

ATOSSA GENETICS INC
Form 10-Q
May 13, 2015

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 March 31, 2015

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
incorporation or organization)**

26-4753208

**(I.R.S. Employer
Identification No.)**

2345 Eastlake Ave. East, Suite 201

Seattle, WA

(Address of principal executive offices)

98102

(Zip Code)

Edgar Filing: ATOSSA GENETICS INC - Form 10-Q

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 May 11, 2015 was 27,217,257.

ATOSSA GENETICS INC.

FORM 10-Q

QUARTERLY REPORT

INDEX

PART I. FINANCIAL INFORMATION

ITEM 1.	<u>Condensed Consolidated Financial Statements – Unaudited</u>	3
	<u>Condensed Consolidated Balance Sheets as of March 31, 2015 and December 31, 2014</u>	3
	<u>Condensed Consolidated Statements of Operations for the three months ended March 31, 2015 and 2014</u>	4
	<u>Condensed Consolidated Statement of Stockholders' Equity for the three months ended March 31, 2015</u>	5
	<u>Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 2015 and 2014</u>	6
	<u>Notes to Consolidated Financial Statements</u>	7
ITEM 2.	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	18
ITEM 3	<u>Quantitative and Qualitative Disclosures about Market Risk</u>	25
ITEM 4.	<u>Controls and Procedures</u>	25

PART II. OTHER INFORMATION 26

ITEM 1.	<u>Legal Proceedings</u>	26
ITEM 1A.	<u>Risk Factors</u>	26
ITEM 2.	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	28
ITEM 3.	<u>Defaults upon Senior Securities</u>	28
ITEM 4.	<u>Mine Safety Disclosures</u>	28
ITEM 5.	<u>Other Information</u>	28
ITEM 6.	<u>Exhibits</u>	28

SIGNATURES

29

2

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

	March 31, 2015 (Unaudited)	December 31, 2014
Assets		
Current assets		
Cash and cash equivalents	\$9,728,369	\$8,500,718
Accounts receivable, net	1,280,209	297,958
Prepaid expense	263,763	247,207
Inventory, net	94,628	39,788
Total current assets	11,366,969	9,085,671
Furniture and equipment, net	381,590	357,532
Intangible assets, net	1,877,755	1,920,645
Deferred financing costs	-	351,961
Other assets	176,551	48,193
Total assets	\$13,802,865	\$11,764,002
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	\$966,208	\$594,357
Accrued expenses	1,117,932	444,861
Payroll liabilities	1,279,528	1,056,705
Short-term lease obligations	79,974	76,025
Other current liabilities	42,914	42,228
Total current liabilities	3,486,556	2,214,176
Deferred rent, net of current portion	7,227	2,483
Long-term lease obligations	25,230	49,216
Total liabilities	3,519,013	2,265,875

Commitments and contingencies (note 13)

Edgar Filing: ATOSSA GENETICS INC - Form 10-Q

Stockholders' equity		
Preferred stock - \$.001 par value; 10,000,000 shares authorized, 0 shares issued and outstanding	-	-
Common stock - \$.001 par value; 75,000,000 shares authorized, 27,217,257 and 24,564,058 shares issued and outstanding	27,217	24,564
Additional paid-in capital	48,766,466	44,648,103
Accumulated deficit	(38,509,831)	(35,174,540)
Total stockholders' equity	10,283,852	9,498,127
 Total liabilities and stockholders' equity	 \$ 13,802,865	 \$ 11,764,002

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 March 31 ,	
	2015	2014
Revenue		
Diagnostic testing services	\$ 1,872,798	\$ 24,124
Product sales	470	-
Total revenue	1,873,268	24,124
Cost of revenue		
Diagnostic testing services	1,206,312	-
Product sales	1,642	-
Total cost of revenue	1,207,954	-
Gross profit	665,314	24,124
Selling expenses	546,854	237,838
Research and development expenses	797,225	422,503
General and administrative expenses	2,605,111	1,774,708
Total operating expenses	3,949,190	2,435,049
Operating loss	(3,283,876)	(2,410,925)
Interest income	279	143
Interest expense	1,784	749
Other losses	49,910	-
Loss before income taxes	(3,335,291)	(2,411,531)
Income taxes	-	-
Net loss	\$(3,335,291)	\$(2,411,531)
Loss per common share - basic and diluted	\$(0.13)	\$(0.10)
Weighted average shares outstanding, basic and diluted	24,916,867	24,419,060

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

ATOSSA GENETICS, INC.**CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY**

	Common Stock		Additional	Accumulated	Total
	Shares	Amount	Paid-in Capital	Deficit	Stockholders' Equity
Balance at December 31, 2014	24,564,058	\$24,564	\$44,648,103	\$(35,174,540)	\$9,498,127
Issuance of common shares for cash	2,653,199	2,653	4,289,696	-	4,292,349
Amortization of deferred financing costs	-	-	(351,961)	-	(351,961)
Compensation cost for stock options granted to executives and employees	-	-	180,628	-	180,628
Net loss for the three months ended March 30, 2015	-	-	-	(3,335,291)	(3,335,291)
Balance at March 31, 2015	27,217,257	\$27,217	\$48,766,466	\$(38,509,831)	\$10,283,852

