, the aggregate intrinsic value of options outstanding was $3,604,669 and $1,150,416, respectively.

NOTE 13: ASSET PURCHASE

On September 30, 2012, the Company entered into an asset purchase agreement with Acueity Healthcare, Inc ("Acueity") to acquire substantially all of the assets of Acueity. Through the asset purchase, the Company acquired 35 issued patents (18 issued in the U.S. and 17 issued in foreign countries), 41 patent applications (32 in the U.S. and 9 in foreign countries), six 510(k) FDA marketing authorizations related to the manufacturing, use, and sale of the Viaduct Miniscope and accessories, the Manoa Breast Biopsy system, the Excisor Bioptome, the Acueity Medical Light Source, the Viaduct Microendoscope and accessories, and cash in the amount of $400,000; no liabilities were assumed in the transaction. In consideration for the assets, the Company issued 862,500 shares of common stock, valued at $5.00 per share, the offering price listed on the prospectus filed pursuant to Rule 424(b)(4) on November 9, 2012, and warrants to purchase up to 325,000 shares of common stock at an exercise price of $5.00 per share, to the shareholders of Acueity, subject to a six-month lock up agreement which has since lapsed. The warrants, which have a five-year term, do not have a cashless exercise provision. The warrants were valued at $2.3457 per warrant, using a Black-Scholes-Merton Valuation Technique because it embodies all of the requisite assumptions (including trading

volatility, estimated terms and risk-free rates) necessary to determine the fair value of the warrants (see Note 8). There are no future financial obligations from the Company to Acueity from the commercialization of the acquired assets.

NOTE 14: SUBSEQUENT EVENTS

Voluntary Product Recall

On October 4, 2013 we initiated a voluntary recall to remove the ForeCYTE Breast Health Test and the MASCT device from the market. This voluntary recall includes the MASCT System Kit and Patient Sample Kit. The vast majority of these products (approximately ninety percent) are in inventory with our distributors and the remaining quantities are at customer sites across the United States. Distributors and customers have been instructed to stop using affected products and return them to Atossa immediately.

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

We are working with the FDA on this matter and this voluntary recall. We have notified distributors and customers by certified mail and we are arranging for the return of all recalled products. We plan to prepare a new premarket notification or 510(k) application for submission to the FDA that covers the collection, preparation, and processing of NAF specimens at our laboratory and includes the spray method of fixing specimens to the collection membrane. However, we cannot market or distribute the modified product in the U.S. unless or until the new 510(k) is cleared by the FDA.

To ensure that the 510(k) includes the information that FDA feels is appropriate, we have requested a pre-submission meeting with the FDA. This meeting is scheduled to be held on November 14, 2013. Once we understand what types of data FDA is seeking, we intend to submit the 510(k) shortly after the meeting. Once filed we hope that the FDA will complete their review of our submission within 90 days; but of course we cannot predict if they will ask us for additional information or otherwise complete their review within the 90 days.

The Company has recorded a loss contingency as of September 30, 2013 of $402,840 related to the estimated costs of the recall, including the estimated costs of pursuing the additional 510(k) clearance. The recall and 510(k) process may take longer than expected and we may incur costs that we have not anticipated. Accordingly, the actual amount of the loss contingency may be higher than we currently expect.

Aspire Common Stock Purchase Agreement

From the October 1, 2013 through November 7, 2013, the Company has sold 200,000 shares of common stock to Aspire Capital with gross proceeds to the Company of $349,670, pursuant to the terms of the Common Stock Purchase Agreement with Aspire dated March 27, 2013. The March 27, 2013 Common Stock Purchase Agreement with Aspire Capital was terminated on November 8, 2013 and on that date we entered into a new stock purchase agreement with Aspire Capital Fund, LLC. The new stock purchase agreement 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. We cannot, however, sell any shares to Aspire under the new agreement unless and until a new registration statement is filed with and declared effective by the SEC.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

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

Forward-Looking Statements

This report contains, in addition to historical information, certain information, assumptions and discussions that may constitute forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act") and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). We have made these statements in reliance on the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These statements are subject to certain risks and uncertainties, which could cause actual results to differ materially from those projected or anticipated. Although we believe our assumptions underlying our forward-looking statements are reasonable as of the date of this 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," "estimate," "anticipate" or the negative version of those words or other comparable words. Forward-looking statements contained in this report include, but are not limited to, statements about:

- our ability to successfully sell our products and services at currently expected prices or otherwise at prices acceptable to us;
- whether we will obtain in a timely manner clearance from the Food and Drug Administration to sell, market and distribute our MASCT System and ForeCYTE Test;
- our ability to successfully re-launch our MASCT System and ForeCYTE Test;
- the estimated costs associated with our product recall;
- our ability to successfully develop and commercialize new tests, tools and technologies currently in development and in the time frames currently expected;
- our ability to maintain our business relationships, including with our distributors, suppliers and customers, while we are undergoing the recall we commenced October 4, 2013 and while we seek additional regulatory clearance to market, sell and distribute our MASCT System and ForeCYTE Test;
- our ability to engage third-party suppliers to manufacture the MASCT System, Microcatheter System, other devices under development and their components at quantities and costs acceptable to us;
- our ability to satisfy ongoing FDA requirements for the MASCT System, ForeCYTE Test and Microcatheter System and to obtain regulatory approvals for our other products and services in development, including our ability to timely and adequately respond to the warning letter we received from the FDA on February 21, 2013 and any issues resulting therefrom;

- our ability to defend the securities class action law suit filed against us on October 10, 2013, and other similar complaints that may be brought in the future, in a timely manner and within the coverage, scope and limits of our insurance policies;

- the benefits and clinical accuracy of the ForeCYTE and ArgusCYTE tests and whether any product or service that we commercialize is safer or more effective than competing products and services;

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

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

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

- our expectations regarding, and our ability to satisfy, federal, state and foreign regulatory requirements;

- the accuracy of our estimates of the size and characteristics of the markets that our products and services may address;

- our expectations as to future financial performance, expense levels and liquidity sources;

- our ability to attract and retain key personnel; and

- our ability to sell additional shares of our Common Stock to Aspire Capital under the terms of our Purchase Agreement with Aspire.

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 entitled “Risk Factors,” that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any new information, future events or circumstances that may affect our business after the date of this 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.

Company Overview

We are a healthcare company focused on breast health. We are developing a suite of tests and therapeutic medical devices, laboratory developed tests and services (LDT and/or invitro diagnostics) that address each of the four stages of the breast health care path: the cytological analysis of cells in nipple aspirate fluid (NAF), the cytological analysis of cells in ductal lavage fluid collected from each individual breast duct with manual breast duct microcatheters; the profiling of newly diagnosed breast cancers through the determination of gene expression profiles in formalin-fixed paraffin embedded breast cancer biopsy tissue; and the monitoring of breast cancer survivors for pre-clinical recurrence through a blood test for circulating tumor cells. We also have a therapeutic program to provide targeted, localized treatment of cancerous and pre-cancerous conditions through our patented microcatheters. All of our products and services are currently under development and are awaiting additional regulatory clearances prior to marketing and commercialization. Our products and services under development include:

- ForeCYTE Breast Health Test System: a test system comprised of a medical device for the collection and preparation of NAF specimens that are then processed using cytological testing procedures in our wholly-owned CLIA-certified laboratory, the NRLBH. The ForeCYTE Breast Health Test is not intended to be used to diagnose breast cancer or to serve as a replacement for

mammography. We are currently seeking 510(k) clearances from the FDA for this test, which we anticipate receiving in the first quarter of 2014. Upon receiving the 510(k) clearances, we intend to re-launch the ForeCYTE Test.

