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): October 4, 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 8.01. Other Events

On October 4, 2013, Atossa Genetics Inc. issued a press release announcing it had commenced the voluntary recall of the ForeCYTE Breast Health Test Mammary Aspiration Specimen Cytology Test (MASCT). 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.

On October 4, 2013 Atossa Genetics Inc. held a conference call and discussed the voluntary recall. A script of that conference call is attached to this Report on Form 8-K as Exhibit 99.2 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 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 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.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits

99.1	Atossa Genetics Inc. Press Release issued October 4, 2013
99.2	Atossa Genetics Inc. Script of Conference Call Held on October 4, 2013

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: October 4, 2013

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

EXHIBIT INDEX

Exhibit	Description
99.1	Atossa Genetics Inc. Press Release issued on October 4, 2013
99.2	Atossa Genetics Inc. Script of Conference Call Held on October 4, 2013

EXHIBIT 99.1

Medical Device Voluntary Recall - News Release

ForeCYTE Breast Health Test; Mammary Aspiration Specimen Cytology Test (MASCT)

FOR IMMEDIATE RELEASE: October 4, 2013

1616 EastLake Ave East, Suite 510
Seattle, WA 98102
(800) 351-3902
www.atossagenetics.com
www.GetForecyte.com
www.nlrbh.com

On October 4, 2013 Atossa Genetics Inc. (NASDAQ: ATOS) initiated a voluntary recall to remove the ForeCYTE Breast Health Test and the Mammary Aspiration Specimen Cytology Test (MASCT) device from the market. This voluntary recall includes the MASCT System Kit and Patient Sample Kit. The vast majority of these products (approximately ninety percent) are in inventory with Atossa's distributors and the remaining quantities are at customer sites across the United States. Distributors and customers should stop using affected products and return them to Atossa immediately.

Atossa is removing the ForeCYTE Breast Health Test and the MASCT device from the market to address concerns raised by the U.S. Food and Drug Administration (FDA) in a warning letter received by Atossa in February 2013. The FDA raised concerns about (1) the current instructions for use (IFU); (2) certain promotional claims used to market these devices; and (3) the need for FDA clearance for certain changes made to the Nipple Aspirate Fluid (NAF) specimen collection process identified in the current IFU. Atossa will remove existing product from the market until FDA's concerns are addressed.

The MASCT device has been cleared by the FDA for use as a sample collection device, with the provision that the fluid collected using this device can be used to determine and/or differentiate between normal, pre-cancerous, and cancerous cells. The MASCT device has not been cleared by the FDA for the screening or diagnosis of breast cancer. In addition, the ForeCYTE Breast Health Test has not been cleared or approved by the FDA for any indication. The ForeCYTE Breast Health Test and the MASCT device are not a replacement for screening mammograms, diagnostic imaging tests, or biopsies. Patients should follow the recommendations and instructions of their physician with respect to breast cancer screening and diagnosis.

To date, Atossa is unaware of any adverse incidents or injuries associated with the use of the ForeCYTE Breast Health test and the MASCT device or the processing method currently identified in the IFU. Additionally, Atossa is unaware of any risk to health or injury for clinicians or the patient population that have used these devices. However, these devices may produce false positive or false negative results. Although not cleared or intended for this use, if these devices are used as a substitute for recommended screening or diagnosis of breast cancer, FDA is concerned that patients may choose to forgo recommended mammograms and necessary biopsies.

Atossa is working with the FDA on this matter and this voluntary recall. Atossa is notifying its distributors and customers by certified mail and is arranging for the return of all recalled product(s). Products affected by this recall are listed in the table below (table 1):

TABLE 1

Product Code	***Part Number***	***Description***	***Lot Number***
AG-MASCT	9002528	MASCT System Kits	All
AG-MASCT	9002528MD	MASCT System Kits	All
DTG-MASCT	9002587	Clarity System Kits	All
AG-FC5	9002513	MASCT Patient Sample Kits	All
AG-FC5	9002513MD	MASCT Patient Sample Kits	All
DTG-FC5	9002614	Clarity Patient Sample Kits	All
NRLBH-5	9002717MD	Nipple Aspirate Fluid Laboratory Kit	All

