ATOSSA GENETICS INC
Form 10-Q
November 14, 2018

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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, 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)

Delaware	**26-4753208**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer 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, every Interactive Data File required to be submitted 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 such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	Accelerated filer	Non-accelerated filer	Smaller reporting company	Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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, $0.18 par value per share, outstanding at November 9, 2018 was 5,646,552.

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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)

	September 30, 2018	December 31, 2017
Assets		
Current assets		
Cash and cash equivalents	$12,935,587	$7,217,469
Restricted cash	55,000	55,000
Prepaid expenses	290,331	250,944
Research and development tax rebate receivable	480,495	358,277
Other current assets	161,530	16,344
Total current assets	13,922,943	7,898,034
Furniture and equipment, net	57,804	11,467
Intangible assets, net	55,107	75,686
Other assets	88,518	178,907
Total Assets	$14,124,372	$8,164,094
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$550,704	$334,901
Accrued expenses	51,673	90,105
Payroll liabilities	706,150	784,867
Stock-based compensation liability	2,180,659	
Other current liabilities	66,077	15,534
Total Current Liabilities	3,555,263	1,225,407
Commitments and contingencies (note 11)		
Stockholders' equity		
Preferred stock - $0.001 par value; 10,000,000 shares authorized, consisting of Series A convertible preferred stock- $0.001 par value; 4,000 shares authorized, and 0 shares outstanding as of September 30, 2018 and December 31, 2017; Series B convertible preferred stock- $0.001 par value; 25,000 and 0 shares authorized, and 3,517 and 0 shares issued and outstanding as of September 30, 2018 and December 31, 2017,	4	

respectively		
Additional paid-in capital- Series B convertible preferred stock	3,516,996	
Common stock - $0.18 par value; 175,000,000 shares authorized, and 5,523,255 and 2,651,952 shares issued and outstanding, as of September 30, 2018 and December 31, 2017, respectively	994,175	477,342
Additional paid-in capital	80,811,088	71,887,674
Accumulated deficit	(74,753,154)	(65,426,329)
Total Stockholders' Equity	10,569,109	6,938,687
Total Liabilities and Stockholders' Equity	$14,124,372	$8,164,094

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

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ATOSSA GENETICS INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(UNAUDITED)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2018	2017	2018	2017
Operating Expenses				
Research and development	$1,421,851	$742,450	$3,360,563	$2,110,846
General and administrative	1,888,119	1,313,477	5,966,504	3,544,935
Total operating expenses	3,309,970	2,055,927	9,327,067	5,655,781
Operating loss	(3,309,970)	(2,055,927)	(9,327,067)	(5,655,781)
Change in fair value of common stock warrants		(128,300)		(280,747)
Warrant financing expense				(192,817)
Other income (expense)	104	(283)	242	(208)
Loss before income taxes	(3,309,866)	(2,184,510)	(9,326,825)	(6,129,553)
Income taxes				
Net loss	$(3,309,866)	$(2,184,510)	$(9,326,825)	$(6,129,553)
Deemed Dividend attributable to preferred stock			(11,479,308)	(2,568,132)
Net loss applicable to common shareholders	$(3,309,866)	$(2,184,510)	$(20,806,133)	$(8,697,685)
Loss per common share - basic and diluted	$(0.64)	$(2.11)	$(5.71)	$(13.23)
Weighted average shares outstanding - basic and diluted	5,183,492	1,034,262	3,645,682	657,184

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

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ATOSSA GENETICS INC.

CONDENSED CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY

(UNAUDITED)

	Series B Convertible Preferred Stock			Common Stock				
	Shares	Amount	Additional Paid-in Capital	Shares	Amount	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
Balance at December 31, 2017		$	$	2,651,952	$477,342	$71,887,674	$(65,426,329)	$6,938,687
Issuance of Series B convertible preferred stock and warrants, net of issuance costs of $1,333,449	13,624	14	6,926,778			5,363,759		12,290,551
Allocation of Series B convertible preferred stock proceeds to beneficial conversion feature			(4,782,100)			4,782,100		
Deemed Dividend on Series B convertible preferred stock			11,479,308			(11,479,308)		
Conversion of Series B convertible	(10,107)	(10)	(10,106,990)	2,871,303	516,833	9,590,167		

preferred stock to common stock								
Amortization of commitment shares						(59,556)		(59,556)
Compensation cost for stock options granted to executives and employees						726,252		726,252
Net loss							(9,326,825)	(9,326,825)
Balance at September 30, 2018	3,517	$4	$3,516,996	5,523,255	$994,175	$80,811,088	$(74,753,154)	$10,569,109

