

ATOSSA GENETICS INC
Form 8-K
November 01, 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): November 1, 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.)

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. has scheduled a pre-510(k) submission meeting with the Food & Drug Administration on November 14, 2013 to discuss regulatory pathway and data requirements to support Atossa's planned Premarket Notification (510(k) Notice) submission for the reintroduction of the ForeCYTE Breast Health Test System.

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, the proposed the pre-submission meeting date, 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, the market demand for and acceptance of Atossa's products and services, performance of distributors, estimated future expenses and cash needs, 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: November 1, 2013 By: /s/ Steven C. Quay
Steven C. Quay, M.D., Ph.D.
Chief Executive Officer