

ATOSSA GENETICS INC  
Form 10-Q  
November 14, 2016

**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, 2016**

**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)**

Edgar Filing: ATOSSA GENETICS INC - Form 10-Q

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

**107 Spring Street** **98104**  
**Seattle, WA** (Zip Code)  
(Address of principal executive offices)

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

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☐ No ☐

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

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

Large accelerated filer ☐ Accelerated filer ☐ Non-accelerated filer ☐ Smaller reporting company ☐

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

The number of shares of the registrant's common stock, \$0.015 par value per share, outstanding at November 11, 2016 was 3,787,967.

**ATOSSA GENETICS INC.**

**FORM 10-Q**

**QUARTERLY REPORT**

**INDEX**

<b><u>PART I. FINANCIAL INFORMATION</u></b>	<b>3</b>
ITEM 1. <u>Condensed Consolidated Financial Statements – Unaudited</u>	3
<u>Condensed Consolidated Balance Sheets as of September 30, 2016 and December 31, 2015</u>	3
<u>Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2016 and 2015</u>	4
<u>Condensed Consolidated Statement of Stockholders' Equity for the nine months ended September 30, 2016</u>	5
<u>Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2016 and 2015</u>	6
<u>Notes to Consolidated Financial Statements</u>	7
ITEM 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	17
ITEM 3. <u>Quantitative and Qualitative Disclosures about Market Risk</u>	25
ITEM 4. <u>Controls and Procedures</u>	25
<b><u>PART II. OTHER INFORMATION</u></b>	<b>25</b>
ITEM 1. <u>Legal Proceedings</u>	25
ITEM 1A. <u>Risk Factors</u>	26
ITEM 2. <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	26
ITEM 3. <u>Defaults upon Senior Securities</u>	27
ITEM 4. <u>Mine Safety Disclosures</u>	27
	3

ITEM 5. <u>Other Information</u>	27
ITEM 6. <u>Exhibits</u>	27
<u>SIGNATURES</u>	28

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

	September 30, 2016 (Unaudited)	December 31, 2015
Assets		
Current assets		
Cash and cash equivalents	\$4,388,177	\$3,715,895
Restricted cash	55,000	275,000
Prepaid expense	120,751	193,293
Other current assets	-	110,663
Total current assets	4,563,928	4,294,851
Furniture and equipment, net	84,537	171,568
Intangible assets, net	1,401,899	1,700,565
Other assets	227,877	76,337
Total assets	\$6,278,241	\$6,243,321
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	\$197,354	\$814,448
Accrued expenses	12,480	463,676
Payroll liabilities	635,047	1,159,335
Other current liabilities	18,886	64,128
Total current liabilities	863,767	2,501,587
Commitments and contingencies (note 13)		
Stockholders' equity		
Preferred stock - \$.001 par value; 10,000,000 shares authorized, 0 shares issued and outstanding	-	-
Common stock - \$.015 par value; 75,000,000 shares authorized, 3,787,967 and 2,177,151 shares issued and outstanding	56,820	32,657
Additional paid-in capital	60,137,752	54,643,940

Edgar Filing: ATOSSA GENETICS INC - Form 10-Q

Accumulated deficit	(54,780,098 )	(50,934,863 )
Total stockholders' equity	5,414,474	3,741,734
Total liabilities and stockholders' equity	\$ 6,278,241	\$ 6,243,321

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

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

	<b>For the Three Months Ended September 30,</b>		<b>For the Nine Months Ended September 30,</b>	
	<b>2016</b>	<b>2015</b>	<b>2016</b>	<b>2015</b>
Net revenue	\$ -	\$ -	\$ -	\$ -
Operating expenses:				
Selling	-	498,609	-	1,187,777
Research and development	85,000	948,961	403,963	1,888,236
General and administrative	1,473,435	2,395,089	5,040,939	7,208,508
Total operating expenses	1,558,435	3,842,659	5,444,902	10,284,521
Operating loss	(1,558,435 )	(3,842,659 )	(5,444,902 )	(10,284,521 )
Other income, net	1,763,124	69,350	1,599,667	116,108
Income (Loss) before income taxes	204,689	(3,773,309 )	(3,845,235 )	(10,168,413 )
Income taxes	-	-	-	-
Income (Loss) from continuing operations	204,689	(3,773,309 )	(3,845,235 )	(10,168,413 )
Loss from discontinued operations	-	(544,802 )	-	(630,314 )
Net income (loss)	\$ 204,689	\$ (4,318,111 )	\$ (3,845,235 )	\$ (10,798,727 )
Income (Loss) per common share from continuing operations - basic and diluted	\$ 0.07	\$ (2.04 )	\$ (1.72 )	\$ (5.91 )
Loss per common share from discontinued operations – basic and diluted	-	\$ (0.30 )	-	\$ (0.37 )
Weighted average shares outstanding, basic & diluted	2,799,082	1,845,747	2,240,869	1,720,353

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

**ATOSSA GENETICS, INC.****CONDENSED CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY****(UNAUDITED)**

	<b>Common Stock</b>		<b>Additional</b>	<b>Accumulated</b>	<b>Total</b>
	<b>Shares</b>	<b>Amount</b>	<b>Paid-in</b>	<b>Deficit</b>	<b>Stockholders'</b>
			<b>Capital</b>		<b>Equity</b>
Balance at December 31, 2015	2,177,151	\$32,657	\$54,643,940	\$(50,934,863 )	\$ 3,741,734
Issuance of common shares and warrants (net of issuance costs of \$356,214)	1,561,080	23,417	4,672,452	-	4,695,869
Issuance of common shares as commitment fees	49,736	746	197,777	-	198,523
Amortization of commitment shares			(26,470 )		(26,470 )
Compensation cost for stock options granted to executives and employees	-	-	650,053	-	650,053
Net loss	-	-	-	(3,845,235 )	(3,845,235 )
Balance at September 30, 2016	3,787,967	\$56,820	\$60,137,752	\$(54,780,098 )	\$ 5,414,474

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



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

	<b>For the Nine Months Ended September 30,</b>	
	<b>2016</b>	<b>2015</b>
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>		
Net loss	\$(3,845,235)	\$(10,798,727)
Net loss from discontinued operations	-	630,314
Compensation cost for stock options granted	650,053	633,962
Loss (gain) on disposal of intangible asset	163,333	(74,800 )
Depreciation and amortization	227,387	168,264
Changes in operating assets and liabilities:		
Change in restricted cash	220,000	(275,000 )
Inventory	-	(78,265 )
Prepaid expenses	72,542	72,723
Other assets	131,176	(4,456 )
Accounts payable	(617,094 )	408,081
Payroll liabilities	(524,288 )	62,772
Deferred rent	-	11,298
Accrued expenses	(451,196 )	(1,000,662 )
Other current liabilities	(45,242 )	(27,720 )
Net cash used in continuing operating activities	(4,018,564)	(10,272,216)
Net cash provided by discontinued operating activities	-	272,344
Net cash used in operating activities	(4,018,564)	(9,999,872 )
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>		
Purchase of furniture and equipment	(5,023 )	(51,395 )
Purchase of intangible assets	-	(15,553 )
Net cash used in continuing investing activities	(5,023 )	(66,948 )
Net cash used in discontinued investing activities	-	(43,801 )
Net cash used in investing activities	(5,023 )	(110,749 )
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>		
Net proceeds from issuance of common stock and warrants, net of issuance costs of \$356,214 and \$577,790, respectively	4,695,869	9,498,557
Payments on capital lease obligations	-	(49,215 )
Net cash provided by financing activities	4,695,869	9,449,342
<b>NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS</b>	<b>672,282</b>	<b>(661,279 )</b>
<b>CASH AND CASH EQUIVALENTS, BEGINNING BALANCE</b>	<b>3,715,895</b>	<b>8,500,718</b>
<b>CASH AND CASH EQUIVALENTS, ENDING BALANCE</b>	<b>\$4,388,177</b>	<b>\$7,839,439</b>

**SUPPLEMENTAL DISCLOSURES:**

Interest paid	\$ 1,304	\$3,311
---------------	----------	---------

**NONCASH INVESTING AND FINANCING ACTIVITIES:**

Common stock issued as commitment fee under stock purchase agreement	\$ 198,523	\$-
Amortization of commitment shares	\$26,470	\$392,711

*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 31.

