

ATOSSA GENETICS INC  
Form 10-Q  
November 13, 2017

**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, 2017**

**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 13, 2017 was 26,522,741.

**ATOSSA GENETICS INC.**

**FORM 10-Q**

**QUARTERLY REPORT**

**INDEX**

<u>PART I. FINANCIAL INFORMATION</u>	3
<u>ITEM 1. Condensed Consolidated Financial Statements – Unaudited</u>	3
<u>Condensed Consolidated Balance Sheets as of September 30, 2017 and December 31, 2016</u>	3
<u>Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2017 and 2016</u>	4
<u>Condensed Consolidated Statement of Stockholders’ Equity for the nine months ended September 30, 2017</u>	5
<u>Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2017 and 2016</u>	6
<u>Notes to Consolidated Financial Statements</u>	7
<u>ITEM 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	22
<u>ITEM 3. Quantitative and Qualitative Disclosures about Market Risk</u>	29
<u>ITEM 4. Controls and Procedures</u>	29
<u>PART II. OTHER INFORMATION</u>	30
<u>ITEM 1. Legal Proceedings</u>	30
<u>ITEM 1A. Risk Factors</u>	30
<u>ITEM 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	31
<u>ITEM 3. Defaults upon Senior Securities</u>	32
<u>ITEM 4. Mine Safety Disclosures</u>	32

<u>ITEM 5. Other Information</u>	32
<u>ITEM 6. Exhibits</u>	32
<u>SIGNATURES</u>	33

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

	September 30, 2017	December 31, 2016
Assets		
Current assets		
Cash and cash equivalents	\$2,733,663	\$3,027,962
Restricted cash	55,000	55,000
Prepaid expenses	157,406	171,601
Other accounts receivable	4,040	
Total current assets	2,950,109	3,254,563
Furniture and equipment, net	14,435	55,119
Intangible assets, net	561,354	640,440
Other assets	108,723	194,250
Total assets	\$3,634,621	\$4,144,372
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	\$380,399	\$254,320
Accrued expenses	50,542	16,964
Payroll liabilities	627,587	769,899
Other current liabilities	13,295	6,083
Total current liabilities	1,071,823	1,047,266
Commitments and contingencies (note 13)		
Stockholders' equity		
Preferred stock - \$.001 par value; 10,000,000 shares authorized, no shares issued or outstanding		
Common stock - \$.015 par value; 75,000,000 shares authorized, 14,022,741 and 3,786,913 shares issued and outstanding, as of September 30, 2017 and December 31, 2016, respectively	210,341	56,804

Edgar Filing: ATOSSA GENETICS INC - Form 10-Q

Additional paid-in capital	65,785,758	60,344,050
Accumulated deficit	(63,433,301)	(57,303,748)
Total stockholders' equity	2,562,798	3,097,106
Total liabilities and stockholders' equity	\$3,634,621	\$4,144,372

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

## ATOSSA GENETICS INC.

## CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(UNAUDITED)

	For the Three Months Ended September 30,		For The Nine Months Ended September 30,	
	2017	2016	2017	2016
Operating expenses:				
Research and development	\$742,450	\$85,000	\$2,110,846	\$403,963
General and administrative	1,313,477	1,473,435	3,528,189	5,040,939
Total operating expenses	2,055,927	1,558,435	5,639,035	5,444,902
Operating loss	(2,055,927 )	(1,558,435 )	(5,639,035 )	(5,444,902 )
Change in fair value of common stock warrants	(128,300 )		(280,747 )	
Warrant financing expense			(192,817 )	
Other income (expense), net	(283 )	1,763,124	(16,954 )	1,599,667
Income (loss) before income taxes	(2,184,510 )	204,689	(6,129,553 )	(3,845,235 )
Income taxes				
Net income (loss)	\$(2,184,510 )	\$204,689	\$(6,129,553 )	\$(3,845,235 )
Deemed dividends attributable to Series A Preferred Stock			(2,568,132)	
Net income (loss) applicable to common stockholders	\$(2,184,510 )	\$204,689	\$(8,697,685 )	\$(3,845,235 )
Income (loss) per common share - basic and diluted	\$(0.18 )	\$0.07	\$(1.10 )	\$(1.44 )
Weighted average shares outstanding, basic and diluted	12,411,145	3,024,393	7,886,210	2,665,904

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

## ATOSSA GENETICS, INC.

## CONDENSED CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY

(UNAUDITED)

	Series A Convertible Preferred Stock			Common Stock		Additional	Accumulated	Total
	Shares	Amount	Additional Paid-in Capital	Shares	Amount	Paid-in Capital	Deficit	Stockholders' Equity
<b>Balance at December 31, 2016</b>	—	\$—	\$—	3,786,913	\$56,804	\$60,344,050	\$(57,303,748)	\$3,097,106
Issuance of common stock in Class A units, net of issuance costs of \$65,816				1,194,000	17,910	811,774		829,684
Allocation of Class A unit proceeds to warrant liability						(328,350)		(328,350)
Issuance of Series A convertible preferred stock in Class B units, net of issuance costs of \$267,231	3,502	4	3,234,769					3,234,773
Allocation of Series A convertible preferred stock to warrants and beneficial conversion feature			(2,568,132)			1,284,066		(1,284,066)
Deemed Dividends on Series A			2,568,132			(2,568,132)		



convertible preferred stock							
Conversion of Series A convertible preferred stock to common stock	(3,502)	(4)	(3,234,769 )	4,669,329	70,040	3,164,733	
Reclassification of warrant liability upon exercise of common stock warrants				1,490,833	22,362	1,870,798	1,893,160
Issuance of common stock upon warrant exercise for cash				2,881,666	43,225	706,008	749,233
Amortization of commitment shares						(59,558 )	(59,558 )
Compensation cost for stock options granted to executives and employees						560,369	560,369
Net loss						(6,129,553 )	(6,129,553 )
<b>Balance at September 30, 2017</b>		\$	\$	<b>14,022,741</b>	<b>\$210,341</b>	<b>\$65,785,758</b>	<b>\$(63,433,301) \$2,562,798</b>