- FullCYTE Breast Health Test: a test system for women identified by their physician as being at high risk for breast cancer. The test is designed for a surgeon to use our patented Class II microcatheter medical devices to collect NAF specimens from individual breast ducts which are then analyzed using cytological testing procedures at the NRLBH. We plan to complete additional validation studies and regulatory clearance of our manufacturing precedures and processes for this test in 2014 and to launch the test in the second half of 2014.

- NextCYTE Breast Cancer Test: a test for women newly diagnosed by their physician as having breast cancer that is a qualitative in vitro diagnostic test service, performed in a single laboratory, using the gene expression profile of formalin-fixed, paraffin embedded breast cancer tissue samples to assess a patient's risk for distant metastasis. It uses advanced microarray expression technologies to quantify and analyze the entire tumor genetic transcriptome, which represents all genes that are being actively expressed within the tumor. This test is in the validation phase and after receiving FDA regulatory clearance we anticipate launching it in the second half of 2014.

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

- Therapeutic Program: We are also developing our patented microcatheters for the delivery of pharmaceutical formulations directly into the milk ducts. We plan to initially target pre-cancerous lesions and ductal carcinoma in situ, or DCIS, a condition diagnosed in more than 65,000 patients each year. By using this localized delivery method, patients are expected to receive high local concentrations of these drugs at the site of the pre-cancerous lesions or DCIS potentially promoting efficacy of the treatment while limiting systemic exposure, which has the potential to lower the overall toxicity of these treatments. This program has not been approved by the FDA. We plan to identify a partner for the clinical development of the pharmaceutical to be used with our device in the first half of 2014.

Our leading test, the ForeCYTE Breast Health Test, was launched in a "field experience" trial in 2012 and nationally in the beginning of 2013. In October 2013, we voluntarily recalled the ForeCYTE Breast Health Test (also known as the MASCT System or ForeCYTE Test). As a result of this recall, we are not currently marketing this product in the U.S. We intend to obtain an additional FDA 510(k) clearance for the ForeCYTE Test and to re-launch the test upon receiving regulatory clearance. However, the regulatory pathway to obtaining a 510(k) clearance can be lengthy, expensive and unpredictable; we therefore cannot provide any assurances that we will receive a new 510(k) clearance for ForeCYTE or any of our other tests under development in a timely fashion or at all.

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

Current Operations

We launched our commercial operations in late 2011. In 2012 we initiated and completed the field experience trial of our first two tests, the ForeCYTE test and the ArgusCYTE test. In January 2013, we announced the national launch of the ForeCYTE Test. On April 30, 2013, we entered into a Distribution and Marketing Services Agreement with Millennium Medical Devices LLC, pursuant to which Millennium will market and distribute the ForeCYTE breast health test kits in New York City and Northern New Jersey. In May 2013, we entered into a distribution agreement with Fisher Healthcare, a division of Fisher Scientific Company, LLC, and in September 2013 we entered into a distribution agreement with McKesson Medical Surgical.

Our Voluntary Product Recall

On October 4, 2013 we initiated a voluntary recall to remove the ForeCYTE Breast Health Test and the MASCT device from the market. This voluntary recall includes the MASCT System Kit and Patient Sample Kit. The vast majority of these products (approximately ninety percent) are in inventory with our distributors and the remaining quantities are at customer sites across the United States. Distributors and customers have been instructed to stop using affected products and return them to Atossa immediately.

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

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

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

We are working with the FDA on this matter and this voluntary recall. We have notified distributors and customers by certified mail and we are arranging for the return of all recalled products. As of the date of this report, approximately 8% of the MASCT pumps and 84% of the MASCT patient collection kits have been returned to our processing center. We also plan to prepare a new premarket notification or 510(k) application for submission to the FDA that covers the collection, preparation, and processing of NAF specimens at our laboratory and includes the spray method of fixing specimens to the collection membrane. However, we cannot market or distribute the modified product in the U.S. unless or until the new 510(k) is cleared by the FDA.

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To ensure that the 510(k) includes the information that FDA feels is appropriate, we have requested a pre-submission meeting with the FDA. This meeting is scheduled to be held on November 14, 2013. Once we understand what types of data the FDA is seeking, we intend to submit the 510(k) shortly after the meeting. Once filed we hope that the FDA will complete their review of our submission within 90 days; but of course we cannot predict if they will ask us for additional information or otherwise complete their review within the 90 days.

We have recorded a loss contingency as of September 30, 2013 of $402,840 related to the estimated costs of the recall, including the estimated costs of pursuing the additional 510(k) clearance. The recall and 510(k) process may take longer than expected and we may incur costs that we have not anticipated. Accordingly, the actual amount of the loss contingency may be higher than we currently expect.

When we re-launch our ForeCYTE Test, we will incur additional sales and marketing expenses. We will need to revise our sales and marketing tools and continue hiring direct sales employees in an effort to build a regional, and ultimately national, sales force. We also expect to continue to hire clinical consultants to help healthcare providers begin to use our ForeCYTE Test.

From our inception (April 30, 2009) through September 30, 2013, 357 physicians have enrolled to provide the ForeCYTE Test and as of that date we have received, processed, and reported the results to physicians from 2,744 NAF samples processed and reported with our ForeCYTE Test (representing 1,372 patients) and 41 ArgusCYTE samples. From inception through September 30, 2013, we have generated $1,068,687 in product and service revenue. We incurred net losses of $3,501,845 and $8,026,984 for the three months and nine months ended September 30, 2013 and $17,758,892 since inception. As of September 30, 2013, we had an accumulated deficit of approximately $17,758,892. We have not yet established an ongoing source of revenue sufficient to cover our operating costs and allow us to continue as a going concern. Our ability to continue as a going concern is dependent on obtaining adequate capital to fund operating losses until we become profitable. We plan to obtain additional capital resources by selling our equity securities, selling the ForeCYTE test kits and generating laboratory service revenue from our tests, and borrowing from stockholders or others when needed. However, we cannot assure you that we will be successful in accomplishing any of these plans and, if we are unable to obtain adequate capital, we could be forced to cease operations.

Finally, the acquisition of the Acueity assets may become a complement to our current business at some point in the future. We are not currently allocating human or financial resources to these assets and do not expect to do so until after the launch of our other diagnostic tests in the United States. We intend to complete the steps necessary to begin marketing and selling these tools, such as re-establishment of the supply chain of component parts, securing manufacturers, performing test builds and commercial scale manufacturing, in the first half of 2014. This asset purchase is not expected to have an impact on the development and commercialization timetables of our existing product lines. We cannot, however, provide any assurances that delays related to the launch of our four diagnostic tests, independent of this asset purchase, would not delay the expected development of these diagnostic tools or that we will ultimately be successful selling these tools.

Our Common Stock Purchase Agreements with Aspire Capital Fund, LLC

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

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

the agreement, we must register the shares and have the registration statement declared effective by the SEC. Other terms and conditions of the agreement are described below.

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

As described in more detail below, generally under the purchase agreement we have two ways we can elect to sell shares of common stock to Aspire on any business day we select: (1) through a regular purchase of up to 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"). After the SEC declares the initial registration statement effective, on any business day on which the closing sale price of our common stock equals or exceeds $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 the ForeCYTE Breast Health Test and the Mammary Aspiration Specimen Cytology Test device. The purchase price for this milestone event will be equal to the lower of $2.00 per share or the Regular Purchase Price on the date of the event. The second milestone event is the clearance by the FDA of the foregoing 510(k) application and the purchase price for the shares sold upon the occurrence of this milestone event is the lower of $4.00 per share or the Regular Purchase Price on the date of the event.

