

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): August 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 August 13, 2019, Atossa Genetics Inc. (the "Company") issued a press release announcing quarter end June 30, 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>
99.1	Press Release, dated August 13, 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: August 13, 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 August 13, 2019



Atossa Genetics Announces Second Quarter 2019 Financial Results and Provides Company Update
Completes Second Quarter with Cash and Cash Equivalents of \$17.1 Million

SEATTLE, August 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 second quarter ended June 30, 2019 and provided an update on recent company developments.

Steven C. Quay, M.D., Ph.D., Atossa Genetics' President and CEO commented, "During the quarter we were very pleased to have achieved our primary endpoint in our Phase 2 trial of topical Endoxifen to reduce mammographic breast density (MBD). We are now focusing our efforts on the oral formulation of Endoxifen and are developing a modified-release oral tablet which is being tested in a Phase 1 study and that we plan to use in a Phase 2 study to reduce MBD. The Phase 2 study is scheduled to start in the fourth quarter and should be completed by mid-2020. We completed the quarter with \$17.1 million in cash which will enable us to continue to make clinical progress with our programs."

Recent Developments

Recent developments include the following:

- July 2019 – Provided update on expanded access program, which now allows physicians and patients to visit the company website to obtain information on compassionate use access
- July 2019 – Initiated a Phase 1 study of our proprietary modified-release oral Endoxifen tablet
- June 2019 – Successfully reached the primary endpoint of MBD reduction using the topical formulation of Endoxifen in a Phase 2 study

Q2 2019 Financial Results

For the three and six months ended June 30, 2019 and 2018, we have no source of sustainable revenue and no associated cost of revenue.

Total operating expenses were approximately \$7,286,000 and \$11,350,000 for the three and six months ended June 30, 2019, respectively, consisting of research and development (R&D) expenses of approximately \$2,612,000 and \$4,063,000 respectively, and general and administrative (G&A) expense of approximately \$4,674,000 and \$7,287,000, respectively. Total operating expenses were approximately \$4,143,000 and \$6,017,000 for the three and six months ended June 30, 2018, respectively, consisting of research and development expenses of approximately \$1,468,000 and \$1,939,000, respectively, and general and administrative expenses of approximately \$2,675,000 and \$4,078,000, respectively.

R&D expenses for the three months ended June 30, 2019, were approximately \$2,612,000, an increase of approximately \$1,144,000 or 78% from total R&D expenses for the three months ended June 30, 2018 of approximately \$1,468,000. R&D expenses for the six months ended June 30, 2019, were approximately \$4,063,000, an increase of approximately \$2,124,000 or 110% from total R&D expenses for the six months ended June 30, 2018 of approximately \$1,939,000. The increase in R&D expenses for the period ended June 30, 2019, is mainly attributed to an increase in stock-based compensation expense (non-cash). We expect our R&D expenses to increase throughout 2019 as we commence an additional Phase 2 clinical study of oral Endoxifen, develop and manufacture our modified release tablet form of oral Endoxifen, continue our 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 \$4,674,000 for the three months ended June 30, 2019, an increase of approximately \$1,999,000, or 75% from the total G&A expenses for the three months ended June 30, 2018, of approximately \$2,675,000. G&A expenses were approximately \$7,287,000 for the six months ended June 30, 2019, an increase of approximately \$3,209,000, or 79% from the total G&A expenses for the six months ended June 30, 2018, of approximately \$4,078,000. 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 period ended June 30, 2019, is mainly attributed to an increase in stock-based compensation expense (non-cash). Additionally, payroll expenses have increased resulting from salary increases over the prior year.

As of June 30, 2019, Atossa had approximately \$17.1 million in cash and cash equivalents and working capital of approximately \$17.4 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.

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 Form 10-K and 10-Q, each as amended and supplemented from time to time.

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Source: Atossa Genetics Inc.

ATOSSA GENETICS INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

	As of June 30, 2019 (Unaudited)	As of December 31, 2018
<u>Assets</u>		
Current assets		
Cash and cash equivalents	\$ 17,058,527	\$ 10,380,493
Restricted cash	110,000	110,000
Prepaid expenses	813,168	509,833
Research and development tax rebate receivable	406,306	518,098
Other current assets	140	30,942
Total current assets	<u>18,388,141</u>	<u>11,549,366</u>
Furniture and equipment, net	44,174	54,487
Intangible assets, net	83,958	99,375
Right-of-use asset	75,822	-
Other assets	17,218	17,218
Total Assets	<u>\$ 18,609,313</u>	<u>\$ 11,720,446</u>
<u>Liabilities and Stockholders' Equity</u>		
Current liabilities		
Accounts payable	\$ 318,266	\$ 353,328
Accrued expenses	53,485	177,074
Payroll liabilities	589,445	935,070
Stock-based compensation liability	-	1,410,025
Lease liability	51,795	-
Other current liabilities	19,838	39,939
Total current liabilities	<u>1,032,829</u>	<u>2,915,436</u>
Long term liabilities		
Lease liability long term	24,027	-
Total Liabilities	<u>1,056,856</u>	<u>2,915,436</u>
Commitments and contingencies		
Stockholders' equity		
Preferred stock - \$0.001 par value; 10,000,000 shares authorized; 676 and 2,379 shares issued and outstanding as of June 30, 2019 and December 31, 2018, respectively	1	2
Additional paid-in capital- Series B convertible preferred stock	675,999	2,378,997
Common stock - \$0.18 par value; 175,000,000 shares authorized, and 9,129,563 and 5,846,552 shares issued and outstanding, as of June 30, 2019 and December 31, 2018, respectively	1,643,309	1,052,372
Additional paid-in capital	103,400,247	82,204,902
Accumulated deficit	(88,167,099)	(76,831,263)
Total Stockholders' Equity	<u>17,552,457</u>	<u>8,805,010</u>
Total Liabilities and Stockholders' Equity	<u>\$ 18,609,313</u>	<u>\$ 11,720,446</u>

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

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2019	2018 (as restated)	2019	2018 (as restated)
Operating expenses				
Research and development	\$ 2,611,948	\$ 1,467,736	\$ 4,063,184	\$ 1,938,712
General and administrative	4,674,121	2,674,920	7,287,214	4,078,385
Total operating expenses	<u>7,286,069</u>	<u>4,142,656</u>	<u>11,350,398</u>	<u>6,017,097</u>
Operating loss	(7,286,069)	(4,142,656)	(11,350,398)	(6,017,097)
Other income	23,540	79	14,562	138
Loss before income taxes	(7,262,529)	(4,142,577)	(11,335,836)	(6,016,959)
Income taxes	-	-	-	-
Net loss	<u>\$ (7,262,529)</u>	<u>\$ (4,142,577)</u>	<u>\$ (11,335,836)</u>	<u>\$ (6,016,959)</u>
Deemed dividends attributable to preferred stock	-	(11,479,308)	-	(11,479,308)
Net loss applicable to common shareholders	\$ (7,262,529)	\$ (15,621,885)	\$ (11,335,836)	\$ (17,496,267)
Loss per common share - basic and diluted	<u>\$ (0.80)</u>	<u>\$ (5.08)</u>	<u>\$ (1.44)</u>	<u>\$ (6.11)</u>
Weighted average shares outstanding - basic and diluted	<u>9,126,153</u>	<u>3,073,803</u>	<u>7,852,907</u>	<u>2,864,033</u>