Atossa THERAPEUTICS

Nasdaq: **ATOS**

REDCHIP

Market Data

Atossa Therapeutics, Inc.
Nasdaq: **ATOS**

Fiscal Year	Dec. 31
Price	$0.97
52-wk Range	$0.55-$1.71
Market Cap	$125.3M
Shares Out.	129.2M
Float	129.1M
Inst. Ownership	28%
Cash (mrq)	$65.1M

Price & share data as of May 16, 2025

Auditor:
Ernst & Young LLP

Legal Counsel:
Gibson, Dunn & Crutcher LLP

Transfer Agent:
VStock Transfer, LLC

atossatherapeutics.com

Company Overview

Atossa Therapeutics, Inc. (Nasdaq: ATOS) is a clinical-stage biopharmaceutical company advancing (Z)-endoxifen, a next-generation selective estrogen receptor modulator (SERM) with best-in-class potential across the breast cancer treatment spectrum. The company is strategically prioritizing metastatic breast cancer, where (Z)-endoxifen has shown encouraging clinical activity, favorable tolerability, and potential to address endocrine resistance through dual targeting of ERα and PKCβ1. With multiple Phase 2 trials completed, a proprietary oral formulation, and a strong intellectual property portfolio, Atossa is positioned to deliver meaningful therapeutic innovation and create long-term value for patients and investors alike.

Investment Highlights

Focused on high-impact opportunity in metastatic breast cancer

- Prioritizing (Z)-endoxifen as a treatment for metastatic breast cancer, where existing endocrine therapies often fail due to resistance or poor tolerability.
- In prior clinical studies, (Z)-endoxifen demonstrated superior progression-free survival (7.2 vs. 2.4 months) vs. tamoxifen in CDK4/6 inhibitor–naïve patients.
- Strong activity was also observed in heavily pretreated patients, including durable responses and tumor shrinkage after progression on multiple lines of therapy. Recent results from the I-SPY 2 Endocrine Optimization substudy support rapid biomarker response and tumor shrinkage, even at low doses.
- A favorable safety profile supports its use as a potential backbone for future combination regimens.

Differentiated next-generation SERM with broad therapeutic potential

- (Z)-endoxifen is 100x more potent than tamoxifen and overcomes key resistance mechanisms seen with aromatase inhibitors and fulvestrant.
- Unlike standard therapies, it also targets PKCβ1 and ESR1 mutations—two drivers of endocrine resistance—which may enhance anti-tumor activity in endocrine-refractory patients.
- Designed as an encapsulated oral formulation to bypass the stomach and preserve drug integrity, enhancing bioavailability.
- Well-tolerated across trials with fewer "on-target, off-tissue" side effects—potentially improving adherence and long-term outcomes.

Compelling clinical data across multiple breast cancer indications

- Metastatic: Extended PFS, tumor shrinkage, and disease stabilization in patients with limited options.
- Neoadjuvant: In the EVANGELINE trial, >85% of patients achieved target Ki-67 reduction at 4 weeks; clinical responses include partial & complete tumor regressions.
- Prevention: In the KARISMA-Endoxifen study, low doses reduced mammographic breast density (MBD) by up to 23.5 percentage points—comparable to tamoxifen, but with improved tolerability.

Strategic regulatory approach to accelerate time to market

- Targeting metastatic breast cancer as the lead indication may allow for a more streamlined regulatory pathway and earlier access.
- Parallel development underway for prevention, neoadjuvant, and adjuvant settings to expand addressable market and leverage existing data.
- Engaged with the FDA to advance clinical development and align on registrational trial designs.

Strong balance sheet and IP position support execution and growth

- $65.1M in cash and no debt as of Q1 2025—sufficient runway to advance key trials and support regulatory planning.
- Multiple issued patents covering (Z)-endoxifen's composition, method of use, and formulation—now totaling over 200 issued and pending claims.
- Potential for non-dilutive funding and strategic partnerships to extend resources and enhance commercialization efforts.

