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 31, 2021

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	The Nasdaq Capital Market

Item 2.02. Results of Operations and Financial Condition.

On March 31, 2021, Atossa Therapeutics, Inc. (the "Company") issued a press release announcing the year ended December 31, 2020 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 31, 2021

* * *

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 31, 2021

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 31, 2021

Atossa Therapeutics Announces Year End 2020 Financial Results and Provides Corporate Update

SEATTLE, March 31, 2021 (GLOBE NEWSWIRE) -- Atossa Therapeutics, Inc. (Nasdaq: ATOS), a clinical-stage biopharmaceutical company seeking to discover and develop innovative medicines in oncology and infectious disease with a current focus on breast cancer and COVID-19, today announced financial results for the fiscal year ended December 31, 2020, and provided an update on recent company developments.

Key recent developments and from Q4 2020 include:

- Demonstrated positive interim results of the Company's open-label Phase 2 clinical study of oral Endoxifen administered in the "window of opportunity" between diagnosis of breast cancer and surgery and, based on those results, Atossa concluded the study early and is accelerating its Endoxifen program in the United States
- Announced updated findings following 24 months of an Expanded Access (or "compassionate use") single-patient study of Endoxifen. The patient in the study had no cancer recurrence and suffered no side effects. Endoxifen did not cause other safety and tolerability concerns in this patient
- Received a "Safe to Proceed" letter from the FDA permitting the use Atossa's oral Endoxifen as a treatment in an ovarian cancer patient (expanded access)
- Announced final results from its Phase 1 double-blinded, randomized, placebo-controlled clinical study using Atossa's proprietary drug candidate AT-301 administered by nasal spray. AT-301 was considered to be safe and well tolerated in healthy male and female participants in this study at two different dose levels over 14 days. AT-301 is being developed for at home use for patients recently diagnosed with COVID-19
- Completed financing transactions with net proceeds of approximately $136 million in December 2020 and Q1 2021

"We believe that in 2020 Atossa rose to meet the challenges of a pandemic through innovation and rapid response to the global events impacting economies, institutions, and pharmaceutical research and development," said Dr. Steven Quay, Atossa's President and Chief Executive Officer. "Despite these challenges, 2020 was the year our proprietary Endoxifen programs began to show the potential breadth and depth of its medical and ultimate commercial value. Three recent Endoxifen-related events stand out:

- the reporting of two-year experience in the adjuvant setting in breast cancer in a single-patient Expanded Access study in which Endoxifen was well tolerated and cancer recurrence was not seen clinically;
- the better-than-expected response in the breast cancer window-of-opportunity study, allowing that study to be closed early based on success, accelerating that program almost one year; and
- the initiation of an Expanded Access treatment program in an ovarian cancer patient, based on sensitivity to Endoxifen of laboratory cancer organoids from this patient.

"Our nasal spray AT-301 being developed for COVID-19 patients to use at home showed encouraging results in preclinical and Phase 1 studies. We believe that AT-301 has the potential to provide an important and necessary component of a broader global response to COVID-19. Although it is encouraging that traditional vaccines are becoming available, there are many people who won't take a vaccine, and current vaccines may not protect against future variants.

"Finally, the ability to strengthen our balance sheet over the last few months, even in these challenging times, places Atossa in a good position to execute on business opportunities, both internal and potentially external, during the remainder of 2021 and beyond," concluded Dr. Quay.

Year Ended December 31, 2020 Financial Results

For the year ended December 31, 2020, Atossa has no source of sustainable revenue and no associated cost of revenue.

Operating Expenses
Total operating expenses were $14,607,000 for the year ended December 31, 2020, which is a decrease of $2,658,000 or 15%, from the year ended December 31, 2019. Operating expenses for 2020 consisted of research and development ("R&D") expenses of $6,608,000 and general and administrative ("G&A") expenses of $7,999,000. Operating expenses for 2019 consisted of R&D expenses of $6,645,000, and G&A expenses of $10,620,000.

Research and Development Expenses
R&D expenses for the year ended December 31, 2020, were $6,608,000, a decrease of $37,000 or 1% from total R&D expenses in 2019 of $6,645,000. The decrease in R&D expense is attributed primarily to a decrease in stock-based compensation of approximately $2,214,000, which is a non-cash charge, offset by an increase in salaries of approximately $428,000, and an increase professional fees and clinical trials expenses of approximately $1,696,000, as compared to the same period in 2019. We expect our R&D expenses to increase into 2021 as Atossa seeks to commence a study of AT-H201, complete a preclinical and commence a clinical study of AT-301, launch a Phase 2 clinical trial of Endoxifen in women with high breast density, and continue the development of other indications and therapeutics.

