

ATOSSA GENETICS INC  
Form 10-Q  
November 12, 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 September 30, 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.)

**2300 Eastlake Ave. East, Suite 200**

**Seattle, WA**

(Address of principal executive offices)

**98102**

(Zip Code)

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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 November 12, 2015 was 30,446,260.

**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 September 30, 2015 and December 31, 2014</u>                            | 3  |
| <u>Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2015 and 2014</u> | 4  |
| <u>Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2015 and 2014</u>           | 5  |
| <u>Notes to Consolidated Financial Statements</u>  | 6  |
| ITEM 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>                   | 14 |
| ITEM 3. <u>Quantitative and Qualitative Disclosures about Market Risk</u>  | 22 |
| ITEM 4. <u>Controls and Procedures</u>   | 22 |

**PART II. OTHER INFORMATION** 23

|  |    |
|--|----|
| ITEM 1. <u>Legal Proceedings</u>   | 23 |
| ITEM 1A. <u>Risk Factors</u>   | 23 |
| ITEM 2. <u>Unregistered Sales of Equity Securities and Use of Proceeds</u> | 26 |
| ITEM 3. <u>Defaults upon Senior Securities</u>                             | 26 |
| ITEM 4. <u>Mine Safety Disclosures</u>                                     | 26 |
| ITEM 5. <u>Other Information</u>   | 26 |

ITEM 6. Exhibits

27

SIGNATURES

27

2

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

|   | September 30,<br>2015<br>(Unaudited) | December 31,<br>2014 |
|---|--------------------------------------|----------------------|
| Assets                                  |                                      |                      |
| Current assets                          |                                      |                      |
| Cash and cash equivalents               | \$ 7,839,439                         | \$ 8,500,718         |
| Restricted cash                         | 275,000                              | -                    |
| Accounts receivable, net                | 1,055,059                            | 297,958              |
| Prepaid expenses                        | 201,652                              | 247,207              |
| Inventory, net                          | 170,860                              | 39,788               |
| Total current assets                    | 9,542,010                            | 9,085,671            |
| Furniture and equipment, net            | 484,544                              | 357,532              |
| Intangible assets, net                  | 1,768,812                            | 1,920,645            |
| Deferred financing costs                | 509,375                              | 351,961              |
| Other assets                            | 52,649                               | 48,193               |
| Total assets                            | \$ 12,357,390                        | \$ 11,764,002        |
| Liabilities and Stockholders' Equity    |                                      |                      |
| Current liabilities                     |                                      |                      |
| Accounts payable                        | \$ 1,179,329                         | \$ 594,357           |
| Accrued expenses                        | 934,675                              | 444,861              |
| Payroll liabilities                     | 1,156,000                            | 1,056,705            |
| Short-term lease obligations            | -                                    | 76,025               |
| Other current liabilities               | 22,601                               | 42,228               |
| Total current liabilities               | 3,292,605                            | 2,214,176            |
| Deferred rent                           | 5,688                                | 2,483                |
| Long-term lease obligations             | -                                    | 49,216               |
| Total liabilities                       | 3,298,293                            | 2,265,875            |
| Commitments and contingencies (note 13) |                                      |                      |

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|  |               |               |
|--|---------------|---------------|
| 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, 30,446,260 and 24,564,058 shares issued and outstanding | 30,446        | 24,564        |
| Additional paid-in capital   | 55,001,918    | 44,648,103    |
| Accumulated deficit  | (45,973,267 ) | (35,174,540 ) |
| Total stockholders' equity   | 9,059,097     | 9,498,127     |
| <br>   |               |               |
| Total liabilities and stockholders' equity   | \$ 12,357,390 | \$ 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<br>September 30, |                | For The Nine Months Ended<br>September 30, |                |
|--|---|----------------|--|----------------|
|  | 2015  | 2014           | 2015                                       | 2014           |
| Net revenue  | \$ 772,244                                  | \$ 3,426       | \$ 5,339,669                               | \$ 37,425      |
| Cost of revenue                                      | 313,406                                     | -              | 3,376,071                                  | -              |
| Gross profit   | 458,838                                     | 3,426          | 1,963,598                                  | 37,425         |
| Operating expenses:                                  |   |                |  |                |
| Selling  | 738,036                                     | 282,374        | 2,016,951                                  | 743,597        |
| Research and development                             | 1,090,349                                   | 923,169        | 2,398,032                                  | 1,856,439      |
| General and administrative                           | 3,017,909                                   | 2,043,138      | 8,413,891                                  | 6,280,102      |
| Total operating expenses                             | 4,846,294                                   | 3,248,681      | 12,828,874                                 | 8,880,138      |
| Operating loss                                       | (4,387,456 )                                | (3,245,255 )   | (10,865,276 )                              | (8,842,713 )   |
| Other income (expense)                               | 69,345                                      | (140 )         | 66,549                                     | (2,189 )       |
| Loss before income taxes                             | (4,318,111 )                                | (3,245,395 )   | (10,798,727 )                              | (8,844,902 )   |
| Income taxes   | -   | -              | -  | -              |
| Net loss   | \$(4,318,111 )                              | \$(3,245,395 ) | \$(10,798,727 )                            | \$(8,844,902 ) |
| Loss per common share - basic and diluted            | \$(0.15 )                                   | \$(0.13 )      | \$(0.39 )                                  | \$(0.37 )      |
| Weighted average shares outstanding, basic & diluted | 28,766,012                                  | 24,537,379     | 27,500,855                                 | 23,860,843     |

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

## ATOSSA GENETICS INC.

## CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(UNAUDITED)

|   | <b>For the Nine Months<br/>Ended<br/>September 30,</b> |                     |
|---|--|---------------------|
|   | 2015   | 2014                |
| <b>CASH FLOWS FROM OPERATING ACTIVITIES</b>             |  |                     |
| Net loss  | \$(10,798,727)   | \$(8,844,902)       |
| Compensation cost for stock options granted             | 703,726  | 545,115             |
| Depreciation and amortization                           | 249,744  | 380,977             |
| Gain on disposal of assets                              | (74,800 )  | -                   |
| Bad debt expense  | 1,188,193  | 80,870              |
| Changes in operating assets and liabilities:            |  |                     |
| Restricted cash   | (275,000 )   | -                   |
| Accounts receivable                                     | (1,878,795 )   | 29,051              |
| Inventory   | (131,072 )   | (45,867 )           |
| Prepaid expenses  | 45,555   | (71,099 )           |
| Other assets  | (4,456 )   | (42,512 )           |
| Accounts payable  | 326,769  | 191,106             |
| Payroll liabilities                                     | 99,295   | 205,879             |
| Deferred rent   | 11,298   | (39,608 )           |
| Accrued expenses  | 566,118  | (5,774 )            |
| Product recall liabilities                              | -  | (208,108 )          |
| Other current liabilities                               | (27,720 )  | (11,274 )           |
| Net cash used in operating activities                   | (9,999,872 )   | (7,836,146 )        |
| <b>CASH FLOWS FROM INVESTING ACTIVITIES</b>             |  |                     |
| Purchase of furniture and equipment                     | (95,196 )  | (102,530 )          |
| Purchase of intangible assets                           | (15,553 )  | (184,979 )          |
| Net cash used in investing activities                   | (110,749 )   | (287,509 )          |
| <b>CASH FLOWS FROM FINANCING ACTIVITIES</b>             |  |                     |
| Net proceeds from issuance of common stock and warrants | 9,498,557  | 13,155,745          |
| Payments on capital lease obligations                   | (49,215 )  | -                   |
| Net cash provided by financing activities               | 9,449,342  | 13,155,745          |
| <b>NET DECREASE IN CASH AND CASH EQUIVALENTS</b>        | <b>(661,279 )</b>                                      | <b>5,032,090</b>    |
| <b>CASH AND CASH EQUIVALENTS, BEGINNING BALANCE</b>     | <b>8,500,718</b>                                       | <b>6,342,161</b>    |
| <b>CASH AND CASH EQUIVALENTS, ENDING BALANCE</b>        | <b>\$7,839,439</b>                                     | <b>\$11,374,251</b> |

SUPPLEMENTAL DISCLOSURES:



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|   |           |          |
|---|-----------|----------|
| Interest paid                                       | \$284     | \$2,343  |
| NONCASH INVESTING AND FINANCING ACTIVITIES:         |           |          |
| Noncash reclassification of prepaid license fees    | \$-       | \$15,000 |
| Purchases of equipment recorded in accounts payable | \$128,875 | \$-      |
| Amortization of deferred financing costs            | \$453,836 | \$-      |

*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 was formed to develop and market medical devices, laboratory tests and therapeutics to address breast health conditions. The Company’s fiscal year ends on December 31st.

