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 15, 2023

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) 588-0256

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 15, 2023, Atossa Therapeutics, Inc. (the "Company") issued a press release announcing the quarter ended March 31, 2023 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 15, 2023
104	Cover page Interactive Data File (embedded within the Inline XBRL document)

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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 15, 2023

Atossa Therapeutics, Inc.

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

Atossa Therapeutics Announces First Quarter 2023 Financial Results and Provides Corporate Update

- *Two Phase 2 trials investigating (Z)-endoxifen in neoadjuvant setting initiated and are enrolling patients*
- *Full enrollment of Phase 2 KARISMA mammographic breast density study expected by end of 2023*
- *Ended first quarter 2023 with $103.9 million of cash and cash equivalents and no debt*

SEATTLE, May 15, 2023 (GLOBE NEWSWIRE) — Atossa Therapeutics, Inc. (Nasdaq: ATOS), a clinical stage biopharmaceutical company developing innovative proprietary medicines to address significant unmet needs in oncology with a current focus on breast cancer, today announces financial results for the fiscal quarter ended March 31, 2023, and provides an update on recent company developments.

Key developments from Q1 2023 and year to date include:

- **Initiation of and First Patient Dosed in Phase 2 EVANGELINE Study** – EVANGELINE (Endoxifen Versus exemestANe GosEreLIn), is a Phase 2 randomized non-inferiority study of (Z)-endoxifen compared to exemestane plus goserelin as a neoadjuvant treatment for premenopausal women with Grade 1 or 2 ER+ / HER2- breast cancer. Participants receive neoadjuvant treatment for up to 24 weeks, followed by surgery.
- **Initiation of New Study Arm in the Ongoing Phase 2 I-SPY 2 Clinical Trial** – I-SPY 2 is a collaborative effort among academic investigators from major cancer research centers across the United States, Quantum Leap Healthcare Collaborative, the U.S. Food and Drug Administration, and the Foundation for the National Institutes of Health (FNIH) Cancer Biomarkers Consortium. Approximately 20 patients will be treated with (Z)-endoxifen for up to 24 weeks prior to surgery.
- **Additional Intellectual Property Protection for (Z)-endoxifen** – The United States Patent and Trademark Office granted a new patent (No. 11,572,334) directed to (Z)-endoxifen encapsulated in an enteric capsule. Enteric capsules have an acid resistant coating to prevent them from dissolving when they pass through the stomach. Enteric capsules are dissolved when they pass through an alkaline environment, which is usually when they reach the small intestine. Delivering oral (Z)-endoxifen via an enteric capsule prevents breakdown of the (Z)-endoxifen in the stomach.
- **Poster Presentation at 2023 American Society of Clinical Oncology (ASCO) Annual Meeting** – A Trial in Progress poster for the Phase 2 clinical study of (Z)-endoxifen in premenopausal women with early stage ER+ / HER2- breast cancer will be presented at the 2023 ASCO Annual Meeting, taking place June 2-6, 2023 in Chicago.

“I am proud of the progress we’ve made to date in 2023 and look forward to further accelerating our (Z)-endoxifen development programs over the coming months,” said Dr. Steven Quay, Atossa’s President and Chief Executive Officer. “With three ongoing Phase 2 studies investigating (Z)-endoxifen, $103.9 million of cash and cash equivalents on our balance sheet, broad patent protection and a talented team in place, we are well positioned to change the treatment paradigm for women with dense breast tissue and those diagnosed with estrogen receptor positive breast cancer."

Comparison of the three months ended March 31, 2023 and 2022 ***(dollar amounts in thousands unless otherwise noted)***

Revenue and Cost of Revenue:
For the three months ended March 31, 2023 and 2022, we had no source of sustainable revenue and no associated cost of revenue.

Operating Expenses:
The following table provides a breakdown of major categories within Research and Development (R&D) and General and Administrative (G&A) expenses for the three months ended March 31, 2023 and 2022, together with the dollar and percentage change in those categories:

	March 31, 2023	March 31, 2022	Change	% Change
Research and Development				
Clinical trials	$ 2,336	$ 1,288	$ 1,048	81%
Compensation	1,034	1,094	(60)	-5%
Professional fees	101	115	(14)	-12%
Exclusivity agreements	-	(1,000)	1,000	-100%
Other	37	2	35	*
Research and Development Total	$ 3,508	$ 1,499	$ 2,009	134%
General and Administrative				
Compensation	$ 2,084	$ 2,005	$ 79	4%
Legal and professional fees	926	669	257	38%
Insurance and other	580	574	6	1%
General and Administrative Total	$ 3,590	$ 3,248	$ 342	11%

*Percentage is not meaningful

Total operating expenses were $7,098 for the three months ended March 31, 2023, which was an increase of $2,351, or 50%, from the three months ended March 31, 2022. Operating expenses for the three months ended March 31, 2023 consisted of R&D expenses of $3,508 and G&A expenses of $3,590.

Operating expenses for the three months ended March 31, 2022 consisted of R&D expenses of $1,499 and G&A expenses of $3,248. Factors contributing to the increased operating expenses for the three months ended March 31, 2023 are explained below.

