Atossa Therapeutics Announces Third Quarter 2023 Financial Results and Provides Corporate Update

November 13, 2023 2:00 PM EST

- *Achieved significant enrollment milestones in ongoing Phase 2 clinical trials*
- *Four ongoing Phase 2 studies evaluating (Z)-endoxifen, including recently announced study in DCIS*
- *Ended third quarter 2023 with $94.0 million of cash and cash equivalents*

SEATTLE, Nov. 13, 2023 (GLOBE NEWSWIRE) -- Atossa Therapeutics, Inc. (Nasdaq: ATOS), a clinical stage biopharmaceutical company developing innovative proprietary medicines to address significant unmet needs in oncology with a focus on breast cancer, today announces financial results for the quarter ended September 30, 2023, and provides an update on recent company developments.

Key developments from Q3 2023 and year to date include:

- **80% Enrollment in Ongoing Phase 2 Karisma-Endoxifen Clinical Trial** – the study is investigating (Z)-endoxifen in premenopausal women with measurable breast density. Participants receive daily doses of (Z)-endoxifen for six months, over the course of which mammograms are conducted to measure reduction in breast density. Full enrollment is expected by the end of 2023 and data is expected in the second half of 2024.
- **80% Enrollment in Phase 2 I-SPY 2 Clinical Trial** – (Z)-endoxifen is being evaluated as a neoadjuvant treatment in a study arm of the ongoing I-SPY 2 clinical trial. The study arm targets patients with newly diagnosed estrogen receptor-positive breast cancer whose tumors are predicted to be sensitive to endocrine therapy but for whom chemotherapy is expected to provide little or no benefit. Data is expected in the second half of 2024.
- **Initiation of Phase 2 Re-Evaluating Conditions for Active Surveillance Suitability as Treatment: Ductal Carcinoma In Situ (RECAST DCIS) Study** – (Z)-endoxifen is being evaluated as a treatment option in patients diagnosed with DCIS. The RECAST DCIS study, which is organized by Quantum Leap Healthcare Collaborative, is aimed at preventing the progression of DCIS to breast cancer, which could significantly change the way DCIS is treated. Dosing is expected to start in Q4 2023.
- **Approval from Health Canada to Conduct Phase 2 EVANGELINE Clinical Trial in Canada** – Atossa was authorized to open sites and enroll patients in the Phase 2 EVANGELINE study throughout Canada.
- **Research agreement with Weill Cornell Medicine** – partnership to study the potential of inducing estrogen receptor (ER) expression in triple-negative breast cancer (TNBC). The goal of this research is to determine if treating TNBC with extracellular vesicles carrying the ER will convert the tumor to ER+ and render it sensitive to treatment with Selective Estrogen Receptor Modulators, including Atossa's proprietary (Z)-endoxifen.
- **Appointment of Jonathan Finn to Atossa's Board of Directors** – Mr. Finn has more than 25 years of experience in the financial industry with a focus on early to mid-stage biotech and technology companies. He currently serves as Executive Vice President and Chief Investment Officer at Vantage Consulting Group, an investment advisory firm.

"Q3 was another period of significant advancement for our Company and our (Z)-endoxifen development program," said Dr. Steven Quay, Atossa's President and Chief Executive Officer. "With two Phase 2 trials approaching full enrollment, we are preparing for expected data readouts in the second half of 2024. We also made important progress with our EVANGELINE study by initiating the 80mg PK run-in cohort and announced a fourth Phase 2 study in DCIS, which like our trial in mammographic breast density, is investigating (Z)-endoxifen in a population of women who are at high risk of developing breast cancer. We expect data from these four ongoing Phase 2 trials to further strengthen the growing body of evidence that (Z)-endoxifen may play an important role in both the prevention and treatment of breast cancer."

