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 27, 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 7.01. Regulation FD Disclosure.

On June 27, 2019, Atossa Genetics Inc. (the "Company") issued a press release announcing preliminary results from its Phase 2 study of topical Endoxifen to reduce mammographic breast density. A copy of the press release is attached as Exhibit 99.1 to this current report and is incorporated herein by reference.

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 the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 8.01.Other Events

See the information included in Item 7.01 to this current report which is incorporated into this Item 8.01 by this reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release, dated June 27, 2019

* * *

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 27, 2019

Atossa Genetics Inc.

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

Exhibit Index

Exhibit No.	Description
99.1	Press Release, dated June 27, 2019

Exhibit 99.1

Atossa Genetics' Preliminary Phase 2 Study Achieves Primary Endpoint: Topical Endoxifen Rapidly Reduces Breast Density

SEATTLE, WA -- (Marketwired) – June 27, 2019 -- Atossa Genetics Inc. (Nasdaq:**ATOS**), a clinical-stage biopharmaceutical company developing novel therapeutics and delivery methods for breast cancer and other breast conditions, today announced that a preliminary analysis from its recently completed Phase 2 study of the company's proprietary 20mg daily topical Z Endoxifen ("Endoxifen") showed significant and rapid reduction in mammographic breast density (MBD). Studies by others using tamoxifen have demonstrated that density reduction induced by tamoxifen is associated with a significant reduction in breast cancer incidence.

A summary of preliminary results of the study follows:

- MBD was reduced by an average of 14.3 percent in the group applying 20mg daily topical Endoxifen, which was statistically significant (p = 0.02). In the lower dose group (10mg), MBD was reduced by an average of 9.0 percent. These results are based on MBD measurements at the time of enrollment in the study and again at the time dosing ended, which was a mean of 55 and 88 days for the 20mg and 10mg groups, respectively.

- Approximately 70 percent of participants receiving 20mg topical Endoxifen experienced a reduction in MBD, and of those, the mean reduction in MBD was 27 percent.

- There were no significant differences in systemic endocrine or vascular side effects (for example, hot flashes) in the placebo versus active groups. Systemic side effects were measured using a modified validated symptom questionnaire. The most commonly experienced side effect for both groups receiving active drug were skin rashes and local irritation.

- The results indicate a study with approximately 50-100 subjects per dosage group would be appropriate to demonstrate efficacy for regulatory approval purposes.

Steven C. Quay, Ph.D., M.D., CEO and President of Atossa, commented "We are thrilled that our proprietary topical Endoxifen significantly reduced breast density. We believe that no other drug, other than tamoxifen, has been clinically demonstrated to significantly reduce breast density. We observed both a strong and a rapid treatment effect, as demonstrated by our topical Endoxifen producing treatment results in only 55 days of dosing for the 20mg dose. This compares to the one year of dosing previously used in oral tamoxifen studies. Our study also demonstrated that topical Endoxifen did not produce the systemic endocrine and vascular side effects that are often experienced with tamoxifen, such as hot flashes. Because the 20mg dose produced a treatment effect in only 55 days and because daily dosing eventually produced skin rashes and local irritation in most women, the topical form appears to be particularly well-suited for short-term use – perhaps less than 60 days with dosing every-other day. These data will now inform our decisions about dosing as well as development of our oral form of Endoxifen. Our goal is to ultimately reduce the incidence of breast cancer – by reducing MBD with our Endoxifen, which we believe can reduce the number of women getting estrogen dependent (ER+) breast cancer. This is analogous to statins rapidly reducing cholesterol which has now been shown to reduce the risk of heart attack long term."

The Phase 2 MBD Study of Topical Endoxifen

Atossa's Phase 2 study of topical Endoxifen was led by principal investigator Dr. Per Hall, MD, Ph.D., Head of the Department of Medical Epidemiology and Biostatistics at Karolinska Institutet, Stockholm, Sweden. The double-blinded, placebo-controlled study enrolled 90 participants who were randomized to one of three different dose groups (30 per group): placebo; 10mg daily topical Endoxifen; and 20mg daily topical Endoxifen. Participants applied the topical product to the skin of each breast daily for up to six months. The primary objective was to determine if there was a change in breast density compared to placebo in order to permit sample size calculations for statistical significance in a future Phase 3 trial. The primary endpoint was individual reduction of MBD as measured by mammography, and the secondary endpoints were to assess and characterize safety and tolerability. Each participant received a baseline (pre-treatment) mammogram with additional mammograms taken at month 3 and 6, or at the time of study exit.

