

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 12, 2015

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.)

2300 Eastlake Ave. East, Suite 200
Seattle, Washington

(Address of principal executive offices)

98102

(Zip Code)

Registrant's telephone number, including area code: (206) 588-0256

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))
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Item 2.02. Results of Operations and Financial Condition.

On November 12, 2015, Atossa Genetics Inc. (the “Company”) issued a press release announcing third quarter 2015 financial results and a company update. 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

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release, dated November 12, 2015

* * *

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: November 12, 2015

Atossa Genetics Inc.

By: /s/ Kyle Guse

Kyle Guse

Chief Financial Officer, General Counsel and Secretary

Exhibit Index

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release, dated November 12, 2015



Atossa Genetics Announces Third Quarter 2015 Financial Results and Provides Company Update

Conference Call to be Held Today at 4:30 pm Eastern Time

SEATTLE, November 12, 2015 — Atossa Genetics Inc. (NASDAQ: ATOS) today announced third quarter 2015 financial results and provided an update on recent company developments.

Dr. Steven C. Quay, Chairman, CEO & President, commented, “We are very pleased with our ongoing progress in establishing our two Phase II pharmaceutical clinical programs, topical Afimoxifene Gel and intraductal fulvestrant, both of which have extensive patent portfolios. Today we are announcing that the National Cancer Institute has approved protocol development for a study to be funded by them using Afimoxifene Gel in their Cancer Prevention Clinical Trials Program. With respect to intraductal fulvestrant, we are on track to commence the study in women with ductal carcinoma in situ, or DCIS, during December 2015.”

Dr. Quay added, “We are taking a number of steps to address recent adverse changes in Medicare reimbursement for our pharmacogenomics test and to improve our pharmacogenomics test revenue, including the recent addition of additional sales personnel, targeting conditions and drugs that provide a higher rate of reimbursement, and enhancing sales incentives to drive sales volume.”

Concluding, Dr. Quay commented, “We have much to look forward to in the last quarter of 2015 and into 2016. Our Phase II pharmaceutical development programs are expected to produce a number of value-creating milestones over the next six months for our shareholders

Recent Corporate Developments

Important recent corporate developments include the following:

- Announced today that the National Cancer Institute, Division of Cancer Prevention, has approved a Letter of Intent submitted by a member of the Consortia for Cancer Prevention Clinical Trials Program for the study of Afimoxifene Gel in women with DCIS. The Consortia includes five major medical research centers: the University of Arizona, Northwestern University, Mayo Clinic Foundation, M. D. Anderson Cancer Center and the University of Wisconsin.
- Held an advisory meeting in San Francisco with leading breast surgeons and oncologists and received advice on the clinical pathway and commercial opportunities for Afimoxifene Gel.
- Announced FDA acceptance of our Investigational New Drug Application to begin a Phase II clinical trial of Fulvestrant for the potential treatment of DCIS and cancer using Atossa's patented intraductal microcatheter and patented methods of delivering pharmaceuticals.
- Filed an application with the American Medical Association for a CPT code for the collection of nipple aspirate fluid at a doctor's office.
- Signed manufacturing and quality agreements with AAIPharma Services Corp. / Cambridge Major Laboratories, Inc. (AAI/CML) for the manufacturing of a clinical supply for 4-Hydroxytamoxifen, the active pharmaceutical ingredient in Afimoxifene Gel.
- Received approval to begin a clinical study in Israel to evaluate Atossa's ForeCYTE breast aspirator in the collection of nipple aspirate fluid.
- Hired Janet Rose Rea, M.S.P.H. as VP Regulatory Affairs and Quality.
- Atossa Genetics' laboratory received ISO 15189:2012 certification.
- Promoted Scott Youmans to Chief Operating Officer.

Third Quarter 2015 Financial Results

For the three months and nine months ended September 30, 2015, we had total net revenue of \$772,244 and \$5,339,669, respectively, consisting of pharmacogenomics testing, compared to \$3,426 and \$37,425 of revenue in the same periods in 2014, which consisted of additional cash collections on NAF cytology tests performed in 2013. Our pharmacogenomics test was launched in the fourth quarter of 2014 and we did not generate revenue in 2014 prior to that. In March 2015, we introduced the FullCYTE Breast Aspirator in the U.S. and the ForeCYTE Breast Aspirator in the EU; however, we have not generated any revenue in 2015 from sales of these products.

For the three months and nine months ended September 30, 2015, gross profit totaled \$458,838 and \$1,963,598, respectively, which was attributable to pharmacogenomics testing, compared to \$3,426 and \$37,425, in the same period in 2014. Total cost of revenue for the three months and nine months ended September 30, 2015 was \$313,406 and \$3,376,071, respectively, consisting of costs relating to pharmacogenomics testing services; there was no cost of revenue during the same periods in 2014 as the only revenue generated during those periods was from additional cash collections on NAF cytology tests performed in 2013.

For the three months ended September 30, 2015, total operating expenses were \$4,846,294, consisting of general and administrative (G&A) expenses of \$3,017,909, research and development (R&D) expenses of \$1,090,349, and selling expenses of \$738,036, representing an increase of \$1,597,613, or 49% from \$3,248,681 in the same period in 2014, consisting of G&A expenses of \$2,043,138, R&D expenses of \$923,169, and selling expenses of \$282,374. Operating expenses for the nine months ended September 30, 2015 were \$12,828,874 consisting of G&A expenses of \$8,413,891, R&D expenses of \$2,398,032, and selling expenses of \$2,016,951. Operating expenses increased \$3,948,736, or 44% from \$8,880,138 for the same period in 2014 consisting of \$6,280,102 in G&A expenses, \$1,856,439 in R&D expenses, and \$743,597 in selling expenses.