Comparison of the Three Months Ended September 30, 2023 and 2022

Operating Expenses:

The following table provides a breakdown of major categories within Research and Development (R&D) and General and Administrative (G&A) expenses for the three months ended September 30, 2023 and 2022, together with the dollar and percentage change in those categories:

	September 30, 2023	September 30, 2022	Change	% Change
Research and Development				
Clinical and non-clinical trials	$ 3,365	$ 3,663	$ (298)	(8%)
Compensation	763	1,050	(287)	(27%)
Professional fees and other	339	447	(108)	(24%)
Research and Development Total	$ 4,467	$ 5,160	$ (693)	(13%)
General and Administrative				
Compensation	$ 1,534	$ 1,743	$ (209)	(12%)
Legal and professional fees	946	699	247	35%
Insurance and other	521	603	(82)	(14%)

General and Administrative Total	$ 3,001	$ 3,045	$ (44)	(1%)

Total operating expenses were $7,468 for the three months ended September 30, 2023, which was a decrease of $737, or 9%, from the three months ended September 30, 2022. Factors contributing to the decreased operating expenses for the three months ended September 30, 2023 are explained below.

Research and Development Expenses: R&D expenses for the three months ended September 30, 2023 were $4,467, a decrease of $693 from R&D expenses for the three months ended September 30, 2022 of $5,160. Key changes were as follows:

- The decrease in R&D expense was attributed primarily to decreased spending on clinical and non-clinical trials of $298 compared to the prior year period due to decreased spending on (Z)-endoxifen trial costs.
- The decrease in R&D compensation expense for the three months ended September 30, 2023 compared to the prior year period was primarily attributable to the decrease in non-cash stock-based compensation expense of $300 due to the weighted average fair value of options amortizing in 2023 being lower quarter over quarter.
- The decrease in R&D professional fees for the three months ended September 30, 2023 compared to the prior year period was primarily attributable to the higher consulting fees in 2022 related to our immunotherapy research.

G&A Expenses: G&A expenses for the three months ended September 30, 2023, were $3,001, a decrease of $44 from total G&A expenses for the three months ended September 30, 2022 of $3,045. Key changes were as follows:

- The decrease in G&A compensation expense of $209 for the three months ended September 30, 2023 compared to the prior year period, was primarily attributable to the decrease in non-cash stock-based compensation expense of $440 due to the weighted average fair value of options amortizing in 2023 being lower quarter over quarter. This decrease for the three months ended September 30, 2023 was partially offset by an increase of $231 in cash compensation due to increase headcount compared to the prior year period.
- G&A legal and professional fees increased by $247 for the three months ended September 30, 2023 compared to the prior year period due to an increase in legal fees for patent-related activity of $76 and an increase in professional fees of $171 due to higher investor relations costs.

Interest Income: Interest income was $1,274 for the three months ended September 30, 2023, an increase of $1,080 from interest income of $194 for the three months ended September 30, 2022. The increase was due to the higher average balance invested in money market funds of $41,905 and higher average interest rates for the three months ended September 30, 2023 compared to the prior year period.

Comparison of the Nine Months Ended September 30, 2023 and 2022

Operating Expenses:

The following table provides a breakdown of major categories within R&D and G&A expenses for the nine months ended September 30, 2023 and 2022, together with the dollar and percentage change in those categories:

	September 30, 2023	September 30, 2022	Change	% Change
Research and Development				
Clinical trials	$ 8,239	$ 6,772	$ 1,467	22%
Compensation	2,696	3,249	(553)	(17%)
Professional fees and other	745	776	(31)	(4%)
Exclusivity agreements	-	(700)	700	(100%)
Research and Development Total	$ 11,680	$ 10,097	$ 1,583	16%
General and Administrative				
Compensation	$ 6,153	$ 5,573	$ 580	10%
Legal and professional fees	2,835	2,044	791	39%
Insurance and other	1,690	1,839	(149)	(8%)
General and Administrative Total	$ 10,678	$ 9,456	$ 1,222	13%

Total operating expenses were $22,358 for the nine months ended September 30, 2023, which was an increase of $2,805, or 14%, from the nine months ended September 30, 2022. Factors contributing to the increased operating expenses for the nine months ended September 30, 2023 are explained below.