General and Administrative Expenses
G&A expenses were $7,999,000 for the year ended December 31, 2020, a decrease of $2,621,000, or 25% from the total G&A expenses for the year ended December 31, 2019, of $10,620,000. The decrease in G&A expenses for the year ended December 31, 2020, is mainly attributed to a decrease in stock-based compensation of approximately $3,610,000, which is a non-cash charge, offset by an increase in legal fees of approximately $507,000, professional fees of approximately $169,000 and insurance costs of approximately $268,000 compared to the same period in 2019. G&A expenses consist primarily of personnel and related benefit costs, facilities, professional services, insurance, and public company related expenses.

As of December 31, 2020, the Company had cash, cash equivalents and restricted cash of $39.7 million.

About Atossa Therapeutics

Atossa Therapeutics, Inc. is a clinical-stage biopharmaceutical company seeking to discover and develop innovative medicines in oncology and infectious diseases with a current focus on breast cancer and COVID-19. 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 interim 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 of AT-H201, AT-301 and Endoxifen, lower than anticipated rate of patient enrollment, estimated market size of drugs under development, the safety and efficacy of Atossa's products, performance of clinical research organizations and investigators, obstacles resulting from proprietary rights held by others such as patent rights, whether reduction in Ki-67 or any other result from a neoadjuvant study is an approvable endpoint for oral Endoxifen, 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 Therapeutics, Inc.

ATOSSA THERAPEUTICS, INC.
CONSOLIDATED BALANCE SHEETS

	As of December 31,	
Assets	**2020**	**2019**
Current assets		
Cash and cash equivalents	$ 39,553,671	$ 12,581,136
Restricted cash	110,000	110,000
Prepaid expenses	1,813,902	862,344
Research and development tax rebate receivable	634,940	739,656
Other current assets	657,662	26,130
Total current assets	42,770,175	14,319,266
Furniture and equipment, net	20,632	34,350
Intangible assets, net	13,375	68,542
Right-of-use asset	18,053	50,479
Other assets	17,218	17,218
Total Assets	$ 42,839,453	$ 14,489,855
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 1,588,613	$ 293,171
Accrued expenses	93,367	77,888
Payroll liabilities	963,665	899,420
Common stock warrant liability	13,003,075	-
Lease liability	18,053	39,371
Other current liabilities	4,748	12,892
Total current liabilities	15,671,521	1,322,742
Long term liabilities		
Lease liability long term	-	11,108
Total Liabilities	15,671,521	1,333,850
Commitments and contingencies		
Stockholders' equity		
Preferred stock - $0.001 par value; 10,000,000 shares authorized; 621 and 671 shares issued and outstanding as of December 31, 2020 and December 31, 2019, respectively	1	1
Additional paid-in capital - Series B convertible preferred stock	620,999	670,999
Common stock - $0.18 par value; 175,000,000 shares authorized; 47,548,835 and 9,130,984 shares issued and outstanding as of December 31, 2020 and December 31, 2019, respectively	8,558,778	1,643,565
Additional paid-in capital	129,887,146	104,912,480
Accumulated deficit	(111,898,992)	(94,071,040)
Total Stockholders' Equity	27,167,932	13,156,005
Total Liabilities and Stockholders' Equity	$ 42,839,453	$ 14,489,855

ATOSSA THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS

	For the Year Ended December 31,	
	2020	**2019**
Operating expenses		
Research and development	$ 6,608,392	$ 6,645,417
General and administrative	7,999,000	10,620,008
Total operating expenses	14,607,392	17,265,425
Operating loss	(14,607,392)	(17,265,425)
Change in fair value of common stock warrants	(2,332,567)	-
Warrant financing expense	(938,794)	-
Other income	50,801	25,648
Loss before income taxes	(17,827,952)	(17,239,777)
Income taxes	-	-
Net loss	$ (17,827,952)	$ (17,239,777)
Deemed dividend attributable to preferred stock	(4,502,799)	-
Net loss applicable to common shareholders	$ (22,330,751)	$ (17,239,777)
Loss per common share - basic and diluted	$ (1.97)	$ (2.03)
Weighted average shares outstanding - basic and diluted	11,308,532	8,496,964