MASCT System Kit	***Patient Sample Kit***
1. MASCT Breast Pump 2. Instructions for Use (IFU) 3. Heating Pad 4. Timer 5. Saccomono's Fixative 6. Nu Prep Gel 7. Welcome and Training Materials Coversheet 8. MASCT System Order Form 9. ForeCYTE Training Video DVD 10. MASCT System Instructions with pictures - pink	1.) Two (2) flower assemblies (e.g., filter, filter retainer, and filter holder), 2.) Instructions for Use (IFU) 3.) Two (2) specimen collection devices, 4.) Two (2) breast bags for transporting the specimen collection container 5.) Barcode labels 6.) Saccomono's Fixative 7.) Nu Prep Gel 8.) MASCT System package insert 9.) ForeCYTE Test Requisition Form 10.) Patient Information Sheet 11.) Atossa Patient Information 12.) FED EX Clinical PAK 13.) MASCT System Order Form 14.) FED EX Pouch 15.) FED EX Airbill

Distributors and customers should contact Atossa at XXX to obtain instructions on how to return these products. Customers with questions may contact the company via telephone at 1-888-219-4629 at any time.

Any problems experienced with the use of this product may be reported to the FDA:
at http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm.

- Online (form available to fax or mail), or call FDA 1-800-FDA-1088

Contact:

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Exhibit 99.2

Atossa Genetics
"Company Update Conference Call"

Friday, October 4, 2013, 5:45 PM ET
Dr. Steven Quay
Kyle Guse
Matthew Haines

OPERATOR: Welcome to the Atossa Genetics Update Conference Call. All participants will be in a listen-only mode. Should you need assistance, please signal a conference specialist by pressing the "*" key followed by "0." After today's presentation, there will be an opportunity to ask questions. To ask a question you may press "*" then "1" on your touchtone phone, to withdraw your question, please press "*" then "2." Please note this event is being recorded.

I would now like to turn the conference over to Mr. Matthew Haines, Managing Director of MBS Value Partners. Please go ahead, sir.

MATTHE WHAINES: Thanks. Good afternoon and thank you for joining today's conference call to discuss the Company's voluntary recall of its MASCT System. With us today are Dr. Steven Quay, Chairman, CEO and President, and Kyle Guse, CFO. Today Atossa issued a press release announcing a voluntary recall of the Company's MASCT System. If you have not received Atossa's press release, please visit www.atossagenetics.com.

Following management's formal remarks, we will open up the call to your questions. Before we begin, I would like to note that comments made during this call will include forward-looking statements regarding predictions about future events, including the future financial performance of the company. Such statements are predictions only and actual events or results could differ materially from those made in any forward-looking statements due to a number of risks and uncertainties, including assumptions about future events based on current expectations, plans, regulatory actions, business development efforts, near and long-term objectives, potential new business, strategies or organizational changes, changing markets, future business performance and outlook. Please see Atossa's most recent filings with the SEC including without limitations Forms 10-K, 10-Q and 8-K. I will now turn the call over to Dr. Quay.

DR. STEVEN QUAY: Thank you and good afternoon.

After the close of the market today we announced initiation of a voluntary recall of the ForeCYTE Breast Health Test and the Mammary Aspiration Specimen Cytology Test (MASCT) device from the market. This voluntary recall includes the MASCT System Kit and Patient Sample Kit. The vast majority of these products (approximately ninety percent) are in inventory with Atossa's distributors and the remaining quantities are at customer sites across the United States.

We have been in discussions with FDA for several weeks about its disposition of our 510(k) application and its position about the version of the MASCT System and ForeCYTE test that have been on the market. We reached our conclusion to adopt the approach we have announced today within the last few days and FDA cleared our press release concerning the recall a few hours ago.