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

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

	For the Three Months Ended March 31,	
	2015	2014
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	\$(3,335,291)	\$(2,411,531)
Compensation cost for stock options granted	180,628	230,181
Depreciation and amortization	84,867	125,097
Bad debt expense	218,482	27,860
Changes in operating assets and liabilities:		
Accounts receivable	(1,200,733)	19,796
Inventory	(54,840)	-
Prepaid expenses	(16,556)	(245,178)
Increase in other assets	(128,359)	(24,863)
Accounts payable	371,851	42,944
Payroll liabilities	222,823	(150,504)
Deferred rent	4,744	(13,134)
Accrued expenses	653,034	(75,905)
Product recall liability	-	(115,292)
Other current liabilities	687	(13,460)
Net cash used in operating activities	(2,998,663)	(2,603,989)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of furniture and equipment	(54,860)	(2,966)
Purchase of intangible assets	(11,175)	(100,000)
Net cash used in investing activities	(66,035)	(102,966)
CASH FLOWS FROM FINANCING ACTIVITIES		
Net proceeds from issuance of common stock and warrants	4,292,349	12,955,745
Net cash provided by financing activities	4,292,349	12,955,745
NET INCREASE IN CASH AND CASH EQUIVALENTS	1,227,651	10,248,790
CASH AND CASH EQUIVALENTS, BEGINNING BALANCE	8,500,718	6,342,161
CASH AND CASH EQUIVALENTS, ENDING BALANCE	\$9,728,369	\$16,590,951
SUPPLEMENTAL DISCLOSURES:		
Interest paid	\$1,784	\$749
NONCASH INVESTING AND FINANCING ACTIVITIES:		
Noncash reclass of prepaid license fees	\$	15,000
Amortization of commitment shares	\$351,961	\$75,000

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

ATOSSA GENETICS INC.

NOTES TO 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’s operations began in December 2008 with the negotiations for the acquisition of the Mammary Aspirate Specimen Cytology Test System, or the MASCT System, patent rights and assignments and the FDA clearance for marketing, which acquisition was completed in January 2009. The Company was formed to develop and market the MASCT System, which is a medical device that collects specimens of nipple aspirate fluid (NAF). The Company’s fiscal year ends on December 31st.

In December 2011, the Company established The National Reference Laboratory for Breast Health, Inc., or NRLBH, as a wholly-owned subsidiary which performs the Company’s NAF cytology test on NAF specimens including those collected with the MASCT System. The NRLBH is certified by College of American Pathologists (CAP) and by Clinical Laboratory Improvement Amendments (CLIA). The current version of the MASCT System is called the ForeCYTE Breast Aspirator. The NRLBH is providing other test services, including the pharmacogenomics test which provides physicians with genetic information that can be used to guide therapeutic decisions and may mitigate the incidence of costly adverse drug reactions and improve efficiencies.

Since its inception, the Company has been dependent upon the receipt of capital investment to fund its continuing activities. In addition to the normal risks associated with a new business venture, there can be no assurance that the Company’s business plan will be successfully executed. The Company’s ability to execute its business plan will depend on its ability to obtain additional financing and achieve a profitable level of operations. There can be no assurance that sufficient financing will be obtained. Further, the Company cannot give any assurance that it will generate substantial revenue or that its business operations will prove to be profitable.

NOTE 2: GOING CONCERN

The Company’s consolidated financial statements are prepared using generally accepted accounting principles in the United States of America (“GAAP”) applicable to a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The Company has incurred net losses and negative operating cash flows since inception. For the three months ended March 31, 2015, the Company recorded a net loss of

approximately \$3.3 million and used approximately \$3.0 million of cash in operating activities. As of March 31, 2015, the Company had approximately \$9.7 million in cash and cash equivalents and working capital of approximately \$7.9 million. The Company has not yet established an ongoing source of revenue sufficient to cover its operating costs and allow it to continue as a going concern. The ability of the Company to continue as a going concern is dependent on the Company obtaining adequate capital to fund operating losses until it becomes profitable. The Company can give no assurances that any additional capital that it is able to obtain, if any, will be sufficient to meet its needs, or that any such financing will be obtainable on acceptable terms. If the Company is unable to obtain adequate capital, it could be forced to cease operations or substantially curtail its commercial activities. These conditions raise substantial doubt as to the Company's ability to continue as a going concern. The accompanying consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts and classification of liabilities should the Company be unable to continue as a going concern.

Management's Plan to Continue as a Going Concern

In order to continue as a going concern, the Company will need, among other things, additional capital resources. Management's plans to obtain such resources for the Company include (1) obtaining capital from the sale of its equity securities during 2015, (2) sales of the ForeCYTE and FullCYTE Breast Aspirators and laboratory service revenue in 2015, and (3) short-term borrowings from the banks, stockholders or related party(ies), if needed. However, management cannot provide any assurance that the Company will be successful in accomplishing any of its plans.

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

NOTE 3: SUMMARY OF ACCOUNTING POLICIES

Basis of Presentation:

The accompanying 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, 2014, which contain information useful to understanding the Company's business and financial statement presentations. The Condensed Consolidated Balance Sheet as of December 31, 2014 was derived from the Company's most recent audited financial statements, but does not include all disclosures required by GAAP for a year-end balance sheet. The Company's significant accounting policies and practices are presented as Note 3 to the consolidated financial statements included in the Annual Report. The accompanying condensed consolidated financial statements include the financial statements of Atossa Genetics Inc. and its wholly-owned subsidiary NRLBH. All significant intercompany account balances and transactions have been eliminated in consolidation. These condensed consolidated financial statements have been prepared in accordance with GAAP.

