

ATOSSA GENETICS INC  
Form 10-Q  
August 13, 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 June 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)**

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

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

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

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

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

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

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

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

The number of shares of the registrant's common stock, \$0.18 par value per share, outstanding at August 10, 2018 was 5,069,559.

**ATOSSA GENETICS INC.**

**FORM 10-Q**

**QUARTERLY REPORT**

**INDEX**

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

|                                                                                                                                                                                                                                                                                                                                                 | June 30,<br>2018 | December 31,<br>2017 |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|----------------------|
| Assets                                                                                                                                                                                                                                                                                                                                          |                  |                      |
| Current assets                                                                                                                                                                                                                                                                                                                                  |                  |                      |
| Cash and cash equivalents                                                                                                                                                                                                                                                                                                                       | \$15,236,736     | \$7,217,469          |
| Restricted cash                                                                                                                                                                                                                                                                                                                                 | 55,000           | 55,000               |
| Prepaid expenses                                                                                                                                                                                                                                                                                                                                | 440,389          | 250,944              |
| Research and development tax rebate receivable                                                                                                                                                                                                                                                                                                  | 626,011          | 358,277              |
| Other current assets                                                                                                                                                                                                                                                                                                                            | 50,035           | 16,344               |
| Total current assets                                                                                                                                                                                                                                                                                                                            | 16,408,171       | 7,898,034            |
| Furniture and equipment, net                                                                                                                                                                                                                                                                                                                    | 60,926           | 11,467               |
| Intangible assets, net                                                                                                                                                                                                                                                                                                                          | 59,882           | 75,686               |
| Other assets                                                                                                                                                                                                                                                                                                                                    | 48,867           | 178,907              |
| Total assets                                                                                                                                                                                                                                                                                                                                    | \$16,577,846     | \$8,164,094          |
| Liabilities and Stockholders' Equity                                                                                                                                                                                                                                                                                                            |                  |                      |
| Current liabilities                                                                                                                                                                                                                                                                                                                             |                  |                      |
| Accounts payable                                                                                                                                                                                                                                                                                                                                | \$191,217        | \$334,901            |
| Accrued expenses                                                                                                                                                                                                                                                                                                                                | 286,713          | 90,105               |
| Payroll liabilities                                                                                                                                                                                                                                                                                                                             | 952,657          | 784,867              |
| Stock-based compensation liability                                                                                                                                                                                                                                                                                                              | 1,557,163        |                      |
| Other current liabilities                                                                                                                                                                                                                                                                                                                       | 23,331           | 15,534               |
| Total current liabilities                                                                                                                                                                                                                                                                                                                       | 3,011,081        | 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 June 30, 2018 and December 31, 2017; Series B convertible preferred stock- \$0.001 par value; 25,000 and 0 shares authorized, and 5,802 and 0 | 6                |                      |

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shares issued and outstanding, as of June 30, 2018 and December 31, 2017,  
respectively