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

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ATOSSA GENETICS INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(UNAUDITED)

	For the Nine Months Ended September 30,	
	2018	**2017**
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$(9,326,825)	$(6,129,553)
Adjustments to reconcile net loss to net cash used in operating activities		
Compensation cost for stock options granted	726,252	560,369
Loss on disposal of assets		17,695
Depreciation and amortization	28,690	102,074
Change in fair value of common stock warrants		280,747
Change in stock-based compensation liability	2,180,659	
Warrant financing expense		192,817
Changes in operating assets and liabilities:		
Prepaid expenses	(39,387)	14,195
Research and development tax rebate receivable	(122,218)	
Other assets	(114,353)	25,831
Accounts payable	215,803	126,079
Payroll liabilities	(78,717)	(142,312)
Accrued expenses	(38,432)	33,578
Other current liabilities	50,543	7,212
Net cash used in operating activities	(6,517,985)	(4,911,268)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of furniture, fixtures and equipment	(54,448)	
Net cash used in investing activities	(54,448)	
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceed from issuance of Series B convertible preferred stock and warrants, net of issuance costs	12,290,551	
Proceeds from issuance of Class A and Class B Units, net of issuance costs		3,871,636
Proceeds from exercise of warrants		745,333
Net cash provided by financing activities	12,290,551	4,616,969
NET INCREASE (DECREASE) IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH	5,718,118	(294,299)
CASH, CASH EQUIVALENTS AND RESTRICTED CASH, BEGINNING BALANCE	7,272,469	3,082,962

CASH, CASH EQUIVALENTS AND RESTRICTED CASH, ENDING BALANCE	$12,990,587	$2,788,663
NONCASH INVESTING AND FINANCING ACTIVITIES		
Reclassification of warrant liability upon exercise of common stock warrants	$	$1,893,160
Amount receivable for warrant exercise		3,900
Allocation of Class A and Class B Unit proceeds to warrant liability		1,612,413
Amortization of commitment shares issued for shares distributed for capital contribution	$59,556	$59,558

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

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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, 2018, the Company recorded a net loss of approximately $9.3 million and used approximately $6.5 million of cash in operating activities. As of September 30, 2018, the Company had approximately $12.9 million in cash and cash equivalents and working capital of approximately $10.4 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 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, entering into strategic partnership arrangements, 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, we expect that our existing resources will be sufficient to fund our planned operations for the next 9 to 15 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.

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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 nine months ended September 30, 2018 are not necessarily indicative of the results that may be expected for the year ending December 31, 2018.

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. 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 entities. The Company has not currently adopted the provisions of ASU No. 2016-02 and believes that the impact of adopting ASU 2016-02 will not be material to its consolidated financial statements, though will require the recognition of an operating lease liability and right-of-use asset upon adoption, based on the lease composition disclosed in Footnote 11.

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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 has included restricted cash with cash and cash equivalents on the accompanying statement of cash flows, including reclassifying 2017 balances. For the three and nine months ended September 30, 2018 and September 30, 2017, we included $55,000 of restricted cash in cash and cash equivalents on the statement of cash flows. 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 early adopted the provisions of ASU No. 2017-11 as of January 1, 2018. As the Company does not have any financial instruments with down round features, this ASU did not have a material impact on the financial statements upon adoption.

In June 2018, the FASB issued ASU 2018-07, *Compensation-Stock Compensation Improvements to Nonemployee Share Based Payment Accounting.* This ASU simplifies several aspects of the accounting for non-employee share-based payment transactions resulting from expanding the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. An entity should apply the requirements of Topic 718 to nonemployee awards except for specific guidance on inputs to an option pricing model and the attribution of cost. The amendments also clarify that Topic 718 does not apply to share-based payments used to effectively provide financing to the issuer or was granted in conjunction with selling goods or services to customers as part of a contract accounted for under Topic 606, *Revenue from Contracts with Customers*. This update is effective for public entities for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year. Early adoption is permitted. The Company early adopted the provisions of ASU No. 2018-17 as of April 1, 2018 and it did not have a material impact on the financial statements upon adoption.