In December 2011, the Company established the National Reference Laboratory for Breast Health, Inc., or NRLBH, as a wholly-owned subsidiary. NRLBH was the Company’s CLIA-certified laboratory which performed the Company’s nipple aspirate fluid, or NAF, cytology test on NAF specimens including those collected with the Company’s Mammary Aspiration Specimen Cytology Test (MASCT) System. The current version of the MASCT System is called the ForeCYTE Breast Aspirator. The NRLBH provides other test services, including pharmacogenomics tests. On December 16, 2015, the Company sold approximately 81% of the capital stock of the NRLBH to the NRL Investment Group, LLC, with the Company retaining a 19% ownership through preferred stock. The Company received \$50,000 at the time of the sale and the right to receive, commencing December 2016, monthly earn-out payments equal to 6% of gross revenue of NRLBH up to \$10,000,000, and the right to sell its preferred stock after four years for the greater of \$4,000,000 or fair market value. The Company has elected to recognize any subsequent gain from the earn-out payments as they are determined realizable.

As a result of the sale of the laboratory business, the Company is now focusing on development of its pharmaceutical programs.

**NOTE 2: GOING CONCERN**

The Company’s consolidated financial statements are prepared using generally accepted accounting principles in the United States of America applicable to a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The Company has incurred net losses and negative operating cash flows since inception. For the nine months ended September 30, 2016, the Company recorded a net loss of approximately \$3.8 million and used approximately \$4.0 million of cash in operating activities. As of September 30, 2016, the Company had approximately \$4.4 million in cash and cash equivalents and working capital

of approximately \$3.7 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 capital will be obtained on acceptable terms. If the Company is unable to obtain adequate capital, it could be forced to cease operations or substantially curtail its 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 is as follows. 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 obtaining capital from the sale of its equity securities and short-term borrowings from banks, stockholders or other 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 consolidated financial statements have been prepared pursuant to the rules of the Securities and Exchange Commission (“SEC”) and in accordance with U.S. generally accepted accounting principles (“GAAP”). The accompanying consolidated financial statements include the financial statements of Atossa Genetics Inc. and its formerly wholly-owned subsidiary, NRLBH. The Company sold a majority of its interest in the NRLBH in December 2015 and all of its activities are reported as discontinued operations in the accompanying consolidated financial statements. All significant intercompany account balances and transactions have been eliminated in consolidation. Certain amounts from prior years have been reclassified to conform with the 2016 presentation.

On August 26, 2016, the Company completed a 1-for-15 reverse stock split of the shares of the Company’s common stock (the “Reverse Stock Split”). As a result of the Reverse Stock Split, every 15 shares of issued and outstanding common stock were combined into one issued and outstanding share of Common Stock, and the par value per share was changed to \$.015 per share. No fractional shares were issued because of the Reverse Stock Split and any fractional shares that would otherwise have resulted from the Reverse Stock Split were paid in cash. As a result of the Reverse Stock Split, as of November 11, 2016, there are 3,787,967 shares of common stock outstanding. The number of authorized shares of common stock was not reduced as a result of the Reverse Stock Split. The Company’s common stock began trading on a reverse stock split-adjusted basis on August 26, 2016. All share and per share data included in this report has been retroactively restated to reflect the Reverse Stock Split.

#### **Use of Estimates:**

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

#### **Recently Issued Accounting Pronouncements:**

In May 2014, the Financial Accounting Standards Board (the “FASB”) issued Accounting Standards Update (“ASU”) No. 2014-09, *Revenue from Contracts with Customers: Topic 606* (“ASU 2014-09”), to supersede nearly all existing revenue

recognition guidance under U.S. GAAP. The core principle of ASU 2014-09 is to recognize revenues when promised goods or services are transferred to customers in an amount that reflects the consideration that is expected to be received for those goods or services. ASU 2014-09 defines a five step process to achieve this core principle and, in doing so, it is possible more judgment and estimates may be required within the revenue recognition process than required under existing GAAP including identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation. ASU 2014-09 is effective for the Company in the first quarter of 2018 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 the management to determine whether substantial doubt exists regarding the entity's going concern presumption, which generally refers to an entity's ability to meet its obligations as they become due. If substantial doubt exists but is not alleviated by management's plan, the footnotes must specifically state that "there is substantial doubt about the entity's ability to continue as a going concern within one year after the financial statements are issued." In addition, if substantial doubt exists, regardless of whether such doubt was alleviated, entities must disclose (a) principal conditions or events that raise substantial doubt about the entity's ability to continue as a going concern (before consideration of management's plans, if any); (b) management's evaluation of the significance of those conditions or events in relation to the entity's ability to meet its obligations; and (c) management's plans that are intended to mitigate the conditions or events that raise substantial doubt, or that did alleviate substantial doubt, about the entity's ability to continue as a going concern. If substantial doubt has not been alleviated, these disclosures should become more extensive in subsequent reporting periods as additional information becomes available. In the period that substantial doubt no longer exists (before or after considering management's plans), management should disclose how the principal conditions and events that originally gave rise to substantial doubt have been resolved. The ASU applies prospectively to all entities for annual periods ending after December 15, 2016, and to annual and interim periods thereafter. Early adoption is permitted. The Company has not yet adopted the provisions of ASU 2014-15.

In February 2016, FASB issued ASU No. 2016-02, *Lease Accounting Topic 842*. This ASU requires a lessee to recognize lease assets and liabilities on the balance sheet for all arrangements with terms longer than 12 months, the new standard applies a right-of-use (ROU) model that requires a lessee to record, for all leases with a lease term of more than 12 months, an asset representing its right to use the underlying asset for the lease term and a liability to make lease payments. The lease term is the non-cancellable period of the lease, and includes both periods covered by an option to extend the lease, if the lessee is reasonably certain to exercise that option, and periods covered by an option to terminate the lease, if the lessee is reasonably certain not to exercise that termination option. For leases with a lease term of 12 months or less, a practical expedient is available whereby a lessee may elect, by class of underlying asset, not to recognize an ROU asset or lease liability. A lessee making this accounting policy election would recognize lease expense over the term of the lease, generally in a straight-line pattern. The Lessor accounting remains largely consistent with existing U.S. GAAP. The new standard takes effect in 2019 for public business entities and 2020 for all other entities. We have not adopted the provisions of ASU No. 2016-02. The Company is currently evaluating the impact of adopting ASU 2016-02 on its consolidated financial statements.

In April 2016, the FASB issued ASU No. 2016-09, *Stock Compensation Topic 718: Improvements to Employee Share-based Payment Accounting*. This ASU simplifies the accounting for stock compensation on income tax accounting, classification of awards as either equity or liabilities, estimating forfeitures, and cash flow presentation. Based on this ASU, an entity should recognize all excess tax benefits and tax deficiencies, including tax benefits of dividends on share-based payment awards, as income tax expense or benefit in the income statement; they do not need to include the effects of windfalls and shortfalls in the annual effective tax rate estimate from continuing operations used for interim reporting purposes. As a result of including income tax effects from windfalls and shortfalls in income tax expense, the calculation of both basic and diluted EPS will be affected. The ASU also provides an accounting policy election for awards with service conditions to either estimate the number of awards that are expected to vest (consistent with existing U.S. GAAP) or account for forfeitures when they occur. The ASU increases the allowable statutory tax withholding threshold to qualify for equity classification from the minimum statutory withholding requirements up to the maximum statutory tax rate in the applicable jurisdiction(s). The ASU clarifies that cash paid to a taxing authority by an employer when directly withholding equivalent shares for tax withholding purposes should be considered similar to a share repurchase, and thus classified as a financing activity. All other employer withholding taxes on compensation transactions and other events that enter into the determination of net income continue to be presented within operating activities. The new standard takes effect in 2017 for public business entities and 2018 for all other entities. The Company has not adopted the provisions of ASU No. 2016-09. The Company is currently evaluating the impact of adopting ASU 2016-09 on its consolidated financial statements.

