UNITED STATES SECURITIES AND EXCHANGE COMMISSION



CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of Earliest Event Reported): August 12, 2014

# **Atossa Genetics Inc.**

(Exact name of registrant as specified in its charter).

Delaware (State or other jurisdiction of

incorporation)

001-35610 (Commission File Number) 26-4753208 (I.R.S. Employer Identification No.)

1616 Eastlake Ave. East, Suite 510 Seattle, Washington

(Address of principal executive offices)

98102 (Zip Code)

Registrant's telephone number, including area code: (206) 325-6086

Not Applicable

Former name or former address, if changed since 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 2.02. Results of Operations and Financial Condition.

On August 12, 2014, Atossa Genetics Inc. (the "Company") issued a press release announcing second quarter 2014 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

Exhibit No.	Description
99.1	Press Release, dated August 12, 2014

\* \* \*

# SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: August 12, 2014

Atossa Genetics Inc.

By: /s/ Kyle Guse

Kyle Guse Chief Financial Officer, General Counsel and Secretary

# Exhibit Index

Exhibit No. 99.1 Description Press Release, dated August 12, 2014



#### Atossa Genetics Announces Second Quarter 2014 Financial Results and Provides Company Update

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

SEATTLE, August 12, 2014 -- Atossa Genetics, Inc. (NASDAQ: ATOS) today announced Second Quarter 2014 financial results and provided an update on recent corporate developments.

"During the second quarter of 2014 we hired two key executives and we received important registration certifications, including ISO 13485:2003, EN ISO 13485:2012 and AC:2012, and ISO 9001:2008" stated Dr. Steven C. Quay, Chairman, CEO & President. "We have also generated the information and data that we plan to submit to the FDA on or before August 20, 2014 in response to questions we received from them on our 510(k) submission for the ForeCYTE Breast Aspirator" added Dr. Quay.

#### **Recent Corporate Developments**

Important recent corporate developments include the following:

- Hired two key executives: John E. Sawyer, Sr. VP of Global Regulatory Affairs and Quality Assurance, and Jelle W. Kylstra, M.D., M.B.A., VP of Clinical Research and Development. These executives each have more than 20 years of experience in their respective fields.
- · Continued to execute on our non-U.S. strategy and have now received registration certificates under the following standards:
  - ISO 13485:2003 "Medical devices Quality management systems Requirements for regulatory purposes"
  - EN ISO 13485:2012 and AC:2012 (Canadian)
  - ISO 9001:2008 "Quality managements systems Requirements"

The International Organization for Standardization, or "ISO," is the world's largest developer of international standards which are recognized globally for their stringent criteria.

- Atossa is nearing completion of the preparation of additional information and data to be submitted to the FDA in response to a request from the FDA on February 28, 2014, related to Atossa's 510(k) submission on the ForeCYTE Breast Aspirator. Atossa intends to submit this information and data to the FDA on or before August 20, 2014.
- Atossa entered into a new lease agreement for office space in Seattle, Washington, which will replace Atossa's current administrative offices that are under a lease that will expire in November 2014.

#### Second Quarter 2014 Financial Results

Revenue for the three months and six months ended June 30, 2014 totaled \$9,875 and \$33,999, consisting of additional cash collected in excess of the amounts we previously accrued at the Medicare rates. Total revenue for the three and six months ended June 30, 2013 was \$326,078 and \$508,748. Cost of revenue totaled \$0 for the three months and six months ended June 30, 2014, compared to \$222,160 and \$288,624 in the same periods in 2013.

For the three months and six months ended June 30, 2014, gross profit totaled \$9,875 and \$33,999, compared to \$103,918 and \$220,124 in the same period in 2013. The Company has recognized virtually no revenue or cost of revenue since the voluntary recall in October 2013.