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

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

The purchase agreement contains customary representations, warranties, covenants, closing conditions and indemnification and termination provisions. The purchase agreement may be terminated by us at any time, at our discretion, without any cost or penalty. Aspire has covenanted not to cause or engage in any manner whatsoever, any direct or indirect short selling or hedging of our common stock. We did not pay any additional amounts to reimburse or otherwise compensate Aspire in connection with the transaction other than the commitment shares. There are no limitations on use of proceeds, financial or business covenants, 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(2) of the Securities Act and Rule 506 of Regulation D promulgated thereunder.

Revenue Sources

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

Commencing in December 2011, we began to market the ForeCYTE Test to physicians, primarily obstetric-gynecologists, as well as breast health and mammography clinics, for use in conjunction with other health screening examinations, including annual physical examinations and regularly scheduled cervical Pap smears and mammograms. We plan to initially use regional specialty product distributors, with independent sales representatives specializing in Women's Health, to commercialize the ForeCYTE and ArgusCYTE Tests.

Commercial Lease Agreements

On September 29, 2010, the Company entered into a commercial lease agreement with CompleGen, Inc. for laboratory space located in Seattle, WA. The lease provided for monthly rent of $3,658 and a security deposit of $3,658. The lease terms were from September 29, 2010 through March 31, 2011, at which time the lease has converted to month to month. The monthly rent for the lease increased to $4,267 commencing January 2012. The lease was terminated in December 2012, and the rental deposit was applied to the rent of the final month.

On March 4, 2011, the Company entered into a commercial lease agreement with Sanders Properties, LLC for office space located in Seattle, WA. The lease provides for monthly rent of $1,100 and a security deposit of $1,500. The lease terms are from April 1, 2011 through March 31, 2014. For the nine months and three months ended September 30, 2013, the Company incurred $8,800 and $3,300 of rent expense, respectively, for the lease.

On December 9, 2011, the Company entered into another commercial lease agreement with Fred Hutchinson Research Center for lab and office space located in Seattle, WA. The lease provides for monthly rent of $16,395 for the period from February 24, 2012 to August 31, 2012, $19,923 for the period from September 1, 2012 to August 31, 2013, and $20,548 for the period from September 1, 2013 to November 29, 2014. The security deposit of $32,789 was paid in March 2012 and recorded as Security Deposit on the consolidated balance sheet. For the three months and nine months ended September 30, 2013, the Company incurred $87,521 and $251,659 of rent expense, respectively, which included leasing office management expenses.

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

We expect that these new laboratory facilities will be sufficient to meet our needs for the foreseeable future and we do not expect to need additional laboratory space for at least the next 24 months. We may need to secure additional office space as we grow our sales and marketing force and add to our administrative staff. Additional office space is readily available in our local market and we believe we can rent when necessary additional office space on acceptable terms.

Legal Proceedings

On June 30, 2011, Robert Kelly, the Company's former President, filed a counterclaim against the Company in an arbitration proceeding, alleging breach of contract in connection with the termination of a consulting agreement between Mr. Kelly (dba Pitslayer LLC) and the Company that was entered into in July 2010 in connection with his resignation from the Company as President and a director. The consulting agreement was terminated by the Company

in September 2010. Mr. Kelly seeks $450,000 in compensatory damages, which is the amount he claims would have been earned had the consulting agreement been fulfilled to completion.

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

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

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

The Company is reasonably confident in its defenses to Mr. Kelly's and Mr. Cononi's claims. Consequently, no provision or liability has been recorded for these claims as of June 30, 2013. However, it is at least reasonably possible that the Company's estimate of liability may change in the near term. Any payments by reason of an adverse determination in this matter will be charged to earnings in the period of determination.

On October 10, 2013, a putative securities class action complaint was filed in the United States District Court for the Western District of Washington against us, certain of our directors and officers and the underwriters of our November 2012 initial public offering. The complaint alleges that all defendants violated Sections 11 and 12(a)(2), and that we and certain of our directors and officers violated Section 15, of the Securities Act by making false and misleading statements and omissions in the offering's registration statement, and that we and certain of our directors and officers violated Sections 10(b) and 20A of the Exchange Act and SEC Rule 10b-5 promulgated thereunder by making false and misleading statements and omissions in the registration statement and in certain of our subsequent press releases and SEC filings with respect to our NAF specimen collection process, our ForeCYTE Breast Health Test and our MASCT device. This action seeks, on behalf of persons who purchased our common stock between November 8, 2012 and October 4, 2013, inclusive, damages of an unspecific amount.

We believe this complaint is without merit and plan to defend ourselves vigorously. Failure by us to obtain a favorable resolution of the claims set forth in the complaint could have a material adverse effect on our business, results of operations and financial condition. Currently, the amount of such material adverse effect cannot be reasonably estimated, and no provision or liability has been recorded for these claims as of September 30, 2013. The costs associated with defending and resolving the complaint and ultimate outcome cannot be predicted. These matters are subject to inherent uncertainties and the actual cost, as well as the distraction from the conduct of our business, will depend upon many unknown factors and management's view of these may change in the future.

Critical Accounting Policies and Estimates

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

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

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Revenue Recognition

Overview

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

Product Revenue

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

Service Revenue

We record revenue for diagnostic testing on an accrual basis at the Medicare allowed and invoiced amount. Amounts invoiced above the Medicare amount, namely non-Medicare, are not recognized on an accrual basis and instead are recognized on a cash basis as received. Diagnostic testing revenue at the Medicare rate is recognized upon completion of the test, communication of results to the patient's physician, and when collectability is reasonably assured. Customer purchase orders and/or contracts will generally be used to determine the existence of an arrangement. Once the Company has historical sales and can determine the proper amount to recognize as uncollectible, it will then begin to recognize the entire amount, both Medicare and non-Medicare billing on an accrual basis, with an offsetting allowance for doubtful accounts recorded based on history. We estimate we will utilize the diagnostic testing revenue history to determine a proper allowance for doubtful accounts beginning in 2014.

Accounts Receivable

Accounts receivable are recorded at net realizable value consisting of the carrying amount less allowance for doubtful accounts, as needed. The Company assesses the collectability of accounts receivable based primarily upon the creditworthiness of the customer as determined by credit checks and analysis, as well as the customer's payment history. Management reviews the composition of accounts receivable and analyzes historical bad debts, customer concentrations, customer credit worthiness, current economic trends, and changes in customer payment patterns to evaluate the adequacy of these reserves. The Company's allowance for doubtful accounts and bad debt expenses as of September 30, 2013 and December 31, 2012 was $228,841 and $0, respectively.

Inventory

The Company's inventories are stated at lower of cost or market. Cost is determined on a moving-average basis. Costs of inventories include purchase and related costs incurred in delivering the products to their present location and condition. Market value is determined by reference to selling prices after the balance sheet date or to management's estimates based on prevailing market conditions. Inherent in the lower of cost or market calculation are several significant judgments based on a review of the aging of the inventory, inventory movement of products, economic conditions, and replacement costs. Because the sales price of the MASCT System was substantially lower than its cost for the nine months ended September 30, 2013 and since inception through September 30, 2013, resulting in the net

realizable value of the MASCT System being determined at zero as of the balance sheet dates through taking the average sales price subtracted by selling expenses per unit, $0 and $121,910 of loss on reduction of inventory to the lower of cost or market was assessed and recorded as of September 30, 2013 and since inception through September 30, 2013, respectively. Additionally, management periodically evaluates the composition of its inventories at least quarterly to identify slow-moving and obsolete inventories to determine if valuation allowance is required. As of September 30, 2013, we had no inventory.