Use of Estimates:

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

Recently Issued Accounting Pronouncements:

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

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

NOTE 4: PREPAID EXPENSES

Prepaid expenses consisted of the following:

	March 31, 2015	December 31, 2014
Prepaid insurance	103,649	87,633
Prepaid hardware and software	41,313	38,268
Retainer and security deposits	25,000	25,000
Lab supplies	6,804	14,976
Tradeshow and other marketing events	5,995	50,000
Other	81,002	31,330
Total prepaid expenses	\$ 263,763	\$ 247,207

NOTE 5: FURNITURE AND EQUIPMENT

Furniture and equipment consisted of the following:

March 31, 2015	December 31, 2014
-------------------	----------------------

Edgar Filing: ATOSSA GENETICS INC - Form 10-Q

Machinery and equipment	\$ 574,848	\$ 522,813
Leasehold improvements	96,491	93,665
Furniture and equipment	671,339	616,478
Less: Accumulated depreciation	(289,749)	(258,946)
Total furniture and equipment	\$ 381,590	\$ 357,532

Depreciation expense for the three months ended March 31, 2015 and 2014 was \$30,802 and \$21,171, respectively.

NOTE 6: INTANGIBLE ASSETS

Intangible assets consisted of the following:

	March 31, 2015	December 31, 2014
Patents	\$1,630,000	\$ 1,630,000
Capitalized license costs	200,000	200,000
Software	214,212	203,038
Intangible assets	2,044,212	2,033,038
Less: Accumulated amortization	(166,457)	(112,393)
Total intangible assets, net	\$1,877,755	\$ 1,920,645

Intangible assets amounted to \$1,877,755 and \$1,920,645 as of March 31, 2015 and December 31, 2014, respectively, and consisted of patents, capitalized license costs and software acquired. The amortization period for the purchased software is 3 years. Amortization expense related to software for the three months ended March 31, 2015 and 2014 was \$11,811 and \$8,761, respectively.

Patents amounted to \$1,630,000 as of March 31, 2015 and December 31, 2014, 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 was from 7 to 12 years. Amortization expense related to patents was \$37,254 and \$93,497 for the three months ended March 31, 2015 and 2014, respectively.

Capitalized license costs consist of fees paid to A5 Genetics KFT, Corporation, pursuant to which the Company received the world-wide (other than the European Union) exclusive license to use the software in the NextCYTE test. Amortization expense related to license costs was \$5,000 and \$1,668 for the three months ended March 31, 2015 and 2014, respectively.

Future estimated amortization expenses as of March 31, 2015 for the five succeeding years is as follows:

For the Year Ending December 31,	Amounts
2015 (includes the remainder of the year)	\$163,126
2016	228,529
2017	197,168
2018	169,325
2019	169,015
Thereafter	950,592
	\$1,877,755

NOTE 7: PAYROLL LIABILITIES:

Payroll liabilities consisted of the following:

	March 31, 2015	December 31, 2014
Accrued bonus payable	\$896,884	\$ 752,828
Accrued payroll liabilities	157,959	109,653
Accrued payroll tax liabilities	224,685	194,224
Total payroll liabilities	\$1,279,528	\$ 1,056,705

NOTE 8: ACCRUED EXPENSES:

Accrued expenses consisted of the following:

	March 31, 2015	December 31, 2014
Accrued commissions	\$924,825	\$ 174,398
Accrued expenses	138,144	254,126
Accrued royalties	54,963	16,337
Total accrued expenses	\$1,117,932	\$ 444,861

NOTE 9: 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. 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 at \$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 175,027 warrants, 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”). Each 2014 Placement Agent Warrant entitles the Placement Agent to purchase one share of the Company’s common stock at \$3.00 per share. The cash payment of the \$980,151 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 on November 29, 2018 (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 provided in current GAAP accounting standards for equity classification.

Outstanding Warrants

As of March 31, 2015, warrants to purchase 6,033,426 shares of common stock are outstanding including:

	Outstanding Warrants to purchase shares	Exercise price	Expiration date
2011 private placement	4,252,050	\$1.25 - 1.60	June 23, 2016
Acueity warrants	325,000	5.00	September 30, 2017
2014 public offering	1,166,849	3.00	January 29, 2019
Placement agent fees for Company’s offerings	242,027	2.12 – 12.43	March - November, 2018
Outside consulting	47,500	\$4.24	January 14, 2018
	6,033,426		

From March 4, 2015 to March 31, 2015 we sold 2,653,199 shares of Common Stock to Aspire Capital under the November 8, 2013 agreement with them, with total gross proceeds to the Company of \$4,292,349.

NOTE 10: 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 ended March 31, 2015 and 2014 because the effect of them would be anti-dilutive since the Company recorded net losses for both periods:

	Three Months Ended	
	March 31,	
	2015	2014
Options to purchase common stock	4,354,418	2,246,651
Warrants to purchase common stock	6,033,426	4,775,550
Restricted stock units	-	-
	10,387,844	7,022,201

NOTE 11: INCOME TAXES

Deferred income tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between the financial reporting and tax bases of assets and liabilities and are measured using enacted tax rates in effect for the year in which those temporary differences are expected to be recovered or settled. A valuation allowance is provided for the amount of deferred tax assets that, based on available evidence, are not expected to be realized.

