

ATOSSA GENETICS INC  
Form 10-Q  
May 14, 2018

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**WASHINGTON, DC 20549**

**FORM 10-Q**

**(Mark One)**

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

**For the quarterly period ended March 31, 2018**

**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)



**ATOSSA GENETICS INC.**

**FORM 10-Q**

**QUARTERLY REPORT**

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

	March 31, 2018	December 31, 2017
Assets		
Current assets		
Cash and cash equivalents	\$4,779,519	\$7,217,469
Restricted cash	55,000	55,000
Prepaid expenses	495,667	250,944
Research and development tax rebate receivable	395,872	358,277
Other current assets	9,316	16,344
Total current assets	5,735,374	7,898,034
Furniture and equipment, net	59,810	11,467
Intangible assets, net	70,547	75,686
Other assets	114,571	178,907
Total assets	\$5,980,302	\$8,164,094
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	\$168,347	\$334,901
Accrued expenses	172,613	90,105
Payroll liabilities	356,427	784,867
Other current liabilities	23,323	15,534
Total current liabilities	720,710	1,225,407
Commitments and contingencies (note 11)		
Stockholders' equity		
Preferred stock - \$.001 par value; 10,000,000 shares authorized, no shares issued or outstanding		
Common stock - \$.18 par value; 75,000,000 shares authorized, 2,651,952 shares issued and outstanding	477,342	477,342

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Additional paid-in capital	72,082,961	71,887,674
Accumulated deficit	(67,300,711)	(65,426,329)
Total stockholders' equity	5,259,592	6,938,687
Total liabilities and stockholders' equity	\$5,980,302	\$8,164,094

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

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

	For the Three Months Ended March 31,	
	2018	2017
Operating expenses:		
Research and development	\$470,976	\$544,302
General and administrative	1,403,465	1,159,289
Total operating expenses	1,874,441	1,703,591
Operating loss	(1,874,441)	(1,703,591)
Other income, net	59	37
Loss before income taxes	(1,874,382)	(1,703,554)
Income taxes		
Net loss	\$(1,874,382)	\$(1,703,554)
Loss per common share - basic and diluted	\$(0.71 )	\$(5.40 )
Weighted average shares outstanding, basic and diluted	2,651,952	315,576

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

## ATOSSA GENETICS INC.

## CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(UNAUDITED)

	For the Three Months Ended March 31,	
	2018	2017
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>		
Net loss	\$(1,874,382)	\$(1,703,554)
Compensation cost for stock options granted	215,139	154,707
Loss on disposal of asset		17,695
Depreciation and amortization	7,864	40,087
Changes in operating assets and liabilities:		
Prepaid expenses	(244,723 )	(123,230 )
Research and development tax rebate receivable	(37,595 )	
Other assets	51,512	25,834
Accounts payable	(166,554 )	132,557
Payroll liabilities	(428,440 )	(439,010 )
Accrued expenses	82,508	17,646
Other current liabilities	7,789	16,317
Net cash used in operating activities	(2,386,882)	(1,860,951)
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>		
Purchase of furniture and equipment	(51,068 )	
Net cash used in investing activities	(51,068 )	
<b>NET DECREASE IN CASH AND CASH EQUIVALENTS AND RESTRICTED CASH</b>	<b>(2,437,950)</b>	<b>(1,860,951)</b>
<b>CASH AND CASH EQUIVALENTS AND RESTRICTED CASH, BEGINNING BALANCE</b>	<b>7,272,469</b>	<b>3,082,962</b>
<b>CASH AND CASH EQUIVALENTS AND RESTRICTED CASH, ENDING BALANCE</b>	<b>\$4,834,519</b>	<b>\$1,222,011</b>
<b>NONCASH INVESTING AND FINANCING ACTIVITIES</b>		
Amortization of commitment shares	\$19,852	\$19,852

*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 three months March 31, 2018 and the year ended December 31, 2017, the Company recorded a net loss of approximately \$1.9 million and \$8.1 million, respectively and used approximately \$2.4 million and \$6.6 million of cash in operating activities, respectively. As of March 31, 2018 and December 31, 2017 the Company had approximately \$4.8 million and \$7.2 million, respectively in cash and cash equivalents and working capital of approximately \$5.0 million and \$6.7 million, respectively. 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 includes obtaining additional capital resources. Management’s plans to obtain such resources for the Company include obtaining capital from the sale of its equity securities, potential exercise of outstanding warrants, and short-term borrowings from banks, stockholders or other related parties, 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 report, *without giving effect to the rights offering described in “Liquidity and Capital Resources” included in Part I, Item 2, “Management’s Discussion and Analysis of Financial Condition and Results of Operations,”* we expect that our existing resources will be sufficient to fund our planned operations for the next five to eight 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.

