ATOSSA GENETICS INC
Form 10-Q
November 12, 2014

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, 2014

OR

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

For the transition period from _____ to _____

Commission file number: 001-35610

ATOSSA GENETICS INC.

(Exact name of registrant as specified in its charter)

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

1616 Eastlake Ave. East, Suite 510 **98102**
Seattle, WA (Zip Code)
(Address of principal executive offices)

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 12, 2014 was 24,564,058.

ATOSSA GENETICS INC.

FORM 10-Q

QUARTERLY REPORT

INDEX

PART I. FINANCIAL INFORMATION

ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

ATOSSA GENETICS INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2014 (Unaudited)	December 31, 2013 (Audited)
Assets		
Current assets		
Cash and cash equivalents	$ 11,374,251	$ 6,342,161
Accounts receivable, net	29,151	139,072
Prepaid expense	266,726	280,627
Inventory, net	45,867	-
Total current assets	11,715,995	6,761,860
Furniture and equipment, net	185,000	163,147
Intangible assets, net	4,365,312	4,395,633
Deferred financing costs	426,961	651,961
Security deposit	78,958	36,446
Total assets	$ 16,772,226	$ 12,009,047
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 439,248	$ 248,142
Accrued expenses	393,704	399,478
Deferred rent	8,549	48,157
Payroll liabilities	682,356	476,477
Product recall liabilities	3,385	211,493
Other current liabilities	12,375	23,649
Total current liabilities	1,539,617	1,407,396
Stockholders' Equity		
Preferred stock - $.001 par value; 10,000,000 shares authorized, 0 shares issued and outstanding at September 30, 2014 and December 31, 2013, respectively	-	-
Common stock - $.001 par value; 75,000,000 shares authorized, 24,564,058 and 18,574,334 shares issued and outstanding at September 30, 2014 and December 31, 2013, respectively	24,564	18,574

Additional paid-in capital	44,569,561	31,099,691
Accumulated deficit	(29,361,516)	(20,516,614)
Total stockholders' equity	15,232,609	10,601,651
Total liabilities and stockholders' equity	$ 16,772,226	$ 12,009,047

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

ATOSSA GENETICS INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(UNAUDITED)

	For the Three Months Ended September 30,		For The Nine Months Ended September 30,	
	2014	2013	2014	2013
Revenue				
Diagnostic testing service	$3,426	$72,187	$37,425	$361,905
Product sales	-	4,410	-	223,440
Total Revenue	3,426	76,597	37,425	585,345
Cost of Revenue				
Diagnostic testing service	-	25,938	-	75,893
Product sales	-	-	-	238,669
Total Cost of Revenue	-	25,938	-	314,562
Gross Profit	3,426	50,659	37,425	270,783
Selling expenses	282,374	373,418	743,597	965,383
Research and development expenses	923,169	321,111	1,856,439	731,258
General and administrative expenses	2,043,138	2,858,027	6,280,102	6,600,819
Total operating expenses	3,248,681	3,552,556	8,880,138	8,297,460
Operating Loss	(3,245,255)	(3,501,897)	(8,842,713)	(8,026,677)
Interest income	11	53	154	53
Interest expense	151	1	2,343	360
Loss before Income Taxes	(3,245,395)	(3,501,845)	(8,844,902)	(8,026,984)
Income Taxes	-	-	-	-
Net Loss	$(3,245,395)	$(3,501,845)	$(8,844,902)	$(8,026,984)
Loss per common share - basic and diluted	$(0.13)	$(0.22)	$(0.37)	$(0.55)
Weighted average shares outstanding, basic & diluted	24,537,379	15,830,033	23,860,843	14,697,221

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

ATOSSA GENETICS, INC.

CONDENSED CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY

	Common Stock				
	Shares	**Amount**	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
Balance at December 31, 2013	18,574,334	$ 18,574	$ 31,099,691	$ (20,516,614)	$ 10,601,651
Issuance of common shares for cash	5,834,234	5,834	13,996,328	-	14,002,162
Issuance of common shares for services	22,731	23	(23)	-	-
Financing fees from 2014 Public Offering	-	-	(1,078,417)	-	(1,078,417)
Amortization of deferred financing costs	-	-	(225,000)	-	(225,000)
Issuance of Common shares upon exercise of warrants	20,000	20	31,980	-	32,000
Employees option exercise and cancellation of restricted stock grants	112,759	113	199,887	-	200,000
Compensation cost for stock options granted to executives and employees	-	-	545,115	-	545,115
Net loss for the nine months ended September 30, 2014	-	-	-	(8,844,902)	(8,844,902)
Balance at September 30, 2014	24,564,058	$ 24,564	$ 44,569,561	$ (29,361,516)	$ 15,232,609

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

ATOSSA GENETICS INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(UNAUDITED)

	For the Nine Months Ended September 30,	
	2014	2013
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$(8,844,902)	$(8,026,984)
Adjustments to reconcile net loss to net cash used in operating activities:		
Common shares issued for services	-	144,391
Compensation cost for stock options granted	545,115	1,187,717
Depreciation and amortization	380,977	350,536
Bad debt expense	80,870	228,841
Changes in operating assets and liabilities:		
Accounts receivable	29,051	(386,514)
Inventory	(45,867)	-
Prepaid expenses	(71,099)	71,439
Security deposits	(42,512)	(43,160)
Accounts payable	191,106	(37,086)
Payroll liabilities	205,879	149,493
Deferred rent	(39,608)	60,753
Accrued expenses	(5,774)	(304,626)
Product recall liabilities	(208,108)	402,840
Other current liabilities	(11,274)	20,300
Net cash used in operating activities	(7,836,146)	(6,182,060)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of furniture and fixtures	(102,530)	(346,007)
Purchase of software	(184,979)	(54,667)
Net cash used in investing activities	(287,509)	(400,674)
CASH FLOWS FROM FINANCING ACTIVITIES		
Net proceeds from issuance of common stock and warrants	13,155,745	12,551,098
Net cash provided by financing activities	13,155,745	12,551,098
NET INCREASE IN CASH & CASH EQUIVALENTS	5,032,090	5,968,364
CASH & CASH EQUIVALENTS, BEGINNING BALANCE	6,342,161	1,725,197
CASH & CASH EQUIVALENTS, ENDING BALANCE	$11,374,251	$7,693,561
SUPPLEMENTAL DISCLOSURES:		
Interest paid	$2,343	$359
NONCASH INVESTING AND FINANCING ACTIVITIES:		

Reclassification of furniture and equipment to prepaid expenses	$15,000	$-
Common stock issued as commitment fee under stock purchase agreement	$-	$2,387,250

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

ATOSSA GENETICS INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

NOTE 1: NATURE OF OPERATIONS

Atossa Genetics Inc. (the "Company") was incorporated on April 30, 2009 in the State of Delaware. The Company was initially formed to develop and market medical devices that collect specimens for further testing. The Company's fiscal year ends on December 31st.

