



Atossa Therapeutics Announces First Quarter 2025 Financial Results and Provides a Corporate Update

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Announced strategic plan to advance (Z)-endoxifen for metastatic breast cancer indication

Enhanced (Z)-endoxifen intellectual property portfolio with three new U.S. patents, expanding IP portfolio to more than 200 patent claims related to (Z)-endoxifen

Ended first quarter 2025 with \$65.1 million in cash and cash equivalents and no debt

SEATTLE, May 13, 2025 /PRNewswire/ -- [Atossa Therapeutics, Inc.](#) (Nasdaq: ATOS) (Atossa or the Company), a clinical-stage biopharmaceutical company developing innovative medicines for breast cancer, today announced its financial results for the first quarter ended March 31, 2025 and provided an update on recent company developments.



First Quarter 2025 Highlights:

- **Announced Strategic Decision to Pursue Metastatic Breast Cancer Indication:** Atossa announced plans to target metastatic breast cancer as its lead program for (Z)-endoxifen. The decision reflects its commitment to addressing the persistent unmet medical need in metastatic breast cancer and the potential for a more streamlined regulatory pathway to deliver (Z)-endoxifen to these patients. Current treatment options for metastatic breast cancer often provide limited durability of response and substantial side effects. In previous clinical trials, (Z)-endoxifen has been shown to be well-tolerated as a selective estrogen receptor modulator (SERM), which Atossa believes supports its potential to fill this critical gap in treatment.
- **Significantly Strengthened (Z)-endoxifen Patent Portfolio with Three New U.S. Patents:** Atossa continued to bolster the intellectual property portfolio of (Z)-endoxifen with the grant of three new U.S. patents covering 31 claims directed at: sustained release compositions of (Z)-endoxifen (U.S. Patent No. 12,201,591); enteric oral formulations of (Z)-endoxifen and salts thereof as well as their use in treating hormone-dependent breast and reproductive tract disorders (U.S. Patent No. 12,275,684); and 58 claims covering (Z)-endoxifen formulations, including various levels of purity and stability as well as methods of using those formulations (U.S. Patent No. 12,281,056). Atossa's robust patent portfolio now encompasses more than 200 patent claims related to (Z)-endoxifen formulations and their clinical applications.

"Our focus remains firmly on advancing (Z)-endoxifen as a next-generation therapy for breast cancer patients across the full spectrum of care—including a strategic emphasis on metastatic breast cancer, where therapeutic innovation is urgently needed," said Steven Quay, M.D., Ph.D., President and Chief Executive Officer of Atossa. "Across multiple clinical trials involving hundreds of patients, (Z)-endoxifen has consistently demonstrated strong tolerability and therapeutic versatility, which we believe shows its potential as a therapy for breast cancer from early-stage disease to more advanced stages. We are committed to unlocking the full potential of (Z)-endoxifen for patients while delivering value to our shareholders. A cornerstone of this strategy is the robust intellectual property portfolio we are building in an effort to protect our programs globally. As we look ahead to the remainder of 2025 and beyond, we are energized by the many opportunities to position (Z)-endoxifen as a potentially safer, more effective endocrine therapy for breast cancer patients worldwide."

Comparison of Three Months Ended March 31, 2025 and 2024

Revenue and Cost of Revenue. For the three months ended March 31, 2025 and 2024, we had no source of revenue and no associated cost of revenue.

Operating Expenses. Total operating expenses were \$7.4 million for the three months ended March 31, 2025, which was an increase of \$0.4 million, compared to \$7.0 million for the three months ended March 31, 2024.

from the three months ended March 31, 2024 of \$7.0 million. Factors contributing to the increased operating expenses in the three months ended March 31, 2025 are explained below.

Research & Development (R&D) Expenses. The following table provides a breakdown of major categories within R&D expenses for the three months ended March 31, 2025 and 2024, together with the dollar change and percentage change in those categories (dollars in thousands):

		For the Three Months Ended March 31,		Increase (Decrease)	% Increase (Decrease)
		2025	2024		
Research and Development Expenses					
	Clinical and pre-clinical trials	\$ 2,747	\$ 2,884	\$ (137)	(5) %
	Compensation	880	626	254	41 %
	Professional fees and other	530	238	292	123 %
	Research and Development Expenses Total	\$ 4,157	\$ 3,748	\$ 409	11 %

- Clinical and pre-clinical trial expenses decreased \$0.1 million for the three months ended March 31, 2025, compared to the three months ended March 31, 2024, due to a slight decrease in spend related to our (Z)-endoxifen trials, including drug development costs.
- The increase in R&D compensation expenses of \$0.3 million for the three months ended March 31, 2025, compared to the three months ended March 31, 2024 was due to an increase in headcount.
- The increase in R&D professional fees and other of \$0.3 million was due to an increase in spending on regulatory consulting services.

General and Administrative (G&A) Expenses. The following table provides a breakdown of major categories within G&A expenses for the three months ended March 31, 2025 and 2024, together with the dollar change and percentage change in those categories (dollars in thousands):

		For the Three Months Ended March 31,		Increase (Decrease)	% Increase (Decrease)
		2025	2024		
General and Administrative Expenses					
	Compensation	\$ 1,462	\$ 1,325	\$ 137	10 %
	Professional fees and other	1,614	1,680	(66)	(4) %
	Insurance	181	227	(46)	(20) %
	General and Administrative Expenses Total	\$ 3,257	\$ 3,232	\$ 25	1 %

- The increase in G&A compensation expenses of \$0.1 million for the three months ended March 31, 2025, compared to the three months ended March 31, 2024 was due to an increase in headcount quarter over quarter.