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

## ATOSSA GENETICS INC.

## CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(UNAUDITED)

	<b>For the Nine Months Ended September 30,</b>	
	<b>2017</b>	<b>2016</b>
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>		
Net loss	\$(6,129,553 )	\$ (3,845,235)
Compensation cost for stock options granted	560,369	650,053
Loss on disposal of intangible asset	17,695	163,333
Depreciation and amortization	102,074	227,387
Change in fair value of common stock warrants	280,747	
Warrant financing expense	192,817	
Changes in operating assets and liabilities:		
Change in restricted cash		220,000
Prepaid expenses	14,195	72,542
Other assets	25,831	131,176
Accounts payable	126,079	(617,094 )
Payroll liabilities	(142,312 )	(524,288 )
Accrued expenses	33,578	(451,196 )
Other current liabilities	7,212	(45,242 )
Net cash used in operating activities	(4,911,268 )	(4,018,564)
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>		
Purchase of furniture and equipment		(5,023 )
Net cash used in investing activities		(5,023 )
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>		
Proceeds from issuance of Class A and Class B Units, net of issuance costs	3,871,636	
Proceeds from exercise of warrants	745,333	
Proceeds from issuance of common stock, net of issuance costs		4,695,869
Net cash provided by financing activities	4,616,969	4,695,869
<b>NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS</b>	(294,299)	672,282
<b>CASH AND CASH EQUIVALENTS, BEGINNING BALANCE</b>	3,027,962	3,715,895
<b>CASH AND CASH EQUIVALENTS, ENDING BALANCE</b>	\$2,733,663	\$ 4,388,177
<b>SUPPLEMENTAL DISCLOSURES:</b>		
Interest paid	\$	\$ 1,304
<b>NONCASH INVESTING AND FINANCING ACTIVITIES:</b>		
Reclassification of warrant liability upon exercise of common stock warrants	\$1,893,160	\$
Amount receivable for warrant exercise	3,900	

Edgar Filing: ATOSSA GENETICS INC - Form 10-Q

Allocation of Class A and Class B Unit proceeds to warrant liability	1,612,413	
Common stock issued as commitment fee under stock purchase agreement		198,523
Amortization of commitment shares	\$59,558	\$ 26,470

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

**ATOSSA GENETICS INC.**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**(UNAUDITED)**

**NOTE 1: NATURE OF OPERATIONS**

Atossa Genetics Inc. (the “Company”) was incorporated on April 30, 2009 in the State of Delaware. The Company was 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. The Company is focused on development of its pharmaceutical and drug delivery 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, 2017, the Company recorded a net loss of approximately \$6.1 million and used approximately \$4.9 million of cash in operating activities. As of September 30, 2017, the Company had approximately \$2.7 million in cash and cash equivalents and working capital of approximately \$1.9 million. The Company has not yet established an ongoing source of revenue sufficient to cover its operating costs and allow it to continue as a going concern. The ability of the Company to continue as a going concern is dependent on the Company obtaining adequate capital to fund operating losses until it becomes profitable. The Company can give no assurances that any additional capital that it is able to obtain, if any, will be sufficient to meet its needs, or that any such 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.

As of the date of filing this quarterly report, we expect that our existing resources will be sufficient to fund our planned operations for the next 8-12 months; however, additional capital resources will be needed to fund operations longer-term.

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 paragraphs and eventually to secure other sources of financing and attain profitable operations.

On October 26, 2017, the Company entered into an underwriting agreement with Maxim Group LLC relating to a public offering of common stock which closed on October 30, 2017. The offering generated gross proceeds to the Company of approximately \$5.5 million and net proceeds of \$5.1 million after deducting underwriting discounts and commission.

### **NOTE 3: SUMMARY OF ACCOUNTING POLICIES**

#### **Basis of Presentation:**

The accompanying unaudited Condensed Consolidated Financial Statements have been prepared in accordance with accounting principles generally accepted in the United States (“GAAP”) for interim financial information and with the instructions to Form 10-Q and Rule 10-01 of Regulation S-X. They do not include all information and notes required by GAAP for complete financial statements. However, except as disclosed herein, there has been no material change in the information disclosed in the Notes to Consolidated Financial Statements included in the Annual Report on Form 10-K of the Company for the year ended December 31, 2016.

In the opinion of management, all adjustments (including normal recurring accruals) considered necessary for a fair presentation have been included. Operating results for the three and nine months ended September 30, 2017 are not necessarily indicative of the results that may be expected for the year ending December 31, 2017.

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. 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.

#### **Financial Instruments with Characteristics of Both Liabilities and Equity:**

During the nine months ended September 30, 2017, the Company issued certain financial instruments, consisting of warrants to purchase common stock, which have characteristics of both liability and equity. Financial instruments such as warrants that are classified as liabilities are fair valued upon issuance and are remeasured at fair value at subsequent reporting periods with the resulting change in fair value recorded in “change in fair value of common stock warrants”. The fair value of warrants is estimated using valuation models that require the input of subjective assumptions including stock price volatility, expected life, and the probability of future equity issuances and their impact to the price protection feature.

**Recently Issued Accounting Pronouncements:**

In February 2016, Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“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. The Company has 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, *Compensation - Stock Compensation*, simplifying the accounting for share-based payment transactions including the income tax consequences, classification of awards as either equity or liabilities and classification on the statements of cash flows. Under the new standard, all excess tax benefits and tax deficiencies (including tax benefits of dividends on share-based payment awards) should be recognized as income tax expense or benefit on the statements of income. We adopted ASU No. 2016-09 effective January 1, 2017. As a result of the adoption of this guidance, we made an accounting policy election to recognize the effect of forfeitures in compensation cost when they occur. There was an immaterial impact on results of operations and financial position and no impact on cash flows at adoption.

In November 2016, the FASB issued ASU No. 2016-18, *Statement of Cash Flows*, amending the presentation of restricted cash within the statement of cash flows. The new guidance requires that restricted cash be included within cash and cash equivalents on the statement of cash flows. The ASU is effective retrospectively for reporting periods beginning after December 15, 2017, with early adoption permitted. The Company has not yet adopted the provisions of ASU No. 2016-18 and does not expect it will have a material impact on the financial statements upon adoption.

In July 2017, the FASB issued ASU 2017-11, *Accounting for Certain Financial Instruments with Down Round Features and Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception*. Part I of this ASU addresses the complexity of accounting for certain financial instruments with down round features. Down round features are features of certain equity-linked instruments (or embedded features) that result in the strike price being reduced on the basis of future equity offerings. Current accounting guidance requires financial instruments with down round features to be accounted for at fair value. Part II of the Update applies only to nonpublic companies and is therefore not applicable to the Company. The amendments in Part I of the Update change the classification analysis of certain equity-linked financial instruments (or embedded features) with down round features. When determining whether certain financial instruments should be classified as liabilities or equity instruments, a down round feature no longer precludes equity classification when assessing whether the instrument is indexed to an entity's own stock. As a result, a freestanding equity-linked financial instrument (or embedded conversion option) no longer would be accounted for as a derivative liability at fair value as a result of the existence of a down round feature. For freestanding equity-classified financial instruments, the amendments require entities that present earnings per share (EPS) in accordance with Topic 260 to recognize the effect of the down round feature when it is triggered. That effect is treated as a dividend and as a reduction of income available to common shareholders in basic EPS. This Update is effective for public entities for fiscal years beginning after December 15, 2018. Early adoption is permitted. The Company has not yet determined when it will adopt the provisions of this Update and has not yet determined the impact on its consolidated financial statements upon adoption.