As a result of the Company's cumulative losses, management has concluded that a full valuation allowance against the Company's net deferred tax assets is appropriate. No income tax liabilities existed as of March 31, 2015 and December 31, 2014 due to the Company's continuing operating losses.

NOTE 12: 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 March 31, 2015 and December 31, 2014, the Company had \$9,478,369 and \$8,250,718 in excess of the FDIC insured limit, respectively.

NOTE 13: COMMITMENTS AND CONTINGENCIES***Affymetrix Purchase Commitment***

In connection with the development of the NextCYTE test by the NRLBH, the NRLBH entered into an “OwnerChip Program Agreement” with Affymetrix, Inc. (“Affymetrix”), a manufacturer of GeneChip Systems, where Affymetrix has agreed to loan a GeneChip System 3000Dx v.2 (“instrument”) to the Company if it purchases and takes delivery of a minimum thirty GeneChip Human Genome U133 Plus 2.0 (30-pack) arrays at \$21,590 per 30-pack for the next three years for a total purchase obligation of \$647,700 with a minimum purchase of ten 30-pack arrays per contract year. At the end of the three year contract, upon fulfillment of the purchase commitment, the instrument title and ownership transfer to the NRLBH at no additional cost. Because the Company takes ownership of the equipment at the completion of the three-year contract, the Company determined that the arrangement represents a capital lease for the equipment. The Company recorded \$206,702 as a capital lease for the equipment and began amortizing the equipment on a straight line basis over five years. In addition to the GeneChip Human Genome, the NRLBH must purchase a two year service contract for \$51,600 to cover maintenance of the instrument during the contract period. The NRLBH placed an initial order for four 30-pack arrays during 2013 for \$94,723. In September 2014, the NRLBH purchased six additional 30-pack arrays for \$142,005.

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

Year Ending December 31,	Amount
2015	\$53,045
2016	49,194
Total minimum lease payments	\$102,239

A5 Software Development Commitment

On June 10, 2013 the Company entered into an irrevocable license and service agreement with A5 Genetics KFT, Corporation (“A5 Genetics”), pursuant to which the Company received the world-wide (other than the European Union) exclusive license to the software used in the NextCYTE test. The Company has the right to prosecute patents related to this software, two of which the Company has filed in the United States. The patent applications have been assigned to the Company. The Company paid a one-time fee of \$100,000 to A5 Genetics in 2013 and in March 2014 the Company completed software validation and paid an additional \$100,000 to A5 Genetics. The Company is obligated to pay up to an additional \$1.2 million to A5 Genetics upon receiving the regulatory clearance for the NextCYTE test. The Company must also pay a royalty of \$50 for each NextCYTE test performed and a service fee of \$65 for each NextCYTE test performed. The NextCYTE test is still in validation stage and no royalty or service fees have been paid as of March 31, 2015. The agreement terminates on the later of June 10, 2023 or the expiration of the latest

patents covering the software.

Luminex Reagent Rental Agreement and Assay License Agreement

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

BioVentive Laboratory Marketing Service Agreement

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

Targeted Medical Education (TME) Master Service Agreement

On September 1, 2014, the NRLBH entered into a three year agreement with TME Research LLC (TME) which requires TME to provide to the NRLBH 100 tissue specimens in connection with the development of the NextCYTE test. Fees payable to TME under the agreement includes \$99,600 up front, \$31,500 upon supplying the first 25 specimens and \$31,500 at the time of final delivery of all specimens. The agreement is terminable with 60 days prior written notice or immediately upon a material breach. As of March 31, 2015, the Company has paid \$162,600 in fees, which were recorded as R&D expenses.

Litigation and Contingencies

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. On October 6, 2014 the Court granted defendants' motion dismissing all claims against Atossa and all other defendants. On October 30, 2014, the Court entered a final order of dismissal. On November 3, 2014, plaintiffs filed a notice of appeal with the Court and have appealed the Court's dismissal order to the U.S. Court of Appeals for the Ninth Circuit. On February 11, 2015, plaintiffs filed their opening appellate brief. Defendants filed an answer on April 13, 2015. If plaintiffs choose to file a reply brief in support of their appeal, it is due May 18, 2015. A hearing for the appeal has not been set.

The Company believes this lawsuit is without merit and plans to defend itself vigorously; however, failure by the Company to obtain a favorable resolution of the claims set forth in the complaint could have a material adverse effect on the Company's business, results of operations and financial condition. Currently, the amount of such material adverse effect cannot be reasonably estimated, and no provision or liability has been recorded for these claims as of

March 31, 2015. 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.

NOTE 14: STOCK BASED COMPENSATION

Stock Options and Incentive Plan

On September 28, 2010, the Board of Directors approved the adoption of the 2010 Stock Option and Incentive Plan, or the 2010 Plan, to provide for the grant of equity-based awards to employees, officers, non-employee directors and other key persons providing services to the Company. Awards of incentive options may be granted under the 2010 Plan until September 2020. No other awards may be granted under the 2010 Plan after the date that is 10 years from the date of stockholder approval. An aggregate of 1,000,000 shares were initially reserved for issuance in connection with awards granted under the 2010 Plan, such number of shares to be subject to adjustment as provided in the plan and in any award agreements entered into by the Company under the plan, and upon the exercise or conversion of any awards granted under the plan. On January 1, 2012, 450,275 shares were added to the 2010 Plan and on January 1, 2013, 516,774 shares were added to the 2010 Plan, on January 1, 2014, 742,973 shares, on January 1, 2015, 983,362 shares were added to the 2010 plan as provided under the terms of the 2010 Plan.

