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, 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 August 13, 2021, Atossa Therapeutics, Inc. (the "Company") issued a press release announcing the quarter ended June 30, 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 August 13, 2021
104	Cover page Interactive Data File (embedded within the Inline XBRL document)

* * *

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, 2021

Atossa Therapeutics, Inc.

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

Atossa Therapeutics Announces Second Quarter 2021 Financial Results - Provides Corporate Update and Information about Upcoming Stockholder Meeting

SEATTLE, August 13, 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 June 30, 2021, and provides an update on recent company developments.

Key developments from Q2 2021 and to date include:

- Atossa received final data from its open-label Phase 2 clinical study of oral Endoxifen administered in the “window of opportunity” between diagnosis of breast cancer and surgery, which showed that the primary endpoint of the study was achieved: Ki-67, a common measure of tumor cell activity, was reduced from an average of 25.6% at screening to 6% on the day of surgery, a 65.1% reduction. Ki-67 was reduced below 25% for all patients, which is potentially clinically meaningful because studies by others have shown that a reduction below 25% improves long term survival.

- Received authorization from Swedish regulators to initiate a Phase 2 clinical study of Endoxifen to reduce mammographic breast density (MBD).

- Received authorization from Australian regulators to initiate a clinical study of AT-H201 which is being developed for the treatment of patients with COVID-19 and “long haul” respiratory illness.

- 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 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 treatment of oral Endoxifen in an ovarian cancer patient under the FDA’s Expanded Access Pathway. The patient has recurring, metastatic, late-stage ovarian cancer and had not improved on other therapies. Although organoid testing conducted by a third party had previously shown a strong response to Endoxifen in combination with Apelisib, she has unfortunately continued to experience disease progression and is not expected to continue treatment with Endoxifen.

- Through the completion of capital raising transactions and the exercise of warrants, Atossa has grown its cash balances quarter over quarter for the past three quarters, ending the second quarter 2021 with $142.4 million in cash and cash equivalents.

- Scheduled a special stockholder meeting for September 7, 2021 for the purpose of approving an increase in authorized shares of common stock. If the proposal is approved by the stockholders, Atossa does not intend to issue any of the newly authorized shares of common stock for the purpose of raising capital in the nine months following approval of the proposal at a price less than $10 per share. The newly authorized shares of common stock are intended to be used at any time to complete and/or support acquisitions, collaborations, partnerships and licensing transactions.

“We continue to experience encouraging progress in our MBD and COVID-19 programs, with new regulatory approvals being granted in Sweden for a Phase 2 trial in MBD and authorization in Australia to commence a Phase 2 study of AT-H201 for respiratory illness associated with COVID-19,” said Dr. Steven Quay, Atossa’s President and Chief Executive Officer.

“In the meantime, we continue to enjoy a strong balance sheet, which we have significantly expanded over the last three quarters and will facilitate our development plans over the near term. As we actively explore the possibility for strategic expansion into other areas where we might see near-term milestones and results, we also urge all of our shareholders to exercise their right to vote at our special stockholder’s meeting on September 7, 2021. We urge a vote in favor of the proposal to increase authorized shares, which will provide the Company with the flexibility to issue shares as part of these potential acquisitions, collaborations and partnerships, a common strategy successful biotech companies seeking to grow shareholder value employ in order to create a more attractive opportunity for all. We look forward to continuing to update our stockholders on these opportunities as they develop,” concluded Dr. Quay.

Quarter Ended June 30, 2021, Financial Results

For the quarter ended June 30, 2021, Atossa has no source of sustainable revenue and no associated cost of revenue.

As of June 30, 2021, the Company had cash, cash equivalents and restricted cash of approximately $142.5 million.

Operating Expenses
Total operating expenses were approximately $7,004,000 and $10,534,000 for the three and six months ended June 30, 2021, respectively, consisting of research and development ("R&D") expenses of approximately $3,799,000 and $5,177,000 respectively, and general and administrative ("G&A") expenses of approximately $3,205,000 and $5,357,000, respectively. Total operating expenses were approximately $3,936,000 and $6,873,000, respectively for the three and six month ended June 30, 2020, and consisted of R&D expenses of approximately $1,653,000 and $2,592,000, respectively, and G&A expenses of approximately $2,283,000 and $4,281,000 respectively. Total operating expenses for the three and six months ended June 30, 2021, as compared to the same period in 2020 increased approximately $3,068,000 and $3,661,000 or 78% and 53%, respectively.

