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): June 6, 2022 (June 1, 2022)

Atossa Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware	001-35610	26-4753208
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

107 Spring Street Seattle, Washington	98104
(Address of principal executive offices)	(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 ☐

Home
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 pursuance 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

On June 1, 2022, Atossa Therapeutics, Inc. ("Atossa") submitted an Investigational New Drug (IND) application to the U.S. Food and Drug Administration (FDA) for Atossa's proprietary oral (Z)-endoxifen capsules for the pre-surgical treatment of patients with estrogen receptor positive and HER2 negative (ER+/HER2-) breast cancer. The initial investigation will be a Phase 2 study of premenopausal women with ER+/HER2- breast cancer titled "A Randomized Phase 2 Noninferiority Trial of (Z)-endoxifen and Exemestane + Goserelin as Neoadjuvant Treatment in Premenopausal Women with ER+/HER2- Breast Cancer." This study is designed to first determine a target dose for therapy and then to investigate the safety and efficacy of (Z)-endoxifen therapy for premenopausal women with ER+/HER2- breast cancer.

The FDA has 30 days to review the Atossa application. As matter of regulation no assurance can be given that the IND will go into effect within 30 days allowing Atossa to proceed with opening the study. The FDA could request that Atossa provide additional information during the review period and Atossa may not be able to provide the additional information in a timely manner or at all which could result in clinical hold or permanent delay in opening or completing the study. These are standard risks associated with typical IND submissions to the FDA.

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.

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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: June 6, 2022

Atossa Therapeutics, Inc.

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