

ATOSSA GENETICS INC  
Form 10-Q  
August 12, 2014

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**WASHINGTON, DC 20549**

**FORM 10-Q**

**(Mark One)**

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

**For the quarterly period ended June 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**  
(State or other jurisdiction of

**26-4753208**  
(I.R.S. Employer

Edgar Filing: ATOSSA GENETICS INC - Form 10-Q

incorporation or organization) 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  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  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

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

The number of shares of the registrant's common stock, \$0.001 par value per share, outstanding at August 12, 2014 was 24,564,058.

**ATOSSA GENETICS INC.**

**FORM 10-Q**

**QUARTERLY REPORT**

**INDEX**

**PART I. FINANCIAL INFORMATION**

<b><u>ITEM 1. Condensed Consolidated Financial Statements – Unaudited</u></b>	<b>3</b>
<u>Condensed Consolidated Balance Sheets as of June 30, 2014 and December 31, 2013</u>	3
<u>Condensed Consolidated Statements of Operations for the three and six months ended June 30, 2014 and 2013</u>	4
<u>Condensed Consolidated Statement of Stockholders' Equity for the six months ended June 30, 2014</u>	5
<u>Condensed Consolidated Statements of Cash Flows for the six months ended June 30, 2014 and 2013</u>	6
<u>Notes to Condensed Consolidated Financial Statements</u>	7
<b><u>ITEM 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u></b>	<b>17</b>
<b><u>ITEM 3. Quantitative and Qualitative Disclosures about Market Risk</u></b>	<b>25</b>
<b><u>ITEM 4. Controls and Procedures</u></b>	<b>25</b>

**PART II. OTHER INFORMATION**

<b><u>ITEM 1. Legal Proceedings</u></b>	<b>26</b>
<b><u>ITEM 1A. Risk Factors</u></b>	<b>27</b>
<b><u>ITEM 2. Unregistered Sales of Equity Securities and Use of Proceeds</u></b>	<b>27</b>
<b><u>ITEM 3. Defaults upon Senior Securities</u></b>	<b>27</b>
<b><u>ITEM 4. Mine Safety Disclosures</u></b>	<b>27</b>
<b><u>ITEM 5. Other Information</u></b>	<b>27</b>

ITEM 6. Exhibits

27

SIGNATURES

28

2

**PART I. FINANCIAL INFORMATION****ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS****ATOSSA GENETICS INC.  
CONDENSED CONSOLIDATED BALANCE SHEETS**

	June 30, 2014 (Unaudited)	December 31, 2013 (Audited)
Assets		
Current assets		
Cash and cash equivalents	\$ 14,298,491	\$ 6,342,161
Accounts receivable, net	48,155	139,072
Prepaid expense	325,346	280,627
Inventory, net	1,910	-
Total current assets	14,673,902	6,761,860
Furniture and equipment, net	127,741	163,147
Intangible assets, net	4,454,185	4,395,633
Deferred financing costs	501,961	651,961
Security deposit	61,309	36,446
Total assets	\$ 19,819,098	\$ 12,009,047
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	\$ 790,184	\$ 248,142
Accrued expenses	226,642	399,478
Deferred rent	21,372	48,157
Payroll liabilities	508,646	476,477
Product recall liabilities	12,028	211,493
Other current liabilities	4,622	23,649
Total current liabilities	1,563,494	1,407,396
Stockholders' Equity		
Preferred stock - \$.001 par value; 10,000,000 shares authorized, 0 shares issued and outstanding at June 30, 2014 and December 31, 2013, respectively	-	-
Common stock - \$.001 par value; 75,000,000 shares authorized, 24,444,058 and 18,574,334	24,444	18,574

