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): September 13, 2018

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))

Item 7.01. Regulation FD Disclosure

On September 13, 2018, Atossa Genetics Inc. (the "Company") issued a press release announcing preliminary results from its Phase 1 study of topical Endoxifen in men. Also on September 13, 2018, the Company plans to hold a conference call and present information about these preliminary results. A copy of the press release and slides for the conference call are attached as Exhibit 99.1 and 99.2, respectively, to this current report and are incorporated herein by reference.

* * *

The Company is furnishing the information in this Current Report on Form 8-K to comply with Regulation FD. Such information 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, and shall not be deemed to be incorporated by reference into any of the Company's filings under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date hereof and regardless of any general incorporation language in such filings, except to the extent expressly set forth by specific reference in such a filing.

"Safe harbor" statement under the Private Securities Litigation Reform Act of 1995: Some of the information presented herein may contain projections or other forward-looking statements regarding future events or the future financial performance of the Company, which the Company undertakes no obligation to update. These statements are based on management's current expectations and 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 preliminary study results varying from final results, estimates of potential markets for drugs under development, clinical trials, actions by the FDA and other governmental agencies, regulatory clearances, responses to regulatory matters, the market demand for and acceptance of the Company's products and services, performance of clinical research organizations and other risks detailed from time to time in the Company's filings with the Securities and Exchange Commission, including without limitation its most recent annual report on form 10-K, subsequent quarterly reports on Forms 10-Q and Forms 8-K, each as amended and supplemented from time to time.

Item 8.01 Other Events.

See item 7.01 above 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 September 13, 2018
99.2	Topical Endoxifen Phase 1 Study in Men Slide Presentation, dated September 13, 2018

* * *

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: September 13, 2018

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 September 13, 2018
99.2	Topical Endoxifen Phase 1 Study in Men Slide Presentation, dated September 13, 2018

Exhibit 99.1
Atossa Genetics Announces Preliminary Results from
Male Phase 1 Study of Topical Endoxifen
*****All Objectives Successfully Met*****

Conference Call to Be Held Today at 10 am Eastern Time

SEATTLE, Sept. 13, 2018 (GLOBE NEWSWIRE) -- Atossa Genetics Inc. (NASDAQ:**ATOS**), a clinical-stage biopharmaceutical company developing novel therapeutics and delivery methods for breast cancer and other breast conditions, reported preliminary results from its Phase 1 dose- escalation study of its proprietary topical Endoxifen in male subjects. All objectives were successfully met:

- **Safety:** There were no clinically significant safety signals and no clinically significant adverse events in participants receiving topical Endoxifen.
- **Tolerability:** Topical Endoxifen was well tolerated at each dose level and for the dosing duration utilized in the study.
- **Pharmacokinetics:** Blood samples showed no measurable topical Endoxifen.

“Based on these positive preliminary results, we are advancing our topical Endoxifen into a Phase 2 study to reduce gynecomastia in men starting prostate cancer therapy,” commented Dr. Steven C. Quay, CEO and President. “We anticipate retaining a clinical research organization to manage that study in the fourth quarter 2018. In addition to advancing our mens’ program into a Phase 2 study, we also have multiple Phase 2 studies in women addressing large markets with significant unmet needs: breast cancer and a condition called mammographic breast density. We look forward to reporting progress on these programs in the fourth quarter 2018 and into 2019,” added Dr. Quay.

Summary of Atossa’s Clinical Pipeline

Atossa’s current programs include:

Topical Endoxifen

- Phase 2 study to determine if topical Endoxifen reduces mammographic breast density (now enrolling in Sweden)
- Phase 1 study of topical Endoxifen in men (study complete with preliminary results announced today)
- Phase 2 study of topical Endoxifen to treat gynecomastia in men being treated for prostate cancer (retaining CRO in Q4 2018)

Oral Endoxifen

- Phase 2 study to determine if oral Endoxifen reduces tumor activity in early stage breast cancer patients in the “window of opportunity” between diagnosis of breast cancer and surgery (now enrolling in Australia)

- Phase 2 study of oral Endoxifen for patients who are “refractory” to Tamoxifen (retaining CRO in Q4 2018)

