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): August 8, 2022

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 August 8, 2022, Atossa Therapeutics, Inc. (the "Company") issued a press release announcing the quarter ended June 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 August 8, 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: August 8, 2022

Atossa Therapeutics, Inc.

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

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

SEATTLE, August 8, 2022 (GLOBE NEWSWIRE) -- Atossa Therapeutics, Inc. (Nasdaq: ATOS), a clinical-stage biopharmaceutical company seeking to develop innovative proprietary medicines in oncology and infectious disease with a current focus on breast cancer and COVID-19, today announces financial results for the fiscal quarter ended June 30, 2022, and provides an update on recent company developments.

Key developments from Q2 2022 and to date include:

- 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 was developing as an inhalation therapy for moderately to severely ill hospitalized COVID-19 patients and for "long-haul" patients with post-infection pulmonary disease.

- Announced plans to shift the development of AT-H201 to more closely align with its oncology focus by continuing the development in patients with compromised lung function due to the damaging effects of cancer treatment.

- Entered into an agreement with a venture-capital backed, private company based in the United States that is in the pre-clinical stage of developing novel Chimeric Antigen Receptor (CAR) T-cell therapies based on technology licensed from a leading U.S. adult and pediatric cancer treatment and research institution. The agreement requires that up until November 1, 2022 the CAR-T company will negotiate exclusively with Atossa for Atossa to acquire the CAR-T company, and address certain matters related to personnel, operations and intellectual property.

- Filed an investigational new drug application with the FDA to initiate a Phase 2 neoadjuvant clinical study of Atossa's proprietary Endoxifen in premenopausal women with early-stage estrogen receptor positive and Human Epidermal Growth Factor Receptor 2 negative breast cancer in the United States. The FDA has issued a clinical hold letter requesting additional information which Atossa plans to submit by the end of the third quarter 2022 and to initiate enrollment in the fourth quarter 2022.

"We continue to make steady progress with our Endoxifen programs: one to reduce tumor cell activity in breast cancer patients in the neoadjuvant setting; and another to reduce dense breast tissue in women. Our work on AT-H201 demonstrated valuable outcomes, not the least of which was an understanding of how to pursue its development in the field of oncology. With the widespread availability of SARS-CoV-2 vaccines and other therapies now approved to treat COVID-19, we believe that altering the development pathways for AT-H201 in cancer patients with compromised lung-function resulting from radiation treatment may fill a compelling unmet medical need and create additional value for our stockholders. Lung injury caused by radiation treatment affects 30-40% of lung cancer patients, and ~35% of esophageal cancer patients. In non-small cell cancer patients receiving concurrent chemotherapy and radiation therapy the incidence of lung injury is estimated to be greater than 60%. As we previously announced, rather than proceeding with Part D of the AT-H201 study in COVID-19 patients, we plan to quickly initiate a clinical study of patients with compromised lung function caused by radiation treatment and we anticipate announcing next steps in the coming months," commented Dr. Steven Quay, Atossa's President and Chief Executive Officer.

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

As of June 30, 2022, the Company had cash, cash equivalents and restricted cash of approximately $125,647.

For the quarter ended June 30, 2022, Atossa had no source of sustainable revenue and no associated cost of revenue.

Operating Expenses: Total operating expenses were $6,595 for the three months ended June 30, 2022, which is a decrease of $409 or 6%, from the three months ended June 30, 2021, of $7,004. Operating expenses for 2022 consisted of research and development (R&D) expenses of $3,433 and general and administrative (G&A) expenses of $3,162. Operating expenses for 2021 consisted of R&D expenses of $3,799, and G&A expenses of $3,205.

Research and Development Expenses: R&D expenses for the three months ended June 30, 2022, were $3,433, a decrease of $366 or 10% from total R&D expenses for the same period in 2021 of $3,799. Clinical and non-clinical trial costs as well as drug formulation and analysis for our clinical trials were consistent quarter over quarter. Total R&D compensation expense increased primarily due to an increase in stock-based compensation of $270 and increased salaries, bonus and benefits of $123. In addition, the Company paid a no-shop fee of $300 to negotiate the potential acquisition of a company focused on the pre-clinical stage of developing novel Chimeric Antigen Receptor (CAR) T-cell therapies based on technology licensed from a leading U.S. cancer treatment and research institution**.** Included in 2021 R&D expenses is an increase of $1,000 attributable to a one-time fee we paid in June 2021 to a U.S. leading research institution for the exclusive right to negotiate for the acquisition of the world-wide rights to two oncology R&D programs.

