

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): March 09, 2024

Atossa Therapeutics, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-35610
(Commission File Number)

26-4753208
(IRS Employer
Identification No.)

107 Spring Street
Seattle, Washington
(Address of Principal Executive Offices)

98104
(Zip Code)

Registrant's Telephone Number, Including Area Code: (206) 588-0256

N/A

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.18 par value	ATOS	The Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

On March 9, 2024, the Board of Directors (the “Board”) of Atossa Therapeutics, Inc. (the “Company”) expanded its size and appointed Dr. Tessa Cigler, M.D., M.P.H. as a Class II director to hold office until the 2026 Annual Meeting of Stockholders and until her successor shall have been duly elected and qualified, effective immediately. The Board also appointed Dr. Cigler to serve on the Company’s Nominating and Governance Committee. Dr. Cigler will receive compensation as a non-employee director, as described in the Company’s Proxy Statement for its 2023 Annual Meeting of Stockholders filed with the Securities and Exchange Commission on March 30, 2023. The Company also intends to enter into its standard form of indemnification agreement with Dr. Cigler.

Dr. Cigler received her undergraduate degree from Harvard College, and her M.D. from Duke University School of Medicine. She also holds a Master’s in Public Health from the Harvard School of Public Health. She completed her residency in Internal Medicine at the New York Presbyterian Hospital Weill Cornell Medical Center, followed by a fellowship in Medical Oncology and Hematology at the Dana-Farber Harvard Cancer Center. Dr. Cigler joined the Cornell faculty in August 2007 as a medical oncologist and clinical investigator at the Weill Cornell Breast Center. At Weill Cornell, she heads several clinical trials designed to provide patients with access to new and promising options for therapy and supportive care.

There are no arrangements or understandings between Dr. Cigler and any other persons pursuant to which she was selected to serve as a director; she has no family relationships with any of the Company’s directors or executive officers; and she has no direct or indirect material interest in any transaction required to be disclosed pursuant to Item 404(a) of Regulation S-K.

Item 7.01 Regulation FD Disclosure.

A copy of the Company’s press release announcing the foregoing appointment is furnished hereto as Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits.

Exhibits

	Exhibit Number	Description of Exhibit
	99.1	Press release, dated March 12, 2024
	104	Cover page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Atossa Therapeutics, Inc.

Date: March 12, 2024

By: /s/ Heather Rees
Senior Vice President, Finance and Accounting

Atossa Therapeutics Appoints Breast Cancer Specialist Tessa Cigler, M.D., M.P.H. to its Board of Directors

SEATTLE, March 12, 2024 — Atossa Therapeutics, Inc. (Nasdaq: ATOS) (“Atossa” or the “Company”), a clinical stage biopharmaceutical company developing innovative medicines in areas of significant unmet medical need in oncology with a focus on breast cancer, today announced that Tessa Cigler, M.D., M.P.H. was appointed to Atossa’s board of directors, effective immediately. Dr. Cigler is a medical oncologist and clinical investigator at the Weill Cornell Breast Center in New York City.

“We are pleased to welcome Dr. Cigler to our board of directors,” said Steven Quay, M.D., Ph.D., Atossa’s President and Chief Executive Officer. “Tessa works daily with breast cancer patients and knows firsthand the critical need for more effective and tolerable treatment options. We look forward to leveraging both her clinical trial and patient care experience to further accelerate our (Z)-endoxifen development program, which currently includes four Phase 2 trials, two of which we expect to readout primary data in the second half of this year.”

Dr. Cigler added, “I am excited to join the Atossa Therapeutics board and look forward to furthering the Company’s mission to prevent breast cancer, as well as to improve treatment options and outcomes for individuals diagnosed with the disease. While progress has been made over the past decade, breast cancer remains a deadly disease for hundreds of thousands of women globally each year. Current treatments are often limited by side effects. I believe (Z)-endoxifen has the potential to transform care, as a well-tolerated, safe, and effective breast cancer prevention and treatment agent.”

Dr. Cigler received her undergraduate degree from Harvard College, and her M.D. from Duke University School of Medicine. She also holds a Master’s in Public Health from the Harvard School of Public Health. She completed her residency in Internal Medicine at the New York Presbyterian Hospital Weill Cornell Medical Center, followed by a fellowship in Medical Oncology and Hematology at the Dana-Farber Harvard Cancer Center. Dr. Cigler joined the Cornell faculty in August 2007 as a medical oncologist and clinical investigator at the Weill Cornell Breast Center. At Weill Cornell, she heads several clinical trials designed to provide patients with access to new and promising options for therapy and supportive care.

About (Z)-Endoxifen

(Z)-endoxifen is the most active metabolite of the FDA approved Selective Estrogen Receptor Modulator (SERM), tamoxifen. Studies 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 PKC β 1, a known oncogenic protein. (Z)-endoxifen also appears to deliver similar or even greater bone agonistic effects while resulting in little or no endometrial proliferative effects compared with 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 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.

Contact

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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 data related to the (Z)-endoxifen program, the potential of (Z)-endoxifen as a breast cancer prevention and treatment agent, 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.
