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): April 1, 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 April 1, 2024, Atossa Therapeutics, Inc. (the "Company") issued a press release announcing the year ended December 31, 2023 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 April 1, 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: April 1, 2024

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

Exhibit 99.1

Atossa Therapeutics Announces Year-End 2023 Financial Results and Provides Corporate Update

- *Fully enrolled two Phase 2 studies with data from both expected in the second half of 2024*
- *First patient dosed in new Phase 2 breast cancer prevention study*
- *Data from ongoing Phase 2 EVANGELINE study scheduled to be presented at 2024 AACR Annual Meeting*
- *Ended 2023 with $88.5 million of cash and cash equivalents and no debt*

SEATTLE, April 1, 2024— Atossa Therapeutics, Inc. (Nasdaq: ATOS) ("Atossa" or the "Company"), today announced financial results for the forth quarter and full year ended December 31, 2023, and provided an update on recent Company developments. Atossa is a clinical stage biopharmaceutical company developing proprietary innovative medicines in areas of significant unmet medical need in oncology with a focus on breast cancer and other breast conditions.

Key developments from Q4 2023 and the year to date include:

- **Full enrollment of Phase 2 Karisma-Endoxifen Clinical Trial** – the study is investigating (Z)-endoxifen in premenopausal women with measurable breast density. Participants receive daily doses of (Z)-endoxifen for six months, over the course of which mammograms are conducted to measure reduction in breast density. Full enrollment was achieved in November 2023 and data is expected in the second half of 2024.
- **Full enrollment of 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.
- **Expanded access patient concluded five-years of (Z)-endoxifen treatment** – the pre-menopausal, Estrogen Receptor positive (ER+) / Human Epidermal Growth Factor Receptor 2 negative (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.
- **Data from ongoing EVANGELINE study scheduled to be presented at the AACR Annual Meeting** – safety and efficacy data from the 40mg pharmacokinetic run-in cohort of the ongoing Phase 2 EVANGELINE (Endoxifen Versus exemestANe GosEreLIn) study is scheduled to be presented on April 9, 2024 at the American Association for Cancer Research (AACR) Annual Meeting. The data is scheduled to be presented by Dr. Matthew Goetz, deputy director of translational research for the Mayo Clinic Comprehensive Cancer Center and co-leader of the Mayo Clinic Women's Cancer Program. Dr. Goetz is also the primary investigator of the EVANGELINE study.
- **Appointment of Tessa Cigler, M.D., M.P.H and Jonathan Finn, CFA 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. Mr. Finn has more than 25 years of experience in the financial industry with a focus on early to mid-stage biotech and technology companies. He currently serves as Executive

Vice President and Chief Investment Officer at Vantage Consulting Group, an investment advisory firm.

"I am very proud of the progress we made in Q4 2023 and the momentum we have continued to generate in 2024," said Steven Quay, M.D., Ph.D., Atossa's President and Chief Executive Officer. "With important data from our EVANGELINE study being presented at AACR this month and primary data from two of our Phase 2 studies expected in the second half of this year, the remainder of 2024 will be a critical period for our Company. Our focus continues to be on accelerating our (Z)-endoxifen development program and generating additional data to support the growing body of evidence that (Z)-endoxifen has the potential to address significant unmet needs that exist in both the breast cancer prevention and treatment settings."

Comparison of the Year Ended December 31, 2023 and 2022

*Operating Expenses.*Total operating expenses were $31.4 million for the year ended December 31, 2023, which was an increase of $3.7 million, from the year ended December 31, 2022 of $27.7 million. Factors contributing to the increased operating expenses in the year ended December 31, 2023 are explained below.

The following table provides a breakdown of major categories within R&D expense for the years ended December 31, 2023 and 2022, together with the dollar change in those categories (in thousands):

		Year Ended December 31, 2023	Year Ended December 31, 2022	Increase (decrease)
Research and Development Expense				
	Clinical and non-clinical trials	$ 12,722	$ 10,225	$ 2,497
	Compensation	$ 3,474	4,268	(794)
	Professional fees and other	$ 1,138	590	548
	Research and Development Expense Total	$ 17,334	$ 15,083	$ 2,251

R&D Expenses. R&D expenses for the year ended December 31, 2023, were $17.3 million, an increase of $2.3 million from total R&D expenses for the year ended December 31, 2022 of $15.1 million. Key changes were as follows:

- The increase in R&D expense was in part due to increased spending on clinical and non-clinical trials of $1.1 million compared to the prior year due to increased spending on (Z)-endoxifen trials, including drug development costs. The additional increase of $1.4 million was due to a change in estimate of the amount that no longer met the reasonably assured threshold to be sustained under a potential ATO audit related to R&D expenditures under the Australian R&D tax incentive program as a result of recent Australian Taxation Office guidance.