Research and Development Expenses: R&D expenses for the nine months ended September 30, 2023, were $11,680, an increase of $1,583 from total R&D expenses for the nine months ended September 30, 2022 of $10,097. Key changes were as follows:

- The increase in R&D expense was primarily due to increased spending on clinical and non-clinical trials of $1,467 compared to the prior year period due to increased spending on (Z)-endoxifen trial costs.
- The decrease in R&D compensation expense for the nine months ended September 30, 2023 compared to the prior year period was primarily due to a decrease in non-cash stock-based compensation of $588. Non-cash stock-based compensation decreased compared to the prior year period due to the weighted average fair value of options amortizing in 2023 being lower period over period.
- An exclusivity agreement refund in the prior year period of $1,000 from a research institution with which the Company had an exclusive right to negotiate for the acquisition of worldwide rights of two oncology programs. No exclusivity payments were made or refunded during the nine months ended September 30, 2023.

G&A Expenses: G&A expenses for the nine months ended September 30, 2023, were $10,678, an increase of $1,222 from total G&A expenses for quarter ended September 30, 2022 of $9,456. Key changes were as follows:

- The increase in G&A compensation expense of $580 for the nine months ended September 30, 2023 compared to the prior year period partially due to an increase in cash compensation expense of $1,133, offset by a decrease in non-cash stock-based compensation of $553. The increase in compensation expense compared to the prior year period was primarily driven by salary and bonus severance costs for our former General Counsel and Chief Financial Officer (CFO) of $554, an increase of $579 due to compensation for new employees as well as an increase in salaries, bonus and benefits overall. Non-cash stock-based compensation decreased by $553 in part due to a decrease in other employee non-cash stock-based compensation expense of $873 due to the decrease in the weighted average fair value of options amortizing in 2023 was lower period over period. This decrease was partially offset by the acceleration of expense recognized for options granted to the CFO of $320.
- G&A legal and professional fees increased by $791 for the nine months ended September 30, 2023 compared to the prior year period due to an increase in legal fees for higher patent-related activity of $421 and an increase in professional fees of $370 primarily due to higher investor relations costs.

Interest Income: Interest income was $3,107 for the nine months ended September 30, 2023, an increase of $2,900 from interest income of $207 for the nine months ended September 30, 2022. The increase was due to the higher average balance invested in a money market funds of $44,513 and higher average interest rates for the nine months ended September 30, 2023 compared to the prior year period.

Impairment Charge on Investment in Equity Securities: For the nine months ended September 30, 2023, we wrote down our investment in DCT by $2,990 due to an impairment. For the nine months ended September 30, 2022 there was no investment in equity securities or related impairment.

About (Z)-Endoxifen
(Z)-endoxifen is the most active metabolite of the FDA approved Selective Estrogen Receptor Modulator (SERM), tamoxifen. Studies by others have demonstrated that the therapeutic effects of tamoxifen are driven in a concentration-dependent manner by (Z)-endoxifen. In addition to its potent anti-estrogen effects, (Z)-endoxifen at higher concentrations has been shown to target PKCβ1, a known oncogenic protein.

Atossa is developing a proprietary oral formulation of (Z)-endoxifen that does not require liver metabolism to achieve therapeutic concentrations and is encapsulated to bypass the stomach as acidic conditions in the stomach convert a greater proportion of (Z)-endoxifen to the inactive (E)-endoxifen. Atossa's (Z)-endoxifen has been shown to be well tolerated in Phase 1 studies and in a small Phase 2 study of women with breast cancer. (Z)-endoxifen is currently being studied in four Phase 2 trials: one in healthy women with measurable breast density, one in women diagnosed with ductal carcinoma in situ, and two other studies including the EVANGELINE study, in women with ER+/HER2- breast cancer. Atossa's (Z)-endoxifen is protected by three issued U.S. patents and numerous pending patent applications.

About Atossa Therapeutics
Atossa Therapeutics, Inc. is a clinical-stage biopharmaceutical company developing innovative medicines in areas of significant unmet medical need in oncology with a focus on breast cancer. For more information, please visit www.atossatherapeutics.com