The Company granted options to purchase 768,322 shares of common stock to employees and directors during the three months ended March 31, 2015. There are 743,966 options available for grant under the 2010 Plan as of March 31, 2015.

Compensation costs associated with the Company's stock options are recognized, based on the grant-date fair values of these options, over the requisite service period, or vesting period. Accordingly, the Company recognized stock based compensation expense of \$180,628 and \$230,181 for the three months ended March 31, 2015 and 2014, respectively.

Three Months Ended**March 31,
2015 2014**

General and administrative	\$ 129,360	\$ 209,629
Research and development	18,970	4,627
Selling	32,298	15,926
Total stock compensation expense	\$ 180,628	\$ 230,181

The following table presents information concerning stock option grants for the three months ended March 31, 2015:

Date of Grant	Employees		Executives & Officers	
	January –March 2015		January – March 2015	
Fair value of common stock on date of grant	\$ 1.19 – 1.59		\$ 1.59	
Exercise price of the options	\$ 1.40 – 1.88		\$ 1.88	
Expected life of the options (years)	6.04-6.13		6.06	
Dividend yield	0.00	%	0.00	%
Expected volatility	113.5-	115	113.5	%
Risk-free interest rate	1.64 – 1.79	%	1.74	%
Expected forfeiture per year (%)	10.00	%	10.00	%
Weighted average fair value of the options per unit	\$ 1.56		\$ 1.59	

Options issued and outstanding as of March 31, 2015 and their activities during the three 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, 2015	3,675,634	\$ 2.86		\$ 344,000
Granted	768,322	1.56		
Forfeited	(89,538)	0.70		51,750
Exercised	-	-		
Outstanding as of March 31, 2015	4,354,418	2.71	8.20	\$ 884,650

Edgar Filing: ATOSSA GENETICS INC - Form 10-Q

Exercisable as of March 31, 2015	1,494,728	4.21	6.23	\$ 140,282
Vested and expected to vest (1)	3,967,136	\$ 2.79	8.09	\$ 797,960

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

At March 31, 2015, there were 2,859,690 unvested options outstanding and the related unrecognized total compensation cost associated with these options was \$2,302,162. This expense is expected to be recognized over a weighted-average period of 3.16 years.

NOTE 15: SUBSEQUENT EVENTS

All subsequent events requiring recognition as of March 31, 2015 have been incorporated into these consolidated financial statements and there are no subsequent events that require disclosure in accordance with FASB ASC Topic 855, "Subsequent Events".

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 maintain our clearances from the U.S. Food and Drug Administration, or FDA, and foreign regulatory bodies, and the CE Certificates of Conformity granted by our notified body, to sell, market and distribute our medical devices;

• whether we can achieve our revenue forecast and other financial projections for 2015;

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

our ability to successfully continue selling and servicing Pharmacogenomics and NAF cytology testing in our laboratory;

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

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

our ability to maintain our business relationships, including with our distributors, suppliers and customers, while we launch and commercialize the FullCYTE Breast Aspirator in the United States and ForeCYTE Breast Aspirator and laboratory tests outside the United States;

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

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

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

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

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

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

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

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

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

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

our ability to attract and retain key personnel.

These and other forward-looking statements made in this report are presented as of the date on which the statements are made. We have included important factors in the cautionary statements included in this report, particularly in the section titled "ITEM 1A. RISK FACTORS," that we believe could cause actual results or events to differ materially from the anticipated results as set forth in the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any new information, future events or circumstances that may affect our business after the date of this report. Except as required by law, we do not intend to update any forward-looking statements after the date on which the statement is made, whether as a result of new information, future events or circumstances or otherwise.

Company Overview

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

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

The ForeCYTE Breast Aspirator will not be launched in the United States unless and until we receive additional regulatory clearance from the FDA.

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

Our 2015 objectives consist of the following:

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

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

(3) Maximize total gross revenue from our products and services: We plan to grow our revenue by selling our products and promoting the tests currently being offered by the NRLBH, including NAF cytology tests and pharmacogenomics tests, and by developing and commercializing additional laboratory tests.

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

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

Summary of Our Products and Services

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

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

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

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

Follow-up FDA Inspection

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

Revenue Sources

Our business provides us with two potential revenue sources: (i) sales-based revenue from the sale of our medical devices, such as our ForeCYTE Breast Aspirator and FullCYTE Breast Aspirator and patient kits to distributors, physicians, breast health clinics, and mammography clinics and (ii) service, or use-based, revenue from laboratory services performed by the NRLBH, such as preparation and interpretation of the NAF samples sent to our laboratory for analysis, pharmacogenomics tests and other tests that may be developed and commercialized by the NRLBH. Our main source of revenue beginning in October 2014 has been from pharmacogenomics testing and we anticipate generating additional revenue from other resources when we develop and launch new laboratory tests and/or when we further commercialize the FullCYTE Breast Aspirator in the United States and the ForeCYTE Breast Aspirator outside the United States. We plan to initially sell the breast aspirators and our laboratory services through regional and national specialty product distributors, with independent sales representatives specializing in women's health, and through our own direct sale force.

