

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): November 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 November 13, 2019, Atossa Genetics Inc. (the “Company”) issued a press release announcing quarter end September 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	<a href="#">Press Release, dated November 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: November 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 November 13, 2019



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

### *Completes Third Quarter with Cash and Cash Equivalents of \$15.3 Million*

SEATTLE, November 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 third quarter ended September 30, 2019 and provides an update on recent company developments.

Steven C. Quay, M.D., Ph.D., Atossa Genetics' President and CEO commented "In the third quarter we made substantial headway in advancing the development of our lead drug candidate - Endoxifen - as we turn our concentration towards treating mammographic breast density (MBD). We recently announced meeting all objectives in our Phase 1 study of the modified-release tablet form of oral Endoxifen, which paves the way toward advancing our modified-release tablet into Phase 2 studies. The final analysis of the results demonstrated that the modified-release tablet had no treatment-related side effects that were rated as moderate or severe in intensity, strongly supporting the continued development of this proprietary formulation. We also initiated our Phase 2 clinical study of Atossa's intraductal technology for the administration of fulvestrant in patients with early-stage breast cancer with a major institution and supported by the Dr. Susan Love Research Foundation. Many of the approximately 64,000 women with ductal carcinoma *in situ* (DCIS) who opt for 'watchful waiting' rather than extensive surgery could benefit from a gentler, intermediate treatment of DCIS with intraductal ablation with fulvestrant."

"Before the end of the year, we look forward to reporting several significant milestones: contracting with a clinical research organization for our Phase 2 study of oral Endoxifen to treat MBD, completing additional pre-clinical work of our cell-based therapy candidate and our intraductal technology, as well as reporting additional results from our recently completed clinical study of our modified-release form of Endoxifen tablets," concluded Dr. Quay.

### Recent Corporate Developments

Recent developments include the following:

- October 2019 - Atossa received IRB approval for Phase 2 breast cancer study using intraductal technology to administer fulvestrant at a major institution.
- September 2019 - Atossa announced preliminary results from Phase 1 study of new proprietary modified-release oral Endoxifen tablet.
- September 2019 - Atossa announced completion of enrollment and dosing in Phase 1 clinical trial of the new oral Endoxifen tablet.

### Q3 2019 Financial Results

For the three and nine months ended September 30, 2019 and 2018, Atossa has no source of sustainable revenue and no associated cost of revenue.

Total operating expenses were approximately \$3,298,000 and \$14,649,000 for the three and nine months ended September 30, 2019, respectively, consisting of research and development (R&D) expenses of approximately \$1,684,000 and \$5,747,000 respectively, and general and administrative (G&A) expense of approximately \$1,614,000 and \$8,901,000, respectively. Total operating expenses were approximately \$3,310,000 and \$9,327,000 for the three and nine months ended September 30, 2018, respectively, consisting of research and development expenses of approximately \$1,422,000 and \$3,361,000, respectively, and general and administrative expenses of approximately \$1,888,000 and \$5,967,000, respectively. Total operating expense for the three months ended September 30, 2019 were consistent with the same period in 2018. Total operating expenses for the nine months ended September 30, 2019 as compared to the same period in 2018 increased approximately \$5,322,000 or 57%, of which approximately \$1,742,000 is attributable to non-cash compensation expenses resulting from cancellation of the 2018 Liability Options in the first quarter 2019 and an increase of approximately \$2,759,000 due to the grant of options to executives.

R&D expenses for the three months ended September 30, 2019, were approximately \$1,684,000, an increase of approximately \$262,000 or 18% from total R&D expenses for the three months ended September 30, 2018 of approximately \$1,422,000. R&D expenses for the nine months ended September 30, 2019, were approximately \$5,747,000, an increase of approximately \$2,386,000 or 71% from total R&D expenses for the nine months ended September 30, 2018 of approximately \$3,361,000. The increase in R&D expense is attributed to non-cash stock-based compensation, salaries and clinical trial expenses associated with our Endoxifen program. Stock-based compensation expense, which is a non-cash charge, increased approximately \$668,000 in the first quarter of 2019 resulting from the cancellation of the 2018 Liability Options. There were no Liability Option cancellations in the comparable period of 2018. Stock-based compensation expense also increased approximately \$1.0 million due to the grant of options to the CEO that were 75% vested. Clinical trial expense also increased approximately \$535,000 in the nine month period ended September 30, 2019 over the same period in 2018. We expect our R&D expenses to increase throughout 2019 as we commence additional Phase 2 clinical studies of oral Endoxifen, continue development and manufacturing our tablet modified-release form of oral Endoxifen, continue our clinical trial of fulvestrant administered via our intraductal technology at a new institution and continue the development of other indications and therapeutics, including CAR-T and immunotherapies administered via our intraductal technologies.