#### **NOTE 4: PREPAID EXPENSES**

Prepaid expenses consisted of the following:



	September 30, 2017	December 31, 2016
Prepaid insurance	\$ 39,132	\$ 121,333
Trade show		20,000
Retainer and security deposits	14,218	14,218
Professional services	81,250	
Financial exchange fees	10,500	
Other	12,306	16,050
Total prepaid expenses	\$ 157,406	\$ 171,601

**NOTE 5: FURNITURE AND EQUIPMENT**

Furniture and equipment consisted of the following:

	September 30, 2017	December 31, 2016
Furniture and equipment	\$170,917	\$210,528
Less: Accumulated depreciation	(156,482)	(155,409)
Total furniture and equipment, net	\$14,435	\$55,119

Depreciation expense for the three months ended September 30, 2017 and 2016 was \$4,554 and \$29,698, respectively, and \$22,988, and \$92,054, for the nine months ended September 30, 2017 and 2016, respectively.

**NOTE 6: INTANGIBLE ASSETS**

Intangible assets consisted of the following:

	September 30, 2017	December 31, 2016
Patents	\$639,000	\$639,000
Software	113,540	113,540
Total intangible assets	752,540	752,540
Less: Accumulated amortization	(191,186)	(112,100)
Total intangible assets, net	\$561,354	\$640,440

Software amounted to \$113,540 as of September 30, 2017 and December 31, 2016. The amortization period for the purchased software is three years. Amortization expense related to software for the three months ended September 30, 2017 and 2016 was \$6,759 and \$7,857, respectively, and was \$26,373 and \$23,572, for the nine months ended September 30, 2017 and 2016, respectively.

Edgar Filing: ATOSSA GENETICS INC - Form 10-Q

Patents amounted to \$639,000 as of September 30, 2017 and December 31, 2016, and mainly consisted of patents acquired from Acueity on September 30, 2012 in an asset purchase transaction. Patent assets are amortized based on their determined useful life, and tested annually for impairment. The amortization period is from 7 to 12 years. Amortization expense related to patents was \$17,571 and \$37,253 for the three months ended September 30, 2017 and 2016, respectively and was \$52,713 and \$111,761 for the nine months ended September 30, 2017 and 2016, respectively.

Future estimated amortization expenses as of September 30, 2017 for the five succeeding years is as follows:

<b>For the years ending December 31,</b>	<b>Amounts</b>
2017 (includes the remainder of the year)	\$23,952
2018	73,433
2019	70,285
2020	70,285
2021	70,285
Thereafter	253,114
	\$561,354

**NOTE 7: PAYROLL LIABILITIES**

Payroll liabilities consisted of the following:

	September 30, 2017	December 31, 2016
Accrued bonus payable	\$423,000	\$609,337
Accrued vacation	140,384	94,514
Accrued payroll liabilities	64,203	66,048
Total payroll liabilities	\$627,587	\$769,899

**NOTE 8: STOCKHOLDERS' EQUITY**

The Company is authorized to issue a total of 85,000,000 shares of stock consisting of 75,000,000 shares of common stock, par value \$0.015 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, and 4,000 shares of Series A convertible preferred stock, par value \$0.001 per share through the filings of certificates of designation with the Delaware Secretary of State, none of which are issued and outstanding as of September 30, 2017.

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.

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

On November 11, 2015, we terminated our prior agreement with Aspire Capital Fund, LLC ("Aspire Capital") and entered into a new common stock purchase agreement. Concurrently with entering into the new 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 under the stock purchase agreement dated November 11, 2015 with aggregate gross proceeds to the Company of \$2,177,083, or net proceeds of \$2,133,973 after deducting costs of the offering.

On May 25, 2016, the Company 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, the Company also entered into a registration rights agreement with Aspire Capital, in which the Company 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 has been reflected as an addition to common stock and additional paid in capital of \$746 and \$197,777, respectively, which is 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. In connection with our public offering that closed on April 3, 2017, we agreed not to utilize the financing arrangement with Aspire Capital for 90 days after that financing and on June 30, 2017 in connection with the temporary modification of our common stock warrants to allow for the net exercise of those warrants we agreed to extend this stand still for an additional 45 days. As of September 30, 2017, 467,650 shares are available for sale to Aspire Capital under the May 25, 2016 purchase agreement.

#### 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 net proceeds of \$2,561,896 after deducting underwriter discounts, commissions, non-accountable expense allowance and expense reimbursement.

#### 2017 Public Offering of Class A and Class B Units Consisting of Common Stock, Series A Convertible Preferred Stock and Warrants

On March 28, 2017, the Company entered into an underwriting agreement with Aegis Capital Corp. relating to a public offering which closed on April 3, 2017. The offering generated gross proceeds to the Company of approximately \$4.4 million and net proceeds of approximately \$3.9 million after deducting underwriting discounts and commissions and other offering expenses paid by the Company.

The offering included 664,000 Class A Units at a public offering price of \$0.75 per Class A Unit, which consisted of 664,000 shares of common stock and warrants to purchase 664,000 shares of common stock. The offering also included 3,502 Class B Units at a public offering price of \$1,000 per Class B Unit, which consisted of 3,502 shares of Series A convertible preferred stock convertible into a total of 4,669,329 shares of common stock and warrants to purchase 4,669,329 shares of common stock. In addition, the underwriter exercised the over-allotment to purchase an additional 530,000 shares of common stock and warrants to purchase 530,000 shares of common stock, which are included in the gross proceeds of \$4.4 million. The warrants had a per share exercise price of \$0.9375, were exercisable immediately and were scheduled to expire five years from the date of issuance.

As of September 30, 2017, all of the warrants issued in the April 3, 2017 offering have been exercised and are no longer outstanding and all of the shares of Series A convertible preferred stock have been converted into shares of common stock.

*Accounting Treatment*

The Company allocated the proceeds from the sale of the Class A and Class B units to the separate securities issued. The Company determined that, on the date of issuance, the warrants were not considered indexed to its own stock because the underlying instruments were not “fixed-for-fixed” due to the price protection and fundamental transaction provisions and, therefore, the warrants should be accounted for as liabilities. At the end of each reporting period, the changes in fair value of the warrants during the period are recorded in non-operating income (expense) in the consolidated statement of operations.

The Company allocated the amount representing the fair value of the warrants at the date of issuance separately to the warrant liability and recorded the remaining proceeds as common stock, in the case of the Class A units, or as Series A convertible preferred stock, in the case of the Class B units. Due to the allocation of a portion of the proceeds to the warrants, the Series A convertible preferred stock contained a beneficial conversion feature upon issuance, which was recorded in the amount of \$1,284,066 based on the intrinsic value of the beneficial conversion feature. The discount on the Series A convertible preferred stock of \$1,284,066 caused by allocation of the proceeds to the warrant was recorded as a deemed dividend upon issuance of the Series A convertible preferred stock. As a result, total deemed dividends of \$2,568,132 was recorded upon issuance of the Series A convertible preferred stock, which is reflected as an addition to net loss in the consolidated statement of operations to arrive at net loss applicable to common shareholders.