Research and Development Expenses: R&D expenses for the three months ended March 31, 2023, were $3,508, an increase of $2,009, from total R&D expenses for the three months ended March 31, 2022 of $1,499. Key changes were as follows:

- The increase in R&D expense was attributed primarily to increased spending on clinical and non-clinical trials of $1,048 compared to the prior year period due to (Z)-endoxifen trial costs and increased spending on active pharmaceutical ingredients (API) and drug product formulation and development.
- The decrease in R&D compensation expense for the three months ended March 31, 2023 compared to the prior year quarter, was in part attributable to the increase in compensation expense of $43, or 9%, compared to the prior year period due to an increase in headcount, salaries and bonus accruals partially offset by a decrease in non-cash stock-based compensation. Non-cash stock-based compensation decreased by $103, or 17%, compared to the prior year quarter due to the weighted average fair value of options amortizing in 2023 being lower quarter over quarter.
- In the first quarter of 2022, the Company received a refund of $1,000 from the research institution with which the Company had an exclusive right to negotiate for the acquisition of the worldwide rights to two oncology R&D programs. No exclusivity payments were made or refunded during the three months ended March 31, 2023.

G&A Expenses: G&A expenses for the three months ended March 31, 2023, were $3,590, an increase of $342, from total G&A expenses for quarter ended March 31, 2022 of $3,248. Key changes were as follows:

- The increase in G&A compensation expense for the three months ended March 31, 2023 compared to the prior year quarter, was in part attributable to the increase in compensation expense of $209, or 26%, compared to the prior year quarter due to an increase in headcount, salaries and bonus accruals that was partially offset by a decrease in non-cash stock-based compensation. Non-cash stock-based compensation decreased by $130, or 11%, compared to the prior year period as the weighted average fair value of options amortizing in 2023 was lower quarter over quarter.
- Legal and professional fees increased by $257 for the three months ended March 31, 2023, compared to the prior year period due primarily to higher patent activity for (Z)-endoxifen and our immunotherapy research.

Interest Income: Interest income was $850 for the three months ended March 31, 2023 an increase of $849, from interest income of $1 for the three months ended March 31, 2022. The increase was due to the higher average balance of invested cash in a money market account and higher average interest rates for the three months ended March 31, 2023 compared to the prior year period.

About (Z)-Endoxifen
(Z)-endoxifen is the most active metabolite of the FDA approved Selective Estrogen Receptor Modulator (SERM), tamoxifen. Studies by others have demonstrated that the anti-estrogenic effects of tamoxifen are driven in a concentration-dependent manner by (Z)-endoxifen. In addition to its potent anti-estrogen effects, (Z)-endoxifen at higher concentrations has been shown to target PKCβ1, a known oncogenic protein.

Atossa is developing a proprietary oral formulation of (Z)-endoxifen that does not require liver metabolism to achieve therapeutic concentrations and is encapsulated to bypass the stomach as acidic conditions in the stomach convert a greater proportion of (Z)-endoxifen to the inactive (E)-endoxifen. Atossa's (Z)-endoxifen has been shown to be well tolerated in Phase 1 studies and in a small Phase 2 study of women with breast cancer. We are currently studying our (Z)-endoxifen in healthy women with measurable breast density and women with ER+/HER2- breast cancer. Atossa's (Z)-endoxifen is protected by two issued U.S. patents and numerous pending patent applications.

About Atossa Therapeutics

Atossa Therapeutics, Inc. is a clinical-stage biopharmaceutical company developing innovative medicines in areas of significant unmet medical need in oncology with a current focus on breast cancer. For more information, please visit www.atossatherapeutics.com

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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 (Z)-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 breast density or in Ki-67 or any other result from a neoadjuvant study is an approvable endpoint for (Z)-endoxifen, whether Atossa can complete acquisitions, 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.

ATOSSA THERAPEUTICS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(amounts in thousands, except for par value)

	As of March 31, 2023 (unaudited)	As of December 31, 2022
Assets		
Current assets		
Cash and cash equivalents	$ 103,868	$ 110,890
Restricted cash	110	110
Prepaid expenses	5,295	4,031
Research and development tax rebate receivable	738	743
Other current assets	858	2,423
Total current assets	110,869	118,197
Investment in equity securities	4,700	4,700
Other assets	631	635
Total assets	$ 116,200	$ 123,532
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 1,444	$ 2,965
Accrued expenses	613	1,059
Payroll liabilities	822	1,525
Other current liabilities	65	19
Total current liabilities	2,944	5,568
Total liabilities	2,944	5,568
Commitments and contingencies		
Stockholders' equity		
Series B convertible preferred stock - $0.001 par value; 10,000 shares authorized; 1 shares issued and outstanding as of March 31, 2023 and December 31, 2022	-	-
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, 2023 and December 31, 2022	22,792	22,792
Additional paid-in capital - common stock	252,357	250,784
Accumulated deficit	(162,475)	(156,194)
Total stockholders' equity	113,256	117,964
Total liabilities and stockholders' equity	$ 116,200	$ 123,532

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

	For the Three Months Ended March 31,	
	2023	**2022**
Operating expenses		
Research and development	$ 3,508	$ 1,499
General and administrative	3,590	3,248
Total operating expenses	7,098	4,747
Operating loss	(7,098)	(4,747)
Interest income	850	1
Other expense, net	(33)	(40)
Loss before income taxes	(6,281)	(4,786)
Income taxes	-	-
Net loss	(6,281)	(4,786)
Loss per share of common stock - basic and diluted	$ (0.05)	$ (0.04)
Weighted average shares outstanding - basic and diluted	126,624	126,624