In December 2011, the Company established The National Reference Laboratory for Breast Health, Inc., or the NRLBH, as a wholly-owned subsidiary. The NRLBH is a CLIA-certified laboratory which performs tests including nipple aspirate fluid ("NAF") cytology testing and pharmacogenetics testing. The NRLBH is also developing other tests such as the NextCYTE test.

In September 2012, the Company acquired the assets of Acueity Healthcare, Inc. ("Acueity"). The purchased assets included intellectual property rights related to the Viaduct Miniscope and accessories, the Manoa Breast Biopsy system, the Excisor Bioptome, the Acueity Medical Light Source, the Viaduct Microendoscope and accessories, and cash in the amount of $400,000. No liabilities were assumed by Atossa and Atossa assumed no future financial obligations. In consideration for the assets, Atossa provided the following consideration to the shareholders of Acueity: 862,500 shares of common stock, valued at $5.00 per share, and warrants to purchase up to 325,000 shares of common stock at an exercise price of $5.00 per share, valued at $2.3457 per warrant, using a Black-Scholes-Merton Valuation Technique. The acquired 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.

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 condensed 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. These matters raise substantial doubt about the Company's ability to continue as a going concern for the foreseeable future. The accompanying condensed 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 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 its medical devices including the ForeCYTE Breast Aspirator and FullCYTE Breast Aspirator, (3) laboratory services, and (4) 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 condensed consolidated financial statements have been prepared pursuant to the rules of the Securities and Exchange Commission ("SEC"). Certain information and footnote disclosures, normally included in annual financial statements prepared in accordance with U.S. generally accepted accounting principles ("GAAP"), have been condensed or omitted pursuant to those rules and regulations. The Company believes disclosures made are adequate to make the information presented not misleading. In the opinion of management, all adjustments, consisting only of normal recurring adjustments necessary to fairly state the financial position, results of operations and cash flows with respect to the interim condensed consolidated financial statements have been included. The results of operations for the interim periods are not necessarily indicative of the results of operations for the entire fiscal year. Reference is made to the Company’s audited annual financial statements included in its Annual Report on Form 10-K for the year ended December 31, 2013, which contain information useful to understanding the Company's business and financial statement presentations. The Condensed Consolidated Balance Sheet as of December 31, 2013 was derived from the Company's most recent audited financial statements, but does not include all disclosures required by GAAP for a year-end balance sheet. The Company’s significant accounting policies and practices are presented as Note 3 to the consolidated financial statements included in the Annual Report. The accompanying condensed 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 condensed consolidated financial statements have been prepared in accordance with GAAP in the United States of America.

Use of Estimates:

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

Recently Issued Accounting Pronouncements:

The Company has adopted all recently issued accounting pronouncements that management believes to be applicable to the Company.

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

In June 2014, FASB issued ASU 2014-10, *Elimination of Development Stage Entity Requirements.* This ASU eliminates the concept of Development Stage Entities (DSE's) from U.S. GAAP and is intended to result in cost-savings for certain entities, such as start-ups or research and development entities. As a result of these changes; the financial statements of developing entities no longer need to meet the inception-to-date income cash flow and equity information; developing companies do not have to label their financial statements as "development stage"; and certain disclosures related to the nature of the entity's development stage activities are no longer required. The Company adopted the provisions of this ASU beginning with the quarter ended June 30, 2014.

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

Reclassifications:

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

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

NOTE 4: PREPAID EXPENSES

Prepaid expenses consisted of the following:

	September 30, 2014	December 31, 2013
Tradeshow and other marketing events	$ 150,000	$ -
Prepaid hardware and software	42,426	131,204
Prepaid insurance	36,800	112,517
Retainer and security deposits	29,500	36,906
Other	8,000	-
	$ 266,726	$ 280,627

NOTE 5: FURNITURE AND EQUIPMENT

Property, plant furniture and equipment consisted of the following:

	September 30, 2014	December 31, 2013
Machinery and equipment	$ 429,355	$ 326,824
Leasehold improvements	93,665	93,665
Capitalized new product development costs	-	15,000
Less: Accumulated depreciation	(179,728)	(114,050)
Less: Allowance for loss on impairment	(158,292)	(158,292)
Furniture and equipment, net	$ 185,000	$ 163,147

Depreciation expense for the three months ended September 30, 2014 and 2013 were $24,643 and $27,165, respectively, and $65,678 and $62,849 for the nine month periods then ended.

NOTE 6: INTANGIBLE ASSETS

Intangible assets consisted of the following:

	September 30, 2014	December 31, 2013
Patents	$ 4,794,853	$ 4,794,853
Capitalized license costs	200,000	-
Software	190,817	105,839
Less: Accumulated amortization	(820,358)	(505,059)
	$ 4,365,312	$ 4,395,633

Intangible assets amounted to $4,365,312 and $4,395,633 as of September 30, 2014 and December 31, 2013, respectively, and consisted of patents, capitalized license costs and software acquired. The acquired software mainly consisted of $58,000 in laboratory software, $31,500 in the newly developed Company website and $70,400 in internal use SAP Business One ERP system which is under development. The amortization period for the purchased software is three years. Amortization expense related to software for the three months ended September 30, 2014 and 2013 was $4,913 and $5,730, respectively, and $22,436 and $15,322 for the nine month periods then ended.

Patents amounted to $4,794,853 as of both September 30, 2014 and December 31, 2013 and mainly consisted of patents acquired from Acueity on September 30, 2012 in an asset purchase transaction. Patent assets are amortized based on their determined useful life, and tested annually for impairment. The amortization period is from 9 to 14 years. Amortization expense related to patents was $93,497 and $281,196 for the three months and nine months ended September 30, 2014. Amortization expense for patents was $90,977 and $272,992 for the three months and nine months ended September 30, 2013.

Capitalized license costs consist of fees paid to A5 Genetics KFT, Corporation, pursuant to which the Company received the world-wide (other than the European Union) exclusive license to use the software in the NextCYTE test. Amortization expense related to license costs were $5,000 and $11,667 for the three and nine months ended September 30, 2014, respectively.

