Atossa Therapeutics Announces Third Quarter 2020 Financial Results and Provides Corporate Update

SEATTLE, Nov. 13, 2020 (GLOBE NEWSWIRE) -- Atossa Therapeutics, Inc. (Nasdaq: ATOS), a clinical-stage biopharmaceutical company seeking to discover and develop innovative medicines in areas of significant unmet medical need with a current focus on breast cancer and COVID-19, today announced financial results for the third quarter ended September 30, 2020, and provided an update on recent company developments.

Key recent developments included:

- Significantly advanced the development of AT-301 proprietary nasal spray as potential at-home treatment against COVID-19, with completion of a randomized, placebo controlled, double-blinded Phase 1 study and a preliminary assessment of the blinded data indicating that AT-301 was safe and well tolerated by participants at two different dose levels in both single and multiple dose forms over 14 days.
- Applied for regulatory approval from the European Medical Product Authority to commence a Phase 2 clinical study of Endoxifen in Sweden to reduce mammographic breast density (MBD).
- Announced interim findings following 18 months of an Expanded Access (or "compassionate use") single-patient study of Endoxifen. The patient in the study had no cancer recurrence and suffered no side effects. Endoxifen did not cause other safety and tolerability concerns in this patient.

"Our COVID-19 nasal spray program has progressed very well during the quarter, with our Phase 1 study of AT-301 nasal spray demonstrating good safety and tolerability at two different dose levels in both single and multiple dose forms over a 14-day trial period," said Dr. Steven Quay, Atossa's President and Chief Executive Officer. "We are very encouraged by these preliminary results. In the next 30 days we plan to file a pre-IND meeting request with the FDA and, subject to their input, plan to immediately commence a Phase 2 study, either in the U.S. or abroad, in patients recently diagnosed with COVID-19.

"We believe AT-301 nasal spray is unique among the various therapies under development for COVID-19. While other companies are focused on therapies for patients being treated in hospitals, we are developing AT-301 for at-home use for the vast majority of COVID-19 patients who do not require hospitalization. Although great progress has been made by companies developing vaccines, it has become clear that a vaccine won't provide a complete solution to the pandemic. No vaccine will be 100 percent effective and surveys have shown that many people won't take a vaccine even when one becomes available. Similar to the seasonal flu where vaccines don't provide complete community protection and people also rely on therapies, our AT-301 nasal spray therapy should form an important and necessary component of a comprehensive response to the COVID-19 pandemic," added Dr. Quay.

Upcoming 2020 milestones include the following:

- File pre-IND meeting request with FDA for AT-301 nasal spray for potential at-home treatment of COVID-19.
- Commence Phase 2 study in Sweden for our Endoxifen to reduce MBD.

September 30, 2020 Financial Results

For the three and nine months ended September 30, 2020 and 2019, we have no source of sustainable revenue and no associated cost of revenue.

Operating Expenses: Total operating expenses were approximately $3,509,000 and $10,382,000 for the three and nine months ended September 30, 2020, respectively, consisting of R&D expenses of approximately $1,659,000 and $4,251,000, respectively, and general and administrative ("G&A") expenses of approximately $1,850,000 and $6,131,000, respectively. Total operating expenses were approximately $3,298,000 and $14,649,000 for the three and nine months ended September 30, 2019, respectively, consisting of R&D expenses of approximately $1,684,000 and $5,747,000, respectively, and G&A expense of approximately $1,614,000 and $8,901,000, respectively. Total operating expense for the nine months ended September 30, 2020 as compared to the same period in 2019 decreased approximately $4,267,000 or 29% and for the three months ended September 30, 2020 as compared to the same period in 2019 increased approximately $211,000 or 6%.