#### NOTE 4: PREPAID EXPENSES

Prepaid expenses consisted of the following:

	September 30, 2016	December 31, 2015
Prepaid insurance	38,538	104,954
Retainer and security deposits	39,218	39,218
Other	42,995	49,121
Total prepaid expenses	\$ 120,751	\$ 193,293

**NOTE 5: FURNITURE AND EQUIPMENT**

Furniture and equipment consisted of the following:

	September 30, 2016	December 31, 2015
Machinery and equipment	\$ 206,336	\$ 206,337
Leasehold improvements	84,539	79,518
Total furniture and equipment	290,875	285,855
Less: Accumulated depreciation	(206,338 )	(114,287 )
Total furniture and equipment, net	\$ 84,537	\$ 171,568

Depreciation expense for the three months ended September 30, 2016 and 2015 was \$29,698 and \$32,620, respectively, and \$92,054 and \$97,059, for the nine months ended September 30, 2016 and 2015, respectively.

**NOTE 6: INTANGIBLE ASSETS**

Intangible assets consisted of the following:

	September 30, 2016	December 31, 2015
Patents	\$ 1,630,000	\$ 1,630,000
Capitalized license costs	-	200,000
Software	113,540	113,540
Intangible assets	1,743,540	1,943,540
Less: Accumulated amortization	(341,641 )	(242,975 )
Total intangible assets, net	\$ 1,401,899	\$ 1,700,565

Intangible assets amounted to \$1,401,899 and \$1,700,565 as of September 30, 2016 and December 31, 2015, respectively, and consisted of patents, capitalized license costs and software acquired. The amortization period for the purchased software is 3 years. Amortization expense related to software for the three months ended September 30, 2016 and 2015 was \$7,857 and \$11,261, respectively and \$23,572 and \$34,090 for the nine months ended September 30, 2016 and 2015, respectively.



## Edgar Filing: ATOSSA GENETICS INC - Form 10-Q

Patents amounted to \$1,630,000 as of September 30, 2016 and December 31, 2015, and mainly consisted of patents acquired from Acueity on September 30, 2012 in an asset purchase transaction. Patent assets are amortized based on their determined useful life, and tested annually for impairment. The amortization period was from 7 to 12 years. Amortization expense related to patents was \$37,253 for the three months ended September 30, 2016 and 2015, respectively and \$111,761 for each of the nine months ended September 30, 2016 and 2015, 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. As the Company shifted its focus to developing pharmaceutical products and discontinued NextCYTE test development, the A5 agreement was terminated in February 2016 and the entire net assets of \$163,333, including \$36,666 in accumulated amortization was written off.

Future estimated amortization expenses as of September 30, 2016 for the five succeeding years is as follows:

For the Year Ending December 31,	Amounts
2016 (includes the remainder of the year)	\$42,489
2017	169,576
2018	149,623
2019	149,015
2020	149,015
Thereafter	742,181
	\$1,401,899

**NOTE 7: PAYROLL LIABILITIES:**

Payroll liabilities consisted of the following:

	September 30, 2016	December 31, 2015
Accrued bonus payable	\$ 438,098	\$ 555,345
Accrued payroll liabilities	96,248	510,179
Accrued vacation	100,701	93,811
Total payroll liabilities	\$ 635,047	\$ 1,159,335

**NOTE 8: DISCONTINUED OPERATIONS**

On December 16, 2015, the Company entered into a Stock Purchase Agreement (the “Purchase Agreement”) with the NRLBH and NRL Investment Group, LLC (the “NRL Group”) pursuant to which the Company sold to the NRL Group all of its shares of common stock in the NRLBH as of that date. Under the terms of the Purchase Agreement, the Company retained its ownership of the Preferred Stock of the NRLBH, which constitutes approximately 19% of the outstanding capital stock of the NRLBH, and the Company will have the right to sell to the NRL Group on or after the fourth anniversary of the Purchase Agreement at the greater of \$4,000,000 or fair market value. The Company has the right to receive earn-out payments from NRL Group starting in December 2016 up to a total of \$10,000,000. The Earn-out Payments are payable to the Company each calendar month commencing with December 2016 and are equal to 6% of NRLBH gross sales calculated in accordance with U.S. Generally Accepted Accounting Principles. The operations of the NRLBH sold to the NRL Group were accounted for as discontinued operations as the operations and cash flows of the discontinued business were eliminated from ongoing operations of the Company and the Company has no significant involvement in the NRLBH’s operations after the disposal transaction.

The results of the NRLBH were segregated from continuing operations and reflected as discontinued operations for the 2015 periods on the Company’s Consolidated Statements of Operations and cash flow for the three and six months ended September 30, 2015. The loss from discontinued operations related to the operations of the NRLBH for the three and nine months ended September 30, 2015 was as follows:

<b>Three Months Ended September 30, 2015</b>	<b>Nine Months Ended September 30, 2015</b>
--	---

Edgar Filing: ATOSSA GENETICS INC - Form 10-Q

Revenue	\$ 772,591	\$ 5,337,911
Cost of revenue	(311,074 )	(3,365,901 )
Gross profit	461,517	1,972,010
Expenses:		
Selling expenses	239,427	829,174
Research and development expenses	141,388	509,796
General and administrative expenses	625,499	1,213,795
Other expenses, net	5	49,559
Net loss from discontinued operations	\$ (544,802 )	\$ (630,314 )

**NOTE 9: STOCKHOLDERS' EQUITY**

The Company is authorized to issue a total of 85,000,000 shares of stock consisting of 75,000,000 shares of Common Stock, par value \$0.015 per share, and 10,000,000 shares of Preferred Stock, par value \$0.001 per share. The Company has designated 750,000 shares of Series A Junior Participating Preferred Stock, par value \$0.001 per share through the filing of certificate of designation with the Delaware Secretary of State.

On May 19, 2014, the Company adopted a stockholder rights agreement which provides that all stockholders of record on May 26, 2014 received a non-taxable distribution of one preferred stock purchase right for each share of the Company's common stock held by such stockholder. Each right is attached to and trades with the associated share of common stock. The rights will become exercisable only if one of the following occurs: (1) a person becomes an "Acquiring Person" by acquiring beneficial ownership of 15% or more of the Company's common stock (or, in the case of a person who beneficially owned 15% or more of the Company's common stock on the date the stockholder rights agreement was executed, by acquiring beneficial ownership of additional shares representing 2.0% of the Company's common stock then outstanding (excluding compensatory arrangements)), or (2) a person commences a tender offer that, if consummated, would result in such person becoming an Acquiring Person. If a person becomes an Acquiring Person, each right will entitle the holder, other than the Acquiring Person and certain related parties, to purchase a number of shares of the Company's common stock with a market value that equals twice the exercise price of the right. The initial exercise price of each right is \$15.00, so each holder (other than the Acquiring Person and certain related parties) exercising a right would be entitled to receive \$30.00 worth of the Company's common stock. If the Company is acquired in a merger or similar business combination transaction at any time after a person has become an Acquiring Person, each holder of a right (other than the Acquiring Person and certain related parties) will be entitled to purchase a similar amount of stock of the acquiring entity.

#### 2015 and 2016 Issuances of Additional Shares to Aspire Capital

During the first quarter of 2015, we sold a total of 176,880 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, which provided that, upon the terms and subject to the conditions and limitations set forth therein, Aspire Capital was 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.

On November 11, 2015, we terminated the May 26, 2015 agreement with Aspire Capital and entered into a new common stock 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 register 405,747 shares of our common stock.

During the first quarter of 2016, we sold a total of 405,747 shares of Common Stock to Aspire Capital Fund LLC under the stock purchase agreement dated November 11, 2015 with aggregate gross proceeds to the Company of \$2,153,583.

On May 25, 2016, we terminated the November 11, 2015 stock purchase agreement with Aspire Capital and entered into a new common stock purchase agreement with Aspire Capital which provided 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 \$10.0 million of shares of our common stock over the 30-month term of the purchase agreement, subject to the terms and conditions set forth therein. 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. As part of the stock purchase agreement we issued 49,736 common shares as a commitment fee. The value of the common shares issued as a commitment fee of \$198,523 have been reflected as an addition to common stock of \$746 and \$197,777 in additional paid in capital which will be amortized over the life of the stock purchase agreement. As of the date of filing this Quarterly Report with the SEC no shares of stock have been sold to Aspire Capital under the May 25, 2016 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 96,934 shares of common stock at the purchase price of \$17.25 per share and pre-funded warrants to purchase 240,733 shares of common stock (the “Pre-Funded Warrants”) at a purchase price of \$17.10 per share for net proceeds of \$5.2 million after deducting \$577,790 of offering expenses (the “2015 Offering”). Each Pre-Funded Warrant was exercisable for \$0.15 per share and all of these warrants had been exercised as of December 31, 2015.