Future estimated amortization expenses as of September 30, 2014 for the five succeeding years is as follows:

For the Year Ending December 31,	Amounts
2014 (includes the remainder of the year)	$110,215
2015	440,539
2016	433,277
2017	414,957
2018	393,990
Thereafter	2,572,334
	$4,365,312

NOTE 7: PAYROLL LIABILITIES

Payroll liabilities consisted of the following:

	September 30, 2014	December 31, 2013
Accrued bonus payable	$ 566,185	$ 408,362
Accrued payroll liabilities	102,892	48,232
Accrued payroll tax liabilities	13,279	19,883
	$ 682,356	$ 476,477

NOTE 8: STOCKHOLDERS' EQUITY

The Company is authorized to issue a total of 85,000,000 shares of stock consisting of 75,000,000 shares of Common Stock, par value $0.001 per share, and 10,000,000 shares of Preferred Stock, par value $0.001 per share. The Company has designated 750,000 shares of Series A Junior Participating Preferred Stock, par value $0.001 per share through the filing of certificate of designation with the Delaware Secretary of State.

On May 19, 2014, the Company adopted a stockholder rights agreement which provides that all stockholders of record on May 26, 2014 received a non-taxable distribution of one preferred stock purchase right for each share of the Company's common stock held by such stockholder. Each right is attached to and trades with the associated share of common stock. The rights will become exercisable only if one of the following occurs: (1) a person becomes an "Acquiring Person" by acquiring beneficial ownership of 15% or more of the Company's common stock (or, in the case of a person who beneficially owned 15% or more of the Company's common stock on the date the stockholder rights agreement was executed, by acquiring beneficial ownership of additional shares representing 2.0% of the Company's common stock then outstanding (excluding compensatory arrangements) or (2) a person commences a tender offer that, if consummated, would result in such person becoming an Acquiring Person. If a person becomes an Acquiring Person, each right will entitle the holder, other than the Acquiring Person and certain related parties, to purchase a

number of shares of the Company’s common stock with a market value that equals twice the exercise price of the right. The initial exercise price of each right is $15.00, so each holder (other than the Acquiring Person and certain related parties) exercising a right would be entitled to receive $30.00 worth of the Company’s common stock. If the Company is acquired in a merger or similar business combination transaction at any time after a person has become an Acquiring Person, each holder of a right (other than the Acquiring Person and certain related parties) will be entitled to purchase a similar amount of stock of the acquiring entity.

2014 Public Offering of Common Stock and Warrants

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

Placement Agent Fees

In connection with the 2014 Public Offering, the Company paid Dawson James Securities, Inc. (the "Placement Agent"), a cash fee equal to 7% of the gross proceeds from sale of the units, which resulted in a payment to the Placement Agent of an aggregate of $980,151 (the "Placement Agent Fee"). In addition, the Company entered into Warrant Agreements with the Placement Agent pursuant to which the Placement Agent received a warrant to purchase 175,027 shares of common stock, or 3% of the aggregate number of shares sold in the offering (the "2014 Placement Agent Warrants" and together with the 2014 Investor Warrants, the "2014 Warrants"). The 2014 Placement Agent Warrant entitles the Placement Agent to purchase 175,027 shares of the Company's common stock at $3.00 per share. The cash payment of $980,151 for 2014 Placement Agent Fee and the $121,707 aggregated initial fair value of the 2014 Placement Agent Warrants (see *Fair Value Considerations* below) were directly attributable to an actual offering and were charged through additional paid-in capital in accordance with the SEC Staff Accounting Bulletin (SAB) Topic 5A.

Warrants

The 2014 Warrants are exercisable at any time commencing after January 29, 2014 (the "Initial Exercise Date"). Subject to the call right described above, the 2014 Warrants shall expire and no longer be exercisable on the fifth anniversary of the Initial Exercise Date (the "Expiration Date"). The 2014 Warrants cannot be exercised on a cashless basis. There are no redemption features embodied in the 2014 Warrants and they have met the conditions for equity classification.

Fair Value Consideration

The Company's accounting for the issuance of the 2014 Warrants required the estimation of fair values of the financial instruments. The development of fair values of financial instruments requires the selection of appropriate methodologies and the estimation of often subjective assumptions. The Company selected the valuation techniques

based upon consideration of the types of assumptions that market participants would likely consider in exchanging the financial instruments in market transactions. The 2014 Warrants were valued using a Black-Scholes-Merton Valuation Technique because it embodies all of the requisite assumptions (including trading volatility, estimated terms and risk free rates) necessary to assess the fair value of these instruments.

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

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

Outstanding Warrants

As of September 30, 2014, warrants to purchase 6,033,426 shares of common stock are outstanding including:

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

NOTE 9: NET LOSS PER SHARE

The Company accounts for and discloses net loss per common share in accordance with FASB ASC Topic 260, *Earnings Per Share*. Basic net loss per common share is computed by dividing net loss attributable to common stockholders by the weighted average number of common shares outstanding. Diluted net loss per common share is computed by dividing net loss attributable to common stockholders by the weighted average number of common shares that would have been outstanding during the period assuming the issuance of common shares for all potential dilutive common shares outstanding. Potential common shares consist of shares issuable upon the exercise of stock options and warrants. Because the inclusion of potential common shares would be anti-dilutive for all periods presented, diluted net loss per common share is the same as basic net loss per common share.

The following table sets forth the number of potential common shares excluded from the calculation of net loss per diluted share for the three-month and nine-month periods ended September 30, 2014 and 2013:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Options to purchase common stock	3,464,232	2,246,651	3,464,232	2,246,651
Warrants to purchase common stock	6,033,426	4,775,550	6,033,426	4,775,550
Restricted stock units	-	-	-	-
	9,497,658	7,022,201	9,497,658	9,497,658

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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, 2014 and December 31, 2013, the Company had $11,124,251 and $6,092,161 in excess of the FDIC insured limit, respectively.