### **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, 2017.

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 months ended March 31, 2018 are not necessarily indicative of the results that may be expected for the year ending December 31, 2018.

Subsequent to the balance sheet date, on April 20, 2018, the Company completed a 1-for-12 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 12 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 \$0.18 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 rounded up. As a result of the Reverse Stock Split, fractional shares totaling approximately 57 were rounded up and issued to stockholders. 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 April 20, 2018. All share and per share data included in this report has been retroactively restated to reflect the Reverse Stock Split.

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

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

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

In 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 GAAP. The new standard takes effect in 2019 for public business entities. The Company has not adopted the provisions of ASU No. 2016-02 and is currently evaluating the impact of adopting ASU 2016-02 on its consolidated financial statements.

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 Company adopted the provisions of ASU No. 2016-18 on January 1, 2018. Upon adoption, we included \$55,000 of restricted cash on the statement of cash flows for the three months ended March 31, 2018 and 2017. The restricted cash represents a required deposit for the Company credit card and is restricted until the Company no longer has the credit card or the limit changes on the credit card.

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:

	March 31, 2018	December 31, 2017
Prepaid insurance	\$ 136,670	\$ 125,056
Retainer and security deposits	16,718	14,218
Professional services	168,181	97,788
Prepaid research and development	125,797	
Financial exchange fees	41,250	

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Other	7,051	13,882
Total prepaid expenses	\$495,667	\$250,944

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**NOTE 5: RESEARCH AND DEVELOPMENT TAX REBATE RECEIVABLE**

On May 23, 2017 Atossa formed a wholly-owned subsidiary in Australia called Atossa Genetics AUS Pty Ltd. The purpose of this subsidiary is to perform research and development activities (“R&D”) including our Phase 1 and Phase 2 endoxifen clinical trials. Australia offers an R&D cash rebate of \$0.435 per dollar spent on qualified R&D activities incurred in the country. For the three months ended March 31, 2018, the Company incurred qualified R&D expenses of approximately \$86,000 resulting in an increase to the R&D rebate receivable of approximately \$38,000 from the December 31, 2017 balance, and a corresponding offset to R&D expenses in the same amount. At March 31, 2018, we had a total R&D rebate receivable of approximately \$396,000.

**NOTE 6: PAYROLL LIABILITIES**

Payroll liabilities consisted of the following:

	March 31, 2018	December 31, 2017
Accrued bonus payable	\$143,556	\$566,000
Accrued vacation	142,922	147,861
Accrued payroll liabilities	69,949	71,006
Total payroll liabilities	\$356,427	\$784,867

**NOTE 7: STOCKHOLDERS' EQUITY**

As of the date of this filing, the Company is authorized to issue a total of 185,000,000 shares of stock consisting of 175,000,000 shares of common stock, par value \$0.18 per share, and 10,000,000 shares of preferred stock, par value \$0.001 per share (Note 13). 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 March 31, 2018.



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.

**Outstanding Warrants**

As of March 31, 2018, warrants to purchase 914,777 shares of common stock were outstanding including:

	Outstanding Warrants to Purchase Shares	Exercise Price	Expiration Date
2011 private placement	23,623	\$225 - 288.00	May 8, 2018
2014 public offering	6,483	540.00	January 29, 2019
Placement agent fees for Company's offerings	1,331	381.60 – 1,044.00	May - November, 2018
2017 Warrant A private placement	441,670	3.78	August 22, 2018
2017 Warrant B private placement	441,670	3.78	December 22, 2018
	914,777		

**NOTE 8: NET LOSS PER SHARE**

The Company accounts for and discloses net income (loss) per common share in accordance with ASC Topic 260, *Earnings Per Share*. Basic net loss per common share is computed by dividing net loss attributable to common stockholders by the weighted average number of common shares outstanding. In addition, in computing the dilutive effect of convertible securities, the numerator is adjusted to add back any convertible preferred dividends. Diluted net loss per common share is computed by dividing net loss attributable to common stockholders by the weighted average number of common shares that would have been outstanding during the period assuming the issuance of common shares for all potential dilutive common shares outstanding. Potential common shares consist of 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 they have been excluded from the calculation.

