



## **Atossa Therapeutics Announces Second Quarter 2021 Financial Results - Provides Corporate Update and Information about Upcoming Stockholder Meeting**

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SEATTLE, Aug. 13, 2021 (GLOBE NEWSWIRE) -- Atossa Therapeutics, Inc. (Nasdaq: ATOS), a clinical-stage biopharmaceutical company seeking to discover and develop innovative 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, 2021, and provides an update on recent company developments.

Key developments from Q2 2021 and to date include:

- Atossa received final data from its open-label Phase 2 clinical study of oral Endoxifen administered in the “window of opportunity” between diagnosis of breast cancer and surgery, which showed that the primary endpoint of the study was achieved: Ki-67, a common measure of tumor cell activity, was reduced from an average of 25.6% at screening to 6% on the day of surgery, a 65.1% reduction. Ki-67 was reduced below 25% for all patients, which is potentially clinically meaningful because studies by others have shown that a reduction below 25% improves long term survival.
- Received authorization from Swedish regulators to initiate a Phase 2 clinical study of Endoxifen to reduce mammographic breast density (MBD).
- Received authorization from Australian regulators to initiate a clinical study of AT-H201 which is being developed for the treatment of patients with COVID-19 and “long haul” respiratory illness.
- Announced final results from its Phase 1 double-blinded, randomized, placebo-controlled clinical study using Atossa’s proprietary drug candidate AT-301 administered by nasal spray. AT-301 was considered safe and well tolerated in healthy male and female participants in this study at two different dose levels over 14 days. AT-301 is being developed for at home use for patients recently diagnosed with COVID-19.
- Completed treatment of oral Endoxifen in an ovarian cancer patient under the FDA’s Expanded Access Pathway. The patient has recurring, metastatic, late-stage ovarian cancer and had not improved on other therapies. Although organoid testing conducted by a third party had previously shown a strong response to Endoxifen in combination with Apolisib, she has unfortunately continued to experience disease progression and is not expected to continue treatment with Endoxifen.
- Through the completion of capital raising transactions and the exercise of warrants, Atossa has grown its cash balances quarter over quarter for the past three quarters, ending the second quarter 2021 with \$142.4 million in cash and cash equivalents.
- Scheduled a special stockholder meeting for September 7, 2021 for the purpose of approving an increase in authorized shares of common stock. If the proposal is approved by the stockholders, Atossa does not intend to issue any of the newly authorized shares of common stock for the purpose of raising capital in the nine months following approval of the proposal at a price less than \$10 per share. The newly authorized shares of common stock are intended to

be used at any time to complete and/or support acquisitions, collaborations, partnerships and licensing transactions.

"We continue to experience encouraging progress in our MBD and COVID-19 programs, with new regulatory approvals being granted in Sweden for a Phase 2 trial in MBD and authorization in Australia to commence a Phase 2 study of AT-H201 for respiratory illness associated with COVID-19," said Dr. Steven Quay, Atossa's President and Chief Executive Officer.

"In the meantime, we continue to enjoy a strong balance sheet, which we have significantly expanded over the last three quarters and will facilitate our development plans over the near term. As we actively explore the possibility for strategic expansion into other areas where we might see near-term milestones and results, we also urge all of our shareholders to exercise their right to vote at our special stockholder's meeting on September 7, 2021. We urge a vote in favor of the proposal to increase authorized shares, which will provide the Company with the flexibility to issue shares as part of these potential acquisitions, collaborations and partnerships, a common strategy successful biotech companies seeking to grow shareholder value employ in order to create a more attractive opportunity for all. We look forward to continuing to update our stockholders on these opportunities as they develop," concluded Dr. Quay.

#### **Quarter Ended June 30, 2021, Financial Results**

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

As of June 30, 2021, the Company had cash, cash equivalents and restricted cash of approximately \$142.5 million.

#### *Operating Expenses*

Total operating expenses were approximately \$7,004,000 and \$10,534,000 for the three and six months ended June 30, 2021, respectively, consisting of research and development ("R&D") expenses of approximately \$3,799,000 and \$5,177,000 respectively, and general and administrative ("G&A") expenses of approximately \$3,205,000 and \$5,357,000, respectively. Total operating expenses were approximately \$3,936,000 and \$6,873,000, respectively for the three and six months ended June 30, 2020, and consisted of R&D expenses of approximately \$1,653,000 and \$2,592,000, respectively, and G&A expenses of approximately \$2,283,000 and \$4,281,000 respectively. Total operating expenses for the three and six months ended June 30, 2021, as compared to the same period in 2020 increased approximately \$3,068,000 and \$3,661,000 or 78% and 53%, respectively.

