ATOSSA GENETICS INC
Form 10-Q
November 12, 2015

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

x **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15 (d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the quarterly period ended September 30, 2015

OR

.. **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15 (d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from _____ to _____

Commission file number: 001-35610

ATOSSA GENETICS INC.

(Exact name of registrant as specified in its charter)

Delaware	**26-4753208**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
2300 Eastlake Ave. East, Suite 200 Seattle, WA	**98102**
(Address of principal executive offices)	(Zip Code)

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

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes þ No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes þ No ¨

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See definition of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ¨ Accelerated filer ¨ Non-accelerated filer ¨ Smaller reporting company þ

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ¨ No þ

The number of shares of the registrant's common stock, $0.001 par value per share, outstanding at November 12, 2015 was 30,446,260.

ATOSSA GENETICS INC.

FORM 10-Q

QUARTERLY REPORT

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PART I. FINANCIAL INFORMATION

ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

ATOSSA GENETICS INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2015 (Unaudited)	December 31, 2014
Assets		
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
Liabilities and Stockholders' Equity		
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
Commitments and contingencies (note 13)		

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

The accompanying notes are an integral part of these condensed consolidated financial statements.

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

The accompanying notes are an integral part of these condensed consolidated financial statements.

ATOSSA GENETICS INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(UNAUDITED)

	For the Nine Months Ended September 30,	
	2015	2014
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$(10,798,727)	$(8,844,902)
Compensation cost for stock options granted	703,726	545,115
Depreciation and amortization	249,744	380,977
Gain on disposal of assets	(74,800)	-
Bad debt expense	1,188,193	80,870
Changes in operating assets and liabilities:		
Restricted cash	(275,000)	-
Accounts receivable	(1,878,795)	29,051
Inventory	(131,072)	(45,867)
Prepaid expenses	45,555	(71,099)
Other assets	(4,456)	(42,512)
Accounts payable	326,769	191,106
Payroll liabilities	99,295	205,879
Deferred rent	11,298	(39,608)
Accrued expenses	566,118	(5,774)
Product recall liabilities	-	(208,108)
Other current liabilities	(27,720)	(11,274)
Net cash used in operating activities	(9,999,872)	(7,836,146)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of furniture and equipment	(95,196)	(102,530)
Purchase of intangible assets	(15,553)	(184,979)
Net cash used in investing activities	(110,749)	(287,509)
CASH FLOWS FROM FINANCING ACTIVITIES		
Net proceeds from issuance of common stock and warrants	9,498,557	13,155,745
Payments on capital lease obligations	(49,215)	-
Net cash provided by financing activities	9,449,342	13,155,745
NET DECREASE IN CASH AND CASH EQUIVALENTS	(661,279)	5,032,090
CASH AND CASH EQUIVALENTS, BEGINNING BALANCE	8,500,718	6,342,161
CASH AND CASH EQUIVALENTS, ENDING BALANCE	$7,839,439	$11,374,251
SUPPLEMENTAL DISCLOSURES:		

Interest paid	$284	$2,343
NONCASH INVESTING AND FINANCING ACTIVITIES:		
Noncash reclassification of prepaid license fees	$-	$15,000
Purchases of equipment recorded in accounts payable	$128,875	$-
Amortization of deferred financing costs	$453,836	$-

The accompanying notes are an integral part of these condensed consolidated financial statements.

ATOSSA GENETICS INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

NOTE 1: NATURE OF OPERATIONS

Atossa Genetics Inc. (the "Company") was incorporated on April 30, 2009 in the State of Delaware. The Company was formed to develop and market medical devices, laboratory tests and therapeutics to address breast health conditions. The Company's fiscal year ends on December 31st.

The Company's current therapeutic programs include Afimoxifene Gel and Fulvestrant administered through the Company's patented intraductal Microcatheters, both of which are in Phase II clinical development. The Company's medical devices consist primarily of its ForeCYTE Breast Aspirator (formerly called the Mammary Aspirate Specimen Cytology Test System, or MASCT), the FullCYTE Breast Aspirator and the intraductal Microcatheters. In December 2011, the Company established The National Reference Laboratory for Breast Health, Inc., the NRLBH, as a wholly-owned subsidiary which performs nipple aspirate fluid ("NAF") cytology testing on NAF specimens, including those collected with the Company's breast aspirator devices, and pharmacogenomics tests. The NRLBH is certified by College of American Pathologists (CAP) and by Clinical Laboratory Improvement Amendments (CLIA) and it is certified under ISO 15189:2012.