The increase in selling expenses is mainly due to increases in compensation expenses, travel, and advertisement as a result of the ForeCYTE and FullCYTE launch in Europe and the United States. We expect that our selling expenses will continue to increase during 2015, as we build a sales force in the United States to support primarily the services offered by the NRLBH, pharmacogenomics tests and potentially other tests.

G&A expenses consist primarily of personnel and related benefit costs, facilities, professional services, insurance, and public company related expenses. The increase in G&A expenses is mainly due to an increase in compensation expenses, professional fees, and recruiting fees as we increased our headcount to support the launch of our new products. The increase also reflects an increase in bad debt expenses as a result of significant increases in revenue and also higher than expected denials on non-Medicare appeals from prior periods.

We expect our G&A and selling expenses to continue to grow throughout 2015 as we hire additional administrative and manufacturing personnel to support the increased sales and operating activities as we promote, market and sell our pharmacogenomics testing and our other products and services under development.

The increase in R&D expenses is attributed to additional R&D expenditures on the launch and development of ForeCYTE and FullCYTE in the first quarter of 2015. We expect that our R&D expenditures will continue to grow as we develop our new products and tests in the pipeline, including Afimoxifene Gel, our intraductal microcatheters and our NextCYTE test and other laboratory tests we may develop. We will add additional full-time employees and incur additional costs to continue the development of our products and services under development, including the development of our potential pharmaceuticals and conducting clinical studies.

Conference Call Information

Management will host a conference call on Thursday, November 12, 2015 at 4:30 pm eastern time to review financial results and corporate highlights. Following management's formal remarks, there will be a question and answer session.

To listen to the call by phone, interested parties within the U.S. should call 1-866-652-5200 and International callers should call 1-412-317-6060. 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. Details for the webcast may be found on the Company's IR events page at <http://ir.atossagenetics.com/ir-calendar>.

A replay of the call will be available approximately one hour after the end of the call through December 12, 2015. The replay can be accessed via Atossa's website or by dialing 877-344-7529 (domestic) or 412-317-0088 (international) or Canada Toll Free at 855-669-9658. The replay conference ID number is 10075755.

About Atossa Genetics

Atossa Genetics Inc. is focused on improving breast health through the development of pharmaceuticals to treat breast health conditions and through the commercialization of medical devices and laboratory services. The laboratory services are being developed by its subsidiary, The National Reference Laboratory for Breast Health Inc. The laboratory's services 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 more information, please visit 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, the outcome or timing of regulatory approvals needed by Atossa to sell its products, responses to regulatory matters, including recalls of products, Atossa's ability to achieve its objectives, successfully complete clinical studies, continue to manufacture and sell its products, and the safety and efficacy of Atossa's products and services, performance of distributors, whether Atossa can launch and commercialize 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. Atossa does not undertake any obligation to update any forward-looking statement.

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ATOSSA GENETICS INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2015 (Unaudited)	December 31, 2014
<u>Assets</u>		
Current assets		
Cash and cash equivalents	\$ 7,839,439	\$ 8,500,718
Restricted cash	275,000	-
Accounts receivable, net	1,055,059	297,958
Prepaid expenses	201,652	247,207
Inventory, net	170,860	39,788
Total current assets	9,542,010	9,085,671
Furniture and equipment, net	484,544	357,532
Intangible assets, net	1,768,812	1,920,645
Deferred financing costs	509,375	351,961
Other assets	52,649	48,193
Total assets	\$ 12,357,390	\$ 11,764,002
<u>Liabilities and Stockholders' Equity</u>		
Current liabilities		
Accounts payable	\$ 1,179,329	\$ 594,357
Accrued expenses	934,675	444,861
Payroll liabilities	1,156,000	1,056,705
Short-term lease obligations	-	76,025
Other current liabilities	22,601	42,228
Total current liabilities	3,292,605	2,214,176
Deferred rent	5,688	2,483
Long-term lease obligations	-	49,216
Total liabilities	3,298,293	2,265,875
Stockholders' equity		
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, 30,446,260 and 24,564,058 shares issued and outstanding	30,446	24,564
Additional paid-in capital	55,001,918	44,648,103
Accumulated deficit	(45,973,267)	(35,174,540)
Total stockholders' equity	9,059,097	9,498,127
Total liabilities and stockholders' equity	\$ 12,357,390	\$ 11,764,002

ATOSSA GENETICS INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(UNAUDITED)

	For the Three Months Ended September 30,		For The Nine Months Ended September 30,	
	2015	2014	2015	2014
Net revenue	\$ 772,244	\$ 3,426	\$ 5,339,669	\$ 37,425
Cost of revenue	313,406	-	3,376,071	-
Gross profit	458,838	3,426	1,963,598	37,425
Operating expenses:				
Selling	738,036	282,374	2,016,951	743,597
Research and development	1,090,349	923,169	2,398,032	1,856,439
General and administrative	3,017,909	2,043,138	8,413,891	6,280,102
Total operating expenses	4,846,294	3,248,681	12,828,874	8,880,138
Operating loss	(4,387,456)	(3,245,255)	(10,865,276)	(8,842,713)
Other income (expense)	69,345	(140)	66,549	(2,189)
Loss before income taxes	(4,318,111)	(3,245,395)	(10,798,727)	(8,844,902)
Income taxes	-	-	-	-
Net loss	\$ (4,318,111)	\$ (3,245,395)	\$ (10,798,727)	\$ (8,844,902)
Loss per common share - basic and diluted	\$ (0.15)	\$ (0.13)	\$ (0.39)	\$ (0.37)
Weighted average shares outstanding, basic & diluted	28,766,012	24,537,379	27,500,855	23,860,843