NOTE 11: COMMITMENTS AND CONTINGENCIES

Lease Commitments

The future minimum lease payments due subsequent to September 30, 2014 under all non-cancelable operating leases are as follows:

Year Ending December 31,	**Amount**
2014 (remainder of the year)	$105,723
2015	480,007
2016	464,771
2017	105,894
Total minimum lease payments	**$1,156,395**

Affymetrix Purchase Commitment

In September 2013, in connection with the development of the NextCYTE test by the NRLBH, the NRLBH entered into an "OwnerChip Program Agreement" with Affymetrix, Inc, a manufacturer of GeneChip Systems, where Affymetrix has agreed to loan a GeneChip System 3000Dx v.2 ("instrument") to the Company if it purchases and takes delivery of a minimum thirty GeneChip Human Genome U133 Plus 2.0 (30-pack) arrays at $21,590 per 30 pack for the next three years for a total purchase obligation of $647,700 with a minimum purchase of ten 30-pack arrays per contract year. At the end of the three year contract, upon fulfillment of the purchase commitment, the instrument title and ownership transfer to the NRLBH at no additional cost. In addition to the GeneChip Human Genome, the NRLBH must purchase a two year service contract for $51,600 to cover maintenance of the instrument during the contract period. The NRLBH placed an initial order for four 30-pack arrays during 2013 for $94,723. In September 2014, the NRLBH purchased six additional 30-pack arrays for $142,005. The NRLBH obligated to purchase 20 additional arrays during the next two year contract term

A5 Software Development Commitment

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

Luminex Reagent Rental Agreement and Assay License Agreement

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

BioVentive Laboratory Marketing Service Agreement

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

Targeted Medical Education (TME) Master Service Agreement

On September 1, 2014, the NRLBH entered into a Master Service Agreement with Targeted Medical Education (TME), where TME provides matched sets of de-identified tissue samples and clinically annotated retrospective data on 100 cancer patients for testing and evaluation of the NextCYTE test for a total cost of $162,600. As of September 30, 2014, the Company has paid $100,000 in set-up fees as R&D expenses.

Contingencies

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

On 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.

On February 26, 2013, Mr. Victor Cononi filed a complaint in the United States District Court, Western Division of Washington seeking compensatory damages, interest and attorneys' fees related to the rescission of shares issued to

him in July 2010 in connection with Mr. Kelly's resignation from the Company as President and a director

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

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

On February 14, 2014, the Court appointed plaintiffs Miko Levi, Bandar Almosa and Gregory Harrison (collectively, the "Levi Group") as lead plaintiffs, and approved their selection of co-lead counsel and liaison counsel. The Court also amended the caption of the case to read In re Atossa Genetics, Inc. Securities Litigation. No. 2:13-cv-01836-RSM. An amended complaint was filed on April 15, 2014. The Company and other defendants filed motions to dismiss the amended complaint on May 30, 2014. The plaintiffs filed briefs in opposition to these motions on July 11, 2014. The Company replied to the opposition brief on August 11, 2014. On October 6, 2014 the Court granted defendants' motion dismissing all claims against Atossa and all other defendants. The Court's order provided plaintiffs with a deadline of October 26, 2014 to file a motion for leave to amend their complaint and the plaintiffs did not file such a motion by that date. On October 30, 2014, the Court entered a final order of dismissal. On November 3, 2014, plaintiffs filed a notice of appeal with the Court and have appealed the Court's dismissal order to the U.S. Court of Appeals for the Ninth Circuit.

The Company believes this lawsuit is without merit and plans to defend itself vigorously; however, failure by the Company to obtain a favorable resolution of the claims set forth in the complaint could have a material adverse effect on the Company's business, results of operations and financial condition. Currently, the amount of such material adverse effect cannot be reasonably estimated, and no provision or liability has been recorded for these claims as of September 30, 2014. The costs associated with defending and resolving the lawsuit and ultimate outcome cannot be predicted. These matters are subject to inherent uncertainties and the actual cost, as well as the distraction from the conduct of the Company's business, will depend upon many unknown factors and management's view of these may change in the future.

FDA Warning Letter

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

On October 4, 2013, the Company initiated a voluntary recall of the system to address FDA's concerns regarding the modifications identified in the Warning Letter. As a result of this recall, this product is currently not being marketed or distributed in the United States. The Company submitted a new premarket notification, or 510(k) application, with the FDA on December 23, 2013 that covered the collection, preparation, and processing of NAF specimens and includes the spray method of fixing specimens to the collection membrane and in September 2014 the FDA rendered a decision that the ForeCYTE Breast Aspirator is not "substantially equivalent" to its predicate device. The ForeCYTE Breast Aspirator is therefore not cleared by the FDA for marketing in the United States. We cannot market or distribute the ForeCYTE Breast Aspirator within the United States until we receive clearance for this device from the FDA.

On March 14, 2014, the FDA completed a follow up inspection at the Company's Seattle facility. A Form 483 was provided to the Company at the conclusion of the inspection. In the FDA's most recent Form 483, five inspectional observations were identified regarding the Company's quality management system. The FDA investigator also orally identified five additional discussion points related to the Company's product labeling prior to the recall of the MASCT System; sufficiency of the content of the Company's pending 510(k) submission for the ForeCYTE Breast Aspirator; and other compliance issues. On March 26, 2014, the Company submitted a response to the FDA, which included its proposed corrective actions to address the FDA's observations and discussion points. Whether the FDA will accept the Company's response is uncertain, particularly in light of the similar nature of certain of the current inspectional observations to previous inspectional observations. If the FDA does not agree with the Company's proposed corrective actions, or accepts them but finds that the Company has not implemented them adequately, or if the Company otherwise is found to be out of compliance with applicable regulatory requirements at a later date, the FDA could initiate additional warning letters, or initiate without further notice an enforcement action, fines and penalties. The FDA also may not clear a 510(k) for the ForeCYTE Breast Aspirator or our other devices and services under development. Any of the foregoing would have a material adverse effect on our business.

NOTE 12: STOCK BASED COMPENSATION

Compensation costs associated with the company's stock options are recognized, based on the grant-date fair values of these options, over the requisite service period, or vesting period. Accordingly, the Company recognized stock based compensation expense of $147,399 and $545,115 for the three months and nine months ended September 30, 2014, respectively. The stock based compensation for the three months and nine months ended September 30, 2013 was $188,763 and $1,187,717, respectively.

The following table presents information concerning stock option grants for the nine months ended September 30, 2014:

	Employees		**Executives & Officers**		**Directors**	
Date of Grant	January – September 2014		January – September 2014		January - September 2014	
Fair value of common stock on date of grant	$ 1.66 - 2.20		$ 1.22 - 2.20		$ 1.22 - 2.20	
Exercise price of the options	$ 1.66 - 2.20		$ 1.22- 2.20		$ 1.22-2.20	
Expected life of the options (years)	6.06		6.06 - 6.11		5.09 – 5.31	
Dividend yield	0.00	%	0.00	%	0.00	%
Expected volatility	40.28- 41.72	%	40.69 - 41.70	%	38.64 - 38.68	%
Risk-free interest rate	1.91 - 2.11	%	1.85 - 2.11	%	1.53 – 1.75	%
Expected forfeiture per year (%)	10.00	%	10.00	%	10.00	%
Weighted average fair value of the options per unit	$ 0.87		$ 0.53		$ 0.70	

Options issued and outstanding as of September 30, 2014 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	Aggregate Intrinsic Value
Outstanding as of January 1, 2014	2,282,719	$ 4.43		$ 282,063
Granted	2,081,669	1.53		
Forfeited	(740,156)	4.36		21,540
Exercised	(160,000)	1.20		69,388
Outstanding as of September 30, 2014	3,464,232	3.10	8.21	117,267
Exercisable as of September 30, 2014	1,347,215	4.49	6.47	15,856
Vested and expected to vest (1)	3,190,856	$ 3.17	8.11	$ 108,485

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

At September 30, 2014, there were 2,117,017 unvested options outstanding that will vest over a weighted-average period of 2.98 years. The total estimated compensation expense to be recognized in connection with these options is $1,596,602.