For the three months ended June 30, 2014, total operating expenses were \$3,196,408 consisting of general and administrative (G&A) expenses of \$2,462,256, research and development (R&D) expenses of \$510,767, and selling expenses of \$223,385, representing an increase of \$509,143, or 19% from \$2,687,265 in the same period in 2013, consisting of G&A expenses of \$2,177,920, R&D expenses of \$189,955, and selling expenses of \$319,390. Operating expenses for the six months ended June 30, 2014 were \$5,631,457 consisting of G&A expenses of \$4,236,964, R&D expenses of \$933,270, and selling expenses of \$461,223. Operating expenses increased \$886,553, or 19% from \$4,744,904 for the same period in 2013 consisting of \$3,742,792 in G&A expenses, \$410,147 in R&D expenses, and \$591,965 in selling expenses.

We expect that our G&A and selling expenses will continue to increase in the foreseeable future, and if we successfully relaunch the ForeCYTE Breast Aspirator and begin to offer laboratory tests, we would also begin to incur additional sales and marketing expenses as we continue building a regional, and ultimately national, sales force for both our medical device business and for the laboratory tests offered through our subsidiary, The National Reference Laboratory for Breast Health, Inc., or NRLBH.

Selling expenses for the three months ended June 30, 2014 were \$223,385, a decrease of \$96,005, or 30%, from \$319,390 for the three months ended June 30, 2013. Selling expenses for the three months ended June 30, 2014 consisted primarily of \$115,640 in selling and marketing professional fees and \$106,985 in compensation expenses. Selling expenses for the six months ended June 30, 2014 were \$461,223, a decrease of \$130,742, or 22% from \$591,965 for the same period in 2013. Selling expenses for the six months ended June 30, 2014 consisted of \$192,989 in salaries and \$267,474 in selling and marketing professional fees.

Selling expenses decreased as a result of the voluntary recall in October 2013. We expect selling expenses will increase when we receive the FDA clearance and prepare for and execute the relaunch of ForeCYTE Breast Aspirator and as the NRLBH begins to offer laboratory tests.

R&D expenses for the three months ended June 30, 2014 were \$510,767, an increase of \$320,812, or 169%, from \$189,955 for the three months ended June 30, 2013. R&D expenses for the six months ended June 30, 2014 were \$933,270, an increase of \$523,123, or 128% from the same period in 2013.

The increase in R&D expenses in 2014 is attributed to additional R&D expenditures on the development of our new products and tests in the pipeline, including the NextCYTE Test and FullCYTE microcatheters. We expect that our R&D expenses will continue to increase as we add additional full time employees and incur additional costs to continue the development of our products and services under development throughout 2014.

G&A expenses for the three months ended June 30, 2014 were \$2,462,256, an increase of \$284,336, or 13%, from \$2,177,920 in the same period in 2013. The G&A expenses for the three months ended June 30, 2014 consisted primarily of \$818,906 in compensation expenses, \$606,696 in legal and regulatory expenses, \$330,992 in consulting and professional fees, \$53,737 in travel expenses, \$124,101 in insurance expenses, \$127,827 in amortization and depreciation expenses, and \$104,167 in Board of Directors fees. G&A expenses for the three months ended June 30, 2013 were \$2,177,920 which primarily consisted of \$457,165 in compensation expenses, \$162,106 in legal expenses, \$615,846 in consulting and professional fee expenses, \$48,059 in travel expenses, \$96,588 in insurance expenses, and \$391,029 in Board of Directors annual fees consisting of cash fees and the non-cash expense associated with fees paid in the form of options.

G&A expenses for the six months ended June 30, 2014 were \$4,236,964, an increase of \$494,172, or 13% from \$3,742,792 for the same period in 2013. G&A expenses for the six months June 30, 2014 primarily consisted of \$1,484,041 in compensation expenses, \$816,459 in legal fees, \$589,197 in consulting and professional fees, \$97,763 in travel expenses, \$256,893 in insurance expenses, \$64,758 in bad debt expenses, \$252,921 in amortization and depreciation expenses, and \$123,167 in Board of Directors fees. G&A expenses for the six months ended June 30, 2013 mainly consisted of \$964,025 in compensation expenses, \$340,053 in legal expenses, \$1,219,099 in consulting and professional fees, \$68,545 in travel expenses, \$159,510 in insurance expenses, \$105,771 in marketing expenses, and \$436,029 in Board of Directors fees.