The Company’s current therapeutic programs include Afimoxifene Gel and Fulvestrant administered through the Company’s patented intraductal Microcatheters, both of which are in Phase II clinical development. The Company’s medical devices consist primarily of its ForeCYTE Breast Aspirator (formerly called the Mammary Aspirate Specimen Cytology Test System, or MASCT), the FullCYTE Breast Aspirator and the intraductal Microcatheters. In December 2011, the Company established The National Reference Laboratory for Breast Health, Inc., the NRLBH, as a wholly-owned subsidiary which performs nipple aspirate fluid (“NAF”) cytology testing on NAF specimens, including those collected with the Company’s breast aspirator devices, and pharmacogenomics tests. The NRLBH is certified by College of American Pathologists (CAP) and by Clinical Laboratory Improvement Amendments (CLIA) and it is certified under ISO 15189:2012.

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 nine months ended September 30, 2015, the Company recorded a net loss of approximately \$10.8 million and used approximately \$10 million of cash in operating activities. As of

September 30, 2015, the Company had approximately \$7.8 million in cash and cash equivalents and working capital of approximately \$6.2 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, (2) sales of the ForeCYTE and FullCYTE Breast Aspirators and laboratory service revenue, 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 which consist 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

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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, the 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.

***Revenue Recognition***

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.

**Service Revenue**

Diagnostic testing revenue 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.

Services are provided to self-pay patients or patients covered by various commercial insurance plans and Medicare programs. Revenue for services under insurance plans are recognized net of allowances for contractual discounts and allowances for differences between the amounts we bill and expected payment amounts. The Company records revenue for diagnostic testing on an accrual basis based on the amount expected to be collected based on historical benefits allowed for Medicare and non-Medicare payer. The expected revenues from non-Medicare payers are based on the historical experience of each payer or payer group, as appropriate. The assumptions used to determine the expected benefits allowed are reasonable considering known facts and circumstances and may change as we develop more history. If the actual amount received from the payers or patients are different than the original accrual amount, revenue is subsequently adjusted.

***Accounts Receivable***

Accounts receivable are recorded at net realizable value consisting of the carrying amount less an 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 creditworthiness, current economic trends, and changes in customer payment patterns to evaluate the adequacy of the allowance for doubtful accounts. Based on the historical experience for our accounts, management has determined, based on a detailed analysis, that accounts receivable associated with certain billings are unlikely to be collected. The Company's allowance for doubtful accounts was \$1,182,777 and \$564,456 at September 30, 2015 and December 31, 2014, respectively. Bad debt expense is included in general and administrative expense on the Company's consolidated statements of operations. Bad debt expense was \$1,188,193 and \$80,870 for the nine months ended September 30, 2015 and 2014, respectively, and was \$625,499 and \$16,111 for the three months ended September 30, 2015 and 2014, respectively.

### **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: RESTRICTED CASH**

Our restricted cash balance of \$275,000 as of September 30, 2015, consists entirely of cash pledged as security for the Company's newly issued commercial credit cards.

**NOTE 5: PREPAID EXPENSES**

Prepaid expenses consisted of the following:

|                                      | <b>September 30,<br/>2015</b> | <b>December 31,<br/>2014</b> |
|--------------------------------------|-------------------------------|------------------------------|
| Prepaid hardware and software        | 46,568                        | 38,268                       |
| Prepaid insurance                    | 41,668                        | 87,633                       |
| Professional fees                    | 41,196                        | -                            |
| Retainer and security deposits       | 39,218                        | 25,000                       |
| Tradeshaw and other marketing events | 12,500                        | 50,000                       |
| Lab supplies                         | 10,481                        | 14,976                       |
| Other                                | 10,021                        | 31,330                       |
| Total prepaid expenses               | \$ 201,652                    | \$ 247,207                   |

**NOTE 6: FURNITURE AND EQUIPMENT**

Furniture and equipment consisted of the following:

|                                | <b>September 30,<br/>2015</b> | <b>December 31,<br/>2014</b> |
|--------------------------------|-------------------------------|------------------------------|
| Machinery and equipment        | \$ 718,953                    | \$ 522,813                   |
| Leasehold improvements         | 121,596                       | 93,665                       |
| Furniture and equipment        | 840,549                       | 616,478                      |
| Less: Accumulated depreciation | (356,005 )                    | (258,946 )                   |
| Total furniture and equipment  | \$ 484,544                    | \$ 357,532                   |

Depreciation expense for the three months ended September 30, 2015 and 2014 was \$32,620 and \$24,643, respectively, and \$97,059 and \$65,678 for the nine months then ended.

**NOTE 7: INTANGIBLE ASSETS**

Intangible assets consisted of the following:



|                                | September 30,<br>2015 | December 31,<br>2014 |
|--------------------------------|-----------------------|----------------------|
| Patents                        | \$ 1,630,000          | \$ 1,630,000         |
| Capitalized license costs      | 200,000               | 200,000              |
| Software                       | 203,890               | 203,038              |
| Intangible assets              | 2,033,890             | 2,033,038            |
| Less: Accumulated amortization | (265,078 )            | (112,393 )           |
| Total intangible assets, net   | \$ 1,768,812          | \$ 1,920,645         |

Intangible assets amounted to \$1,768,812 and \$1,920,645 as of September 30, 2015 and December 31, 2014, respectively, and consisted of patents, capitalized license costs and software acquired. The amortization period for the purchased software is three years. Amortization expense related to software for the three months ended September 30, 2015 and 2014 was \$11,261 and \$4,913, respectively, and \$34,090 and \$22,436 for the nine months ended September 30, 2015 and September 30, 2014, respectively.

Patents amounted to \$1,630,000 as of September 30, 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 seven to fourteen years. Amortization expense related to patents was \$37,253 and \$93,497 for the three months ended September 30, 2015 and 2014, respectively, and \$111,761 and \$281,196 for the nine months ended September 30, 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 \$5,000 for the three months ended September 30, 2015 and 2014, respectively, and \$15,000 and \$5,000 for the nine months ended September 30, 2015 and 2014, respectively.

Future estimated amortization expenses as of September 30, 2015 for the five succeeding years are as follows:

|   |             |
|---|-------------|
| For the Year Ending December 31,          | Amounts     |
| 2015 (includes the remainder of the year) | \$53,515    |
| 2016                                      | 227,130     |
| 2017                                      | 198,628     |
| 2018                                      | 169,934     |
| 2019                                      | 169,015     |
| Thereafter                                | 950,590     |
|   | \$1,768,812 |

**NOTE 8: ACCRUED EXPENSES**

Accrued expenses consisted of the following:

|                        | <b>September 30,<br/>2015</b> | <b>December 31,<br/>2014</b> |
|------------------------|-------------------------------|------------------------------|
| Accrued commissions    | \$ 737,991                    | \$ 174,398                   |
| Accrued expenses       | 106,802                       | 254,126                      |
| Accrued royalties      | 89,882                        | 16,337                       |
| Total accrued expenses | \$ 934,675                    | \$ 444,861                   |

**NOTE 9: PAYROLL LIABILITIES**

Payroll liabilities consisted of the following:

|                                 | <b>September 30,<br/>2015</b> | <b>December 31,<br/>2014</b> |
|---------------------------------|-------------------------------|------------------------------|
| Accrued bonus payable           | \$ 741,596                    | \$ 752,828                   |
| Accrued payroll tax liabilities | 236,582                       | 194,224                      |
| Accrued payroll liabilities     | 177,822                       | 109,653                      |
| Total payroll liabilities       | \$ 1,156,000                  | \$ 1,056,705                 |

**NOTE 10: 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 a certificate of designation with the Delaware Secretary of State.

On May 19, 2014, the Company adopted a stockholder rights agreement which provided 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 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. Subject to the call right described above, the 2014 Warrants shall expire and no longer be exercisable on November 29, 2018. 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.

