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): March 22, 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) 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 March 22, 2023, Atossa Therapeutics, Inc. (the "Company") issued a press release announcing the year ended December 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 March 22, 2023
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: March 22, 2023

Atossa Therapeutics, Inc.

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

EXHIBIT 99.1

Atossa Therapeutics Announces Year-End 2022 Financial Results and Provides Corporate Update

SEATTLE, March 22, 2023 (GLOBE NEWSWIRE) — Atossa Therapeutics, Inc. (Nasdaq: ATOS), a clinical stage biopharmaceutical company developing innovative proprietary medicines to address significant unmet needs in cancer, today announced financial results for the fiscal quarter and fiscal year ended December 31, 2022 and provided an update on recent company developments.

Key developments from Q4 2022 and year to date include:

Initiation and First Patient Dosed in Phase 2 EVANGELINE Study – EVANGELINE (Endoxifen Versus exemestANe GosEreLIn), is our 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 six months, followed by surgery. Several FDA-approved neoadjuvant therapies exist for ER- breast cancers, but few exist for ER+ patients, which account for approximately 78% of breast cancers. We expect to enroll approximately 175 patients at up to 25 sites across the United States.

Continued Enrollment in Phase 2 Karisma-Endoxifen Study – The Karisma-Endoxifen study is our randomized, double-blind, placebo-controlled trial of healthy, pre-menopausal women with increased breast density. The treatment cohort receives daily doses of (Z)-endoxifen for six months, over the course of which mammograms will be conducted to measure reduction in mammographic breast density (MBD). Patients will also be given a mammogram at 24 months to assess the durability of the MBD changes. MBD affects more than 10 million women in the United States and many millions more worldwide. Increased MBD reduces the ability of mammograms to detect cancer. Studies have also shown that women with MBD have an increased risk of developing breast cancer and that the higher the MBD, the higher the incidence of breast cancer. We expect to fully enroll the study by the end of 2023.

Initiation of New Study Arm in the Ongoing Phase 2 I-SPY 2 Clinical Trial – (Z)-endoxifen is being evaluated in a new study arm of the ongoing I-SPY 2 clinical trial. The I-SPY 2 TRIAL evaluates neoadjuvant treatments for locally advanced breast cancer and 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 endoxifen in the stomach. This patent further reinforces Atossa's broad Intellectual Property portfolio related to (Z)-endoxifen.

Investment in Dynamic Cell Therapies, Inc. (DCT) – DCT is a privately held, venture capital backed developer of CAR-T therapies in the pre-clinical phase of developing controllable CAR-T cells to address difficult-to-treat cancers. Its platform technology of dynamic control of engineered T-cells is designed to improve the safety, efficacy, and durability of CAR-T cell therapies. Our investment totaled $4.7 million and resulted in Atossa owning approximately 19% of the outstanding capital stock of DCT.

"Our focus remains on both helping reduce the incidence of breast cancer and changing the treatment paradigm for patients who are not benefiting from, or are unable to tolerate, currently approved therapies," said Dr. Steven Quay, Atossa's President and Chief Executive Officer. "With a strong balance sheet and three Phase 2 trials underway, we are well positioned to continue accelerating the development of (Z)-endoxifen, which we feel has the potential to address significant unmet needs across the continuum of breast cancer."

YEAR ENDED DECEMBER 31, 2022, FINANCIAL RESULTS (IN THOUSANDS)

As of December 31, 2022, we had cash, cash equivalents and restricted cash of $111,000.

Results of Operations

Comparison of Years Ended December 31, 2022 and 2021

Revenue and Cost of Revenue:

For the years ended December 31, 2022 and 2021, we have 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 years ended December 31, 2022 and 2021, together with the dollar change in those categories:

		2022	2021	Period-Period Change
Research and Development				
	Clinical trials	$ 10,225	$ 4,656	$ 5,569
	Compensation	1,875	1,482	393
	Stock-based compensation	2,393	1,591	802
	Professional fees	1,242	454	788
	Exclusivity agreements	(700)	1,000	(1,700)
	Other	48	27	21
	Research and Development Total	$ 15,083	$ 9,210	$ 5,873
General and Administrative				
	Compensation	$ 3,034	$ 2,371	$ 663
	Stock-based compensation	4,395	3,676	719
	Professional fees	1,625	2,317	(692)
	Legal	1,135	534	601
	Insurance	1,640	1,576	64
	Other	779	837	(58)
	General and Administrative Total	$ 12,608	$ 11,311	$ 1,297

Total operating expenses were $27,691 for the year ended December 31, 2022, which was an increase of $7,170, or 35% from the year ended December 31, 2021. Operating expenses for 2022 consisted of R&D expenses of $15,083 and G&A expenses of $12,608. Operating expenses for 2021 consisted of R&D expenses of $9,210 and G&A expenses of $11,311. Factors contributing to the increased operating expenses in the year ended December 31, 2022 are explained below.

