



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

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SEATTLE, Nov. 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.

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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	