### 2015 Issuance of Additional Shares to Aspire Capital

During the first quarter of 2015, we sold a total of 2,653,199 shares of common stock to Aspire Capital Fund, LLC (“Aspire Capital”) 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 Capital under the terms of the November 8, 2013 agreement with them.

On May 26, 2015, we entered into a new common stock purchase agreement with Aspire Capital Fund, LLC, which provides that, upon the terms and subject to the conditions and limitations set forth therein, Aspire Capital is committed to purchase up to an aggregate of \$25.0 million of shares of our common stock over the 30-month term of the purchase agreement. Concurrently with entering into the purchase agreement, we also entered into a registration rights agreement with Aspire Capital, in which we agreed to file one or more registration statements, as permissible and necessary to register under the Securities Act of 1933, registering the sale of the shares of our common stock that have been and may be issued to Aspire Capital under the purchase agreement.

2015 Offering of Common Stock and Pre-Funded Warrants

In June 2015, the Company entered into a Placement Agent Agreement with Roth Capital Partners, LLC. and Dawson James Securities, Inc. (the “2015 Placement Agents”), pursuant to which the Company issued and sold an aggregate of 1,454,003 shares of common stock at the purchase price of \$1.15 per share and pre-funded warrants to purchase 3,610,997 shares of common stock (the “Pre-Funded Warrants”) at a purchase price of \$1.14 per share for net proceeds of \$5.2 million after deducting \$577,790 of offering expenses (the “2015 Offering”). Each Pre-Funded Warrant is exercisable for \$0.01 per share, subject to adjustments from time to time and certain limits on each holder’s beneficial ownership of common stock of the Company. Each Pre-Funded Warrant is perpetual in duration.

*Placement Agent and Other Fees*

In connection with the 2015 Offering, the Company paid the 2015 Placement Agents a cash fee of \$463,091, including reimbursement of the legal fees incurred by the 2015 Placement Agents of \$57,886, and incurred legal fees of \$114,699.

*Outstanding Warrants*

As of September 30, 2015, warrants to purchase 8,244,423 shares of common stock are outstanding including:

|  | <b>Outstanding<br/>Warrants to<br/>Purchase Shares</b> | <b>Exercise<br/>Price</b> | <b>Expiration Date</b> |
|--|--|---------------------------|------------------------|
| 2011 private placement                       | 4,252,050  | \$1.25 - 1.60             | June 23, 2016          |
| Acueity warrants                             | 325,000  | 5.00                      | September 30, 2017     |
| 2014 public offering                         | 1,166,849  | 3.00                      | January 29, 2019       |
| 2015 offering prefunded warrants             | 2,210,997  | 0.01                      | Perpetual              |
| 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       |
|  | 8,244,423  |                           |                        |

**NOTE 11: NET LOSS PER SHARE**

The Company accounts for and discloses net loss per common share in accordance with FASB Accounting Standards Codification (“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 and nine months ended September 30, 2015 and 2014 because the effect of them would be anti-dilutive since the Company recorded net losses for all of these periods:

|                                   | <b>Three Months Ended</b> |           | <b>Nine Months Ended</b> |           |
|-----------------------------------|---------------------------|-----------|--------------------------|-----------|
|                                   | <b>September 30,</b>      |           | <b>September 30,</b>     |           |
|                                   | 2015                      | 2014      | 2015                     | 2014      |
| Options to purchase common stock  | 4,407,409                 | 3,464,232 | 4,407,409                | 3,464,232 |
| Warrants to purchase common stock | 8,244,423                 | 6,033,426 | 8,244,423                | 6,033,426 |
|                                   | 12,651,832                | 9,497,658 | 12,651,832               | 9,497,658 |

#### **NOTE 12: 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 September 30, 2015 and December 31, 2014 due to the Company's continuing operating losses.

#### **NOTE 13: CONCENTRATION OF CREDIT RISK**

Financial instruments that potentially subject the Company to concentration of credit risk consist principally of cash deposits. Accounts at each institution are insured by the Federal Deposit Insurance Corporation ("FDIC") up to \$250,000. At September 30, 2015 and December 31, 2014, the Company had \$7,864,439 and \$8,250,718 in excess of the FDIC insured limit, respectively.

#### **NOTE 14: COMMITMENTS AND CONTINGENCIES**

##### *Affymetrix Purchase Commitment*

On September 1, 2013, 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. On September 29, 2015, the Company entered into a new agreement with Affymetrix to purchase the instrument for \$129,000. All of the prior purchase commitments under the old agreement were terminated.

#### ***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 worldwide (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 September 30, 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.





***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 include \$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 September 30, 2015, the Company has paid \$172,600 in fees, which were recorded as R&D expenses.

***Besins Healthcare Luxembourg SARL Agreement***

On May 14, 2015, the Company entered into an Intellectual Property License Agreement with Besins Healthcare Luxembourg SARL (“Besins”). The agreement provides the Company with an exclusive worldwide license to develop and commercialize Besins’ patented gel formulation of 4-Hydroxytamoxifen, or Afimoxifene Gel, for the potential treatment and prevention of hyperplasia of the breast.

The agreement requires that the Company pay a royalty of 8% to 9% of net sales for the first 15 years of commercialization. The Company has the non-exclusive right to also develop Afimoxifene Gel for breast cancer and other breast diseases, subject to the payment of the following milestone payments for these additional indications: (i) \$5,000,000 for the exclusive right to review, access, and reference a Besins investigational new drug application (IND) for each additional indication; and (ii) \$20,000,000 when the Company commences a Phase III clinical trial for each additional indication. If and when Atossa decides to sublicense its rights to commercialize the Afimoxifene Gel in a country in the territory, Besins has the right of first refusal to commercialize the Afimoxifene Gel on a country-by-country basis in countries where Besins has a marketing presence.

The agreement automatically expires on a country-by-country basis fifteen years after the first commercial sale of Afimoxifene Gel in the particular country. The Agreement may be terminated (i) by either party upon a material breach of the agreement that is not cured by the breaching party, (ii) by mutual agreement of the parties, (iii) by the Company at its discretion if it elects to stop developing or commercializing Afimoxifene Gel, (iv) by Besins on a country-by-country basis or indication-by-indication basis if the Company fails to commercialize or commence commercial sales within a specified time, or (v) by Besins if Atossa fails to accomplish any aspect of the development plan within six months of target date set forth in the development plan. The development plan covers an 18-month period and is required to be updated by the Company every six months during the term of the agreement.

***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's 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 the Company's subsequent press releases and SEC filings with respect to its NAF specimen collection process, its ForeCYTE Breast Health Test and its MASCT device. This action seeks, on behalf of persons who purchased the Company's 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 the Company 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. On May 18, 2015, Plaintiffs filed a reply brief in support of their appeal. 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 September 30, 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 15: 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.

The following table presents the additions to the 2010 Plan since inception:

| January 1,              | <b>Number of shares</b> |
|-------------------------|-------------------------|
| 2012                    | 450,275                 |
| 2013                    | 516,774                 |
| 2014                    | 742,973                 |
| 2015                    | 983,362                 |
| Total additional shares | 2,693,384               |

The Company granted options to purchase 1,640,822 shares of common stock to employees and directors during the nine months ended September 30, 2015. There are 703,003 options available for grant under the 2010 Plan as of September 30, 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 \$317,986 and \$703,726 for the three months and nine months ended September 30, 2015, respectively. The stock based compensation expense for the three months and nine months ended September 30, 2014 was \$147,399 and \$545,115, respectively.

