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): May 14, 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 May 14, 2021, Atossa Therapeutics, Inc. (the "Company") issued a press release announcing the quarter ended March 31, 2021 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 May 14, 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: May 14, 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 May 14, 2021

Atossa Therapeutics Announces First Quarter 2021 Financial Results and Provides Corporate Update

SEATTLE, May 14, 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 announces financial results for the fiscal quarter ended March 31, 2021, and provides an update on recent company developments.

Key developments from Q1 2021 and to date include:

- Atossa concluded its open-label Phase 2 clinical study of oral Endoxifen administered in the “window of opportunity” between diagnosis of breast cancer and surgery based on positive results allowing acceleration of the Endoxifen program in the United States
- Announced updated findings following 24 months of an Expanded Access (or “compassionate use”) single-patient study of Endoxifen for breast cancer. 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 under the Expanded Access Pathway from the FDA permitting the use of Atossa’s oral Endoxifen as a treatment in an ovarian cancer patient and began treatment
- 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 beginning in December 2020 through the end of Q1

Atossa’s 2021 Annual Stockholder Meeting is scheduled for today, May 14, 2021 at 1 p.m. Pacific Time. As part of the meeting, Atossa management has decided to withdraw from consideration the proposal to increase authorized shares of common stock by 325 million.

“During the first quarter of 2021 we continued our two key development programs, namely our Phase 2 study of oral Endoxifen for the ‘window of opportunity’ between diagnosis of breast cancer and surgery and our Phase 1 study of AT-301 nasal spray for at-home use for patients recently diagnosed with COVID-19,” said Dr. Steven Quay, Atossa’s President and Chief Executive Officer. “In addition, we continued our ongoing expanded access program with Endoxifen in which the drug continues to be well tolerated and breast cancer recurrence has not been seen clinically. We also received an important authorization from the FDA for an additional expanded access treatment program in an ovarian cancer patient. Combined with very encouraging results in our COVID-19 program with AT-301 nasal spray, we continued to make great progress over the quarter."

“In the meantime, we leveraged favorable conditions in the capital markets to strengthen our balance sheet over the last few months placing Atossa in a good position to execute on these and potential additional business opportunities during the remainder of 2021. As a result, we are diligently moving our existing programs forward, while actively exploring the possibility for strategic expansion into other areas where we might see near-term milestones and results. We look forward to continuing to update our stockholders on these opportunities as they develop,” concluded Dr. Quay.

Quarter Ended March 31, 2021 Financial Results

For the quarter ended March 31, 2021, Atossa has no source of sustainable revenue and no associated cost of revenue.

As of March 31, 2021, the Company had cash, cash equivalents and restricted cash of approximately $137.7 million.

Operating Expenses
Total operating expenses were $3,531,000 for the quarter ended March 31, 2021, compared to $2,937,000 during the same period of 2020, an increase of $594,000 or approximately 20%. Operating expenses for 2021 consisted of research and development ("R&D") expenses of $1,379,000 and general and administrative ("G&A") expenses of $2,152,000. Operating expenses for 2020 consisted of R&D expenses of $939,000, and G&A expenses of $1,998,000.

Research and Development Expenses
R&D expenses for the three months ended March 31, 2021, were $1,379,000, an increase of $440,000 or 47% from total R&D expenses for the same period in 2020 of $939,000. The increase in R&D expense is attributed primarily an increase in clinical trial expense of approximately $319,000 and an increase in salaries of approximately $118,000 due to the addition of employees, as compared to the same period in 2020. We expect our R&D expenses to continue to increase into 2021 as we seek to commence a study of AT-H201, complete studies 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 $2,152,000 for the three months ended March 31, 2021, an increase of $154,000, or 8% from the total G&A expenses for the three months ended March 31, 2020, of $1,998,000. The increase in G&A expenses for the three months ended March 31, 2021, is mainly attributed to an increase in insurance and professional fees of approximately $286,000 offset by a reduction in legal fees and compensation of approximately $152,000 compared to the same period in 2020. G&A expenses consist primarily of personnel and related benefit costs, facilities, professional services, insurance, and public company related expenses.

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.
CONDENSED CONSOLIDATED BALANCE SHEETS

	As of March 31, 2021 (Unaudited)	As of December 31, 2020
Assets		
Current assets		
Cash and cash equivalents	$ 137,573,593	$ 39,553,671
Restricted cash	110,000	110,000
Prepaid expenses	2,550,452	1,813,902
Research and development tax rebate receivable	720,029	634,940
Other current assets	77,239	657,662
Total current assets	141,031,313	42,770,175
Furniture and equipment, net	15,835	20,632
Intangible assets, net	8,917	13,375
Right-of-use asset	8,013	18,053
Other assets	16,468	17,218
Total Assets	$ 141,080,546	$ 42,839,453
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 722,281	$ 1,588,613
Accrued expenses	151,155	93,367
Payroll liabilities	490,001	963,665
Common stock warrant liability	-	13,003,075
Lease liability	8,013	18,053
Other current liabilities	7,697	4,748
Total current liabilities	1,379,147	15,671,521
Commitments and contingencies		
Stockholders' equity		
Preferred stock - $0.001 par value; 10,000,000 shares authorized; 620 and 621 shares issued and outstanding as of March 31, 2021 and December 31, 2020, respectively	1	1
Additional paid-in capital - Series B convertible preferred stock	619,999	620,999
Common stock - $0.18 par value; 175,000,000 shares authorized; 120,824,368 and 47,548,835 shares issued and outstanding as of March 31, 2021 and December 31, 2020, respectively	21,748,374	8,558,778
Additional paid-in capital	229,498,725	129,887,146
Accumulated deficit	(112,165,700)	(111,898,992)
Total Stockholders' Equity	139,701,399	27,167,932
Total Liabilities and Stockholders' Equity	$ 141,080,546	$ 42,839,453

ATOSSA THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(UNAUDITED)

	For the Three Months Ended March 31,	
	2021	**2020**
Operating expenses		
Research and development	$ 1,378,487	$ 938,620
General and administrative	2,152,241	1,998,389
Total operating expenses	3,530,728	2,937,009
Operating loss	(3,530,728)	(2,937,009)
Other expense	(7,341)	(10,411)
Loss before income taxes	(3,538,069)	(2,947,420)
Income taxes	-	-
Net loss	$ (3,538,069)	$ (2,947,420)
Loss per common share - basic and diluted	$ (0.04)	$ (0.32)
Weighted average shares outstanding - basic and diluted	92,587,168	9,130,984