*Exercise of 2017 Warrants*

On June 29, 2017, the Company offered to modify the rights of the holders of the warrants issued in the public offering the Company completed on April 3, 2017. The temporary modification included (a) lowering the exercise price of the warrants to \$0.26 per share, (b) setting the applicable volume-weighted average price (VWAP) at \$0.52 per share, and (c) allowing for temporary cashless exercise of the warrants for all holders that accepted the temporary modification before 8:00 a.m. Eastern daylight time on June 30, 2017. Holders of warrants to purchase a total of approximately 3.0 million shares of Common Stock accepted the offer resulting in the cancellation of those warrants and the issuance by the Company of a total of approximately 1.5 million shares of Common Stock (including shares held in abeyance). The shares of Common Stock are registered under the Securities Act of 1933, as amended. If delivery of the shares of Common Stock pursuant to the foregoing would result in the holder exceeding the 4.99% “Beneficial Ownership Limitation” (as defined in the warrant) then the shares in excess of such 4.99% will be held in abeyance by the Company pending further instruction from the holder. In connection with the temporary modification, the Company agreed to extend the “Lock-up Period” of the underwriting agreement between the Company and Aegis Capital Corp., dated March 28, 2017, by 45 days and the Company agreed not to enter into any further amendments to the warrants during such extended Lock-up Period without the prior written consent of each holder. During the three months ended September 30, 2017, all remaining warrants were exercised for cash so that no warrants issued in the April 3, 2017 financing remain outstanding. Upon exercise of these warrants, the amount of the warrant liability at the date of exercise was reclassified from warrant liability to additional paid-in capital.

The following table summarizes the 2017 liability warrant activity:

	<b>Shares</b>	<b>Weighted Average Exercise Price</b>
Outstanding as of December 31, 2016		
Warrants granted	5,863,332	\$ 0.9375
Warrants exercised	(5,863,332)	0.26
Outstanding as of September 30, 2017		\$



The Company estimated the fair value of the warrants using the Monte Carlo simulation (MCS) model, which is a type of income approach, where the current value of an asset is expressed as the sum of probable future cash flows across various scenarios and time frames discounted for risk and time. The significant assumptions include timing of future rounds of financing, timing and success rates of oncology clinical trials, and the probability of a merger and acquisition adjusted for a lack of marketability discount. The MCS model also includes a full term and an early conversion scenario that are each weighted at 50% in the final concluded fair value.

Inputs used in the valuation of the warrants at the issuance date of April 3, 2017 and June 30, 2017 are set forth below. All remaining warrants were exercised during the quarter and no warrants issued in the April 2017 financing remain outstanding at September 30, 2017.

**Initial valuation**

Common stock price	\$0.75	
Exercise price	\$0.9375	
Expected Volatility	50	%
Dividend Yield	0	%
Risk-Free Interest Rate	0.79% - 1.88	%
Expected Term (years)	0.24 - 5	

**June 30, 2017 valuation**

Common stock price	\$0.50	
Exercise price	\$0.26	
Expected Volatility	50	%
Dividend Yield	0	%
Risk-Free Interest Rate	0.79-1.88	%
Expected Term (years)	0.08-4.76	

**Outstanding Warrants**

As of September 30, 2017, warrants to purchase 380,561 shares of common stock were outstanding including:

	<b>Outstanding</b>		
	<b>Warrants to Purchase Shares</b>	<b>Exercise Price</b>	<b>Expiration Date</b>
2011 private placement	283,470	\$ 18.75 - 24.00	May 8, 2018
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
	380,561		

***Conversion of Series A Convertible Preferred Stock***

During the three months ended September 30, 2017, certain holders of the Series A convertible preferred stock exercised their conversion option and converted an aggregate of 839 shares of Series A convertible preferred stock into 1,118,665 shares of the Company's common stock based on the conversion ratio of 1,333.33 shares of common stock for each share of Series A convertible preferred stock. During the nine months ended September 30, 2017, certain holders of the Series A convertible preferred stock exercised their conversion option and converted an aggregate of 3,502 shares of Series A convertible preferred stock into 4,669,329 shares of the Company's common stock. As of September 30, 2017, no shares of Series A convertible preferred stock are outstanding.

**NOTE 9: FAIR VALUE OF FINANCIAL INSTRUMENTS**

Pursuant to the accounting guidance for fair value measurement and its subsequent updates, fair value is defined as the price that would be received to sell an asset or paid to transfer a liability (i.e., the "exit price") in an orderly transaction between market participants at the measurement date. The accounting guidance establishes a hierarchy for inputs used in measuring fair value that minimizes the use of unobservable inputs by requiring the use of observable market data when available. Observable inputs are inputs that market participants would use in pricing the asset or liability based on active market data. Unobservable inputs are inputs that reflect the assumptions market participants would use in pricing the asset or liability based on the best information available in the circumstances.

The fair value hierarchy is broken down into the three input levels summarized below:

*Level 1* —Valuations are based on quoted prices in active markets for identical assets or liabilities and readily accessible by us at the reporting date. Examples of assets and liabilities utilizing Level 1 inputs are certain money market funds, U.S. Treasuries and trading securities with quoted prices on active markets.

*Level 2* —Valuations based on inputs other than the quoted prices in active markets that are observable either directly or indirectly in active markets. Examples of assets and liabilities utilizing Level 2 inputs are U.S. government agency bonds, corporate bonds, commercial paper, certificates of deposit and over-the-counter derivatives.

*Level 3*—Valuations based on unobservable inputs in which there are little or no market data, which require the Company to develop its own assumptions.

There were no financial assets outstanding that were required to be measured at fair value at September 30, 2017 or December 31, 2016.

Warrants issued in the April 3, 2017 offering contained provisions that could have required the Company to settle the warrants in cash in an event outside the Company’s control or had price protection rights and were therefore accounted for as liabilities while they were outstanding, with changes in the fair values included in net loss for the respective periods. Because some of the inputs to the valuation model were either not observable or were not derived principally from or corroborated by observable market data by correlation or other means, the warrant liability was classified as Level 3 in the fair value hierarchy.

The following table summarizes the changes in the Company’s Level 3 warrant liability for the nine months ended September 30, 2017:

Warrant liability	
Beginning balance	\$
Issuances of warrants	1,612,413
Warrant exercises	(1,893,160)
Change in fair value	280,747
Ending balance	

There were no transfers between Level 1, Level 2 or Level 3 for the three and nine months ended September 30, 2017 or the year ended December 31, 2016.