General and Administrative Expenses: G&A expenses were $3,162 for the three months ended June 30, 2022, a decrease of $43, or 1% from the total G&A expenses for the three months ended June 30, 2021, of $3,205. G&A expenses for the three months ended June 30, 2022, increased $454 primarily due to an increase in non-cash stock-based compensation expense of $287 and an increase in other compensation of $167 due to the addition of a new employee quarter over quarter as well as salary, bonus and benefits increases. This increase was offset by a decrease of $533 in professional fees primarily due to a decrease in proxy costs in 2022.

Six Months Ended June 30, 2022 Financial Results (in thousands):

For the six months ended June 30, 2022, Atossa had no source of sustainable revenue and no associated cost of revenue.

Operating Expenses: Total operating expenses were $11,348 for the six months ended June 30, 2022, which is an increase of $814 or 8%, from the six months ended June 30, 2021 of $10,534. Operating expenses for 2022 consisted of R&D expenses of $4,937 and general and G&A expenses of $6,411. Operating expenses for 2021 consisted of R&D expenses of $5,177, and G&A expenses of $5,357.

Research and Development Expenses: R&D expenses for the six months ended June 30, 2022, were $4,937, a decrease of $240 or 5% from total R&D expenses for the same period in 2021 of $5,177. R&D expenses decreased because of a refund of $1,000 from the research institution that 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, the other party did not honor its obligation to negotiate with us which lead to a cancellation of the agreement and refund of the $1,000 previously paid. Included in 2021 R&D expenses is an increase of $1,000 attributable the same one-time fee paid in June 2021. Additionally, on June 27, 2022, this decrease was offset by increased spending on clinical and non-clinical trials of $434 over the same period in 2021 due to additional drug manufacturing costs. Stock-based compensation, which is a non-cash charge, also increased $703 period over period, and other R&D compensation was up $202 due to salary, bonus and benefit increases. Professional expenses also increased $100 during the six months ended June 30, 2022 as compared to the same period in 2021. Finally, we paid $300 for the exclusive right to negotiate with a CAR-T Company for us to acquire the company.

General and Administrative Expenses: G&A expenses were $6,411 for the six months ended June 30, 2022, an increase of $1,054 or 20% from the total G&A expenses for the six months ended June 30, 2021, of $5,357. The increase in G&A expenses for the six months ended June 30, 2022, is primarily attributable to the increase in non-cash stock-based compensation expense of $1,020. Compensation expense also increased $431 due to the addition of a two new employees year over year as well as salary, bonus and benefit increases. Legal fees also increased $147 period over period due to increased patent activity. These increases are offset by the decrease in professional fees of $532 due primarily to the reduction of proxy costs period over period.

About Atossa Therapeutics

Atossa Therapeutics, Inc. is a clinical-stage biopharmaceutical company seeking to discover and develop innovative medicines in oncology and infectious diseases with a current focus on breast cancer and COVID-19. 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, AT-301 and 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 Ki-67 or any other result from a neoadjuvant study is an approvable endpoint for oral 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.

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Source: Atossa Therapeutics, Inc.

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

	As of June 30, 2022 (Unaudited)	As of December 31, 2021
Assets		
Current assets		
Cash and cash equivalents	$ 125,537	$ 136,377
Restricted cash	110	110
Prepaid expenses	5,304	2,488
Research and development rebate receivable	900	1,072
Other current assets	1,570	1,193
Total current assets	133,421	141,240
Other assets	627	22
Total Assets	$ 134,048	$ 141,262
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 2,052	$ 1,717
Accrued expenses	834	204
Payroll liabilities	875	1,184
Other current liabilities	31	21
Total current liabilities	3,792	3,126
Total Liabilities	3,792	3,126
Commitments and contingencies		
Stockholders' equity		
Preferred stock - $0.001 par value; 10,000 shares authorized; 1 share issued and outstanding as of June 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 June 30, 2022 and December 31, 2021	22,792	22,792
Additional paid-in capital - common stock	247,573	243,996
Accumulated deficit	(140,691)	(129,234)
Total Stockholders' Equity	130,256	138,136
Total Liabilities and Stockholders' Equity	$ 134,048	$ 141,262

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

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2022	2021	2022	2021
Operating expenses				
Research and development	$ 3,433	$ 3,799	$ 4,937	$ 5,177
General and administrative	3,162	3,205	6,411	5,357
Total operating expenses	6,595	7,004	11,348	10,534
Operating loss	(6,595)	(7,004)	(11,348)	(10,534)
Other expense, net	(77)	(35)	(109)	(43)
Loss before income taxes	(6,672)	(7,039)	(11,457)	(10,577)
Income taxes	-	-	-	-
Net loss	$ (6,672)	$ (7,039)	$ (11,457)	$ (10,577)
Loss per common share - basic and diluted	$ (0.05)	$ (0.06)	$ (0.09)	$ (0.10)
Weighted average shares outstanding - basic and diluted	126,624	121,572	126,624	107,160