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

SEATTLE, Aug. 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 second quarter ended June 30, 2020, and provided an update on recent company developments.

Key recent developments included:

- Received approval from the Australian Human Research *Ethics Committee* (HREC) to open a Phase 1 clinical study in Australia using Atossa's proprietary drug candidate AT-301 administered by nasal spray. As of August 3, 2020, all necessary approvals were obtained and enrollment is expected to begin in the coming weeks.
- Contracted with Avance Clinical Pty. Ltd. to conduct a clinical study of Atossa's AT-301. Avance is a leading Australian clinical research organization and has successfully completed multiple clinical studies of Atossa's proprietary Endoxifen.
- Announced successful in vitro testing of both of Atossa's COVID-19 therapies under development: AT-301 and AT-H201. The preliminary study results show that AT-301 and the components of AT-H201 inhibit SARS-CoV-2 infectivity of VERO cells in a laboratory culture, which is the standard disease model used for initial screening of COVID-19 drug candidates.
- 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.
- Advanced product development programs with multiple key hires in clinical, regulatory, and chemistry manufacturing and controls. The hiring of these talented and highly accomplished individuals will help accelerate the advancement of Atossa's development pipeline, which includes programs in breast cancer and COVID-19.
- Completed sales of all available shares under Atossa's at-the-market financing program with total gross proceeds to Atossa of $5 million through July 2020. As of June 30, 2020, the Company had approximately $7.5 million in cash and cash equivalents and with this program we received an additional $4.3 million in July 2020.

"We continue to progress both our Endoxifen and COVID-19 programs," said Dr. Steven Quay, Atossa's President and Chief Executive Officer. "Our COVID-19 programs continue to evolve at breakneck speed as we announced successful in vitro testing of the components of AT-H201 as well as our AT-301 nasal spray formulation, a contract with Avance Clinical in Australia to conduct the trial for AT-301 and receiving approval from the Australian ethics committee to initiate a Phase 1 clinical trial. The goal of our AT-301 program is to develop the therapy to treat COVID-19 patients that are not ill enough to require hospitalization. As we have previously stated, the U.S. Food and Drug Administration has accepted well-controlled, high quality studies conducted outside the U.S. and our existing relationship with Avance and their history of success with our other Phase 1 trials, expedited our ability to get the drug in the clinic, which in the case of COVID-19 is of paramount importance. Assuming a favorable outcome, we anticipate the results of this trial to be readily included in future applications with the FDA. We will also explore regulatory approval in Australia, where unfortunately COVID-19 cases are rising again."

"Meanwhile we continue to add to the body of strong clinical evidence for our Endoxifin program with the interim findings following 18 months of an Expanded Access single patient study showing the patient had no cancer recurrence and suffered no side effects," added Dr. Quay.

Upcoming 2020 milestones include the following:

- Receive regulatory approvals to initiate a Phase 2 study in Stockholm, Sweden using Atossa's Endoxifen to reduce mammographic breast density (MBD).
- Commence enrollment in the Phase 2 study in Stockholm to treat MBD.
- Commence enrollment in the AT-301 Phase 1 study in Australia.
- Receive regulatory approval to initiate a clinical study of AT-H201.
- Commence enrollment in the clinical study of AT-H201.

June 30, 2020 Financial Results

For the quarter ended June 30, 2020, Atossa had no source of sustainable revenue and no associated cost of revenue.

Operating Expenses: Total operating expenses were approximately $3,936,000 and $6,873,000 for the three and six months ended June 30, 2020, respectively, consisting of research and development ("R&D") expenses of approximately $1,653,000 and $2,592,000, respectively, and general and administrative ("G&A") expenses of approximately $2,283,000 and $4,281,000, respectively. Total operating expenses were approximately $7,286,000 and $11,350,000 for the three and six months ended June 30, 2019, respectively, consisting of R&D expenses of approximately $2,612,000 and $4,063,000, respectively, and G&A expense of approximately $4,674,000 and $7,287,000, respectively. Total operating expense for the three and six months ended June 30, 2020 as compared to the same period in 2019 decreased approximately $3,350,000 and $4,477,000 or 46% and 39%, respectively.