The Company provides, either directly or through distributors, the ForeCYTE testing specimen collection kits to doctors with our MASCT System for doctors to collect specimens that are returned to the Company for diagnostic analysis. These collection kits are considered part of the MASCT System. During the initial marketing phase in 2012, the Company distributed the kits to customers at no cost and bundled them with the MASCT System, and has not intended to deem the kits as a primary product line due to their nominal cost and value per unit. As a result, the kits are immediately expensed and recorded as selling expense upon purchasing of the kits.

Use of Estimates

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

Intangible Assets

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

Share-Based Payments

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

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

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

three years so long as the executive remains employed with the company. These options have five-year contractual terms.

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

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

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

(ii) 11,250 option shares shall vest one hundred and eighty (180) days after the date of grant;

(iii) 11,250 option shares shall vest two hundred and seventy (270) days after the date of grant; and

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

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

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

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

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

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

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

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

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

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

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

Results of Operations

Three Months and Nine Months Ended September 30, 2013 and 2012

Revenue and Cost of Goods Sold. For the three months ended September 30, 2013, revenue totaled $76,597, consisting of $72,187 diagnostic testing service revenue from our ForeCYTE testing services and $4,410 in product sales revenue from sales of ForeCYTE kits and MASCT Systems. This represents a decrease of $28, 979, or 27 %, from the total revenue of $105,576 for the three months ended September 30, 2012. Revenue for the nine months ended September 30, 2013 totaled $585,345, consisting of $361,905 in diagnostic testing and $223,440 in product sales, an increase of $201,959, or 53%, from the total revenue of $383,386 in the same period in 2012. The growth in revenue is mainly due to $205,590 in product sales to Millennium for the initial purchase of 10,000 ForeCYTE kits.

Cost of revenue totaled $25,938 and $314,562 for the three and nine months ended September 30, 2013, compared to $9,000 and $29,985 in the same periods in 2012. The increase in cost of revenue is primarily attributable to cost of product sales to Millennium. Since the inventory of MASCT System was recorded at zero net realizable value as a result of the lower of cost or market analysis performed at December 31, 2012, no corresponding cost of goods sold was recorded for the sales of MASCT System during 2013.

For the three months ended September 30, 2013, gross profit totaled $50,659, compared to $90,499 profit in the same period in 2012. For the nine months ended September 30, 2013, gross profit totaled $270,783 ($286,012 gross profit on diagnostic testing and $15,229 loss on product sales), compared to $323,517 in the same period in 2012. Loss on reduction of inventory to lower of cost or market was $0 for the nine months ended September 30, 2013. Our MASCT System is sometimes sold at a price substantially lower than its cost as is customary for laboratories that supply specimen collection kits. For these reasons, the manufacturing cost allocated to each inventory unit is high.

Operating Expenses. For the three months ended September 30, 2013, total operating expenses were $3, 552,556 consisting of G&A expenses of $2, 858,027, research and development expenses of $321,111, and selling expenses of $373,418, representing an increase of $2, 326,385, or 190% from $1,226,171 in the same period in 2012, consisting of G&A expenses of $548,108, research and development expenses of $590,359, and selling expenses of $87,704. For the nine months ended September 30, 2013, total operating expenses were $8,297,460, consisting of G&A expenses of $6,600,819, research and development expenses of $731,258, and selling expenses of $965,383, an increase of $4,610,291,or 125% , from total operating expenses of $3,687,169 in nine months ended September 30, 2012.

The Company distributes the kits to customers at no cost and bundles them with the MASCT System and has not intended to deem the kits as a primary product line due to their nominal cost and value per unit. We expect that our G&A and selling expenses continue to increase in the foreseeable future, and that if we successfully launch the MASCT System and our related laboratory service offerings, we would also begin to incur additional sales and marketing expenses as we continue building a regional, and ultimately national, sales force. The Company also expected to incur additional sales and marketing expenses when if and when it receives additional FDA 510(k) clearance for its ForeCYTE Test and re-launches the test.

General and Administrative Expenses. G&A expenses for the three months ended September 30, 2013 were $2,858,027, an increase of $2, 267,668, or 384%, from $590,359 in the same period in 2012. The G&A expenses for the three months ended September 30, 2013 consisted primarily of $581,591 in salaries and bonus expense, $155,558 in legal and regulatory expense, $193,671 in consulting expense, $435,243 in estimated recall expenses ($402,840 in contingent liabilities and $32,403 in actual expenses), $228,841 in bad debt expenses, $67,141 in travel expense, $88,263 in insurance expense, and $248,759 in marketing expenses. G&A expenses for the nine months ended September 30, 2013 were $6,600,819, an increase of $4,704,565, or 248%, from $1,896,254 for the nine months ended 2012. The G&A expenses for the nine months ended September 2013 consisted of $1,548,899 in salaries and bonus expense, $428,872 in capital raising fees, $622,581 in legal and regulatory expenses, $646,548 in consulting expense, $435,243 in estimated recall expenses ($402,840 in contingent liabilities and $32,403 in actual expenses), $228,841 in bad debt expenses, $135,686 in travel expense, $247,774 in insurance expense, $250,109 in marketing expenses, and $462,029 in Board of Directors annual fees primarily related to expenses associated with stock option grants for service on the Board in 2012 and 2013.

G&A expenses for the three months ended September 30, 2012 were $590,359 which primarily consisted of $23,357 in salaries and bonus expense, $310,301 in legal expenses, $49,579 in consulting expense, and $19,494 in insurance expense, G&A expenses for the nine months ended September 30, 2012 were $1,896,254 and primarily consisted of $224,521 in salaries and bonus expense, $883,399 in legal expenses, $151,245 in consulting expense, $25,541 in travel expense, $53,584 in insurance expense, and $38,500 in Board of Directors annual fees.

The increase in 2013 G&A expenses over 2012 was primarily attributable to an increase in administrative staff, an increase in consulting and professional fees related to regulatory matters and investor relations, an increased cost of insurance, estimated product recall expenses, bad debt expenses and an increased cost of fees to our non-employee directors resulting from the estimated value of options granted in 2013 for service in 2012 and 2013. We expect our G&A expenses will continue to grow as we hire additional administrative and manufacturing personnel to continue our launch of the MASCT System, and in particular when we re-launch our ForeCYTE Test after receiving additional FDA clearance, and our other products under development and as we incur additional costs associated with being a

publicly traded company.

Research and Development Expenses. Research and Development expenses for the three months ended September 30, 2013 were $321,111, a decrease of $226,997, or 41%, from $548,108 for the three months ended September 30, 2012. R&D expenses for the nine months ended September 30, 2013 were $731,258, a decrease of $777,686, or 52%, $1,508,944 from the same period in 2012. The decrease in R&D expenses over the three and nine months ended September 30, 2012 is attributed to the completion of the development of the MASCT System for the national launch in 2013. We expect that our R&D expenses will increase as we add additional full time employees and incur additional costs to continue the development of our products and services under development.

Selling Expenses. Selling expenses for the three months ended September 30, 2013 were $373,418, an increase of $285,714, or 326%, from $87,704 for the three months ended September 30, 2012. Selling expense for the three months ended September 30, 2013 consisted primarily of $52,237 in selling and marketing professional fees, $205,875 in salaries, $22,500 in advertising, and $92,349 in patient collection kits provided to physicians without charge. Selling expenses for the nine months ended September 30, 2013 were $965,383, an increase of $683,412, or 242%, from $281,971 for the same period in 2012. Selling expense for the nine months ended September 30, 2013 consisted primarily of $384,893 in selling and marketing professional fees, $405,474 in salaries, $81,587 in advertising, and $92,349 in patient collection kits provided to physicians without charge. Selling expenses increased as a result of increased sales and marketing expenses paid to one of our distributors, and increased salaries and other selling and marketing expenses related to the national launch of ForeCYTE.

