

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): March 27, 2014

**ATOSSA GENETICS INC.**  
(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction of incorporation or organization)

**001-35610**  
(Commission file number)

**26-4753208**  
(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))
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## **Item 2.02. Results of Operations and Financial Condition**

On March 27, 2014, Atossa Genetics Inc. (the “**Company**”) issued a press release announcing fiscal year 2013 financial results. A copy of the press release is attached as Exhibit 99.1 to this current report and is incorporated herein by reference.

The information in the report, including Exhibit 99.1 attached hereto, 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 or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information contained herein and in the accompanying exhibit shall not be incorporated by reference into any filing with the U.S. Securities and Exchange Commission made by the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

## **Item 9.01. Financial Statements and Exhibits**

### (d) Exhibits

99.1 Atossa Genetics Inc. Press Release issued March 27, 2014

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**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: March 27, 2014

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

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**EXHIBIT INDEX**

**Exhibit**

**Description**

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99.1 Atossa Genetics Inc. Press Release issued on March 27, 2014

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**Atossa Genetics Announces 2013 Financial Results  
and Provides Company Update**

**Conference Call to be Held Today at 4:45 pm Eastern Time**

**SEATTLE, March 27, 2014** -- Atossa Genetics, Inc. (NASDAQ: ATOS) today announced 2013 financial results and provided an update on recent corporate developments.

“With cash and cash equivalents of \$6.3 million at December 31, 2013, an additional \$13 million net raised in January of this year in a public offering, and up to \$24 million available through our common stock purchase agreement with Aspire Capital Fund, LLC, we are well positioned to execute on our business plan and achieve our key objectives for this year,” stated Dr. Steven C. Quay, Chairman, CEO & President. “On December 23, 2013, we submitted a Premarket 510(k) Notification to the FDA for our ForeCYTE Breast Aspirator and on February 28, 2014, we received questions from the FDA regarding the submission. We are currently in the process of addressing the FDA’s questions. The FDA also completed a re-inspection of our Seattle facility on March 14, 2014, and on March 26, 2014, we responded to the observations and issues that resulted from that inspection.”

Dr. Quay added, “2014 looks to be an exciting year of significant milestones for Atossa. These include, after receiving FDA clearance, the planned re-launch of the ForeCYTE Breast Aspirator through our specialty sales team and distributors, including Fisher Healthcare, and McKesson; the launch of the FullCYTE microcatheters to collect ductal lavage fluid for cytology testing in Q4 of 2014 after completing additional validation studies and regulatory clearance of our manufacturing procedures and processes for this test; and, launch of the NextCYTE Breast Cancer Test and the ArgusCYTE Test in Q4 2014 or Q1 2015 after completing validation studies and upon receiving any necessary FDA regulatory clearance. In addition, in 2014 we plan to advance our therapeutic program by initiating studies using our medical devices as companion diagnostics.”

**Recent Corporate Developments**

- Substantially completed the voluntary recall of the MASCT System and ForeCYTE Breast Health Test devices,
- Following the submission of the Premarket 510(k) Notification on December 23, 2013 for the ForeCYTE Breast Aspirator, the Company received additional questions from the FDA on February 28, 2014. Atossa is preparing a response to those questions,

- On March 14, 2014, the FDA completed a follow-up inspection of Atossa's Seattle facility and on March 26, 2014, Atossa responded to the observations and issues resulting from the inspection,
- In November 2013, Atossa entered into a stock purchase agreement with Aspire Capital Fund, LLC. Under terms of the agreement, Aspire has committed to purchasing up to an aggregate of \$25 million of shares of Atossa common stock,
- Commenced validation studies on NextCYTE test and manufacturing validation studies on the FullCYTE microcatheters,
- Closed a public offering of approximately 5.8 million Units of common stock and warrants for approximately \$13 million in net proceeds,
- Richard I. Steinhart joined the Board of Directors, including the Audit and Compensation Committees. Mr. Steinhart brings a wealth of experience addressing the business needs of development stage, technology driven companies, including medical device companies and pharmaceutical companies, and
- Began validating a new contract manufacturer for the ForeCYTE Breast Aspirator.

