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): November 15, 2021

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 November 15, 2021, Atossa Therapeutics, Inc. (the "Company") issued a press release announcing the quarter ended September 30, 2021 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 15, 2021
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 15, 2021

Atossa Therapeutics, Inc.

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

Atossa Therapeutics Announces Third Quarter 2021 Financial Results and Provides Corporate Update

SEATTLE, November 15, 2021 (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 September 30, 2021, and provides an update on recent company developments.

Key developments from Q3 2021 and to date include:

- Began to enroll participants in its clinical study of AT-H201 in Australia. The nebulized formulation, AT-H201, is being developed as an inhalation therapy for moderately to severely ill hospitalized COVID-19 patients and for “long-haul” patients with post-infection pulmonary disease.

- Received authorization from Swedish regulators to initiate a Phase 2 clinical study of Endoxifen to assess safety and pharmacodynamics in women with mammographic breast density (MBD).

- Scheduled a pre-IND meeting with the U.S. FDA to obtain input on the potential clinical and regulatory pathway for use of Atossa’s Endoxifen to treat breast cancer patients in the neoadjuvant (sometimes called “window of opportunity”) setting. The meeting is currently scheduled for December 2021.

“Our progress in both the Endoxifen and COVID-19 programs, with our initiation of our trial in Australia for AT-H201, and our receipt of regulatory authorization in Sweden to commence an Endoxifen Phase 2 trial, have been key recent milestones, positioning us to move both of these programs forward and take the next steps toward developing therapies in urgent unmet patient needs,” said Dr. Steven Quay, Atossa’s President and Chief Executive Officer.

“Further, our strong balance sheet will continue to facilitate our development plans as we not only execute on these trials but also explore additional options that could create significant shareholder value,” concluded Dr. Quay.

Quarter Ended September 30, 2021, Financial Results

For the quarter ended September 30, 2021, Atossa has no source of sustainable revenue and no associated cost of revenue.

As of September 30, 2021, the Company had cash, cash equivalents and restricted cash of approximately $140 million.

Operating Expenses: Total operating expenses were approximately $5,159,000 and $15,693,000 for the three and nine months ended September 30, 2021, respectively, consisting of research and development ("R&D") expenses of approximately $2,206,000 and $7,383,000 respectively, and general and administrative ("G&A") expenses of approximately $2,952,000 and $8,310,000, respectively. Total operating expenses were approximately $3,509,000 and $10,382,000, respectively for the three and nine month ended September 30, 2020, and consisted of R&D expenses of approximately $1,659,000 and $4,251,000, respectively, and G&A expenses of approximately $1,850,000 and $6,131,000 respectively. Total operating expenses for the three and nine months ended September 30, 2021 as compared to the same period in 2020 increased approximately $1,650,000 and $5,311,000 or 47% and 51%, respectively. The basis for the increased operating expenses in 2021 is explained below.

Research and Development Expenses: R&D expenses for the three months ended September 30, 2021, were approximately $2,206,000, an increase of approximately $547,000 or 33% from total R&D expenses for the three months ended September 30, 2020, of approximately $1,659,000. The increase of approximately $547,000 for the three month period is attributed to an increase in clinical trial expense of approximately $81,000, an increase in compensation of approximately $380,000 driven by non-cash stock-based compensation and an increase in R&D professional fees of approximately $82,000. R&D expenses for the nine months ended September 30, 2021, were approximately $7,383,000, an increase of approximately $3,132,000 or 74% from total R&D expenses for the nine months ended September 30, 2020, of approximately $4,251,000. The increase in R&D expense for the nine months ended September 30, 2021, is attributed primarily to an increase in clinical trial expense of approximately $1,390,000 and an increase in compensation of approximately $591,000 due primarily to non-cash stock-based compensation and the addition of two employees, as compared to the same period in 2020. Also included in R&D expenses is an increase of $1,000,000 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. Those negotiations are ongoing, and no assurance can be given that they will lead to a definitive agreement. We expect our R&D expenses to continue to increase through 2021 as we have commenced a clinical study of AT-H201, complete studies of AT-301, launch a Phase 2 clinical trial of Endoxifen in women with high breast density, and continue the development of other indications and therapeutics.