Critical Accounting Policies and Estimates

In our Annual Report on Form 10-K for the year ended December 31, 2014, 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, 2014. Readers are encouraged to review these disclosures in conjunction with the review of this report.

Revenue Recognition

Overview

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

Product Revenue

The Company generally recognizes revenue for sales of our devices on an accrual basis. Shipping documents and the completion of any customer acceptance requirements, when applicable, will be used to verify product delivery. The Company will assess whether a price is fixed or determinable based upon the payment terms associated with the transaction and whether the sales price is subject to refund or adjustment.

Service Revenue

The Company records revenue for diagnostic testing on an accrual basis at the Medicare allowed and invoiced amount. Diagnostic testing revenue at the Medicare rate is recognized upon completion of the test, communication of results to the patient's physician, and when collectability is reasonably assured. Patient requisition forms and/or contracts are generally used to determine the existence of an arrangement. Once the Company has historical sales and can determine the proper amount to recognize as uncollectible, it will then begin to recognize the entire amount, both Medicare and non-Medicare billing on an accrual basis, with an offsetting allowance for doubtful accounts recorded based on history.

Cost of Revenue

Cost of revenue consists of cost of diagnostic testing services and cost of product sales. Cost of diagnostic testing services primarily includes direct cost of material, direct labor, equipment, commissions, royalty and shipping costs to process the patient samples (including pathology, quality control analysis, and shipping charges to transport tissue sample) in our laboratory. Costs associated with performing the Company's tests are recorded as tests are processed. Costs recorded for tissue sample processing and shipping charges represent the cost of all the tests processed during the period regardless of whether revenue was recognized with respect to that test. Cost of product sales primarily includes manufacturing cost of our ForeCYTE and FullCYTE devices for sales to distributors, which is recorded upon transfer of ownership of the goods.

Accounts Receivable

Accounts receivable are recorded at net realizable value consisting of the carrying amount less allowance for doubtful accounts, as needed. The Company assesses the collectability of accounts receivable based primarily upon the creditworthiness of the customer as determined by credit checks and analysis, as well as the customer's payment history. Management reviews the composition of accounts receivable and analyzes historical bad debts, customer concentrations, customer credit worthiness, current economic trends, and changes in customer payment patterns to evaluate the adequacy of these reserves. The Company's allowance for doubtful accounts as of March 31, 2015 and December 31, 2014 was \$317,094 and \$564,456, respectively. Bad debt expense is included in general and administrative expense on the Company's consolidated statements of operations. Bad debt expense was \$218,481 and \$27,860 for the three months ended March 31, 2015 and 2014, respectively.

Results of Operations

Three Months Ended March 31, 2015 and 2014

Revenue and Cost of Revenue: For the three months ended March 31, 2015, we had total net revenue of \$1,873,268, consisting of mainly pharmacogenomics testing, compared to \$24,124 revenue in the same period in 2014 from additional cash collections on NAF cytology tests. We ceased generating any revenue from October 2013 through October 2014 due to our product recall. In March 2015, we began the launch of the FullCYTE Breast Aspirator in the U.S. and the ForeCYTE Breast Aspirator in the EU, focusing initially on the Netherlands, Germany, Switzerland, and the United Kingdom.

Edgar Filing: ATOSSA GENETICS INC - Form 10-Q

Total cost of revenue for the three months ended March 31, 2015 was \$1,207,954 and consisted of costs relating to pharmacogenomics testing services; compared to \$0 for the same period in 2014. Gross profit for the three months ended March 31, 2015 was \$665,314 which was attributable to pharmacogenomics testing.

Operating Expenses: Total operating expenses were \$3,949,190 for the three months ended March 31, 2015, consisting of general and administrative (G&A) expenses of \$2,605,111, R&D expenses of \$797,225, and selling expenses of \$546,854 representing an increase of \$1,514,141, or 62%, from \$2,435,049 for the three months ended March 31, 2014, which consisted of G&A expenses of \$1,774,708, R&D expenses of \$422,503, and selling expenses of \$237,838.

Selling Expenses: Selling expenses for the three months ended March 31, 2015 were \$546,854, an increase of \$309,016, or 130%, from \$237,838 for the three months ended March 31, 2014. The increase in selling expenses is mainly due to increase in compensation expenses, travel, and advertisement as a result of ForeCYTE and FullCYTE launch and commercialization in Europe and the United States. We expect that our selling expenses will continue to increase during 2015, as we build a sales force in the United States and outside the United States to support the launch and commercialization of the ForeCYTE and FullCYTE Breast Aspirators and our laboratory service offerings. Selling expenses may also increase as we market and sell the services offered by the NRLBH, including NAF cytology tests, pharmacogenomics tests and potentially other tests.

General and Administrative Expenses: G&A expenses for the three months March 31, 2015 were \$2,605,111, an increase of \$830,403, or 47% from \$1,774,708 for the same period in 2014. G&A expenses consists primarily of personnel and related benefit costs, facilities, professional services, insurance, and public company related expenses. The increase in G&A expenses is increased in compensation expenses, professional fees, and recruiting fees as we hired additional headcounts to support the launch of our new products; and an increase in bad debt expenses as a result of significant increases in revenue.