Stock-based compensation expense was included in the following captions in the condensed consolidated statements of operations for the periods shown:

|                                     | <b>Three Months Ended</b> |            | <b>Nine Months Ended</b> |            |
|-------------------------------------|---------------------------|------------|--------------------------|------------|
|                                     | <b>September 30,</b>      |            | <b>September 30,</b>     |            |
|                                     | 2015                      | 2014       | 2015                     | 2014       |
| Selling expenses                    | \$ 29,374                 | \$ 26,755  | \$ 74,773                | \$ 68,592  |
| Research and development expenses   | 32,124                    | 15,997     | 75,914                   | 30,763     |
| General and administrative expenses | 256,488                   | 104,647    | 553,039                  | 445,759    |
|                                     | \$ 317,986                | \$ 147,399 | \$ 703,726               | \$ 545,114 |

The following table presents information concerning stock option grants for the nine months ended September 30, 2015:

| Date of Grant                                       | <b>Employees</b>         | <b>Executives &amp; Officers</b> |
|---|--------------------------|----------------------------------|
|   | January – September 2015 | January – September 2015         |
| Fair value of common stock on date of grant         | \$ 0.76 – 1.59           | \$ 1.21 – 1.59                   |
| Exercise price of the options                       | \$ 1.40 – 1.88           | \$ 1.44 – 1.88                   |
| Expected life of the options (years)                | 6.03 – 6.13              | 6.06 – 6.11                      |
| Dividend yield                                      | 0.00                     | % 0.00 %                         |
| Expected volatility                                 | 107.1 – 115.0            | % 111.3 – 113.5 %                |
| Risk-free interest rate                             | 1.64 – 1.81              | % 1.72 – 1.74 %                  |
| Expected forfeiture per year (%)                    | 10.00                    | % 10.00 %                        |
| Weighted average fair value of the options per unit | \$ 0.82                  | \$ 1.46                          |

Options issued and outstanding as of September 30, 2015 and their activities during the nine months then ended are as follows:

|                                      | <b>Number of<br/>Underlying<br/>Shares</b> | <b>Weighted-<br/>Average<br/>Exercise<br/>Price Per<br/>Share</b> | <b>Weighted-<br/>Average<br/>Contractual<br/>Life<br/>Remaining<br/>in<br/>Years</b> | <b>Aggregate<br/>Intrinsic Value</b> |
|--------------------------------------|--|---|--|--------------------------------------|
| Outstanding as of January 1, 2015    | 3,675,634                                  | \$ 2.86   |  | \$ 344,000                           |
| Granted                              | 1,640,822                                  | 1.53  |  | -                                    |
| Forfeited/canceled                   | (559,047 )                                 | 2.01  |  | 63,223                               |
| Expired                              | (350,000 )                                 |   |  |                                      |
| Exercised                            | -  | -   |  | -                                    |
| Outstanding as of September 30, 2015 | 4,407,409                                  | 2.31  | 8.6  | \$ 500                               |
| Exercisable as of September 30, 2015 | 1,618,524                                  | 3.38  | 7.9  | \$ -                                 |
| Vested and expected to vest (1)      | 4,047,912                                  | \$ 2.37   | 8.6  | \$ 406                               |

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

As of September 30, 2015, there were 2,788,885 unvested options outstanding and the related unrecognized total compensation cost associated with these options was \$2,250,594. This expense is expected to be recognized over a weighted average period of 2.85 years.

#### **NOTE 16: SUBSEQUENT EVENTS**

All subsequent events requiring recognition as of September 30, 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 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 our pharmaceutical candidates, including Afimoxifene Gel and drugs such as Fulvestrant delivered via our Microcatheters, and our ability to manufacture sufficient quantities of the active ingredients, enroll and successfully complete clinical studies and obtain necessary approvals from the FDA and other regulatory authorities;

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;

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, ForeCYTE Breast Aspirator, NAF cytology test and FullCYTE Microcatheter and to obtain regulatory approvals, clearances and CE Certificate of Conformity for our other products and services in development;

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

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

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

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

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

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

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

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

our ability to attract and retain key personnel;

our ability to sell additional shares of our common stock to Aspire Capital under the terms of our purchase agreement with them; and

our ability to obtain, maintain and defend our intellectual property rights covering our devices, specimens, collection kits, diagnostic tests and compositions.

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 the development of locally-administered pharmaceuticals for the treatment of pre-cancer and early stage breast cancer. Our leading pharmaceutical under development is Afimoxifene Gel, which is in Phase II clinical development. We are also planning a Phase II clinical trial using our patented intraductal Microcatheters to deliver Fulvestrant to treat ductal carcinoma in-situ, or DCIS, and breast cancer. We have also developed and are commercializing proprietary laboratory tests and medical devices which, subject to receiving regulatory approvals, we may also develop to act as companions to our pharmaceuticals. Our laboratory tests are being developed and performed by our wholly-owned subsidiary, The National Reference Laboratory for Breast Health, Inc., or the “NRLBH.” The NRLBH has developed and is currently marketing nipple aspirate fluid, or NAF, cytology tests and pharmacogenomics tests.

In May 2015, we acquired the world wide exclusive rights to develop and commercialize Afimoxifene Gel for the potential treatment of hyperplasia of the breast and the rights to expand the license to other indications including breast cancer (which would require that we pay milestone payments for each additional indication). Afimoxifene Gel has been used in 16 Phase I and Phase II studies conducted in a variety of indications with over 450 patients. We are in the process of re-establishing the clinical supply of Afimoxifene Gel and plan to commence a Phase II clinical trial in mid-2016. The National Cancer Institute, Division of Cancer Prevention, has approved a Letter of Intent submitted by a member of the Consortia for Cancer Prevention Clinical Trials Program for the study of Afimoxifene Gel in women with DCIS. The Consortia includes five major medical research centers: the University of Arizona, Northwestern University, Mayo Clinic Foundation, M. D. Anderson Cancer Center and the University of Wisconsin.

In October 2015 the FDA accepted our investigational new drug application, or IND, to commence a Phase II clinical study using Fulvestrant administered via our patented intraductal Microcatheters to treat DCIS and breast cancer. We expect this study will be performed by Columbia University Medical Center and will commence in December 2015.

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 available for sale in the European Union and the countries of the European Free Trade Association (EFTA). The FullCYTE Breast Aspirator has been cleared by the FDA for the collection of NAF for cytological purposes and is available for sale for the U.S. market through Atossa’s distributors. Other devices under development include intraductal microcatheters for the collection of ductal lavage fluid and for the potential administration of targeted pharmaceuticals, and various tools for potential use by

breast surgeons.

15

Our key objectives are currently:

(1) **Pharmaceutical Development:** We plan to advance our pharmaceutical candidates through Phase II trials. A Phase II study of Fulvestrant administered via our patented intraductal Microcatheters is planned to commence in December 2015. A Phase II study of Afimoxifene Gel is planned to begin enrollment in the mid-2016.

(2) **Breast Aspirators:** Our FullCYTE Breast Aspirator is FDA-cleared and is available in the United States through our distributors, which are currently Thermo Fisher Scientific and Henry Schein Medical. Our ForeCYTE Breast Aspirator is CE-marked and is available in the EU and related markets through Rhenus Logistics. We plan to commence approximately three clinical studies in the EU and related markets of our ForeCYTE device to demonstrate clinical utility of the ForeCYTE device and/or to identify biomarkers in NAF that, subject to additional regulatory clearances, may enhance clinical utility of the device and the laboratory test of the NAF specimen. In September 2015, we received approval from the institutional review board to commence the first of these studies using the ForeCYTE device in Israel.

(3) **Laboratory Tests:** We plan to grow our revenue by promoting the pharmacogenomics test currently being offered by the NRLBH, and by developing and commercializing additional laboratory tests. We reported total gross revenue of \$5.3 million for the nine months ended September 30, 2015, substantially all of which was from pharmacogenomics testing. In October 2015, we hired four additional fulltime sales and marketing professionals and beginning in October 2015 substantially all of our internal sales and marketing resources are being devoted to our pharmacogenomics test. An adverse Medicare local coverage determination, or LCD, was made on June 22, 2015 that limits the medical conditions and drugs that are covered by Medicare for our pharmacogenomics tests. As a result, our revenue from Medicare as well as from commercial payers has been negatively impacted. Due to the uncertainty around the impact that this change is having and could continue to have on our business, we are not at this time providing a revenue forecast for 2015 and are withdrawing any forecasts that we have previously provided. The NRLBH has in-network arrangements with Meridian Health Plan of Michigan and Washington Medicaid and is in the process of securing additional in-network arrangements with Medicaid and commercial payers.

The ForeCYTE Breast Aspirator will not be launched in the United States unless and until we receive additional regulatory clearance from the FDA. Our planned pharmaceuticals and our devices and laboratory tests under development, either separately or in combination, will require clearance and/or approval from the FDA prior to commercialization. No assurance can be given that such approvals and/or clearances will be obtained in a timely manner.

Our common stock is currently quoted on The NASDAQ Capital Market under the symbol "ATOS."