G&A expenses were approximately \$1,614,000 for the three months ended September 30, 2019, a decrease of approximately \$274,000, or 15% from the total G&A expenses for the three months ended September 30, 2018, of approximately \$1,888,000. G&A expenses were approximately \$8,901,000 for the nine months ended September 30, 2019, an increase of approximately \$2,934,000, or 49% from the total G&A expenses for the nine months ended September 30, 2018, of approximately \$5,967,000. 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 nine months ended September 30, 2019, is mainly attributed to an increase in stock-based compensation expense, which is a non-cash charge, due to the cancellation of the 2018 Liability Options of approximately \$1,074,000 during the first quarter of 2019. There were no Liability Option cancellations in the comparable period of 2018. During the nine months ended September 30, 2019, stock-based compensation expense increased approximately \$1.75 million due to the grant of options to the CEO and CFO that were 75% vested. Additionally, payroll expenses have increased resulting from salary increases over the prior year.

As of September 30, 2019, the Company had approximately \$15.3 million in cash and cash equivalents and working capital of approximately \$14.8 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 Form 10-K and 10-Q, each as amended and supplemented from time to time.

#### Atossa Genetics Company Contact:

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Source: Atossa Genetics Inc.

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

	<b>As of September 30, 2019 (Unaudited)</b>	<b>As of December 31, 2018</b>
<b><u>Assets</u></b>		
Current assets		
Cash and cash equivalents	\$ 15,289,543	\$ 10,380,493
Restricted cash	110,000	110,000
Prepaid expenses	430,042	509,833
Research and development tax rebate receivable	568,980	518,098
Other current assets	2,064	30,942
Total current assets	16,400,629	11,549,366
Furniture and equipment, net	39,142	54,487
Intangible assets, net	76,250	99,375
Right-of-use asset	63,284	-
Other assets	17,218	17,218
Total Assets	\$ 16,596,523	\$ 11,720,446
<b><u>Liabilities and Stockholders' Equity</u></b>		
Current liabilities		
Accounts payable	\$ 501,430	\$ 353,328
Accrued expenses	225,472	177,074
Payroll liabilities	769,727	935,070
Stock-based compensation liability	-	1,410,025
Lease liability	49,266	-
Other current liabilities	18,415	39,939
Total current liabilities	1,564,310	2,915,436
Long term liabilities		
Lease liability long term	14,018	-
Total Liabilities	1,578,328	2,915,436
Commitments and contingencies		
Stockholders' equity		
Preferred stock - \$0.001 par value; 10,000,000 shares authorized; 671 and 2,379 shares issued and outstanding as of September 30, 2019 and December 31, 2018, respectively	1	2
Additional paid-in capital- Series B convertible preferred stock	670,999	2,378,997
Common stock - \$0.18 par value; 175,000,000 shares authorized, and 9,130,984 and 5,846,552 shares issued and outstanding, as of September 30, 2019 and December 31, 2018, respectively	1,643,565	1,052,372
Additional paid-in capital	104,156,643	82,204,902
Accumulated deficit	(91,453,013)	(76,831,263)
Total Stockholders' Equity	15,018,195	8,805,010
Total Liabilities and Stockholders' Equity	\$ 16,596,523	\$ 11,720,446

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

	<u>For the Three Months Ended September 30,</u>		<u>For the Nine Months Ended September 30,</u>	
	<u>2019</u>	<u>2018</u>	<u>2019</u>	<u>2018</u>
Operating expenses				
Research and development	\$ 1,684,215	\$ 1,421,851	\$ 5,747,399	\$ 3,360,563
General and administrative	1,613,983	1,888,119	8,901,197	5,966,504
Total operating expenses	<u>3,298,198</u>	<u>3,309,970</u>	<u>14,648,596</u>	<u>9,327,067</u>
Operating loss	(3,298,198)	(3,309,970)	(14,648,596)	(9,327,067)
Other income	12,284	104	26,846	242
Loss before income taxes	<u>(3,285,914)</u>	<u>(3,309,866)</u>	<u>(14,621,750)</u>	<u>(9,326,825)</u>
Income taxes	-	-	-	-
Net loss	<u>\$ (3,285,914)</u>	<u>\$ (3,309,866)</u>	<u>\$ (14,621,750)</u>	<u>\$ (9,326,825)</u>
Deemed dividends attributable to preferred stock	-	-	-	(11,479,308)
Net loss applicable to common shareholders	<u>\$ (3,285,914)</u>	<u>\$ (3,309,866)</u>	<u>\$ (14,621,750)</u>	<u>\$ (20,806,133)</u>
Loss per common share - basic and diluted	<u>\$ (0.36)</u>	<u>\$ (0.64)</u>	<u>\$ (1.77)</u>	<u>\$ (5.71)</u>
Weighted average shares outstanding - basic and diluted	<u>9,130,057</u>	<u>5,183,492</u>	<u>8,283,302</u>	<u>3,645,682</u>