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

	Three Months Ended March 31,	
	2018	2017
Net loss per share		
Numerator		
Net loss attributable to common shareholders	\$(1,874,382)	\$(1,703,554)
Denominator		
Weighted average common shares outstanding	2,651,952	315,576
Basic and diluted net loss per share	\$(0.71 )	\$(5.40 )



The following table sets forth the number of potential common shares excluded from the calculation of net loss per diluted share for the three months ended March 31, 2018 and 2017 because including them would be anti-dilutive:

	Three Months Ended March 31,	
	2018	2017
Options to purchase common stock	173,677	30,140
Warrants to purchase common stock	914,820	33,519
Total	1,088,497	63,659

For the three months ended March 31, 2018 and 2017, the average price of our common stock was less than the exercise price of the vested stock options and exercisable warrants.

#### **NOTE 9: INCOME TAXES**

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

As a result of the Company's cumulative losses, management has concluded that a full valuation allowance against the Company's net deferred tax assets is appropriate. No income tax liabilities existed as of March 31, 2018 and December 31, 2017 due to the Company's continuing operating losses.

#### **NOTE 10: CONCENTRATION OF CREDIT RISK**

Financial instruments that potentially subject the Company to concentration of credit risk consist principally of cash deposits. Accounts at each institution are insured by the Federal Deposit Insurance Corporation ("FDIC") up to \$250,000. At March 31, 2018 and December 31, 2017, the Company had \$4,529,519 and \$6,967,469 in excess of the FDIC insured limit, respectively.



## **NOTE 11: COMMITMENTS AND CONTINGENCIES**

### **Lease Commitments**

The Company has a commitment under an operating lease to pay future minimum lease payments of \$12,325, all of which is due in the year ending December 31, 2018.

### **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 March 23, 2018, the parties filed a stipulation of settlement with the court to settle the matter for \$3.5 million, completely funded by defendants' insurers, subject to the Court's approval. On April 13, 2018, the court entered an order preliminarily approving the settlement. A final approval hearing is set for July 20, 2018. We do not believe the ultimate resolution of this matter will have a material effect on our financial position, results of operations or cash flows.

We are subject to other legal proceedings and claims that arise in the normal course of business. We believe these matters are either without merit or of a kind that should not have a material effect, individually or in the aggregate, on our financial position, results of operations or cash flows.

**NOTE 12: 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 the ("2010 Plan") to provide for the grant of equity-based awards to employees, officers, non-employee directors and other key persons providing services to the Company. Awards of incentive options may be granted under the 2010 Plan until September 2020. No other awards may be granted under the 2010 Plan after the date that is 10 years from the date of stockholder approval. An aggregate of 5,556 shares were initially reserved for issuance in connection with awards granted under the 2010 Plan and on May 18, 2016, an additional 11,111 shares were reserved for issuance under the 2010 Plan. On May 9, 2017, the stockholders approved an additional 125,000 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:

January 1,	Number of shares
2012	2,502
2013	2,871
2014	4,128
2015	5,463
2016	18,368
2017	12,623

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2018	106,076
Total additional shares	152,031



The Company granted 1,667 options to purchase shares of common stock during the three months ended March 31, 2018. No options were exercised during the three months ended March 31, 2018. There are 112,780 shares available for grant under the 2010 Plan as of March 31, 2018.