Edgar Filing: ATOSSA GENETICS INC - Form 10-Q

shares issued and outstanding at June 30, 2014 and December 31, 2013, respectively		
Additional paid-in capital	44,347,281	31,099,691
Accumulated deficit	(26,116,121)	(20,516,614 )
Total stockholders' equity	18,255,604	10,601,651
Total liabilities and stockholders' equity	\$ 19,819,098	\$ 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 June 30,		For The Six Months Ended June 30,	
	2014	2013	2014	2013
Revenue				
Diagnostic testing service	\$9,875	\$120,488	\$33,999	\$289,718
Product sales	-	205,590	-	219,030
Total Revenue	9,875	326,078	33,999	508,748
Cost of Revenue				
Diagnostic testing service	-	2,356	-	49,955
Product sales	-	219,804	-	238,669
Total Cost of Revenue	-	222,160	-	288,624
Gross Profit	9,875	103,918	33,999	220,124
Selling expenses	223,385	319,390	461,223	591,965
Research and development expenses	510,767	189,955	933,270	410,147
General and administrative expenses	2,462,256	2,177,920	4,236,964	3,742,792
Total operating expenses	3,196,408	2,687,265	5,631,457	4,744,904
Operating Loss	(3,186,533 )	(2,583,347 )	(5,597,458 )	(4,524,780 )
Interest income	-	-	143	-
Interest expense	1,443	352	2,192	359
Loss before Income Taxes	(3,187,976 )	(2,583,699 )	(5,599,507 )	(4,525,139 )
Income Taxes	-	-	-	-
Net Loss	\$(3,187,976 )	\$(2,583,699 )	\$(5,599,507 )	\$(4,525,139 )
Loss per common share - basic and diluted	\$(0.23 )	\$(0.17 )	\$(0.24 )	\$(0.32 )
Weighted average shares outstanding, basic & diluted	24,430,346	14,808,728	23,515,576	14,120,962

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

## ATOSSA GENETICS, INC.

## CONDENSED CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
<b>Balance at December 31, 2013</b>	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	-	-	(150,000 )	-	(150,000 )
Issuance of Common shares upon exercise of warrants	20,000	20	31,980	-	32,000
Employees option exercise and cancellation of restricted stock grants	(7,241 )	(7 )	50,007	-	50,000
Compensation cost for stock options granted to executives and employees	-	-	397,715	-	397,715
Net loss for the six months ended June 30, 2014	-	-	-	(5,599,507 )	(5,599,507 )
<b>Balance at June 30, 2014</b>	<b>24,444,058</b>	<b>\$ 24,444</b>	<b>\$44,347,281</b>	<b>\$(26,116,121)</b>	<b>\$ 18,255,604</b>

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



**ATOSSA GENETICS INC.****CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS****(UNAUDITED)**

	<b>For the Six Months Ended June 30,</b>	
	<b>2014</b>	<b>2013</b>
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>		
Net loss	\$(5,599,507 )	\$ (4,525,139)
Adjustments to reconcile net loss to net cash used in operating activities:		
Common shares issued for services	-	181,798
Compensation cost for stock options granted	397,715	1,011,820
Inventory Write-downs	-	20,323
Depreciation and amortization	252,924	226,643
Bad debt expense	64,759	-
Changes in operating assets and liabilities:		
Accounts receivable	26,158	(378,759 )
Inventory	(1,910 )	(20,323 )
Prepaid expenses	(129,719 )	(36,526 )
Security deposits	(24,863 )	(47,500 )
Accounts payable	542,042	(16,822 )
Payroll liabilities	32,169	(11,123 )
Deferred rent	(26,785 )	72,537
Accrued expenses	(172,836 )	47,327
Product recall liabilities	(199,465 )	-
Other current liabilities	(19,027 )	31,654
Net cash used in operating activities	(4,858,345 )	(3,444,090)
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>		
Purchase of furniture & fixtures	(20,629 )	(81,370 )
Purchase of software	(170,441 )	(8,500 )
Net cash used in investing activities	(191,070 )	(89,870 )
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>		
Net proceeds from issuance of common stock and warrants	13,005,745	4,248,275
Net cash provided by financing activities	13,005,745	4,248,275
<b>NET INCREASE IN CASH &amp; CASH EQUIVALENTS</b>	<b>7,956,330</b>	<b>714,315</b>
<b>CASH &amp; CASH EQUIVALENTS, BEGINNING BALANCE</b>	<b>6,342,161</b>	<b>1,725,197</b>
<b>CASH &amp; CASH EQUIVALENTS, ENDING BALANCE</b>	<b>\$ 14,298,491</b>	<b>\$ 2,439,512</b>