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NOTE 4: PREPAID EXPENSES

Prepaid expenses consisted of the following:

	September 30, 2018	December 31, 2017
Prepaid insurance	$ 46,618	$ 125,056
Retainer and security deposits	16,718	14,218
Professional services	93,557	97,788
Prepaid research and development	104,299	
Financial exchange fees	13,750	
Other	15,389	13,882
	$ 290,331	$ 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 nine months ended September 30, 2018, the Company incurred qualified R&D expenses of approximately $764,000 and recorded a rebate receivable of approximately $333,000 and a corresponding credit to R&D expenses for the nine months ended September 30, 2018. At September 30, 2018, we had a total R&D rebate receivable of approximately $481,000 that includes approximately $148,000 receivable remaining from the year ended December 31, 2017.

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NOTE 6: PAYROLL LIABILITIES

Payroll liabilities consisted of the following:

	September 30, 2018	December 31, 2017
Accrued bonus payable	$ 480,917	$ 566,000
Accrued vacation	156,775	147,861
Accrued payroll liabilities	68,458	71,006
Total payroll liabilities	$ 706,150	$ 784,867

NOTE 7: STOCKHOLDERS' EQUITY

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. The Company has designated 750,000 shares of Series A junior participating preferred stock, par value $0.001 per share, 4,000 shares of Series A convertible preferred stock, par value $0.001 per share, and 25,000 shares of Series B convertible preferred stock, par value $0.001 per share, through the filings of certificates of designation with the Delaware Secretary of State. No shares of Series A junior participating preferred stock and no shares of Series A convertible preferred stock are issued and outstanding as of September 30, 2018.

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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.

2018 Subscription Rights Offering of Units Consisting of Series B Convertible Preferred Stock and Warrants

On May 9, 2018, the Company's Registration Statement on Form S-1 with the Securities and Exchange Commission was declared effective to offer subscription rights to purchase up to 25,000 units at $1,000 per unit with each unit consisting of one share of Series B convertible preferred stock and warrants to purchase 284 shares of common stock.

On May 29, 2018, the Company filed a Certificate of Designation of Preferences, Rights and Limitations of Series B convertible preferred stock with the Delaware Secretary of State creating a new series of its authorized preferred stock, par value $0.001 per share, designated as the Series B convertible preferred stock. The number of shares initially constituting the Series B preferred stock was set at 25,000 shares.

On May 30, 2018, the Company completed its previously announced rights offering pursuant to which the Company sold an aggregate of 13,624 units consisting of an aggregate of 13,624 shares of Series B convertible preferred stock and 3,869,216 warrants, with each warrant exercisable for one share of common stock at an exercise price of $4.048 per share (the "2018 Warrants"), resulting in net proceeds to the Company of approximately $12.3 million, after deducting expenses relating to the rights offering, including dealer-manager fees and expenses, and excluding any proceeds received upon exercise of any warrants.

Series B Convertible Preferred Stock.

The terms and provisions of our Series B convertible preferred stock are:

Conversion. Each share of Series B convertible preferred stock is convertible at our option at any time on or after the first anniversary of the closing of the rights offering or at the option of the holder at any time, into the number of shares of our common stock determined by dividing the $1,000 stated value per share of the Series B convertible preferred stock by a conversion price of $3.52 per share. In addition, the conversion price per share is subject to adjustment for stock dividends, distributions, subdivisions, combinations or reclassifications. Subject to limited exceptions, a holder of the Series B convertible preferred stock will not have the right to convert any portion of the Series B convertible preferred stock to the extent that, after giving effect to the conversion, the holder, together with its affiliates, would beneficially own in excess of 9.99% of the number of shares of our common stock outstanding immediately after giving effect to its conversion.

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Fundamental Transactions. In the event we effect certain mergers, consolidations, sales of substantially all of our assets, tender or exchange offers, reclassifications or share exchanges in which our common stock is effectively converted into or exchanged for other securities, cash or property, we consummate a business combination in which another person acquires 50% of the outstanding shares of our common stock, or any person or group becomes the beneficial owner of 50% of the aggregate ordinary voting power represented by our issued and outstanding common stock, then, upon any subsequent conversion of the Series B convertible preferred stock, the holders of the Series B convertible preferred stock will have the right to receive any shares of the acquiring corporation or other consideration it would have been entitled to receive if it had been a holder of the number of shares of common stock then issuable upon conversion in full of the Series B convertible preferred stock.

Dividends. Holders of Series B convertible preferred stock shall be entitled to receive dividends (on an as-if-converted-to-common-stock basis) in the same form as dividends actually paid on shares of the common stock when, as and if such dividends are paid on shares of common stock.

Voting Rights. Except as otherwise provided in the certificate of designation or as otherwise required by law, the Series B convertible preferred stock has no voting rights.