Issuance of Restricted Common Stock and Stock Options for Directors' and Executives' Compensation

On October 10, 2013, the Company issued 24,510 shares of restricted stock with a grant date value of $50,000 or $2.04 per share to a new board member. On March 1, 2014, the Company agreed to issue 22,728 shares of restricted stock with a grant date value of $50,000 or $2.20 per share to a new board member. These share issuances were canceled in May 2014 in connection with a new compensation plan adopted by the Board of Directors for independent members of the Board and the grants were each replaced with $35,000 in cash payment.

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

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

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

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

Stock Options and Incentive Plan

On September 28, 2010, the Board of Directors approved the adoption of the 2010 Stock Option and Incentive Plan, or the 2010 Plan, to provide for the grant of equity-based awards to employees, officers, non-employee directors and other key persons providing services to the Company. Awards of incentive options may be granted under the 2010 Plan until September 2020. No other awards may be granted under the 2010 Plan after the date that is 10 years from the date of stockholder approval. An aggregate of 1,000,000 shares were initially reserved for issuance in connection with awards granted under the 2010 Plan, such number of shares to be subject to adjustment as provided in the plan and in any award agreements entered into by the Company under the plan, and upon the exercise or conversion of any awards granted under the plan. On January 1, 2012, 450,275 shares were added to the 2010 Plan and on January 1, 2013, 516,774 shares were added to the 2010 Plan, and on January 1, 2014, 742,973 shares were added to the 2010 plan as provided under the terms of the 2010 Plan.

The Company granted options to purchase 2,081,669 shares of common stock to employees and directors and issued 160,000 shares of common stock in connection with the exercise of directors stock options during the nine months ended September 30, 2014. There are 329,426 options available for grant under the 2010 Plan as of September 30, 2014.

NOTE 13: SUBSEQUENT EVENTS

Management has evaluated subsequent events through November 12, 2014, the date which the condensed consolidated financial statements were available to be issued. All subsequent events requiring recognition as of September 30, 2014 have been incorporated into these condensed consolidated financial statements, there are no subsequent events that require disclosure in accordance with FASB ASC Topic 855, "Subsequent Events."

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:

- Whether we will obtain in a timely manner, and maintain once obtained, clearance from the Food and Drug Administration and foreign regulatory bodies, including our CE Mark, to sell, market and distribute our medical devices;

- our ability to successfully launch the FullCYTE Breast Aspirator in the United States and our ForeCYTE Breast Aspirator outside the United States;

- the estimated costs associated with our product recall;

- our ability to successfully sell our products and services at currently expected prices or otherwise at prices acceptable to us;

- our ability to successfully develop and commercialize new tests, devices and treatments currently in development, including the FullCYTE Breast Aspirator, and in the time frames currently expected;

- our ability to maintain our business relationships, including with our distributors, suppliers and customers, while we seek launch the FullCYTE Breast Aspirator and while we seek additional regulatory clearance in the United States and overseas to market, sell and distribute our ForeCYTE Breast Aspirator and laboratory tests;

- our ability to engage third-party suppliers to manufacture the ForeCYTE Breast Aspirator, FullCYTE Breast Aspirator, FullCYTE Microcatheter, other devices under development and their components at quantities and costs acceptable to us;

- our ability to satisfy ongoing FDA requirements for manufacturing, distributing, and promoting the FullCYTE Breast Aspirator, NAF cytology test and FullCYTE Microcatheter and to obtain regulatory approvals and/or clearances for our other products and services in development, including our ability to timely and adequately respond to and ultimately close-out the Warning Letter we received from the FDA on February 21, 2013, and the inspectional observations and discussion points we received March 14, 2014 and any issues resulting therefrom;

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

- the benefits and clinical accuracy of our laboratory tests, including the NAF cytology test;

- 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 them.

These and other forward-looking statements made in this report are presented as of the date on which the statements are made. We have included important factors in the cautionary statements included in this report, particularly in the section titled “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 improving breast health through the development of a suite of laboratory services, medical devices and therapeutics. Our laboratory services are being developed by our subsidiary, The National Reference Laboratory for Breast Health, Inc. (the NRLBH), and are intended to address each of the four stages of the breast health care path: the cytological analysis of nipple aspirate fluid (NAF); the cytological analysis of ductal lavage fluid collected from each individual breast duct with our proprietary microcatheters; the profiling of newly diagnosed breast cancers through the determination of gene expression profiles in breast cancer biopsy tissue; and the monitoring of breast cancer survivors for pre-clinical recurrence through a blood test for circulating tumor cells. The NRLBH has developed and is currently marketing NAF cytology tests and pharmacogenomics tests.

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

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

Our strategy consists of the following:

(1) Launch the FullCYTE Breast Aspirator in the United States and the ForeCYTE Breast Aspirator Outside the U.S.: We intend to launch our FullCYTE Breast Aspirator in the United States through distributors. We also intend to introduce the ForeCYTE Breast Aspirator into one or more foreign markets. In October 2014, we received a CE Mark for the ForeCYTE Breast Aspirator.

(2) Continue to Promote and Commercialize the NRLBH's Laboratory Tests and our other Medical Devices: We plan to promote the tests currently being offered by the NRLBH, including NAF cytology tests and pharmacogenetics tests,

and to continue the development and commercialization of our other tests and devices under development.

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

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

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

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

The MASCT System (which we currently refer to as the ForeCYTE Breast Aspirator) was launched in a "field experience" trial in 2012 and nationally in the beginning of 2013. In October 2013, we voluntarily recalled the MASCT System to address concerns raised by the FDA in a Warning Letter we received in February 2013. In December 2013, we submitted a pre-market notification to the FDA for a 510(k) clearance for the ForeCYTE Breast Aspirator, and in September 2014 the FDA determined that the ForeCYTE Breast Aspirator is not substantially equivalent to its predicate device which means that as of the date of this report the device is not cleared by the FDA for marketing in the United States. We are currently evaluating the feedback we received from the FDA and the U.S. regulatory pathway for the ForeCYTE device.