#### 2016 Public Offering of Common Stock

In August 2016, the Company completed an underwritten public offering of 1,150,000 shares of Common Stock at a price per share of \$2.50, with gross proceeds of \$2,875,000 to the Company, or proceeds of \$2,645,000 after deducting underwriter discounts, commissions, non accountable expense allowance and expense reimbursement.

**Outstanding Warrants**

As of September 30, 2016, warrants to purchase 402,228 shares of common stock were outstanding including:

	Outstanding Warrants to Purchase Shares	Exercise Price	Expiration Date
2011 private placement	283,470	\$ 18.75 - 24.00	May 18, 2018
Acueity warrants	21,667	75.00	September 30, 2017
2014 public offering	77,790	45.00	January 29, 2019
Placement agent fees for Company's offerings	16,135	31.80 – 186.45	March - November, 2018
Outside consulting	3,166	\$ 63.60	January 14, 2018
	402,228		

**NOTE 10: NET LOSS PER SHARE**

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

The following table sets forth the number of potential common shares excluded from the calculation of net loss per diluted share for the three months and nine months ended September 30, 2016 and 2015 because the effect of them would be anti-dilutive:

Three Months Ended September 30,	Nine Months Ended September 30,
-------------------------------------	------------------------------------

	2016	2015	2016	2015
Options to purchase common stock	414,177	287,494	414,177	287,494
Warrants to purchase common stock	402,228	642,962	402,228	642,962
Total	816,405	930,456	816,405	930,456

**NOTE 11: INCOME TAXES**

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

As a result of the Company's cumulative losses, management has concluded that a full valuation allowance against the Company's net deferred tax assets is appropriate. No income tax liabilities existed as of September 30, 2016 and December 31, 2015 due to the Company's continuing operating losses.

**NOTE 12: CONCENTRATION OF CREDIT RISK**

Financial instruments that potentially subject the Company to concentration of credit risk consist principally of cash deposits. Accounts at each institution are insured by the Federal Deposit Insurance Corporation ("FDIC") up to \$250,000. At September 30, 2016 and December 31, 2015, the Company had \$4,138,177 and \$3,465,895 in excess of the FDIC insured limit, respectively.

## NOTE 13: COMMITMENTS AND CONTINGENCIES

### Lease Commitments

The future minimum lease payments due subsequent to September 30, 2016 under all non-cancelable operating and capital leases for the next five years are as follows:

Year Ending December 31,	Operating Leases Amount
2016 (remainder of year)	\$87,812
2017	23,470
Total minimum lease payments	\$ 111,282

The total rent expense for the three months ended September 30, 2016 and 2015 was \$87,315 and \$154,291, respectively and \$238,565 and \$469,748 for the nine months ended September 30, 2016 and 2015, respectively. Rent expense was included in general and administrative expenses for both years.

### Purchase Commitments

Effective May 19, 2016 the Company entered into a services agreement with KriSan Biotech Co. Ltd., a corporation organized under the laws of Taiwan, Republic of China (“KSB”). The agreement directs KSB to research and develop for the Company processes for manufacturing endoxifen and to produce an initial supply of endoxifen so that release and stability studies may be conducted. The Company has agreed to pay \$136,000 to KSB when certain benchmarks have been delivered by KSB under the services 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 November 2012 initial public offering. The complaint alleges that all defendants violated Sections 11 and 12(a)(2), and that the Company and



certain of its directors and officers violated Section 15, of the Securities Act by making material false and misleading statements and omissions in the offering's registration statement, and that we and certain of our directors and officers violated Sections 10(b) and 20A of the Exchange Act and SEC Rule 10b-5 promulgated thereunder by making false and misleading statements and omissions in the registration statement and in certain of our subsequent press releases and SEC filings with respect to our NAF specimen collection process, our ForeCYTE Breast Health Test and our MASCT device. This action seeks, on behalf of persons who purchased our common stock between November 8, 2012 and October 4, 2013, inclusive, damages of an unspecified amount.

On February 14, 2014, the Court appointed plaintiffs Miko Levi, Bandar Almosa and Gregory Harrison (collectively, the "Levi Group") as lead plaintiffs, and approved their selection of co-lead counsel and liaison counsel. The Court also amended the caption of the case to read In re Atossa Genetics, Inc. Securities Litigation. No. 2:13-cv-01836-RSM. An amended complaint was filed on April 15, 2014. The Company and other defendants filed motions to dismiss the amended complaint on May 30, 2014. The plaintiffs filed briefs in opposition to these motions on July 11, 2014. The Company replied to the opposition brief on August 11, 2014. On October 6, 2014 the Court granted defendants' motion dismissing all claims against Atossa and all other defendants. The Court's order provided plaintiffs with a deadline of October 26, 2014 to file a motion for leave to amend their complaint and the plaintiffs did not file such a motion by that date. On October 30, 2014, the Court entered a final order of dismissal. On November 3, 2014, plaintiffs filed a notice of appeal with the Court and have appealed the Court's dismissal order to the U.S. Court of Appeals for the Ninth Circuit. On February 11, 2015, plaintiffs filed their opening appellate brief. Defendants' filed their answering brief on April 13, 2015, and plaintiffs filed their reply brief on May 18, 2015. A hearing for the appeal has not been set.

The Company believes this lawsuit is without merit and plans to defend itself vigorously; however, failure by the Company to obtain a favorable resolution of the claims set forth in the complaint could have a material adverse effect on the Company's business, results of operations and financial condition. Currently, the amount of such material adverse effect cannot be reasonably estimated, and no provision or liability has been recorded for these claims as of September 30, 2016. 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.

On January 28, 2016, the Company filed a complaint in the United States District Court for the District of Delaware captioned *Atossa Genetics Inc. v. Besins Healthcare Luxembourg SARL*, Case No. 1:16-cv-00045-UNA. The complaint asserts claims for breach of contract, breach of the implied covenant of good faith and fair dealing, and for declaratory relief against Defendant Besins Healthcare Luxembourg SARL ("Besins"). The complaint was served upon Besins on February 15, 2016. The Company's claims arise from Besins' breach of an Intellectual Property License Agreement dated May 14, 2015 (the "License Agreement"), under which Besins licensed to the Company the worldwide exclusive rights to develop and commercialize Afimoxifene Topical Gel, or AfTG, for the potential treatment and prevention of hyperplasia of the breast. The complaint seeks compensatory damages, a declaration of the parties' rights and obligations under the License Agreement, and injunctive relief. On March 7, 2016, Besins filed its response to the Company's complaint, generally denying liability for the Company's claims and asserting counterclaims for breach of contract, fraud, negligent misrepresentation, and declaratory judgment. Besins seeks unspecified money damages and preliminary and permanent injunctive relief, among other forms of relief, for its counterclaims. The Company filed its answer to Besins' counterclaims on March 31, 2016, in which the Company disputed Besins' allegations and denied that Besins is entitled to relief on its counterclaims. On August 4, 2016, the parties entered into a settlement agreement pursuant to which the parties dismissed this legal action and have settled all claims and counterclaims. Pursuant to the settlement agreement, Besins assumed, and Atossa shall have no further rights to, 4-hydroxy tamoxifen and AfTG in return for a termination payment to Atossa in the total amount of \$1,762,931. The termination payment was received in August 2016 and has been included in other income on the Condensed Consolidated Statement of Operations for both the three and nine months ended September 30, 2016.

#### **NOTE 14: STOCK BASED COMPENSATION**

##### ***Stock Options and Incentive Plan***

On September 28, 2010, the Board of Directors approved the adoption of the 2010 Stock Option and Incentive Plan, or the 2010 Plan, to provide for the grant of equity-based awards to employees, officers, non-employee directors and other key persons providing services to the Company. Awards of incentive options may be granted under the 2010 Plan until September 2020. No other awards may be granted under the 2010 Plan after the date that is 10 years from the date of stockholder approval. An aggregate of 66,667 shares were initially reserved for issuance in connection with awards granted under the 2010 Plan and on May 18, 2016, an additional 133,333 shares were reserved for issuance

under the 2010 Plan.