Since its inception, the Company has been dependent upon the receipt of capital investment to fund its continuing activities. In addition to the normal risks associated with a new business venture, there can be no assurance that the Company's business plan will be successfully executed. The Company's ability to execute its business plan will depend on its ability to obtain additional financing and achieve a profitable level of operations. There can be no assurance that sufficient financing will be obtained. Further, the Company cannot give any assurance that it will generate substantial revenue or that its business operations will prove to be profitable.

NOTE 2: GOING CONCERN

The Company's consolidated financial statements are prepared using generally accepted accounting principles in the United States of America ("GAAP") applicable to a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The Company has incurred net losses and negative operating cash flows since inception. For the nine months ended September 30, 2015, the Company recorded a net loss of approximately $10.8 million and used approximately $10 million of cash in operating activities. As of

September 30, 2015, the Company had approximately $7.8 million in cash and cash equivalents and working capital of approximately $6.2 million. The Company has not yet established an ongoing source of revenue sufficient to cover its operating costs and allow it to continue as a going concern. The ability of the Company to continue as a going concern is dependent on the Company obtaining adequate capital to fund operating losses until it becomes profitable. The Company can give no assurances that any additional capital that it is able to obtain, if any, will be sufficient to meet its needs, or that any such financing will be obtainable on acceptable terms. If the Company is unable to obtain adequate capital, it could be forced to cease operations or substantially curtail is commercial activities. These conditions raise substantial doubt as to the Company's ability to continue as a going concern. The accompanying consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts and classification of liabilities should the Company be unable to continue as a going concern.

Management's Plan to Continue as a Going Concern

In order to continue as a going concern, the Company will need, among other things, additional capital resources. Management's plans to obtain such resources for the Company include (1) obtaining capital from the sale of its equity securities, (2) sales of the ForeCYTE and FullCYTE Breast Aspirators and laboratory service revenue, and (3) short-term borrowings from the banks, stockholders or related party(ies), if needed. However, management cannot provide any assurance that the Company will be successful in accomplishing any of its plans.

The ability of the Company to continue as a going concern is dependent upon its ability to successfully accomplish the plans described in the preceding paragraph and eventually to secure other sources of financing and attain profitable operations.

NOTE 3: SUMMARY OF ACCOUNTING POLICIES

Basis of Presentation:

The accompanying condensed consolidated financial statements have been prepared pursuant to the rules of the Securities and Exchange Commission ("SEC"). Certain information and footnote disclosures, normally included in annual financial statements prepared in accordance with U.S. generally accepted accounting principles ("GAAP"), have been condensed or omitted pursuant to those rules and regulations. The Company believes disclosures made are adequate to make the information presented not misleading. In the opinion of management, all adjustments which consist only of normal recurring adjustments necessary to fairly state the financial position, results of operations and cash flows with respect to the interim condensed consolidated financial statements have been included. The results of operations for the interim periods are not necessarily indicative of the results of operations for the entire fiscal year. Reference is made to the Company's audited annual financial statements included in its Annual Report on Form 10-K for the year ended December 31, 2014, which contain information useful to understanding the Company's business and financial statement presentations. The Condensed Consolidated Balance Sheet as of December 31, 2014 was derived from the Company's most recent audited financial statements, but does not include all disclosures required by

GAAP for a year-end balance sheet. The Company's significant accounting policies and practices are presented as Note 3 to the consolidated financial statements included in the Annual Report. The accompanying condensed consolidated financial statements include the financial statements of Atossa Genetics Inc. and its wholly-owned subsidiary, the NRLBH. All significant intercompany account balances and transactions have been eliminated in consolidation. These condensed consolidated financial statements have been prepared in accordance with GAAP.

Use of Estimates:

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Actual results could differ from those estimates.

Revenue Recognition

The Company recognizes product and service revenue in accordance with GAAP when the following overall fundamental criteria are met: (i) persuasive evidence of an arrangement exists, (ii) delivery has occurred or the service has been performed, (iii) the Company's price to the customer is fixed or determinable, and (iv) collection of the resulting accounts receivable is reasonably assured.

Service Revenue

Diagnostic testing revenue is recognized upon completion of the test, communication of results to the patient's physician, and when collectability is reasonably assured. Patient requisition forms and/or contracts are generally used to determine the existence of an arrangement.

Services are provided to self-pay patients or patients covered by various commercial insurance plans and Medicare programs. Revenue for services under insurance plans are recognized net of allowances for contractual discounts and allowances for differences between the amounts we bill and expected payment amounts. The Company records revenue for diagnostic testing on an accrual basis based on the amount expected to be collected based on historical benefits allowed for Medicare and non-Medicare payer. The expected revenues from non-Medicare payers are based on the historical experience of each payer or payer group, as appropriate. The assumptions used to determine the expected benefits allowed are reasonable considering known facts and circumstances and may change as we develop more history. If the actual amount received from the payers or patients are different than the original accrual amount, revenue is subsequently adjusted.