|                                                                                                                                                                                      |                  |                 |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|-----------------|
| Additional paid-in capital-Series B convertible preferred stock                                                                                                                      | 5,234,116        |                 |
| Common stock - \$0.18 par value; 175,000,000 shares authorized, 4,874,099 and<br>2,651,952 shares issued and outstanding, as of June 30, 2018 and December 31, 2017,<br>respectively | 877,329          | 477,342         |
| Additional paid-in capital                                                                                                                                                           | 78,898,602       | 71,887,674      |
| Accumulated deficit                                                                                                                                                                  | (71,443,288)     | (65,426,329)    |
| Total stockholders' equity                                                                                                                                                           | 13,566,765       | 6,938,687       |
| <br>Total liabilities and stockholders' equity                                                                                                                                       | <br>\$16,577,846 | <br>\$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<br>June 30, |                 | For The Six Months Ended<br>June 30, |                 |
|--------------------------------------------------------|----------------------------------------|-----------------|--------------------------------------|-----------------|
|                                                        | 2018                                   | 2017            | 2018                                 | 2017            |
| Operating expenses:                                    |                                        |                 |                                      |                 |
| Research and development                               | \$ 1,467,736                           | \$ 824,094      | \$ 1,938,712                         | \$ 1,368,396    |
| General and administrative                             | 2,674,920                              | 1,072,169       | 4,078,385                            | 2,231,458       |
| Total operating expenses                               | 4,142,656                              | 1,896,263       | 6,017,097                            | 3,599,854       |
| Operating loss                                         | (4,142,656 )                           | (1,896,263 )    | (6,017,097 )                         | (3,599,854 )    |
| Change in fair value of common stock warrants          |                                        | (152,447 )      |                                      | (152,447 )      |
| Warrant financing expense                              |                                        | (192,817 )      |                                      | (192,817 )      |
| Other income                                           | 79                                     | 38              | 138                                  | 75              |
| Loss before income taxes                               | (4,142,577 )                           | (2,241,489 )    | (6,016,959 )                         | (3,945,043 )    |
| Income taxes                                           |                                        |                 |                                      |                 |
| Net loss                                               | \$ (4,142,577 )                        | \$ (2,241,489 ) | \$ (6,016,959 )                      | \$ (3,945,043 ) |
| Deemed dividends attributable to preferred stock       | (4,782,100 )                           | (2,568,132 )    | (4,782,100 )                         | (2,568,132 )    |
| Net loss applicable to common stockholders             | \$ (8,924,677 )                        | \$ (4,809,621 ) | \$ (10,799,059 )                     | \$ (6,513,175 ) |
| Loss per common share - basic and diluted              | \$ (2.90 )                             | \$ (7.72 )      | \$ (3.77 )                           | \$ (13.85 )     |
| Weighted average shares outstanding, basic and diluted | 3,073,803                              | 623,004         | 2,864,033                            | 470,139         |

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

## ATOSSA GENETICS INC.

## CONDENSED CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY

(UNAUDITED)

|                                                                                                                                                                                    | Series B<br>Convertible<br>Preferred Stock |        |                                  | Common Stock     |                  |                               | Total                  |                         |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|--------|----------------------------------|------------------|------------------|-------------------------------|------------------------|-------------------------|
|                                                                                                                                                                                    | Shares                                     | Amount | Additional<br>Paid-in<br>Capital | Shares           | Amount           | Additional<br>Paid-in Capital | Accumulated<br>Deficit | Stockholders'<br>Equity |
| <b>Balance at<br/>December 31,<br/>2017</b>                                                                                                                                        |                                            | \$     | \$                               | <b>2,651,952</b> | <b>\$477,342</b> | <b>\$71,887,674</b>           | <b>\$(65,426,329)</b>  | <b>\$6,938,687</b>      |
| Issuance of<br>Series B<br>convertible<br>preferred<br>stock, net of<br>issuance costs<br>of \$1,333,449                                                                           | 13,624                                     | 14     | 12,290,537                       |                  |                  |                               |                        | 12,290,551              |
| Allocation of<br>Series B<br>convertible<br>preferred<br>stock to<br>beneficial<br>conversion<br>feature<br>Deemed<br>Dividend on<br>Series B<br>convertible<br>preferred<br>stock |                                            |        | (4,782,100)                      |                  |                  | 4,782,100                     |                        |                         |
| Conversion of<br>Series B<br>convertible<br>preferred<br>stock to<br>common stock                                                                                                  | (7,822 )                                   | (8 )   | (7,056,421 )                     | 2,222,147        | 399,987          | 6,656,442                     |                        |                         |
|                                                                                                                                                                                    |                                            |        |                                  |                  |                  | (39,703 )                     |                        | (39,703 )               |