Liquidity and Capital Resources

We have a history of operating losses as we have focused our efforts on raising capital and building the MASCT System. The report of our independent auditors issued on our consolidated financial statements as of and for the years ended December 31, 2012 and 2011 expresses substantial doubt about our ability to continue as a going concern. In 2011, we were successful in raising net proceeds of $5.7 million through a private placement in order to fund the growth of our operations and product development. In November 2012 we were successful in our initial public offering and raising net proceeds of approximately $3.5 million.

On March 27, 2013 we entered into a stock purchase agreement with Aspire Capital Fund, LLC, which provides that, upon the terms and subject to the conditions and limitations set forth therein, Aspire is committed to purchase up to an aggregate of $30 million of shares of our common stock over the three-year term of the agreement. Under the agreement, Aspire purchased $1,000,000 of our common stock on March 27, 2013 for $12 per share and since that date through November 7, 2013 Aspire has purchased an additional 2,150,000 shares of our common stock for a total aggregate purchase price of $10,303,745. On November 8, 2013, we terminated this stock purchase agreement and entered into a new agreement with Aspire which provides that we may sell common stock to Aspire under the terms and subject to the conditions and limitations set forth therein. Under the new agreement, Aspire is committed to purchase up to an aggregate of $25 million of shares of our common stock over the 30 month term of the new agreement. One condition to utilizing the new agreement and selling stock to Aspire is that we file a registration statement with the SEC covering the resale of the shares to be sold to Aspire and that the registration statement be declared and remain effective.

Our ability to continue as a going concern is dependent on our obtaining additional adequate capital to fund additional operating losses until we become profitable. If we are unable to obtain adequate capital, we could be forced to cease operations.

Cash Flows

For the nine months ended September 30, 2013, we incurred a net loss of $8,026,984. Net cash used in operating activities was $6,182,060, net cash used in investing activities was $400,674 and net cash provided by financing activities was $12,551,098. For the for the nine months ended September 30, 2012, we incurred a net loss of

$3,374,249, net cash used in operating activities was $1,967,626, net cash used in investing actives was $0 and net cash used by financing activities was $475,375.

Funding Requirements

We expect to incur substantial expenses and generate ongoing operating losses for the foreseeable future as we prepare for the scale-up manufacturing and ongoing launch of the MASCT System, complete the development of and launch the FullCYTE and NextCYTE Tests, and build and operate our planned diagnostics laboratory in the Fred Hutchinson Cancer Research Center. We expect our existing capital resources as of the date of this report to be sufficient to fund our planned operations for at least the next six to ten months. To fund our operations for at least the next 12 months under our current business plan, we estimate that we would need between $2 million and $5 million of additional capital. If we are unable to raise this amount of capital, however, we could be forced to curtail or cease operations. Our future capital uses and requirements depend on numerous forward-looking factors. These factors include the following:

- the time and funds needed to complete our recall, receive an additional 510(k) clearance from the FDA and to re-launch our ForeCYTE Test;

- the time and funds needed to complete the development and manufacturing of the ForeCYTE Test devices and Microcatheter Systems and any necessary regulatory clearances;

- the expense associated with building a network of sales representatives to market the ForeCYTE System and ArgusCYTE Test; and

- the degree and speed of patient and physician acceptance of our products and the degree to which third-party payors approve the ForeCYTE and ArgusCYTE Tests for reimbursement.

Since inception (April 30, 2009) through September 30, 2013, we have generated $1,068,687 in revenue. We do not expect to generate significant revenue until we are able to manufacture and launch the MASCT System more broadly. We expect our continuing operating losses to result in increases in cash used in operations over at least the next year. Although we expect our existing resources as of the date of this report, to be sufficient to fund our planned operations for at least the next six to ten months, we may require additional funds earlier than we currently expect to successfully commercialize the ForeCYTE System. Because of the numerous risks and uncertainties associated with the development and commercialization of the ForeCYTE Test and our services, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated research and development activities and commercialization efforts.

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

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

Off-Balance Sheet Arrangements

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

Recent Accounting Pronouncements

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

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ITEM 3. QUANTATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

Not applicable.

ITEM 4. CONTROLS AND PROCEDURES

Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2013. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended ("Exchange Act"), means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the Securities and Exchange Commission's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of September 30, 2013, our principal executive officer and principal financial officer concluded that, as of such date, the Company's disclosure controls and procedures were effective at the reasonable assurance level.

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the quarter ended September 30, 2013 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

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

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

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

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

The Company is reasonably confident in its defenses to Mr. Kelly's and Mr. Cononi's claims. Consequently, no provision or liability has been recorded for these claims as of September 30, 2013. However, it is at least reasonably possible that the Company's estimate of liability may change in the near term. Any payments by reason of an adverse determination in this matter will be charged to earnings in the period of determination.

On October 10, 2013, a putative securities class action complaint was filed in the United States District Court for the Western District of Washington against us, certain of our directors and officers and the underwriters of our November 2012 initial public offering. The complaint alleges that all defendants violated Sections 11 and 12(a)(2), and that we and certain of our directors and officers violated Section 15, of the Securities Act by making false and misleading statements and omissions in the offering's registration statement, and that we and certain of our directors and officers violated Sections 10(b) and 20A of the Exchange Act and SEC Rule 10b-5 promulgated thereunder by making false and misleading statements and omissions in the registration statement and in certain of our subsequent press releases and SEC filings with respect to our NAF specimen collection process, our ForeCYTE Breast Health Test and our MASCT device. This action seeks, on behalf of persons who purchased our common stock between November 8, 2012 and October 4, 2013, inclusive, damages of an unspecific amount.

We believe this complaint is without merit and plan to defend ourselves vigorously. Failure by us to obtain a favorable resolution of the claims set forth in the complaint could have a material adverse effect on our business, results of operations and financial condition. Currently, the amount of such material adverse effect cannot be reasonably estimated, and no provision or liability has been recorded for these claims as of September 30, 2013. The costs associated with defending and resolving the complaint and ultimate outcome cannot be predicted. These matters are subject to inherent uncertainties and the actual cost, as well as the distraction from the conduct of our business, will depend upon many unknown factors and management's view of these may change in the future.

ITEM 1A. RISK FACTORS

RISK FACTORS

A purchase of our shares of Common Stock is an investment in our securities and involves a high degree of risk. You should carefully consider the following information about these risks, together with the other information contained in this report, before purchasing our securities. If any of the following risks actually occur, our business, financial condition and results of operations would likely suffer. In that case, the market price of the Common Stock could decline, and you may lose part or all of your investment in our company. Additional risks of which we are not presently aware or that we currently believe are immaterial may also harm our business and results of operations.

Risks Relating to our Business

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

We are a development stage company, with operations beginning in December 2008 around acquiring the MASCT System patent rights and assignments and the FDA clearance for marketing, which was completed in January 2009. We were incorporated in Delaware in April 2009 and our operations to date have consisted primarily of securing manufacturing for the MASCT and the Duct Microcatheter Systems, establishing our CLIA-certified laboratory, validating the laboratory developed tests we use in the ForeCYTE and ArgusCYTE tests, conducting research and development on the FullCYTE and NextCYTE tests, securing distribution partners and beginning the commercialization of our products. We did not begin the national launch of the ForeCYTE test until January 2013 and we subsequently recalled that product in October 2013. We will require significant additional capital to achieve our business objectives, and the inability to obtain such financing on acceptable terms or at all could lead to closure of the business.