Research and Development Expenses: R&D expenses for the three months ended June 30, 2020, were approximately $1,653,000, a decrease of approximately $959,000 or 37% from total R&D expenses for the three months ended June 30, 2019 of approximately $2,612,000. R&D expenses for the six months ended June 30, 2020, were approximately $2,592,000, a decrease of approximately $1,471,000 or 36% from total R&D expenses for the six months ended June 30, 2019 of approximately $4,063,000. The

decrease in R&D expense is attributed primarily to a decrease in stock-based compensation of approximately $2,097,000, which is a non-cash charge, offset by an increase in salaries, professional fees and clinical trials expenses of approximately $626,000, as compared to the same period in 2019. We expect our R&D expenses to increase throughout 2020 as we commence studies of AT-H201 and AT-301, additional Phase 2 clinical trials of Endoxifen, and continue the development of other indications and therapeutics.

General and Administrative Expenses: G&A expenses were approximately $2,283,000 for the three months ended June 30, 2020, a decrease of approximately $2,391,000, or 51% from the total G&A expenses for the three months ended June 30, 2019 of approximately $4,674,000. G&A expenses were approximately $4,281,000 for the six months ended June 30, 2020, a decrease of approximately $3,006,000, or 41% from the total G&A expenses for the six months ended June 30, 2019, of approximately $7,287,000. 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 period ended June 30, 2020, is mainly attributed to a decrease in stock-based compensation expense of approximately $3,515,000, which is a non-cash charge, offset by an increase in legal, professional fees and insurance costs of approximately $510,000 compared to the same period in 2019.

As of June 30, 2020, the Company had approximately $7.5 million in cash and cash equivalents and in July 2020 Atossa received an additional $4.3 million in cash by completing the sale of all shares available under its at-the-market financing facility.

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.

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 June 30, 2020 (Unaudited)	As of December 31, 2019
Assets		
Current assets		
Cash and cash equivalents	$ 7,462,736	$ 12,581,136
Restricted cash	110,000	110,000
Prepaid expenses	1,464,366	862,344
Research and development tax rebate receivable	760,622	739,656
Other current assets	263,957	26,130
Total current assets	10,061,681	14,319,266
Furniture and equipment, net	29,440	34,350
Intangible assets, net	53,125	68,542
Right-of-use asset	44,235	50,479
Other assets	17,218	17,218
Total Assets	$ 10,205,699	$ 14,489,855
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 1,032,707	$ 293,171
Accrued expenses	92,855	77,888
Payroll liabilities	655,408	899,420
Lease liability	39,515	39,371
Other current liabilities	6,188	12,892
Total current liabilities	1,826,673	1,322,742
Long term liabilities		
Lease liability long term	4,720	11,108
Total Liabilities	1,831,393	1,333,850
Commitments and contingencies		
Stockholders' equity		
Preferred stock - $0.001 par value; 10,000,000 shares authorized; 626 and 671 shares issued and outstanding as of June 30, 2020 and December 31, 2019, respectively	1	1
Additional paid-in capital - Series B convertible preferred stock	625,999	670,999
Common stock - $0.18 par value; 175,000,000 shares authorized; 9,303,878 and 9,130,984 shares issued and outstanding as of June 30, 2020 and December 31, 2019, respectively	1,674,686	1,643,565
Additional paid-in capital	106,998,222	104,912,480
Accumulated deficit	(100,924,602)	(94,071,040)
Total Stockholders' Equity	8,374,306	13,156,005
Total Liabilities and Stockholders' Equity	$ 10,205,699	$ 14,489,855

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

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2020	2019	2020	2019
Operating expenses				
Research and development	$ 1,653,239	$ 2,611,948	$ 2,591,859	$ 4,063,184
General and administrative	2,282,568	4,674,121	4,280,957	7,287,214
Total operating expenses	3,935,807	7,286,069	6,872,816	11,350,398
Operating loss	(3,935,807)	(7,286,069)	(6,872,816)	(11,350,398)
Other income	29,665	23,540	19,254	14,562
Loss before income taxes	(3,906,142)	(7,262,529)	(6,853,562)	(11,335,836)
Income taxes	-	-	-	-
Net loss	$ (3,906,142)	$ (7,262,529)	$ (6,853,562)	$ (11,335,836)
Loss per common share - basic and diluted	$ (0.43)	$ (0.80)	$ (0.75)	$ (1.44)
Weighted average shares outstanding - basic and diluted	9,187,588	9,126,153	9,159,286	7,852,907

Atossa THERAPEUTICS

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