**SUPPLEMENTAL DISCLOSURES:**

Interest paid	\$2,192	\$ 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 the Mammary Aspirate Specimen Cytology Test System, a modified breast pump, which is a medical device that collects specimens of nipple aspirate fluid (NAF). The current version of the medical device is called the ForeCYTE Breast Aspirator. The Company’s fiscal year ends on December 31st.

In December 2011, the Company established The National Reference Laboratory for Breast Health, Inc., or NRLBH, as a wholly-owned subsidiary. NRLBH is the Company’s CLIA-certified laboratory which performs our NAF cytology testing on NAF specimens including those collected with our breast aspirator. The NRLBH is developing other tests such as the ArgusCYTE test, NextCYTE test and FullCYTE 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. 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 the ForeCYTE 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 yearend 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.

**Reclassification:**

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:

	June 30, 2014	December 31, 2013
Tradeshow and other marketing events	\$153,000	\$ -
Prepaid insurance	89,970	112,517
Prepaid hardware and software	36,876	131,204
Retainer and security deposits	29,500	36,906
Other	16,000	-
	\$325,346	\$ 280,627

**NOTE 5: FURNITURE AND EQUIPMENT**

Property, plant furniture and equipment consisted of the following:

	June 30, 2014	December 31, 2013
Machinery and equipment	\$347,453	\$ 326,824
Leasehold improvements	93,665	93,665
Capitalized new product development costs	-	15,000
Less: Accumulated depreciation	(155,085)	(114,050 )
Less: Allowance for loss on impairment	(158,292)	(158,292 )
Furniture and equipment, net	\$127,741	\$ 163,147

Depreciation expense for the three months ended June 30, 2014 and 2013 were \$19,864 and \$30,668, respectively, and \$41,035 and \$35,536 for the six month periods then ended.

**NOTE 6: INTANGIBLE ASSETS**

Intangible assets consisted of the following:

	June 30, 2014	December 31, 2013
Patents	\$4,794,853	\$ 4,794,853
Capitalized license costs	200,000	-
Software	176,280	105,839
Less: Accumulated amortization	(716,948 )	(505,059 )
	\$4,454,185	\$ 4,395,633



Intangible assets amounted to \$4,454,185 and \$4,395,633 as of June 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 June 30, 2014 and 2013 was \$9,466 and \$4,913, respectively, and \$18,227 and \$9,591 for the six month periods then ended.

Patents amounted to \$4,794,853 as of June 30, 2014 and December 31, 2013, respectively, and mainly consisted of patents acquired from Acueity on September 30, 2012 in an asset purchase transaction. Patent assets are amortized based on their determined useful life, and tested annually for impairment. The amortization period is from 9 to 14 years. Amortization expenses related to patents was \$93,498 and \$186,995 for the three months and six months ended June 30, 2014. Amortization expenses for patents was \$92,216 and \$181,514 for the three months and six months ended June 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 \$4,999 and \$6,667 for the three and six months ended June 30, 2014, respectively.