Atossa is removing the ForeCYTE Breast Health Test and the MASCT device from the market to address concerns raised by the FDA in a warning letter received by Atossa in February 2013. The FDA raised concerns about (1) the current instructions for use (IFU); (2) certain promotional claims used to market these devices; and (3) the need for FDA clearance for certain changes made to the Nipple Aspirate Fluid (NAF) specimen collection process identified in the current IFU. Atossa will remove existing product from the market until FDA's concerns are addressed. I would like to add that we are not aware of any adverse incidents or injuries resulting from the use of our devices.

In the next few minutes, I'd like to tell you how and why we reached this decision and why we believe this is the right decision for the Company and its shareholders.

So let me start by giving you a framework to understand what has happened.

As you know the MASCT System and ForeCYTE Breast Health Test were developed by Atossa to provide clinically useful diagnostic information from nipple aspirate fluid. Three steps are involved in these products:

Step 1. The collection of nipple aspirate fluid specimens at a healthcare provider's clinic or office.

Step 2. The preparation of the nipple aspirate fluid specimens at the healthcare provider's clinic or office for shipment to a laboratory for cytology analysis.

Step 3. The processing of the nipple aspirate fluid at the laboratory for cytopathology.

Step 1 is achieved with the MASCT System, a modified breast pump which collects nipple aspirate fluid from the breasts of a non-lactating woman.

In step 2, the collected fluid is prepared at the clinical site of collection by the healthcare professional for shipment to a cytology laboratory.

In step 3, the nipple aspirate fluid specimen is received by Atossa's CLIA registered laboratory, The National Reference Laboratory for Breast Health, in Seattle, WA, and the nipple aspirate fluid is processed for cytopathological screening and diagnosis by licensed cytotechnologists and physicians. This is what we have called the ForeCYTE Breast Health Test.

From a regulatory point of view, the company believes the MASCT System for collection and preparation of nipple aspirate fluid is a Class II medical device which requires FDA clearance before marketing in the United States.

We have also believed that the processing of the nipple aspirate fluid specimens at a laboratory is typically regulated by the Centers for Medicare & Medicaid Services or CMS through its Clinical Laboratory Improvement Amendment or CLIA registration process as a Laboratory Developed Test or LDT. However, based on recent input from the FDA and our professional advisors, we understand that the processing of the nipple aspirate fluid specimens can be viewed as a Class II in vitro diagnostic test service that requires premarket notification before commercialization in the United States. FDA has informed us that it takes that position.

We have therefore decided to perform a voluntary recall of the current MASCT System collection and preparation materials that are in the field, and to discontinue marketing of the MASCT System and ForeCYTE test for the time being. We plan to prepare a new premarket notification or 510(k) application for submission to the FDA that covers the collection, preparation, **AND** processing of nipple aspirate fluid specimens. This 510(k) supersedes an earlier 510(k) submission, which we later withdrew.

We have told the FDA this will be submitted by the end of October 2013 although we would like to have a pre-submission meeting before filing. Unfortunately, the government shutdown makes the timing of a meeting and therefore of the subsequent 510(k) filing impossible to predict. Once filed we hope that the FDA will complete their review of our submission within 90 days; but of course we cannot predict if they will ask us for additional information or otherwise complete their review within the 90 days.

FDA's warning letter raised a number of matters, as you know. Since our receipt of the FDA warning letter last February, we have been working diligently with FDA, including through our professional advisors, to clarify, respond to and resolve the matters noted in the FDA warning letter. We believe several of the issues are resolved to the Agency's satisfaction; however, there remain a number of open issues, as today's announcement partially reflects. We continue to work with FDA to clear all open matters in the FDA warning letter.

As a reminder, in the MASCT System as cleared for marketing, the nipple aspirate fluid is prepared for shipment to the laboratory by pouring cytology fixative on the collection membrane to wash the specimen into a vial for shipment. The specimen vial with fluid inside is received by the laboratory and processed by routine manual methods for cytology screening and diagnosis.

Atossa modified the nipple aspirate fluid preparation step by spraying the collection membrane with fixative rather than pouring fixative over the membrane and washing the specimen into a vial. Atossa's laboratory processes the membranes by clipping the membranes to glass slides and processing by routine manual methods for cytological screening and diagnosis. This processing method was developed and validated in Atossa's laboratory before we began to market and sell the MASCT System.