**NOTE 10: NET INCOME (LOSS) PER SHARE**

The Company accounts for and discloses net income (loss) per common share in accordance with FASB Accounting Standards Codification (“ASC”) Topic 260, *Earnings Per Share*. Basic net income (loss) per common share is computed by dividing net income (loss) attributable to common stockholders by the weighted average number of common shares outstanding. In addition, in computing the dilutive effect of convertible securities, the numerator is adjusted to add back any convertible preferred dividends. Diluted net income (loss) per common share is computed by dividing net income (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 conversion of Series A convertible preferred stock, and potential future exercises of outstanding stock options and common stock warrants. Because the inclusion of potential common shares would be anti-dilutive for all periods presented except for the three months ended September 30, 2016, diluted net loss per common share is the same as basic net loss per common share for those periods. Diluted net income per share was the same as basic net income per share for the three months end September 30, 2016 as the impact of potential common shares included in earnings per share was insignificant.

The following table summarizes the Company's calculation of net income (loss) per common share:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Net income (loss) Per share				
Numerator				
Net income (loss)	\$(2,184,510 )	\$204,689	\$(6,129,553 )	\$(3,845,235 )
Deemed dividend attributable to preferred stock			(2,568,132)	
Net income (loss) attributable to common shareholders	\$(2,184,510 )	\$204,689	\$(8,697,685 )	\$(3,845,235 )
Denominator				
Weighted average common shares outstanding	12,411,145	3,024,393	7,886,210	2,665,904
Basic and diluted net income (loss) per share	\$(0.18 )	\$0.07	\$(1.10 )	\$(1.44 )

The following table sets forth the number of potential common shares excluded from the calculation of net income (loss) per diluted share for the three months and nine months ended September 30, 2017 and 2016 because the effect of them would be anti-dilutive:

	<b>Three Months Ended</b>		<b>Nine Months Ended</b>	
	<b>September 30, 2017</b>	<b>2016</b>	<b>September 30, 2017</b>	<b>2016</b>
Options to purchase common stock	2,118,021	390,424	1,206,057	390,424
Series A convertible preferred stock	509,762		895,809	
Warrants to purchase common stock	1,660,379	402,228	2,726,751	402,228
Total	4,288,162	792,652	4,828,617	792,652

#### **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, 2017 and December 31, 2016 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, 2017 and December 31, 2016, the Company had \$2,483,663 and \$2,777,962 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, 2017 under all non-cancelable operating and capital leases for the next five years are as follows:

<b>Year Ending December 31,</b>	<b>Operating Leases Amount</b>
2017 (remainder of year)	\$ 7,395
2018	22,185
Total minimum lease payments	\$ 29,580

The total rent expense for the three months ended September 30, 2017 and 2016 was \$7,395 and \$87,315, respectively, and \$25,775 and \$238,565 for the nine months ended September 30, 2017 and 2016, respectively. Rent expense was included in general and administrative expenses for both years.

**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 our directors and officers and the underwriters of our November 2012 initial public offering. The complaint alleged 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. The complaint sought, 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 district 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 appealed the Court's dismissal order to the U.S. Court of Appeals for the Ninth Circuit. On August 18, 2017, the Ninth Circuit affirmed in part and reversed in part the district court's judgment.

On September 11, 2017, the Ninth Circuit entered an order and mandate remanding the case to the United States District Court for the Western District of Washington. On October 19, 2017, plaintiffs filed an amended complaint that conforms to the ruling by the Ninth Circuit. Defendants' answer to the amended complaint is due December 8, 2017. Since the claims under Sections 11, 12(a)(2) and 15 were dismissed by the district court and not appealed, the amended complaint only alleges violations of Section 10(b) and 20A of the Exchange Act and SEC Rule 10b-5 promulgated thereunder against the company and one officer. All other claims and defendants have been dismissed. The alleged class period in the amended complaint is December 20, 2012 through October 4, 2013.



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, 2017. The costs associated with defending and resolving the lawsuit and ultimate outcome cannot be predicted. These matters are subject to inherent uncertainties and the actual cost, as well as the distraction from the conduct of the Company's business, will depend upon many unknown factors and management's view of these may change in the future.

**NOTE 14: STOCK BASED COMPENSATION**

*Stock Options and Incentive Plan*

On September 28, 2010, the Board of Directors approved the adoption of the 2010 Stock Option and Incentive Plan ("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. On May 9, 2017, the stockholders approved an additional 1,500,000 shares 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:

<b>January 1,</b>	<b>Number of shares</b>
2012	30,018
2013	34,452
2014	49,532
2015	65,557
2016	220,419
2017	151,477
Total additional shares	551,455

Edgar Filing: ATOSSA GENETICS INC - Form 10-Q

The Company granted 0 and 1,716,323 options to purchase shares of common stock during the three and nine months ended September 30, 2017. No options were exercised during the three or nine months ended September 30, 2017. There are 100,456 shares available for grant under the 2010 Plan as of September 30, 2017.

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 \$224,254 and \$257,389 for the three months ended September 30, 2017 and 2016, respectively, and \$560,369 and \$650,053 for the nine months ended September 30, 2017 and 2016, respectively. The fair value of stock options granted for the nine months ended September 30, 2017 and 2016 was calculated using the Black-Scholes option-pricing model applying the following assumptions:

	<b>Period ended September 30,</b>	
	<b>2017</b>	<b>2016</b>
Risk free interest rate	1.86% - 2.04%	1.48% - 1.55%
Expected term	5.32- 6.36 years	5.58 - 6.06 years
Dividend yield	- %	- %
Expected volatility	112.86% - 114.19%	115.52% - 115.58%

Options issued and outstanding as of September 30, 2017 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, 2017	378,924	\$ 26.25		\$
Granted	1,716,323	0.47		
Forfeited	(3,167 )	15.00		
Expired	(19,081 )	25.05		
Outstanding as of September 30, 2017	2,072,999	4.10	9.29	\$ 102,679
Exercisable as of September 30, 2017	418,636	16.39	8.44	\$ 9,645
Vested and expected to vest	2,072,999	\$ 4.10	9.29	\$ 102,679

At September 30, 2017, there were 1,651,052 unvested options outstanding and the related unrecognized total compensation cost associated with these options was approximately \$1,203,000. This expense is expected to be recognized over a weighted-average period of 2.0 years.

#### **NOTE 15: SUBSEQUENT EVENTS**

On October 26, 2017, the Company entered into an underwriting agreement with Maxim Group LLC relating to a public offering of common stock which closed on October 30, 2017. The offering generated gross proceeds to the Company of approximately \$5.5 million and net proceeds of \$5.1 million after deducting underwriting discounts and commission.

The offering included 11,500,000 shares of common stock at a public offering price of \$0.44 per share. In addition, the underwriter exercised the over-allotment to purchase an additional 1,000,000 shares of common stock, which are included in the estimated gross proceeds of \$5.5 million.

## 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 our study 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 a sufficient number of subjects 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 November 3, 2014 appeal of a dismissal of a securities class action law suit filed against us, 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;

whether the final study results will vary from preliminary study results that we may announce; and

our ability to attract and retain key personnel;

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

## **Company Overview**

We are a clinical-stage pharmaceutical company focused on developing novel, proprietary therapeutics and delivery methods for the treatment of breast cancer and other breast conditions. We are developing Endoxifen with two routes of delivery: a topical formulation, applied like a lotion, for the treatment of a condition called mammographic breast density (or, MBD), and an oral formulation for breast cancer survivors who do not benefit from taking oral tamoxifen which is the current FDA-approved standard of care. We are also developing our patented intraductal microcatheter technology to potentially target the delivery of therapies, including fulvestrant and CAR-T cell therapies, directly to the site of breast cancer.