Research and Development Expenses
R&D expenses for the three months ended June 30, 2021, were approximately $3,799,000, an increase of approximately $2,146,000 or 130% from total R&D expenses for the three months ended June 30, 2020, of approximately $1,653,000. R&D expenses for the six months ended June 30, 2021, were approximately $5,177,000, an increase of approximately $2,585,000 or 100% from total R&D expenses for the six months ended June 30, 2020, of approximately $2,592,000. The increase in R&D expense is attributed primarily to an increase in clinical trial expense of approximately $1,309,000 and an increase in compensation of approximately $211,000 due to the addition of two employees, as compared to the same period in

2020. Also included in R&D expenses is an increase of $1,000,000 attributable to a one-time fee we paid in June 2021 to a U.S. leading research institution for the exclusive right to negotiate for the acquisition of the world-wide rights to two oncology R&D programs. We expect our R&D expenses to continue to increase into 2021 as we seek to commence a clinical 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 $3,205,000 for the three months ended June 30, 2021, an increase of approximately $922,000, or 40% from the total G&A expenses for the three months ended June 30, 2020, of approximately $2,283,000. G&A expenses for the six months ended June 30, 2021, were approximately $5,357,000, an increase of approximately $1,076,000 or 25% from total R&D expenses for the six months ended June 30, 2020, of approximately $4,281,000. The increase in G&A expenses for the three and six months ended June 30, 2021, is attributed to an increase in insurance costs of approximately $387,000 due to the addition of the COVID-19 clinical trials, professional fees of approximately $703,000 due primarily to increased proxy costs and increased compensation of approximately $170,000, offset by a reduction in legal fees of approximately $301,000 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 June 30, 2021 (Unaudited)	As of December 31, 2020
Assets		
Current assets		
Cash and cash equivalents	$ 142,432,961	$ 39,553,671
Restricted cash	110,000	110,000
Prepaid expenses	2,391,966	1,813,902
Research and development tax rebate receivable	817,109	634,940
Other current assets	78,882	657,662
Total current assets	145,830,918	42,770,175
Furniture and equipment, net	14,501	20,632
Intangible assets, net	4,458	13,375
Right-of-use asset	4,720	18,053
Other assets	13,408	17,218
Total Assets	$ 145,868,005	$ 42,839,453
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 537,915	$ 1,588,613
Accrued expenses	531,602	93,367
Payroll liabilities	700,588	963,665
Common stock warrant liability	-	13,003,075
Lease liability	4,720	18,053
Other current liabilities	21,278	4,748
Total current liabilities	1,796,103	15,671,521
Commitments and contingencies		
Stockholders' equity		
Preferred stock - $0.001 par value; 10,000,000 shares authorized; 587 and 621 shares issued and outstanding as of June 30, 2021 and December 31, 2020, respectively	1	1
Additional paid-in capital - Series B convertible preferred stock	586,999	620,999
Common stock - $0.18 par value; 175,000,000 shares authorized; 125,925,096 and 47,548,835 shares issued and outstanding as of June 30, 2021 and December 31, 2020, respectively	22,666,505	8,558,778
Additional paid-in capital	240,023,345	129,887,146
Accumulated deficit	(119,204,948)	(111,898,992)
Total Stockholders' Equity	144,071,902	27,167,932
Total Liabilities and Stockholders' Equity	$ 145,868,005	$ 42,839,453

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

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2021	**2020**	**2021**	**2020**
Operating expenses				
Research and development	$ 3,798,636	$ 1,653,239	$ 5,177,123	$ 2,591,859
General and administrative	3,205,130	2,282,568	5,357,371	4,280,957
Total operating expenses	7,003,766	3,935,807	10,534,494	6,872,816
Operating loss	(7,003,766)	(3,935,807)	(10,534,494)	(6,872,816)
Other income (expense), net	(35,482)	29,665	(42,823)	19,254
Loss before income taxes	(7,039,248)	(3,906,142)	(10,577,317)	(6,853,562)
Income taxes	-	-	-	-
Net loss	$ (7,039,248)	$ (3,906,142)	$ (10,577,317)	$ (6,853,562)
Loss per common share - basic and diluted	$ (0.06)	$ (0.43)	$ (0.10)	$ (0.75)
Weighted average shares outstanding - basic and diluted	121,572,091	9,187,588	107,159,698	9,159,286