This modified specimen processing methodology was also examined by representatives from the U.S. Department of Health and Human Services' Centers for Medicare and Medicaid Services (CMS) during certification under the Clinical Laboratory Improvement Amendments (CLIA) of 1988 of the National Reference Laboratory for Breast Health. This certification followed an inspection of our facilities, processes, and personnel, including review of the validation and clinical reports from the ForeCYTE Breast Health Test.

While we are disappointed that the matter has not been resolved as we had hoped and anticipated based on our interpretation of the FDA guidelines and the CMS CLIA certification processes and in discussions with FDA, I want to assure you that the Company remains fundamentally sound. At this time, our intention is to continue to work with the FDA for an expedited review of our new 510(k), which we hope to file by the end of October so that we can resume marketing the MASCT System as soon as possible.

During the pendency of the 510(k) submission, we will not be marketing, promoting or selling the MASCT device or the ForeCYTE test. We do not expect any meaningful revenues from the sale of the MASCT System device nor from the ForeCYTE laboratory tests while the 510(k) is pending. We are currently assessing the likely cost impact of the recall, and while we cannot yet provide details, the Company does expect to record a reserve to cover anticipated expenses associated with the recall as part of its financial results for the quarter ended September 30, 2013.

We will update you on this when we announce our financial results for that quarter, which we currently expect to do around the second week of November. As most of you know, we have a financing facility with Aspire Capital, and so long as the contractual conditions to our right to sell shares to Aspire remain satisfied, we expect that we will be able to continue to sell shares to them.

We will be updating everyone on our cash position, along with our financial performance for the quarter ended September 30, 2013, once the financial statements are ready for filing with the SEC, which we expect will be on or before November 14. However, we currently estimate that we have sufficient cash for the next 8-12 months of operations without raising additional capital. This estimate is subject to change if our plans change or if we incur unanticipated expenses. In addition, we believe physicians will remain enthusiastic about the MASCT System and ForeCYTE test and will be ready to resume testing upon regulatory clearance. Once we have clearance to sell the test, we will be ready to resume our marketing activities without delay.

Meanwhile, development of the FullCYTE, NextCyte and ArgusCYTE tests, which we expect to launch next year, will continue. We will be reassessing the regulatory status of these products as Laboratory Developed Tests in light of our recent experience.

We will also continue our partnership efforts for the intraductal treatment program, another 2014 event. In short, at this point in time we do not anticipate any other significant disruptions to our operations, including terminations, nor any changes in our arrangements with our current distributors.

We do intend to reduce certain discretionary marketing expenses until such time as the new 510(K) is cleared. In the event that the Agency takes significantly more time to review our new 510(k) application than we would anticipate, or that the filing is turned back for further work, we would likely have to revisit our expenses with a goal of conserving cash more aggressively. However, we are optimistic that the FDA will review the application in a timely manner.

That concludes my formal remarks.

Operator, please open the call for questions.

Q&A

OPERATOR: Thank you, sir. We will now begin the question and answer session. To ask a question, you may press “*” then “1” on a touchtone phone. If you are using a speakerphone, please pickup your handset before pressing the keys. If at any time your question has been addressed and you would like to withdraw your question, please press “*” then “2.” Again it is “*” then “1” to ask a question. At this time we will just pause momentarily to assemble our roster.

The first question we have comes from…

DR. STEVEN QUAY: In closing, we are disappointed, as I know you are as well, to be recalling the MASCT System.

However, we do remain confident that the path we are on is the right way to go and is in the best interests of the Company and our other stakeholders, including patients and our investors. Our third quarter earnings call will likely be held the first or second week of November, at which time we look forward to providing a more detailed update on our activities. And it goes without saying that we will update the market on any significant developments with respect to the MASCT System.

Thank you for your attention and continued support. If you have any additional questions, please feel free to contact us.

OPERATOR: Ladies and gentlemen, the conference call has now concluded. We thank you all for attending today's presentation. At this time you may disconnect your lines.