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): October 14, 2019

Atossa Genetics 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 or Rule 12b-2 of the Securities Exchange Act of 1934.

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 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	NASDAQ

Item 8.01 Other Events

On October 14, 2019, Atossa Genetics Inc. ("Atossa") entered into a clinical trial agreement with The Johns Hopkins University to conduct a Phase 2 clinical study of Atossa's intraductal microcatheter technology for the administration of fulvestrant in patients with early-stage breast cancer or ductal carcinoma *in situ* (DCIS). The Institutional Review Board (IRB) has approved the study. Susan Love, M.D., inventor of the technology, which was subsequently acquired by Atossa, will advise Atossa on the study.

This trial is a Phase 2 study in women with Stage 1 or 2 breast cancer (invasive ductal carcinoma) or DCIS scheduled for mastectomy or lumpectomy within 14 to 45 days. This study will assess the safety, tolerability, cellular activity and distribution of fulvestrant when delivered directly into breast milk ducts via Atossa's intraductal technology, compared to those who receive the same drug by injection. Of the 30 patients required for full enrollment, six will receive the standard intramuscular injection of fulvestrant and 24 will receive fulvestrant with Atossa's intraductal technology. Fulvestrant is FDA-approved for metastatic breast cancer. It is administered as a monthly intramuscular injection of two injections, typically into the buttocks.

The primary endpoint of the clinical trial is to compare the safety, tolerability and distribution of fulvestrant between the two routes of administration (intramuscular injection or through Atossa's intraductal technology). The secondary endpoint of the study is to determine if there are changes in the expression of Ki67 as well as estrogen and progesterone receptors between a pre-fulvestrant biopsy and post-fulvestrant surgical specimens. Digital breast imaging before and after drug administration in both groups will also be performed to determine the effect of fulvestrant on any lesions as well as breast density of the participant. This Phase 2 study is currently underway at Montefiore Medical Center, which will transition all future work to Johns Hopkins.

Atossa Genetics is the owner of issued patents, pending patent applications, and medical device FDA 510(k) premarket notifications related to the treatment of breast conditions, including breast cancer and DCIS.

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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: October 14, 2019

Atossa Genetics Inc.

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