Research and Development Expenses: R&D expenses for the three months ended September 30, 2020, were approximately $1,659,000, which were comparable to total R&D expenses for the three months ended September 30, 2019, of approximately $1,684,000. R&D expenses for the nine months ended September 30, 2020, were approximately $4,251,000, a decrease of approximately $1,496,000 or 26% from total R&D expenses for the nine months ended September 30, 2019, of approximately $5,747,000. The decrease in R&D expense is attributed primarily to a decrease in stock-based compensation of approximately $2,165,000, which is a non-cash charge, offset by an increase in salaries, professional fees and clinical trials expenses of approximately $669,000, as compared to the same period in 2019. We expect our R&D expenses to increase for the remainder of 2020 as we seek to commence a study of AT-H201, complete our Phase 1 study 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 $1,850,000 for the three months ended September 30, 2020, an increase of approximately $236,000, or 15% from the total G&A expenses for the three months ended September 30, 2019, of approximately $1,614,000. The $236,000 increase in G&A expenses for the three month period ended September 30, 2020, is mainly attributed to an increase in legal, professional fees and insurance costs. G&A expenses were approximately $6,131,000 for the nine months ended September 30, 2020, a decrease of approximately $2,770,000, or 31% from the total G&A expenses for the nine months ended September 30, 2019, of approximately $8,901,000. G&A expenses consist primarily of personnel and related benefit costs, facilities, professional services, insurance, and public company related expenses. The decrease in G&A expenses for the nine month period ended September 30, 2020, is mainly attributed to a decrease in stock-based compensation expense of approximately $3,535,000, which is a non-cash charge, offset by an increase in legal, professional fees and insurance costs of approximately $765,000 compared to the same period in 2019.

As of September 30, 2020, the Company had approximately $9.2 million in cash and cash equivalents.

About Atossa Therapeutics

Atossa Therapeutics, Inc. is a clinical-stage biopharmaceutical company seeking to discover and develop innovative medicines in areas of significant unmet medical need 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.

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Source: Atossa Therapeutics, Inc.

ATOSSA THERAPEUTICS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

Assets	As of September 30, 2020 (Unaudited)	As of December 31, 2019
Current assets		
Cash and cash equivalents	$ 9,105,950	$ 12,581,136
Restricted cash	110,000	110,000
Prepaid expenses	1,484,251	862,344
Research and development tax rebate receivable	439,205	739,656
Other current assets	178,911	26,130
Total current assets	11,318,317	14,319,266
Furniture and equipment, net	25,429	34,350
Intangible assets, net	45,417	68,542
Right-of-use asset	31,279	50,479
Other assets	17,218	17,218
Total Assets	$ 11,437,660	$ 14,489,855
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 682,612	$ 293,171
Accrued expenses	85,173	77,888
Payroll liabilities	752,847	899,420
Lease liability	30,063	39,371
Other current liabilities	14,671	12,892
Total current liabilities	1,565,366	1,322,742
Long term liabilities		
Lease liability long term	1,217	11,108
Total Liabilities	1,566,583	1,333,850
Commitments and contingencies		
Stockholders' equity		
Preferred stock - $0.001 par value; 10,000,000 shares authorized; 623 and 671 shares issued and outstanding as of September 30, 2020 and December 31, 2019, respectively	1	1
Additional paid-in capital - Series B convertible preferred stock	622,999	670,999
Common stock - $0.18 par value; 175,000,000 shares authorized; 10,464,250 and 9,130,984 shares issued and outstanding as of September 30, 2020 and December 31, 2019, respectively	1,883,553	1,643,565
Additional paid-in capital	111,780,197	104,912,480
Accumulated deficit	(104,415,673)	(94,071,040)
Total Stockholders' Equity	9,871,077	13,156,005
Total Liabilities and Stockholders' Equity	$ 11,437,660	$ 14,489,855

The accompanying notes are an integral part of these condensed consolidated financial statements.

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

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2020	2019	2020	2019
Operating expenses				
Research and development	$ 1,659,075	$ 1,684,215	$ 4,250,934	$ 5,747,399
General and administrative	1,849,741	1,613,983	6,130,698	8,901,197
Total operating expenses	3,508,816	3,298,198	10,381,632	14,648,596
Operating loss	(3,508,816)	(3,298,198)	(10,381,632)	(14,648,596)
Other income	17,745	12,284	36,999	26,846
Loss before income taxes	(3,491,071)	(3,285,914)	(10,344,633)	(14,621,750)
Income taxes	-	-	-	-
Net loss	$ (3,491,071)	$ (3,285,914)	$ (10,344,633)	$ (14,621,750)
Loss per common share - basic and diluted	$ (0.34)	$ (0.36)	$ (1.09)	$ (1.77)
Weighted average shares outstanding - basic and diluted	10,162,770	9,130,057	9,496,222	8,283,302

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