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

For the Year Ending December 31,	Amounts
2014 (includes the remainder of the year)	\$212,137
2015	435,692
2016	428,431
2017	411,600
2018	393,990
Thereafter	2,572,335
	\$4,454,185

#### **NOTE 7: PAYROLL LIABILITIES**

Payroll liabilities consisted of the following:

	June 30, 2014	December 31, 2013
Accrued bonus payable	\$410,449	\$ 408,362
Accrued payroll liabilities	85,457	48,232
Accrued payroll tax liabilities	12,740	19,883
	\$508,646	\$ 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

Edgar Filing: ATOSSA GENETICS INC - Form 10-Q

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

	<b>Outstanding Warrants to purchase shares</b>	<b>Exercise price</b>	<b>Expiration date</b>
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 six-month periods ended June 30, 2014 and 2013:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2014	2013	2014	2013
Options to purchase common stock	94,921	13,882	94,920	195,977
Warrants to purchase common stock	-	-	-	-
Restricted stock units	-	-	-	-

94,921 13,882 94,920 195,977

**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 June 30, 2014 and December 31, 2013, the Company had \$14,048,491 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 June 30, 2014 under all non-cancelable operating leases are as follows:

<b>Year Ending December 31,</b>	<b>Amount</b>
2014 (remainder of the year)	\$ 177,561
2015	480,007
2016	464,771
2017	105,894
<b>Total minimum lease payments</b>	<b>\$ 1,228,233</b>

Affymetrix Purchase Commitment

In September 2013, the Company entered into an “OwnerChip Program Agreement” with Affymetrix, Inc, a manufacturer of GeneChip Systems, where Affymetrix has agreed to loan a GeneChip System 3000Dx v.2 (“instrument”) to 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 Company at no additional cost. In addition to the GeneChip Human Genome, the Company must purchase a two year service contract for \$51,600 to cover maintenance of the instrument during the contract period. The Company placed an initial order for four 30-pack arrays during 2013 for \$94,723. The Company is obligated to purchase 26 additional arrays during the next three year contract term.

A5 Software Development Commitment

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

Contingencies

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

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

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

A hearing in the arbitration has been held in abeyance to accommodate other third party civil and federal criminal proceedings alleging securities and wire fraud that have been brought against Mr. Kelly with respect to his prior employment and predating his service with the Company. On March 11, 2014 a press release was issued by the FBI stating that Mr. Kelly had pled guilty in Manhattan federal court to securities and wire fraud charges related to his employment as CEO of Wwebnet. Mr. Kelly also agreed to forfeit \$2,111,600 and, separately, pay \$2,111,600 in restitution. The sentencing hearing is scheduled for September 18, 2014.

The Company is reasonably confident in its defenses to Mr. Kelly's and Mr. Cononi's claims. Consequently, no provision or liability has been recorded for these claims as of June 30, 2014. However, it is at least reasonably possible that the Company's estimate of liability may change in the near term. Any payments by reason of an adverse determination in this matter will be charged to earnings in the period of determination.



On October 10, 2013, a putative securities class action complaint, captioned Cook v. Atossa Genetics, Inc., et al., No. 2:13-cv-01836-RSM, was filed in the United States District Court for the Western District of Washington against us, certain of 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 unspecified 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.

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 June 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 (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...” and that “this change fixes the NAF specimen to the filter paper rather than washing it into a collection vial.” At the time that the changes were made the Company determined and documented that the change could not significantly affect the safety or effectiveness of the MASCT System, and thus, that a new 510(k) was not required in accordance with the FDA’s guidance document entitled, “Deciding When to Submit a 510(k) for a Change to an Existing Device.” The Warning Letter also identified certain issues with respect to the Company’s marketing of the System and the Company’s compliance with FDA Good Manufacturing Practices (cGMP) regulations, among other matters. The Company responded to the Warning Letter on March 13, 2013, and identified the corrective actions that had been made, or were otherwise underway. The Company also filed a new 510(k) application for the MASCT System which was withdrawn in August 2013 after receiving feedback from the FDA.