## **Endoxifen**

Oral tamoxifen has been widely used for over 30 years to both treat and prevent breast cancer. Tamoxifen, however, has significant drawbacks: First, it can cause side effects including headaches, nausea and early menopausal symptoms as well as rare but serious side effects such as cataracts, strokes and cancer of the uterus. Second, tamoxifen is a “pro-drug,” meaning that it must be processed by the liver in order to produce therapeutic metabolites. The metabolite in tamoxifen that accounts for most of its therapeutic activity is called Endoxifen. Unfortunately, up to 50% of breast cancer survivors who are taking tamoxifen do not produce therapeutic levels of Endoxifen (meaning they are “refractory”) for a number of reasons including that they do not have the requisite liver enzymes. We are developing Endoxifen because of these drawbacks to tamoxifen.

We are developing two different presentations of proprietary Endoxifen for two different potential treatment settings:

First, we are developing topical Endoxifen for women with MBD for transdermal administration. Legislation that has been recently enacted in approximately 30 states (and that is now pending on the federal level) currently requires that women be notified if they have MBD and those notifications typically state that women with MBD have a higher risk

of developing breast cancer, and that mammography may not be as effective because of the MBD. We estimate that approximately ten million women in the United States have MBD, for which there is no FDA-approved treatment. Although oral tamoxifen is approved to prevent breast cancer in “high-risk” women, it is used by less than 5% of women with an increased risk of developing breast cancer because of the actual or perceived side effects and risks of tamoxifen. We believe our topical Endoxifen may provide an effective treatment for MBD because, unlike an oral medication, it is applied directly to the breast and penetrates the skin; it does not require metabolism by the liver; and it may produce fewer side effects than tamoxifen.

Second, we are developing oral Endoxifen for breast cancer patients who are refractory to tamoxifen. Approximately one million breast cancer patients take tamoxifen to prevent recurrence and new breast cancer; however, up to 50% of those patients are refractory to tamoxifen. We believe our oral Endoxifen may provide an effective treatment supplement or option for these refractory patients because Endoxifen, unlike tamoxifen, does not require liver metabolism.

We recently completed a comprehensive Phase 1 study in 48 healthy women in Australia using both the topical and oral forms of our proprietary Endoxifen. The objectives of this double-blinded, placebo-controlled, Phase 1 study were to assess the pharmacokinetics of our proprietary Endoxifen dosage forms as single (oral) and repeat (oral and topical) doses, as well as to assess safety and tolerability. The study was conducted in two parts based on route of administration.

In September 2017, we reported preliminary results for the topical arm of the study and in October 2017 we reported preliminary results for the oral arm of the study. We concluded that all objectives were successfully met in both arms of the study: there were no clinically significant safety signals and no clinically significant adverse events and both the oral and topical Endoxifen were well tolerated. In the topical arm of the study, there were low but measurable Endoxifen levels detected in the blood in a dose-dependent fashion and in the oral arm of the study participants exhibited dose-dependent Endoxifen levels in published reports of the therapeutic range. In September 2017, we contracted Stockholm South General Hospital in Sweden to conduct a Phase 2 study of our topical Endoxifen. The study will be led by principal investigator Dr. Per Hall, MD, Ph.D., Head of the Department of Medical Epidemiology and Biostatistics at Karolinska Institutet. We have applied for approval from the Institutional Review Board and Swedish regulatory authority (Medical Products Agency) to begin enrollment. The placebo-controlled, double-blinded study is expected to enroll up to 480 subjects. The primary endpoint is MBD reduction, which will be measured after six and twelve months of dosing, as well as safety and tolerability. We are planning to start enrollment in this study in the first quarter of 2018.

We plan to commence a Phase 2 clinical study of our oral Endoxifen for patients who are refractory to tamoxifen. We currently expect that we will retain a clinical research organization to manage the study and that we will commence the study the first quarter of 2018.

### **Proprietary Intraductal Microcatheter Technology**

In October 2017, we announced a new program using Chimeric Antigen Receptor Therapy, or CAR-T. We plan to use our proprietary intraductal microcatheter technology for the potential transpapillary, or “TRAP,” delivery of T-cells that have been genetically modified to attack breast cancer cells. We believe this method has several potential advantages: reduced toxicity by limiting systemic exposure of the T-cells; improved efficacy by placing the T-cells in direct contact with the target ductal epithelial cells that are undergoing malignant transformation; and, lymphatic migration of the CAR-T cells along the same path taken by migrating cancer cells, potentially extending their cytotoxic actions into the regional lymph system, which could limit tumor cell dissemination. This program is in the research and development phase and has not been approved by the FDA or any other regulatory body. Pre-clinical studies, and clinical studies demonstrating safety and efficacy among other things, and regulatory approvals will be required before commercialization.

We have developed a foundational intellectual property position with respect to TRAP CAR-T, and we intend to continue research and development through partnership with leading investigators, institutions, and organizations around the world, bringing our technology and expertise in TRAP delivery together with experts in cancer immunology and T-cell biology.



We are currently conducting a Phase 2 study using our microcatheter technology to deliver fulvestrant at Montefiore Medical Center. This trial is a Phase 2 study in women with ductal carcinoma in situ (“DCIS”) or Stage 1 or 2 breast cancer (invasive ductal carcinoma) scheduled for mastectomy or lumpectomy within 30 to 45 days. This study is assessing the safety, tolerability, cellular activity and distribution of fulvestrant when delivered directly into breast milk ducts of these patients compared to those who receive the same drug by injection. Of the 30 patients required for full enrollment, six will receive the standard intramuscular injection of fulvestrant and 24 will receive fulvestrant with our microcatheter device.

The primary endpoint of the clinical trial is to compare the safety, tolerability and distribution of fulvestrant between the two routes of administration (intramuscular injection or through our microcatheters). The secondary endpoint of the study is to determine if there are changes in the expression of Ki67 (a measure of cellular proliferation that correlates with tumor growth) as well as estrogen and progesterone receptors between a pre-fulvestrant biopsy and post-fulvestrant surgical specimens. 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.

## **Research and Development Phase**

We are in the research and development phase and are not currently marketing any products or services. We do not anticipate generating revenue unless and until we develop and launch our pharmaceutical programs.

## **Critical Accounting Policies and Estimates**

In our Annual Report on Form 10-K/A for the year ended December 31, 2016, 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, 2016, other than discussed in the following paragraph. Readers are encouraged to review these disclosures in conjunction with the review of this report.

