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

August 12, 2024 12:30 PM EDT

- *Presented data showing 100% disease control rate after 24-week treatment with (Z)-Endoxifen in 40mg cohort of Phase 2 EVANGELINE study at the American Association for Cancer Research (AACR) Annual Meeting*
- *Completed enrollment in 80mg PK Run-in Cohort for EVANGELINE trial*
- *Completed Phase 2 Karisma-Endoxifen clinical trial dosing*
- *Updated protocol for (Z)-Endoxifen and abemaciclib clinical trial*
- *Ended second quarter 2024 with $79.5 million in cash and cash equivalents and no debt*

SEATTLE, Aug. 12, 2024 (GLOBE NEWSWIRE) -- Atossa Therapeutics, Inc. (Nasdaq: ATOS) ("Atossa" or the "Company") today announced financial results for the fiscal quarter ended June 30, 2024, and provided an update on recent company developments. Atossa is a clinical-stage biopharmaceutical company developing proprietary innovative medicines in areas of significant unmet medical need in oncology, with a focus on women's breast cancer and other breast conditions.

Key developments from Q2 2024 and the year to date include:

- **Completed enrollment in 80mg PK Run-in Cohort for EVANGELINE trial -** fully enrolled the 12-patient 80mg pharmacokinetic Run-in Cohort in the Phase 2 EVANGELINE study evaluating (Z)-endoxifen as a neoadjuvant treatment for estrogen receptor-positive (ER+)/ Human Epidermal Growth Factor Receptor 2 negative (HER2-) breast cancer.
- **Completed Phase 2 Karisma-Endoxifen clinical trial dosing -** the last patient received the final dose in the 240-person trial investigating (Z)-endoxifen in premenopausal women with measurable mammographic breast density (MBD).
- **Supported Phase 2 study of AI breast cancer risk assessment model -** announced support for the SMART study, a Phase 2 trial to validate an AI-driven breast cancer risk assessment model for identifying women at highest risk of developing breast cancer within two years.
- **Presented data from 40mg cohort of Phase 2 EVANGELINE clinical trial at AACR** - demonstrated 100% disease control rate after 24-weeks of treatment with (Z)-endoxifen.
- **Initiated new study evaluating (Z)-endoxifen in combination with abemaciclib (VERZENIO®) with Quantum Leap Healthcare Collaborative™-** new study arm is part of the ongoing I-SPY 2 Endocrine Optimization Pilot Protocol (EOP), which targets patients with newly diagnosed ER+ invasive breast cancer.
- **Joined Russell 3000® Index -** Atossa Therapeutics was included in the Russell 3000® Index effective June 28, 2024.
- **Appointed Heather Rees as Chief Financial Officer -** announced the promotion of Heather Rees, formerly Senior Vice President of Finance and Principal Accounting Officer, to the position of CFO.

"The second quarter of 2024 was highlighted by significant advancements in our clinical programs and strategic development initiatives as we seek to maximize our (Z)-endoxifen platform to address areas of unmet need across the breast cancer treatment continuum," said Steven Quay, M.D., Ph.D., Atossa's President and Chief Executive Officer. "Over the next several months, we anticipate key data readouts from both the Phase 2 Karisma-Endoxifen clinical trial and the monotherapy arm of our Phase 2 I-SPY 2 clinical trial, setting the stage for what is expected to be a milestone-rich period for Atossa. These potential value drivers are supported by a strong financial foundation, including a cash balance of $79.5 million, which we believe positions Atossa for continued growth through the second half of 2024 and beyond. This is a very exciting time for Atossa."

Comparison of Three and Six Months Ended June 30, 2024 and 2023

Operating Expenses. Total operating expenses were $7.1 million and $14.1 million for the three and six months ended June 30, 2024, respectively, which was a decrease of $0.7 million and $0.8 million, respectively, from total operating expenses for the three and six months ended June 30, 2023 of $7.8 million and $14.9 million, respectively. Factors contributing to the decrease in operating expenses in the three and six months ended June 30, 2024 are explained below.

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

	For the Three Months Ended June 30,				For the Six Months Ended June 30,			
	2024	2023	Increase (Decrease)	% Increase (Decrease)	2024	2023	Increase (Decrease)	% Increase (Decrease)
Research and Development Expense								
Clinical and non-clinical trials	$ 2,501	$ 2,538	$ (37)	(1)%	$ 5,384	$ 4,874	$ 510	10 %
Compensation	679	899	(220)	(24)%	1,305	1,932	(627)	(32)%
Professional fees and other	373	268	105	39 %	613	407	206	51 %
Research and Development Expense Total	$ 3,553	$ 3,705	$ (152)	(4)%	$ 7,302	$ 7,213	$ 89	1 %

- Clinical and non-clinical trial expense decreased for the three months ended June 30, 2024 compared to the prior year period by $37 thousand. Clinical and non-clinical trial expense increased by $0.5 million for the six months ended June 30, 2024 compared to the prior year period due to an increase in spending for the (Z)-endoxifen trials, including an increase in drug development costs.