We expect our G&A expenses to continue grow as we hire additional administrative and manufacturing personnel to support the increased sales and operating activities as we commercialize the ForeCYTE Breast Aspirator and FullCYTE Breast Aspirator, pharmacogenomics testing and our other products and services under development and as we incur additional costs associated with being a publicly traded company.

Research and Development Expenses: R&D expenses for the year three months ended March 31, 2015 were \$797,225, an increase of \$374,722, or 89%, from the three months ended March 31, 2014. The increase in R&D expenses is attributed to additional R&D expenditures on the development of our new products and tests in the pipeline, including the FullCYTE Microcatheters and FullCYTE Breast Aspirator. We expect that our R&D expenses will continue to increase throughout 2015 as we add additional full time employees and incur additional costs to continue the development of our products and services under development, including the development of a potential pharmaceutical and conducting one or more clinical studies.

Liquidity and Capital Resources

We have a history of operating losses as we have focused our efforts on raising capital and building the MASCT System. The Company's consolidated financial statements are prepared using generally accepted accounting principles in the United States of America applicable to a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The Company has incurred net losses and negative operating cash flows since inception. For the three months ended March 31, 2015, the Company recorded a net loss of approximately \$3.3 million and used approximately \$3.0 million of cash in operating activities. As of March 31, 2015, the Company had approximately \$9.7 million in cash and cash equivalents and working capital of approximately \$7.9

million. The Company has not yet established an ongoing source of revenue sufficient to cover its operating costs and allow it to continue as a going concern. The ability of the Company to continue as a going concern is dependent on the Company obtaining adequate capital to fund operating losses until it becomes profitable. The Company can give no assurances that any additional capital that it is able to obtain, if any, will be sufficient to meet its needs, or that any such financing will be obtainable on acceptable terms. If the Company is unable to obtain adequate capital, it could be forced to cease operations or substantially curtail its commercial activities. These conditions raise substantial doubt as to the Company's ability to continue as a going concern. The accompanying consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts and classification of liabilities should the Company be unable to continue as a going concern.

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

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

During the first quarter of 2015, we sold a total of 2,653,199 shares of Common Stock to Aspire Capital Fund LLC under the stock purchase agreement dated November 8, 2013 with aggregate gross proceeds to us of \$4,292,349. No shares remain available for sale to Aspire under the terms of the November 8, 2013 agreement with them.

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.

Medicare Reimbursement

The majority of the pharmacogenomics tests performed by the NRLBH have been for Medicare patients and at an average Medicare rate of approximately \$1,100 per test. On May 7, 2015, the Medicare Administrative Contractor covering the region in which the NRLBH operates issued a local coverage determination, or LCD, that affects the Medicare reimbursement we expect to receive for our pharmacogenomics tests for tests performed on or after the effective date of the LCD which is June 22, 2015. The LCD provides that Medicare reimbursement will be provided

for pharmacogenomics tests only for patients on a few specific drugs or for specific conditions at the reimbursement rate of \$243 to \$669 per test, depending on the drug and condition, which is lower than our historic average reimbursement. Most of the pharmacogenomics tests previously performed by the NRLBH have been for drugs and conditions for which Medicare reimbursement will not be available under the new LCD after it becomes effective. In response to this LCD, we plan to focus our pharmacogenomics sales and marketing efforts on commercial payors, rather than Medicare, and we plan to focus on the drugs and conditions for which reimbursement is available.

Cash Flows

As of March 31, 2015, we had cash and cash equivalents of \$9,728,369.

Net Cash Flows from Operating Activities: Net cash used in operating activities was approximately \$2,998,663 for the three months ended March 31, 2015, compared with \$2,603,989 for the same period in 2014. The increase in cash used in operating activities of \$394,674 resulted primarily from an increase in R&D activities related to our new product developments, additional salaries to support the operations, and legal expenses related to the recall and ongoing litigation.

Net Cash Flows from Investing Activities: Net cash used in investing activities was \$66,035 for the three months ended March 31, 2015, compared with \$102,966 for the three months ended March 31, 2014. The decrease was primarily attributable to the reduction in purchases of fixed asset equipment in 2015 as compared to 2014.

Net Cash Flows from Financing Activities: Net cash provided by financing activities was \$4,292,349 for the three months ended March 31, 2015, compared with \$12,995,745 for the three months ended March 31, 2014. In both years, we recognized financing cash flows from the sale of our common stock to Aspire in 2015 or the 2014 public offering. The decrease in net cash flows from financing activities is due to the sales of common stock to Aspire being lower than the proceeds from the 2014 public offering.

