

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): July 1, 2022 (June 28, 2022)

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

(I.R.S. Employer  
Identification No.)

107 Spring Street  
Seattle, Washington

(Address of principal executive offices)

98104

(Zip Code)

Registrant's telephone number, including area code: (206) 325-6086

Not Applicable

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))

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.

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

**Item 7.01** Regulation FD Disclosure

As previously announced, Atossa Therapeutics, Inc. (“Atossa”) filed an investigational new drug application (the “IND”) with the U.S. Food and Drug Administration (the “FDA”) to initiate a Phase 2 neoadjuvant clinical study of Atossa’s proprietary (Z)-endoxifen formulation (the “Drug Product”) in premenopausal women with early-stage estrogen receptor positive and HER2 negative breast cancer in the United States (the “Neoadjuvant Study”).

The FDA has communicated to Atossa that the IND requires the following additional information: (i) certain additional stability data concerning the Drug Product (studies supporting the Drug Product stability are ongoing) and (ii) non-significant revisions to the Neoadjuvant Study protocol and informed consent form.

Atossa plans to complete the required ongoing studies and submit the information required by the FDA by the end of the third quarter 2022 and to initiate enrollment into the Neoadjuvant Study, on schedule, in the fourth quarter 2022. Unless and until the required information, and any additional information the FDA may require, can be provided to the FDA the Neoadjuvant Study is on clinical hold and cannot commence. No assurance can be provided that the FDA will accept the information Atossa plans to provide or that the Neoadjuvant Study will commence.

Atossa continues to recruit participants for its ongoing Phase 2 clinical study of (Z)-endoxifen in premenopausal women with measurable breast density in Stockholm, Sweden.

*The information in Item 7.01 shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information contained in this Item 7.01 shall not be incorporated by reference into any filing with the U.S. Securities and Exchange Commission made by Atossa, whether made before or after the date hereof, regardless of any general incorporation language in such filing.*

\* \* \*

**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.

Date: July 1, 2022

Atossa Therapeutics, Inc.

By: /s/ Kyle Guse  
Kyle Guse  
Chief Financial Officer, General Counsel and  
Secretary