Atossa Therapeutics Announces First Quarter 2020 Financial Results and Provides Company Update on COVID-19 HOPE and Endoxifen Programs

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SEATTLE, May 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 first quarter ended March 31, 2020, and provided an update on recent company developments.

Key recent developments include:

- Launched a new drug development program called COVID-19 HOPE to test AT-H201, a novel combination of two drugs that have been previously approved by the FDA for other diseases. The goal of the COVID-19 HOPE program is to develop a therapy to improve lung function and reduce the amount of time that COVID-19 patients are on ventilators. Atossa has applied to the FDA for approval to commence a clinical study in this setting.

- Announced that Atossa has contracted with NYC Health + Hospitals/Metropolitan in New York City to conduct the COVID-19 HOPE study of AT-H201.

- Announced positive interim results from Atossa's Phase 2 study of oral Endoxifen to treat breast cancer in the "window of opportunity" between diagnosis of breast cancer and surgery. A statistically significant ($p = 0.031$) reduction of about 74% in tumor cell proliferation was achieved over an average of 22 days of dosing. Proliferation was measured by Ki-67, a recognized standard measurement of breast cancer cell proliferation. Other recent progress with this program includes contracting with Avance Clinical to open a second site for the study in Geelong, Victoria, Australia, with the goal of increasing the rate of enrollment; applying to the Institutional Review Board for approval to open the second site; and, manufacturing sufficient Endoxifen necessary for all patients expected to enroll in this study.

- Announced that recent input from the FDA on Atossa's oral Endoxifen program will inform Atossa's clinical trial strategy and study design both in the U.S. and in Stockholm, Sweden, where Atossa is planning a Phase 2 study to reduce MBD. Atossa plans to commence the MBD study in Stockholm after receiving approval by the European Medical Product Authority (MPA) and the re-opening of mammography clinics in Stockholm following the COVID-19 closures.

"The beginning of 2020 has been eventful both in terms of our accomplishments in moving our Endoxifen clinical programs forward, as well as the launch of our COVID-19 HOPE program," said Dr. Steven Quay, Atossa's President and Chief Executive Officer. "We achieved tremendous success with the initial group of patients in our oral Endoxifen window of opportunity Phase 2 study. We look forward to continuing enrollment in our window of opportunity study and to commencing our Endoxifen Phase 2 study in Stockholm, Sweden when the COVID-19 restrictions are eased."

March 31, 2020 Financial Results

For the quarter ended March 31, 2020, Atossa had no source of sustainable revenue and no associated cost of revenue.

Operating Expenses: Total operating expenses were approximately $2,937,000 for the three months ended March 31, 2020, which is a decrease of approximately $1,127,000 or 28%, from the three months ended March 31, 2019. Operating expenses consisted of research and development ("R&D") expenses of approximately $939,000 and general and administrative ("G&A") expenses of approximately $1,998,000. Operating expenses for 2019 consisted of R&D expenses of approximately $1,451,000, and G&A expenses of approximately $2,613,000. The basis for decreased operating expenses in 2020 is explained below.

Research and Development Expenses: R&D expenses for the three months ended March 31, 2020, were approximately $939,000, a decrease of approximately $512,000 or 35% from total R&D expenses for the three months ended March 31, 2019 of approximately $1,451,000. R&D expense consists primarily of clinical trial expenses associated with our Endoxifen program, salaries and non-cash stock-based compensation expense. The

decrease in R&D expense is attributed to the decrease in non-cash stock-based compensation expense of approximately $514,000. We expect our R&D expenses to increase throughout 2020 as we commence studies of AT-H201 including the COVID-19 HOPE study, additional Phase 2 clinical trials of Endoxifen, continue the clinical trial of Fulvestrant administered via our intraductal technology and continue the development of other indications and therapeutics, including CAR-T and immunotherapies administered via our intraductal technologies.

General and Administrative Expenses: G&A expenses were approximately $1,998,000 for the three months ended March 31, 2020, a decrease of approximately $615,000, or 24% from total G&A expenses for the three months ended March 31, 2019, of approximately $2,613,000. G&A expenses consist primarily of salaries and related benefit costs, non-cash stock-based compensation, facilities, professional services, insurance, and public company related expenses. The decrease in G&A expenses for the quarter ended March 31, 2020, is mainly attributed to the decrease in non-cash stock-based compensation expense of approximately $816,000, offset by an increase in salaries, legal and professional fees of approximately $200,000, as compared to the same period in 2019.

As of March 31, 2020, the Company had approximately $9.4 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 such as the COVID-19 HOPE study, 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 March 31, 2020 (Unaudited)	As of December 31, 2019
Assets		
Current assets		
Cash and cash equivalents	$ 9,351,141	$ 12,581,136
Restricted cash	110,000	110,000
Prepaid expenses	1,337,120	862,344
Research and development tax rebate receivable	734,340	739,656
Other current assets	134,519	26,130
Total current assets	11,667,120	14,319,266
Furniture and equipment, net	29,734	34,350
Intangible assets, net	60,833	68,542
Right-of-use asset	37,397	50,479
Other assets	17,218	17,218
Total Assets	$ 11,812,302	$ 14,489,855
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 356,252	$ 293,171
Accrued expenses	52,474	77,888
Payroll liabilities	466,383	899,420
Lease liability	29,385	39,371

Other current liabilities	3,458	12,892
Total current liabilities	907,952	1,322,742
Long term liabilities		
Lease liability long term	8,013	11,108
Total Liabilities	915,965	1,333,850
Commitments and contingencies		
Stockholders' equity		
Preferred stock - $0.001 par value; 10,000,000 shares authorized; 671 shares issued and outstanding as of March 31, 2020 and December 31, 2019, respectively	1	1
Additional paid-in capital - Series B convertible preferred stock	670,999	670,999
Common stock - $0.18 par value; 175,000,000 shares authorized, and 9,130,984 shares issued and outstanding, as of March 31, 2020 and December 31, 2019, respectively	1,643,565	1,643,565
Additional paid-in capital	105,600,232	104,912,480
Accumulated deficit	(97,018,460)	(94,071,040)
Total Stockholders' Equity	10,896,337	13,156,005
Total Liabilities and Stockholders' Equity	$ 11,812,302	$ 14,489,855

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

	For the Three Months Ended March 31,	
	2020	**2019**
Operating expenses		
Research and development	$ 938,620	$ 1,451,236
General and administrative	1,998,389	2,613,093
Total operating expenses	2,937,009	4,064,329
Operating loss	(2,937,009)	(4,064,329)
Other expense	(10,411)	(8,978)
Loss before income taxes	(2,947,420)	(4,073,307)
Income taxes	-	-
Net loss	$ (2,947,420)	$ (4,073,307)
Loss per common share - basic and diluted	$ (0.32)	$ (0.62)
Weighted average shares outstanding - basic and diluted	9,130,984	6,565,514