On October 4, 2013, the Company initiated a voluntary recall of the system to address FDA’s concerns regarding the modifications identified in the Warning Letter. As a result of this recall, this product is currently not being marketed or distributed in the U.S. The Company submitted a new premarket notification, or 510(k) application, with the FDA on December 23, 2013 that covers the collection, preparation, and processing of NAF specimens and includes the spray method of fixing specimens to the collection membrane. We received a request from the FDA on February 28, 2014 to submit additional information in support of the application. We have until August 20, 2014 to respond to the FDA. We cannot market or distribute the ForeCYTE Breast Aspirator within the United States until we receive clearance for this device from the FDA.

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 inspector 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 our pending 510(k) for the ForeCYTE Breast Aspirator or our other devices and services under development. Any of the foregoing would have a material adverse effect on our business.

The Company recorded a product recall liability of \$211,493 on December 2013; as of June 30, 2014, the Company has \$12,028 remaining in product recall liabilities and has incurred \$390,812 in actual expenses related to the costs of the recall, including the estimated costs of pursuing the additional 510(k) clearance. The recall and 510(k) process may take longer than expected and the Company may incur costs that it has not anticipated. Accordingly, the actual amount of the loss contingency may be higher than the Company currently expects.

**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 \$167,534 and \$397,715 for the three months and six months ended June 30, 2014, respectively. The stock based compensation for the three months and six months ended June 30, 2013 was \$737,309 and \$1,011,820, respectively.

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

	<b>Employees</b>	<b>Executives &amp; Officers</b>	<b>Directors</b>
Date of Grant	January 8, 2014	January – June 2014	January - June 2014
Fair value of common stock on date of grant	\$2.20	\$ 1.22 - 2.20	\$ 1.22 - 2.20
Exercise price of the options	\$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	41.70- 41.72	% 40.98 - 41.70	% 38.64 - 38.68
Risk-free interest rate	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	\$0.95	\$0.66	\$0.53

Options issued and outstanding as of June 30, 2014 and their activities during the six 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	1,436,669	1.46		
Forfeited	(69,236 )	4.64		450
Exercised	(40,000 )	1.25		14,400

Edgar Filing: ATOSSA GENETICS INC - Form 10-Q

Outstanding as of June 30, 2014	3,610,152	3.28	8.32	561,650
Exercisable as of June 30, 2014	1,413,969	4.50	6.63	88,150
Vested and expected to vest (1)	3,326,450	\$ 3.34	8.22	\$ 508,716

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

At June 30, 2014, there were 2,196,183 unvested options outstanding that will vest over a weighted-average period of 3.07 years. The total estimated compensation expense to be recognized in connection with these options is \$1,858,544.

Issuance of Restricted Common Stock for Directors' 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.

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 1,459,397 shares of common stock to employees and directors and issued 40,000 shares of common stock in connection with the exercise of directors stock options during the six months ended June 30, 2014. There are 267,870 options available for grant under the 2010 Plan as of June 30, 2014.

**NOTE 13: SUBSEQUENT EVENTS**

Management has evaluated subsequent events through August 12, 2014, the date which the condensed consolidated financial statements were available to be issued. All subsequent events requiring recognition as of June 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," except as follows:.

The Company entered into a new lease agreement in August 2014 for office space located in Seattle, Washington. The lease agreement provides for average monthly rent of \$17,249 for a period of 31 months from the lease commencement of December 1, 2014. These lease payments are reflected in the lease commitments table in Note 11.

## 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 clearance from the Food and Drug Administration to sell, market and distribute our ForeCYTE Breast Aspirator;

• our ability to successfully re-launch our ForeCYTE Breast Aspirator;

• the estimated costs associated with our product recall;

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

• our ability to successfully develop and commercialize new tests, tools and treatments currently in development and in the time frames currently expected;



our ability to maintain our business relationships, including with our distributors, suppliers and customers, while we are undergoing the recall we commenced in October 2013 and while we seek additional regulatory clearance to market, sell and distribute our ForeCYTE Breast Aspirator and laboratory test;

