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 26, 2020

Atossa Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	001-35610	26-4753208
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

107 Spring Street Seattle, Washington	98104
(Address of principal executive offices)	(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 pursuance 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 March 26, 2020, Atossa Therapeutics, Inc. (the "Company") issued a press release announcing year end December 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

Exhibit No.	Description
99.1	Press Release, dated March 26, 2020

* * *

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 26, 2020

Atossa Therapeutics, Inc.

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

Exhibit Index

Exhibit No.	Description
99.1	Press Release, dated March 26, 2020

Atossa Therapeutics Announces Fourth Quarter and Year End 2019 Financial Results and Provides Company Update

SEATTLE, March 26, 2020 (GLOBENEWSWIRE) -- Atossa Therapeutics, 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 fourth quarter and year ended December 31, 2019 and provides an update on recent company developments.

“We are very proud of our 2019 accomplishments, as we focused on developing our proprietary drug Endoxifen to reduce mammographic breast density (MBD) and to treat breast cancer in the ‘window of opportunity’ - after a patient is diagnosed but before her surgery,” said Dr. Steven Quay, Atossa’s President and Chief Executive Officer. “We have received positive data from the expanded access (or, ‘compassionate-use’) patient taking our oral Endoxifen and from our Phase 2 study of our topical Endoxifen to reduce MBD, all while minimizing costs and managing our cash position.”

Key strategic highlights for 2019 included:

- Completed additional Phase 1 work with our proprietary oral Endoxifen.
- Contracted with South General Hospital in Stockholm, Sweden to conduct a Phase 2 study with oral Endoxifen to reduce MBD.
- Continued Phase 2 study underway in Australia administering our oral Endoxifen to newly diagnosed breast cancer patients in the “window of opportunity.”
- In developing topical Endoxifen, Phase 2 studies showed significant and rapid reduction of MBD.
- Received favorable results from our single-patient expanded access program: the Ki-67 activity decreased by 50%, and the estrogen receptor content decreased by more than 20% with no safety or tolerability issues, including vasomotor symptoms such as hot flashes and night sweats.
- Received IRB approval for a Phase 2 clinical study using our intraductal microcatheter technology to administer fulvestrant in patients with early-stage breast cancer or ductal carcinoma *in situ* (DCIS) at a major institution.

Recent Corporate Developments

Recent developments include the following:

- Changed the name of the company from Atossa Genetics to Atossa Therapeutics, which we believe more clearly reflects our focus on developing therapies and continues to honor Princess Atossa, the great queen of the Achaemenid Empire who reigned in the fifth century BCE and who is the earliest recorded woman with breast cancer.
- Submitted an application to initiate a Phase 2 study of our oral Endoxifen for the reduction of MBD to the Swedish Medical Product Agency and the Institutional Review Board.
- Announced that we will meet with the U.S. F.D.A. on April 30, 2020. The objective of this meeting is to discuss the clinical development of oral Endoxifen to reduce MBD.

2019 Financial Results

For the years ended December 31, 2019 and 2018, we have no source of sustainable revenue and no associated cost of revenue.

Operating Expenses: Total operating expenses were $17.3 million for the year ended December 31, 2019, which is an increase of $5.8 million, or 51%, from the year ended December 31, 2018. Operating expenses for 2019 consisted of research and development (R&D) expenses of $6.6 million and general and administrative (G&A) expenses of $10.6 million. Operating expenses for 2018 consisted of R&D expenses of $4.2 million, and G&A expenses of $7.2 million.

Research and Development Expenses: R&D expenses for the year ended December 31, 2019, were $6.6 million, an increase of $2.4 million, or 58%, from total R&D expenses in 2018 of $4.2 million. The increase in R&D expense is attributed to non-cash stock-based compensation, salaries and clinical trial expenses associated with our Endoxifen program. R&D stock-based compensation expense, which is a non-cash charge, increased approximately $2.3 million during 2019 resulting from the cancellation of certain 2018 options and the 2019 replacement grant of options that were 75% vested and that were granted at fair market value on the date approval by the Board of Directors but were in-the-money on the date they were subsequently approved by the stockholders. There were no option cancellations or in-the-money option grants in the comparable period of 2018. Clinical trial expenses also increased by approximately $250,000 over the same period in 2018.

General and Administrative Expenses: G&A expenses were $10.6 million for the year ended December 31, 2019, an increase of $3.4 million, or 47% from the total G&A expenses for the year ended December 31, 2018, of $7.2 million. 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 year ended December 31, 2019, is attributed to non-cash stock-based compensation. G&A stock-based compensation expense, which is a non-cash charge, increased approximately $4.0 million during 2019 resulting from the cancellation of certain 2018 options and the 2019 replacement grant of options that were 75% vested and that were granted at fair market value on the date of approval by the Board of Directors but were in-the-money on the date they were subsequently approved by the stockholders. There were no option cancellations or in-the-money option grants in the comparable period of 2018. The increase in 2019 expense G&A expense was offset by a reduction in bonus compensation expense of approximately $350,000 as a one-time 2018 bonus was not paid in 2019.

As of December 31, 2019, the Company had approximately $12.6 million in cash and cash equivalents and working capital of approximately $13.0 million.

About Atossa Therapeutics

Atossa Therapeutics, 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.atossatherapeutics.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 Therapeutics, Inc.

ATOSSA THERAPEUTICS, INC.
CONSOLIDATED BALANCE SHEETS

	As of December 31, 2019	As of December 31, 2018
Assets		
Current assets		
Cash and cash equivalents	$ 12,581,136	$ 10,380,493
Restricted cash	110,000	110,000
Prepaid expenses	862,344	509,833
Research and development tax rebate receivable	739,656	518,098
Other current assets	26,130	30,942
Total current assets	14,319,266	11,549,366
Furniture and equipment, net	34,350	54,487
Intangible assets, net	68,542	99,375
Right-of-use asset	50,479	-
Other assets	17,218	17,218
Total Assets	$ 14,489,855	$ 11,720,446
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 293,171	$ 353,328
Accrued expenses	77,888	177,074
Payroll liabilities	899,420	935,070
Stock-based compensation liability	-	1,410,025
Lease liability	39,371	-
Other current liabilities	12,892	39,939
Total current liabilities	1,322,742	2,915,436
Long term liabilities		
Lease liability long term	11,108	-
Total Liabilities	1,333,850	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 December 31, 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 December 31, 2019 and December 31, 2018, respectively	1,643,565	1,052,372
Additional paid-in capital	104,912,480	82,204,902
Accumulated deficit	(94,071,040)	(76,831,263)
Total Stockholders' Equity	13,156,005	8,805,010
Total Liabilities and Stockholders' Equity	$ 14,489,855	$ 11,720,446

ATOSSA THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS

	For the Year Ended December 31,	
	2019	**2018**
Operating expenses		
Research and development	$ 6,645,417	$ 4,209,981
General and administrative	10,620,008	7,224,252
Total operating expenses	17,265,425	11,434,233
Operating loss	(17,265,425)	(11,434,233)
Other income	25,648	29,299
Loss before income taxes	(17,239,777)	(11,404,934)
Income taxes	-	-
Net loss	$ (17,239,777)	$ (11,404,934)
Deemed dividends attributable to preferred stock	-	(11,479,308)
Net loss applicable to common shareholders	$ (17,239,777)	$ (22,884,242)
Loss per common share - basic and diluted	$ (2.03)	$ (5.50)
Weighted average shares outstanding - basic and diluted	8,496,964	4,157,746