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 NAF samples from all 50 states under its CLIA certification, its state licenses, or, in New York under recognized exemption provisions while its license application is pending, examines the NAF specimens by cytological analysis. In mid-October 2014, the NRLBH began providing pharmacogenetics testing, which are marketed by the NRLBH's sales and marketing partner, BioVentive, Inc., and through the date of this report the NRLBH has processed approximately 238 tests.

Prior to the recall of the ForeCYTE Breast Aspirator, we entered into the following agreements for the distribution of the ForeCYTE Breast Aspirator in the U.S. market: On April 30, 2013, we entered into a Distribution and Marketing Services Agreement with Millennium Medical Devices LLC, covering 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. On August 26, 2014, the NRLBH entered into an agreement with BioVentive, Inc. for the sales and marketing of our laboratory services.

We have not yet established an ongoing source of revenue sufficient to cover our operating costs and allow us to continue as a going concern. Our ability to continue as a going concern is dependent on obtaining adequate capital to fund operating losses until we become profitable. We plan to obtain additional capital resources by: selling our equity securities; selling the FullCYTE Breast Aspirator in the United States and the ForeCYTE Breast Aspirator outside the United States; generating laboratory service revenue from our services performed by the NRLBH; and borrowing from stockholders or others when needed. However, we cannot assure you that we will be successful in accomplishing any of these plans and, if we are unable to obtain adequate capital, we could be forced to cease operations.

Our Voluntary Product Recall

On October 4, 2013, we initiated a voluntary recall to remove the MASCT device (which was also called the “ForeCYTE Test” prior to the recall) from the market. This voluntary recall includes the MASCT System Kit and Patient Sample Kit. The recall has now been completed.

The purpose of this voluntary recall was 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 instructions for use (IFU) for the MASCT device; (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 then-current IFU.

As of September 30, 2014, we have incurred cumulative actual recall expenses of $429,829 including the estimated costs of pursuing the additional 510(k) clearance.

Prior to the commencement of the recall in October 2013, substantially all of our revenue was from sales of the MASCT System and patient collection kits and from testing services performed by our laboratory. As a result of the recall of the MASCT System and patient collection kits, we have ceased generating product revenue. Our laboratory services revenue has also virtually ceased as of October 2013.

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

Follow-up FDA Inspection

On March 14, 2014, the FDA completed a follow up inspection at our Seattle facility. A Form 483 was provided to us at the conclusion of the inspection. In the FDA's most recent Form 483, five inspectional observations were identified. The FDA inspector also verbally identified five additional discussion points related to our product labeling prior to the recall of the MASCT System; sufficiency of the content of our then-pending 510(k) submission for the ForeCYTE Breast Aspirator; and other compliance issues. On March 26, 2014, we submitted a response to the FDA, which included our proposed corrective actions to address the FDA's observations and discussion points. Whether the FDA will accept our response is uncertain, particularly in light of the similar nature of certain of the current inspectional observations to previous inspectional observations. If the FDA does not agree with our proposed corrective actions, or accepts them but finds that we have not implemented them adequately, or if we otherwise are found to be out of compliance with applicable regulatory requirements at a later date, the FDA could initiate additional warning letter, or initiate without further notice an enforcement action, fines and penalties. The FDA also may not clear our devices and services under development. Any of the foregoing would have a material adverse effect on our business.

Revenue Sources

Our business provides us with two potential revenue sources: (i) sales-based revenue from the sale of our medical devices, such as our ForeCYTE Breast Aspirator and FullCYTE Breast Aspirator and patient kits to distributors, physicians, breast health clinics, and mammography clinics and (ii) service, or use-based, revenue from laboratory services performed by the NRLBH, such as preparation and interpretation of the NAF samples sent to our laboratory for analysis, pharmacogenetic tests and other tests that may be developed and commercialized by the NRLBH. We do not anticipate generating revenue until and unless we develop and launch new laboratory tests and/or until we launch the FullCYTE Breast Aspirator in the United States and the ForeCYTE Breast Aspirator outside the United States. We plan to initially sell the breast aspirators and our laboratory services through regional and national specialty product distributors, with independent sales representatives specializing in women's health, and through our own direct sale force.

Commercial Lease Agreements

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

On December 9, 2011, 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. In July 2013, the Company entered into an agreement with ARE LLC (Alexandria) to lease additional office spaces in our existing building under a separate lease agreement. The lease is from August 2013 through November 2014, and the gross rent is $ 4,800 per month. For the nine months ended September 30, 2014, the Company incurred $197,744 of rent expense for the lease, which included leasing office management expenses and the new agreement with ARE LLC.

On March 24, 2014, the Company entered into another commercial lease agreement with ARE LLC (Alexandria) for the Company's laboratory space which extends the term of the existing lease with Fred Hutchison Research Center which expires in November 2014 through November 30, 2016. The lease provides for monthly rent payments of $22,736 from December 2014 through November 2015 and $23,258 from December 2015 through November 2016. As of September 30, 2014, the Company incurred and recorded security deposits of $25,000.

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

We expect that these laboratory facilities will be sufficient to meet our needs for the foreseeable future and we do not expect to need additional laboratory space for at least the next 24 months. 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.

Critical Accounting Policies and Estimates

In our Annual Report on Form 10-K for the year ended December 31, 2013, we disclosed our critical accounting policies and estimates upon which our financial statements are derived. There have been no changes to these policies since December 31, 2013. Readers are encouraged to review these disclosures in conjunction with the review of this report.

Results of Operations

Three Months and Nine Months Ended September 30, 2014 and 2013

Revenue and Cost of Goods Sold. For the three months and nine months ended September 30, 2014, revenue totaled $3,426 and $37,425, consisting of additional cash collected in excess of the amounts we accrued previously at the Medicare rates. Total revenue for the three and nine months ended September 30, 2013 was $76,597 and $585,345. Cost of revenue was $ 0 for the three months and nine months ended September 30, 2014, compared to $25,938 and $314,562 in the same periods in 2013.

For the three months and nine months ended September 30, 2014, gross profit totaled $3,426 and $37,425, compared to $50,659 and $270,783 in the same period in 2013. The Company has recognized virtually no revenue or cost of revenue since the voluntary recall in October 2013.

Operating Expenses. For the three months ended September 30, 2014, total operating expenses were $3,248,681 consisting of general and administrative (G&A) expenses of $2,043,138, research and development (R&D) expenses of $923,169, and selling expenses of $282,374, representing an decrease of $303,875, or 9% from $3,552,556 in the same period in 2013, consisting of G&A expenses of $2,858,027, R&D expenses of $321,111, and selling expenses of $373,418. Operating expenses for the nine months ended September 30, 2014 were $8,880,138 consisting of G&A expenses of $6,280,102, R&D expenses of $1,856,439, and selling expenses of $743,597. Operating expenses increased $582,678, or 7% from $8,297,460 for the same period in 2013 consisting of $6,600,819 in G&A expenses, $731,258 in R&D expenses, and $965,383 in selling expenses.

