Atossa Therapeutics Announces Year-End 2021 Financial Results and Provides Corporate Update

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SEATTLE, Feb. 28, 2022 (GLOBE NEWSWIRE) -- Atossa Therapeutics, Inc. (Nasdaq: ATOS), a clinical-stage biopharmaceutical company seeking to 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 and fiscal year ended December 31, 2021 and provides an update on recent company developments.

Key developments from Q4 2021 and to date include:

- Initiated enrollment of our Phase 2 clinical study of proprietary oral Z-endoxifen (or "Endoxifen") in Sweden. Participants in the study will be premenopausal women with measurable mammographic breast density.

- Completed a pre-investigational new drug (PIND) meeting with the FDA. The purpose of the meeting was to obtain input from the FDA on pre-clinical, clinical, manufacturing and regulatory matters in the U.S. for Atossa's proprietary Endoxifen to treat breast cancer in the neoadjuvant (prior to surgery) setting.

- Completed enrollment of Part A of our Phase 1/2a clinical study of AT-H201 in Australia, consisting of single ascending dose cohorts in healthy participants. 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, subject to future studies in this patient population.

"We continue to make significant progress on our Endoxifen and COVID-19 programs, with the continuation of enrollment of the Australian trial for AT-H201, as well as enrollment in our Swedish Endoxifen Phase 2 trial. We look forward to moving into the next milestones during 2022, and to providing updates on these developing therapies for urgent unmet patient needs. 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," said Dr. Steven Quay, Atossa's President and Chief Executive Officer.

The Company's upcoming plans with its current programs include the following:

- Endoxifen neoadjuvant program: Atossa plans to submit to the FDA an IND to conduct a Phase 2 study in the U.S. to compare Endoxifen to standard of care in premenopausal women with breast cancer. It will conduct a pharmacokinetic run-in study as a part of the Phase 2 study to further define potential dose levels. A CRO has been engaged to work on this study and the Company also intends to retain a leading U.S. research institution to help design and manage the study. Atossa anticipates submitting an IND in the second quarter of 2022 and then promptly commencing a Phase 2 study in this neoadjuvant setting, assuming FDA acceptance.

- Endoxifen for women with measurable breast density: The Company will continue to enroll participants in its Endoxifen Phase 2 clinical study in Stockholm.

- COVID-19 therapies under development: With respect to the ongoing AT-H201 Phase 1/2a clinical study, Atossa plans to complete enrollment in the second part in the second quarter 2022 and complete the third part of the study in the third quarter 2022. In 2022, the Company plans to continue the additional pre-clinical testing on its nasal spray AT-301 and then to further characterize the API in AT-301 starting in the third quarter 2022.

Year Ended December 31, 2021, Financial Results (in thousands)

As of December 31, 2021, we had cash, cash equivalents and restricted cash of $136 million.

For the years ended December 31, 2021 and 2020, we have no source of sustainable revenue and no associated cost of revenue.

Operating Expenses: Total operating expenses were $20,521 for the year ended December 31, 2021, which is an increase of $5,914, or 40% from the year ended December 31, 2020. Operating expenses for 2021 consisted of research and development (R&D) expenses of $9,210 and general and administrative (G&A) expenses of $11,311. Operating expenses for 2020 consisted of R&D expenses of $6,608 and G&A expenses of $7,999. The basis for the increased operating expenses in 2021 is explained below.

Research and Development Expenses: R&D expenses for the year ended December 31, 2021, were $9,210, an increase of $2,602 or 39% from total R&D expenses for the year ended December 31, 2020, of $6,608. The increase in R&D expense is attributed to increased spending on clinical and non-clinical trials of $422 over 2020 due to additional pre-clinical testing and manufacturing expenses for Endoxifen. Stock-based compensation, which is a non-cash charge, increased $693 year over year. R&D compensation was also up $227 due to salary, bonus and benefit increases during 2021. 2021 R&D expenses also include a $1,000 exclusivity payment for the exclusive right to negotiate with a leading research organization for the rights to two oncology programs. There were no similar exclusivity payments made during 2020. The remaining increase is due to increased spending on professional fees in 2021 as compared to 2020, due to the hiring of regulatory consultants and other vendors.

General and Administrative Expenses: G&A expenses were $11,311 for the year ended December 31, 2021, an increase of $3,312, or 41% from total G&A expenses for the year ended December 31, 2020, of $7,999. The increase in G&A expenses for the year ended December 31, 2021, is attributable to non-cash stock-based compensation expense of $1,555. Compensation also increased $460 due to the addition of a new employee during 2021, increased hourly employees time, and employee bonus increases over the prior year. Insurance expense has also increased $668 due to the addition of the COVID-19 program year over year. Professional fees have also increased $897 due primarily to an increase of proxy costs for investor outreach on a proposal to increase authorized shares, expenses related to a special stockholder meeting and increased consulting and auditing fees. Legal fees decreased $360 year over year due to lower patent activity in 2021.

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 and continue 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.
CONSOLIDATED BALANCE SHEETS
(amounts in thousands, except for par value)

	As of December 31,	
Assets	**2021**	**2020**
Current assets		
Cash and cash equivalents	$ 136,377	$ 39,554
Restricted cash	110	110
Prepaid expenses	2,488	1,814
Research and development tax rebate receivable	1,072	635
Other current assets	1,193	657
Total current assets	141,240	42,770
Furniture and equipment, net	20	21
Intangible assets, net	-	13
Right-of-use asset	-	18
Other assets	2	17

Total Assets	$ 141,262	$ 42,839
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 1,717	$ 1,589
Accrued expenses	204	93
Payroll liabilities	1,184	964
Common stock warrant liability	-	13,003
Lease liability	-	18
Other current liabilities	21	4
Total current liabilities	3,126	15,671
Total Liabilities	3,126	15,671
Commitments and contingencies		
Stockholders' equity		
Preferred stock - $0.001 par value; 10,000 shares authorized; 1 share issued and outstanding as of December 31, 2021 and December 31, 2020, respectively	-	-
Additional paid-in capital - Series B convertible preferred stock	582	621
Common stock - $0.18 par value; 175,000 shares authorized; 126,624 and 47,550 shares issued and outstanding as of December 31, 2021 and December 31, 2020, respectively	22,792	8,559
Additional paid-in capital	243,996	129,887
Accumulated deficit	(129,234)	(111,899)
Total Stockholders' Equity	138,136	27,168
Total Liabilities and Stockholders' Equity	$ 141,262	$ 42,839

ATOSSA THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(amounts in thousands, except for per share amounts)

	For the Year Ended December 31,	
	2021	**2020**
Operating expenses		
Research and development	$ 9,210	$ 6,608
General and administrative	11,311	7,999
Total operating expenses	20,521	14,607
Operating loss	(20,521)	(14,607)
Change in fair value of common stock warrants	-	(2,333)
Warrant financing expense	-	(939)
Other (expense) income, net	(85)	51
Loss before income taxes	(20,606)	(17,828)
Income taxes	-	-
Net loss	$ (20,606)	$ (17,828)
Deemed dividend attributable to preferred stock	-	(4,503)
Net loss applicable to common shareholders	$ (20,606)	$ (22,331)
Loss per common share - basic and diluted	$ (0.18)	$ (1.97)
Weighted average shares outstanding - basic and diluted	116,950	11,309