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 13, 2024

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)**	**(IRS 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

N/A
(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))

Securities registered pursuant 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

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).
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. ☐

Item 2.02. Results of Operations and Financial Condition.

On May 13, 2024, Atossa Therapeutics, Inc. (the "Company") issued a press release announcing the quarter ended March 31, 2024 financial results and providing a Company update. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K 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 13, 2024
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.

Atossa Therapeutics, Inc.

Date: May 13, 2024

By: /s/ Heather Rees
Heather Rees
Senior Vice President, Finance & Accounting

Exhibit 99.1

Atossa Therapeutics Announces First Quarter 2024 Financial Results and Provides Corporate Update

- *Presented data from EVANGELINE study showing 100% disease control rate at 24-weeks*
- *Initiated study evaluating (Z)-endoxifen in combination with abemaciclib (VERZENIO®)*
- *Ended first quarter 2024 with $84.0 million of cash and cash equivalents and no debt*

SEATTLE, May 13, 2024— Atossa Therapeutics, Inc. (Nasdaq: ATOS) ("Atossa" or the "Company") today announced financial results for the fiscal quarter ended March 31, 2024, and provides an update on recent company developments. Atossa is a clinical stage biopharmaceutical company developing innovative medicines in areas of significant unmet medical need in oncology with a focus on breast cancer

Key developments from Q1 2024 and the year to date include:

- **Presented data from 40mg pharmacokinetic run-in cohort of ongoing EVANGELINE study at the AACR annual meeting –** data showed 100% disease control rate, 37% average MRI-based lesion size decrease and a 92% reduction in Ki-67, at 24 weeks. Treatment related toxicities included grade 3 headache (one patient), grade 2 amenorrhea (one patient), and grade 2 hot flashes (one patient). There were no grade 4 or 5 treatment related toxicities.
- **Initiated study evaluating (Z)-endoxifen in combination with abemaciclib (VERZENIO®) –** the study will enroll 20 women with newly diagnosed Estrogen Receptor positive (ER+) / Human Epidermal Growth Factor Receptor 2 negative (HER2-) invasive breast cancer. Participants will receive (Z)-endoxifen daily in combination with abemaciclib, a cyclin-dependent kinase (CDK) 4/6 inhibitor marketed by Eli Lilly and Company, twice daily for a total of 24 weeks prior to surgery.
- **Expanded access patient concluded five-years of (Z)-endoxifen treatment –** the pre-menopausal, ER+ / HER2-, breast cancer patient who received neoadjuvant and adjuvant (Z)-endoxifen therapy under an FDA-approved "expanded access" program completed five years of successful treatment. The patient remains cancer-free and reported no significant safety or tolerability issues over the course of her treatment.
- **Fully enrolled Phase 2 I-SPY 2 Clinical Trial –** (Z)-endoxifen is being evaluated as a neoadjuvant treatment in a study arm of the ongoing I-SPY 2 clinical trial. The study arm targets patients with newly diagnosed estrogen receptor-positive breast cancer whose tumors are predicted to be sensitive to endocrine therapy but for whom chemotherapy is expected to provide little or no benefit. Full enrollment was achieved in February 2024 and data is expected in the second half of 2024.
- **First patient dosed with (Z)-endoxifen in RECAST DCIS study –** the Re-Evaluating Conditions for Active Surveillance Suitability as Treatment: Ductal Carcinoma In Situ (RECAST DCIS) study is an ongoing Phase 2 platform study designed to offer women diagnosed with DCIS six months of neoadjuvant endocrine therapy with the intent of determining their suitability for long-term active surveillance without surgery.
- **Appointed Tessa Cigler, M.D., M.P.H to Atossa's Board of Directors –** Dr. Cigler is a medical oncologist and clinical investigator at the Weill Cornell Breast Center in New York City. As a member of the Weill Cornell Breast Center research team, she heads several clinical trials designed to provide her patients with access to the new promising options for therapy and supportive care.

"The first quarter of 2024 was a period of significant progress for our Company," said Steven Quay, M.D., Ph.D., Atossa's President and Chief Executive Officer. "We initiated a new combination study, presented extremely promising monotherapy data at AACR and fully enrolled the second of our five ongoing Phase 2 studies. Our focus for the remainder of 2024 will be to continue driving our (Z)-endoxifen development program forward, preparing for critical data readouts expected in the second half of this year and further progressing conversations with regulatory

authorities and prospective partners. Even with all of our significant accomplishments in the quarter, our cash balance remains strong, at $84.0 million."