Liquidation Preference. Upon our liquidation, dissolution or winding-up, whether voluntary or involuntary, holders of Series B convertible preferred stock will be entitled to receive out of our assets, whether capital or surplus, the same amount that a holder of common stock would receive if the Series B convertible preferred stock were fully converted (disregarding for such purpose any conversion limitations under the certificate of designation) to common stock, which amounts shall be paid pari passu with all holders of common stock.

Redemption Rights. We are not obligated to redeem or repurchase any shares of Series B convertible preferred stock. Shares of Series B convertible preferred stock are not otherwise entitled to any redemption rights, or mandatory sinking fund or analogous provisions.

2018 Warrants

The terms and conditions of the warrants included in the 2018 rights offering are as follows:

Exercisability. Each warrant is exercisable at any time and will expire four years from the date of issuance. The warrants are exercisable, at the option of each holder, in whole or in part by delivering to us a duly executed exercise notice and payment in full for the number of shares of our common stock purchased upon such exercise, except in the

case of a cashless exercise as discussed below.

The number of shares of common stock issuable upon exercise of the warrants is subject to adjustment in certain circumstances, including a stock split of, stock dividend on, or a subdivision, combination or recapitalization of the common stock. Upon the merger, consolidation, sale of substantially all of our assets, or other similar transaction, the holders of warrants shall, at the option of the company, be required to exercise the warrants immediately prior to the closing of the transaction, or such warrants shall automatically expire. Upon such exercise, the holders of warrants shall participate on the same basis as the holders of common stock in connection with the transaction.

Cashless Exercise. If at any time there is no effective registration statement registering, or the prospectus contained therein is not available for issuance of, the shares issuable upon exercise of the warrant, the holder may exercise the warrant on a cashless basis. When exercised on a cashless basis, a portion of the warrant is cancelled in payment of the purchase price payable in respect of the number of shares of our common stock purchasable upon such exercise.

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Exercise Price. Each warrant represents the right to purchase one share of common stock at an exercise price of $4.048 per share. In addition, the exercise price per share is subject to adjustment for stock dividends, distributions, subdivisions, combinations, or reclassifications, and for certain dilutive issuances. Subject to limited exceptions, a holder of warrants will not have the right to exercise any portion of the warrant to the extent that, after giving effect to the exercise, the holder, together with its affiliates, and any other person acting as a group together with the holder or any of its affiliates, would beneficially own in excess of 4.99% of the number of shares of our common stock outstanding immediately after giving effect to its exercise. The holder, upon notice to the Company, may increase or decrease the beneficial ownership limitation provisions of the warrant, provided that in no event shall the limitation exceed 9.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise of the warrant.

Transferability. Subject to applicable laws and restrictions, a holder may transfer a warrant upon surrender of the warrant to us with a completed and signed assignment in the form attached to the warrant. The transferring holder will be responsible for any tax that liability that may arise as a result of the transfer.

Exchange Listing. We do not intend to apply to list the warrants on any securities exchange or recognized trading system.

Rights as Stockholder. Except as set forth in the warrant, the holder of a warrant, solely in such holder's capacity as a holder of a warrant, will not be entitled to vote, to receive dividends, or to any of the other rights of our stockholders.

Redemption Rights. We may redeem the warrants for $0.18 per warrant if the volume-weighted-average-price of our common stock equals or exceeds $10.56 per share for ten consecutive trading days, provided that we may not do so prior to the first anniversary of closing of the rights offering.

Accounting Treatment

The Company allocated the proceeds from the sale of the Series B convertible preferred stock and the warrants to purchase common stock to the separate securities issued. The Company allocated the amount representing the fair value of the warrants at the date of issuance to common stock based on the relative warrant fair value in the amount of $5,363,759, which is net of issuance costs allocated to the warrants. Due to the allocation of a portion of the proceeds to the warrants, the convertible preferred stock contained a beneficial conversion feature upon issuance, which was recorded in the amount of $4,782,100 based on the relative fair value of the beneficial conversion feature. The discount on the convertible preferred stock was $11,479,308, which consists of the beneficial conversion feature of $4,782,100, the allocation of a portion of the proceeds to the warrants in the amount of $5,363,759, and the total issuance costs related to the financing of $1,333,449. The discount on the convertible preferred stock of $11,479,308 was recorded as a deemed dividend upon issuance of the convertible preferred stock. The deemed dividend is reflected as an addition to net loss in the condensed consolidated statements of operations to arrive at net loss applicable to

common shareholders. The Company has made an accounting policy election to record the deemed dividend related to discounts on convertible instruments at the time of issuance of the convertible instruments.