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

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

our ability to 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 the NAF cytology test and ArgusCYTE tests;

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

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

our ability to establish and maintain an independent sales representative force, including with our current and future distributors and their sub-distributors, to market our 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 developed tests (LDTs), invitro diagnostics, medical devices and therapeutics. Our laboratory tests are being developed by our subsidiary, The National Reference Laboratory for Breast Health, Inc. (the NRLBH), and are intended to address each of the four stages of the breast health care path: the cytological analysis of nipple aspirate fluid (NAF); the cytological analysis of ductal lavage fluid collected from each individual breast duct with our proprietary microcatheters; the profiling of newly diagnosed breast cancers through the determination of gene expression profiles in breast cancer biopsy tissue; and the monitoring of breast cancer survivors for pre-clinical recurrence through a blood test for circulating tumor cells.

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

We plan to develop certain of our medical devices and laboratory tests so that they can be used in clinical laboratory 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) Re-launch ForeCYTE Breast Aspirator sales: We hope to obtain FDA clearance for the ForeCYTE Breast Aspirator, our lead medical device, and, if FDA clearance is obtained to re-launch it in the United States through a direct sales force and our distributors, including Fisher Healthcare and PSS McKesson. We also intend to introduce the ForeCYTE Breast Aspirator into one or more foreign markets following receipt of the CE mark.

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

(3) Develop Pharmaceutical Therapies 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 ForeCYTE Breast Aspirator and we may partner with one or more laboratories to act as NAF collection sites using our ForeCYTE Breast Aspirator if and when it is cleared by the FDA. We plan to retain clinical research organizations (CROs) for clinical development of potential therapeutic programs and we intend to partner with pharmaceutical companies to develop companion diagnostic systems, which may include therapeutics to treat PED, DCIS and/or high risk women.

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

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

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

The NRLBH has been certified pursuant to the Clinical Laboratory Improvement Amendments, or CLIA. CLIA certification is legally required to receive reimbursement from federal or state medical benefit programs, like Medicare and Medicaid, and is a practical requirement for most third-party insurance benefit programs. Our CLIA-certified laboratory, which is permitted to accept 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.

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

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

### **Our Voluntary Product Recall**

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

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

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

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

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

As of June 30, 2014, we have incurred cumulative actual recall expenses of \$390,812 and have recorded \$12,028 as a product recall liability related to the estimated remaining costs of the recall, including the estimated costs of pursuing the additional 510(k) clearance. The recall and 510(k) process may take longer than expected; for example the FDA may require additional actions that we have not anticipated. As a result, we may incur costs that we have not anticipated. Accordingly, the actual expenses for the recall may be higher than we currently expect. Prior to the commencement of the recall in October 2013, substantially all of our revenue was from sales of the MASCT System and patient collection kits and from testing services performed by our laboratory. As a result of the recall of the MASCT System and patient collection kits, we have ceased generating product revenue. Our laboratory services revenue has also virtually ceased as of October 2013.

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

### **Follow-up FDA Inspection**

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

### **Revenue Sources**

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

### **Commercial Lease Agreements**

On 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 six months ended June 30, 2014, the Company incurred \$160,631 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 Hutchinson 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 June 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 new laboratory facilities will be sufficient to meet our needs for the foreseeable future and we do not expect to need additional laboratory space for at least the next 24 months. We may need to secure additional office space as we grow our sales and marketing force and add to our administrative staff. Additional office space is readily available in our local market and we believe we can rent when necessary additional office space on acceptable terms.

## 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 Six Months Ended June 30, 2014 and 2013

*Revenue and Cost of Goods Sold.* For the three months and six months ended June 30, 2014, revenue totaled \$9,875 and \$33,999, consisting of additional cash collected in excess of the amounts we accrued previously at the Medicare rates. Total revenue for the three and six months ended June 30, 2013 was \$326,078 and \$508,748. Cost of revenue totaled \$0 for the three months and six months ended June 30, 2014, compared to \$222,160 and \$288,624 in the same periods in 2013.