**Intellectual Property**

As of September 30, 2015, and based on a recent periodic review of our patent estate, we own 147 issued patents (45 in the United States and at least 102 in foreign countries), and 22 pending patent applications (10 in the United States, and 12 pending international applications) directed to our products, services, and technologies. Our patent estate consists primarily of the following:

| <b>Description</b>  | <b>United States</b>         |                   |                               | <b>Foreign/PCT</b>           |                   |                |
|---|------------------------------|-------------------|-------------------------------|------------------------------|-------------------|----------------|
|   | <b>Issued <sup>(1)</sup></b> | <b>Expiration</b> | <b>Pending <sup>(1)</sup></b> | <b>Issued <sup>(1)</sup></b> | <b>Expiration</b> | <b>Pending</b> |
| <b>ForeCYTE Breast Aspirator Program</b>                                | 7                            | 2016 – 2031       | 4                             | 12                           | 2016 – 2031       | 8              |
| <b>FullCYTE Microcatheters &amp; FullCYTE Breast Aspirators Program</b> | 20                           | 2019 – 2031       | 5                             | 53                           | 2019 – 2031       | 4              |
| <b>NextCYTE Test Program</b>  | 0                            | 2031              | 1                             | 0                            | 2031              | 1              |
| <b>Intraductal Treatment Program</b>                                    | 12                           | 2030              | 3                             | 47                           | 2030              | 1              |
| <b>Carbohydrate Biomarkers Program</b>                                  | 2                            | 2022              | 0                             | 3                            | 2022              | 0              |
| <b>Acueity Tools</b>  | 12                           | 2015 – 2024       | 0                             | 2                            | 2015 – 2024       | 0              |

The total number of patents issued or pending, as applicable, in the respective descriptive columns exceed the (1) totals because some patents and applications contain more than one type of claim directed to methods, kits, compositions, devices and/or technology and the patent counts disclosed herein are subject to change.

Atossa, Atossa Genetics (stylized), MASCT, ArgusCYTE, and National Reference Laboratory for Breast Health (stylized) are our registered trademarks. We have pending allowed applications with the United States Patent and Trademark Office for registration of the use of the marks FullCYTE and NextCYTE.

## Summary of Our Products and Services

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

|   | <b>Product or Service</b>  | <b>Regulatory Status</b>   | <b>Primary Market</b>    | <b>Commercialization Status</b>                                   |
|---|--|--|--------------------------|---|
| <b>Pharmaceuticals</b>  | Afimoxifene Gel to Treat Ductal Hyperplasia  | Phase II; not approved by the FDA or any other foreign competent authorities | United States; Europe    | Licensed from Besins in May 2015; Phase II Trial planned for 2016 |
|   | Fulvestrant Delivered via our Microcatheter to Treat DCIS or Cancer                            | Phase II; not approved by the FDA or any other foreign competent authorities | United States; Europe    | Phase II Trial planned to commence December 2015 or early 2016    |
| <b>Laboratory Tests Offered or Being Developed by the NRLBH</b> | 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   |
| <b>Medical Devices</b>  | 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                   |

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 our medical devices; 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 and 2015 has been 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 market and sell our laboratory tests and we continue to make our medical devices available for commercial distribution and for clinical studies in their respective markets. We will need to revise our sales and marketing materials, continue hiring direct sales employees and engage new third parties to market and sell our products and services. The FullCYTE Breast Aspirator may not gain adoption and may not sell at acceptable margins. The clinical studies we plan to perform with the ForeCYTE device may not be successful. If so, our potential sales and revenues will be negatively impacted.

## **Recent Capital Raising Transactions**

### *May 2015 Common Stock Purchase Agreements with Aspire Capital Fund, LLC*

During the first quarter of 2015, we sold a total of 2,653,199 shares of common stock to Aspire Capital 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 and the agreement was subsequently terminated.

On May 26, 2015, we entered into a new common stock purchase agreement with Aspire Capital Fund, LLC, which provides that, upon the terms and subject to the conditions and limitations set forth therein, Aspire Capital is committed to purchase up to an aggregate of \$25.0 million of shares of our common stock over the 30-month term of the purchase agreement. Concurrently with entering into the purchase agreement, we also entered into a registration rights agreement with Aspire Capital, in which we agreed to file one or more registration statements, as permissible and necessary to register under the Securities Act of 1933, registering the sale of the shares of our common stock that have been and may be issued to Aspire Capital under the purchase agreement.

Under the new purchase agreement, we have the right to present Aspire Capital with a purchase notice, directing Aspire Capital to purchase up to 150,000 shares of our common stock per business day, up to \$25.0 million of the Company's common stock in the aggregate at a per share price equal to the lesser of: (i) the lowest sale price of our common stock on the purchase date; or (ii) the arithmetic average of the three (3) lowest closing sale prices for our common stock during the twelve (12) consecutive trading days ending on the trading day immediately preceding the purchase date.





In addition, on any date on which we submit a purchase notice to Aspire Capital in an amount equal to 150,000 shares and our stock price is not less than \$0.50 per share, we also have the right, in our sole discretion, to present Aspire Capital with a volume-weighted average price purchase notice (each, a “VWAP Purchase Notice”) directing Aspire Capital to purchase an amount of stock equal to up to 30% of the aggregate shares of our common stock traded on its principal market on the next trading day (the “VWAP Purchase Date”), subject to a maximum number of shares we may determine. The purchase price per share pursuant to such VWAP purchase notice is generally 95% of the volume-weighted average price for our common stock traded on its principal market on the VWAP purchase date.

The purchase price will be adjusted for any reorganization, recapitalization, non-cash dividend, stock split, or other similar transaction occurring during the period(s) used to compute the purchase price. We may deliver multiple purchase notices and VWAP purchase notices to Aspire Capital from time to time during the term of the purchase agreement, so long as the most recent purchase has been completed.

The purchase agreement provides that we and Aspire Capital shall not affect any sales under the purchase agreement on any purchase date where the closing sale price of our common stock is less than \$0.25. There are no trading volume requirements or restrictions under the purchase agreement, and we will control the timing and amount of sales of our common stock to Aspire Capital. Aspire Capital has no right to require any sales by us, but is obligated to make purchases from us as directed by us in accordance with the purchase agreement. There are no limitations on use of proceeds, financial or business covenants, restrictions on future funding, rights of first refusal, participation rights, penalties or liquidated damages in the purchase agreement.

In consideration for entering into the purchase agreement, concurrently with the execution of the purchase agreement, we issued to Aspire Capital 375,000 shares of our common stock (the “Commitment Shares”). The purchase agreement may be terminated by us at any time, at our discretion and without any cost to us. Aspire Capital has agreed that neither it nor any of its agents, representatives and affiliates shall engage in any direct or indirect short-selling or hedging of our common stock during any time prior to the termination of the purchase agreement. Any proceeds we receive under the purchase agreement are expected to be used for working capital and general corporate purposes.

The purchase agreement provides that on the date of its execution, that certain Purchase Agreement, dated as of November 8, 2013, as amended, by and between us and Aspire Capital, was terminated.

### *June 2015 Offering*

In June 2015, we sold 1,454,003 shares of common stock at the purchase price of \$1.15 per share and pre-funded warrants to purchase 3,610,997 shares of common stock (the “Pre-Funded Warrants”) at a purchase price of \$1.14 per share for total gross proceeds of \$5.8 million (the “2015 Offering”). Each Pre-Funded Warrant is exercisable for \$0.01

per share, subject to adjustments from time to time and certain limits on each holder's beneficial ownership of common stock of the Company. Each Pre-Funded Warrant is perpetual in duration.

## **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 our laboratory services through independent sales representatives specializing in women's health, and through our own direct sales force. The FullCYTE Breast Aspirator is available in the United States through our U.S. distributors. The ForeCYTE Breast Aspirator is available in EU and related markets through Rhenus Logistics.

## **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.

### Service Revenue

Diagnostic testing revenue 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.

Services are provided to self-pay patients or patients covered by various commercial insurance plans and Medicare programs. Revenue for services under insurance plans are recognized net of allowances for contractual discounts and allowances for differences between the amounts we bill and expected payment amounts. The Company records revenue for diagnostic testing on an accrual basis based on the amount expected to be collected based on historical benefits allowed for Medicare and non-Medicare payers. The expected revenues from non-Medicare payers are based on the historical experience of each payer or payer group, as appropriate. The assumptions used to determine the expected benefits allowed are reasonable considering known facts and circumstances and may change as we develop more history. If the actual amount received from the payors or patients are different than the original accrual amount, revenue is subsequently adjusted.