Accounts Receivable

Accounts receivable are recorded at net realizable value consisting of the carrying amount less an allowance for doubtful accounts, as needed. The Company assesses the collectability of accounts receivable based primarily upon the creditworthiness of the customer as determined by credit checks and analysis, as well as the customer's payment history. Management reviews the composition of accounts receivable and analyzes historical bad debts, customer concentrations, customer creditworthiness, current economic trends, and changes in customer payment patterns to evaluate the adequacy of the allowance for doubtful accounts. Based on the historical experience for our accounts, management has determined, based on a detailed analysis, that accounts receivable associated with certain billings are unlikely to be collected. The Company's allowance for doubtful accounts was $1,182,777 and $564,456 at September 30, 2015 and December 31, 2014, respectively. Bad debt expense is included in general and administrative expense on the Company's consolidated statements of operations. Bad debt expense was $1,188,193 and $80,870 for the nine months ended September 30, 2015 and 2014, respectively, and was $625,499 and $16,111 for the three months ended September 30, 2015 and 2014, respectively.

Recently Issued Accounting Pronouncements:

In May 2014, the Financial Accounting Standards Board (the "FASB") issued Accounting Standards Update ("ASU") No. 2014-09, *Revenue from Contracts with Customers: Topic 606* ("ASU 2014-09"), to supersede nearly all existing revenue recognition guidance under GAAP. The core principle of ASU 2014-09 is to recognize revenues when promised goods or services are transferred to customers in an amount that reflects the consideration that is expected to be received for those goods or services. ASU 2014-09 defines a five step process to achieve this core principle and, in doing so, it is possible more judgment and estimates may be required within the revenue recognition process than required under existing GAAP including identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation. ASU 2014-09 is effective for the Company in the first quarter of 2017 using either of two methods: (i) retrospective to each prior reporting period presented with the option to elect certain practical expedients as defined within ASU 2014-09; or (ii) retrospective with the cumulative effect of initially applying ASU 2014-09 recognized at the date of initial application and providing certain additional disclosures as defined per ASU 2014-09. The Company is currently evaluating the impact of its pending adoption of ASU 2014-09 on its consolidated financial statements.

In August, 2014, FASB issued ASU 2014-15, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern.* This ASU requires management to determine whether substantial doubt exists regarding the entity's going concern presumption, which generally refers to an entity's ability to meet its obligations as they become due. If substantial doubt exists but is not alleviated by management's plan, the footnotes must specifically state that "there is substantial doubt about the entity's ability to continue as a going concern within one year after the financial statements are issued." In addition, if substantial doubt exists, regardless of whether such doubt was alleviated, entities must disclose: (a) principal conditions or events that raise substantial doubt about the entity's ability to continue as a going concern (before consideration of management's plans, if any); (b) management's evaluation of the significance of those conditions or events in relation to the entity's ability to meet its obligations; and (c) management's plans that are intended to mitigate the conditions or events that raise substantial doubt, or that did alleviate substantial doubt, about the entity's ability to continue as a going concern. If substantial doubt has not been alleviated, these disclosures should become more extensive in subsequent reporting periods as additional information becomes available. In the period that substantial doubt no longer exists (before or after considering management's plans), management should disclose how the principal conditions and events that originally gave rise to substantial doubt have been resolved. The ASU applies prospectively to all entities for annual periods ending after December 15, 2016, and to annual and interim

periods thereafter. Early adoption is permitted. The Company has not yet adopted the provisions of ASU 2014-15.

NOTE 4: RESTRICTED CASH

Our restricted cash balance of $275,000 as of September 30, 2015, consists entirely of cash pledged as security for the Company's newly issued commercial credit cards.

NOTE 5: PREPAID EXPENSES

Prepaid expenses consisted of the following:

	September 30, 2015	December 31, 2014
Prepaid hardware and software	46,568	38,268
Prepaid insurance	41,668	87,633
Professional fees	41,196	-
Retainer and security deposits	39,218	25,000
Tradeshow and other marketing events	12,500	50,000
Lab supplies	10,481	14,976
Other	10,021	31,330
Total prepaid expenses	$ 201,652	$ 247,207

NOTE 6: FURNITURE AND EQUIPMENT

Furniture and equipment consisted of the following:

	September 30, 2015	December 31, 2014
Machinery and equipment	$ 718,953	$ 522,813
Leasehold improvements	121,596	93,665
Furniture and equipment	840,549	616,478
Less: Accumulated depreciation	(356,005)	(258,946)
Total furniture and equipment	$ 484,544	$ 357,532

Depreciation expense for the three months ended September 30, 2015 and 2014 was $32,620 and $24,643, respectively, and $97,059 and $65,678 for the nine months then ended.

