ATOSSA GENETICS INC
Form 8-K
December 16, 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): December 12, 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 1.01 Entry Into a Material Definitive Agreement

See Item 8.01 below, which is incorporated into this Item 1.01 by this reference.

Item 7.01 Regulation FD Disclosure

The results from two research programs involving software that has been licensed to Atossa Genetics Inc. (the "Company") by A5 Genetics KFT, Corporation (the "A5 License") were presented on December 12 and 13 at the 2013 San Antonio Breast Cancer Symposium in San Antonio, Texas (the "Symposium"). The software is intended for use in a laboratory developed test being developed by the Company's subsidiary, The National Reference Laboratory for Breast Health, Inc. (the "NRLBH"), a CLIA-certified laboratory.

The poster presentation titles and main conclusions are as follows:

Poster Session 3: Prognosis and Response Prediction: Biomarkers - Methods

P3-05-05 Classification using dynamic re-discovery of the strongest prognostic features in each analysis outperforms static gene expression signatures for prognostic prediction in breast cancer
Györffy B, Karn T, Sztupinszki Z, Weltz B, Müller V, Pusztai L. Hungarian Academy of Sciences; J. W. Goethe-University; University of Hamburg; Yale Cancer Center.

- The software uses case-specific training cohorts to produce personalized, prognostic predictions of breast cancer survival, lymph node status, ER, PR and HER2 gene expression status, and chemotherapy responsiveness.
- The data set used by the software comprises 3,534 patients with clinical annotation and recurrence data and gene expression levels for 9,886 genes in each of these patients.
- The software yields different training sets and different predictors for each new patient.
- The training set used in the software was validated in an independent set of patients (n=325) that yielded similar classification power.
- Analytical performance of the software showed that sensitivity and specificity for predicting five-year survival are 84% and 58%, respectively, and showed that the overall sensitivity, specificity, and accuracy were analytically superior to the 21-gene, 70-gene, and 97-gene algorithms compared in this study (although the 70-gene algorithm showed a higher level of sensitivity).

Poster Session 4: Detection and Diagnosis

P4-03-03 Determination of lymph node status using the primary tumor's gene expression signature
Gyorffy B, Sztupinszki Z, Weltz B, Chen S-C, Quay S. Research Laboratory of Pediatrics and Nephrology,

Budapest, Hungary; Atossa Genetics, Inc. and the National Reference Laboratory for Breast Health, Seattle

- The software uses gene expression technology to predict lymph node positivity from the primary tumor gene expression profile.
- Analytical performance of the software showed that gene expression data from 40 genes predicted lymph node positivity with sensitivity and specificity of 71% and 78%, respectively.

The NRLBH's laboratory developed test using this technology is currently in the pre-clinical development stage. The NRLBH is now enrolling investigators in a prospective observational study to continue development of the test.

In accordance with General Instruction B.2 of Form 8-K, the information in this Current Report on Form 8-K, Item 7.01, shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section. The information in this Item 7.01 shall not be incorporated by reference into any filing or other document pursuant to the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such filing or document.

Item 8.01. Other Events

The research programs presented at the Symposium include data and information about software that has been licensed to the Company pursuant to the A5 License, dated as of June 10, 2013. The A5 License provides for the irrevocable license by A5 to the Company of software for the purpose of analyzing genes in biopsy samples of breast cancer and pre-cancerous lesions. The license is exclusive and world-wide outside of the European Union. Fees paid or potentially payable to A5 include: (i) $100,000 up front payment, (ii) $100,000 upon installation of the software at the NRLBH, (iii) $200,000 upon the earlier of submission of an application to the U.S. Food and Drug Administration (the "FDA") seeking clearance of a device using the licensed software or commercial launch, (iv) $1,000,000 upon the receipt of FDA clearance of the test using the licensed software, and (v) a royalty of $50 and a fee of $65 for the provision of certain services for each test performed by the NRLBH that utilizes the licensed software. The Company and the NRLBH have the right to seek, and the obligation to pay for, patents on the licensed software and FDA clearances on the devices using the licensed software, which are owned by the Company and the NRLBH. The A5 License terminates on the later of the 10 year anniversary of the A5 License or the expiration of related patents on a country by country basis.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits

99.1 License and Services Agreement between A5 Genetics KFT, Corporation, and Atossa Genetics Inc., dated as of June 10, 2013.

“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 feedback from the pre-submission meeting and actions related thereto, the outcome or timing of regulatory clearances needed by the Company to sell its products and services, responses to regulatory matters, the Company's ability to continue to manufacture and sell its products, recalls of products, the efficacy of the Company's products and services, the market demand for and acceptance of the Company’s products and services, performance of distributors, estimated future expenses and cash needs, and other risks detailed from time to time in the Company'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: December 16, 2013 By: /s/ Steven C. Quay
Steven C. Quay, M.D., Ph.D.
Chief Executive Officer

EXHIBIT INDEX

Exhibit	Description
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