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 23, 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 8.01. Other Events

On September 23, 2014, Atossa Genetics Inc. (“Atossa”) issued a press release announcing a regulatory and commercial update on its ForeCYTE Breast Aspirator and its FullCYTE Breast Aspirator. A copy of the press release is attached to this Report on Form 8-K as Exhibit 99.1 and is incorporated into this Item 8.01 by this reference.

“Safe harbor” statement under the Private Securities Litigation Reform Act of 1995: Forward-looking statements in this report 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 the outcome of the FDA re-inspection completed on March 14, 2014, the outcome or timing of regulatory clearances, Atossa's ability to continue to manufacture and sell its products in a timely fashion, recalls of products, the efficacy of Atossa's products and services, performance of distributors, 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.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits

99.1 Atossa Genetics Inc. Press Release issued September 23, 2014.

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: September 23, 2014

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

Exhibit 99.1

Atossa Genetics Inc. Provides Regulatory and Commercial Update on its ForeCYTE Breast Aspirator and its FullCYTE Breast Aspirator

Investor Call Scheduled for September 24, 2014 at 9:00 am EDT

SEATTLE – September 23, 2014 – Atossa Genetics Inc. (NASDAQ: ATOS) today announced that the U.S. Food and Drug Administration has issued a determination that the ForeCYTE Breast Aspirator is "not substantially equivalent" to its predicate device. The ForeCYTE Breast Aspirator is, therefore, not cleared by the FDA for marketing in the United States. Atossa plans to now commercialize in the U.S. an alternative breast aspirator, called the FullCYTE Breast Aspirator. The FullCYTE Breast Aspirator is an FDA-cleared device that was acquired by Atossa in 2012 and is a subset of Atossa's FullCYTE Microcather which Atossa has been preparing for commercialization over the past 12 months. Atossa will now prioritize the commercial launch of the FullCYTE Breast Aspirator in the U.S. market.

ForeCYTE Breast Aspirator

The FDA determined that the ForeCYTE Breast Aspirator did not meet the criteria for substantial equivalence based on data submitted by Atossa. In a letter to Atossa, the FDA provided guidance on additional performance data that Atossa may gather and provide in a potential new 510(k) notification for the device. Atossa intends to request a pre-submission meeting with the FDA to reach agreement on the studies FDA is seeking and then intends to perform those studies and submit a new 510(k) notification for the ForeCYTE Breast Aspirator to the FDA.

Outside the United States, Atossa's commercial strategy is to obtain the CE Mark for its ForeCYTE Breast Aspirator, which it anticipates receiving in the next 30 days, and then in the first quarter of 2015 to launch the device through distributors in select European countries. Atossa is also evaluating Asian markets for this device.

FullCYTE Breast Aspirator

Based in part on the recent feedback received from FDA on the ForeCYTE submission, Atossa has decided to prioritize commercialization of its FullCYTE Breast Aspirator in the United States. The FullCYTE Breast Aspirator is a 510(k) cleared aspirator intended to obtain nipple aspirate fluid for cytological evaluation and as a means of identifying breast ducts for cannulation with the Atossa FullCYTE Microcatheter.

Atossa acquired the FullCYTE Breast Aspirator and FullCYTE Microcatheter, together with their respective 510(k) clearances and U.S. and foreign patents, in 2012 from Hologic, Inc. and has been in the process of preparing for a potential commercial launch. The aspirator device is comprised of a rigid polycarbonate cup which is placed around the breast nipple. The polycarbonate cup is attached to a user supplied standard syringe, which is used to pull a gentle vacuum to express breast ductal fluid. This fluid can be placed directly into a non-gyn liquid-based cytology fixative for transport to a pathology laboratory. The FullCYTE Breast Aspirator device is intended for single patient use only.

Dr. Steven Quay, CEO and President of Atossa stated, "While we are disappointed in the FDA's decision on the ForeCYTE device, we believe this alternative aspirator can help us reach our commercialization goals without a significant delay. We are highly encouraged that we presently possess an FDA-cleared, patented, commercially viable alternative that will permit us to return to the U.S. market with our FullCYTE Breast Aspirator device. We also remain optimistic that our ForeCYTE device will soon receive the CE Mark and we expect our ForeCYTE device will soon be available for commercial marketability in Europe. Our strategy to commercially launch our devices remains on track and we believe we have the appropriate and compliant solutions to enable us to return to revenue generation in the near future."

Conference Call Information

Management will host a conference call on Wednesday, September 24, 2014, at 9:00 am Eastern Time to provide a Regulatory and Commercial Update. Following management's formal remarks, there will be a question and answer session.

To listen to the call by phone, interested parties within the U.S. should call (Toll Free):1-866-652-5200. International callers should call 1-412-317-6060. All callers should ask for the Atossa Genetics conference call. The conference call will also be available through a live webcast at www.atossagenetics.com.

About Atossa Genetics

Atossa Genetics Inc. is focused on improving breast health through the development of laboratory services, medical devices and therapeutics. The laboratory services are being developed by its subsidiary, The National Reference Laboratory for Breast Health, Inc. The laboratory services and the Company's medical devices are being developed so they can be used as companions to therapeutics to treat various breast health conditions. For additional information, please visit www.atossagenetics.com.

Forward-Looking Statements

Forward-looking statements in this press release 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 the outcome of the FDA re-inspection completed on March 14, 2014, the outcome or timing of regulatory clearances, Atossa's ability to continue to manufacture and sell its products in a timely fashion, recalls of products, the efficacy of Atossa's products and services, performance of distributors, whether Atossa can launch in the United States and foreign markets it tests, devices and therapeutics 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.

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