Options issued and outstanding as of March 31, 2018 and their activities during the three months then ended are as follows:

	Number of Underlying Shares	Weighted- Average Exercise Price Per Share	Weighted- Average Contractual Life Remaining in Years	Aggregate Intrinsic Value
Outstanding as of January 1, 2018	172,474	\$ 49.22		\$
Granted	1,667	5.04		
Forfeited				
Expired				
Outstanding as of March 31, 2018	174,141	48.10	8.805	\$ 520
Exercisable as of March 31, 2018	66,453	112.18	8.304	\$ 0
Vested and expected to vest	174,141	\$ 48.10	8.805	\$ 520

At March 31, 2018, there were 107,688 unvested options outstanding and the related unrecognized total compensation cost associated with these options was approximately \$768,234. This expense is expected to be recognized over a weighted-average period of 2.0 years.

### NOTE 13: SUBSEQUENT EVENTS

On April 20, 2018 an amendment to the Company's Amended and Restated Certificate of Incorporation (the "Amended Certificate") became effective to effectuate a reverse split of Atossa's common stock and to increase the authorized shares of common stock by 100 million to 175 million. The Amended Certificate provides that each 12 shares of outstanding common stock will be reconstituted into one share of common stock with a proportional increase in the par value of the common stock. Any resulting fractional shares were rounded up to the nearest whole share. All share and per share data included in this report has been retroactively restated to reflect the Reverse Stock Split.

On April 12, 2018, the Company held its 2018 Annual Meeting of Stockholders (the "Annual Meeting"). At the Annual Meeting, the shareholders approved an increase to authorized shares under Atossa Genetics 2010 Stock Option and

Incentive Plan by 500,000 shares.

## 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 ("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;

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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 a breast disorder in men called gynecomastia; and an oral formulation for breast cancer survivors who do not benefit from taking oral tamoxifen, a current FDA-approved standard of care. We are also developing our patented intraductal microcatheter technology to potentially target the delivery of therapies, including fulvestrant, immunotherapies and Chimeric Antigen Receptor T-cell therapies (CAR-T therapies), directly to the site of breast cancer.

In 2017, we completed a Phase 1 clinical study of our proprietary oral and topical formulations of Endoxifen. All objectives were met: 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, low but measurable Endoxifen levels were detected in the blood in a dose-dependent fashion. In the oral arm of the study, participants exhibited dose-dependent Endoxifen levels that met or exceeded the published therapeutic level. The median time for patients in the study to reach the steady-state serum levels of Endoxifen while taking daily doses of oral Endoxifen was 7 days. Published literature indicates that it takes approximately 50-200 days for patients to reach steady-state Endoxifen levels when taking daily doses of oral tamoxifen.

We are currently conducting a Phase 2 study at Montefiore Medical Center, Bronx, New York, using our intraductal microcatheter technology to deliver fulvestrant. Our program to use our intraductal microcatheters to deliver CAR-T and other immunotherapies is in the research and development phase.

In March 2018, we expanded our breast health program by launching a mens’ breast health initiative with enrollment opening in a Phase 1 study of our topical Endoxifen in men. The objectives of the placebo-controlled, repeat dose study of 24 healthy male volunteers are to assess the pharmacokinetics of proprietary topical Endoxifen dosage forms over 28 days, as well as to assess safety and tolerability. Depending on the results of this study, we plan to develop our

topical Endoxifen for gynecomastia.

We plan to open enrollment in two Phase 2 studies of our proprietary Endoxifen in the first half of 2018: a study in Stockholm, Sweden using our topical Endoxifen to treat MBD and a study of our oral Endoxifen to treat patients who do not benefit from taking tamoxifen. We expect to complete enrollment in these studies in the second half of 2018.

Our key objectives are to advance our programs through Phase 2 trials and then evaluate further development independently or with partners.

### **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 for the year ended December 31, 2017, 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, 2017. Readers are encouraged to review these disclosures in conjunction with the review of this report.

### **Results of Operations**

#### **Three Months Ended March 31, 2018 and 2017**

*Operating Expenses:* Total operating expenses were approximately \$1.9 million and \$1.7 million for the three months ended March 31, 2018 and 2017, respectively, consisting of general and administrative (G&A) expenses of approximately \$1.4 million and \$1.2 million, respectively, and research and development (R&D) expenses of approximately \$0.5 million in each period.

Total operating expenses for the three months ended March 31, 2018 as compared to the same period of 2017 increased approximately \$0.2 million or 11.8%.

