

UNITED STATES SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

**FORM 8-K**

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of Earliest Event Reported): May 13, 2019

**Atossa Genetics Inc.**

(Exact name of registrant as specified in its charter)

Delaware  
(State or other jurisdiction of  
incorporation)

001-35610  
(Commission File Number)

26-4753208  
(I.R.S. Employer  
Identification No.)

107 Spring Street  
Seattle, Washington  
(Address of principal executive offices)

98104  
(Zip Code)

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

Not Applicable

Former name or former address, if changed since last report

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 or Rule 12b-2 of the Securities Exchange Act of 1934.

Emerging growth company

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

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common Stock, \$0.18 par value	ATOS	NASDAQ

**Item 2.02. Results of Operations and Financial Condition.**

On May 13, 2019, Atossa Genetics Inc. (the “Company”) issued a press release announcing quarter end March 31, 2019 financial results and a Company update. A copy of the press release is attached as Exhibit 99.1 to this current report and is incorporated herein by reference.

*The information in Items 2.02 and 9.01 of this report, including Exhibit 99.1 attached hereto, shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information contained herein and in the accompanying exhibit shall not be incorporated by reference into any filing with the U.S. Securities and Exchange Commission made by the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.*

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
<a href="#">99.1</a>	<a href="#">Press Release, dated May 13, 2019</a>

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**SIGNATURES**

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

Date: May 13, 2019

Atossa Genetics Inc.

By: /s/ Kyle Guse  
\_\_\_\_\_  
Kyle Guse  
Chief Financial Officer, General Counsel and  
Secretary

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## Exhibit Index

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release, dated May 13, 2019



## Atossa Genetics Announces First Quarter 2019 Financial Results and Provides Company Update

### *Completes First Quarter with Cash and Cash Equivalents of \$19.6 Million*

SEATTLE, May 13, 2019 (GLOBENEWSWIRE) -- Atossa Genetics Inc. (Nasdaq:ATOS), a clinical-stage biopharmaceutical company developing novel therapeutics and delivery methods to treat breast cancer and other breast conditions, today announced financial results for the quarter ended March 31, 2019 and provided an update on recent company developments.

Steven C. Quay, M.D., Ph.D., Atossa Genetics' President and CEO commented, "As we anticipated, we completed dosing in the topical Endoxifen breast density study in April and we look forward to announcing initial top-line results later this quarter. Further, as previously reported, the FDA approved an 'Expanded Access' program for use of our oral Endoxifen to treat a breast cancer patient prior to her surgery and in March 2019 we received a second approval for this patient to continue treatment post-surgery. We are planning a Phase 2 clinical study using our oral Endoxifen to reduce breast density and we look forward to providing updates on the launch of that study and progress with our other programs."

#### **Q1 2019 Corporate Developments**

Developments during the first quarter include the following:

- April 2019 – Completed dosing of Phase 2 topical Endoxifen breast density trial
- April 2019 – Completed the first phase of a preclinical study using proprietary intraductal delivery technology. The company is now advancing to the next preclinical phase, which involves the intraductal administration of immune modulating formulations. These results will form the basis for advancing the intraductal delivery program into humans and to ultimately deliver immunotherapy to treat breast cancer using Atossa's proprietary intraductal delivery technology
- March 2019 – FDA approval of oral Endoxifen for expanded access as post-mastectomy treatment for a U.S. breast cancer patient
- March 2019 – Atossa received \$11.3 million from the exercise of warrants that were previously outstanding
- February 2019 – Atossa provided breast cancer prevention recommendations to the United States Preventative Services Task Force
- February 2019 – Atossa reports results from expanded access program for a U.S. breast cancer patient taking oral Endoxifen: sizeable reduction in cancer cell biological activity; no safety or tolerability issues
- January 2019 – Successfully completed and provided final results from male Phase 1 study of topical Endoxifen; no clinically significant safety nor tolerability issues and acceptable pharmacokinetics

#### **Q1 2019 Financial Results**

For the quarter ended March 31, 2019 the company reported no revenue and no associated cost of revenue.

Total operating expenses were approximately \$4,064,000 for the three months ended March 31, 2019, which is an increase of approximately \$2,190,000 or 117 percent, from the three months ended March 31, 2018. Operating expenses for the three months ended March 31, 2019 consisted of research and development (R&D) expenses of approximately \$1,451,000 and general and administrative (G&A) expenses of approximately \$2,613,000. Operating expenses for the same period in 2018 consisted of R&D expenses of approximately \$471,000, and G&A expenses of approximately \$1,403,000.

R&D expenses for the three months ended March 31, 2019, were approximately \$1,451,000, an increase of approximately \$980,000 or 208 percent from total R&D expenses for the three months ended March 31, 2018 of approximately \$471,000. The increase in R&D expense is attributed to salaries, stock-based compensation, and clinical trial expenses associated with our Endoxifen program. Stock-based compensation expense increased approximately \$668,000 in 2019 resulting from the cancellation of stock options. There were no option cancellations in the comparable period in 2018. We expect our R&D expenses to increase throughout 2019 as we commence additional Phase 2 clinical studies of Endoxifen, continue the clinical trial of Fulvestrant administered via our intraductal technology and continue the development of other indications and therapeutics, including CAR-T and immunotherapies administered via our intraductal technologies.