## **2013 Financial Results**

Total revenue for the year ended December 31, 2013, was \$632,558, consisting of \$223,440 of product revenue from sales of MASCT Systems and \$409,118 in diagnostic testing service revenue. This represents an increase of \$150,716, or 31%, from the total revenue of \$481,842 for the year ended December 31, 2012. The growth in revenue was mainly due to \$205,590 in product sales to Millennium HealthCare for the initial purchase of 10,000 ForeCYTE specimen collection kits. Substantially all of Atossa's revenue in 2013 was recognized during the period prior to the voluntary recall of the MASCT System, which commenced in October 2013.

Total cost of revenue in 2013 was \$345,519, consisting of \$239,755 in costs related to the production of the MASCT systems and \$105,764 in costs for NAF cytology testing. Loss on reduction of inventory to lower of cost or market and obsolete inventory was \$149,946 due to the recall of MASCT Systems in October 2013.

Gross profit for the twelve months ended December 31, 2013, was \$303,354 for the diagnostic testing service and a loss of \$166,261 for the product sales of MASCT, including \$149,946 loss on obsolete inventory, compared to gross profit of \$416,213 for the twelve months ended December 31, 2012, consisting of \$23,444 loss for the product sales (\$29,884 loss in LCM) and \$439,657 in diagnostic testing.

Total operating expenses were \$10,921,736 for the twelve months ended December 31, 2013, consisting of G&A expenses of \$8,558,835, R&D expenses of \$1,105,110, and selling expenses of \$1,257,791, representing an increase of \$5,436,493, or 99%, from \$5,485,243 in the same period in 2012, consisting of G&A expenses of \$3,044,409, R&D expenses of \$1,974,013, and selling expenses of \$466,821. The increase in operating expenses was mainly due to the Company's growth and commercialization of the MASCT System.

Selling expenses for the year ended December 31, 2013, were \$1,257,791, an increase of \$790,970, or 169%, from \$466,821 in the same period in 2012. Our selling expenses consisted of \$560,111 in personnel expenses, \$570,092 in advertising and marketing, and \$126,507 in cost of ForeCYTE specimen collection kits that were provided complimentary to the physicians as promotional kits. Prior to the voluntary recall in October 2013, Atossa distributed the kits to customers at no cost and bundled them with the MASCT System.

General and administrative expenses for the year ended December 31, 2013, were \$8,558,835, an increase of \$5,514,426, or 181%, from the \$3,044,409 for the twelve months ended December 31, 2012. G&A expenses for the twelve months ended December 31, 2013, primarily consisted of \$2,219,685 in salaries and bonus expense, \$3,202,036 in regulatory, legal and other professional services, \$163,623 in travel expense, \$185,123 in payroll taxes, \$418,860 in insurance expense, \$435,243 in recall expenses, and \$354,860 in bad debt expenses. G&A expenses for the twelve months ended December 31, 2012, consisted of \$340,516 in personnel expenses, \$1,754,483 in legal and other professional services, \$113,399 in insurance expenses, and \$86,488 in payroll taxes. The year-over-year increase in G&A expenses is mainly due to hiring additional staff and outside professional services to support the launch of the Company's MASCT System, NAF cytology test, and the related growth to expand the Company's operations.

Research and development expenses for year ended December 31, 2013, were \$1,105,110, a decrease of \$868,903, or 44%, from \$1,974,013 in the same period in 2012. The decrease in R&D expenses is attributed to the completion of the development of the MASCT System for the national launch in 2013.

Net loss for the year ended December 31, 2013, was \$10,784,708, or \$(0.70) per share, compared with net loss of \$5,079,851, or \$(0.41) per share, for 2012. The increase in net loss was primarily attributable to an increase in general and administrative expense, including increased expenses related to the national launch of the MASCT System.

### **Conference Call Information**

Management will host a conference call today, March 27, 2014, at 4:45 pm Eastern Time to review only the financial results, the new financing facility and our pipeline. To listen to the call by phone, interested parties within the U.S. may dial 866-652-5200 or 412-317-6060 for international callers. 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](http://www.atossagenetics.com).

A replay of the call will be available one hour after the end of the call through April 28, 2014, and can be accessed via Atossa's website or by dialing 877-344-7529 (domestic) or 412-317-0088 (international). The replay conference ID number is 10041148.