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Outstanding Warrants

As of September 30, 2018, warrants to purchase 4,318,475 shares of common stock were outstanding including:

	Outstanding Warrants to Purchase Shares	Exercise Price	Expiration Date
2014 public offering	6,483	$540.00	January 29, 2019
Placement agent fees for Company's offerings	1,106	381.60 – 540.00	November 4, 2018
2017 Warrant B private placement	441,670	3.78	December 22, 2018
2018 Warrants	3,869,216	4.05	May 30, 2022
	4,318,475		

Conversion of Series B Convertible Preferred Stock

During the three and nine months ended September 30, 2018, certain holders of the Series B convertible preferred stock exercised their conversion option and converted an aggregate of 2,285 and 10,107 shares, respectively, into 649,156 and 2,871,303 shares, respectively, of the Company's common stock based on the conversion ratio of approximately 284 shares of common stock for each share of Series B convertible preferred stock.

NOTE 8: NET LOSS PER SHARE

The Company accounts for and discloses net income (loss) per common share in accordance with Accounting Standards Codification ("ASC") Topic 260, *Earnings Per Share*. Basic net loss per common share is computed by dividing net loss attributable to common stockholders by the weighted average number of common shares outstanding. 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 September 30,		Nine months Ended September 30,	
	2018	**2017**	**2018**	**2017**
Net Loss Per Share				
Numerator				
Net loss	$(3,309,866)	$(2,184,510)	$(9,326,825)	$(6,129,553)
Deemed dividend attributable to preferred stock			(11,479,308)	(2,568,132)
Net loss attributable to common shareholders	$(3,309,866)	$(2,184,510)	$(20,806,133)	$(8,697,685)
Denominator				
Weighted average common shares outstanding	5,183,492	1,034,262	3,645,682	657,184
Basic and diluted net loss per share	$(0.64)	$(2.11)	$(5.71)	$(13.23)

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The following table sets forth the number of potential common shares excluded from the calculation of net loss per diluted share for the three and nine months ended September 30, 2018 and 2017 because including them would be anti-dilutive:

	Three Months Ended September 30,		Nine months Ended September 30,	
	2018	2017	2018	2017
Options to purchase common stock	783,794	176,502	388,377	100,505
Series A convertible preferred stock		42,480		74,651
Series B convertible preferred stock	1,338,916		751,332	
Warrants to purchase common stock	4,716,935	138,365	2,644,946	227,229
Total	6,839,645	357,347	3,784,655	402,385

For the three and nine months ended September 30, 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 September 30, 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 September 30, 2018 and December 31, 2017, the Company had $12,685,587 and $6,967,469 in excess of the FDIC insured limit, respectively.

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NOTE 11: COMMITMENTS AND CONTINGENCIES

Lease Commitments

On November 1, 2018, the Company entered into an operating lease to pay $3,660 monthly rent for a term of 22 months. The total future minimum lease payments due under this lease are $80,500.

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 unspecific amount.

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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, and on July 20, 2018 the Court approved the settlement. This case is considered closed as of September 30, 2018.

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 Option 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 stock-holder 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. On April 12, 2018, the stockholders approved an additional 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:

January 1,	**Number of shares**
2012	2,502
2013	2,871
2014	4,128
2015	5,463
2016	18,368
2017	12,623
2018	106,076

Total additional shares 152,031

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The Company did not grant options to purchase shares of common stock during the three months ended September 30, 2018 or 2017. No options were exercised during the three or nine months ended September 30, 2018. There are 3,197 shares available for grant under the 2010 Plan as of September 30, 2018.

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 $332,063 and $224,254 for the three months ended September 30, 2018 and 2017, respectively and $726,252 and $560,369 for the nine months ended September 30, 2018 and 2017, respectively (excluding the liability options discussed below).

Options issued and outstanding as of September 30, 2018 under the 2010 Plan and their activities during the nine 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	172,510	$ 49.27		$
Granted	611,668	2.39		
Forfeited	(417)	5.64		
Expired				
Outstanding as of September 30, 2018	783,761	12.70	9.42	$
Exercisable as of September 30, 2018	199,949	40.62	8.95	$
Vested and expected to vest	783,761	12.70	9.42	$

At September 30, 2018, there were 583,812 unvested options outstanding and the related unrecognized total compensation cost associated with these options was approximately $1,479,610. This expense is expected to be recognized over a weighted-average period of 1.56 years.