Comparison of Three Months Ended March 31, 2024 and 2023

Revenue and Cost of Revenue. For the three months ended March 31, 2024 and 2023, we had no source of revenue and no associated cost of revenue.

Operating Expenses. Total operating expenses were $7.0 million for the three months ended March 31, 2024, which was a decrease of $0.1 million, from total operating expenses for the three months ended March 31, 2023 of $7.1 million. Factors contributing to the decreased operating expenses in the three months ended March 31, 2024 are explained below.

R&D Expenses. R&D expenses for the three months ended March 31, 2024, were $3.7 million, an increase of $0.2 million from R&D expenses for the three months ended March 31, 2023 of $3.5 million

The following table provides a breakdown of major categories within R&D expense for the three months ended March 31 2024 and 2023, together with the dollar change in those categories (in thousands):

		For the Three Months Ended March 31,		
		2024	2023	Increase (Decrease)
Research and Development Expense				
	Clinical and non-clinical trials	$ 2,884	$ 2,336	$ 548
	Compensation	626	1,034	(408)
	Professional fees and other	238	138	100
	Research and Development Expense Total	$ 3,748	$ 3,508	$ 240

- The increase in R&D expense was primarily due to increased spending on clinical and non-clinical trials of $0.5 million compared to the prior year period for (Z)-endoxifen trials, including drug development costs.

- The decrease in R&D compensation expense for the three months ended March 31, 2024 compared to the prior year period was primarily due to a decrease in non-cash stock-based compensation of $0.4 million. Non-cash stock-based compensation decreased compared to the prior year period due to the weighted average fair value of options amortizing in 2024 being lower period over period.

- The increase in R&D professional fees of $0.1 million for the three months ended March 31, 2024 compared to the prior year period was primarily attributable to higher consulting fees in 2024 related to our endoxifen program.

General and Administrative (G&A) Expenses. G&A expenses for the three months ended March 31, 2024 were $3.2 million, a decrease of $0.4 million from total G&A expenses for the three months ended March 31, 2023 of $3.6 million.

The following table provides a breakdown of major categories within G&A expenses for the three months ended March 31, 2024 and 2023, together with the dollar change in those categories (in thousands):

		For the Three Months Ended March 31,		
		2024	2023	Increase (Decrease)
General and Administrative Expense				
	Compensation	$ 1,325	$ 2,084	$ (759)
	Professional fees and other	1,680	1,164	516
	Insurance	227	342	(115)
	General and Administrative Expense Total	$ 3,232	$ 3,590	$ (358)

- The decrease in G&A compensation expense of $0.8 million for the three months ended March 31, 2024 compared to the prior year period was due to a decrease in non-cash stock-based compensation of $0.8 million. Non-cash stock-based compensation decreased compared to the prior year period due to the weighted average fair value of options amortizing in 2024 being lower period over period.

- The increase in G&A professional fees of $0.5 million for the three months ended March 31, 2024 compared to the prior year period was primarily due to an increase in legal fees for higher patent-related activity.

- The decrease in G&A insurance expense of $0.1 million for the three months ended March 31, 2024 compared to the prior year period was due to lower negotiated insurance premiums for the same or better coverage period over period.

Interest Income. Interest income was $1.1 million for the three months ended March 31, 2024, an increase of $0.2 million from interest income of $0.9 million for the three months ended March 31, 2023. The increase was due to a change in the mix of our money market accounts which yielded a higher rate of return.

About (Z)-Endoxifen
(Z)-endoxifen is the most potent Selective Estrogen Receptor Modulator (SERM) for estrogen receptor inhibition and also causes estrogen receptor degradation. It has also been shown to have efficacy in the setting of patients with tumor resistance to other hormonal treatments. In addition to its potent anti-estrogen effects, (Z)-endoxifen has been shown to target PKCβ1, a known oncogenic protein, at clinically attainable blood concentrations. Finally, (Z)-endoxifen appears to deliver similar or even greater bone agonistic effects while resulting in little or no endometrial proliferative effects compared with standard treatments, like tamoxifen.

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 significant 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. (Z)-endoxifen is currently being studied in five Phase 2 trials: one in healthy women with measurable breast density, one in women diagnosed with ductal carcinoma in situ, and two other studies including the EVANGELINE study in women with ER+/HER2- breast cancer. Atossa's (Z)-endoxifen is protected by three 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 focus on using (Z)-endoxifen to prevent and treat breast cancer. For more information, please visit www.atossatherapeutics.com.