General and Administrative Expenses: G&A expenses were approximately $2,952,000 for the three months ended September 30, 2021, an increase of approximately $1,102,000, or 60% from the total G&A expenses for the three months ended September 30, 2020, of approximately $1,850,000. The increase of approximately $1,102,000 for the three-month period is attributed to an increase in insurance costs of approximately $192,000 due to additional COVID-19 clinical trials and an increase in compensation of approximately $900,000 due primarily to non-cash stock-based compensation. G&A expenses for the nine months ended September 30, 2021, were approximately $8,310,000, an increase of approximately $2,179,000 or 36% from total G&A expenses for the nine months ended September 30, 2020, of approximately $6,131,000. The increase in G&A expenses for the nine months ended September 30, 2021, is attributed to an increase in insurance costs of approximately $578,000 due to the addition of the COVID-19 clinical trials, professional fees of approximately $742,000 due primarily to increased proxy costs and increased compensation of approximately $1,070,000 resulting primarily from increased headcount and increased non-cash stock-based compensation, offset by a reduction in legal fees of approximately $343,000 compared to the same period in 2020. G&A expenses consist primarily of personnel and related benefit costs, facilities, professional services, insurance, and public company related expenses.

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, 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:
Atossa Therapeutics, Inc.
Kyle Guse CFO and General Counsel
Office: (866) 893-4927
kyle.guse@atossainc.com

Investor Relations Contact:
Core IR
Office: (516) 222-2560
ir@atossainc.com

Source: Atossa Therapeutics, Inc.

ATOSSA THERAPEUTICS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

	As of September 30, 2021 (Unaudited)	As of December 31, 2020
Assets		
Current assets		
Cash and cash equivalents	$ 140,040,955	$ 39,553,671
Restricted cash	110,000	110,000
Prepaid expenses	1,883,197	1,813,902
Research and development tax rebate receivable	934,672	634,940
Other current assets	18,060	657,662
Total current assets	142,986,884	42,770,175
Furniture and equipment, net	22,138	20,632
Intangible assets, net	-	13,375
Right-of-use asset	1,217	18,053
Other assets	13,408	17,218
Total Assets	$ 143,023,647	$ 42,839,453
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 667,988	$ 1,588,613
Accrued expenses	75,695	93,367
Payroll liabilities	912,670	963,665
Common stock warrant liability	-	13,003,075
Lease liability	1,217	18,053
Other current liabilities	18,251	4,748
Total current liabilities	1,675,821	15,671,521
Total Liabilities	1,675,821	15,671,521
Commitments and contingencies		
Stockholders' equity		
Preferred stock - $0.001 par value; 10,000,000 shares authorized; 584 and 621 shares issued and outstanding as of September 30, 2021 and December 31, 2020, respectively	1	1
Additional paid-in capital - Series B convertible preferred stock	583,999	620,999
Common stock - $0.18 par value; 175,000,000 shares authorized; 126,623,541 and 47,548,835 shares issued and outstanding as of September 30, 2021 and December 31, 2020, respectively	22,792,225	8,558,778
Additional paid-in capital	242,373,694	129,887,146
Accumulated deficit	(124,402,093)	(111,898,992)
Total Stockholders' Equity	141,347,826	27,167,932
Total Liabilities and Stockholders' Equity	$ 143,023,647	$ 42,839,453

ATOSSA THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(UNAUDITED)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2021	**2020**	**2021**	**2020**
Operating expenses				
Research and development	$ 2,206,158	$ 1,659,075	$ 7,383,281	$ 4,250,934
General and administrative	2,952,436	1,849,741	8,309,807	6,130,698
Total operating expenses	5,158,594	3,508,816	15,693,088	10,381,632
Operating loss	(5,158,594)	(3,508,816)	(15,693,088)	(10,381,632)
Other income (expense), net	(38,551)	17,745	(81,374)	36,999
Loss before income taxes	(5,197,145)	(3,491,071)	(15,774,462)	(10,344,633)
Income taxes	-	-	-	-
Net loss	$ (5,197,145)	$ (3,491,071)	$ (15,774,462)	$ (10,344,633)
Loss per common share - basic and diluted	$ (0.04)	$ (0.34)	$ (0.14)	$ (1.09)
Weighted average shares outstanding - basic and diluted	126,537,544	10,162,770	113,689,961	9,496,222