### **About Atossa Genetics**

Atossa Genetics Inc. is focused on improving breast health through the development of laboratory developed tests (LDTs), medical devices and therapeutics. The Company's LDTs are being developed by its subsidiary, The National Reference Laboratory for Breast Health, Inc. The LDT's 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](http://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 timing of review by the FDA of 510(k) submissions, and actions related thereto, whether Atossa can submit additional information to the FDA in a timely fashion and whether the FDA will find that information acceptable and/or request additional information, the outcome of the FDA re-inspection completed on March 14, 2014, 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, performance of distributors, estimated future expenses and cash needs, whether Atossa can launch 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.

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[TABLES FOLLOW]



**ATOSSA GENETICS, INC.**  
**(A DEVELOPMENT STAGE COMPANY)**  
**CONSOLIDATED BALANCE SHEETS**

<u>Assets</u>	<b>As of December 31,</b>	
	<b>2013</b>	<b>2012</b>
<b>Current assets</b>		
Cash and cash equivalents	\$ 6,342,161	\$ 1,725,197
Accounts receivable, net	139,072	141,666
Prepaid expenses	932,588	122,633
Total current assets	7,413,821	1,989,496
<b>Fixed assets</b>		
Furniture and equipment, net	163,147	159,967
Total fixed assets	163,147	159,967
<b>Other assets</b>		
Security deposit	36,446	36,446
Intangible assets, net	4,395,633	4,640,224
Total other assets	4,432,079	4,676,670
Total assets	\$ 12,009,047	\$ 6,826,133
<b><u>Liabilities and Stockholders' Equity</u></b>		
<b>Current liabilities</b>		
Accounts payable	\$ 9,634	\$ 68,217
Accrued expenses	637,986	1,342,358
Deferred rent	48,157	-
Payroll liabilities	476,477	207,997
Contingent liabilities	211,493	-
Other current liabilities	23,649	32,026
Total current liabilities	1,407,396	1,650,598
<b>Stockholders' equity</b>		
Preferred stock - \$.001 par value; 10,000,000 shares authorized, 0 shares issued and outstanding	-	-
Common stock - \$.001 par value; 75,000,000 shares authorized, 18,574,334 and 12,919,367 shares issued and outstanding	18,574	12,919
Additional paid-in capital	31,099,691	14,894,522
Accumulated deficit	(20,516,614)	(9,731,906)
Total stockholders' equity	10,601,651	5,175,535
Total liabilities and stockholders' equity	\$ 12,009,047	\$ 6,826,133

**ATOSSA GENETICS, INC.**  
**(A DEVELOPMENT STAGE COMPANY)**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**

	<b>For the Years Ended December 31,</b>		<b>From April 30, 2009 (Inception) Through December</b>
	<b>2013</b>	<b>2012</b>	<b>31, 2013</b>
<b>Revenue</b>			
Diagnostic testing service	\$ 409,118	\$ 475,402	\$ 884,520
Product sales	223,440	6,440	231,380
<b>Total revenue</b>	<b>632,558</b>	<b>481,842</b>	<b>1,115,900</b>
<b>Cost of revenue</b>			
Diagnostic testing service	105,764	35,745	141,509
Product sales	239,755	-	244,919
<b>Total cost of revenue</b>	<b>345,519</b>	<b>35,745</b>	<b>386,428</b>
Loss on obsolete inventory & LCM	149,946	29,884	271,856
<b>Gross profit</b>	<b>137,093</b>	<b>416,213</b>	<b>457,616</b>
Selling expenses	1,257,791	466,821	1,897,667
Research and development expenses	1,105,110	1,974,013	4,662,496
General and administrative expenses	8,558,835	3,044,409	14,381,171
<b>Total operating expenses</b>	<b>10,921,736</b>	<b>5,485,243</b>	<b>20,941,334</b>
<b>Operating loss</b>	<b>(10,784,643)</b>	<b>(5,069,030)</b>	<b>(20,483,718)</b>
Interest income	295	1,219	6,883
Interest expense	360	12,040	39,531
<b>Net loss before Income taxes</b>	<b>(10,784,708)</b>	<b>(5,079,851)</b>	<b>(20,516,366)</b>
Income taxes	-	-	248
<b>Net loss</b>	<b>\$ (10,784,708)</b>	<b>\$ (5,079,851)</b>	<b>\$ (20,516,614)</b>
Loss per common share - basic and diluted	\$ (0.70)	\$ (0.41)	\$ (2.14)
Weighted average shares outstanding, basic & diluted	15,484,414	12,452,929	9,595,967