March 8, 2018

Atossa Genetics Announces 2017 Financial Results and Provides Company Update

SEATTLE, March 08, 2018 (GLOBE NEWSWIRE) -- Atossa Genetics Inc. (NASDAQ:ATOS), a clinical-stage pharmaceutical company developing novel therapeutics and delivery methods for breast cancer and other breast conditions, today announces 2017 financial results and provides a Company update.

Dr. Steve Quay, President and CEO, commented, “In the later part of 2017, we completed a Phase 1 Study of our proprietary oral and topical Endoxifen formulations, and we were pleased to report that all study objectives were met. We are now looking forward to opening enrollment in two Phase 2 studies. One will use our oral Endoxifen to treat breast cancer patients who are not responding to tamoxifen. Tamoxifen is the current FDA-approved standard of care for the approximately one million breast cancer survivors to prevent a recurrence and new cancer. The second study will use our topical Endoxifen to determine if it can reduce a condition called mammographic breast density, or MBD. Mammographic Breast Density is an independent risk factor for developing breast cancer. It affects approximately 10 million women in the U.S. We are also planning to commence an additional study with topical Endoxifen as well as a study using our intraductal microcatheters to deliver CAR-T or other immunotherapy,” continued Dr. Quay.

Recent Developments

Atossa’s important recent developments include the following:

- *Successful Phase 1 Study*. All objectives of Atossa’s recent Phase 1 study of its proprietary oral and topical formulations of Endoxifen were successfully met: there were no clinically significant safety signals and no clinically significant adverse events and both the oral and topical Endoxifen were well tolerated. In the topical arm of the study, low but measurable Endoxifen levels were detected in the blood in a dose-dependent fashion. In the oral arm of the study, participants exhibited dose-dependent Endoxifen levels that met or exceeded the published therapeutic level. The median time for patients in the study to reach the steady-state serum levels of Endoxifen while taking daily doses of Atossa’s oral Endoxifen was 7 days. Published literature indicates that it takes approximately 50-200 days for patients to reach steady-state Endoxifen levels when taking daily doses of oral tamoxifen.

- *TRAP CAR-T Program*. In October 2017, we announced that we are developing a novel method to deliver CAR-T cells into the ducts of the breast for the potential

targeted treatment of breast cancer. This approach uses our proprietary intraductal microcatheter technology for the potential transpapillary, or "TRAP," delivery of either T-cells that have been genetically modified to attack breast cancer cells or various immunotherapies. We believe this method has several potential advantages including the reduction of toxicity by limiting systemic exposure of the T-cells or immunotherapy; improved efficacy by placing the T-cells or immunotherapy in direct contact with the target ductal epithelial cells that are undergoing malignant transformation; and, lymphatic migration of the CAR-T cells or immunotherapy potentially extending their cytotoxic actions into the regional lymph system, which could limit tumor cell dissemination. Our approach is in the R&D stage and is currently not FDA approved.

- *Expansion of Scientific Advisory Board*. At the end of 2017, we added Dr. Carl Novina to our Scientific Advisory Board. Together with Dr. Jack Cuzick, we now have a world-renowned group advising on the scientific and medical aspects or our programs.

- *Capital Raising Activity*. In 2017, we made significant improvements to our balance sheet by raising approximately $12 million in capital, which strengthened our balance sheet and improved our stockholder base with the addition of institutional biotech-focused investors.

Atossa's 2018 potential milestones include:

- First half of 2018 - opening the Phase 2 Study of topical Endoxifen to treat MBD at Stockholm South General Hospital in Sweden (which we plan to complete in 2018).

- First half of 2018 - opening the Phase 2 Study of oral Endoxifen to treat patients who are not responding to Tamoxifen (which we plan to complete in 2018).

- Second half of 2018 - commencing one or more studies to demonstrate safety and efficacy of administering TRAP CAR-T or another immunotherapy with our microcatheters.

- Throughout 2018:
  -- Identifying additional opportunities for our Endoxifen formulations; and
  -- Continuing our Phase 2 study administering Fulvestrant with our microcatheters.

Breast Cancer Statistics

The American Cancer Society (ACS) estimates that approximately 250,000 women will be diagnosed with breast cancer in the United States this year and that approximately 40,000 will die from the disease. It is the second leading cause of cancer death in American women. Although about 100 times less common than women, breast cancer also affects men. The ACS estimates that the lifetime risk of men getting breast cancer is about 1 in 1,000; 2,470 new cases of invasive breast cancer will be diagnosed; and 460 men will die from breast cancer in 2017.

2017 Financial Results

Revenue and Cost of Revenue: For the years ended December 31, 2017 and 2016, we have no source of sustainable revenue and no associated cost of revenue.