Option Grants Classified as Liabilities ("Liability Grants")

On June 27, 2018, the Company granted 2,300,000 options to the Chief Executive Officer and 700,000 to the Chief Financial Officer. Each option is exercisable for an equivalent number of shares of Company common stock. The options were granted pursuant to an option award agreement and were granted outside the Company's 2010 Plan; however, they are subject to the terms and conditions of the 2010 Plan.

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The Liability Grants are exercisable for shares of common stock at an exercise price of $2.38 per share, which was the fair market value on the date of grant. The options have an exercise period of ten years from their date of issuance. If at the time the options are exercised the Company cannot deliver shares of common stock to the optionee including, for example, if there are insufficient shares available under the Plan at the time of exercise, then in lieu of the optionee paying the exercise price and the Company issuing shares of stock, the option may only be exercised on a cash "net basis" so that the Company will pay cash in an amount equal to the excess of the fair market value of the common stock over the option exercise price. There currently are not sufficient shares available under the Plan and the Company would be obligated to settle these options in cash if they were exercised. Because these options contain provisions that could require the Company to settle the options in cash in an event outside the Company's control, they are accounted for as liabilities.

The Liability Grants are subject to vesting requirements. Twenty-five percent of the options have vested as of the grant date, 50% of the options will vest quarterly over two years, and the remaining 25% vest upon achievement of certain milestones related to clinical trial progress. As of September 30 2018, 80% of the options that vest upon achievement of clinical trial milestones are vested.

Compensation costs associated with the Liability Grants are initially recognized, based on the grant-date fair values of these options, over the requisite or vesting period for time-based options or when it is probable the performance criteria will be achieved for options that vest based on performance. Compensation cost is remeasured each period based on the market value of our underlying stock until award vesting or settlement.

For the three and nine months ended September 30, 2018, the Company recognized compensation expense related to these options of $623,496 and $2,180,659, respectively.

The fair value of liability options granted for the nine months ended September 30, 2018 was calculated using the Black-Scholes option-pricing model applying the following assumptions:

	Nine months ended September 30, 2018	
Risk free interest rate	2.94	%
Expected term (in years)	4.75	
Stock price	$1.75	
Dividend yield		%
Expected volatility	122.0	%

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NOTE 13: RESTATEMENT TO PREVIOUSLY ISSUED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

The Company has corrected an inadvertent error in the calculation of the deemed dividend on Series B convertible preferred stock in the financial statements for the three and six months ended June 30, 2018 that were included in the Company's Form 10-Q filed on August 13, 2018 (the "Original Form 10-Q"). Accounting principles generally accepted in the United States of America require that we allocate the proceeds from the May 2018 financing to the warrants and preferred stock issued in the financing and that we estimate and record any discount on the securities as a deemed dividend. In the financial statements included in the Original Form 10-Q, we did not properly allocate the proceeds to the warrants, and we did not properly record the deemed dividend related to the warrant discount as additional paid in capital to common stock. The Company incorrectly stated the deemed dividend for the three and six months ended June 30, 2018 as $4,782,100, rather than $11,479,308. The corrections result from application of technical accounting rules and do not impact cash or operations.

In accordance with applicable generally accepted accounting principles, the Company has calculated and recognized adjustments accordingly. The following table shows the effect of the restatement on certain line items within the Company's Condensed Consolidated Statement of Operations for the three months and six months ended June 30, 2018:

	For the Three Months Ended June 30, 2018		For the Six Months Ended June 30, 2018	
	Previously Reported	Restated	Previously Reported	Restated
Deemed dividend attributable to preferred stock	$(4,782,100)	$(11,479,308)	$(4,782,100)	$(11,479,308)
Net loss applicable to common stockholders	$(8,924,677)	$(15,621,885)	$(10,799,059)	$(17,496,267)
Loss per common share -basic and diluted	$(2.90)	$(5.08)	$(3.77)	$(6.11)

The following table shows the effect of the restatement on certain line items within the Company's Condensed Consolidated Statement of Stockholders' Equity for the six months ended June 30, 2018:

	Preferred Stock Additional Paid-in Capital		Common Stock Additional Paid-in Capital	
	Previously Reported	Restated	Previously Reported	Restated

Issuance of Series B convertible preferred stock, net of issuance costs	$12,290,537	$6,926,778	$0	$5,363,759
Deemed Dividend on Series B convertible preferred stock	$4,782,100	$11,479,308	$(4,782,100)	$(11,479,308)
Conversion of Series B convertible preferred stock to common stock	$(7,056,421)	$(7,821,992)	$6,656,442	$7,422,013

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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 microcatheter technology 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 and other studies 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 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.