G&A expenses were approximately \$2,613,000 for the three months ended March 31, 2019, an increase of approximately \$1,210,000, or 86 percent from the total G&A expenses for the three months ended March 31, 2018, of approximately \$1,403,000. G&A expenses consist primarily of personnel and related benefit costs, facilities, professional services, insurance, and public company related expenses. The increase in G&A expenses for the quarter ended March 31, 2019, is mainly attributed to an increase in stock-based compensation expense due to the cancellation of 2018 options of approximately \$1,074,000, payroll expenses resulting from salary increases, and increased legal and professional consulting expenses over the prior year.

As of March 31, 2019, Atossa had approximately \$19.6 million in cash and cash equivalents and working capital of approximately \$19.3 million.

#### **About Atossa Genetics**

Atossa Genetics Inc. is a clinical-stage biopharmaceutical company developing novel therapeutics and delivery methods to treat breast cancer and other breast conditions. For more information, please visit [www.atossagenetics.com](http://www.atossagenetics.com).

#### **Forward-Looking Statements**

Forward-looking statements in this press release, which Atossa undertakes no obligation to update, are subject to risks and uncertainties that may cause actual results to differ materially from the anticipated or estimated future results, including the risks and uncertainties associated with any variation between preliminary and final clinical results, actions and inactions by the FDA, the outcome or timing of regulatory approvals needed by Atossa including those needed to commence studies, lower than anticipated rate of patient enrollment, estimated market size of drugs under development, the safety and efficacy of Atossa's products and services, performance of clinical research organizations and investigators, obstacles resulting from proprietary rights held by others with respect to fulvestrant, such as patent rights, potential market sizes for Atossa's drugs under development and other risks detailed

from time to time in Atossa's filings with the Securities and Exchange Commission, including without limitation its periodic reports on Form10-K and 10-Q, each as amended and supplemented from time to time.

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Source: Atossa Genetics Inc.

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**ATOSSA GENETICS INC.  
CONDENSED CONSOLIDATED BALANCE SHEETS**

	<b>As of March 31,</b>	<b>As of December</b>
	<b>2019</b>	<b>31,</b>
	<b>(Unaudited)</b>	<b>2018</b>
<b><u>Assets</u></b>		
Current assets		
Cash and cash equivalents	\$ 19,568,247	\$ 10,380,493
Restricted cash	110,000	110,000
Prepaid expenses	835,468	509,833
Research and development tax rebate receivable	237,856	518,098
Other current assets	27,957	30,942
Total current assets	20,779,528	11,549,366
Furniture and equipment, net	48,212	54,487
Intangible assets, net	91,667	99,375
Right-of-use asset	88,103	
Other assets	17,218	17,218
Total Assets	\$ 21,024,728	\$ 11,720,446
<b><u>Liabilities and Stockholders' Equity</u></b>		
Current liabilities		
Accounts payable	\$ 463,970	\$ 353,328
Accrued expenses	74,844	177,074
Payroll liabilities	891,758	935,070
Stock-based compensation liability		1,410,025
Lease liability	50,706	
Other current liabilities	9,863	39,939
Total current liabilities	1,491,141	2,915,436
Long term liabilities		
Lease liability long term	37,397	
Total Liabilities	1,528,538	2,915,436
Commitments and contingencies		
Stockholders' equity		
Preferred stock - \$0.001 par value; 10,000,000 shares authorized; 702 and 2,379 shares issued and outstanding as of March 31, 2019 and December 31, 2018, respectively	1	2
Additional paid-in capital- Series B convertible preferred stock	701,999	2,378,997
Common stock - \$0.18 par value; 175,000,000 shares authorized, and 9,122,171 and 5,846,552 shares issued and outstanding, as of March 31, 2019 and December 31, 2018, respectively	1,641,979	1,052,372
Additional paid-in capital	98,056,781	82,204,902
Accumulated deficit	(80,904,570)	(76,831,263)
Total Stockholders' Equity	19,496,190	8,805,010
Total Liabilities and Stockholders' Equity	\$ 21,024,728	\$ 11,720,446

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

	<b>For the Three Months Ended March 31,</b>	
	<b>2019</b>	<b>2018</b>
Operating expenses		
Research and development	\$ 1,451,236	\$ 470,976
General and administrative	2,613,093	1,403,465
Total operating expenses	4,064,329	1,874,441
Operating loss	(4,064,329)	(1,874,441)
Other income (expense)	(8,978)	59
Loss before income taxes	(4,073,307)	(1,874,382)
Income taxes		
Net loss	\$ (4,073,307)	\$ (1,874,382)
Loss per common share - basic and diluted	\$ (0.62)	\$ (8.48)
Weighted average shares outstanding - basic and diluted	6,565,514	220,996