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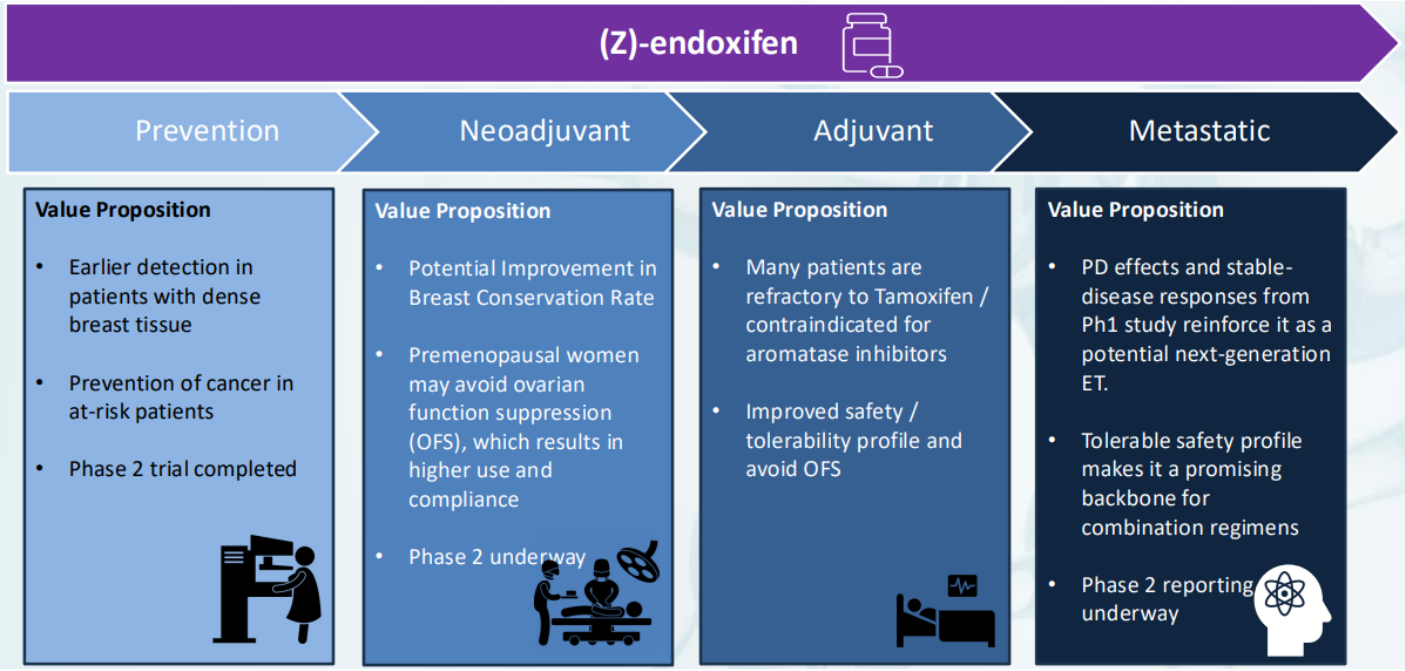
Well-Positioned Across Treatment Paradigm



Value Proposition

Atossa Therapeutics offers a high-upside investment opportunity in the oncology space, with a strategic focus on transforming the treatment of metastatic breast cancer—an area of persistent unmet need. The company's lead asset, (Z)-endoxifen, is a next-generation SERM that has demonstrated superior potency, broad anti-tumor activity, and a differentiated safety profile compared to existing endocrine therapies. By targeting metastatic disease as its initial indication, Atossa aims to accelerate regulatory timelines and reach patients faster, while laying the groundwork for expansion into earlier lines of therapy.

Clinical data to date support (Z)-endoxifen's potential to disrupt the standard of care across the breast cancer continuum. Trials have shown meaningful tumor responses in endocrine-resistant metastatic patients, strong Ki-67 suppression and tumor shrinkage in the neoadjuvant setting, and significant reductions in mammographic breast density—an established breast cancer risk factor. Recent findings from the I-SPY 2 Endocrine Optimization substudy reinforce early bioactivity and tolerability at low doses, paving the way for ongoing trials evaluating higher, PKCβ1-engaging doses in combination with abemaciclib. Atossa also outlined a proposed Phase 3 prevention study (SMART 2.0) designed to reduce interval breast cancer in high-risk women—a potential breakthrough in primary prevention.

These findings, combined with a favorable tolerability profile, position (Z)-endoxifen as a best-in-class endocrine therapy with broad commercial potential. In parallel, Atossa has entered a discovery-stage collaboration with Nona Biosciences to explore next-generation antibody therapies for breast cancer—marking an expansion beyond SERMs into biologics.

Atossa is well-capitalized, debt-free, and advancing a focused, capital-efficient development strategy. A robust intellectual property portfolio protects its proprietary oral formulation and use across multiple indications. With multiple Phase 2 trials in completed, near-term clinical catalysts, and a pathway to registrational studies, Atossa is approaching a major inflection point—offering investors exposure to a potential breakthrough in breast cancer care with long-term value creation.

Upcoming Catalysts

- Regulatory pathway clarity and potential initiation of registrational trial for metastatic breast cancer with regulatory updates in 2025.
- KARISMA-Endoxifen (MBD reduction): Full Phase 2 data readout to be published in 2025.
- EVANGELINE (neoadjuvant treatment): Randomized trial initiation and interim efficacy results expected in 2025.
- I-SPY 2 (combination therapy with abemaciclib): Data from neoadjuvant combination trial with Eli Lilly's Verzenio® expected in 2026.