*Research and Development Expenses:* R&D expenses for the three months ended March 31, 2018 were approximately \$471,000, a decrease of approximately \$73,000, or 13.5% from approximately \$544,000 for the same period in 2017. R&D expenses consist of salaries, manufacturing and clinical trial expenses associated with our Endoxifen and Fulvestrant microcatheter programs. We expect our R&D expenses to increase throughout 2018 as we continue our Phase 1 study of Endoxifen in male subjects and as we begin our Phase 2 Endoxifen clinical studies.

*General and Administrative Expenses:* G&A expenses for the three months ended March 31, 2018 were approximately \$1,404,000, an increase of \$244,000 or 21.1%, from approximately \$1,159,000, for the same period in 2017. G&A expenses consist primarily of personnel and related benefit costs, facilities, professional services, insurance, and public company related expenses. The increase in G&A expense is primarily attributable to increased patent costs and investor relations activities.

## **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 three months ended March 31, 2018, the Company recorded a net loss of approximately \$1.9 million, and used approximately \$2.4 million of cash in operating activities. As of March 31, 2018, the Company had approximately \$4.8 million in cash and cash equivalents and working capital of approximately \$5.0 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, without giving effect to the rights offering described below, we expect that our existing resources will be sufficient to fund our planned operations for the next five to eight months; however, additional capital resources will be needed to fund operations longer-term.

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.

On March 27, 2018, we filed a Registration Statement on Form S-1 with the Securities and Exchange Commission to offer subscription rights to purchase up to 25,000 units consisting of convertible preferred and warrants. Subsequent to the end of the three months ended March 31, 2018 but prior to filing this Quarterly Report on Form 10-Q, the Registration Statement was amended by Amendment No. 1 dated April 23, 2018 and Amendment No. 2 dated May 3, 2018, and was declared effective on May 9, 2018. If the rights offering is fully subscribed, we estimate it will generate net proceeds of approximately \$23 million.

## **Cash Flows**

As of March 31, 2018 the Company had cash and cash equivalents of \$4.8 million.

*Net Cash Flows from Operating Activities:* Net cash used in operating activities was approximately \$2.4 million for the three months ended March 31, 2018, compared with approximately \$1.9 million for the three months ended March 31, 2017. We spent approximately \$1.4 million on general and administrative expenses for the three month period ended March 31, 2018, compared to \$1.2 million for the same period in 2017; this increase was due to higher patent and investor relations activity.

*Net Cash Flows from Investing Activities:* There was \$51,000 net cash used in investing activities for the three months ended March 31, 2018 as compared no cash used for investing activities in the same period of 2017. The increase in 2018 was attributable to purchases of research and development equipment in 2018. There were no corresponding purchases for the three months ending March 31, 2017.

### **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 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 GAAP. The new standard takes effect in 2019 for public business entities. The Company has not adopted the provisions of ASU No. 2016-02 and is currently evaluating the impact of adopting ASU 2016-02 on its consolidated financial statements.

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 Company adopted the provisions of ASU No. 2016-18 as of January 1, 2018 and it did not 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 March 31, 2018. 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 March 31, 2018, the Company's disclosure controls and procedures were effective at the reasonable assurance level.

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the quarter ended March 31, 2018 that has materially affected, or is reasonably likely to materially affect our disclosure controls and procedures.

## **PART II OTHER INFORMATION**

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

#### **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 March 23, 2018, the parties filed a stipulation of settlement with the court to settle the matter for \$3.5 million, completely funded by defendants' insurers, subject to the Court's approval. On April 13, 2018, the court entered an order preliminarily approving the settlement. A final approval hearing is set for July 20, 2018. We do not believe the ultimate resolution of this matter will have a material effect on our financial position, results of operations or cash flows.

We are subject to other legal proceedings and claims that arise in the normal course of business. We believe these matters are either without merit or of a kind that should not have a material effect, individually or in the aggregate, on our financial position, results of operations or cash flows.

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



There have been no material changes to the risk factors described in our Annual Report on Form 10-K, as filed with the SEC on March 8, 2018.

**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**

Not applicable.

**ITEM 6. EXHIBITS**

(a) Exhibits

<b>Exhibit No.</b>	<b>Description</b>	<b>Incorporated by Reference Herein Form</b>	<b>Date</b>
<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	



## SIGNATURES

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

Date: May 14, 2018

/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)