

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): November 7, 2022

Atossa Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation)

001-35610
(Commission File Number)

26-4753208
(I.R.S. Employer Identification No.)

107 Spring Street
Seattle, Washington
(Address of principal executive offices)

98104
(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 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

Item 2.02. Results of Operations and Financial Condition.

On November 7, 2022, Atossa Therapeutics, Inc. (the “Company”) issued a press release announcing the quarter ended September 30, 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 November 7, 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: November 7, 2022

Atossa Therapeutics, Inc.

By: /s/ Kyle Guse

Kyle Guse
Chief Financial Officer, General Counsel and Secretary

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

SEATTLE, November 7, 2022 (GLOBE NEWSWIRE) -- Atossa Therapeutics, Inc. (Nasdaq: ATOS), today announces financial results for the fiscal quarter ended September 30, 2022, and provides an update on recent company developments. Atossa is a clinical-stage biopharmaceutical company seeking to develop innovative medicines in areas of significant unmet medical need in oncology with a current focus on breast cancer and lung injury caused by cancer treatments.

Key developments from Q3 2022 and to date include:

- Received FDA authorization from FDA to initiate its Phase 2 study of neoadjuvant (Z)-endoxifen in premenopausal women with ER+/HER2- breast cancer.
- Invested in a privately-held Dynamic Cell Therapies, a company focused on CAR-T therapies as an important step in pursuing its strategy to develop CAR-T therapies or adjacent opportunities within the immuno-oncology space.
- Completed dosing in both Part B and Part C (of four parts) of Phase 1/2a Clinical Trial of AT-H201 in healthy volunteers, which the Company is now developing for patients with compromised lung function due to the damaging effects of cancer treatment.

“We continue to make progress with our (Z)-endoxifen programs. In particular, our Phase 2 study of neoadjuvant (Z)-endoxifen for pre-menopausal women with ER+/HER2- breast cancer was authorized by FDA to begin in the United States, and we plan to initiate the study during the fourth quarter of this year. We are re-aligning our strategy to address new avenues in the field of oncology. We have altered our approach to the development of AT-H201 in cancer patients with compromised lung-function resulting from cancer treatment, and are beginning to explore the possibility of pursuing immune-oncology programs. In the meantime, we will continue our current programs and will provide progress updates as they become available,” commented Dr. Steven Quay, Atossa’s President and Chief Executive Officer.

Quarter Ended September 30, 2022 Financial Results (in thousands):

As of September 30, 2022, the Company had cash, cash equivalents and restricted cash of approximately \$117,477.

Revenue and Cost of Revenue: For the three months ended September 30, 2022 and 2021, we had no source of revenue and no associated cost of revenue.

Operating Expenses: Total operating expenses were \$8,205 for the three months ended September 30, 2022, which is an increase of \$3,047 or 59% from operating expenses for the three months ended September 30, 2021 of \$5,158. Operating expenses for the three months ended September 30, 2022 consisted of research and development (R&D) expenses of \$5,160 and general and administrative (G&A) expenses of \$3,045. Operating expenses for the three months ended September 30, 2021 consisted of R&D expenses of \$2,206, and G&A expenses of \$2,952. The basis for factors contributing to the increased operating expenses in the three months ended September 30, 2022 are explained below.

Research and Development Expenses: R&D expenses for the three months ended September 30, 2022 were \$5,160, an increase of \$2,954 or 134% from total R&D expenses for the same period in 2021 of \$2,206. The increase in R&D expenses was primarily driven by increases in clinical and non-clinical trial costs as well as drug formulation and analysis costs of \$2,475. Stock-based compensation expense also increased \$62 compared to the prior year period, and other R&D compensation expense increased \$85 due to salary, bonus, and benefit increases.

General and Administrative Expenses: G&A expenses were \$3,045 for the three months ended September 30, 2022, an increase of \$93 or 3% from the total G&A expenses of \$2,952 for the three months ended September 30, 2021. The increase in G&A expenses was primarily driven by an increase in legal fees, professional fees and other expenses of \$159 for the three months ended September 30, 2022. G&A expenses also increased in part due to an increase in salary, bonus, and benefits of \$123, which was offset by a decrease in stock-based compensation expense of \$190.

Nine Months Ended September 30, 2022 Financial Results (in thousands):

Revenue and Cost of Revenue: For the nine months ended September 30, 2022 and 2021, we had no source of revenue and no associated cost of revenue.

Operating Expenses: Total operating expenses were \$19,553 for the nine months ended September 30, 2022, which is an increase of \$3,860 or 25% from operating expenses for the nine months ended September 30, 2021 of \$15,693. Operating expenses for the nine months ended September 30, 2022 consisted of R&D expenses of \$10,097 and G&A expenses of \$9,456. Operating expenses for the nine months ended September 30, 2021 consisted of R&D expenses of \$7,383 and G&A expenses of \$8,310. The basis for factors contributing to the increased operating expenses in the nine months ended September 30, 2022 are explained below.