The following table presents the automatic additions to the 2010 Plan since inception pursuant to the “evergreen” terms of the 2010 Plan:

January 1,	Number of shares
2012	30,018
2013	34,452
2014	49,532
2015	65,557
2016	220,419
Total additional shares	399,978

The Company granted 0 and 185,245 additional options to purchase shares of common stock to employees and directors during the three and nine months ended September 30, 2016. No options were exercised during the three and nine months ended September 30, 2016. There are 140,888 shares available for grant under the 2010 Plan as of September 30, 2016.

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 \$257,389 and \$317,986 for the three months ended September 30, 2016 and 2015, respectively and \$650,053 and \$703,726 (\$633,962 from continuing operations and \$69,764 from discontinued operations) for the nine months ended September 30, 2016 and 2015, respectively.

Options issued and outstanding as of September 30, 2016 and their activities during the nine months then ended are as follows:

	<b>Number of Underlying Shares</b>	<b>Weighted- Average Exercise Price Per Share</b>	<b>Weighted- Average Contractual Life Remaining in Years</b>	<b>Aggregate Intrinsic Value</b>
Outstanding as of January 1, 2016	240,930	\$ 38.89		\$ -
Granted	185,245	3.95		-
Forfeited	(35,751)	28.90		-
Outstanding as of September 30, 2016	390,424	25.81	7.36	\$ 6,451,077
Exercisable as of September 30, 2016	242,356	41.1	5.54	\$ -
Vested and expected to vest <sup>(1)</sup>	414,177	\$ 28.95	7.02	\$ -

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

At September 30, 2016, there were 237,192 unvested options outstanding and the related unrecognized total compensation cost associated with these options was approximately \$1.2 million. This expense is expected to be recognized over a weighted-average period of 2.09 years.

## NOTE 15: RELATED PARTY TRANSACTIONS

Shu-Chih Chen, Ph.D., a member of the Board of Directors and spouse of Steve C. Quay, Ph.D., M.D., the Company's CEO, has provided consultancy services to the Company. Those services primarily include providing scientific and technical expertise in Atossa's negotiations and ongoing arrangements with the manufacturer of endoxifen which is located in Taiwan. The cost of the services provided by Dr. Chen are approximately \$25,000 through September 30, 2016 and have been approved by Atossa's audit committee.

## 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 can obtain approval from the U.S. Food and Drug Administration, or FDA, and foreign regulatory bodies, to sell, market and distribute our therapeutics and devices under development;

- our ability to successfully complete clinical trials of our pharmaceutical candidates under development, including endoxifen and our intraductal microcatheters to administer therapeutics, including the study we recently opened using fulvestrant;

- the success, cost and timing of our product and drug development activities and clinical trials, including whether the ongoing clinical study using our intraductal microcatheters to administer fulvestrant will enroll or be completed in a timely fashion or at all;

- our ability to contract with third-party suppliers, manufacturers and service providers, including clinical research organizations, and their ability to perform adequately;

· our ability to successfully develop and commercialize new therapeutics currently in development or that we might identify in the future and in the time frames currently expected;

· 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;

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

· 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 capital sources;

· our ability to attract and retain key personnel; and

· our ability to raise capital, including our ability to sell shares of common stock to Aspire Capital under the terms of the May 25, 2016 common stock purchase agreement with Aspire Capital.

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 clinical-stage pharmaceutical company focused on the development of novel therapeutics and delivery methods for the treatment of breast cancer and other breast conditions. Our leading program uses our patented intraductal microcatheters which deliver pharmaceuticals through the breast ducts. We initiated a Phase 2 clinical study in March 2016 using our microcatheters to deliver fulvestrant as a potential treatment of ductal carcinoma in-situ, or DCIS, and breast cancer. This study is being conducted by Columbia University Medical Center Breast Cancer Programs. Our second pharmaceutical program under development is oral endoxifen for breast cancer patients who are refractory to tamoxifen. Endoxifen is an active metabolite of tamoxifen which is an FDA approved drug for breast cancer patients to prevent recurrence as well as new breast cancer. In May 2015 we began the development of Afimoxifene Topical Gel, or AfTG, for the treatment and prevention of hyperplasia of the breast; however, that program has been transferred back to the licensor, Besins Healthcare, in return for a payment to us of \$1.7 million.

Through mid-2015, we were primarily focused on the development and commercialization of our medical devices and laboratory tests. Our medical devices include the ForeCYTE Breast Aspirator and the FullCYTE Breast Aspirator. These devices are intended for the collection of nipple aspirate fluid, or NAF, for cytological testing at a laboratory. Our laboratory tests have historically been developed and performed by The National Reference Laboratory for Breast Health, Inc., or the “NRLBH.” The NRLBH was our wholly-owned subsidiary until December 16, 2015 when, pursuant to a stock purchase agreement, we sold approximately 81% of the capital stock of the NRLBH to the NRL Investment Group, LLC. We have determined that the disposition of the lab business qualifies for reporting as a discontinued operation since the sale represents a strategic shift that will have a major effect on our operations and financial results. We have elected to recognize any subsequent gain from the earn-out payments payable to us pursuant to the stock purchase agreement as they are determined realizable.

We are now focusing our business on our pharmaceutical programs and delivery methods. Our key objectives are to advance our pharmaceutical candidates through Phase 2 trials and then evaluate further development independently or through partners.

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

## **Summary of Our Clinical-Stage Programs Under Development**

### ***Delivery of Therapeutics via our Microcatheters***

We believe our patented intraductal microcatheters may be useful in delivering a number of therapeutics to the ducts in the breast. Doing so is intended to provide a therapeutic directly to the breast tissue. We must obtain FDA approval of any drug delivered via our intraductal microcatheters devices which will require expensive and time-consuming studies. For example, we must complete clinical studies to demonstrate the safety and tolerability of fulvestrant using our delivery method. We may not be successful in completing these studies and obtaining FDA approval.



The initial drug we are studying using our microcatheters for intraductal delivery is fulvestrant. Fulvestrant is FDA-approved for metastatic breast cancer. It is administered as a monthly injection of two shots, typically into the buttocks. In 2012 a published study documented that the single dose cost of intramuscular fulvestrant was approximately \$12,000.

We own one issued patent and several pending applications directed to the treatment of breast conditions, including cancer, by the intraductal administration of therapeutics including fulvestrant.

We do not yet have FDA's input, but our preliminary analysis, subject to FDA feedback, is that the intraductal fulvestrant program could qualify for designation under the 505(b)(2) status. This would allow us to file with only clinical data and without having to perform additional, significant clinical or pre-clinical studies. So the path to market is both faster and less expensive than a standard new drug application, or NDA, program.

To support this development program, we have successfully produced microcatheters for the fulvestrant Phase 2 clinical trial. The FDA has also issued a "Safe to Proceed" letter for our first Investigational New Drug application (IND) for the Phase 2 study and the institutional review board approval has also been received.

In March 2016, we opened enrollment in the study ATOS-2015-007, which is being conducted by The Columbia University Medical Center Breast Cancer Program. This is an 18 month Phase 2 study in women with DCIS or invasive breast cancer slated for mastectomy or lumpectomy. This study will assess the safety, tolerability and distribution of fulvestrant when delivered directly into breast milk ducts of these patients compared to those who receive the same product intramuscularly. Six study participants will receive the standard intramuscular fulvestrant dose of 500 mg to establish the reference drug distribution, and 24 participants will receive fulvestrant by intraductal instillation utilizing our microcatheter device. The total dose administered via our microcatheters will not exceed 500 mg.

The study has been accepted for presentation at the CTRC-AARC San Antonio Breast Cancer Symposium to be held December 6-10, 2016. This prestigious symposium is "designed to provide state-of-the-art information on the experimental biology, etiology, prevention, diagnosis, and therapy of breast cancer and premalignant breast disease, to an international audience of academic and private physicians and researchers." The study has been accepted in the "Ongoing Clinical Trials" category, which features studies that have not been completed and which does not permit the presentation of study results.

The primary endpoint of the clinical trial is to assess the safety, tolerability and distribution of intraductally administered fulvestrant in women with DCIS or Stage 1 or 2 invasive ductal carcinoma prior to mastectomy or

lumpectomy. The secondary objective of the study is to determine if there are changes in the expression of Ki67 as well as estrogen and progesterone receptors between a pre-fulvestrant biopsy and post-fulvestrant surgical specimen. Digital breast imaging before and after drug administration in both groups will also be performed to determine the effect of fulvestrant on any lesions as well as breast density of the participant. Additional information about the study can be found at: <https://clinicaltrials.gov/ct2/show/NCT02540330?term=atossa&rank=2>.