Operating Expenses: Total operating expenses were $7,649,171 for the year ended December 31, 2017, which is a decrease of $319,419 or 4.0%, from the year ended December 31, 2016. Operating expenses for 2017 consisted of general and administrative (G&A) expenses of $4,859,369, R&D expenses of $2,328,087, and impairment of our Acueity intangible assets of $461,715.

General and Administrative Expenses: G&A expenses were $4,859,369 for the year ended December 31, 2017, a decrease of $1,619,824, or 25.0% from the total G&A expenses for the year ended December 31, 2016 of $6,479,193. G&A expenses consist primarily of personnel and related benefit costs, facilities, professional services, insurance, and public company related expenses. The 2017 decrease in G&A expense was primarily attributable to a reduction in payroll expenses resulting from deceased headcount, rent and exit costs incurred in 2016. At the beginning of 2016, our strategy shifted away from commercialization of medical devices towards focusing exclusively on development of our pharmaceutical and microcatheter candidates.

Research and Development Expenses: R&D expenses for the year ended December 31, 2017, were $2,328,087, an increase of $1,557,660, or 202% from R&D expenses in 2016 of $770,427. The increase in R&D expenses is attributed to salaries, manufacturing, and clinical trial expenses associated with our Endoxifen program for which manufacturing commenced at the beginning of 2017 and the clinical studies commenced in mid-2017. We expect our R&D expenses to increase throughout 2018 as we commence Phase 2 clinical studies of Endoxifen, continue the clinical trial of fulvestrant administered via our microcatheters and as we continue the development of other indications and therapeutics, including CAR-T and immunotherapies administered via our intraductal microcatheters.

Cash and Cash Equivalents: As of December 31, 2017, the Company had approximately $7.2 million in cash and cash equivalents and working capital of approximately $6.7 million.

About Atossa Genetics

Atossa Genetics Inc., is a clinical-stage pharmaceutical company developing novel therapeutics and delivery methods to treat breast cancer and other breast conditions. For more information, please visit www.atossagenetics.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 preliminary and final clinical results, actions and inactions by the FDA, the outcome or timing of regulatory approvals needed by Atossa, lower than anticipated rate of patient enrollment, preliminary and final results of

clinical studies, the safety and efficacy of Atossa's products and services, performance of clinical research organizations and investigators, obstacles resulting from proprietary rights held by others with respect to fulvestrant, such as patent rights, 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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ATOSSA GENETICS INC.
CONSOLIDATED BALANCE SHEETS

	As of December 31,	
	2017	2016
Assets		
Current assets:		
Cash and cash equivalents	$ 7,217,469	$ 3,027,962
Restricted cash	55,000	55,000
Prepaid expenses	250,944	171,601
Research and development tax rebate receivable	358,277	
Other current assets	16,344	
Total current assets	7,898,034	3,254,563
Furniture and equipment, net	11,467	55,119
Intangible assets, net	75,686	640,440
Other assets	178,907	194,250
Total assets	$ 8,164,094	$ 4,144,372
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 334,901	$ 254,320
Accrued expenses	90,105	16,964
Payroll liabilities	784,867	769,899
Other current liabilities	15,534	6,083

Total current liabilities	1,225,407	1,047,266
Commitments and contingencies		
Stockholders' equity		
Preferred stock - $.001 par value; 10,000,000 shares authorized, no shares issued and outstanding		
Common stock - $.015 par value; 75,000,000 shares authorized, 31,822,741 and 3,786,913 shares issued and outstanding at December 31, 2017 and December 31, 2016, respectively	477,342	56,804
Additional paid-in capital	71,887,674	60,344,050
Accumulated deficit	(65,426,329)	(57,303,748)
Total stockholders' equity	6,938,687	3,097,106
Total liabilities and stockholders' equity	$ 8,164,094	$ 4,144,372

ATOSSA GENETICS INC.
CONSOLIDATED STATEMENTS OF OPERATIONS

	For the Years Ended December 31, 2017	2016
Operating expenses:		
Research and development expenses	$ 2,328,087	$ 770,427
General and administrative expenses	4,859,369	6,479,193
Impairment of intangible assets	461,715	718,970
Total operating expenses	7,649,171	7,968,590
Operating loss	(7,649,171)	(7,968,590)
Change in fair value of common stock warrants	(280,747)	
Warrant financing expense	(192,817)	
Other income, net	154	1,599,705
Loss before income taxes	(8,122,581)	(6,368,885)
Income taxes		
Net loss	(8,122,581)	(6,368,885)
Deemed dividend attributable to Series A preferred stock	(2,568,132)	
Net loss attributable to common stockholders	$ (10,690,713)	$ (6,368,885)
Loss per common share - basic and diluted	$ (0.91)	$ (2.16)
Weighted average shares outstanding, basic and diluted	11,697,273	2,947,282

Source: Atossa Genetics Inc.