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

- execute our business plan and commercialization strategy, including with respect to the assets we acquired from Acueity Healthcare, Inc.;
- work with contract manufacturers to produce the MASCT and Microcatheter Systems in commercial quantities;
- create brand recognition;
- respond effectively to competition;
- manage growth in operations;
- respond to changes in applicable government regulations and legislation;
- access additional capital when required;
- obtain regulatory clearances in a timely manner and maintain those clearances, including for our lead product the ForeCYTE Breast Health Test which was recalled in October 2013 and for which we plan to seek an additional regulatory clearance;
- sell our products and service at the prices currently expected; and
- attract and retain key personnel.

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

The report of our independent auditors contained in our consolidated financial statements explains that we have not yet established an ongoing source of revenue sufficient to cover operating costs and allow us to continue as a going

concern. Our ability to continue as a going concern is dependent on obtaining adequate capital to fund operating losses until we become profitable. If we are unable to obtain adequate capital, we may be unable to expand our product offerings or geographic reach and we could be forced to cease operations.

Anticipated liquidity issues in the next six to ten months.

For the year ended December 31, 2012, we generated $483,342 in revenue from the sale of our products and services and we incurred a net loss of $5,079,851. For the nine months ended September 30, 2013, we generated $585,345 in revenue from the sale of our products and services and incurred a net loss of $8,026,984. Through September 30, 2013, we had an accumulated deficit of approximately $17,758,642. As of the date of this report, we expect that our existing resources will be sufficient to fund our planned operations for at least the next six to ten months. We have not yet established an ongoing source of revenue sufficient to cover our operating costs and allow us to continue as a going concern. Our only source of revenue has historically been from our ForeCYTE Test, which was recalled commencing in October 2013 and will not be re-launched without an additional regulatory clearance. Our ability to continue as a going concern is dependent on obtaining adequate capital to fund operating losses until we become profitable. We may not achieve profitability from the sale of our products and services in the next six to ten months and other sources of capital may not be available when we need them or on acceptable terms. For example, we may not be able to raise capital by selling Common Stock to Aspire because our stock price may not be at the minimum $0.25 price per share required under our agreement with Aspire, or the Aspire registration statement may not become and remain effective. If we are unable to raise in a timely fashion the amount of capital we anticipate needing, from Aspire or otherwise, we would be forced to curtail or cease operations.

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

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

- we may be required to submit additional clinical data that we do not have and cannot obtain in a timely manner;
- the FDA may not agree with the scope or content of our proposed protocol and study design, including our identification and analysis of the devices and processes we are using as predicates;
- the FDA may request that we submit additional information, data and studies, either prospectively or retrospectively, related to the collection and preparation of NAF samples, or the processing and analysis of NAF samples at our laboratory or at other laboratories, which we may not be able to obtain in a timely manner or at all. For example, in connection with a previous 510(k) that we submitted the FDA requested that we provide data on NAF processing by multiple third party laboratories and we were not able to provide that information;
- although we plan to have a meeting with the FDA before submitting our 510(k) to them, any input from the FDA at that meeting is not binding on the FDA and the FDA can raise objections to our 510(k) submission that were not raised at the pre-submission meeting;
- review by the FDA of our proposed 510(k) submission could be delayed because the FDA has up to 90 days to review the application, which time period is extended while we are responding to any FDA questions;
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if we conclude that the FDA is likely not to clear our 510(k) submission for any reason we may decide to withdraw the submission and file a new 510(k) notification. For example, we previously filed a 510(k) for the MASCT System which we withdrew on the 89th day of its pendency because the FDA requested information that we could not provide in a timely fashion;

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

- our responses to the warning letter we received by the FDA in February 2013 could raise questions by the FDA that could impact their review of our 510(k) submission;

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

- we anticipate that the FDA will again inspect our facilities in connection with the warning letter we received in February 2013 and they could make observations resulting from that inspection that could adversely impact our 510(k) submission.

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

The scope of any 510(k) clearance that we might receive from the FDA covering our ForeCYTE Test 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 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 our ForeCYTE Test. For example, the indication for use for our MASCT System that was cleared in 2003 states that the "MASCT device is intended for use in the collection of nipple aspirate fluid for laboratory cytological testing. The collected fluid can be used in the determination and/or differentiation of normal versus premalignant versus malignant cells." The new indication for use that we intend to clear with the FDA is potentially more limited in that it provides that the "ForeCYTE Breast Health Test is intended for use in the collection, preparation, and processing of nipple aspirate fluid (NAF) specimens for cytological testing. The processing of specimens and the cytological testing are performed in a single laboratory. This indication for use could be further limited while we pursue our additional 510(k) clearances.

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

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

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

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

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

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

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

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

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

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

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

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

We expect to spend substantial amounts of capital to:

- complete the recall of the ForeCYTE Test and pursue an additional 510(k) clearance for the device;
- launch and commercialize the ForeCYTE and ArgusCYTE Tests, including the manufacture of the device in commercial quantities and building a direct sales force and an independent distributor sales force to address certain markets;
- maintain laboratory facilities for our testing and analytical services, including necessary testing equipment;
- continue our research and development activities to advance our product pipeline, including our intraductal treatment program; and
- develop and commercialize the assets we recently acquired from Acueity Healthcare, Inc.

We also expect that we may need to raise additional funds if we encounter delays or problems in the production of the ForeCYTE device in commercial quantities, or the establishment of a larger sales force. As of September 30, 2013, we had cash and cash equivalents of $7,693,561. 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, we must first have a registration statement covering the shares declared effective by the SEC and the registration statement must remain effective. Any sales of shares to Aspire will be limited by market conditions and the number of shares that we may be able to sell will be reduced if the volume of our Common Stock declines. We have not identified other sources for additional funding and cannot be certain that additional funding will be available on acceptable terms, or at all. If we are unable to raise additional capital in sufficient amounts or on acceptable terms, we may have to significantly delay, scale back or discontinue the commercialization of our products and services or our research and development activities. Furthermore, such lack of funds may inhibit our ability to respond to competitive pressures or unanticipated capital needs, or may force us to reduce operating expenses, which could significantly harm the business and development of operations. Because our independent auditors have expressed doubt as to our ability to continue as a “going concern,” as reported in their report on our financial statements, our ability to raise capital may be severely hampered. Similarly, our ability to borrow any such capital may be more expensive and difficult to obtain until this “going concern” issue is eliminated.

We have a history of operating losses 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 $17,758,892 from our incorporation in April 2009 through September 30, 2013. We have received $483,342 in revenue as of December 31,

2012 and $585,345 in revenues for the nine months ended September 30, 2013. We do not expect to generate any revenues until we can obtain an additional regulatory clearance for our lead product, the ForeCYTE Test. Additionally, we will continue to incur further losses in connection with inventory costs for our medical test products, marketing and sales expenses in launching our products and services, research and development costs for additional tests, and the maintenance of our CLIA-certified laboratory. For example, the sales price of our MASCT System has historically been substantially lower than its cost because the MASCT System is currently manufactured only in small quantities and because our current marketing strategy is to attempt to quickly penetrate the market of the products and services offered by the Company by offering the MASCT System at a price substantially lower than its cost and to offer rebates of the purchase price to attract market awareness. This practice of selling our MASCT System substantially below its cost and offering rebates negatively impacts our profitability. Although we expect that the cost to manufacture our MASCT System will be substantially lower when we increase the volume of production for post-trial commercial launch and once we have been more successful in penetrating the market, if our expectation is not realized we may not be able to generate significant revenue nor achieve profitability. Accordingly, we may never achieve profitability.