### *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 the sample) in our laboratory. Costs associated with performing the Company's tests are recorded as tests are processed. Costs recorded for 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 or 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 creditworthiness, 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 September 30, 2015 and December 31, 2014 was \$1,182,776 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 \$1,188,193 and \$80,870 for the nine months ended September 30, 2015 and 2014, respectively.

## Results of Operations

### *Three Months and Nine Months Ended September 30, 2015 and 2014*

*Revenue and Cost of Revenue:* For the three months and nine months ended September 30, 2015, we had total net revenue of \$772,244 and \$5,339,669, respectively, consisting of revenues from pharmacogenomics testing, compared to \$3,426 and \$37,425 of revenue in the same periods in 2014, which consisted of additional cash collections on NAF cytology tests performed in 2013. We ceased generating any revenue from October 2013 through October 2014 due to our voluntary product recall. In March 2015, we introduced the FullCYTE Breast Aspirator in the U.S. and the ForeCYTE Breast Aspirator in the EU; however, we have not generated any revenue in 2015 from sales of these products.

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 was 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 has negatively impacted our revenue for the quarter ended September 30, 2015. For example, the LCD has reduced the types of conditions and the pharmaceuticals for which Medicare will reimburse which we believe is causing some commercial carriers to deny and/or reduce coverage for some patients. This has negatively impacted the number of tested we performed in the third quarter 2015. Additionally, after the LCD went into effect, our largest commercial payor has denied coverage for a significant number of our pharmacogenomics tests which has adversely impacted our third quarter 2015 revenue. The LCD could continue to significantly reduce number of tests submitted to the NRLBH, 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.

Total cost of revenue for the three months and nine months ended September 30, 2015 was \$313,406 and \$3,376,071, respectively, consisting of costs relating to pharmacogenomics testing services; there was no cost of revenue during the same periods in 2014 as the only revenue generated during those periods was from additional cash collections on NAF cytology tests performed in 2013. Gross profit for the three months and nine months ended September 30, 2015 was \$458,838 and \$1,963,598, respectively, which was attributable to pharmacogenomics testing.

*Operating Expenses:*

|                            | Three Months Ended    |             | Percentage<br>Change | Nine Months Ended     |             | Percentage<br>Change |   |
|----------------------------|-----------------------|-------------|----------------------|-----------------------|-------------|----------------------|---|
|                            | September 30,<br>2015 | 2014        |                      | September 30,<br>2015 | 2014        |                      |   |
| Selling                    | \$738,036             | \$282,374   | 161                  | % \$2,016,951         | \$743,597   | 171                  | % |
| Research and development   | \$1,090,349           | \$923,169   | 18                   | % \$2,398,032         | \$1,856,439 | 29                   | % |
| General and administrative | \$3,017,909           | \$2,043,138 | 48                   | % \$8,413,891         | \$6,280,102 | 34                   | % |
| Total operating expenses   | \$4,846,294           | \$3,248,681 | 49                   | % \$12,828,874        | \$8,880,138 | 44                   | % |

*Selling Expenses:* The increase in selling expenses is mainly due to increases in compensation expenses, travel, and advertisement as a result of the ForeCYTE and FullCYTE launch 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 to support primarily the services offered by the NRLBH, pharmacogenomics tests and potentially other tests.

*General and Administrative Expenses:* G&A expenses consist primarily of personnel and related benefit costs, facilities, professional services, insurance, and public company related expenses. The increase in G&A expense is mainly due to an increase in compensation expenses, professional fees, and recruiting fees as we increased our headcount to support the launch of our new products. The increase also reflects an increase in bad debt expenses as a result of higher bad debt reserve due to significant increases in revenue and also higher than expected denials on non-Medicare appeals from prior periods. We expect our G&A and selling expenses to continue to grow throughout 2015 as we hire additional administrative and manufacturing personnel to support the increased sales and operating activities as we promote, market and sell our pharmacogenomics testing and our other products and services under development. We also expect to incur additional costs associated with being a publicly traded company.

*Research and Development Expenses:* The increase in R&D expenses is attributed to additional R&D expenditures on the launch and development of ForeCYTE and FullCYTE in the first quarter of 2015. We expect that our R&D expenditures will continue to grow as we develop our new products and tests in the pipeline, including Afimoxifene Gel, our intraductal Microcatheters and our NextCYTE test and other laboratory tests we may develop. We will add additional fulltime employees and incur additional costs to continue the development of our products and services under development, including the development of Afimoxifene Gel and other potential pharmaceuticals and conducting clinical studies.

**Liquidity and Capital Resources**

We have a history of operating losses as we have focused our efforts on raising capital and developing our medical devices and laboratory services. 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 nine months ended September 30, 2015, the Company recorded a net loss of approximately \$10.8 million and used approximately \$10 million of cash in operating activities. As of September 30, 2015, the Company had approximately \$7.8 million in cash and cash equivalents and working capital of approximately \$6.2 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 November 8, 2013, we terminated our prior stock purchase agreement with Aspire Capital and entered into a new agreement for the sale of our common stock to Aspire Capital under the terms and subject to the conditions and limitations set forth therein. Under the November agreement, Aspire Capital was committed to purchase up to an aggregate of \$25 million of shares of our common stock over the 30-month term of the agreement. On December 23, 2013, we sold \$1 million of common stock to Aspire Capital under this agreement. During the first quarter of 2015, we sold a total of 2,653,199 shares of common stock to Aspire Capital with aggregate gross proceeds to us of \$4,292,349. No shares remain available for sale to Aspire Capital under the terms of the November 8, 2013 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.

In May 2015, we entered into another agreement with Aspire Capital which provides that we may sell common stock to Aspire Capital under the terms and subject to the conditions and limitations set forth therein. Under the new agreement, Aspire Capital is committed to purchase up to \$25 million of the Company's common stock over the 30-month term of the new agreement. We have the right to present Aspire Capital with a purchase notice, directing Aspire Capital to purchase up to 150,000 shares of the Company's common stock per business day, up to \$25.0 million of the Company's common stock in the aggregate at a per share price equal to the lesser of: i) the lowest sale price of the Company's common stock on the purchase date; or ii) the arithmetic average of the three lowest closing sale prices for the Company's common stock during the twelve consecutive trading days ending on the trading day immediately preceding the purchase date. Because of limitations imposed by NASDAQ rules, we may not be able to sell shares of stock to Aspire Capital until November 2015.

In June 2015, we sold 1,454,003 shares of common stock at the purchase price of \$1.15 per share and pre-funded warrants to purchase 3,610,997 shares of common stock (the “Pre-Funded Warrants”) at a purchase price of \$1.14 per share for total gross proceeds of \$5.8 million (the “2015 Offering”). Each Pre-Funded Warrant is exercisable for \$0.01 per share, subject to adjustments from time to time and certain limits on each holder’s beneficial ownership of common stock of the Company.

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**

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 was 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 before enactment of the LCD were for drugs and conditions for which Medicare reimbursement is not available under the new LCD. This new LCD has negatively impacted our revenue for the quarter ended September 30, 2015. For example, the LCD has reduced the types of conditions and the pharmaceuticals for which Medicare will reimburse which we believe is indirectly causing some commercial carriers to deny and/or limit coverage for some drugs or patients. This has negatively impacted the expected reimbursement rate on our tests and the number of tests we performed in the third quarter 2015. Additionally, after the LCD went into effect, one of our largest commercial payors has also denied coverage for a significant number of our pharmacogenomics tests which has adversely impacted our third quarter 2015 revenue. The LCD could continue to significantly reduce number of tests submitted to the NRLBH, 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.

### **Cash Flows**

As of September 30, 2015, we had cash and cash equivalents of \$7,839,439.

*Net Cash Flows from Operating Activities:* Net cash used in operating activities was approximately \$9,999,872 for the nine months ended September 30, 2015, compared with \$7,836,146 for the same period in 2014. The increase in cash

used in operating activities of \$2,163,726 resulted primarily from an increase in R&D activities related to our new product developments and additional salaries to support the operations.