- The decrease in R&D compensation expense for the year ended December 31, 2023 compared to the prior year was primarily 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 due to the weighted average fair value of options amortizing in the year ended December 31, 2023 being lower year over year.

- The increase in R&D professional fees and other was due in part to the refund in the prior year of $1.0 million from a research institution with which we had an exclusive right to negotiate for the acquisition of worldwide rights of two oncology programs. No exclusivity payments were made or refunded during the year ended December 31, 2023.

The following table provides a breakdown of major categories within General and Administrative (G&A) expenses for the years ended December 31, 2023 and 2022, together with the dollar change in those categories (in thousands):

		Year Ended December 31, 2023	Year Ended December 31, 2022	Increase (decrease)
General and Administrative Expense				
	Compensation	$ 7,388	$ 7,429	$ (41)
	Professional fees and other	$ 5,367	3,539	1,828
	Insurance	$ 1,288	1,640	(352)
	General and Administrative Expense Total	$ 14,043	$ 12,608	$ 1,435

G&A Expenses. G&A expenses for the year ended December 31, 2023 were $14.0 million an increase of $1.4 million from total G&A expenses for year ended December 31, 2022 of $12.6 million. Key changes were as follows:

- The decrease in G&A compensation expense of $41 thousand for the year ended December 31, 2023 compared to the prior year was partially due to an increase in cash compensation expense of $1.3 million, offset by a decrease in non-cash stock-based compensation of $1.4 million. The increase in cash compensation expense compared to

the prior year was primarily driven by salary and bonus severance costs for former executives of $0.6 million, an increase of $0.4 million due to compensation for new employees as well as an overall increase in salaries, bonuses and benefits of $0.3 million. Non-cash stock-based compensation decreased by $1.4 million due to the weighted average fair value of options amortizing in 2023 being lower year over year.

- The increase in G&A professional fees of $1.8 million for the year ended December 31, 2023 compared to the prior year was primarily due to an increase in legal fees for higher patent-related activity of $0.7 million and an increase in professional fees of $0.8 million primarily due to higher investor relations costs and accounting fees. The additional increase of $0.4 million was due to a change in estimate related to the Australian R&D tax incentive program.

- The decrease in G&A insurance expense of $0.4 million for the year ended December 31, 2023 compared to the prior year was due to lower negotiated insurance premiums for the same or better coverage year over year.

Impairment Charge on Investment in Equity Securities. For the year ended December 31, 2023, we wrote down our investment in DCT by $3.0 million due to an impairment charge. For the year ended December 31, 2022 there were no impairment charges related to our equity securities.

Interest Income. Interest income was $4.3 million for the year ended December 31, 2023, an increase of $3.5 million from interest income of $0.9 million for the year ended December 31, 2022. The increase was due to the higher average balance invested in money market funds of $26.5 million and higher average interest rates for the year ended December 31, 2023 compared to the prior year.

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 four 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)

	As of December 31,	
	2023	2022
Assets		
Current assets		
Cash and cash equivalents	$ 88,460	$ 110,890
Restricted cash	110	110
Prepaid materials	1,487	5,247
Prepaid expenses and other current assets	2,162	1,207
Research and development tax rebate receivable	—	743
Total current assets	92,219	118,197
Investment in equity securities	1,710	4,700
Other assets	2,323	635
Total assets	$ 96,252	$ 123,532
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 806	$ 2,965
Accrued expenses	973	1,059
Payroll liabilities	1,654	1,525
Other current liabilities	1,803	19
Total current liabilities	5,236	5,568
Total liabilities	5,236	5,568
Commitments and contingencies		
Stockholders' equity		
Convertible preferred stock - $0.001 par value; 10,000,000 shares authorized; 582 shares issued and outstanding as of December 31, 2023 and 2022	—	—
Common stock - $0.18 par value; 175,000,000 shares authorized; 125,304,064 and 126,624,110 shares issued and outstanding as of December 31, 2023 and 2022, respectively	22,792	22,792
Additional paid-in capital	255,987	251,366
Treasury stock, at cost; 1,320,046 and 0 shares of common stock at December 31, 2023 and 2022, respectively	(1,475)	—
Accumulated deficit	(186,288)	(156,194)
Total stockholders' equity	91,016	117,964
Total liabilities and stockholders' equity	$ 96,252	$ 123,532

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

	For the Year Ended December 31,	
	2023	2022
Operating expenses		
Research and development	$ 17,334	$ 15,083
General and administrative	14,043	12,608
Total operating expenses	31,377	27,691
Operating loss	(31,377)	(27,691)
Impairment charge on investment in equity securities	(2,990)	—
Interest income		877
Other expense, net	(70)	(146)
Loss before income taxes	(34,437)	(26,960)
Income tax benefit	—	—
Net loss	(34,437)	(26,960)
Net loss per share of common stock - basic and diluted	$ (0.24)	$ (0.21)
Weighted average shares outstanding used to compute net loss per share - basic and diluted	126,081,602	126,624,110