#### *Research and Development Expenses*

R&D expenses for the three months ended June 30, 2021, were approximately \$3,799,000, an increase of approximately \$2,146,000 or 130% from total R&D expenses for the three months ended June 30, 2020, of approximately \$1,653,000. R&D expenses for the six months ended June 30, 2021, were approximately \$5,177,000, an increase of approximately \$2,585,000 or 100% from total R&D expenses for the six months ended June 30, 2020, of approximately \$2,592,000. The increase in R&D expense is attributed primarily to an increase in clinical trial expense of approximately \$1,309,000 and an increase in compensation of approximately \$211,000 due to 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. We expect our R&D expenses to continue to increase into 2021 as we seek to commence 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 \$3,205,000 for the three months ended June 30, 2021, an increase of approximately \$922,000, or 40% from the total G&A expenses for the three months ended June 30, 2020, of approximately \$2,283,000. G&A expenses for the six months ended June 30, 2021, were approximately \$5,357,000, an increase of approximately \$1,076,000 or 25% from total R&D expenses for the six months ended June 30, 2020, of approximately \$4,281,000. The increase in G&A expenses for the three and six months ended June 30, 2021, is attributed to an increase in insurance costs of approximately \$387,000 due to the addition of the COVID-19 clinical trials, professional fees of approximately \$703,000 due primarily to increased proxy costs and increased compensation of approximately \$170,000, offset by a reduction in legal fees of approximately \$301,000 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](http://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](mailto:kyle.guse@atossainc.com)

#### Investor Relations Contact:

Core IR  
Office: (516) 222-2560  
[ir@atossainc.com](mailto:ir@atossainc.com)

Source: Atossa Therapeutics, Inc.

**ATOSSA THERAPEUTICS, INC.  
CONDENSED CONSOLIDATED BALANCE SHEETS**

	<b>As of June 30, 2021 (Unaudited)</b>	<b>As of December 31, 2020</b>
<b><u>Assets</u></b>		
Current assets		
Cash and cash equivalents	\$ 142,432,961	\$ 39,553,671
Restricted cash	110,000	110,000
Prepaid expenses	2,391,966	1,813,902
Research and development tax rebate receivable	817,109	634,940
Other current assets	78,882	657,662
Total current assets	145,830,918	42,770,175
Furniture and equipment, net	14,501	20,632
Intangible assets, net	4,458	13,375
Right-of-use asset	4,720	18,053
Other assets	13,408	17,218
Total Assets	\$ 145,868,005	\$ 42,839,453
<b><u>Liabilities and Stockholders' Equity</u></b>		
Current liabilities		
Accounts payable	\$ 537,915	\$ 1,588,613
Accrued expenses	531,602	93,367
Payroll liabilities	700,588	963,665
Common stock warrant liability	-	13,003,075
Lease liability	4,720	18,053
Other current liabilities	21,278	4,748
Total current liabilities	1,796,103	15,671,521
Commitments and contingencies		
Stockholders' equity		
Preferred stock - \$0.001 par value; 10,000,000 shares authorized; 587 and 621 shares issued and outstanding as of June 30, 2021 and December 31, 2020, respectively	1	1
Additional paid-in capital - Series B convertible preferred stock	586,999	620,999
Common stock - \$0.18 par value; 175,000,000 shares authorized; 125,925,096 and 47,548,835 shares issued and outstanding as of June 30, 2021 and December 31, 2020, respectively	22,666,505	8,558,778
Additional paid-in capital	240,023,345	129,887,146
Accumulated deficit	(119,204,948 )	(111,898,992 )
Total Stockholders' Equity	144,071,902	27,167,932
Total Liabilities and Stockholders' Equity	\$ 145,868,005	\$ 42,839,453

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

	<b>For the Three Months Ended June 30,</b>		<b>For the Six Months Ended June 30,</b>	
	<b>2021</b>	<b>2020</b>	<b>2021</b>	<b>2020</b>
Operating expenses				
Research and development	\$ 3,798,636	\$ 1,653,239	\$ 5,177,123	\$ 2,591,859
General and administrative	3,205,130	2,282,568	5,357,371	4,280,957
Total operating expenses	7,003,766	3,935,807	10,534,494	6,872,816
Operating loss	(7,003,766 )	(3,935,807 )	(10,534,494 )	(6,872,816 )
Other income (expense), net	(35,482 )	29,665	(42,823 )	19,254
Loss before income taxes	(7,039,248 )	(3,906,142 )	(10,577,317 )	(6,853,562 )
Income taxes	-	-	-	-

Net loss	\$ (7,039,248	)	\$ (3,906,142	)	\$ (10,577,317	)	\$ (6,853,562	)
Loss per common share - basic and diluted	\$ (0.06	)	\$ (0.43	)	\$ (0.10	)	\$ (0.75	)
Weighted average shares outstanding - basic and diluted	121,572,091		9,187,588		107,159,698		9,159,286	