For the three months and six months ended June 30, 2014, gross profit totaled \$9,875 and \$33,999, compared to \$103,918 and \$220,124 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 June 30, 2014, total operating expenses were \$3,196,408 consisting of general and administrative (G&A) expenses of \$2,462,256, research and development (R&D) expenses of \$510,767, and selling expenses of \$223,385, representing an increase of \$509,143, or 19% from \$2,687,265 in the same period in 2013, consisting of G&A expenses of \$2,177,920, R&D expenses of \$189,955, and selling expenses of \$319,390. Operating expenses for the six months ended June 30, 2014 were \$5,631,457 consisting of G&A expenses of \$4,236,964, R&D expenses of \$933,270, and selling expenses of \$461,223. Operating expenses increased \$886,553, or 19% from \$4,744,904 for the same period in 2013 consisting of \$3,742,792 in G&A expenses, \$410,147 in R&D expenses, and \$591,965 in selling expenses.

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 and our related laboratory service offerings, we would also begin to incur additional sales and marketing expenses as we continue building a regional, and ultimately national, sales force.

*Selling Expenses.* Selling expenses for the three months ended June 30, 2014 were \$223,385, a decrease of \$96,005, or 30%, from \$319,390 for the three months ended June 30, 2013. Selling expenses for the three months ended June 30, 2014 consisted primarily of \$115,640 in selling and marketing professional fees and \$106,985 in compensation expenses. Selling expenses for the six months ended June 30, 2014 were \$461,223, a decrease of \$130,742, or 22% from \$591,965 for the same period in 2013. Selling expenses for the six months ended June 30, 2014 consisted of \$192,989 in salaries and \$267,474 in selling and marketing professional fees.

Selling expenses decreased as a result of the voluntary recall in October 2013. We expect selling expenses will increase when we receive the FDA clearance and prepare for and execute the relaunch of ForeCYTE 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 June 30, 2014 were \$510,767, an increase of \$320,812, or 169%, from \$189,955 for the three months ended June 30, 2013. R&D expenses for the six months ended June 30, 2014 were \$933,270, an increase of \$523,123, or 128% 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 June 30, 2014 were \$2,462,256, an increase of \$284,336, or 13%, from \$2,177,920 in the same period in 2013. The G&A expenses for the three months ended June 30, 2014 consisted primarily of \$818,906 in compensation expenses, \$606,696 in legal and regulatory expenses, \$330,992 in consulting and professional fees, \$53,737 in travel expenses, \$124,101 in insurance expenses, \$127,827 in amortization and depreciation expenses, and \$104,167 in Board of Directors fees. G&A expenses for the three months ended June 30, 2013 were \$2,177,920 which primarily consisted of \$457,165 in compensation expenses, \$162,106 in legal expenses, \$615,846 in consulting and professional fee expenses, \$48,059 in travel expense, \$96,588 in insurance expenses, and \$391,029 in Board of Directors annual fees consisting of cash fees and the non-cash expense associated with fees paid in the form of options.

G&A expenses for the six months ended June 30, 2014 were \$4,236,964, an increase of \$494,172, or 13% from \$3,742,792 for the same period in 2013. G&A expenses for the six months June 30, 2014 primarily consisted of \$1,484,041 in compensation expenses, \$816,459 in legal fees, \$589,197 in consulting and professional fees, \$97,763 in travel expenses, \$256,893 in insurance expenses, \$64,758 in bad debt expenses, \$252,921 in amortization and depreciation expenses, and \$123,167 in Board of Directors fees. G&A expenses for the six months ended June 30, 2013 mainly consisted of \$964,025 in compensation expenses, \$340,053 in legal expenses, \$1,219,099 in consulting and professional fees, \$68,545 in travel expenses, \$159,510 in insurance expenses, \$105,771 in marketing expenses, and \$436,029 in Board of Directors fees.