Intraductal Delivery

- Phase 2 study of Atossa’s proprietary intraductal microcatheter technology to administer Fulvestrant in cancer patients prior to surgery (now enrolling in the U.S. at Montefiore Medical Center, NY)

- Immuno-oncology (e.g., CAR-T) research

The Phase 1 Study Topical Endoxifen Study in Men
The Phase 1 study was a double-blind, randomized, placebo-controlled, repeat dose study of 24 healthy male subjects. Safety, tolerability and the pharmacokinetics of proprietary topical Endoxifen formulation at varying dose levels over 28 days were assessed. The study was conducted on behalf of Atossa by CPR Pharma Services Pty Ltd., Thebarton, SA, Australia.

Atossa’s Proprietary Topiocal Endoxifen
We are developing our proprietary topical Endoxifen to treat or prevent several health conditions in both men and women. For men, we are developing topical Endoxifen to prevent a condition called gynecomastia. Gynecomastia is male breast enlargement and accompanying pain, which according to the Mayo Clinic affects 25% of men in the U.S. between the ages of 50-69, or approximately 10 million men. It is the most common male breast disorder and is caused by a hormone imbalance where testosterone levels are lower than estrogen. Gynecomastia is caused by, among other things, any number of commonly prescribed medications, such as androgen deprivation therapy to treat prostate enlargement and prostate cancer, anti-anxiety medications, cancer treatments (chemotherapy), and some heart medications.

Gynecomastia is not only painful and embarrassing, it can also cause men to stop taking their prescribed medication. In prostate cancer treatment, testosterone is suppressed resulting in higher estrogen levels that often triggers gynecomastia. One recent study indicates that up to 90% of men taking androgen deprivation therapy suffer from gynecomastia and breast pain (Handoo Rhee, et al., October 18, 2014, *BJU International*).

There is no FDA-approved pharmaceutical to treat gynecomastia. Current therapeutic approaches in these patients include the use of daily oral estrogen-suppressing medications and prophylactic breast bud irradiation which is often repeated. Gynecomastia can create quality of life issues, with some patients attempting to hide the condition with compression garments and, in some cases, undergoing plastic surgery. We believe, subject to further clinical studies and regulatory approval, that our topical Endoxifen could fill a significant unmet medical need in reducing the risk of gynecomastia in men taking certain therapies to treat prostate cancer and helping them maintain their quality of life.

For women, we are also developing topical Endoxifen to treat mammographic breast density or MBD. Legislation has been recently enacted in over 30 states requiring women be notified if they have MBD. These 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. We estimate that approximately 10 million women in the Unites States have MBD, for which there is no FDA-approved treatment. Although oral tamoxifen is approved to prevent breast cancer in “high-risk” women, it is used by less than 5% of women with an increased risk of developing breast cancer because of the actual or perceived side effects and risks of tamoxifen.

We are conducting a double-blinded, placebo-controlled Phase 2 study at Stockholm South General Hospital in Sweden using our topical Endoxifen. The study is being led by principal investigator Dr. Per Hall, MD, Ph.D., Head of the Department of Medical Epidemiology and Biostatistics at Karolinska Institutet in Stockholm. The primary endpoint is to determine if daily topical Endoxifen administration results in an individual change in MBD, which will be measured after three and six months of entering the study. The secondary endpoints are safety and tolerability. Ninety participants will be randomized to one of three groups (one placebo group and two groups of different strengths of topical Endoxifen) with 30 participants per group. The objective of the study is to determine if MBD is reduced, and if so, the results will drive sample size calculations for a future Phase III study. We expect to complete enrollment by the end of 2018.

Conference Call

Atossa Genetics will host a conference call to discuss preliminary results today at 10 am Eastern time.

Due to expected high call attendance, participants are asked to preregister for the call through the following link: http://dpregister.com/10124008. Please note that registered participants will receive their dial in number upon registration and will dial directly into the call without delay. Those without internet access or who are unable to pre-register may dial in by calling: 1-844-824-3830 (domestic), 1-412-317-5140 (international) and Canada Toll Free: 1-855-669-9657. Callers should ask to be joined into the Atossa Genetics call.