The change in operating expenses form last year is due to lower selling and G&A expenses as a result of the recall offset by higher R&D expenses as we develop new products and services. We expect that our G&A and selling expenses will continue to increase in the foreseeable future, and if we successfully relaunch the ForeCYTE Breast Aspirator, FullCyte Breast Aspirator and our laboratory service offerings, we would also begin to incur additional sales and marketing expenses as we continue building a regional, and ultimately national, sales force.

Selling Expenses. Selling expenses for the three months ended September 30, 2014 were $282,374, a decrease of $91,044, or 24%, from $373,418 for the three months ended September 30, 2013. Selling expenses for the three months ended September 30, 2014 consisted primarily of $54,077 in selling and marketing professional fees, $108,329 in compensation expenses, $99,319 in advertisement, and $20,649 in travel. Selling expenses for the nine months ended September 30, 2014 were $743,597, a decrease of $221,786, or 23% from $965,383 for the same period in 2013. Selling expenses for the nine months ended September 30, 2014 consisted of $301,317 in compensation expenses, $116,180 in selling and marketing professional fees, and $305,450 in advertising.

Selling expenses decreased as a result of the voluntary recall in October 2013. We expect selling expenses will increase when we prepare for and execute the relaunch of ForeCYTE Breast Aspirator outside the United States and to launch the FullCYTE Breast Aspirator. Selling expenses may also increase as we market and sell the services offered by the NRLBH, including NAF cytology tests and potentially other tests.

R&D Expenses. R&D expenses for the three months ended September 30, 2014 were $923,169, an increase of $602,058, or 187%, from $321,111 for the three months ended September 30, 2013. R&D expenses for the nine months ended September 30, 2014 were $1,856,439, an increase of $1,125,181, or 154% from the same period in 2013.

The increase in R&D expenses in 2014 is attributed to additional R&D expenditures on the development of our new products and tests in the pipeline, including the NextCYTE Test and FullCYTE microcatheters. We expect that our R&D expenses will continue to increase as we add additional full time employees and incur additional costs to continue the development of our products and services under development throughout 2014.

G&A Expenses. G&A expenses for the three months ended September 30, 2014 were $2,043,138, a decrease of $814,889, or 29%, from $2,858,027 in the same period in 2013. The decrease in 2014 G&A expenses over 2013 was primarily attributable to $275,519 lower capital raising expenses, $396,262 lower recall expenses, $54,510 lower consulting fees, $325,715 lower advertising and marketing fees and $212,279 lower bad debt expenses. This decrease is offset by $358,688 higher legal and regulatory fees in 2014 as a result of the recall, and $88,994 increase in salaries and employees benefits as we grew headcount in our manufacturing and regulatory departments to fulfill the demands of new product development and regulatory requirements.

G&A expenses for the nine months ended September 30, 2014 were $6,280,102, a decrease of $320,717, or 5% from $6,600,819 for the same period in 2013. The decrease in 2014 G&A expenses over 2013 was primarily attributable to the $428,872 lower capital raising costs, $230,062 lower consulting fees, $396,225 lower recall expenses, $327,959 lower advertising and marketing fees, and $147,971 lower bad debt expenses. This decrease is offset by $786,074 in higher legal and regulatory fees as a result of the recall and $402,204 increase in employees and directors compensation as we grew headcount in our manufacturing and regulatory departments to fulfill the demands of new product development and regulatory requirements.

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

Liquidity and Capital Resources

We have a history of operating losses as we have focused our efforts on raising capital and building the MASCT System. The report of our independent auditors issued on our consolidated financial statements as of and for the years ended December 31, 2013 and 2012 expresses substantial doubt about our ability to continue as a going concern.

On March 27, 2013, we entered into a stock purchase agreement with Aspire Capital Fund, LLC, and pursuant to that agreement we sold common stock to Aspire from March 2013 through October 2013 for a total aggregate purchase price of $11,303,745. On November 8, 2013, we terminated this stock purchase agreement and entered into a new agreement with Aspire which provides that we may sell common stock to Aspire under the terms and subject to the conditions and limitations set forth therein. Under the new agreement, Aspire is committed to purchase up to an aggregate of $25 million of shares of our common stock over the 30 month term of the new agreement, subject to certain conditions set forth therein. On December 23, 2013, we sold $1 million of common stock to Aspire under this new agreement so that up to a total of $24 million remains available for sale to them as of the date of this report.

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

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

Cash Flows

As of September 30, 2014, we had cash and cash equivalents of $11,374,251.

Net Cash Flow from Operating Activities

Net cash used in operating activities was approximately $7,836,146 for the nine months ended September 30, 2014, compared with $6,182,060 for the nine months ended September 30, 2013. The increase in cash used in operating activities of $1,654,086 resulted primarily from an increase in R&D activities related to our new product developments, additional salaries to support the operations, and legal expenses related to the recall and ongoing litigation.

Net Cash Flow from Investing Activities

Net cash used in investing activities was $287,509 for the nine months ended September 30, 2014, compared with $400,674 for the nine months ended September 30, 2013. The decrease was due to the additional capitalized fixed assets inventory equipment purchased in 2013.

Net Cash Flow from Financing Activities

Net cash provided by financing activities was $13,155,745 for the nine months ended September 30, 2014, compared with $12,551,098 for the nine months ended September 30, 2013. The increase was primarily due to net proceeds of the public offering in January 2014.

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 launch of the ForeCYTE Breast Aspirator outside the United States and FullCYTE Breast Aspirator in the United States, complete the development of and launch the NextCYTE tests, and other devices and laboratory services in the pipeline and start the development of our planned therapeutic programs. We expect our existing capital resources as of the date of this report to be sufficient to fund our planned operations through at least the first quarter of 2015. If we are unable to raise additional capital when needed, however, we could be forced to curtail or cease operations. Our future capital uses and requirements depend on numerous forward-looking factors. These factors include the following:

- the time and expense needed to launch our medical devices including the ForeCYTE Breast Aspirator and FullCYTE Breast Aspirator;

- the expense associated with building a network of sales representatives to market the our medical devices, laboratory services and our planned therapeutic programs; and

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

We do not expect to generate revenue until we launch our aspirator devices or launch our laboratory services. 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 through the first quarter of 2015, we may require additional funds earlier than we currently expect to successfully commercialize the ForeCYTE Breast Aspirator and FullCYTE Breast Aspirator. Because of the numerous risks and uncertainties associated with the development and commercialization of the aspirators and our other devices, tests and therapeutics in the pipeline, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated research and development activities and commercialization efforts.