|                                                                                        |              |             |                    |                  |                  |                     |                       |                     |              |
|----------------------------------------------------------------------------------------|--------------|-------------|--------------------|------------------|------------------|---------------------|-----------------------|---------------------|--------------|
| Amortization<br>of<br>commitment<br>shares                                             |              |             |                    |                  |                  |                     |                       |                     |              |
| Compensation<br>cost for stock<br>options<br>granted to<br>executives and<br>employees |              |             |                    |                  |                  | 394,189             |                       | 394,189             |              |
| Net loss                                                                               |              |             |                    |                  |                  |                     |                       | (6,016,959 )        | (6,016,959 ) |
| <b>Balance at<br/>June 30, 2018</b>                                                    | <b>5,802</b> | <b>\$ 6</b> | <b>\$5,234,116</b> | <b>4,874,099</b> | <b>\$877,329</b> | <b>\$78,898,602</b> | <b>\$(71,443,288)</b> | <b>\$13,566,765</b> |              |

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

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

|                                                                                       | <b>For the Six Months<br/>Ended June 30,</b> |                    |
|---------------------------------------------------------------------------------------|----------------------------------------------|--------------------|
|                                                                                       | <b>2018</b>                                  | <b>2017</b>        |
| <b>CASH FLOWS FROM OPERATING ACTIVITIES</b>                                           |                                              |                    |
| Net loss                                                                              | \$(6,016,959 )                               | \$(3,945,043 )     |
| Compensation cost for stock options granted                                           | 394,189                                      | 336,115            |
| Loss on disposal of intangible asset                                                  |                                              | 17,695             |
| Change in stock-based compensation liability                                          | 1,557,163                                    |                    |
| Depreciation and amortization                                                         | 17,838                                       | 73,193             |
| Change in fair value of common stock warrants                                         |                                              | 152,447            |
| Warrant financing expense                                                             |                                              | 192,817            |
| Changes in operating assets and liabilities:                                          |                                              |                    |
| Prepaid expenses                                                                      | (189,445 )                                   | (56,769 )          |
| Research and development tax rebate receivable                                        | (267,734 )                                   |                    |
| Other assets                                                                          | 56,644                                       | 25,831             |
| Accounts payable                                                                      | (143,684 )                                   | 241,491 )          |
| Payroll liabilities                                                                   | 167,790                                      | (287,479 )         |
| Accrued expenses                                                                      | 196,608                                      | 27,053             |
| Other current liabilities                                                             | 7,797                                        | 13,074             |
| Net cash used in operating activities                                                 | (4,219,793 )                                 | (3,209,575 )       |
| <b>CASH FLOWS FROM INVESTING ACTIVITIES</b>                                           |                                              |                    |
| Purchase of furniture and equipment                                                   | (51,491 )                                    |                    |
| Net cash used in investing activities                                                 | (51,491 )                                    |                    |
| <b>CASH FLOWS FROM FINANCING ACTIVITIES</b>                                           |                                              |                    |
| Proceeds from issuance of Class A and Class B Units, net of issuance costs            |                                              | 3,871,636          |
| Proceeds from issuance of Series B convertible preferred stock, net of issuance costs | 12,290,551                                   |                    |
| Net cash provided by financing activities                                             | 12,290,551                                   | 3,871,636          |
| <b>NET INCREASE IN CASH, CASH EQUIVALENTS, AND RESTRICTED CASH</b>                    | <b>8,019,267</b>                             | <b>662,061</b>     |
| <b>CASH, CASH EQUIVALENTS, AND RESTRICTED CASH, BEGINNING BALANCE</b>                 | <b>7,272,469</b>                             | <b>3,082,962</b>   |
| <b>CASH, CASH EQUIVALENTS, AND RESTRICTED CASH, ENDING BALANCE</b>                    | <b>\$15,291,736</b>                          | <b>\$3,745,023</b> |

**NONCASH INVESTING AND FINANCING ACTIVITIES**

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|                                                                      |          |           |
|----------------------------------------------------------------------|----------|-----------|
| Common stock issued for cashless exercise of common stock warrants   | \$       | \$900,488 |
| Amount receivable for warrant exercise                               |          | 2,600     |
| Allocation of Class A and Class B Unit proceeds to warrant liability |          | 1,612,416 |
| Amortization of commitment shares                                    | \$39,703 | \$39,705  |