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. Lead plaintiff has not been identified as of the date of this report. The complaint alleges that the defendants made false or misleading statements. Although we believe this complaint is without merit and plan to defend it vigorously, the costs associated with defending and resolving the complaint and ultimate outcome cannot be predicted.

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

Raising funds by issuing equity or debt securities could dilute the value of the common stock and impose restrictions on our working capital.

If we were to raise additional capital by issuing equity securities, including sales of shares of Common Stock to Aspire, the value of the then outstanding common stock would be reduced, unless the additional equity securities were issued at a price equal to or greater than the market value of the common stock at the time of issuance of the new securities. If the additional equity securities were issued at a per share price less than the per share value of the outstanding shares, then all of the outstanding shares would suffer a dilution in value with the issuance of such additional shares. Further, the issuance of debt securities in order to obtain additional funds may impose restrictions on our operations and may impair our working capital as we service any such debt obligations.

The products and services that we have developed or may develop may never achieve significant commercial market acceptance.

We may not succeed in achieving commercial market acceptance of any of our products and services. In order to market the MASCT System and to gain market acceptance for the MASCT System and our ForeCYTE and ArgusCYTE Tests, we will need to demonstrate to physicians and other healthcare professionals the benefits of the MASCT System and its practical and economic application for their particular practice. Even if we obtain FDA clearance for the MASCT System, many physicians and healthcare professionals may be hesitant to introduce new services, or techniques, into their practice for many reasons, including the learning curve associated with the adoption of such new services or techniques into already established procedures and the uncertainty of the applicability or reliability of the results of a new product. In addition, the availability of full or even partial payment for our products and tests, whether by third-party payors (e.g., insurance companies), or the patients themselves, will likely heavily influence physicians' decisions to recommend or use our products and services.

We will likely be increasingly required to offer discounted pricing arrangements and rebates to managed care payors and physicians and other referral services in response to competitive pressures and to promote early adoption.

There are other companies within the medical device product industry that have products used in NAF collection and there are laboratories other than ours that can process NAF samples. Because of this existing competition, as well as potential future competition from additional companies and laboratories and to promote early adoption, we will likely be increasingly required to offer discounted pricing arrangements and rebates to managed care payors, physicians and other referral services so that our products and services are selected over the products and services of others. If we offer such discounted pricing arrangements and rebates, our revenue will decrease and we may not generate sufficient revenue to cover our operating costs, which could materially adversely affect our business.

Additionally, such discounts and rebates could raise issues under the federal Anti-Kickback Statute and Medicare's discriminatory billing prohibition. If we were found to be in violation of such statute or prohibition, we could be subject to significant fines, and these fines would likely materially adversely affect our business and results of operations.

We may encounter difficulties in operating or maintaining our laboratory facility, which could cause delays and unexpected problems.

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

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

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

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

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

retain qualified personnel, revenue and earnings may be adversely affected.

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

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

Although we entered into distribution agreements with Clarity, Fisher Healthcare, Millennium Healthcare and PSS Medical Surgical, they may not be successful in selling our products and we may not achieve any level of commercial success from their efforts. The current recall of the ForeCYTE Test may cause our distributors to terminate our agreements with them or otherwise cause them not to sell our ForeCYTE devices or other products.

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

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

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

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

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

In September 2012, we acquired the assets of Acueity Healthcare, Inc. The purchased assets included 35 issued patents (18 issued in the U.S. and 17 issued in foreign countries) and 41 patent applications (32 in the U.S. and 9 in foreign countries), six 510(k) FDA marketing authorizations related to the manufacturing, use, and sale of the Viaduct Miniscope and accessories, the Manoa Breast Biopsy system, the Excisor Bioptome, the Acueity Medical Light Source, the Viaduct Microendoscope and accessories, and cash in the amount of $400,000. The patents relate to

intraductal diagnostic and therapeutic devices and methods of use. We did not, however, acquire an inventory of these diagnostic tools, manufacturing capabilities or any personnel to market and sell the tools. We do not intend to begin to allocate human and financial resources to further develop and ultimately commercialize these medical devices until completion of the launch of our four diagnostic tests in the United States. We intend to complete the steps necessary to begin marketing and selling these tools, such as re-establishing the supply chain of component parts, securing manufacturers, performing test builds and commercial scale manufacturing in 2014. We cannot, however, provide any assurances that delays related to the launch of our four diagnostic tests, independent of the asset purchase, would not delay the expected development of these diagnostic tools or that, even if we devote resources to the development of these medical devices that we will ultimately be successful selling these tools.

Our intended products and services may expose us to possible litigation and product liability claims.

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

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

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

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

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

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

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

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- misinterpretation of the results of the test or collected data.

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

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

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

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

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

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

- the patents of others will not have an adverse effect on our business;

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

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

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

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

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

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

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

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

scope of protection offered by our patents.

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

Risks Related to our Industry

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

We received a Warning Letter ("Letter") from the FDA on February 21, 2013, regarding our MASCT System and MASCT System Collection Test (together, the "System"). The Letter arose from certain FDA findings during a July 2012 inspection, to which we responded in August 2012, explaining why we believed we are in compliance with applicable regulations and/or were implementing changes responsive to the findings of the FDA inspection. The FDA alleges in the Letter that following 510(k) clearance we changed the System in a manner that requires submission of an additional 510(k) notification to the FDA. Specifically, the FDA observes that the Instructions For Use (IFU) in the original 510(k) submission stated that the user must "Wash the collection membrane with fixative solution into the collection vial…" and the current IFU states "…apply one spray of Saccomanno's Fixative to the collection membrane…" and that "this change fixes the NAF specimen to the filter paper rather than washing it into a collection vial." At the time that the changes were made we determined 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 Letter also raises certain issues with respect to our marketing of the System and our compliance with FDA Good Manufacturing Practices (cGMP) regulations, among other matters. If the FDA does not agree with our position concerning clearance of the System, we may be required to submit and receive clearance of a new 510(k) notice for the current form of the System or revert to marketing the System using the prior NAF processing method.

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

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

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

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

treatment program. However, if we cannot contract with a third party in a timely and efficient manner or if we cannot obtain a PMA for this program our operations would be adversely affected. We are also pursing an additional 510(k) clearance for our MASCT System, and failure to obtain this clearance would adversely affect our business. To help ensure that the 510(k) includes the information that FDA feels is appropriate, we have requested a pre-submission meeting with the FDA. This meeting is scheduled to be held on November 14, 2013. Once we understand what types of data FDA is seeking, we intend to submit the 510(k) shortly after the meeting. Once filed we hope that the FDA will complete their review of our submission within 90 days; but of course we cannot predict if they will ask us for additional information or otherwise complete their review within the 90 days.

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

Sales of our products outside the U.S. are subject to foreign regulatory requirements that vary from country to country. The time required to obtain approvals from foreign countries may be longer or shorter than that required for FDA approval 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.

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

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

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

The HIPAA privacy regulations establish a “floor” of minimum protection for patients as to their medical information and do not supersede state laws that are more stringent. Therefore, we are required to comply with both HIPAA

privacy regulations and various state privacy laws. The failure to do so could subject us to regulatory actions, including significant fines or penalties, and to private actions by patients, as well as to adverse publicity and possible loss of business. In addition, federal and state laws and judicial decisions provide individuals with various rights for violation of the privacy of their medical information by healthcare providers such as us.