Funding Requirements

We expect to incur substantial expenses and generate ongoing operating losses for the foreseeable future as we continue to commercialize the ForeCYTE Breast Aspirator outside the United States and the FullCYTE Breast Aspirator in the United States, continue to launch our laboratory tests including the pharmacogenomics and NAF cytology tests, complete the development of and potentially launch the ArgusCYTE test, NextCYTE test, and potentially other devices in the pipeline, and start the development of our planned therapeutic programs including related clinical studies. We expect that our existing resources as of March 31, 2015 will be sufficient to fund our planned operations through 2015. In addition to our cash and cash equivalents at March 31, 2015 of approximately \$9.7 million, additional potential sources of capital include selling securities that are registered on our Form S-3 registration statement and seeking to raise capital through sales of securities to third parties and existing stockholders. If we are unable to raise additional capital when needed, however, we could be forced to curtail or cease operations. Our future capital uses and requirements depend on numerous factors, which include the following:

- the time and expense needed to continue the launch and commercialization of the ForeCYTE and FullCYTE Breast Aspirators;
- the expense associated with building a network of independent sales representatives to market the ForeCYTE and FullCYTE Breast Aspirators, pharmacogenomics tests, NAF cytology tests, and our planned therapeutic programs; and
- the degree and speed of patient and physician acceptance of our products and the degree to which third party payors approve the tests for reimbursement.

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

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

for raising capital are favorable.

Off-Balance Sheet Arrangements

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

Recent Accounting Pronouncements

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

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

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 March 31, 2015. 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 March 31, 2015, 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 March 31, 2015 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 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. On October 6, 2014 the Court granted defendants' motion dismissing all claims against Atossa and all other defendants. On October 30, 2014, the Court entered a final order of dismissal. On November 3, 2014, plaintiffs filed a notice of appeal with the Court and have appealed the Court's dismissal order to the U.S. Court of Appeals for the Ninth Circuit. On February 11, 2015, plaintiffs filed their opening appellate brief. Defendants filed an answering brief on April 13, 2015. If plaintiffs choose to file a reply brief in support of their appeal, it is due May 18, 2015. A hearing for the appeal has not been set.

The Company believes this complaint is without merit and plan to defend ourselves vigorously; however failure to obtain a favorable resolution of the claims set forth in the complaint could have a material adverse effect on the Company's business, results of operations and financial condition. Currently, the amount of such material adverse effect cannot be reasonably estimated, and no provision or liability has been recorded for these claims as of March 31, 2015. 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 30, 2015, except for the following items which have been updated.

Anticipated liquidity issues in the next four to twelve months.

For the quarter ended March 31, 2015, we generated \$1,873,268 in revenue and we incurred a net loss of \$3,335,291. Through March 31, 2015, we had an accumulated deficit of approximately \$38.5 million. We expect that our existing resources will be sufficient to fund our planned operations through 2015. No shares are available for sale to Aspire Capital under our November 8, 2013 agreement with them. 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 be successful in launch of ForeCYTE and FullCYTE Breast Aspirators and other sources of capital may not be available when we need them or on acceptable terms. 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.

Changes in regulations and policies, including adverse coverage decisions by Medicare Administrative Contractors, or changes in payor mix may adversely affect reimbursement for laboratory services and could have a material adverse impact on our revenue and profitability.

Most of our services are billed to a party other than the physician who ordered the test, including for example, Medicare and commercial insurance companies. The majority of our pharmacogenomics tests are billed to Medicare. Reimbursement levels for healthcare services are subject to continuous and often unexpected changes in policies. Changes in governmental and third party reimbursement rates and policies may result from statutory and regulatory changes, retroactive rate adjustments, administrative rulings, competitive bidding initiatives, and other policy changes. Uncertainty also exists as to the coverage and reimbursement status of new services, including our pharmacogenomics test and NAF test both of which are relatively new services.

Government payors and insurance companies have increased their efforts to control the cost, utilization, and delivery of healthcare services. For example, at least yearly, Congress has considered and enacted changes in the Medicare fee schedule in conjunction with budgetary legislation. Further reductions of reimbursement for Medicare services or changes in policy regarding coverage of tests may be implemented from time to time. The payment amounts under the Medicare fee schedules are often used as a reference for the payment amounts set by other third party payors. As a result, a reduction in Medicare reimbursement rates could result in a corresponding reduction in the reimbursements we may receive from such third party payors. Changes in test coverage policies of other third party payors may also occur. Such reimbursement and coverage changes in the past have resulted in reduced prices, added costs and reduced accession volume, and have imposed more complex regulatory and administrative burdens. Further changes in federal, state, and local third party payor laws, regulations, or policies may have a material adverse impact on our business.

Adverse coverage decisions by Medicare Administrative Contractors could have a material adverse impact on our revenue and operations.

The majority of the pharmacogenomics tests performed by the NRLBH have been for Medicare patients and at an average Medicare rate of approximately \$1,100 per test. On May 7, 2015, the Medicare Administrative Contractor covering the region in which the NRLBH operates issued a local coverage determination, or LCD, that affects the Medicare reimbursement we expect to receive for our pharmacogenomics tests for tests performed on or after the effective date of the LCD which is June 22, 2015. The LCD provides that Medicare reimbursement will be provided for pharmacogenomics tests only for patients on a few specific drugs or for specific conditions at the reimbursement rate of \$243 to \$669 per test, depending on the drug and condition, which is lower than our historic average reimbursement. Most of the pharmacogenomics tests previously performed by the NRLBH have been for drugs and conditions for which Medicare reimbursement will not be available under the new LCD after it becomes effective. This new LCD could significantly reduce the rate at which the NRLBH is reimbursed and could reduce the types of pharmaceuticals and conditions for which reimbursement is available, which could have a significant adverse impact on our revenues and operations.

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

ITEM 6. EXHIBITS

(a) Exhibits

21 Subsidiaries of the Registrant

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

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: May 13, 2015

/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)