R&D Expenses: R&D expenses for the year ended December 31, 2022, were $15,083, an increase of $5,873 or 64% from total R&D expenses for the year ended December 31, 2021 of $9,210. Key changes were as follows:

• The increase in R&D expense was attributed primarily to increased spending on clinical and non-clinical trials of $5,569 compared to the prior year period due to additional pre-clinical toxicology studies in our (Z)-endoxifen and AT-H201 programs as well as increased trial costs and manufacturing expenses for (Z)-endoxifen.

• R&D compensation increased $393 in 2022 compared to the prior year period due to increased headcount, salary, bonuses and benefits during 2022.

• Stock-based compensation, which is a non-cash charge, increased $802 due to the increased number of options being expensed as well as the weighted average fair value of options amortizing in 2022 was higher compared to the prior year period.

• Professional fees increased $788 compared to the prior year period, due primarily to a CAR-T technology market analysis performed during 2022.

• In 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. In 2021, R&D expenses included $1,000 attributable to the same one-time exclusivity fee. Finally, in 2022, we paid $300 for the exclusive right to negotiate with another CAR-T Company.
Net, the exclusivity agreements caused a decrease in expenses of $1,700 compared to the prior year period.

G&A Expenses: G&A expenses were $12,608 for the year ended December 31, 2022, an increase of $1,297, or 11% from total G&A expenses for the year ended December 31, 2021 of $11,311. Key changes were as follows:

• The increase in G&A expense for the year ended December 31, 2022 compared to the prior year period, was in part attributable to the increase in compensation expense of $663 in 2022 due to an increase in headcount, hourly wages, salaries and bonus accruals.

• Non-cash stock-based compensation expense also increased by $719 due to the increased number of options being expensed as well as the weighted average fair value of options amortizing in 2022 was higher compared to the prior year period.

• Professional fees decreased by $692 in 2022 compared to the prior year period, due primarily to a decrease in proxy costs for investor outreach.

• Legal fees increased $601 in 2022 compared to the prior year period, due to higher patent activity in 2022 for (Z)-endoxifen and our immunotherapy research.

Interest Income: Interest income was $877 for the year ended December 31, 2022 compared to the prior year period of $6. The increase is due to the investment of an additional $50,000 in a money market account during 2022 and higher average interest rates for the year ended December 31, 2022 compared to 2021.

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

	As of December 31,	
	2022	**2021**
Assets		
Current assets		
Cash and cash equivalents	$ 110,890	$ 136,377
Restricted cash	110	110
Prepaid expenses	4,031	2,488
Research and development tax rebate receivable	743	1,072
Other current assets	2,423	1,193
Total current assets	118,197	141,240
Investment in equity securities	4,700	-
Other assets	635	22
Total Assets	$ 123,532	$ 141,262
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 2,965	$ 1,717
Accrued expenses	1,059	204
Payroll liabilities	1,525	1,184
Other current liabilities	19	21
Total current liabilities	5,568	3,126
Total Liabilities	5,568	3,126
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 December 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 December 31, 2022 and December 31, 2021	22,792	22,792
Additional paid-in capital - common stock	250,784	243,996
Accumulated deficit	(156,194)	(129,234)
Total Stockholders' Equity	117,964	138,136
Total Liabilities and Stockholders' Equity	$ 123,532	$ 141,262

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

	For the Year Ended December 31,	
	2022	**2021**
Operating expenses		
Research and development	$ 15,083	$ 9,210
General and administrative	12,608	11,311
Total operating expenses	27,691	20,521
Operating loss	(27,691)	(20,521)
Interest income	877	6
Other expense, net	(146)	(91)
Loss before income taxes	(26,960)	(20,606)
Income taxes	-	-
Net loss	(26,960)	(20,606)
Loss per share of common stock - basic and diluted	$ (0.21)	$ (0.18)
Weighted average shares outstanding - basic and diluted	126,624	116,950

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.