Atossa Therapeutics Announces Third Quarter 2024 Financial Results and Provides Corporate Update

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- *Announced positive topline results from KARISMA-Endoxifen Phase 2 study which demonstrated that low doses of (Z)-endoxifen significantly reduced mammographic breast density (MBD), addressing a key breast cancer risk factor*
- *Released a preliminary analysis from I-SPY 2 Endocrine Optimization Pilot (EOP) Phase 2 trial of (Z)-endoxifen which met the primary endpoint with 95 percent (19/20 patients) receiving > 75 percent of planned treatment*
- *Announced the dosing of the first patient in a clinical trial conducted in partnership with Quantum Leap Healthcare Collaborativeä evaluating Atossa's proprietary (Z)-endoxifen in combination with abemaciclib (VERZENIO)*
- *Received a new patent (U.S. Patent No. 12,071,391) covering certain compositions of (Z)-endoxifen in free base or salt forms with enteric material, as well as methods of administering these compositions*
- *Ended third quarter 2024 with $74.8 million in cash and cash equivalents and no debt*

SEATTLE, Nov. 12, 2024 (GLOBE NEWSWIRE) -- Atossa Therapeutics, Inc. (Nasdaq: ATOS) ("Atossa" or the "Company") a clinical-stage biopharmaceutical company developing innovative medicines for breast cancer, today announced financial results for the fiscal quarter ended September 30, 2024, and provided an update on recent company developments.

Key developments from Q3 2024 include:

- **Positive Topline Data from KARISMA-Endoxifen Phase 2 Study:** Atossa reported topline results from its KARISMA-Endoxifen Phase 2 study conducted at the Karolinska Institute in Sweden, evaluating (Z)-endoxifen in premenopausal women with mammographic breast density (MBD). The study demonstrated significant MBD reductions of 19.3 percent and 26.5 percent in the 1 mg and 2 mg treatment arms, respectively, compared to placebo, over a six-month period. The treatment was well tolerated, with minimal side effects and no significant safety concerns. Although vasomotor symptoms slightly increased in active treatment groups, they were not a major reason for discontinuation. The Company believes that these findings support the potential of (Z)-endoxifen as a preventative therapy for women with dense breast tissue, an independent risk factor for breast cancer.
- **Promising Preliminary Analysis from Phase 2 I-SPY 2 EOP Trial:** Atossa released a preliminary analysis from its Phase 2 trial of (Z)-endoxifen in ER+/HER2- breast cancer, showing that (Z)-endoxifen met the primary endpoint with 95 percent (19/20) of patients completing >75 percent of planned treatment. The data showed a rapid reduction in key breast cancer biomarkers, including a 69 percent reduction in Ki-67 and a 30.4 percent reduction in functional tumor volume after three weeks. The treatment was well tolerated, with mild side effects and no dose reductions or treatment discontinuations.
- **Initiation of Combination Trial with Quantum Leap Healthcare Collaborative™:** Atossa, in collaboration with Quantum Leap Healthcare Collaborative™, announced that the first patient was dosed in their clinical trial evaluating (Z)-endoxifen in combination with abemaciclib (VERZENIO®) as a neoadjuvant treatment for high-risk women with newly diagnosed ER+/HER2- breast cancer. Part of the ongoing I-SPY 2 Endocrine Optimization Pilot Protocol (EOP), the trial targets patients whose tumors are predicted to be sensitive to endocrine therapy but unlikely to benefit from chemotherapy. The study is expected enroll approximately 80 participants, with pre- and postmenopausal women receiving daily (Z)-endoxifen and abemaciclib for 24 weeks prior to surgery. The trial aims to assess the efficacy and safety of this combination, with results anticipated in 2026.
- **New U.S. Patent Granted for (Z)-Endoxifen Compositions:** The United States Patent and Trademark Office (USPTO) granted Atossa a new patent covering certain compositions of (Z)-endoxifen in free base or salt forms with enteric material, as well as methods of administering these compositions. This fourth issued patent for (Z)-endoxifen broadens Atossa's protection and validates its intellectual property strategy.
- **Appointment of New Vice President of Investor and Public Relations:** Atossa appointed Michael Parks as Vice President of Investor and Public Relations. With nearly 30 years of experience in investor relations and corporate communications, Mr. Parks leads Atossa's corporate, executive, and digital communications, investor relations, and branding.
- **Appointment of Claudia Lopez, DVM, MSc, as Vice President, Clinical Product Development**: Dr. Lopez brings over 20 years of clinical development experience, including leadership roles at Landos Biopharma, Arena Pharmaceuticals, and Takeda Pharmaceuticals. Her expertise in global clinical programs and regulatory strategy will support Atossa's efforts to advance its clinical pipeline and develop next-generation cancer treatments.