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FORWARD LOOKING STATEMENTS
This press release contains certain information that may constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. We may identify these forward-looking statements by the use of words such as "expect," "potential," "continue," "may," "will," "should," "could," "would," "seek," "intend," "plan," "estimate," "anticipate," "believe," "future," or other comparable words. Forward-looking statements in this press release are subject to risks and uncertainties that may cause actual results, outcomes, or the timing of actual results or outcomes, such as data related to the (Z)-endoxifen program and the potential of (Z)-endoxifen as a breast cancer prevention and treatment agent, to differ materially from those projected or anticipated, including risks and uncertainties associated with: macroeconomic conditions and increasing geopolitical instability; the expected timing of releasing data; any variation between interim and final clinical results; actions and inactions by the FDA and foreign regulatory bodies; the outcome or timing of regulatory approvals needed by Atossa, including those needed to continue our planned (Z)-endoxifen trials; our ability to satisfy regulatory requirements; our ability to remain compliant with the continued listing requirements of the Nasdaq Stock Market; our ability to successfully develop and commercialize new therapeutics; the success, costs and timing of our development activities, including our ability to successfully initiate or complete our clinical trials, including our (Z)-endoxifen trials; our anticipated rate of patient enrollment; our ability to contract with third-parties and their ability to perform adequately; our estimates on the size and characteristics of our potential markets; our ability to successfully defend litigation and other similar complaints and to establish and maintain intellectual property rights covering our products; whether we can successfully complete our clinical trial of oral (Z)-endoxifen in women with mammographic breast density and our trials of (Z)-endoxifen in women with breast cancer, and whether the studies will meet their objectives; our expectations as to future financial performance, expense levels and capital sources, including our ability to raise capital; our ability to attract and retain key personnel; our anticipated working capital needs and expectations around the sufficiency of our cash reserves; and other risks and uncertainties detailed from time to time in Atossa's filings with the Securities and Exchange Commission, including without limitation its Annual Reports on Form 10-K and Quarterly Reports on 10-Q. Forward-looking statements are presented as of the date of this press release. Except as required by law, we do not intend to update any forward-looking statements, whether as a result of new information, future events or circumstances or otherwise.

ATOSSA THERAPEUTICS, INC.
CONSOLIDATED BALANCE SHEETS
(amounts in thousands, except share and per share data)

	March 31, 2024	December 31, 2023
Assets		
Current assets		
Cash and cash equivalents	$ 83,960	$ 88,460
Restricted cash	110	110
Prepaid materials	1,372	1,487
Prepaid expenses and other current assets	1,613	2,162
Total current assets	87,055	92,219
Investment in equity securities	1,710	1,710
Other assets	2,322	2,323
Total assets	$ 91,087	$ 96,252
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 1,230	$ 806
Accrued expenses	1,613	973
Payroll liabilities	659	1,654
Other current liabilities	1,826	1,803
Total current liabilities	5,328	5,236
Total liabilities	5,328	5,236
Commitments and contingencies		
Stockholders' equity		
Convertible preferred stock - $0.001 par value; 10,000,000 shares authorized; 582 shares issued and outstanding as of March 31, 2024 and December 31, 2023	—	—
Common stock - $0.18 par value; 175,000,000 shares authorized; 125,507,814 and 125,304,064 shares issued and outstanding as of March 31, 2024 and December 31, 2023, respectively	22,829	22,792
Additional paid-in capital	256,571	255,987
Treasury stock, at cost; 1,320,046 shares of common stock at March 31, 2024 and December 31, 2023	(1,475)	(1,475)
Accumulated deficit	(192,166)	(186,288)
Total stockholders' equity	85,759	91,016
Total liabilities and stockholders' equity	$ 91,087	$ 96,252

ATOSSA THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(amounts in thousands, except share and per share data)

	For the Three Months Ended March 31,	
	2024	2023
Operating expenses		
Research and development	$ 3,748	$ 3,508
General and administrative	3,232	3,590
Total operating expenses	6,980	7,098
Operating loss	(6,980)	(7,098)
Interest income	1,138	850
Other expense, net	(36)	(33)
Loss before income taxes	(5,878)	(6,281)
Income tax benefit	—	—
Net loss	(5,878)	(6,281)
Net loss per share of common stock - basic and diluted	$ (0.05)	$ (0.05)
Weighted average shares outstanding used to compute net loss per share - basic and diluted	125,319,778	126,624,110