



Atossa Therapeutics Announces First Quarter 2022 Financial Results and Provides Corporate Update

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SEATTLE, May 09, 2022 (GLOBE NEWSWIRE) -- Atossa Therapeutics, Inc. (Nasdaq: ATOS), a clinical-stage biopharmaceutical company seeking to develop innovative proprietary 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 March 31, 2022, and provides an update on recent company developments.

Key developments from Q1 2022 and to date include:

- Received issuance of key U.S. patent covering Endoxifen directed to compositions of storage-stable Endoxifen and methods of treating hormone-dependent breast disorders using the storage-stable Endoxifen.
- Announced planned U.S. Phase 2 clinical study of Endoxifen in the neoadjuvant setting (prior to surgery) to compare Endoxifen to standard of care in premenopausal women with breast cancer. 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 manage the study. The Company anticipates submitting an IND to the FDA in the second quarter of 2022.
- Completed Part B (second of four parts) of Phase 1b/2a clinical study of AT-H201 in Australia

"We continue to make steady progress with our Endoxifen programs: one to reduce tumor cell activity in breast cancer patients in the neoadjuvant setting; and another to reduce dense breast tissue in women," commented Dr. Steven Quay, Atossa's President and Chief Executive Officer. "Our Phase 2 study in women with measurable breast density continues to enroll participants in Stockholm and we have been preparing to submit a request (IND) to the FDA this quarter to open a Phase 2 study in the neoadjuvant setting here in the United States. We began 2022 with significant progress in our COVID-19 program, both initiating and completing key parts of our Phase 1b/2a trial in Australia for AT-H201, and we have now completed the first two parts of that study."

Quarter Ended March 31, 2022 Financial Results (in thousands):

For the quarter ended March 31, 2022, Atossa has no source of sustainable revenue and no associated cost of revenue.

As of March 31, 2022, the Company had cash, cash equivalents and restricted cash of approximately \$131,596.

Operating Expenses:

Total operating expenses were \$4,747 for the three months ended March 31, 2022, which is an increase of \$1,216 or 34%, from the three months ended March 31, 2021. Operating expenses for 2022 consisted of research and development (R&D) expenses of \$1,499 and general and administrative (G&A) expenses of \$3,248. Operating expenses for 2021 consisted of R&D expenses of \$1,379, and G&A expenses of \$2,152.

Research and Development Expenses:

R&D expenses for the three months ended March 31, 2022, were \$1,499, an increase of \$120 or 9% from total R&D expenses for the same period in 2021 of \$1,379. The increase in R&D expense is attributed to increased spending on clinical and non-clinical trials of \$584 over 2021 due to additional drug manufacturing costs. Stock-based compensation, which is a non-cash charge, also increased \$433 quarter over quarter, and other R&D compensation was up \$79 due to salary bonus and benefit increases quarter over quarter. The increase in R&D was offset by a refund of \$1,000 from the research institution that the Company had an exclusive right to negotiate for the acquisition of the world-wide rights to two oncology R&D programs. In February 2022, the other party did not honor its obligation to negotiate with us which led to a cancellation of the agreement and refund of the \$1,000 we paid them.

General and Administrative Expenses:

G&A expenses were \$3,248 for the three months ended March 31, 2022, an increase of \$1,096, or 51% from the total G&A expenses for the three months ended March 31, 2021, of \$2,152. The increase in G&A expenses for the three months ended March 31, 2022, is primarily attributable to non-cash stock-based compensation expense of \$734. Other compensation also increased \$264 due to the addition of a new employee quarter over quarter as well as salary, bonus and benefit increases. Legal fees also increased \$124 quarter over quarter due to increased patent activity.

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 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.

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Source: Atossa Therapeutics, Inc.

ATOSSA THERAPEUTICS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(amounts in thousands, except for par value)

| | As of March 31, 2022 (Unaudited) | As of December 31, 2021 |
|--|---|-------------------------------|
| Assets | | |
| Current assets | | |
| Cash and cash equivalents | \$ 131,486 | \$ 136,377 |
| Restricted cash | 110 | 110 |
| Prepaid expenses | 3,874 | 2,488 |
| Research and development rebate receivable | 668 | 1,072 |
| Other current assets | 710 | 1,193 |
| Total current assets | 136,848 | 141,240 |
| Other assets | 630 | 22 |
| Total Assets | \$ 137,478 | \$ 141,262 |
| Liabilities and Stockholders' Equity | | |
| Current liabilities | | |
| Accounts payable | \$ 1,596 | \$ 1,717 |
| Accrued expenses | 120 | 204 |
| Payroll liabilities | 593 | 1,184 |
| Other current liabilities | 13 | 21 |
| Total current liabilities | 2,322 | 3,126 |
| Total Liabilities | 2,322 | 3,126 |
| Commitments and contingencies | | |
| Stockholders' equity | | |
| Preferred stock - \$0.001 par value; 10,000 shares authorized; 1 share issued and outstanding as of March 31, 2022 and December 31, 2021 | - | - |
| Additional paid-in capital - Series B convertible preferred stock | 582 | 582 |
| Common stock - \$0.18 par value; 175,000 shares authorized; 126,624 shares issued and outstanding as of March 31, 2022 and December 31, 2021 | 22,792 | 22,792 |
| Additional paid-in capital - common stock | 245,802 | 243,996 |
| Accumulated deficit | (134,020) | (129,234) |
| Total Stockholders' Equity | 135,156 | 138,136 |
| Total Liabilities and Stockholders' Equity | \$ 137,478 | \$ 141,262 |

ATOSSA THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(UNAUDITED)
(amounts in thousands, except for per share amounts)

For the Three Months Ended March 31,

| | 2022 | | 2021 | |
|---|-------------|---|-------------|---|
| Operating expenses | | | | |
| Research and development | \$ 1,499 | | \$ 1,379 | |
| General and administrative | 3,248 | | 2,152 | |
| Total operating expenses | 4,747 | | 3,531 | |
| Operating loss | (4,747 |) | (3,531 |) |
| Other expense, net | (39 |) | (7 |) |
| Loss before income taxes | (4,786 |) | (3,538 |) |
| Income taxes | - | | - | |
| Net loss | \$ (4,786 |) | \$ (3,538 |) |
| Loss per common share - basic and diluted | \$ (0.04 |) | \$ (0.04 |) |
| Weighted average shares outstanding - basic and diluted | 126,624 | | 92,587 | |