*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 six months ended June 30, 2018, the Company recorded a net loss of approximately \$6.0 million and used approximately \$4.2 million of cash in operating activities. As of June 30, 2018 the Company had approximately \$15.2 million in cash and cash equivalents and working capital of approximately \$13.4 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, 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 12 to 18 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 six months ended June 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 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 has included restricted cash with cash and cash equivalents on the accompanying statement of cash flows, including reclassifying 2017 balances. For the three and six months ended June 30, 2018 and June 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 outstanding as of June 30, 2018, 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.

**NOTE 4: PREPAID EXPENSES**

Prepaid expenses consisted of the following:

|                                  | June 30,<br>2018 | December<br>31,<br>2017 |
|----------------------------------|------------------|-------------------------|
| Prepaid insurance                | \$ 148,284       | \$ 125,056              |
| Retainer and security deposits   | 16,718           | 14,218                  |
| Professional services            | 110,094          | 97,788                  |
| Prepaid research and development | 115,014          |                         |
| Financial exchange fees          | 27,500           |                         |
| Other                            | 22,779           | 13,882                  |
| Total prepaid expenses           | \$440,389        | \$250,944               |

**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 six months ended June 30, 2018, the Company incurred qualified R&D expenses of approximately \$616,000, resulting in an increase to the R&D rebate receivable of approximately \$268,000 from the year ended December 31, 2017 balance, and a corresponding offset to R&D expenses in the same amount. At June 30, 2018, we had a total R&D rebate receivable of approximately \$626,000.

**NOTE 6: PAYROLL LIABILITIES**

Payroll liabilities consisted of the following:

|                             | June 30,<br>2018 | December<br>31,<br>2017 |
|-----------------------------|------------------|-------------------------|
| Accrued bonus payable       | \$662,512        | \$ 566,000              |
| Accrued vacation            | 167,174          | 147,861                 |
| Accrued payroll liabilities | 122,971          | 71,006                  |
| Total payroll liabilities   | \$952,657        | \$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 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 June 30, 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.

#### 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.

*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 its 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.

*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.

**Outstanding Warrants**

As of June 30, 2018, warrants to purchase 4,760,270 shares of common stock were outstanding including:

|                                              | <b>Outstanding<br/>Warrants to<br/>Purchase<br/>Shares</b> | <b>Exercise Price</b> | <b>Expiration Date</b>  |
|----------------------------------------------|------------------------------------------------------------|-----------------------|-------------------------|
| 2014 public offering                         | 6,483                                                      | \$540.00              | January 29, 2019        |
| Placement agent fees for Company's offerings | 1,231                                                      | 381.60 – 1,044.00     | August - 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       |
| 2018 Warrants                                | 3,869,216                                                  | 4.05                  | May 30, 2022            |
|                                              | 4,760,270                                                  |                       |                         |

***Conversion of Series B Convertible Preferred Stock***

During the three months ended June 30, 2018, certain holders of the Series B convertible preferred stock exercised their conversion option and converted an aggregate of 7,822 shares of Series B convertible preferred stock into 2,222,147 shares 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 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.

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

|                                                 | <b>Three Months Ended<br/>June 30,</b> |               | <b>Six Months Ended<br/>June 30,</b> |               |
|-------------------------------------------------|----------------------------------------|---------------|--------------------------------------|---------------|
|                                                 | <b>2018</b>                            | <b>2017</b>   | <b>2018</b>                          | <b>2017</b>   |
| Net Loss Per share                              |                                        |               |                                      |               |
| Numerator                                       |                                        |               |                                      |               |
| Net loss                                        | \$(4,142,577)                          | \$(2,241,489) | \$(6,016,959)                        | \$(3,945,043) |
| Deemed dividend attributable to preferred stock | (4,782,100)                            | (2,568,132)   | (4,782,100)                          | (2,568,132)   |
| Net loss attributable to common shareholders    | \$(8,924,677)                          | \$(4,809,621) | \$(10,799,059)                       | \$(6,513,175) |
| Denominator                                     |                                        |               |                                      |               |
| Weighted average common shares outstanding      | 3,073,803                              | 623,004       | 2,864,033                            | 470,139       |
| Basic and diluted net loss per share            | \$(2.90 )                              | \$(7.72 )     | \$(3.77 )                            | \$(13.85 )    |