The conference call will also be available through a live webcast at https://services.choruscall.com/links/atos180913.html which is also available at www.atossagenetics.com on the Company’s IR events page at http://ir.atossagenetics.com/ir-calendar.

Management will answer pre-submitted questions gathered prior to the conference call in the Question and Answer period of the call. Interested parties may submit questions for management’s consideration prior to the call by submitting them in writing to Atossa Genetics’ Investor Relations at scottg@coreir.com.

A replay of the call will be available approximately one hour after the end of the call through October 13, 2018. The replay can be accessed via Atossa's website or by dialing 877-344-7529 (domestic) or 412-317-0088 (international) or Canada Toll Free at 855-669-9658. The replay access code is 10124008.

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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Atossa GENETICS

Preliminary Topical Endoxifen

Male Phase 1 Results

All Objectives Successfully Met

September 13, 2018

107 Spring St.
Seattle WA 98104

Forward-Looking Statements

Some of the information presented herein may contain projections or other forward-looking statements regarding future events or the future financial performance of the Company which the Company undertakes no obligation to update. These statements are based on management's current expectations and 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 preliminary study results varying from final results, estimates of potential markets for drugs under development, clinical trials, actions by the FDA and other governmental agencies, regulatory clearances, responses to regulatory matters, the market demand for and acceptance of Atossa's products and services, performance of clinical research organizations and other risks detailed from time to time in Atossa's filings with the Securities and Exchange Commission, including without limitation its most recent annual report on form 10-K, subsequent quarterly reports on Forms 10-Q and Forms 8-K, each as amended and supplemented from time to time.

DISCUSSION TOPICS

- Atossa Genetics Overview
- Endoxifen
- Phase 1 Study
- Preliminary Safety Summary
- Preliminary Tolerability Summary
- Preliminary Pharmacokinetic Summary
- Next Steps

Atossa Genetics Overview

Atossa Genetics:

- Clinical-stage
- Novel drugs & delivery methods
- Breast cancer & other breast conditions
- Headquartered in Seattle, WA

Senior Management

Steven Quay, MD, PhD
Chairman, CEO and President

Kyle Guse, CPA, ESQ, MBA
CFO and General Counsel

Janet R. Rea, MSPH, RAC
SVP Regulatory, Quality and Clinical Affairs

Corporate Summary

Company:	Atossa Genetics Inc. (NASDAQ: ATOS)
Our Mission:	Develop novel pharmaceuticals and delivery systems to treat breast cancer and other breast conditions
Debt June 30, 2018:	None
Cash June 30, 2018:	$15.2M
Capital Structure Sept. 5, 2018:	5.5M shares common stock 1.0M shares preferred stock, as converted basis 3.9M warrants exercisable at $4.05/share 442K warrants exercisable at $3.78/share
Corporate Headquarters:	Seattle, Washington

Clinical Program Summary

- Phase 2 study to determine if oral Endoxifen reduces tumor activity in early stage breast cancer patients in the “window of opportunity” between diagnosis of breast cancer and surgery (now enrolling in Australia)
- Phase 2 study to determine if topical Endoxifen reduces mammographic breast density (now enrolling in Sweden)
- Phase 1 study of topical Endoxifen in men (study complete with preliminary results announced today)
- Phase 2 study of topical Endoxifen to treat gynecomastia in men starting prostate cancer therapy (retaining CRO in Q4 2018)
- Phase 2 study of oral Endoxifen for patients who are “refractory” to Tamoxifen (retaining CRO in Q4 2018)
- Phase 2 study of Atossa’s proprietary intra ductal microcatheter technology to administer Fulvestrant in breast cancer patients prior to surgery (enrolling in the U.S. at Montefiore Medical Center, NY)

Near-Term Milestones

- Q4 2018: Complete enrollment in Phase 2 study to reduce MBD
- Q4 2018: Retain CRO for Phase 2 study of topical Endoxifen to treat gynecomastia in prostate cancer patients
- Q4 2018: Retain CRO for Phase 2 study of oral Endoxifen for patients who are "refractory" to Tamoxifen
- Q4 2018: Release final data from Phase 1 study of topical Endoxifen to treat gynecomastia
- Q4 2018: Develop pre-clinical model using our proprietary microcatheter technology for immuno-oncology
- 2019: Progress clinical programs