### ***Oral Endoxifen***

Our second pharmaceutical program under development is oral endoxifen for breast cancer patients who are refractory to tamoxifen. Endoxifen is an active metabolite of tamoxifen which is an FDA approved drug for breast cancer patients to prevent recurrence as well as new breast cancer. We believe that up to 50% of the one million women who take tamoxifen in the United States each year are refractory, meaning that they have inadequate endoxifen levels (for any number of reasons included low levels of a liver enzyme) and they have an increased risk for breast cancer recurrence.

We have filed patent applications covering endoxifen and we are in the process of procuring an initial supply of the endoxifen drug for initial studies.

### ***Afimoxifene Topical Gel (AfTG)***

On May 14, 2015, we were granted the worldwide exclusive rights to develop and commercialize AfTG for the potential treatment and prevention of hyperplasia of the breast. The active pharmaceutical ingredient in AfTG is Afimoxifene (4-hydroxytamoxifen), which is an active metabolite of tamoxifen.

These AfTG rights were granted to us pursuant to a May 14, 2015, Intellectual Property License Agreement with Besins Healthcare Luxembourg SARL (the "License Agreement").

Besins has informed us that they plan to develop AfTG for the reduction of breast density, which we believe is within the scope of our exclusive rights under the License Agreement. We have informed Besins that its efforts to develop AfTG for breast density would infringe our exclusive rights under the License Agreement, including our exclusive rights to develop AfTG for treatment and prevention of hyperplasia of the breast, and would constitute a breach of the License Agreement by Besins.

On January 28, 2016, we filed a complaint in the United States District Court for the District of Delaware captioned *Atossa Genetics Inc. v. Besins Healthcare Luxembourg SARL* Case No. 1:16-cv-00045-UNA (the “Litigation”). The complaint asserts claims for breach of contract, breach of the implied covenant of good faith and fair dealing, and for declaratory relief against Besins. On March 7, 2016, Besins responded to our complaint by denying our claims and asserting counterclaims against us for breach of contract, fraud, and negligent misrepresentation and declaratory relief. We filed our answer to Besins’ counterclaims on March 31, 2016, in which the Company disputed Besins’ allegations and denied that Besins is entitled to relief on its counterclaims. On August 4, 2016, we and Besins agreed, pursuant to a Termination Agreement, to terminate the License Agreement, dismiss the Litigation, and settle all claims and counterclaims asserted in the Litigation. We and Besins have further agreed, pursuant to and as set forth in the Termination Agreement, that Besins will assume, and we shall have no further rights to, all clinical, regulatory, manufacturing, and all other development and commercialization of 4-hydroxy tamoxifen and Afimoxifene Topical Gel (the “AfTG Program”). In consideration for our comprehensive relinquishment of all rights granted in the License Agreement, termination of the License Agreement, cessation of all efforts to develop Afimoxifene Gel, delivery of all API manufactured to date, assignment of a Drug Master File, delivery to Besins of the work product we have completed to date, and other consideration, Besins reimbursed us for out-of-pocket expenses incurred by us to pursue the AfTG Program and made a termination payment to us in the total amount of \$1,762,931.

## **Our Pre-Clinical Programs Under Development**

In addition to our clinical-stage pharmaceutical programs, we are in the process of evaluating other therapeutic candidates to treat breast conditions, including breast cancer. Factors we are considering in evaluating potential drug candidates include, for example, the ability to obtain expedited regulatory approval, significance of unmet medical need, size of the patient population, intellectual property opportunities and the anticipated pre-clinical and clinical pathway.

## **NRLBH and our Laboratory Tests**

Through December 16, 2015, our laboratory tests consisted of NAF cytology tests, pharmacogenomics tests and various tests under development including our NextCYTE Breast Cancer Test. These tests were developed by the NRLBH, and in the case of the NAF cytology and pharmacogenomics tests, were also marketed and sold by the NRLBH. The NRLBH generally owned the equipment and supplies necessary to develop the tests and to perform the

tests and generally contracted directly with third parties for necessary supplies and services to develop and conduct the tests.

### **Our Medical Devices**

Our medical devices include the ForeCYTE Breast Aspirator and the FullCYTE Breast Aspirator, which collect specimens of nipple aspirate fluid (NAF) for cytological testing at a laboratory, and a universal transport kit to assist with the packaging and transport of NAF samples to a laboratory. We also own the exclusive rights to manufacture and sell various medical devices (although we do not currently maintain an inventory of our devices) consisting primarily of tools to assist breast surgeons, which we acquired from Acueity Healthcare in 2012. We are not currently commercializing our breast aspirator devices, transportation kits, tools for breast surgeons nor any NAF cytology tests.

Our patented intraductal microcatheter devices are being developed for the targeted delivery of potential pharmaceuticals, as described above.

## Revenue Sources

Our business has provided us with two historical 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 and pharmacogenomics tests. Our main source of revenue from October 2014 to December 2015 was from pharmacogenomics testing. We are no longer selling our medical devices and because of the sale of 81% of the stock in the NRLBH, we will generate no revenue from laboratory testing. NRLBH's operations are presented as discontinued operations in our condensed consolidated financial statements. We do not anticipate generating additional revenue from other resources unless and until we develop and launch new pharmaceutical programs.

## Critical Accounting Policies and Estimates

In our Annual Report on Form 10-K for the year ended December 31, 2015, 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, 2015. Readers are encouraged to review these disclosures in conjunction with the review of this report.

## Results of Operations

### Three Months and Nine Months Ended September 30, 2016 and 2015

*Revenue and Cost of Revenue:* As a result of the sale of the NRLBH in December 2015, we generated no revenue or cost of revenue for the three months and nine months ended September 30, 2016. Revenue and cost of revenue from NRLBH activities are presented as discontinued operations for the three months and nine months ended September 30, 2015. The NRLBH had total net revenue of \$772,591 and cost of revenue of \$311,074, for the three months ended September 30, 2015, and \$5,337,911 and \$3,365,901 for the nine months ended September 30, 2015, respectively, consisting of mainly pharmacogenomics testing.

*Operating Expenses:* Total operating expenses were approximately \$1.6 million and \$5.4 million for the three months and nine months ended September 30, 2016, respectively, consisting of general and administrative (G&A) expenses of approximately \$1.5 million and \$5.0 million, respectively and R&D expenses of approximately \$85,000 and \$404,000

respectively. As a result of the sale of NRLBH, operating expenses related to the NRLBH are presented separately as discontinued operations for the three months and nine months ended September 30, 2015.

Operating expenses from continuing operations for the three months and nine months ended September 30, 2016 decreased approximately \$2.2 million and \$4.9 million, or 59.4% and 47.1% respectively, from approximately \$3.8 million and \$10.3 million for the three months and nine months ended September 30, 2015, respectively, which consisted of G&A expenses of approximately \$2.4 million and \$7.2 million, respectively, R&D expenses of approximately \$949,000 and \$1.9 million, respectively, and selling expenses of approximately \$499,000 and \$1.2 million, respectively. The decrease in operating expenses is mainly attributed to the 2015 launch of new devices and services which are not being pursued in 2016 and investing more in new R&D programs in the first quarter of 2015 compared to 2016.

*Selling Expenses:* As a result of the sale of NRLBH and discontinuing commercialization of our devices in Europe and the United States, we incurred no selling expenses for the three and nine months ended September 30, 2016. Selling expenses, for the three months and nine months ended September 30, 2015 were approximately \$499,000 and \$1.2 million, respectively, consisting of compensation expenses, travel, and advertisement as a result of ForeCYTE and FullCYTE launch and commercialization in Europe and the United States. We do not expect any significant selling expenses during 2016, as we continue focusing on developing our pharmaceutical programs and until we receive regulatory clearance to commercialize our new products.

*General and Administrative Expenses:* G&A expenses for continuing operations for the three months and nine months ended September 30, 2016 were approximately \$1.5 million and \$5.0 million, respectively, a decrease of approximately \$922,000 and \$2.2 million, respectively, or 38.5% and 30.6% respectively, from approximately \$2.4 million and \$7.2 million, respectively, for the same periods in 2015. G&A expenses consist primarily of personnel and related benefit costs, facilities, professional services, insurance, and public company related expenses. The decrease in G&A expenses is mainly attributed to cost reductions from sale of the NRLBH and discontinuing the commercialization of our breast aspirators.