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 six months ended June 30, 2018 and 2017 because including them would be anti-dilutive:

|                                      | Three Months Ended<br>June 30, |         | Six Months Ended<br>June 30, |         |
|--------------------------------------|--------------------------------|---------|------------------------------|---------|
|                                      | 2018                           | 2017    | 2018                         | 2017    |
| Options to purchase common stock     | 200,954                        | 93,464  | 187,391                      | 62,841  |
| Series A convertible preferred stock |                                | 182,030 |                              | 91,518  |
| Series B convertible preferred stock | 900,367                        |         | 452,671                      |         |
| Warrants to purchase common stock    | 2,275,808                      | 511,650 | 1,599,074                    | 273,905 |
| Total                                | 3,377,129                      | 787,144 | 2,239,136                    | 428,264 |

For the three and six months ended June 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 June 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 June 30, 2018 and December 31, 2017, the Company had \$14,986,736 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 \$4,930, 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, and on July 20, 2018 the Court approved the settlement.

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:

| <b>January 1,</b>       | <b>Number<br/>of<br/>shares</b> |
|-------------------------|---------------------------------|
| 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                         |



The Company granted 611,668 options to purchase shares of common stock under the 2010 Plan during the six months ended June 30, 2018. No options were exercised during the three or six months ended June 30, 2018. There are 3,118 shares available for grant under the 2010 Plan as of June 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 \$179,050 and \$181,408 for the three months ended June 30, 2018 and 2017, respectively and \$394,189 and \$336,116 for the six months ended June 30, 2018 and 2017, respectively (excluding the liability options discussed below). The fair value of stock options granted for the six months ended June 30, 2018 and 2017 was calculated using the Black-Scholes option-pricing model applying the following assumptions:

|                         | <b>Period ended June 30,</b> |                   |
|-------------------------|------------------------------|-------------------|
|                         | <b>2018</b>                  | <b>2017</b>       |
| Risk free interest rate | 2.47% - 2.71%                | 1.86% - 2.04%     |
| Expected term           | 5.24- 5.57 years             | 5.32- 6.36 years  |
| Dividend yield          | - %                          | - %               |
| Expected volatility     | 108.81% - 126.43%            | 112.86% - 114.19% |

Options issued and outstanding as of June 30, 2018 under the 2010 Plan and their activities during the six months then ended are as follows:

|                                   | Number of<br>Underlying<br>Shares | Weighted-<br>Average<br>Exercise<br>Price<br>Per Share | Weighted-<br>Average<br>Contractual<br>Life<br>Remaining<br>in Years | Aggregate<br>Intrinsic<br>Value |
|-----------------------------------|-----------------------------------|--------------------------------------------------------|----------------------------------------------------------------------|---------------------------------|
| Outstanding as of January 1, 2018 | 172,510                           | \$ 49.27                                               |                                                                      | \$                              |
| Granted                           | 611,668                           | 2.39                                                   |                                                                      |                                 |
| Forfeited                         | (338 )                            | 5.64                                                   |                                                                      |                                 |
| Expired                           |                                   |                                                        |                                                                      |                                 |
| Outstanding as of June 30, 2018   | 783,840                           | 12.70                                                  | 9.67                                                                 | \$                              |
| Exercisable as of June 30, 2018   | 82,536                            | 93.84                                                  | 8.19                                                                 | \$                              |
| Vested and expected to vest       | 783,840                           | 12.70                                                  | 9.67                                                                 | \$                              |

At June 30, 2018, there were 701,304 unvested options outstanding and the related unrecognized total compensation cost associated with these options was approximately \$1,810,227. This expense is expected to be recognized over a

weighted-average period of 1.71 years.