"We are energized by the substantial progress Atossa has made this quarter, particularly the positive results from our KARISMA-Endoxifen Phase 2 study, which demonstrated that low doses of (Z)-endoxifen elicited significant reductions in mammographic breast density—an important risk factor for breast cancer," said Steven Quay, M.D., Ph.D., Atossa's President and Chief Executive Officer. "Combined with the promising preliminary data from the I-SPY 2 EOP trial of (Z)-endoxifen showing rapid reductions in Ki-67 and tumor volume, we believe these results further validate the substantial potential of our programs and demonstrate our commitment to developing innovative therapies that can meaningfully impact breast cancer treatment and prevention."

Comparison of Three and Nine Months Ended September 30, 2024 and 2023

Operating Expenses. Total operating expenses were $6.4 million and $20.5 million for the three and nine months ended September 30, 2024 which was a decrease of $1.1 million and $1.9 million, from total operating expenses for the three and nine months ended September 30, 2023 of $7.5 million and $22.4 million, respectively. Factors contributing to the decrease in operating expenses in the three and nine months ended September 30, 2024 are explained below.

Research & Development (R&D) Expenses. The following table provides a breakdown of major categories within R&D expenses for the three and nine months ended September 30, 2024 and 2023, together with the dollar change in those categories (dollars in thousands):

	For the Three Months Ended September 30,				For the Nine Months Ended September 30,			
	2024	2023	Increase (Decrease)	% Increase (Decrease)	2024	2023	Increase (Decrease)	% Increase (Decrease)
Research and Development Expense								
Clinical and non-clinical trials	$ 2,490	$ 3,365	$ (875)	(26)%	$ 7,875	$ 8,239	$ (364)	(4)%
Compensation	701	763	(62)	(8)%	2,006	2,696	(690)	(26)%
Professional fees and other	221	339	(118)	(35)%	833	745	88	12%
Research and Development Expense Total	$ 3,412	$ 4,467	$ (1,055)	(24)%	$ 10,714	$ 11,680	$ (966)	(8%)

- Clinical and non-clinical trial expense decreased $0.9 million and $0.4 million for the three and nine months ended September 30, 2024, respectively, compared to the prior year periods due to a decrease in spending for the (Z)-endoxifen trials, including a decrease in drug development costs.
- The decrease in R&D compensation expense of $0.1 million and $0.7 million for the three and nine months ended September 30, 2024, respectively, compared to the prior year periods was primarily due to a decrease in non-cash stock-based compensation expense of $0.1 million and $0.8 million for the three and nine months ended September 30, 2024, respectively. Non-cash stock-based compensation expense decreased compared to the prior year periods due to the weighted average fair value of stock options amortizing in the 2024 periods being lower.
- The decrease in R&D professional fees and other expense of $0.1 million for the three months ended September 30, 2024 compared to the prior year period was primarily due to the timing of the study cohorts in clinical and non-clinical trials. The increase in R&D professional fees and other expense of $0.1 million for the nine months ended September 30, 2024 compared to the prior year period was primarily due to higher consulting fees in 2024 related to our (Z)-endoxifen program.

General and Administrative (G&A) Expenses. The following table provides a breakdown of major categories within G&A expenses for the three and nine months ended September 30, 2024 and 2023, together with the dollar change in those categories (dollars in thousands):

	For the Three Months Ended September 30,				For the Nine Months Ended September 30,			
	2024	2023	Increase (Decrease)	% Increase (Decrease)	2024	2023	Increase (Decrease)	% Increase (Decrease)
General and Administrative Expense								
Compensation	$ 1,342	$ 1,534	$ (192)	(13)%	$ 3,698	$ 6,153	$ (2,455)	(40)%
Professional fees and other	1,425	1,127	298	26%	5,374	3,502	1,872	53%
Insurance	206	340	(134)	(39)%	684	1,023	(339)	(33)%
General and Administrative Expense Total	$ 2,973	$ 3,001	$ (28)	(1)%	$ 9,756	$ 10,678	$ (922)	(9)%

- The decrease in G&A compensation expense of $0.2 million and $2.5 million for the three and nine months ended September 30, 2024, respectively, compared to the prior year periods was due to a decrease in both cash compensation and non-cash stock-based compensation expense. Non-cash stock-based compensation expense decreased by $0.1 million and $1.7 million for the three and nine months ended September 30, 2024, respectively, compared to the prior year periods due to the weighted average fair value of stock options amortizing in 2024 being lower. Cash compensation decreased by $0.1 million for the three months ended September 30, 2024 compared to the prior year period due to a different mix of employees. Cash compensation decreased by $0.7 million for the nine months ended September 30, 2024 compared to the prior year period primarily due to salary and bonus severance expense of $0.6 million for the nine months ended September 30, 2023 related to the departure of our former Chief Financial Officer.
- G&A professional fees and other expense increased by $0.3 million and $1.9 million for the three and nine months ended September 30, 2024, respectively, compared to the prior year periods primarily due to the increase in legal fees of $0.2 million and $1.0 million for the three and nine months ended September 30, 2024, respectively, due to higher patent-related activity as well as other legal matters. Investor relations expenses increased by $0.5 million for the nine months ended September 30, 2024 compared to the prior year period due to an increase in investor outreach costs. Accounting fees increased by $0.2 million for the nine months ended September 30, 2024 compared to the prior year period due to a change in our accounting firm as well as the increased complexity of the business.
- The decrease in G&A insurance expense of $0.1 million and $0.3 million for the three and nine months ended September 30, 2024, respectively, compared to the prior year periods was due to lower negotiated insurance premiums for the same or better coverage in 2024.