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Company Overview

We are a clinical-stage biopharmaceutical 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 to treat stage 1 or 2 breast cancer in the "window of opportunity" between diagnosis and surgery and 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 placebo-controlled clinical study of our proprietary oral and topical formulations of Endoxifen in 48 healthy women. 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. In September 2018, we completed a Phase 1 placebo-controlled clinical study of our proprietary topical Endoxifen in 24 healthy men. Preliminary results from that study indicate that all of our objectives of safety, tolerability and pharmakinetics were successfully met. Based on these positive preliminary results, we are advancing our topical Endoxifen into a Phase 2 study to reduce gynecomastia and/or improve quality of life in men starting prostate cancer therapy.

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.

We are currently conducting two Phase 2 studies of our proprietary Endoxifen: one in Stockholm, Sweden using our topical Endoxifen for MBD and another in Australia using our oral Endoxifen for patients in the window of opportunity between diagnosis of breast cancer and surgery. In October 2018, the MBD study in Sweden was fully-enrolled with all 90 participants: 60 participants on two different dose levels and 30 participants on placebo. Some participants have reported skin rashes and irritation and have withdrawn from the study. Skin reactions were also reported in the Phase 1 studies of the same product. We are evaluating approaches to reduce skin reactions and maximize participation in the study; however, additional study participants could experience these and other more serious side effects and the study may not be successfully completed for these or other reasons.

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.

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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 and Nine months Ended September 30, 2018 and 2017

Revenue and Cost of Revenue:

For the three and nine months ended September 30, 2018 and 2017, we had no revenue and no associated cost of revenue.

Operating Expenses: Total operating expenses were approximately $3.3 million and $9.3 million for the three and nine months ended September 30, 2018, respectively, consisting of research and development (R&D) expenses of approximately $1.4 million and $3.4 million, respectively, and general and administrative (G&A) expenses of approximately $1.9 million and $6.0 million, respectively. Total operating expenses were approximately $2.1 million and $5.7 million for the three and nine months ended September 30, 2017, respectively, consisting of R&D expenses of $0.7 million and $2.1 million, respectively, and G&A expense of approximately $1.3 million and $3.5 million, respectively.

Total operating expenses for the three and nine months ended September 30, 2018 as compared to the same periods of 2017 increased approximately $1.3 million, or 61%, and increased $3.7 million, or 65%, respectively.

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Research and Development Expenses: R&D expenses for the three months ended September 30, 2018 were approximately $1,422,000, an increase of $680,000, or 92%, from approximately $742,000, for the same period in 2017. R&D expenses for the nine months ended September 30, 2018 were approximately $3,361,000, an increase of $1,250,000 or 59%, from approximately $2,111,000 for the same period in 2017. The increase in R&D expenses is mainly attributable to an increase in stock-based compensation expense. R&D expenses primarily consist of salaries, manufacturing and clinical trial expenses associated with our Endoxifen program. Our R&D expenses have increased over the same periods in 2017 because of a 2018 increase in stock-based compensation of $0.9 million and because we commenced two Phase 2 studies of our proprietary Endoxifen in 2018 (one of which enrollment was fully completed in 2018) as compared to no Phase 2 studies of Endoxifen in the prior year.

General and Administrative Expenses: G&A expenses for the three months ended September 30, 2018 were approximately $1,888,000, an increase of $575,000 or 44%, from approximately $1,313,000, for the same period in 2017. G&A expenses for the nine months ended September 30, 2018 were approximately $5,967,000, an increase of $2,422,000 or 68%, from approximately $3,545,000 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 expenses for the nine months ended September 30, 2018 is mainly attributed to an increase in stock-based compensation expense of $1.4 million, payroll expenses resulting from salary increases, bonus payments of $350,000 and increased legal and professional consulting expenses of $550,000 over the prior year.

Warrant Financing Costs and Change in Fair Value of Common Stock Warrants: The April 2017 financing included the issuance of common stock liability warrants. The Company incurred financing costs associated with these common stock liability warrants of $192,817 upon issuance. The Company also recorded changes in the fair value of the liability warrants during the three months and nine months ended September 30, 2017 of $128,300 and $280,747, respectively. There were no common stock liability warrants issued during the three and nine months ended September 30, 2018.

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, 2018, the Company recorded a net loss of approximately $9.3 million, and used approximately $6.5 million of cash in operating activities. As of September 30, 2018, the Company had approximately $12.9 million in cash and cash equivalents and working capital of approximately $10.4 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.

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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 9 to 15 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.

Cash Flows

As of September 30, 2018, the Company had cash and cash equivalents and restricted cash of approximately $13.0 million.