Option Grants Classified as Liabilities (“Liability Grants”)

On June 27, 2018, the Company issued option awards to Dr. Steven C. Quay, Chairman of the Board, President and Chief Executive Officer and Kyle Guse, Chief Financial Officer, General Counsel and Secretary. The Company granted Dr. Quay 2,300,000 options and granted Mr. Guse 700,000 options, each 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.

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% will vest upon achievement of certain milestones related to clinical trial progress.

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 six months ended June 30, 2018, the Company recognized compensation expense related to these options of \$1,557,163.

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

**Six months ended June 30,  
2018**

|                         |           |
|-------------------------|-----------|
| Risk free interest rate | 2.71%     |
| Expected term           | 5.0 years |
| Dividend yield          | - %       |
| Expected volatility     | 125.0%    |

## 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 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.

## 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 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 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 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 have opened enrollment in two Phase 2 studies of our proprietary Endoxifen: one in Stockholm, Sweden using our topical Endoxifen to treat MBD and another in Australia using our oral Endoxifen to treat patients in the window of opportunity between diagnosis and surgery.

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 and Six Months Ended June 30, 2018 and 2017**

#### *Revenue and Cost of Revenue:*

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

*Operating Expenses:* Total operating expenses were approximately \$4.1 million and \$6.0 million for the three and six months ended June 30, 2018, respectively, consisting of general and administrative (G&A) expenses of approximately \$2.7 million and \$4.1 million, respectively, and research and development (R&D) expenses of approximately \$1.5 million and \$1.9 million, respectively. Total operating expenses were approximately \$1.9 million and \$3.6 million for the three and six months ended June 30, 2017, respectively, consisting of G&A expense of approximately \$1.1 million and \$2.2 million, respectively, and R&D expenses of \$0.8 million and \$1.4 million, respectively.

Total operating expenses for the three and six months ended June 30, 2018 as compared to the same periods of 2017 increased approximately \$2.3 million, or 118.46%, and increased \$2.4 million, or 67.15%, respectively.

*General and Administrative Expenses:* G&A expenses for the three months ended June 30, 2018 were approximately \$2,675,000, an increase of \$1,603,000 or 149.49%, from approximately \$1,072,000, for the same period in 2017. G&A expenses for the six months ended June 30, 2018 were approximately \$4,078,000, an increase of \$1,847,000 or 82.77%, from approximately \$2,232,000 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 is mainly attributed to an increase in stock-based compensation expense of \$1.0 million, payroll expenses resulting from retroactive salary increases and one-time bonus payments of \$350,000.

*Research and Development Expenses:* R&D expenses for the three months ended June 30, 2018 were approximately \$1,468,000, an increase of \$644,000 or 78.10%, from approximately \$824,000, for the same period in 2017. R&D expenses for the six months ended June 30, 2018 were approximately \$1,939,000, an increase of \$570,000 or 41.68%, from approximately \$1,368,000 for the same period in 2017. The increase in R&D expenses is mainly attributable to an increase in stock-based compensation expense of \$0.6 million. R&D expenses primarily consist of salaries, manufacturing and clinical trial expenses associated with our Endoxifen program. We expect our R&D expenses to increase throughout 2018 as we continue to advance our phase 2 Endoxifen clinical trials and continue the development other indications and pharmaceuticals.

*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 six months ended June 30, 2017 of \$152,447. There were no common stock liability warrants issued during the three and six months ended June 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 six months ended June 30, 2018, the Company recorded a net loss of approximately \$6.0 million, and used approximately \$4.2 million of cash in operating activities. As of June 30, 2018, the Company had approximately \$15.2 million in cash and cash equivalents and working capital of approximately \$13.4 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.