## **Conference Call Information**

Management will host a conference call today, August 12, 2014, at 4:45 pm Eastern Time to review the financial results and recent corporate developments. 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 <u>www.atossagenetics.com</u>.

A replay of the call will be available one hour after the end of the call through September 12, 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 10046259.

#### **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 <u>www.atossagenetics.com</u>.

#### **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 and/or clear the ForeCYTE Breast Aspirator for marketing in the U.S., 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 in the United States and foreign markets 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.

#### **Contact:**

Atossa Genetics, Inc. Kyle Guse CFO and General Counsel (O) 800-351-3902 Kyle.Guse@atossagenetics.com

Investor Relations: CorProminence LLC Scott Gordon President 516 222 2560 scottg@corprominence.com

# ATOSSA GENETICS INC.CONDENSED CONSOLIDATED BALANCE SHEETS

	June 30, 2014 (Unaudited)		December 31, 2013 (Audited)	
Assets				<u> </u>
Current assets				
Cash and cash equivalents	\$	14,298,491	\$	6,342,161
Accounts receivable, net		48,155		139,072
Prepaid expense		325,346		280,627
Inventory, net		1,910		-
Total current assets		14,673,902		6,761,860
Furniture and equipment, net		127,741		163,147
Intangible assets, net		4,454,185		4,395,633
Deferred financing costs		501,961		651,961
Security deposit		61,309		36,446
Total assets	\$	19,819,098	\$	12,009,047
Liabilities and Stockholders' Equity				
Current liabilities				
	\$	700 104	\$	248,142
Accounts payable Accrued expenses	Э	790,184 226,642	Э	240,142 399,478
Deferred rent		220,042		48,157
Payroll liabilities		508,646		46,137
Product recall liabilities		12,028		211,493
Other current liabilities				
Total current liabilities		4,622		23,649
		1,563,494		1,407,396
Stockholders' Equity				
Preferred stock - \$.001 par value; 10,000,000 shares authorized, 0 shares issued and outstanding at June 30,				
2014 and December 31, 2013, respectively		-		-
Common stock - \$.001 par value; 75,000,000 shares authorized, 24,444,058 and 18,574,334 shares issued and				
outstanding at June 30, 2014 and December 31, 2013, respectively		24,444		18,574
Additional paid-in capital		44,347,281		31,099,691
Accumulated deficit		(26,116,121)		(20,516,614)
Total stockholders' equity		18,255,604		10,601,651
Total liabilities and stockholders' equity	¢	10 010 000	¢	12 000 047
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# ATOSSA GENETICS INC. CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (UNAUDITED)

	For the Three Months Ended June 30,				For The Six Months Ended June 30,			
		2014		2013		2014		2013
Revenue								
Diagnostic testing service	\$	9,875	\$	120,488	\$	33,999	\$	289,718
Product sales		-		205,590		-		219,030
Total Revenue		9,875		326,078		33,999		508,748
Cost of Revenue								
Diagnostic testing service		-		2,356		-		49,955
Product sales		-		219,804		-		238,669
Total Cost of Revenue		-		222,160		-		288,624
Gross Profit		9,875		103,918		33,999		220,124
				;				
Selling expenses		223,385		319,390		461,223		591,965
Research and development expenses		510,767		189,955		933,270		410,147
General and administrative expenses		2,462,256		2,177,920		4,236,964		3,742,792
Total operating expenses		3,196,408		2,687,265		5,631,457		4,744,904
Operating Loss		(3,186,533)		(2,583,347)		(5,597,458)		(4,524,780)
Interest income		-		-		143		-
Interest expense		1,443		352		2,192		359
Loss before Income Taxes		(3,187,976)		(2,583,699)		(5,599,507)		(4,525,139)
Income Taxes		-		-		-		-
Net Loss	\$	(3,187,976)	\$	(2,583,699)	\$	(5,599,507)	\$	(4,525,139)
Loss per common share - basic and diluted	\$	(0.23)	\$	(0.17)	\$	(0.24)	\$	(0.32)
Weighted average shares outstanding, basic & diluted	- -	24,430,346	-	14,808,728		23,515,576	-	14,120,962