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

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

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

Any sanction imposed under CLIA, its implementing regulations, or state or foreign laws or regulations governing licensure, or our failure to renew a CLIA certificate, a state or foreign license, or accreditation, could have a material adverse effect on our business. Most CLIA deficiencies are not classified as “condition-level” deficiencies, and there are no adverse effects upon the laboratory operations as long as the deficiencies are corrected. Remediation 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 prospectus we do not have any managed care provider contracts and there can be no assurance any contracts will be established. If we do not have a contract with a managed care provider, we may be unable to gain those physicians as clients. In cases in which we will contract with a specified insurance company as a participating provider, we will be considered "in-network," and the reimbursement of third-party payments is governed by contractual relationships. Our in-network services will be primarily negotiated on a fee-for-service basis at a discount from our patient fee schedule, which could result in price erosion that would adversely affect revenue. Our failure to obtain managed care contracts, or participate in new managed care networks, could adversely affect revenue and profitability. In cases in which we do not have a contractual relationship with an insurance company, or are not an approved provider for a government program, we will have no contractual right to collect for services and such payors may refuse to reimburse us for services, which could lead to a decrease in accession volume and a corresponding decrease in revenue. As an out-of-network provider, reductions in reimbursement rates for non-participating providers could also adversely affect us. Third-party payors, with whom we do not participate as a contracted provider, may also require that we enter into contracts, which may have pricing and other terms that are materially less favorable than the terms under which we intend to operate. While accession volume may increase as a result of these contracts, revenue per accession may decrease.

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

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

Laboratory diagnostic tests developed and validated by a laboratory for its own use, also known as laboratory developed tests, which are referred to as LDTs or "home brew" tests, are subject to regulation under the federal Food, Drug and Cosmetic Act, or FDCA. To date, the FDA has decided, as a matter of enforcement discretion, not to exercise its authority with respect to most "home brew" tests performed by high complexity laboratories certified under CLIA, which is the type of laboratory that we have established. In addition, manufacturers and suppliers of analyte specific reagents, or ASRs, which we may utilize in our LDTs, are required to register with the FDA, conform manufacturing operations to the FDA's Quality System Regulation, or QSR, and comply with certain reporting and other record keeping requirements.

The FDA regularly considers the application of additional regulatory controls over the development and use of LDTs by laboratories. It is possible that the FDA will require premarket notification or approval for LDT diagnostic tests that we may develop and perform in the future. For example, the FDA has indicated to us that our laboratory processing of NAF samples constitutes an in-vitro diagnostic test service that is subject to their regulatory authority and we therefore plan to include our laboratory processing in the 510(k) we are submitting to the FDA for our ForeCYTE Test. The FDA held public hearings in the third quarter of 2010 to discuss how it will oversee LDTs. No definitive recommendations or findings have yet come from these hearings, but it is likely that the FDA will impose additional or new regulations affecting LDTs, including requiring premarket notification or approval for these tests.

Any premarket notification or approval requirements could restrict or delay our ability to provide specialized diagnostic services and may adversely affect our business. FDA regulation of LDTs, or increased regulation of the various medical devices used in laboratory-developed testing, could increase the regulatory burden and generate additional costs and delays in introducing new tests.

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

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

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

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

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

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

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

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

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

Risks Related to the Securities Markets and Investment in our Securities

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

Although our shares of common stock are listed on the NASDAQ Capital Market, we cannot ensure that we will be able to satisfy the continued listing standards of the NASDAQ Capital Market going forward. If we cannot satisfy the continued listing standards going forward, NASDAQ may commence delisting procedures against us, which could result in our stock being removed from listing on the NASDAQ Capital Market. 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 our common stock to Aspire may cause substantial dilution to our existing stockholders and the sale, actual or anticipated, of the shares of common stock acquired by Aspire could cause the price of our common stock to decline.

We have the right to sell up to $25 million of our shares of common stock to Aspire, We are obligated to register these shares with the SEC. It is anticipated that these shares will be sold by Aspire over a period of up to approximately 30 months from the date of this report. Under the rules of the Nasdaq Capital Market, in no event may we issue more than 19.99% of our shares outstanding on 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.

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

Since shares of our common stock were sold in our IPO in November 2012 at a price of $5.00 per share, our stock price has ranged from $1.74 to $12.40 through November 8, 2013. In addition to the factors discussed in this prospectus, the trading price of our common stock may fluctuate significantly in response to numerous factors, many of which are beyond our control, including:

- actual or anticipated growth rates and fluctuations in our revenue and other operating results;
- regulatory and FDA actions, including their response to our 510(k) notification we plan to file for the ForeCYTE Test, the warning letter we received from the FDA on February 21, 2013, and our responses to those actions;
- actions of securities analysts who initiate or maintain coverage of us, and changes in financial estimates by any securities analysts who follow our company, or our failure to meet these estimates or the expectations of investors;
- additional shares of our common stock being sold into the market by us or our existing stockholders or the anticipation of such sales; and
- media coverage of our business and financial performance.

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

Substantial shares of our common stock may be sold into the market by which could cause the price of our common stock to decline.

The price of our common stock could decline if there are substantial sales of our common stock, either by us or our stockholders. For example, substantial sales could result from:

- Sales by Aspire of up to $25 million of shares that we may sell to them from time to time under our stock purchase agreement with them.
- 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.

These and any other substantial sales of our common stock into the market could cause the price of our common stock to decline.

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

Our ownership is concentrated among a small number of stockholders, including our founders, directors, officers and entities related to these persons. Our directors, officers and entities affiliated with them beneficially own approximately 28.5% of our outstanding voting securities. Accordingly, these stockholders, acting together, will have the ability to exert substantial influence over all matters requiring approval by our stockholders, including the election and removal of directors and any proposed merger, consolidation or sale of all or substantially all of our assets. This concentration of ownership could have the effect of delaying, deferring or preventing a change in control of the Company or impeding a merger or consolidation, takeover or other business combination that could be favorable to you.

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

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

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

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

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

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

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

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

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

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

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

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

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

None

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

The March 27, 2013 Common Stock Purchase Agreement with Aspire Capital was terminated on November 8, 2013 and on that date we entered into a new stock purchase agreement with Aspire Capital Fund, LLC. The new stock purchase agreement 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. We cannot, however, sell any shares to Aspire under the new agreement unless and until a new registration statement is filed with and declared effective by the SEC. Information about our agreements with Aspire Capital is contained in Part I, Item 2, which is incorporated in this Part II, Item 5, by this reference.

ITEM 6. EXHIBITS

(a) Exhibits

4.1	Registration Rights Agreement, dated as of November 8, 2013, by and between the Company and Aspire Capital Fund, LLC.
10.1	Ownership Program Agreement dated September 1, 2013 between the National Reference Laboratory for Breast Health, Inc. and Affymetrix, Inc.
10.2	Common Stock Purchase Agreement, dated as of November 8, 2013, by and between the Company and Aspire Capital Fund, LLC.
31.1	Certification pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934 of Steven C. Quay
31.2	Certification pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934 of Kyle Guse
32.1	Certification pursuant to 18 U.S.C. Section 1350 of Steven C. Quay
32.2	Certification pursuant to 18 U.S.C. Section 1350 of Kyle Guse
101*	Interactive Data Files pursuant to Rule 405 of Regulation S-T

* Pursuant to Rule 406T of Regulation S-T, these interactive data files are deemed not filed or part of a registration statement or prospectus for purposes of Section 11 or 12 of the Securities Act, are deemed not filed for purposes of Section 18 of the Exchange Act, and otherwise are not subject to liability under these sections.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Date: November 12, 2013

/s/ Steven C. Quay

President and Chief Executive Officer
(On behalf of the Registrant)

/s/ Kyle Guse
Kyle Guse
Chief Financial Officer, General Counsel and Secretary
(As Principal Financial and Accounting Officer)