## **Financial Instruments with Characteristics of Both Liabilities and Equity**

During the nine months ended September 30, 2017, the Company issued certain financial instruments, consisting of warrants to purchase common stock, which have characteristics of both liability and equity. Financial instruments such as warrants that are classified as liabilities are fair valued upon issuance and are remeasured at fair value at subsequent reporting periods with the resulting change in fair value recorded in other income/(expense). The fair value of warrants is estimated using valuation models that require the input of subjective assumptions including stock price volatility, expected life, and the probability of future equity issuances and their impact to the price protection feature.

## **Results of Operations**

### **Three and Nine Months Ended September 30, 2017 and 2016**

*Operating Expenses:* Total operating expenses were approximately \$2.1 million and \$5.6 million for the three and nine months ended September 30, 2017, respectively, consisting of general and administrative (G&A) expenses of approximately \$1.3 million and \$3.5 million, respectively, and research and development (R&D) expenses of approximately \$0.7 million and \$2.1 million, respectively. Total operating expenses were approximately \$1.6 million and \$5.4 million for the three and nine months ended September 30, 2016, respectively, consisting of G&A expense of approximately \$1.5 million and \$5.0 million, respectively and R&D expenses of \$0.1 million and \$0.4 million,

respectively.

Total operating expenses for the three and nine months ended September 30, 2017 as compared to the same periods of 2016 increased approximately \$0.5 million or 32.0% and increased \$0.2 million or 3.6%, respectively.

25

*General and Administrative Expenses:* G&A expenses for the three months ended September 30, 2017 were approximately \$1,314,000, a decrease of \$159,000 or 10.8%, from approximately \$1,473,000, for the same period in 2016. G&A expenses for the nine months ended September 30, 2017 were approximately \$3,528,000, a decrease of \$1,513,000 or 30.0%, from approximately \$5,041,000 for the same period in 2016. 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 a reduction in payroll expenses resulting from a decrease in headcount, rent, and exit costs incurred in 2016 that were not incurred in 2017.

*Research and Development Expenses:* R&D expenses for the three and nine months ended September 30, 2017 were approximately \$743,000 and \$2,111,000, respectively, an increase of approximately \$658,000, or 774.1% and \$1,707,000 or 422.5% from the three months and nine months ended September 30, 2016, respectively. The increase in R&D expenses is attributed to salaries, manufacturing and clinical trial expenses associated with our Endoxifen program for which manufacturing commenced at the beginning of 2017 and the clinical studies which commenced in the second quarter of 2017. We expect our R&D expenses to increase throughout 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.

*Other Income Expense:* In August 2016, the Company received a termination payment of \$1,762,931 pursuant to the settlement agreement with Besins Healthcare Luxembourg SARL. There were no settlement payments received by the Company for the three and nine months ended September 30, 2017.

## **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, 2017, the Company recorded a net loss of approximately \$6.1 million, and used approximately \$4.9 million of cash in operating activities. As of September 30, 2017, the Company had approximately \$2.7 million in cash and cash equivalents and working capital of approximately \$1.9 million. The Company has not yet established an ongoing source of revenue sufficient to cover its operating costs and allow it to continue as a going concern. The ability of the Company to continue as a going concern is dependent on the Company obtaining adequate capital to fund operating losses until it becomes profitable. The Company can give no assurances that any additional capital that it is able to obtain, if any, will be sufficient to meet its needs, or that any such financing will be obtainable on acceptable terms. If the Company is unable to obtain adequate capital, it could be forced to cease operations or substantially curtail its commercial activities. These conditions raise substantial doubt as to the Company's ability to continue as a going concern. The accompanying 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.



As of the date of filing this quarterly report, we expect that our existing resources will be sufficient to fund our planned operations for the next 8-12 months; however, additional capital resources will be needed to fund operations longer-term.

On October 26, 2017, the Company entered into an underwriting agreement with Maxim Group LLC relating to a public offering of common stock which closed on October 30, 2017. The offering generated gross proceeds to the Company of approximately \$5.5 million and net proceeds of \$5.1 million after deducting underwriting discounts and commission. As of the date of filing his quarterly report, the Company has in excess of \$5 million in total stockholders equity.

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, 2017 the Company had cash and cash equivalents of \$2.7 million.

*Net Cash Flows from Operating Activities:* Net cash used in operating activities was approximately \$4.9 million for the nine months ended September 30, 2017, compared with approximately \$4.0 million for the nine months ended September 30, 2016. We spent approximately \$2.1 million on research and development for the nine month period ended September 30, 2017, compared to \$400,000 for the same period in 2016; this increase was offset by reductions in compensation expense from reduced headcount, reduced occupancy expense, reduced consulting fees, and from severance payments in 2016 that were not incurred in 2017.

*Net Cash Flows from Investing Activities:* There was no net cash used in investing activities for the nine months ended September 30, 2017, compared with approximately \$5,000 for nine months ended Sept 30, 2016. The decrease in 2017 was attributable to the reduction in purchases of fixed asset equipment in 2017 as compared to 2016.

*Net Cash Flows from Financing Activities:* Net cash provided by financing activities generated proceeds of \$4.6 million for the nine months ended September 30, 2017, as compared with \$4.7 million for the nine months ended June 30, 2016. In both of the periods ended September 30, 2017 and 2016 the Company completed public offerings.

## **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 as of the date of filing this quarterly report, our existing resources will be sufficient to fund our planned operations for at least the next 8-12 months.

On October 26, 2017, the Company entered into an underwriting agreement with Maxim Group LLC relating to a public offering of common stock which closed on October 30, 2017. The offering generated gross proceeds to the Company of approximately \$5.5 million and net proceeds of \$5.1 million after deducting underwriting discounts and commission.

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 February 2016, Financial Accounting Standards Board (“FASB”) issued Accounting Standards Updated (“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. The Company has 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, *Compensation - Stock Compensation* simplifying the accounting for share-based payment transactions including the income tax consequences, classification of awards as either equity or liabilities and classification on the statements of cash flows. Under the new standard, all excess tax benefits and tax deficiencies (including tax benefits of dividends on share-based payment awards) should be recognized as income tax expense or benefit on the statements of income. We adopted ASU No. 2016-09 effective January 1, 2017. As a result of the adoption of this guidance, we made an accounting policy election to recognize the effect of forfeitures in compensation cost when they occur. There was an immaterial impact on results of operations and financial position and no impact on cash flows at adoption.

In November 2016, the FASB issued ASU No. 2016-18, *Statement of Cash Flows*, amending the presentation of restricted cash within the statement of cash flows. The new guidance requires that restricted cash be included within cash and cash equivalents on the statement of cash flows. The ASU is effective retrospectively for reporting periods beginning after December 15, 2017, with early adoption permitted. The Company has not yet adopted the provisions



of ASU No. 2016-18 and does not expect it will have a material impact on the financial statements upon adoption.