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 12 to 18 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 June 30, 2018, the Company had cash and cash equivalents and restricted cash of \$15.3 million.

*Net Cash Flows from Operating Activities:* Net cash used in operating activities was approximately \$4.2 million for the six months ended June 30, 2018, compared with approximately \$3.2 million for the six months ended June 30, 2017. The increase in the 2018 period as compared to 2017 results primarily from an increase in compensation, increased consulting fees, and increased patent expenses in 2018.

*Net Cash Flows from Investing Activities:* Net cash used in investing activities was approximately \$51,500 for the six months ended June 30, 2018, compared with no cash used for the six months ended June 30, 2017. The increase in 2018 was attributable to the purchases of fixed asset equipment in 2018 for R&D activities.

*Net Cash Flows from Financing Activities:* Net cash provided by financing activities generated proceeds of \$12.3 million for the six months ended June 30, 2018, as compared with \$3.9 million for the six months ended June 30, 2017. The increase is mainly attributed to our larger completed rights offering in the second quarter of 2018 as

compared to the same period in 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 has included restricted cash within cash and cash equivalents in the statements of cash flows. For the three and six months ended June 30, 2018 and June 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 outstanding as of June 30, 2018, 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 June 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 June 30, 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 June 30, 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, and on July 20, 2018 the Court approved the settlement of \$3.5 million.

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

| Exhibit No. | Description                                                                                                                 | Incorporated by<br>Reference Herein<br>Form                              | Date              |
|-------------|-----------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------|-------------------|
| 1.1         | <u>Form of Dealer-Manager Agreement</u>                                                                                     | Amendment No. 1 to Registration<br>Statement on Form S-1, as Exhibit 1.1 | April 23,<br>2018 |
| 3.3         | <u>Certificate of Amendment to Amended and Restated<br/>Certificate of Incorporation of Atossa Genetics Inc.</u>            | Current Report on Form 8-K, as Exhibit<br>4.1                            | April 23,<br>2018 |
| 4.1         | <u>Form of Certificate of Designation of Preference, Rights and<br/>Limitations of Series B Convertible Preferred Stock</u> | Current Report on Form 8-K as Exhibit<br>3.1                             | May 30,<br>2018   |
| 4.2         | <u>Form of Warrant Agreement</u>                                                                                            | Current Report on Form 8-K as Exhibit<br>4.1                             | May 30,<br>2018   |
| 4.3         | <u>Form of Warrant Certificate</u>                                                                                          |                                                                          |                   |

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Amendment No. 1 to Registration Statement on Form S-1, as Exhibit 4.3 April 23, 2018

4.4 Form of Non-Transferable Subscription Rights Certificate Amendment No. 1 to Registration Statement on Form S-1, as Exhibit 4.4 April 23, 2018

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

99.1 Form of Instructions as to Use of Subscription Rights Certificates Amendment No.2 to Registration Statement on Form S-1, as Exhibit 99.1 May 3, 2018

99.2 Form of Letter to Shareholders Who Are Record Holders Amendment No.2 to Registration Statement on Form S-1, as Exhibit 99.2 May 3, 2018

99.3 Form of Letter to Brokers, Dealers, Banks and Other Nominees Amendment No.2 to Registration Statement on Form S-1, as Exhibit 99.3 May 3, 2018

99.4 Form of Broker Letter to Clients Who Are Beneficial Holders Amendment No.2 to Registration Statement on Form S-1, as Exhibit 99.4 May 3, 2018

99.5 Form of Beneficial Owner Election Form Amendment No. 1 to Registration Statement on Form S-1, as Exhibit 99.5 April 23, 2018

99.6 Form of Nominee Holder Certification Amendment No. 1 to Registration Statement on Form S-1, as Exhibit 99.6 April 23, 2018

99.7 Form of Notice of Important Tax Information Amendment No. 1 to Registration Statement on Form S-1, as Exhibit 99.7 April 23, 2018

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: August 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)