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 9, 2022

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 9, 2022, Atossa Therapeutics, Inc. (the "Company") issued a press release announcing the quarter ended March 31, 2022 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 9, 2022
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: May 9, 2022

Atossa Therapeutics, Inc.

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

Exhibit 99.1

Atossa Therapeutics Announces First Quarter 2022 Financial Results and Provides Corporate Update

SEATTLE, May 09, 2022 (GLOBE NEWSWIRE) -- Atossa Therapeutics, Inc. (Nasdaq: ATOS), a clinical-stage biopharmaceutical company seeking to develop innovative proprietary 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, 2022, and provides an update on recent company developments.

Key developments from Q1 2022 and to date include:

- Received issuance of key U.S. patent covering Endoxifen directed to compositions of storage-stable Endoxifen and methods of treating hormone-dependent breast disorders using the storage-stable Endoxifen.

- Announced planned U.S. Phase 2 clinical study of Endoxifen in the neoadjuvant setting (prior to surgery) to compare Endoxifen to standard of care in premenopausal women with breast cancer. A CRO has been engaged to work on this study and the Company also intends to retain a leading U.S. research institution to help manage the study. The Company anticipates submitting an IND to the FDA in the second quarter of 2022.

- Completed Part B (second of four parts) of Phase 1b/2a clinical study of AT-H201 in Australia.

"We continue to make steady progress with our Endoxifen programs: one to reduce tumor cell activity in breast cancer patients in the neoadjuvant setting; and another to reduce dense breast tissue in women," commented Dr. Steven Quay, Atossa's President and Chief Executive Officer. "Our Phase 2 study in women with measurable breast density continues to enroll participants in Stockholm and we have been preparing to submit a request (IND) to the FDA this quarter to open a Phase 2 study in the neoadjuvant setting here in the Unites States. We began 2022 with significant progress in our COVID-19 program, both initiating and completing key parts of our Phase1b/2a trial in Australia for AT-H201, and we have now completed the first two parts of that study."

Quarter Ended March 31, 2022 Financial Results (in thousands):

For the quarter ended March 31, 2022, Atossa has no source of sustainable revenue and no associated cost of revenue.

As of March 31, 2022, the Company had cash, cash equivalents and restricted cash of approximately $131,596.

Operating Expenses: Total operating expenses were $4,747 for the three months ended March 31, 2022, which is an increase of $1,216 or 34%, from the three months ended March 31, 2021. Operating expenses for 2022 consisted of research and development (R&D) expenses of $1,499 and general and administrative (G&A) expenses of $3,248. Operating expenses for 2021 consisted of R&D expenses of $1,379, and G&A expenses of $2,152. The basis for the increased operating expenses in 2022 is explained below.

Research and Development Expenses: R&D expenses for the three months ended March 31, 2022, were $1,499, an increase of $120 or 9% from total R&D expenses for the same period in 2021 of $1,379. The increase in R&D expense is attributed to increased spending on clinical and non-clinical trials of $584 over 2021 due to additional drug manufactuing costs. Stock-based compensation, which is a non-cash charge, also increased $433 quarter over quarter, and other R&D compensation was up $79 due to salary bonus and benefit increases quarter over quarter. The increase in R&D was offset by a refund of $1,000 from the research institution that the Company had an exclusive right to negotiate for the acquisition of the world-wide rights to two oncology R&D programs. In February 2022, the other party did not honor its obligation to negotiate with us which lead to a cancellation of the agreement and refund of the $1,000 we paid them.

General and Administrative Expenses: G&A expenses were $3,248 for the three months ended March 31, 2022, an increase of $1,096, or 51% from the total G&A expenses for the three months ended March 31, 2021, of $2,152. The increase in G&A expenses for the three months ended March 31, 2022, is primarily attributable to non-cash stock-based compensation expense of $734. Other compensation also increased $264 due to the addition of a new employee quarter over quarter as well as salary, bonus and benefit increases. Legal fees also increased $124 quarter over quarter due to increased patent activity.

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
(amounts in thousands, except for par value)

	As of March 31, 2022 (Unaudited)	As of December 31, 2021
Assets		
Current assets		
Cash and cash equivalents	$ 131,486	$ 136,377
Restricted cash	110	110
Prepaid expenses	3,874	2,488
Research and development rebate receivable	668	1,072
Other current assets	710	1,193
Total current assets	136,848	141,240
Other assets	630	22
Total Assets	$ 137,478	$ 141,262
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 1,596	$ 1,717
Accrued expenses	120	204
Payroll liabilities	593	1,184
Other current liabilities	13	21
Total current liabilities	2,322	3,126
Total Liabilities	2,322	3,126
Commitments and contingencies		
Stockholders' equity		
Preferred stock - $0.001 par value; 10,000 shares authorized; 1 share issued and outstanding as of March 31, 2022 and December 31, 2021	-	-
Additional paid-in capital - Series B convertible preferred stock	582	582
Common stock - $0.18 par value; 175,000 shares authorized; 126,624 shares issued and outstanding as of March 31, 2022 and December 31, 2021	22,792	22,792
Additional paid-in capital - common stock	245,802	243,996
Accumulated deficit	(134,020)	(129,234)
Total Stockholders' Equity	135,156	138,136
Total Liabilities and Stockholders' Equity	$ 137,478	$ 141,262

ATOSSA THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(UNAUDITED)
(amounts in thousands, except for per share amounts)

	For the Three Months Ended March 31,	
	2022	**2021**
Operating expenses		
Research and development	$ 1,499	$ 1,379
General and administrative	3,248	2,152
Total operating expenses	4,747	3,531
Operating loss	(4,747)	(3,531)
Other expense, net	(39)	(7)
Loss before income taxes	(4,786)	(3,538)
Income taxes	-	-
Net loss	$ (4,786)	$ (3,538)
Loss per common share - basic and diluted	$ (0.04)	$ (0.04)
Weighted average shares outstanding - basic and diluted	126,624	92,587