Endoxifen

Phase 1 Study - Men

Preliminary Phase 1 Topical Results

- Study objectives achieved
- Demonstrated:
  - No Safety Issues
  - No Tolerability Issues
  - Topical Endoxifen not detected in the blood stream

Supports continued development

Preliminary Study Conclusions

- **All study objectives successfully achieved**
  - **Safety:** There were no clinically significant safety signals and no clinically significant adverse events in participants receiving topical Endoxifen.
  - **Tolerability:** Topical Endoxifen was well tolerated at each dose level and for the dosing duration utilized in the study.
  - **Pharmacokinetics:** Topical Endoxifen was not detected in the blood at any dosing level.

Topical Design Summary

Double-blinded, placebo controlled, dose escalation trial investigating the safety, tolerability and pharmacokinetics of topical (Z)-Endoxifen in healthy male volunteers

Cohort	Dose		Number of Participants	
	mg per Breast	Total mg	(Z)-Endoxifen	Placebo
1	1	2	6	2
2	3	6	6	2
3	5	10	6	2

- ✓ Healthy males, 18 to 65 years of age
- ✓ Body Mass Index of 18 to 32
- ✓ No chronic or acute disease
- ✓ Daily administration diaries

Safety Summary

Safety Summary

- No safety signals observed in weekly assessments of/in:
  - Blood chemistry
  - Coagulation parameters
  - Hematology parameters
  - Urinalysis
  - Vital Signs
  - Heart
  - Physical Examinations

Adverse Events

- There were no Serious Adverse Events

- No significant treatment-emergent Adverse Events related to study drug

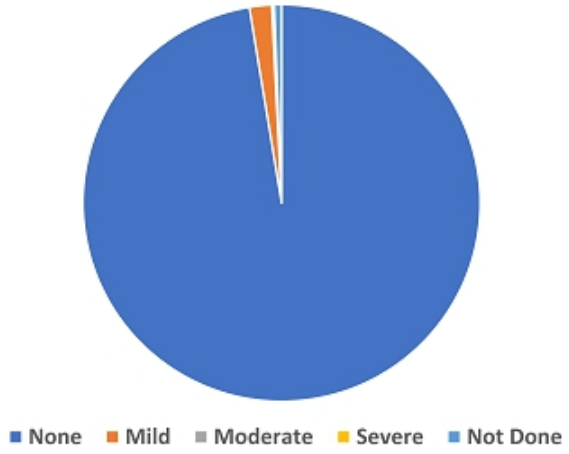
Tolerability Summary

Local Tolerability By Instances

- A daily self-assessment of local tolerance was performed
  - 24 subjects for 28 days for a total of 672 daily assessments
- Redness, Burning, Pain, Itching and Irritation were assessed each day
- Scoring was None, Mild, Moderate or Severe for all five parameters

Overall Tolerability Scoring: Based on Instance

None	**97.2%**
Mild	2.5%
Moderate	0.3%
Severe	0.0%



Parameter by Instance

Parameter	Percent Reporting None
Redness	96%
Burning	98%
Pain	99%
Itching	95%
Irritation	97%

One subject reported itching, irritation, redness and burning, and accounted for over 50% of the reports skin reactions

In-person Interview Results for Side-effects

Each participant was interviewed every seven days for side-effect information

Cohort	Responses per Participant*					
	Not at All	A little Bit	Some-what	Quite a Bit	Very Much	Not Done
Low	6/6					
Intermediate	6/6					
High	6/6					
Placebo	5/6	1/6				

There were sporadic reports of weight change (gain or loss), breast tenderness and headache

A participant who received placebo reported the highest frequency of side-effects and itching, irritation, redness and burning

Pharmacokinetic Summary

Endoxifen blood levels below detection limit of assay

Next Steps in Gynecomastia

- Q4 2018: Report final data
- Q4 2018: Retain CRO for male Phase 2 study of topical Endoxifen to reduce/prevent gynecomastia and maintain and/or improve quality of life

Atossa GENETICS

NASDAQ: ATOS

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Seattle WA 98104