- The decrease in R&D compensation expense of $0.2 million and $0.6 million for the three and six months ended June 30, 2024, respectively, compared to the prior year periods was primarily due to a decrease in non-cash stock-based compensation expense of $0.3 million and $0.7 million for the three and six months ended June 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 increase in R&D professional fees and other expense of $0.1 million and $0.2 million for the three and six months ended June 30, 2024, respectively, compared to the prior year periods was primarily attributable 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 six months ended June 30, 2024 and 2023, together with the dollar change in those categories (dollars in thousands):

	For the Three Months Ended June 30,				For the Six Months Ended June 30,			
	2024	2023	Increase (Decrease)	% Increase (Decrease)	2024	2023	Increase (Decrease)	% Increase (Decrease)
General and Administrative Expense								
Compensation	$ 1,031	$ 2,534	$ (1,503)	(59)%	$ 2,356	$ 4,619	$ (2,263)	(49)%
Professional fees and other	2,269	1,213	1,056	87 %	3,949	2,376	1,573	66 %
Insurance	252	341	(89)	(26)%	479	683	(204)	(30)%
General and Administrative Expense Total	$ 3,552	$ 4,088	$ (536)	(13)%	$ 6,784	$ 7,678	$ (894)	(12)%

- The decrease in G&A compensation expense of $1.5 million and $2.3 million for the three and six months ended June 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 $0.9 million and $1.7 million for the three and six months ended June 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 $0.6 million for the three and six months ended June 30, 2024, compared to the prior year periods due to salary and bonus severance expense for our former CFO of $0.6 million in the three and six months ended June 30, 2023.

- G&A professional fees and other expense increased by $1.1 million and $1.6 million for the three and six months ended June 30, 2024, respectively, compared to the prior year periods due to the increase in legal fees of $0.7 million and $0.8 million for the three and six months ended June 30, 2024, respectively, compared to the prior year periods due to higher patent-related activity as well as other legal matters. Investor relations expenses increased by $0.3 million and $0.5 million for the three and six months ended June 30, 2024, respectively, compared to the prior year periods due to an increase in investor outreach costs. Accounting fees also increased by $0.3 million for the six months ended June 30, 2024 compared to the prior year period due to a change in the Company's accounting firm as well as increased complexity of the business.

- The decrease in G&A insurance expense of $0.1 million and $0.2 million for the three and six months ended June 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 was $1.1 million and $2.2 million for the three and six months ended June 30, 2024, respectively, an increase of $0.1 million and $0.4 million, respectively, from interest income of $1.0 million and $1.8 million for the three and six months ended June 30, 2023, respectively. The increase was 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 three and six months ended June 30, 2024, there were no impairment charges related to our investment in equity securities. For the three and six months ended June 30, 2023, we wrote down our investment in equity securities by $3.0 million due to impairment of our investment in DCT.

About (Z)-Endoxifen

(Z)-endoxifen is the most potent Selective Estrogen Receptor Modulator (SERM) for estrogen receptor inhibition and also causes 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 does not require liver metabolism to achieve therapeutic concentrations and 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 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 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," "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, such as data related to the (Z)-endoxifen program and the potential of (Z)-endoxifen as a breast cancer prevention and treatment agent, and potential milestones and growth opportunities for the Company, 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 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)

	June 30, 2024	December 31, 2023
Assets		
Current assets		
Cash and cash equivalents	$ 79,526	$ 88,460
Restricted cash	110	110
Prepaid materials	1,095	1,487
Prepaid expenses and other current assets	987	2,162
Total current assets	81,718	92,219
Investment in equity securities	1,710	1,710
Other assets	2,430	2,323
Total assets	$ 85,858	$ 96,252
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 1,056	$ 806
Accrued expenses	1,907	973
Payroll liabilities	939	1,654
Other current liabilities	1,794	1,803
Total current liabilities	5,696	5,236
Total liabilities	5,696	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 June 30, 2024 and December 31, 2023	—	—
Common stock - $0.18 par value; 350,000,000 and 175,000,000 shares authorized as of June 30, 2024 and December 31, 2023, respectively; 125,757,416 and 125,304,064 shares issued and outstanding as of June 30, 2024 and December 31, 2023, respectively	22,874	22,792
Additional paid-in capital	256,978	255,987
Treasury stock, at cost; 1,320,046 shares of common stock at June 30, 2024 and December 31, 2023	(1,475)	(1,475)
Accumulated deficit	(198,215)	(186,288)
Total stockholders' equity	80,162	91,016
Total liabilities and stockholders' equity	$ 85,858	$ 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 June 30,		For the Six Months Ended June 30,	
	2024	2023	2024	2023
Operating expenses				
Research and development	$ 3,553	$ 3,705	$ 7,302	$ 7,213
General and administrative	3,552	4,088	6,784	7,678
Total operating expenses	7,105	7,793	14,086	14,891
Operating loss	(7,105)	(7,793)	(14,086)	(14,891)
Impairment charge on investment in equity securities	—	(2,990)	—	(2,990)
Interest income	1,073	983	2,211	1,833
Other expense, net	(17)	(30)	(52)	(63)
Loss before income taxes	(6,049)	(9,830)	(11,927)	(16,111)
Income tax benefit	—	—	—	—
Net loss	(6,049)	(9,830)	(11,927)	(16,111)
Net loss per share of common stock - basic and diluted	$ (0.05)	$ (0.08)	$ (0.10)	$ (0.13)
Weighted average shares outstanding used to compute net loss per share - basic and diluted	125,732,140	126,622,798	125,525,959	126,623,450