

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): March 28, 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.

Item 2.02. Results of Operations and Financial Condition.

On March 28, 2019, Atossa Genetics Inc. (the “Company”) issued a press release announcing year end 2018 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>
99.1	Press Release, dated March 28, 2019

* * *

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: March 28, 2019

Atossa Genetics Inc.

By: /s/ Kyle Guse

Kyle Guse
Chief Financial Officer, General Counsel and
Secretary

Exhibit Index

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release, dated March 28, 2019



Atossa Genetics Announces Year End 2018 Financial Results and Provides Company Update

SEATTLE, March 28, 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 year end 2018 financial results and provided an update on recent company developments.

Steven C. Quay, M.D., Ph.D., Atossa Genetics' President and CEO commented, "The end of 2018 marked two important milestones for Atossa. We completed the enrollment of our Phase 2 trial for topical Endoxifen in women with mammographic dense breasts. In addition, we received our first allowance by the FDA to provide Endoxifen through the federal "Expanded Access" program for a breast cancer patient prior to her surgery. We received a second allowance in March 2019 for this patient to continue treatment post-surgery. In the meantime, we continue to make great progress with our clinical programs and look forward to completing the dosing in the topical Endoxifen MBD trial in April and announcing preliminary results in the second quarter 2019. "

Recent Corporate Developments

Atossa's important recent developments include the following:

- 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 - Update from "Expanded Access" program for the U.S. breast cancer patient taking oral Endoxifen prior to surgery showing sizeable reduction in cancer cell biological activity with no safety or tolerability issues
- February 2019 – Atossa provided breast cancer prevention recommendations to the United States Preventative Services Task Force
- 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
- December 2018 - FDA approval of Endoxifen for "Expanded Access" as preoperative systemic endocrine therapy for a U.S. breast cancer patient
- October 2018 - Completed enrollment in Phase 2 study of topical Endoxifen to treat mammographic breast density.

2018 Financial Results

For the year end December 31, 2018 and 2017, we had no revenue and no associated cost of revenue.

Total operating expenses were \$11,434,000 for the year ended December 31, 2018, which is an increase of \$3,785,000 or 49 percent, from the year ended December 31, 2017. Operating expenses for 2018 consisted of research and development (R&D) expenses of \$4,210,000 and general and administrative (G&A) expenses of \$7,224,000. Operating expenses for 2017 consisted of R&D expenses of \$2,328,000, G&A expenses of \$4,859,000 and impairment of our Acueity intangible assets of \$462,000.

R&D expenses for the year ended December 31, 2018, were \$4,210,000, an increase of \$1,882,000 or 81 percent from total R&D expenses in 2017 of \$2,328,000. The increase in R&D expense is attributed to manufacturing and clinical trials associated with our Endoxifen program, salaries, and stock-based compensation. Our R&D expenses have increased because we commenced two Phase 2 studies of our proprietary Endoxifen during the year ended December 31, 2018. There were no Phase 2 studies of Endoxifen in 2017. Stock-based compensation expense also increased approximately \$627,000 in 2018 as compared to 2017. 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 microcatheters and continue the development of other indications and therapeutics, including CAR-T and immunotherapies administered via our intraductal technology.

G&A expenses were \$7,224,000 for the year ended December 31, 2018, an increase of \$2,365,000, or 49 percent from the total G&A expenses for the year ended December 31, 2017, of \$4,859,000. 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 year ended December 31, 2018, is mainly attributed to an increase in stock-based compensation expense of approximately \$1,049,000, payroll expenses resulting from salary increases, one-time bonus payments of \$350,000 and increased legal and professional consulting expenses of approximately \$600,000 over the prior year.

As of December 31, 2018, the company had cash, cash equivalents and restricted cash of \$10.5 million and in March 2019 received \$11.3 million in additional cash from the exercise of previously outstanding warrants.

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.

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.

ATOSSA GENETICS INC.
CONSOLIDATED BALANCE SHEETS

	As of December 31,	
	2018	2017
<u>Assets</u>		
Current assets		
Cash and cash equivalents	\$ 10,380,493	\$ 7,217,469
Restricted cash	110,000	55,000
Prepaid expenses	509,833	250,944
Research and development tax rebate receivable	518,098	358,277
Other current assets	30,942	16,344
Total current assets	11,549,366	7,898,034
Furniture and equipment, net	54,487	11,467
Intangible assets, net	99,375	75,686
Other assets	17,218	178,907
Total Assets	\$ 11,720,446	\$ 8,164,094
<u>Liabilities and Stockholders' Equity</u>		
Current liabilities		
Accounts payable	\$ 353,328	\$ 334,901
Accrued expenses	177,074	90,105
Payroll liabilities	935,070	784,867
Stock-based compensation liability	1,410,025	
Other current liabilities	39,939	15,534
Total Current Liabilities	2,915,436	1,225,407
Commitments and contingencies		
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 December 31, 2018 and December 31, 2017; Series B convertible preferred stock- \$0.001 par value; 25,000 and 0 shares authorized, and 2,379 and 0 shares issued and outstanding as of December 31, 2018 and December 31, 2017, respectively	2	
Additional paid-in capital- Series B convertible preferred stock	2,378,997	
Common stock - \$0.18 par value; 175,000,000 shares authorized, and 5,846,552 and 2,651,952 shares issued and outstanding, as of December 31, 2018 and December 31, 2017, respectively	1,052,372	477,342
Additional paid-in capital	82,204,902	71,887,674
Accumulated deficit	(76,831,263)	(65,426,329)
Total Stockholders' Equity	8,805,010	6,938,687
Total Liabilities and Stockholders' Equity	\$ 11,720,446	\$ 8,164,094

ATOSSA GENETICS INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

	For the Years Ended December 31,	
	2018	2017
Operating Expenses		
Research and development	\$ 4,209,981	\$ 2,328,087
General and administrative	7,224,252	4,859,369
Impairment of intangible assets		461,715
Total operating expenses	<u>11,434,233</u>	<u>7,649,171</u>
Operating loss	(11,434,233)	(7,649,171)
Change in fair value of common stock warrants		(280,747)
Warrant financing expense		(192,817)
Other income	29,299	154
Loss before income taxes	<u>(11,404,934)</u>	<u>(8,122,581)</u>
Income taxes		
Net loss	<u>\$ (11,404,934)</u>	<u>\$ (8,122,581)</u>
Deemed dividend attributable to preferred stock	<u>(11,479,308)</u>	<u>(2,568,132)</u>
Net loss applicable to common shareholders	<u>\$ (22,884,242)</u>	<u>\$ (10,690,713)</u>
Loss per common share - basic and diluted	<u>\$ (5.50)</u>	<u>\$ (10.97)</u>
Weighted average shares outstanding - basic and diluted	<u>4,157,746</u>	<u>974,773</u>