*Net Cash Flows from Investing Activities:* Net cash used in investing activities was \$110,749 for the nine months ended September 30, 2015, compared with \$287,509 for the nine months ended September 30, 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 \$9,449,342 for the nine months ended September 30, 2015, compared with \$13,155,745 for the nine months ended September 30, 2014. In both years, we recognized financing cash flows from the sale of our common stock to Aspire and the offering in 2015 or the 2014 public offering. The decrease in net cash flows from financing activities is due to the 2015 proceeds from the offering of common stock 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: offer our breast aspirators for sale; continue to launch our laboratory tests including the pharmacogenomics test; complete the development of and potentially launch NextCYTE test, and potentially other tests in the pipeline; continue the development of Afimoxifene Gel and the clinical trial using our intraductal Microcatheters; and start the development of other therapeutics including related clinical studies. We expect that our existing resources as of September 30, 2015 will be sufficient to fund our planned operations through the first quarter of 2016. In addition to our cash and cash equivalents at September 30, 2015 of approximately \$7.8 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 expense associated with hiring our internal sales force and building a network of independent sales representatives to market the pharmacogenomics tests and other tests;

- time, expense and timing associated with the development of Afimoxifene Gel , Fulvestrant administered via our intraductal Microcatheters and our other 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 structured finance or special purpose entities, established for the purpose of facilitating off-balance sheet arrangements 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 September 30, 2015. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the Securities and Exchange Commission’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of September 30, 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 September 30, 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 Aspirator 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. On May 18, 2015, plaintiffs filed a reply brief in support of their appeal. A hearing for the appeal has not been set.

The Company believes this complaint and appeal are without merit and plans to defend itself vigorously; however failure to obtain a favorable resolution of the claims set forth in the complaint and raised on appeal 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 or this appeal as of September 30, 2015. The costs associated with defending and resolving the complaint and appeal 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 have 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 six to twelve months.*

For the nine months ended September 30, 2015, we generated \$5,339,669 in revenue and we incurred a net loss of \$10,798,727. Through September 30, 2015, we had an accumulated deficit of approximately \$45.9 million. We expect that our existing resources will be sufficient to fund our planned operations through the first quarter of 2016. 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 our laboratory tests 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.

*We will need to raise substantial additional capital in the future to fund our operations and we may be unable to raise such funds when needed and on acceptable terms.*

The extent to which we utilize the November 11, 2015 Purchase Agreement with Aspire Capital as a source of funding will depend on a number of factors, including the prevailing market price of our Common Stock, the volume of trading in our Common Stock and the extent to which we are able to secure funds from other sources. The number of shares that we may sell to Aspire Capital under the Purchase Agreement on any given day and during the term of

the Purchase Agreement is limited. See “ITEM 5. OTHER INFORMATION” below. Additionally, we and Aspire Capital may not affect any sales of shares of our Common Stock under the Purchase Agreement unless and until a registration statement covering the shares is declared effective by the SEC and remains effective, nor during the continuance of an event of default or on any trading day that the closing sale price of our Common Stock is less than \$0.10 per share. Even if we are able to access the full \$25.0 million under the Purchase Agreement, we will still need additional capital to fully implement our business, operating and development plans.

When we elect to raise additional funds or additional funds are required, we may raise such funds from time to time through public or private equity offerings, debt financings, corporate collaboration and licensing arrangements or other financing alternatives, as well as through sales of shares to Aspire Capital under the Purchase Agreement. Additional equity or debt financing or corporate collaboration and licensing arrangements may not be available on acceptable terms, if at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we will be prevented from pursuing acquisition, licensing, development and commercialization efforts and our ability to generate revenues and achieve or sustain profitability will be substantially harmed.

If we raise additional funds by issuing equity securities, our stockholders will experience dilution. Debt financing, if available, would result in increased fixed payment obligations and may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Any debt financing or additional equity that we raise may contain terms, such as liquidation and other preferences, which are not favorable to us or our stockholders. If we raise additional funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish valuable rights to our technologies, future revenue streams or product candidates or to grant licenses on terms that may not be favorable to us. Should the financing we require to sustain our working capital needs be unavailable or prohibitively expensive when we require it, our business, operating results, financial condition and prospects could be materially and adversely affected and we may be unable to continue our operations.

***Changes in regulations and policies, including adverse coverage decisions by Medicare Administrative Contractors, or changes in payor mix is adversely affecting, and could continue to 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 have been 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 is having and could continue to have a material adverse impact on our revenue and operations.***

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 was 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 is not available under the new LCD. This new LCD has negatively impacted our revenue for the quarter ended September 30, 2015. For example, the LCD has reduced the types of conditions and the pharmaceuticals for which Medicare will reimburse which we believe is indirectly causing some commercial carriers to deny or limit coverage for some drugs or patients. This has negatively impacted the reimbursement rate on our tests and the number of tests we performed in the third quarter 2015. Additionally, after the LCD went into effect, one of our largest commercial payor has also denied coverage for a significant number of our pharmacogenomics tests which has adversely impacted our third quarter 2015 revenue. The LCD could continue to significantly reduce number of tests submitted to the NRLBH, 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.

***If we are not able to protect our proprietary technology, others could compete against us more directly, which would harm our business.***

Our commercial success will depend, in part, on our ability to obtain additional patents and licenses and protect our existing patent position, both in the United States and in other countries, for devices, kits, diagnostics tests, therapeutics and related technologies, processes, methods, compositions and other inventions that we believe are patentable. Our ability to preserve our trade secrets and other intellectual property is also important to our long-term success. If we do not adequately protect our intellectual property, competitors may be able to use our technologies and erode or negate any competitive advantage we may have, which could harm our business and ability to maintain profitability. Patents may also issue to third parties which could interfere with our ability to bring our molecular diagnostic tests or therapeutics to market. The laws of some foreign countries do not protect our proprietary rights to the same extent as U.S. laws, and we may encounter significant problems in protecting our proprietary rights in these countries. The patent positions of diagnostic companies and pharmaceutical and biotechnology companies, including our patent position, are generally highly uncertain and particularly after the Supreme Court decisions, *Mayo Collaborative Services v. Prometheus Laboratories*, 132 S. Ct. 1289 (2012), *Association for Molecular Pathology v. Myriad*, 133 S. Ct. 2107 (2013), and *Alice Corp. v. CLS Bank Int'l*, 134 S. Ct. 2347 (2014), and involve complex legal and factual questions, and, therefore, any patents issued to us may be challenged, deemed unenforceable, invalidated or circumvented. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our proprietary technologies and any future tests are covered by valid and enforceable patents or are effectively maintained as trade secrets. Our patent applications may never issue as patents, and the claims of any issued patents may not afford meaningful protection for our technology or tests. In addition, any patents issued to us

or our licensors may be challenged, and subsequently narrowed, invalidated or circumvented.

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

- we or our licensors were the first to make the inventions covered by each of our patent applications;
- we or our licensors were the first to file patent applications for these inventions;
- others will not independently develop similar or alternative technologies or duplicate any of our technologies;
- any of our or our licensors' patent applications will result in issued patents;
- any of our or our licensors' patents will be valid or enforceable;



any patents issued to us or our licensors and collaborators will provide a basis for commercially viable tests and/or therapeutics, will provide us with any competitive advantages or will not be challenged by third parties;

we will develop additional proprietary technologies or tests that are patentable;

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

our patents or patents that we license from others will survive legal challenges, and remain valid and enforceable.

If a third party files a patent application with claims to a biomarker or a drug we have discovered or developed, a derivation proceeding may be initiated regarding competing patent applications. If a derivation proceeding is initiated, we may not prevail in the derivation proceeding. If the other party prevails in the derivation proceeding, we may be precluded from commercializing services or tests based on the biomarker or the drug, or may be required to seek a license. A license may not be available to us on commercially acceptable terms, if at all.

We also rely upon unpatented proprietary technologies. Although we require employees, consultants and collaborators to sign confidentiality agreements, we may not be able to adequately protect our rights in such unpatented proprietary technologies, which could have a material adverse effect on our business. For example, others may independently develop substantially equivalent proprietary information or techniques or otherwise gain access to our proprietary technologies or disclose our technologies to our competitors.