Net Cash Flows from Operating Activities: Net cash used in operating activities was approximately $6.5 million for the nine months ended September 30, 2018, compared with approximately $4.9 million for the nine months ended September 30, 2017. The increase in the 2018 period as compared to 2017 results primarily from 2018 increases in clinical study costs, compensation expenses, consulting fees, and patent expenses.

Net Cash Flows from Investing Activities: Net cash used in investing activities was approximately $54,000 for the nine months ended September 30, 2018, compared with no cash used for the nine months ended September 30, 2017. The increase in 2018 was attributable to the purchases of fixed asset equipment in 2018 for R&D activities. There were no corresponding purchases during the corresponding 2017 period.

Net Cash Flows from Financing Activities: Net cash provided by financing activities generated proceeds of $12.3 million for the nine months ended September 30, 2018, as compared with $4.6 million for the nine months ended

September 30, 2017. The increase is mainly attributed to our larger completed rights offering in 2018 as compared to the same period in 2017.

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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 entities. The Company has not currently adopted the provisions of ASU No. 2016-02 and believes that the impact of adopting ASU 2016-02 will not be material to its consolidated financial statements, though will require the recognition of an operating lease liability and right-of-use asset upon adoption, based on the lease composition disclosed in Footnote 11.

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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 has included restricted cash within cash and cash equivalents in the statements of cash flows. For the three and nine months ended September 30, 2018 and September 30, 2017, we included $55,000 of restricted cash in cash and cash equivalents on the statement of cash flows. 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.

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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 early adopted the provisions of ASU No. 2017-11 as of January 1, 2018. As the Company does not have any financial instruments with down round features, this ASU and it did not have a material impact on the financial statements upon adoption.

In June 2018, the FASB issued ASU 2018-07, *Compensation-Stock Compensation Improvements to Nonemployee Share Based Payment Accounting.* This ASU simplifies several aspects of the accounting for non-employee share-based payment transactions resulting from expanding the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. An entity should apply the requirements of Topic 718 to nonemployee awards except for specific guidance on inputs to an option pricing model and the attribution of cost. The amendments also clarify that Topic 718 does not apply to share-based payments used to effectively provide financing to the issuer or was granted in conjunction with selling goods or services to customers as part of a contract accounted for under Topic 606, *Revenue from Contracts with customers*. This update is effective for public entities for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year. Early adoptions is permitted. The Company early adopted the provisions of ASU No. 2018-07 as of April 1, 2018 and it did not have a material impact on the 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, 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 September 30, 2018, 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, 2018, that has materially affected, or is reasonably likely to materially affect our disclosure controls and procedures

For the quarter ended June 30, 2018, we identified a material weakness in the internal controls over the calculation of the deemed dividend on Series B convertible preferred stock (the "deemed dividend") for the three and six months June 30, 2018. Because of this error, an incorrect deemed dividend was included in net loss applicable to common stockholders which caused an incorrect calculation of loss per common share, basic and diluted. Management misinterpreted the technical guidance contained in *ASC 470- Debt* in calculating the deemed dividend. An appropriately detailed knowledge of *ASC 470 -Debt* was not present to prevent or detect this error. We incorrectly stated the amount of the deemed dividend as $4,782,100, rather than $11,479,308, for the three and six months ended June 30, 2018. We also incorrectly stated the loss per common share - basic and diluted, for the three and six months ended June 30, 2018 as $(2.90) and $(3.77) respectively, rather than the correct amount of $(5.08) and $(6.11), respectively.

Management's remediation plan is to enhance the procedures performed to independently review technical accounting memorandums for accuracy and completeness including when appropriate with an outside independent accounting firm in future periods.

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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 unspecific amount.

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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, and on July 20, 2018 the Court approved the settlement. This case is considered closed as of September 30, 2018.

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.

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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.

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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

Exhibit No.	Description	Incorporated by Reference Herein Form	Date
31.1	Certification pursuant to Rule 13a-14(a) under the securities Exchange Act of 1934 of Steven C. Quay	Filed herewith	
31.2	Certification pursuant to Rule 13a-14(a) under the securities Exchange Act of 1934 of Kyle Guse	Filed herewith	
32.1	Certification pursuant to 18 U.S.C. Section 1350 of Steven C. Quay	Filed herewith	
32.2	Certification pursuant to 18 U.S.C. Section 1350 of Kyle Guse	Filed herewith	
101	Interactive Data Files pursuant to Rule 405 of Regulation S-T	Filed herewith	

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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, 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)