ATOSSA GENETICS INC
Form 8-K
August 20, 2014

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): August 19, 2014

ATOSSA GENETICS INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation or organization)

001-35610	**26-4753208**
(Commission file number)	(IRS Employer Identification No.)

1616 Eastlake Ave. East, Suite 510, Seattle, Washington 98102
(Address of principal executive offices and zip code)

(800) 351-3902
(Registrant’s telephone number, including area code)

Not Applicable
(Former name or former address, if changed from 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

Atossa Genetics Inc. ("Atossa" or the "Registrant") has completed a number of studies related to its ForeCYTE Breast Aspirator device (510(k) pending, not for sale in the United States). The studies include the following:

- An IRB-approved, prospective, single-arm, multi-laboratory, non-randomized, non-masked clinical trial in adult women using the ForeCYTE Breast Aspirator for the collection, fixation, transport, and processing of NAF specimens for laboratory cytological testing at multiple, independent CLIA-registered laboratories. The ForeCYTE Breast Aspirator was used to collect 104 specimens from 52 adult female patients ages 21 to 65. Four laboratories performed cytological analysis of the specimens, including a large national laboratory and Atossa's subsidiary, The National Reference Laboratory for Breast Health, Inc., (the "NRLBH"). There were no adverse events observed during specimen collection and 100% of the specimens were properly processed for cytological testing. The study data is intended to demonstrate that the ForeCYTE Breast Aspirator is a "general collection device" that can provide specimens for laboratory cytological testing to any laboratory performing breast cytology. Additional information about this study can be found at www.clinicaltrials.gov and searching the term "Atossa."

- A study of the concordance of positive and negative control Reference Panel Specimens ("RPS") with a blinded cytological interpretation when the specimens were processed and read at multiple, independent laboratories. A total of 280 specimens, 140 positive RPS and 140 negative RPS controls, were shipped to four CLIA-registered laboratories, including a large national laboratory and the NRLBH. The specimens were processed and cytological interpretation was performed in a blinded fashion. The cytological interpretation correctly identified "truth" for 276 of 280 specimens for an overall study concordance of 99%.

- A study intended to demonstrate the analytical performance of the new method of processing specimens by spraying fixative onto the collection membrane in accordance with the Instructions for Use (IFU) is comparable to the predicate method of pouring fixative to wash the specimens into a collection vial, using positive and negative control RPS when read in a blinded fashion.

- A study intended to establish shelf life information and document shipping stability under adverse conditions of the ForeCYTE Breast Aspirator.

Information about these studies has been submitted by Atossa to the U.S. Food and Drug Administration in connection with Atossa's pending 510(k) submission for the ForeCYTE Breast Aspirator.

The Registrant 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 Registrant'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: Forward-looking statements in this Form 8-K 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 actions by the FDA, including timing of review by the FDA of 510(k) submissions, and actions related thereto including whether the FDA agrees with study design, protocol and conclusions, whether Atossa can submit additional information to the FDA in a timely fashion and whether the FDA will find that information acceptable and/or request additional information and/or clear the ForeCYTE Breast Aspirator for marketing in the U.S., the outcome of the FDA re-inspection completed on March 14, 2014, the outcome or timing of regulatory clearances needed by Atossa to sell its products, responses to regulatory matters, Atossa's ability to continue to manufacture and sell its products, recalls of products, the efficacy of Atossa's products and services, performance of distributors, estimated future expenses and cash needs, whether Atossa can launch in the United States and foreign markets the additional tests, devices and therapeutics in its pipeline in a timely and cost effective manner, 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.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Report to be signed on its behalf by the undersigned hereunto duly authorized.

ATOSSA GENETICS INC.

Date: August 20, 2014 By: /s/ Steven C. Quay
Steven C. Quay, M.D., Ph.D.
Chief Executive Officer and President