*Research and Development Expenses:* R&D expenses for the three months and nine months ended September 30, 2016 were approximately \$85,000 and \$404,000 respectively, a decrease of approximately \$864,000 and \$1.5 million respectively, or 91.0% and 78.6% respectively, from the three months and nine months ended September 30, 2015. The decrease in R&D expenses is attributed to discontinuing further development of the FullCYTE Microcatheters, FullCYTE Breast Aspirator, NextCYTE test and AftG late in 2015 and early in 2016. During the first quarter of 2016, we focused all our R&D efforts on the fulvestrant clinical trial that commenced in March 2016 and in the second and third quarter of 2016 we focused our R&D efforts on initiating our oral endoxifen program. We expect our R&D expenses to increase throughout 2016 and into 2017 as we continue the clinical trial of fulvestrant administered via our microcatheters and as we continue the development of endoxifen and potentially other indications and pharmaceuticals.

*Discontinued operations:* As a result of the sale of NRLBH in December 2015, the 2015 financial results of the NRLBH are presented separately as discontinued operations in the Company's Consolidated Statements of Operations for all periods presented. The following summarizes the loss from discontinued operations for the three and nine months ended September 30, 2015:

	Three Months Ended September 30, 2015	Nine Months Ended September 30, 2015
Revenue	\$ 772,591	\$ 5,337,911
Cost of revenue	(311,074)	(3,365,901)
Gross profit	461,517	1,972,010
Expenses:		
Selling expenses	239,427	829,174
Research and development expenses	141,388	509,796
General and administrative expenses	625,499	1,213,795
Other expenses, net	5	49,559
Net loss from discontinued operations	\$ (544,802)	\$ (630,314)

## Liquidity and Capital Resources

We have a history of operating losses as we have focused our efforts on raising capital and building our products and services in our pipeline. 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, 2016, the Company recorded a net loss of \$3.8 million, and used \$4.0 million of cash in operating activities. As of September 30, 2016, the Company had approximately \$4.4 million in cash and cash equivalents and working capital of approximately \$3.7 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 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.



During the first quarter of 2016, we sold 405,747 shares of common stock to Aspire Capital under the November 2015 agreement with them for aggregate gross proceeds to us of \$2,153,583. On May 25, 2016 we entered into a new common stock purchase agreement with Aspire Capital which provides that we may sell up to \$10 million in common stock to Aspire Capital over the 30 month term of the agreement, subject to the terms and conditions set out in the stock purchase agreement, none of which have been sold as of the date of filing this Quarterly Report with the SEC. On August 4, 2016, we entered into a settlement agreement with Besins Healthcare pursuant to which Besins paid us a total of \$1.76 million. See Part II, Item 1 Legal Proceedings. In August 2016, we completed an underwritten public offering of 1,150,000 shares of Common Stock at a price per share of \$2.50, with gross proceeds to us of \$2,875,000, or proceeds of \$2,645,000 after deducting underwriter discounts, commissions, non accountable expense allowance and expense reimbursement.

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

## Cash Flows

As of September 30, 2016, we had cash and cash equivalents of \$4.4 million.

*Net Cash Flows from Operating Activities:* Net cash used in operating activities was approximately \$4.0 million, for the nine months ended September 30, 2016, compared with approximately \$10.0 million, including \$272,000 cash provided by discontinued operations, for the nine months ended September 30, 2015. We spent approximately \$2.0 million in research and development for the nine months ended, September 30, 2015, compared to approximately \$400,000 for the same period in 2016, the decrease in the 2016 period as compared to 2015 resulting primarily from reductions in compensation, occupancy expenses, and outside consulting; offset by severance payments in 2016.

*Net Cash Flows from Investing Activities:* Net cash used in investing activities was approximately \$5,000 for the nine months ended September 30, 2016, compared with approximately \$111,000, including \$44,000 from discontinued operations for the nine months ended September 30, 2015. The decrease in 2016 for both periods was primarily attributable to the reduction in purchases of fixed asset equipment in 2016 as compared to 2015.

*Net Cash Flows from Financing Activities:* Net cash provided by financing activities was approximately \$4.7 million for the nine months ended September 30, 2016, compared with approximately \$9.5 million for the nine months ended September 30, 2015. The decrease is mainly attributed to lower prices at which we were able to sell our stock to Aspire in 2016 and in our public offering in August 2016, compared to prices of our stock and warrants in financing

activities 2015.

## **Funding Requirements**

We expect to incur ongoing operating losses for the foreseeable future as we continue to develop our planned therapeutic programs including related clinical studies and other programs in the pipeline. We expect that our existing resources will be sufficient to fund our planned operations for at least the next six to nine months. In addition to our cash and cash equivalents at September 30, 2016 of approximately \$4.4 million, we will be 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 the time and expenses needed to begin and continue clinical trials for our new drug developments.

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

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

## Off-Balance Sheet Arrangements

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

## Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (the “FASB”) issued Accounting Standards Update (“ASU”) No. 2014-09, *Revenue from Contracts with Customers: Topic 606* (“ASU 2014-09”), to supersede nearly all existing revenue recognition guidance under U.S. GAAP. The core principle of ASU 2014-09 is to recognize revenues when promised goods or services are transferred to customers in an amount that reflects the consideration that is expected to be received for those goods or services. ASU 2014-09 defines a five step process to achieve this core principle and, in doing so, it is possible more judgment and estimates may be required within the revenue recognition process than required under existing GAAP including identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation. ASU 2014-09 is effective for the Company in the first quarter of 2018 using either of two methods: (i) retrospective to each prior reporting period presented with the option to elect certain practical expedients as defined within ASU 2014-09; or (ii) retrospective with the cumulative effect of initially applying ASU 2014-09 recognized at the date of initial application and providing certain additional disclosures as defined per ASU 2014-09. We are currently evaluating the impact of its pending adoption of ASU 2014-09 on 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 the management to determine whether substantial doubt exists regarding the entity’s going concern presumption, which generally refers to an entity’s ability to meet its obligations as they become due. If substantial doubt exists but is not alleviated by management’s plan, the footnotes must specifically state that “there is substantial doubt about the entity’s ability to continue as a going concern within one year after the financial statements are issued.” In addition, if substantial doubt exists, regardless of whether such doubt was alleviated, entities must disclose (a) principal conditions or events that raise substantial doubt about the entity’s ability to continue as a going concern (before consideration of management’s plans, if any); (b) management’s evaluation of the significance of those conditions or events in relation to the entity’s ability to meet its obligations; and (c) management’s plans that are intended to mitigate the conditions or events that raise substantial doubt, or that did alleviate substantial doubt, about the entity’s ability to continue as a going concern. If substantial doubt has not been alleviated, these disclosures should become more extensive in subsequent reporting periods as additional information becomes available. In the period that substantial doubt no longer exists (before or after considering management’s plans), management should disclose how the principal conditions and events that originally gave rise to substantial doubt have been resolved. The ASU applies prospectively to all entities for annual periods ending after December 15, 2016, and to annual and interim

periods thereafter. Early adoption is permitted. We have not yet adopted the provisions of ASU 2014-15.

In February 2016, FASB issued ASU No. 2016-02, *Lease Accounting Topic 842*. This ASU requires a lessee to recognize lease assets and liabilities on the balance sheet for all arrangements with terms longer than 12 months, the new standard applies a right-of-use (ROU) model that requires a lessee to record, for all leases with a lease term of more than 12 months, an asset representing its right to use the underlying asset for the lease term and a liability to make lease payments. The lease term is the non-cancellable period of the lease, and includes both periods covered by an option to extend the lease, if the lessee is reasonably certain to exercise that option, and periods covered by an option to terminate the lease, if the lessee is reasonably certain not to exercise that termination option. For leases with a lease term of 12 months or less, a practical expedient is available whereby a lessee may elect, by class of underlying asset, not to recognize an ROU asset or lease liability. A lessee making this accounting policy election would recognize lease expense over the term of the lease, generally in a straight-line pattern. The Lessor accounting remains largely consistent with existing U.S. GAAP. The new standard takes effect in 2019 for public business entities and 2020 for all other entities. We have not adopted the provisions of ASU No. 2016-02. We are currently evaluating the impact of our pending adoption of ASU 2016-02 on our consolidated financial statements.