In July 2017, the FASB issued ASU 2017-11, *Accounting for Certain Financial Instruments with Down Round Features and Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception*. Part I of this ASU addresses the complexity of accounting for certain financial instruments with down round features. Down round features are features of certain equity-linked instruments (or embedded features) that result in the strike price being reduced on the basis of future equity offerings. Current accounting guidance requires financial instruments with down round features to be accounted for at fair value. Part II of the Update applies only to nonpublic companies and is therefore not applicable to the Company. The amendments in Part I of the Update change the classification analysis of certain equity-linked financial instruments (or embedded features) with down round features. When determining whether certain financial instruments should be classified as liabilities or equity instruments, a down round feature no longer precludes equity classification when assessing whether the instrument is indexed to an entity's own stock. As a result, a freestanding equity-linked financial instrument (or embedded conversion option) no longer would be accounted for as a derivative liability at fair value as a result of the existence of a down round feature. For freestanding equity-classified financial instruments, the amendments require entities that present earnings per share (EPS) in accordance with Topic 260 to recognize the effect of the down round feature when it is triggered. That effect is treated as a dividend and as a reduction of income available to common shareholders in basic EPS. This Update is effective for public entities for fiscal years beginning after December 15, 2018. Early adoption is permitted. The Company has not yet determined when it will adopt the provisions of this Update and has not yet determined the impact on its consolidated financial statements upon adoption.

**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, 2017. 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. Our principal executive officer and principal financial officer concluded that, as of September 30, 2017, the Company’s disclosure controls and procedures were not 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, 2017 that has materially affected, or is reasonably likely to materially affect our disclosure controls and procedures.

For the year ended December 31, 2016, we identified a material weakness in that we did not design and maintain effective controls over the preparation of the 2016 impairment analysis of the Acueity patents, primarily because we did not include potential income taxes in the discounted cash flow model we used to estimate the fair value of the Acueity patents at December 31, 2016. This resulted in an initial overstatement of the fair value of the Acueity patents at December 31, 2016 in the amount of \$366,000 and an initial understatement of the 2016 impairment charge and net loss by the same amount. We corrected our estimate and the related accounts prior to the issuance of the consolidated financial statements contained in our Annual Report on Form 10-K/A. Management’s remediation plan, which we are in the process of implementing, is to use appropriate valuation methodologies in future analyses that may be required to determine the fair value of these intangible assets and to seek the assistance of outside valuation resources, if necessary, in performing such analyses.

For the year ended December 31, 2016, we also identified a material weakness in that we did not design and maintain effective controls over the calculation of the weighted average number of shares outstanding and basic and diluted loss per share for the year ended December 31, 2016 because the calculation of weighted average shares outstanding did not include the shares of common stock we issued in August 2016. The preparation and review of the weighted average share calculation was not performed at an appropriately detailed level to prevent or detect this error, which led to a material error in our calculation of the weighted average number of shares outstanding and the net loss per share for the year ended December 31, 2016. During the first and second quarter of 2017, we began implementing a remediation plan to enhance the procedures performed to document our preparation of and to independently review the calculation of weighted average shares outstanding and income (loss) per share. Our enhanced review procedures and documentation standards were in place during the first, second and third quarter of 2017. The material weakness cannot be considered remediated until the control has operated for a sufficient period of time and until management has concluded that the control is operating effectively.

## 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 alleged 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. The complaint sought, 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 district 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 appealed the Court's dismissal order to the U.S. Court of Appeals for the Ninth Circuit. On August 18, 2017, the Ninth Circuit affirmed in part and reversed in part the district court's judgment.

On September 11, 2017, the Ninth Circuit entered an order and mandate remanding the case to the United States District Court for the Western District of Washington. On October 19, 2017, plaintiffs filed an amended complaint that conforms to the ruling by the Ninth Circuit. Defendants' answer to the amended complaint is due December 8, 2017. Since the claims under Sections 11, 12(a)(2) and 15 were dismissed by the district court and not appealed, the amended complaint only alleges violations of Section 10(b) and 20A of the Exchange Act and SEC Rule 10b-5 promulgated thereunder against the company and one officer. All other claims and defendants have been dismissed. The alleged class period in the amended complaint is December 20, 2012 through October 4, 2013.

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, 2017. The costs associated with defending and resolving the complaint and ultimate outcome cannot be predicted. These matters are subject to inherent uncertainties and the actual cost, as well as the distraction from the conduct of our business, will depend upon many unknown factors and management's view of these may change in the future.

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

### **RISK FACTORS**

*A purchase of our shares of Common Stock is an investment in our securities and involves a high degree of risk. You should carefully consider the following information about these risks, together with the other information contained in this report, before purchasing our securities. If any of the following risks actually occur, our business, financial condition and results of operations would likely suffer. In that case, the market price of the Common Stock could decline, and you may lose part or all of your investment in our company. Additional risks of which we are not presently aware or that we currently believe are immaterial may also harm our business and results of operations.*

There have been no material changes to the risk factors described in our Annual Report on Form 10-K/A, as filed with the SEC on March 21, 2017 except as follows:

*Our shares of Common Stock are listed on The NASDAQ Capital Market, but we cannot guarantee that we will be able to satisfy the continued listing standards going forward.*

Although our shares of Common Stock are listed on The NASDAQ Capital Market, we cannot ensure that we will be able to satisfy the continued listing standards of The NASDAQ Capital Market going forward. If we cannot satisfy the continued listing standards going forward, NASDAQ may commence delisting procedures against us, which could result in our stock being removed from listing on The NASDAQ Capital Market. On May 11, 2017, we received a letter from NASDAQ stating we are not in compliance with Rule 5550(a)(2) because our common stock failed to maintain a minimum closing bid price of \$1.00 per share for 30 consecutive business days. We had until November 7, 2017 to either regain compliance, or request additional time to regain compliance. On November 2, 2017, we requested an additional 180 days to regain compliance.

If our stock price does not satisfy the \$1.00 minimum bid price requirement or we otherwise fail to satisfy other continued listing requirements, we may be delisted from NASDAQ, which could adversely affect our stock price, liquidity, and our ability to raise funding.

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

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>
<u>10.1</u>	<u>Underwriting Agreement between Atossa Genetics Inc. and Maxim Corp. as representative of the several underwriters, dated Oct 26, 2017</u>	Current Report on Form 8-K, as Exhibit 1.1	October 30, 2017
<u>31.1</u>	<u>Certification pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934 of Steven C. Quay</u>	Filed herewith	
<u>31.2</u>	<u>Certification pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934 of Kyle Guse</u>	Filed herewith	
<u>32.1</u>	<u>Certification pursuant to 18 U.S.C. Section 1350 of Steven C. Quay</u>	Filed herewith	
<u>32.2</u>	<u>Certification pursuant to 18 U.S.C. Section 1350 of Kyle Guse</u>	Filed herewith	

101 Interactive Data Files pursuant to Rule 405 of Regulation S-T Filed herewith

32



## 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 13, 2017

/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)