The increase in 2014 G&A expenses over 2013 was primarily attributable to an increase in salaries and employees benefits as we grew headcount in our manufacturing and regulatory departments, travel expenses, cost of insurance, and legal and professional fees. We expect our G&A expenses to continue to grow as we hire additional administrative and manufacturing personnel as we prepare for and execute on the relaunch of the ForeCYTE Breast Aspirator, and our other products 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.

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

## Cash Flows

As of June 30, 2014, we had cash and cash equivalents of \$14,298,491, consisting of net cash used in operating activities of \$4,858,345, net cash used in investing activities of \$191,070 and net cash provided by financing activities of \$13,005,745, compared to \$2,439,512 at June 30, 2013. The \$11.9M increase in cash is mainly attributed to the \$14.0M raised in the 2014 Public Offerings, offset by \$1.4M increase in net cash used in operating activities. For the six months ended June 30, 2014, we incurred a net loss of \$5,599,507.

## 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 relaunch of the ForeCYTE Breast Aspirator, complete the development of and launch the ArgusCYTE test and NextCYTE tests, and other devices 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 for the remainder of 2014. If we are unable to raise additional capital when needed, however, we could be forced to curtail or cease operations. Our future capital uses and requirements depend on numerous forward-looking factors. These factors include the following:

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

We do not expect to generate revenue until we receive FDA clearance to market the ForeCYTE Breast Aspirator. We expect our continuing operating losses to result in increases in cash used in operations over at least the next year. Although we expect our existing resources as of the date of this report, to be sufficient to fund our planned operations through 2014, we may require additional funds earlier than we currently expect to successfully commercialize the ForeCYTE Breast Aspirator. Because of the numerous risks and uncertainties associated with the development and commercialization of the ForeCYTE Breast Aspirator and our other devices, tests and therapeutics in the pipeline, we

are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated research and development activities and commercialization efforts.

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

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

### **Off-Balance Sheet Arrangements**

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

### **Recent Accounting Pronouncements**

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.

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

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

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

A hearing in the arbitration has been postponed pending certain procedures in the above Western Division action and may be delayed further to accommodate other third party civil and federal criminal proceedings alleging securities and wire fraud that have been brought against Mr. Kelly with respect to his prior employment and predating his service with the Company. On March 11, 2014 a press release was issued by the FBI stating that Mr. Kelly had pled guilty in Manhattan federal court to securities and wire fraud charges related to his employment as CEO of Wwebnet. Mr. Kelly also agreed to forfeit \$2,111,600 and, separately, pay \$2,111,600 in restitution. The sentencing hearing is

scheduled for September 18, 2014.

The Company is reasonably confident in its defenses to Mr. Kelly's and Mr. Cononi's claims. Consequently, no provision or liability has been recorded for these claims as of June 30, 2014. However, it is at least reasonably possible that the Company's estimate of liability may change in the near term. Any payments by reason of an adverse determination in this matter will be charged to earnings in the period of determination.

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

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 June 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 six months ended June 30, 2014, we generated no revenue and we incurred a net loss of \$5,599,507. We expect that our existing resources will be sufficient to fund our planned operations through 2014. 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 FDA clearance to relaunch ForeCYTE 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. 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.

**ITEM 6. EXHIBITS**

(a) Exhibits

10.1 Office Space Assignment and Assumption of Lease and Consent to Assignment dated August 8, 2014 between Legacy Group, Inc. and the Company.

31.1 Certification pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934 of Steven C. Quay

31.2 Certification pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934 of Kyle Guse

32.1 Certification pursuant to 18 U.S.C. Section 1350 of Steven C. Quay

32.2 Certification pursuant to 18 U.S.C. Section 1350 of Kyle Guse

101\* Interactive Data Files pursuant to Rule 405 of Regulation S-T

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

## SIGNATURES

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

Date: August 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)