In April 2016, the FASB issued ASU No. 2016-09, *Stock Compensation Topic 718*. This ASU simplifies the accounting for stock compensation on income tax accounting, award classification, estimating forfeitures, and cash flow presentation. Based on this ASU, an entity should recognize all excess tax benefits and tax deficiencies, including tax benefits of dividends on share-based payment awards, as income tax expense or benefit in the income statement; they do not need to include the effects of windfalls and shortfalls in the annual effective tax rate estimate from continuing operations used for interim reporting purposes. As a result of including income tax effects from windfalls and shortfalls in income tax expense, the calculation of both basic and diluted EPS will be affected. The ASU also provides an accounting policy election for awards with service conditions to either estimate the number of awards that are expected to vest (consistent with existing U.S. GAAP) or account for forfeitures when they occur. The ASU increases the allowable statutory tax withholding threshold to qualify for equity classification from the minimum statutory withholding requirements up to the maximum statutory tax rate in the applicable jurisdiction(s). The ASU clarifies that cash paid to a taxing authority by an employer when directly withholding equivalent shares for tax withholding purposes should be considered similar to a share repurchase, and thus classified as a financing activity. All other employer withholding taxes on compensation transactions and other events that enter into the determination of net income continue to be presented within operating activities. The new standard takes effect in 2017 for public business entities and 2018 for all other entities. We have not adopted the provisions of ASU No. 2016-09. We are currently evaluating the impact of our pending adoption of ASU 2016-09 on our consolidated financial statements.

### **ITEM 3. QUANTITATIVE 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, 2016. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (“Exchange Act”), means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the Securities and Exchange Commission’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of September 30, 2016, 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, 2016 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

## **PART II OTHER INFORMATION**

### **ITEM 1. LEGAL PROCEEDINGS**

On October 10, 2013, a putative securities class action complaint, captioned Cook v. Atossa Genetics, Inc., et al., No. 2:13-cv-01836-RSM, was filed in the United States District Court for the Western District of Washington against us, certain of our directors and officers and the underwriters of our November 2012 initial public offering. The complaint

alleges that all defendants violated Sections 11 and 12(a)(2), and that we and certain of our directors and officers violated Section 15, of the Securities Act by making material false and misleading statements and omissions in the offering's registration statement, and that we and certain of our directors and officers violated Sections 10(b) and 20A of the Exchange Act and SEC Rule 10b-5 promulgated thereunder by making false and misleading statements and omissions in the registration statement and in certain of our subsequent press releases and SEC filings with respect to our NAF specimen collection process, our ForeCYTE Breast Health Test and our MASCT device. This action seeks, on behalf of persons who purchased our common stock between November 8, 2012 and October 4, 2013, inclusive, damages of an unspecified amount.

On February 14, 2014, the Court appointed plaintiffs Miko Levi, Bandar Almosa and Gregory Harrison (collectively, the "Levi Group") as lead plaintiffs, and approved their selection of co-lead counsel and liaison counsel. The Court also amended the caption of the case to read In re Atossa Genetics, Inc. Securities Litigation. No. 2:13-cv-01836-RSM. An amended complaint was filed on April 15, 2014. The Company and other defendants filed motions to dismiss the amended complaint on May 30, 2014. On October 6, 2014 the Court granted defendants' motion dismissing all claims against Atossa and all other defendants. On October 30, 2014, the Court entered a final order of dismissal. On November 3, 2014, plaintiffs filed a notice of appeal with the Court and have appealed the Court's dismissal order to the U.S. Court of Appeals for the Ninth Circuit. On February 11, 2015, plaintiffs filed their opening appellate brief. Defendants filed an answering brief on April 13, 2015 and plaintiffs filed a reply brief in support of their appeal on May 18, 2015. A hearing for the appeal has not been set.

We believe this complaint is without merit and plan to defend ourselves vigorously; however failure to obtain a favorable resolution of the claims set forth in the complaint could have a material adverse effect on our business, results of operations and financial condition. Currently, the amount of such material adverse effect cannot be reasonably estimated, and no provision or liability has been recorded for these claims as of September 30, 2016. The costs associated with defending and resolving the complaint and ultimate outcome cannot be predicted. These matters are subject to inherent uncertainties and the actual cost, as well as the distraction from the conduct of our business, will depend upon many unknown factors and management's view of these may change in the future.

On January 28, 2016, we filed a complaint in the United States District Court for the District of Delaware captioned *Atossa Genetics Inc. v. Besins Healthcare Luxembourg SARL*, Case No. 1:16-cv-00045-UNA (the "Litigation"). The complaint asserts claims for breach of contract, breach of the implied covenant of good faith and fair dealing, and for declaratory relief against Defendant Besins Healthcare Luxembourg SARL ("Besins"). The complaint was served upon Besins on February 15, 2016. Our claims arise from Besins' breach of an Intellectual Property License Agreement dated May 14, 2015 (the "License Agreement"), under which Besins licensed to us the worldwide exclusive rights to develop and commercialize Afimoxifene Topical Gel, or AfTG, for the potential treatment and prevention of hyperplasia of the breast. The complaint seeks compensatory damages, a declaration of the parties' rights and obligations under the License Agreement, and injunctive relief. On March 7, 2016, Besins filed its response to the Company's complaint, generally denying liability for the Company's claims and asserting counterclaims for breach of contract, fraud, negligent misrepresentation, and declaratory judgment.

On August 4, 2016, Atossa and Besins agreed, pursuant to a Termination Agreement, to terminate the License Agreement, dismiss the Litigation, and settle all claims and counterclaims asserted in the Litigation. Atossa and Besins have further agreed, pursuant to and as set forth in the Termination Agreement, that Besins will assume, and Atossa shall have no further rights to, all clinical, regulatory, manufacturing, and all other development and commercialization of 4-hydroxy tamoxifen and Afimoxifene Topical Gel (the "AfTG Program"). In consideration for Atossa's comprehensive relinquishment of all rights granted in the License Agreement, termination of the License Agreement, cessation of all efforts to develop Afimoxifene Gel, delivery of all API manufactured to date, assignment of a Drug Master File, delivery to Besins of the work product Atossa has completed to date, and other consideration, Besins reimbursed Atossa for out-of-pocket expenses incurred by Atossa to pursue the AfTG Program and made a termination payment in the total amount of \$1,762,931.

## **ITEM 1A. RISK FACTORS**

### **RISK FACTORS**

*A purchase of our shares of Common Stock is an investment in our securities and involves a high degree of risk. You should carefully consider the following information about these risks, together with the other information contained in*

*this report, before purchasing our securities. If any of the following risks actually occur, our business, financial condition and results of operations would likely suffer. In that case, the market price of the Common Stock could decline, and you may lose part or all of your investment in our company. Additional risks of which we are not presently aware or that we currently believe are immaterial may also harm our business and results of operations.*

There has been no material changes to the risk factors described in the Company's Annual Report on Form 10-K, as filed with the SEC on March 30, 2016.

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

Not applicable.



### ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

### ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

### ITEM 5. OTHER INFORMATION

### ITEM 6. EXHIBITS

(a) Exhibits

<b>Exhibit No.</b>	<b>Description</b>	<b>Incorporated by Reference Herein Form</b>	<b>Date</b>
4.1	Certificate of Amendment to Amended and Restated Certificate of Incorporation	Current Report on Form 8-K, as Exhibit 4.1	August 26, 2016
10.1	Settlement and Termination of License Agreement between Besins Healthcare Luxembourg SARL and its Affiliates and Atossa Genetics Inc. dated August 4, 2016	Current Report on Form 8-K, as Exhibit 10.1	August 5, 2016
10.2	Underwriting Agreement between Atossa Genetics Inc. and Aegis Capital Corp. as representative of the several underwriters, dated August 30, 2016	Current Report on Form 8-K, as Exhibit 10.1	September 2, 2016
10.3	2010 Stock Option and Incentive Plan, as amended	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		Filed herewith	

Edgar Filing: ATOSSA GENETICS INC - Form 10-Q

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

- 32.1 Certification pursuant to 18 U.S.C. Section 1350 of Steven C. Quay 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 14, 2016

/s/ Steven C. Quay  
President and Chief Executive Officer  
(On behalf of the Registrant)

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