Interest Income. Interest income was \$0.7 million for the three months ended March 31, 2025, a decrease of \$0.4 million from interest income of \$1.1 million for the three months ended March 31, 2024. The decrease was due to a decrease in the balance in our money market account.

About (Z)-Endoxifen

(Z)-endoxifen is a highly potent SERM with demonstrated ability to inhibit—and potentially degrade—estrogen receptors. It has shown activity even in tumors that have developed resistance to other endocrine therapies. Beyond its anti-estrogenic properties, (Z)-endoxifen also targets protein kinase C beta 1 (PKCβ1), an oncogenic signaling protein, at clinically achievable blood levels. Importantly, (Z)-endoxifen seems to deliver comparable or superior bone-protective effects relative to tamoxifen, while exhibiting minimal or no endometrial proliferative activity—which we believe addresses key limitations of current standard-of-care therapies. Atossa is developing a proprietary oral formulation of (Z)-endoxifen that is enteric-coated to bypass stomach acid, which would otherwise convert the active (Z)-isomer to its inactive (E)-form. We believe this innovation allows for optimal bioavailability and therapeutic integrity. Clinical studies have shown Atossa's (Z)-endoxifen to be well tolerated in both healthy women and those with breast cancer. Atossa is prioritizing the development of (Z)-endoxifen for the treatment of metastatic breast cancer, where novel therapeutic options are urgently needed. The compound is currently being evaluated in three Phase 2 trials: one in women with ductal carcinoma in situ (DCIS) and two in women with estrogen receptor positive (ER+) / human epidermal growth factor receptor 2 negative (HER2-) breast cancer, including the EVANGELINE study and an I-SPY study. Atossa's (Z)-endoxifen program is supported by a growing global intellectual property portfolio, including three recently issued U.S. patents and numerous pending applications worldwide.

About Atossa Therapeutics

Atossa Therapeutics, Inc. (Nasdaq: ATOS) is a clinical-stage biopharmaceutical company dedicated to transforming breast cancer treatment through innovative science and patient-focused solutions. The company's lead product candidate, (Z)-endoxifen, is a highly potent SERM designed for use across the breast cancer spectrum, including prevention, neoadjuvant, adjuvant, and metastatic settings. Atossa is committed to advancing its robust clinical research programs to improve patient outcomes while creating sustainable value for shareholders. For more information, visit atossatherapeutics.com.

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 safety, tolerability and efficacy of (Z)-endoxifen, the potential of (Z)-endoxifen as a breast cancer prevention and treatment agent, the potential indications that the Company may pursue for (Z)-endoxifen, the potential for (Z)-endoxifen to receive regulatory approval, benefits of the Company's strategy of pursuing a metastatic indication for (Z)-endoxifen, the expected design and enrollment of trials and timing of data and related publications, and the potential market 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: our ability to obtain patent coverage for our product candidates; 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 regain compliance or maintain 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.
CONSOLIDATED BALANCE SHEETS
(amounts in thousands, except share and per share data)

	<u>March 31, 2025</u>	<u>December 31, 2024</u>
<u>Assets</u>		
Current assets		
Cash and cash equivalents	\$ 65,116	\$ 71,084
Restricted cash	110	110
Prepaid materials	2,079	2,098
Prepaid expenses and other current assets	1,439	1,165
Total current assets	<u>68,744</u>	<u>74,457</u>
Other assets	2,003	1,987
Total assets	<u>\$ 70,747</u>	<u>\$ 76,444</u>
<u>Liabilities and stockholders' equity</u>		
Current liabilities		
Accounts payable	\$ 1,165	\$ 679
Accrued expenses	1,788	919
Payroll liabilities	942	1,862
Other current liabilities	1,530	1,507
Total current liabilities	<u>5,425</u>	<u>4,967</u>
Total liabilities	<u>5,425</u>	<u>4,967</u>
Commitments and contingencies	—	—
Stockholders' equity		
Convertible preferred stock - \$0.001 par value; 10,000,000 shares authorized; 582 shares issued and outstanding as of March 31, 2025 and December 31, 2024	—	—
Common stock - \$0.18 par value; 350,000,000 shares authorized; 129,170,004 shares issued and outstanding as of March 31, 2025 and December 31, 2024	23,488	23,488
Additional paid-in capital	261,819	261,256
Treasury stock, at cost; 1,320,046 shares of common stock at March 31, 2025 and December 31, 2024	(1,475)	(1,475)
Accumulated deficit	<u>(218,510)</u>	<u>(211,792)</u>
Total stockholders' equity	<u>65,322</u>	<u>71,477</u>
Total liabilities and stockholders' equity	<u>\$ 70,747</u>	<u>\$ 76,444</u>

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

For the Three Months Ended March 31,**2025** **2024**

Operating expenses		
Research and development	\$ 4,157	\$ 3,748
General and administrative	3,257	3,232
Total operating expenses	7,414	6,980
Operating loss	(7,414)	(6,980)
Interest income	720	1,138
Other expense, net	(24)	(36)
Loss before income taxes	(6,718)	(5,878)
Income tax benefit	—	—
Net loss	\$ (6,718)	\$ (5,878)
Net loss per share of common stock - basic and diluted	\$ (0.05)	\$ (0.05)
Weighted average shares outstanding used to compute net loss per share - basic and diluted	129,170,004	125,319,778

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