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FORWARD LOOKING STATEMENTS
This press release contains certain information that may constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. We may identify these forward-looking statements by the use of words such as "expect," "potential," "continue," "may," "will," "should," "could," "would," "seek," "intend," "plan," "estimate," "anticipate," "believe," "future," or other comparable words. Forward-looking statements in this press release are subject to risks and uncertainties that may cause actual results, outcomes, or the timing of actual results or outcomes, to differ materially from those projected or anticipated, including risks and uncertainties associated with: macroeconomic conditions and increasing geopolitical instability; the expected timing of releasing data; any variation between interim and final clinical results; actions and inactions by the FDA and foreign regulatory bodies; the outcome or timing of regulatory approvals needed by Atossa, including those needed to continue our planned (Z)-endoxifen trials; our ability to satisfy regulatory requirements; our ability to regain compliance with the continued listing requirements of the Nasdaq Stock Market; our ability to successfully develop and commercialize new therapeutics; the success, costs and timing of our development activities, including our ability to successfully initiate or complete our clinical trials, including our (Z)-endoxifen trials; our anticipated rate of patient enrollment; our ability to contract with third-parties and their ability to perform adequately; our estimates on the size and characteristics of our potential markets; our ability to successfully defend litigation and other similar complaints and to establish and maintain intellectual property rights covering our products; whether we can successfully complete our clinical trial of oral (Z)-endoxifen in women with mammographic breast density and our trials of (Z)-endoxifen in women with breast cancer, and whether the studies will meet their objectives; our expectations as to future financial performance, expense levels and capital sources, including our ability to raise capital; our ability to attract and retain key personnel; our anticipated working capital needs and expectations around the sufficiency of our cash reserves; and other risks and uncertainties detailed from time to time in Atossa's filings with the Securities and Exchange Commission, including without limitation its Annual Reports on Form 10-K and Quarterly Reports on 10-Q. Forward-looking statements are presented as of the date of this press release. Except as required by law, we do not intend to update any forward-looking statements, whether as a result of new information, future events or circumstances or otherwise.

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

	As of September 30, 2023	As of December 31, 2022
Assets		
Current assets		
Cash and cash equivalents	$ 94,031	$ 110,890
Restricted cash	110	110
Prepaid expenses	3,472	4,031
Research and development rebate receivable	28	743
Other current assets	7	2,423
Total current assets	97,648	118,197
Investment in equity securities	1,710	4,700
Other assets	2,337	635
Total Assets	$ 101,695	$ 123,532
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 718	$ 2,965
Accrued expenses	1,261	1,059
Payroll liabilities	1,444	1,525
Other current liabilities	21	19
Total current liabilities	3,444	5,568
Total Liabilities	3,444	5,568
Commitments and contingencies		
Stockholders' equity		
Series B convertible preferred stock - $0.001 par value; 10,000 shares authorized; 1 share issued and outstanding as of September 30, 2023 and December 31, 2022	-	-
Additional paid-in capital - Series B convertible preferred stock	582	582
Common stock - $0.18 par value; 175,000 shares authorized; 125,304 and 126,624 shares issued and outstanding as of September 30, 2023 and December 31, 2022, respectively	22,792	22,792
Additional paid-in capital - common stock	254,886	250,784
Treasury stock, at cost; 1,320 and 0 shares of common stock at September 30, 2023 and December 31, 2022, respectively	(1,475)	-
Accumulated deficit	(178,534)	(156,194)
Total Stockholders' Equity	98,251	117,964
Total Liabilities and Stockholders' Equity	$ 101,695	$ 123,532

ATOSSA THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(amounts in thousands, except for per share amounts)
(Unaudited)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2023	2022	2023	2022
Operating expenses				
Research and development	$ 4,467	$ 5,160	$ 11,680	$ 10,097
General and administrative	3,001	3,045	10,678	9,456
Total operating expenses	7,468	8,205	22,358	19,553
Operating loss	(7,468)	(8,205)	(22,358)	(19,553)
Impairment charge on investment in equity securities	-	-	(2,990)	-
Interest income	1,274	194	3,107	207
Other expense, net	(35)	-	(99)	(123)
Loss before income taxes	(6,229)	(8,011)	(22,340)	(19,469)
Income taxes	-	-	-	-
Net loss	(6,229)	(8,011)	(22,340)	(19,469)
Foreign currency translation adjustment	-	(54)	-	(54)
Comprehensive loss	(6,229)	(8,065)	(22,340)	(19,523)
Loss per share of common stock - basic and diluted	$ (0.05)	$ (0.06)	$ (0.18)	$ (0.15)
Weighted average shares outstanding - basic and diluted	125,793	126,624	126,344	126,624