***If we were sued for patent infringement by third parties, we might incur significant costs and delays in test or drug introduction.***

Our tests and drug candidates may also conflict with patents that have been or may be granted to others. Our industry includes many organizations that have or are seeking to discern biomarkers and develop genomic, proteomic and other technologies and also develop drugs. To the extent any patents are issued or have been issued to those organizations, the risk increases that the sale of our molecular diagnostic and companion diagnostic tests, and drugs under development may give rise to claims of patent infringement. Others may have filed and in the future are likely to file patent applications covering biomarkers that are similar or identical to our tests and/or drugs that are similar to our drugs. Any of these patent applications may have priority over our patent applications and these entities or persons could bring legal proceedings against us seeking damages or seeking to enjoin us from testing or marketing our tests. Patent litigation is costly, and even if we prevail, the cost of such litigation could have a material adverse effect on us. If the other parties in any such actions are successful, in addition to any liability for damages, we could be required to cease the infringing activity or obtain a license. Any license required may not be available to us on commercially acceptable terms, if at all. Our failure to obtain a license to any technology that we may require to commercialize our tests could have a material adverse effect on our business. We believe that there may be significant litigation in the industry regarding patent and other intellectual property rights. If we become involved in this litigation, it could

consume a substantial portion of our managerial and financial resources.

***If we fail to comply with our obligations under license or technology agreements with third parties, we could lose license rights that are critical to our business.***

We license intellectual property that is critical to our business, including licenses underlying the technology in our molecular diagnostic and pharmaceutical and clinical services and therapeutics and in the future we may enter into additional agreements that provide us with licenses to valuable intellectual property or technology. These licenses impose various royalty payments, milestones, and other obligations on us. If we fail to comply with any of these obligations, the licensor may have the right to terminate the license. Termination by the licensor would cause us to lose valuable rights, and could prevent us from distributing our current tests and/or drugs, or inhibit our ability to commercialize future test and/or therapeutics candidates. Our business would suffer if any current or future licenses terminate, if the licensors fail to abide by the terms of the license, if the licensors fail to prevent infringement by third parties, if the licensed patents or other rights are found to be invalid or unenforceable, or if we are unable to enter into necessary licenses on acceptable terms.

***If our stock price does not appreciate above \$1.00 per share, we may be delisted from NASDAQ which would adversely affect our stock price, liquidity and our ability to raise funding.***

On September 28, 2015, we received a letter from NASDAQ stating that the Company was not in compliance with NASDAQ Listing Rule 5550(a)(2), because the Company's common stock failed to maintain a minimum closing bid price of \$1.00 per share for 30 consecutive business days. We have until March 28, 2016 to regain compliance. In the event we do not regain compliance by then, we may be eligible for additional time if at that time we meet the continued listing requirement for market value of publicly held shares and all other initial listing standards, with the exception of the bid price requirement, and provide written notice to NASDAQ of our intention to cure the deficiency during the second compliance period, including by effecting a reverse stock split, if necessary. The letter also states that the NASDAQ staff will provide written notification that we have regained compliance if the bid price of our common stock closes at \$1.00 per share or more for a minimum of 10 consecutive business days.

If our stock price does not appreciate above \$1.00 per share we may be delisted from NASDAQ which could adversely affect our stock price, liquidity and our ability to raise funding.

## **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**

On November 11, 2015, the Company entered into a common stock purchase agreement (the “Purchase Agreement”) with Aspire Capital, which provides that, upon the terms and subject to the conditions and limitations set forth therein, Aspire Capital is committed to purchase up to an aggregate of \$25.0 million of shares of the Company’s common stock over the 30-month term of the Purchase Agreement. Concurrently with entering into the Purchase Agreement, the Company also entered into a registration rights agreement with Aspire Capital (the “Registration Rights Agreement”), in which the Company agreed to file one or more registration statements, as permissible and necessary to register under the Securities Act, registering the sale of the shares of the Company’s common stock that have been and may be issued to Aspire Capital under the Purchase Agreement.

Under the Purchase agreement, after the SEC has declared effective the registration statement referred to above, on any trading day selected by the Company, the Company has the right, in its sole discretion, to present Aspire Capital with a purchase notice (each, a “Purchase Notice”), directing Aspire Capital (as principal) to purchase up to 150,000 shares of the Company’s common stock per business day, up to \$25.0 million of the Company’s common stock in the aggregate at a per share price (the “Purchase Price”) equal to the lesser of:

- the lowest sale price of the Company’s common stock on the purchase date; or

the arithmetic average of the three (3) lowest closing sale prices for the Company's common stock during the twelve (12) consecutive trading days ending on the trading day immediately preceding the purchase date.

In addition, on any date on which the Company submits a Purchase Notice to Aspire Capital in an amount equal to 150,000 shares and our stock price is not less than \$0.50 per share, the Company also has the right, in its sole discretion, to present Aspire Capital with a volume-weighted average price purchase notice (each, a "VWAP Purchase Notice") directing Aspire Capital to purchase an amount of stock equal to up to 30% of the aggregate shares of the Company's common stock traded on its principal market on the next trading day (the "VWAP Purchase Date"), subject to a maximum number of shares the Company may determine. The purchase price per share pursuant to such VWAP Purchase Notice is generally 95% of the volume-weighted average price for the Company's common stock traded on its principal market on the VWAP Purchase Date.

The Purchase Price will be adjusted for any reorganization, recapitalization, non-cash dividend, stock split, or other similar transaction occurring during the period(s) used to compute the Purchase Price. The Company may deliver multiple Purchase Notices and VWAP Purchase Notices to Aspire Capital from time to time during the term of the Purchase Agreement, so long as the most recent purchase has been completed.

The Purchase Agreement provides that the Company and Aspire Capital shall not effect any sales under the Purchase Agreement on any purchase date where the closing sale price of the Company's common stock is less than \$0.10. There are no trading volume requirements or restrictions under the Purchase Agreement, and the Company will control the timing and amount of sales of the Company's common stock to Aspire Capital. Aspire Capital has no right to require any sales by the Company, but is obligated to make purchases from the Company as directed by the Company in accordance with the Purchase Agreement. There are no limitations on use of proceeds, financial or business covenants, restrictions on future fundings, rights of first refusal, participation rights, penalties or liquidated damages in the Purchase Agreement. The Purchase Agreement may be terminated by the Company at any time, at its discretion, without any cost to the Company. Aspire Capital has agreed that neither it nor any of its agents, representatives and affiliates shall engage in any direct or indirect short-selling or hedging of the Company's common stock during any time prior to the termination of the Purchase Agreement. Any proceeds from the Company received under the Purchase Agreement are expected to be used for working capital and general corporate purposes.

The Purchase Agreement provides that on the date of its execution, that certain Purchase Agreement, dated as of May 26, 2015 by and between the Company and Aspire Capital, was terminated.

The foregoing is a summary description of certain terms of the Purchase Agreement and the Registration Rights Agreement and, by its nature, is incomplete. Copies of the Purchase Agreement and Registration Rights Agreement are filed herewith as Exhibits 10.1 and 10.2, respectively, to this quarterly report on Form 10-Q. All readers are encouraged to read the entire text of the Purchase Agreement and the Registration Rights Agreement.

The issuance of shares of common stock that may be issued from time to time to Aspire Capital under the Purchase Agreement is exempt from registration under the Securities Act, pursuant to the exemption for transactions by an

issuer not involving any public offering under Section 4(a)(2) of the Securities Act.

**ITEM 6. EXHIBITS**

(a) Exhibits

| <b>Exhibit No.</b> | <b>Description</b>   | <b>Incorporated by Reference Herein<br/>Form</b> | <b>Date</b> |
|--------------------|--|--|-------------|
| 10.1               | Common Stock Purchase Agreement, between the Company and Aspire Capital Fund, LLC, dated as of November 11, 2015 | Filed herewith                                   |             |
| 10.2               | Registration Rights Agreement, between the Company and Aspire Capital Fund, LLC, dated as of November 11, 2015   | Filed herewith                                   |             |
| 31.1               | Certification pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934 of Steven C. Quay             | Filed herewith                                   |             |
| 31.2               | Certification pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934 of Kyle Guse                  | Filed herewith                                   |             |
| 32.1               | Certification pursuant to 18 U.S.C. Section 1350 of Steven C. Quay   | Filed herewith                                   |             |
| 32.2               | Certification pursuant to 18 U.S.C. Section 1350 of Kyle Guse  | Filed herewith                                   |             |
| 101                | Interactive Data Files pursuant to Rule 405 of Regulation S-T  | Filed herewith                                   |             |

**SIGNATURES**

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

Date: November 12, 2015

/s/ Steven C. Quay  
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)