Interest Income. Interest income of $1.0 million for the three months ended September 30, 2024 represented a decrease of $0.3 million compared to the prior year period, and was primarily due to a decrease in funds invested in the money market account. Interest income of $3.2 million for the nine

months ended September 30, 2024 represented an increase of $0.1 million compared to the prior year period, and was primarily due to a change in the mix of our money market accounts which yielded a higher rate of return in 2024.

Impairment Charge on Investment in Equity Securities. For the nine months ended September 30, 2024, we wrote down our Investment in equity securities by $1.7 million and for the nine months ended September 30, 2023, we wrote down our Investment in equity securities by $3.0 million due to impairment of our investment.

About (Z)-Endoxifen
(Z)-endoxifen is one of the most potent Selective Estrogen Receptor Modulator (SERM) for estrogen receptor inhibition and may cause estrogen receptor degradation. It has also been shown to have efficacy in the setting of patients with tumor resistance to other hormonal treatments. In addition to its potent anti-estrogen effects, (Z)-endoxifen has been shown to target PKCβ1, a known oncogenic protein, at clinically attainable blood concentrations. Finally, (Z)-endoxifen appears to deliver similar or even greater bone agonistic effects while resulting in little or no endometrial proliferative effects compared with standard treatments, like tamoxifen.

Atossa is developing a proprietary oral formulation of (Z)-endoxifen that is encapsulated to bypass the stomach, as acidic conditions in the stomach convert a significant 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 five Phase 2 trials: one in healthy women with measurable breast density, one in women diagnosed with ductal carcinoma in situ, and three other studies including the EVANGELINE study and two I-SPY studies in women with ER+/HER2- breast cancer. Atossa's (Z)-endoxifen is protected by four 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 using (Z)-endoxifen to prevent and treat 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," "design," "predict," "future," or other comparable words. All statements made in this press release that are not statements of historical fact, including statements regarding data related to the (Z)-endoxifen program, the potential of (Z)-endoxifen as a breast cancer prevention and treatment agent, the expected timing of data and related publications, and the potential milestones and growth opportunities for the Company, are forward-looking statements. 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 or preliminary and final clinical results or analysis; 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 remain compliant 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 share and per share data)
(Unaudited)

	September 30, 2024	December 31, 2023
Assets		
Current assets		
Cash and cash equivalents	$ 74,766	$ 88,460
Restricted cash	110	110
Prepaid materials	1,285	1,487
Prepaid expenses and other current assets	950	2,162
Total current assets	77,111	92,219
Investment in equity securities	—	1,710
Other assets	2,366	2,323
Total assets	$ 79,477	$ 96,252
Liabilities and stockholders' equity		

Current liabilities		
Accounts payable	$ 1,561	$ 806
Accrued expenses	1,694	973
Payroll liabilities	1,061	1,654
Other current liabilities	1,480	1,803
Total current liabilities	5,796	5,236
Total liabilities	5,796	5,236
Commitments and contingencies		
Stockholders' equity		
Convertible preferred stock - $0.001 par value; 10,000,000 shares authorized; 582 shares issued and outstanding as of September 30, 2024 and December 31, 2023	—	—
Common stock - $0.18 par value; 350,000,000 and 175,000,000 shares authorized as of September 30, 2024 and December 31, 2023, respectively; 125,801,254 and 125,304,064 shares issued and outstanding as of September 30, 2024 and December 31, 2023, respectively	22,882	22,792
Additional paid-in capital	257,719	255,987
Treasury stock, at cost; 1,320,046 shares of common stock at September 30, 2024 and December 31, 2023	(1,475)	(1,475)
Accumulated deficit	(205,445)	(186,288)
Total stockholders' equity	73,681	91,016
Total liabilities and stockholders' equity	$ 79,477	$ 96,252

ATOSSA THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(amounts in thousands, except share and per share data)
(Unaudited)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2024	2023	2024	2023
Operating expenses				
Research and development	$ 3,412	$ 4,467	$ 10,714	$ 11,680
General and administrative	2,973	3,001	9,756	10,678
Total operating expenses	6,385	7,468	20,470	22,358
Operating loss	(6,385)	(7,468)	(20,470)	(22,358)
Impairment charge on investment in equity securities	(1,710)	—	(1,710)	(2,990)
Interest income	1,001	1,274	3,213	3,107
Other expense, net	(136)	(35)	(190)	(99)
Loss before income taxes	(7,230)	(6,229)	(19,157)	(22,340)
Income tax benefit	—	—	—	—
Net loss	(7,230)	(6,229)	(19,157)	(22,340)
Net loss per share of common stock - basic and diluted	$ (0.06)	$ (0.05)	$ (0.15)	$ (0.18)
Weighted average shares outstanding used to compute net loss per share - basic and diluted	125,772,664	125,793,112	125,608,794	126,343,629