Research and Development Expenses: R&D expenses for the nine months ended September 30, 2022 were \$10,097, an increase of \$2,714 or 37% from total R&D expenses for the same period in 2021 of \$7,383. R&D expenses increased due to an increase in spending on clinical and non-clinical trials of \$2,910. Compared to the prior year period, stock-based compensation expense also increased \$763, and other R&D compensation expense increased \$288 due to salary, bonus, and benefit increases in the nine months ended September 30, 2022. Professional expenses also increased \$430 during the nine months ended September 30, 2022, as compared to the same period in 2021. The increases in R&D expenses were offset in part by a refund of \$1,000 from the research institution with which 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. In the nine months ended September 30, 2021, R&D expenses included \$1,000 attributable the same one-time fee, which was paid in June 2021. Finally, on June 27, 2022, we paid \$300 for the exclusive right to negotiate with a CAR-T Company.

General and Administrative Expenses: G&A expenses were \$9,456 for the nine months ended September 30, 2022, an increase of \$1,146 or 14% from the total G&A expenses for the nine months ended September 30, 2021 of \$8,310. The increase in G&A expenses for the nine months ended September 30, 2022 was primarily due to the increase in stock-based compensation expense of \$832. Compensation expense also increased

\$554 due to salary, bonus, and benefit increases related to the addition of employees in the nine months ended September 30, 2022. Legal fees also increased \$321 compared to the prior year period due to increased patent prosecution activity. These increases are offset in part by a decrease in professional fees and other expenses of \$562 due primarily to the reduction of proxy solicitation costs compared to the prior year period.

About Atossa Therapeutics

Atossa Therapeutics, Inc. is a clinical-stage biopharmaceutical company seeking to develop innovative medicines in areas of significant unmet medical need in oncology with a current focus on breast cancer and lung injury caused by cancer treatments. 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 and (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, 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.

Company Contact:

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Source: Atossa Therapeutics, Inc.

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

	As of September 30, 2022 (Unaudited)	As of December 31, 2021
Assets		
Current assets		
Cash and cash equivalents	\$ 117,367	\$ 136,377
Restricted cash	110	110
Prepaid expenses	5,107	2,488
Research and development rebate receivable	610	1,072
Other current assets	201	1,193
Total current assets	<u>123,395</u>	<u>141,240</u>
Deposit on investment in equity securities	2,700	-
Other assets	629	22
Total Assets	<u>\$ 126,724</u>	<u>\$ 141,262</u>
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	\$ 1,653	\$ 1,717
Accrued expenses	117	204
Payroll liabilities	1,071	1,184
Other current liabilities	27	21
Total current liabilities	<u>2,868</u>	<u>3,126</u>
Total Liabilities	<u>2,868</u>	<u>3,126</u>
Commitments and contingencies		
Stockholders' equity		
Series B convertible preferred stock - \$0.001 par value; 10,000 shares authorized; 1 share issued and outstanding as of September 30, 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 September 30, 2022 and December 31, 2021	22,792	22,792
Additional paid-in capital - common stock	249,239	243,996
Accumulated deficit	(148,703)	(129,234)
Accumulated other comprehensive loss	(54)	-
Total Stockholders' Equity	<u>123,856</u>	<u>138,136</u>
Total Liabilities and Stockholders' Equity	<u>\$ 126,724</u>	<u>\$ 141,262</u>

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

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2022	2021	2022	2021
Operating expenses				
Research and development	\$ 5,160	\$ 2,206	\$ 10,097	\$ 7,383
General and administrative	3,045	2,952	9,456	8,310
Total operating expenses	<u>8,205</u>	<u>5,158</u>	<u>19,553</u>	<u>15,693</u>
Operating loss	(8,205)	(5,158)	(19,553)	(15,693)
Other income (expense), net	194	(39)	84	(81)
Loss before income taxes	(8,011)	(5,197)	(19,469)	(15,774)
Income taxes	-	-	-	-
Net loss	(8,011)	(5,197)	(19,469)	(15,774)
Foreign currency translation adjustment	(54)	-	(54)	-
Comprehensive loss	<u>\$ (8,065)</u>	<u>\$ (5,197)</u>	<u>\$ (19,523)</u>	<u>\$ (15,774)</u>
Loss per share of common stock - basic and diluted	<u>\$ (0.06)</u>	<u>\$ (0.04)</u>	<u>\$ (0.15)</u>	<u>\$ (0.14)</u>
Weighted average shares outstanding - basic and diluted	<u>126,624</u>	<u>126,538</u>	<u>126,624</u>	<u>113,690</u>