Approximately 72 participants eventually developed skin rashes and local irritation and did not complete a full six months of dosing. However, the study yielded sufficient data to meet the primary objective of determining sample size calculation for subsequent studies. Based on the results achieved here, a subsequent MBD study using topical Endoxifen would require approximately 50 participants for the high dose formulation and approximately 100 participants for the low dose group to achieve a successful efficacy end point. Moreover, the study produced valuable information about dosing duration and because there was a treatment effect in only 55 days, the topical form of Endoxifen may be particularly well suited for short-term use – for example fewer than 60 days.

A study led by Sir Jack Cusick, director of the Wolfson Institute of Preventive Medicine in London and head of the Centre for Cancer Prevention, concluded that a 10 percent reduction in MBD after one year of oral tamoxifen conferred at 63 percent reduction in ER+ breast cancer (the most common form of breast cancer) after five years ("Tamoxifen-Induced Reduction in Mammographic Density and Breast Cancer Risk Reduction: A Nested Case–Control Study," Jack Cuzick, et. al. Journal of the National Cancer Institute, Vol 103, May 2011, pp. 744–752). Based on this and other work, the company believes the positive results from this study are clinically meaningful in the context of breast cancer risk reduction.

Further Development of Atossa's Endoxifen

Preliminary results of the study produced useful information regarding dosing frequency and duration. A significant treatment effect was achieved in only 55 days in the higher dose group. Because daily dosing will eventually result in rashes and local skin irritation in most patients, the company believes the topical form of Endoxifen may be particularly well suited for short-term use. Atossa will now be evaluating alternative dosing regimens, such as every other day, as well as shorter overall dosing such as fewer than 60 days.

Atossa is also preparing a Phase 2 study of its oral Endoxifen to reduce MBD which we will begin as soon as possible.

About MBD

Legislation has been recently enacted in approximately 35 states requiring that women be notified if they have MBD and those notifications typically state that women with MBD have a higher risk of developing breast cancer, and that mammography may not be as effective in detecting breast cancer because the MBD can “mask” the detection of cancers. In February 2019, Federal legislation was enacted that requires that the FDA adopt rules requiring that mammography reports include information about breast density and inform women about their breast density. There is no FDA-approved treatment to reduce MBD.

Atossa estimates that approximately ten million women in the Unites States have MBD. Although oral tamoxifen is approved to prevent breast cancer in “high-risk” women, it is used by less than 5 percent of women with an increased risk of developing breast cancer because of the actual or perceived side effects and risks of tamoxifen. The company believes its Endoxifen may provide an option for women to proactively reduce the density of their breasts, thereby reducing their risk of developing breast cancer. Moreover, Atossa’s Endoxifen may improve mammography accuracy and patient care by unmasking cancerous tumors that are otherwise obscured by high breast density.

About Atossa Genetics

Atossa Genetics Inc. is a clinical-stage biopharmaceutical company developing novel therapeutics and delivery methods to treat breast cancer and other breast conditions. For more information, please visit www.atossagenetics.com.

Forward-Looking Statements

Forward-looking statements in this press release, which Atossa undertakes no obligation to update, are subject to risks and uncertainties that may cause actual results to differ materially from the anticipated or estimated future results, including the risks and uncertainties associated with any variation between preliminary and final clinical results, actions and inactions by the FDA, the outcome or timing of regulatory approvals needed by Atossa including those needed to commence studies, lower than anticipated rate of patient enrollment, estimated market size of drugs under development, the safety and efficacy of Atossa's products and services, performance of clinical research organizations and investigators, obstacles resulting from proprietary rights held by others with respect to fulvestrant, such as patent rights, potential market sizes for Atossa's drugs under development and other risks detailed from time to time in Atossa's filings with the Securities and Exchange Commission, including without limitation its periodic reports on Form 10-K and 10-Q, each as amended and supplemented from time to time.

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