ATOSSA GENETICS INC
Form 8-K
February 25, 2013

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): February 21, 2013

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.)**

4105 E. Madison Street, Suite 320, Seattle, Washington 98112
(Address of principal executive offices and zip code)

(206) 325-6086
(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 February 21, 2013, Atossa Genetics, Inc. ("Atossa" or the "Company") received a Warning Letter ("Letter") from the FDA regarding its Mammary Aspirate Specimen Cytology Test (MASCT) System and MASCT System Collection Test (together, the "System"). The Letter arises from certain FDA findings during a July 2012 inspection, to which the Company responded in August 2012, explaining why the Company believed it was in compliance with applicable regulations and/or was implementing changes responsive to the findings of the FDA inspection. FDA alleges in the Letter that following 510(k) clearance the Company changed the System in a manner that requires submission of an additional 510(k) notification to the FDA. Specifically, the FDA observes that the Instructions For Use (IFU) in the original 510(k) submission stated that the user must "Wash the collection membrane with fixative solution into the collection vial…" and the current IFU states "…apply one spray of Saccomanno's Fixative to the collection membrane…" and that "this change fixes the NAF specimen to the filter paper rather than washing it into a collection vial." At the time that the changes were made the Company determined that a new 510(k) was not required in accordance with the FDA's guidance document entitled, "Deciding When to Submit a 510(k) for a Change to an Existing Device."

The Letter also raises certain issues with respect to the Company's marketing of the System and the Company's compliance with FDA Good Manufacturing Practices (cGMP) regulations, among other matters.

The Company is committed to working with the FDA to resolve these issues in the best interests of patients and their doctors. If the FDA does not agree with the Company's position concerning clearance of the System, Atossa may be required to submit and receive clearance of a new 510(k) notice for the current form of the System or revert to marketing the System using the prior NAF processing method.

The Company has until March 14, 2013 to respond to the Letter and is currently working to prepare that response. Among other things, the Company currently expects that the response will explain why the Company believes that the System in its current form has been and continues to be appropriately marketed under a cleared 510(k) premarket notification, and why it is in substantial compliance with applicable regulations, including cGMP.

Management notes that the FDA could direct other compliance-verification activities or take other actions in connection with matters raised in the Letter and in connection with other matters that the FDA could identify in the future. Until these issues are resolved Atossa may be subject to additional regulatory action by the FDA, and any such actions could disrupt the Company's ongoing business and operations.

"Safe harbor" statement under the Private Securities Litigation Reform Act of 1995: Except for the historical information contained herein, the matters set forth in this Form 8-K, including statements regarding Atossa's plans, regulatory actions, Atossa's responses to regulatory actions, expectations, projections, potential opportunities, goals

and objectives are forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements 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, regulatory clearances, responses to regulatory matters, Atossa's ability to continue to manufacture and sell its products, the efficacy of Atossa's products and services, the market demand for and acceptance of Atossa's products and services and other risks detailed from time to time in the Atossa's, filings including its registration statement form S-1 filed January 28, 2013, as amended and supplemented from time to time. All forward-looking statements are qualified in their entirety by this cautionary statement, and Atossa undertakes no obligation to revise or update any forward-looking statement to reflect events or circumstances after the issuance of this press release.

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: February 25, 2013 By: /s/ Steven C. Quay
Steven C. Quay, M.D., Ph.D.
Chief Executive Officer