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

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

Off-Balance Sheet Arrangements

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

Recent Accounting Pronouncements

The Company has adopted all recently issued accounting pronouncements that management believes to be applicable to the Company.

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

In June 2014, FASB issued ASU 2014-10, *Elimination of Development Stage Entity Requirements.* This ASU eliminates the concept of Development Stage Entities (DSE's) from U.S. GAAP and is intended to result in

cost-savings for certain entities, such as start-ups or research and development entities. As a result of these changes, the financial statements of developing entities no longer need to meet the inception-to-date income, cash flow and equity information; the requirement to label financial statements as those of a developing company was eliminated; and certain disclosures related to the nature of the entities development stage activities were eliminated. We adopted ASU 2014-10 for the reporting period ended June 30, 2014.

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

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, 2014. 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, 2014, 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, 2014 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.

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.

On February 26, 2013, Mr. Victor Cononi filed a complaint in the United States District Court, Western Division of Washington seeking compensatory damages, interest and attorneys' fees related to the rescission of shares issued to him in July 2010 in connection with Mr. Kelly's resignation from the Company as President and a director.

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

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

On February 14, 2014, the Court appointed plaintiffs Miko Levi, Bandar Almosa and Gregory Harrison (collectively, the "Levi Group") as lead plaintiffs, and approved their selection of co-lead counsel and liaison counsel. The Court also amended the caption of the case to read In re Atossa Genetics, Inc. Securities Litigation. No. 2:13-cv-01836-RSM. An amended complaint was filed on April 15, 2014. The Company and other defendants filed motions to dismiss the amended complaint on May 30, 2014. The plaintiffs filed briefs in opposition to these motions on July 11, 2014. The Company replied to the opposition briefs on August 11, 2014. On October 6, 2014 the Court granted defendants' motion dismissing all claims against Atossa and all other defendants. The Court's order provided plaintiffs with a deadline of October 26, 2014 to file a motion for leave to amend their complaint and the plaintiffs did not file such a motion by that date. On October 30, 2014, the Court entered a final order of dismissal. On November 3, 2014, plaintiffs filed a notice of appeal with the Court and have appealed the Court's dismissal order to the U.S. Court of Appeals for the Ninth Circuit.

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, 2014. The costs associated with defending and resolving the complaint and ultimate outcome cannot be predicted. These matters are subject to inherent uncertainties and the actual cost, as well as the distraction from the conduct of our business, will depend upon many unknown factors and management's view of these may change in the future.

ITEM 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.

There has been no material changes to the risk factors described in the Company's Annual Report on Form 10-K, as filed with the SEC on March 27, 2014, and which are incorporated into this report by this reference, except for the following items which have been updated.

Anticipated liquidity issues beginning in 2015.

For the nine months ended September 30, 2014, we generated no revenue and we incurred a net loss of $8,848,265. We expect that our existing resources will be sufficient to fund our planned operations through at least the first quarter of 2015. We have not yet established an ongoing source of revenue sufficient to cover our operating costs and allow us to continue as a going concern. Our ability to continue as a going concern is dependent on obtaining adequate capital to fund operating losses until we become profitable. We may not receive or maintain regulatory clearance for our medical devices and laboratory service, including the ForeCYTE Breast Aspirator and FullCYTE Breast Aspirator, and other sources of capital may not be available when we need them or on acceptable terms. For example, we may not be able to raise capital by selling Common Stock to Aspire because the Aspire registration statement may not remain effective. If we are unable to raise in a timely fashion the amount of capital we anticipate needing, from Aspire or otherwise, we would be forced to curtail or cease operations.

Potential Changes in FDA policies regarding FDA regulation of laboratory developed tests or "home brew" tests could adversely affect our business and results of operations.

The FDA has asserted that laboratory diagnostic tests developed and validated by a laboratory for its own use, also known as LDTs or "home brew" tests, are subject to regulation under the Federal Food, Drug and Cosmetic Act, or FDCA. 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 has not historically asserted authority with respect to most LDTs performed by high complexity laboratories certified under CLIA, which is the type of laboratory that we have established. However, on July 31, 2014, the FDA announced plans to formally regulate most LDTs. The announcement came in the form of letters to Congress attaching the preliminary drafts of guidance documents describing the FDA's proposed framework for regulatory oversight of LDTs. The documents were provided to Congress in order to satisfy Section 1143 of the Food and Drug Administration Safety and Innovation Act, which required the FDA to notify Congress at least 60 days prior to issuance of draft or final guidances on the regulation of LDTs. The FDA is expected to wait at least 60 days before issuing the regulatory framework in official draft form for public comment. The FDA expects to have a 90-day comment period for interested stakeholders prior to implementation of the proposed regulatory plan.

The documents were provided to Congress in order to satisfy Section 1143 of the Food and Drug Administration Safety and Innovation Act, which required the FDA to notify Congress at least 60 days prior to issuance of draft or final guidances on the regulation of LDTs. The FDA is expected to wait at least 60 days before issuing the regulatory framework in official draft form for public comment. The FDA expects to have a 90-day comment period for interested stakeholders prior to implementation of the proposed regulatory plan. Although we have not studied the potential impact of the proposed new regulations, we believe that if they become effective, the new FDA guidelines may require premarket notification or approval for LDTs that we are currently developing, potentially including our NAF test, as well as tests that we may develop and perform in the future; however, the proposed new regulations do provide that the FDA will continue to exercise regulatory discretion for LDTs for "unmet needs" when no FDA cleared or approved alternative exists. Additionally, the FDA has indicated to us that the manner in which our laboratory previously processed NAF samples combined with the manner in which they were marketed prior to our October 2013 recall constitutes an in-vitro diagnostic test service that is subject to their regulatory authority and we may therefore be required to obtain a 510(k) clearance covering our laboratory processing. The FDA may also choose to exercise regulatory authority over our laboratory because it is wholly-owned by us and as a medical device manufacturer we are subject to FDA regulation.

Any additional 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.

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

None.

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ITEM 6. EXHIBITS

(a)	Exhibits
10.1[(a)]	BioVentive Laboratory Marketing Service Agreement dated August 28, 2014 between BioVentive, Inc. and NRLBH.
10.2	TME Master Service Agreement dated September 1, 2014 between Targeted Medical Education (TME) and NRLBH.
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

(a) Confidential treatment requested for portions of this Exhibit.

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, 2014

/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)

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