NOTE 7: INTANGIBLE ASSETS

Intangible assets consisted of the following:

	September 30, 2015	December 31, 2014
Patents	$ 1,630,000	$ 1,630,000
Capitalized license costs	200,000	200,000
Software	203,890	203,038
Intangible assets	2,033,890	2,033,038
Less: Accumulated amortization	(265,078)	(112,393)
Total intangible assets, net	$ 1,768,812	$ 1,920,645

Intangible assets amounted to $1,768,812 and $1,920,645 as of September 30, 2015 and December 31, 2014, respectively, and consisted of patents, capitalized license costs and software acquired. The amortization period for the purchased software is three years. Amortization expense related to software for the three months ended September 30, 2015 and 2014 was $11,261 and $4,913, respectively, and $34,090 and $22,436 for the nine months ended September 30, 2015 and September 30, 2014, respectively.

Patents amounted to $1,630,000 as of September 30, 2015 and December 31, 2014, and mainly consisted of patents acquired from Acueity on September 30, 2012 in an asset purchase transaction. Patent assets are amortized based on their determined useful life, and tested annually for impairment. The amortization period was from seven to fourteen years. Amortization expense related to patents was $37,253 and $93,497 for the three months ended September 30, 2015 and 2014, respectively, and $111,761 and $281,196 for the nine months ended September 30, 2015 and 2014, respectively.

Capitalized license costs consist of fees paid to A5 Genetics KFT, Corporation, pursuant to which the Company received the world-wide (other than the European Union) exclusive license to use the software in the NextCYTE test. Amortization expense related to license costs was $5,000 and $5,000 for the three months ended September 30, 2015 and 2014, respectively, and $15,000 and $5,000 for the nine months ended September 30, 2015 and 2014, respectively.

Future estimated amortization expenses as of September 30, 2015 for the five succeeding years are as follows:

For the Year Ending December 31,	Amounts
2015 (includes the remainder of the year)	$53,515
2016	227,130
2017	198,628
2018	169,934
2019	169,015
Thereafter	950,590
	$1,768,812

NOTE 8: ACCRUED EXPENSES

Accrued expenses consisted of the following:

	September 30, 2015	**December 31, 2014**
Accrued commissions	$ 737,991	$ 174,398
Accrued expenses	106,802	254,126
Accrued royalties	89,882	16,337
Total accrued expenses	$ 934,675	$ 444,861

NOTE 9: PAYROLL LIABILITIES

Payroll liabilities consisted of the following:

	September 30, 2015	**December 31, 2014**
Accrued bonus payable	$ 741,596	$ 752,828
Accrued payroll tax liabilities	236,582	194,224
Accrued payroll liabilities	177,822	109,653
Total payroll liabilities	$ 1,156,000	$ 1,056,705

NOTE 10: STOCKHOLDERS' EQUITY

The Company is authorized to issue a total of 85,000,000 shares of stock consisting of 75,000,000 shares of common stock, par value $0.001 per share, and 10,000,000 shares of preferred stock, par value $0.001 per share. The Company has designated 750,000 shares of Series A Junior Participating Preferred Stock, par value $0.001 per share through the filing of a certificate of designation with the Delaware Secretary of State.

On May 19, 2014, the Company adopted a stockholder rights agreement which provided that all stockholders of record on May 26, 2014 received a non-taxable distribution of one preferred stock purchase right for each share of the Company's common stock held by such stockholder. Each right is attached to and trades with the associated share of common stock. The rights will become exercisable only if one of the following occurs: (1) a person becomes an "Acquiring Person" by acquiring beneficial ownership of 15% or more of the Company's common stock (or, in the case of a person who beneficially owned 15% or more of the Company's common stock on the date the stockholder rights agreement was executed, by acquiring beneficial ownership of additional shares representing 2.0% of the Company's common stock then outstanding (excluding compensatory arrangements) or (2) a person commences a tender offer that, if consummated, would result in such person becoming an Acquiring Person. If a person becomes an Acquiring Person, each right will entitle the holder, other than the Acquiring Person and certain related parties, to purchase a number of shares of the Company's common stock with a market value that equals twice the exercise price of the right. The initial exercise price of each right is $15.00, so each holder (other than the Acquiring Person and certain related parties) exercising a right would be entitled to receive $30.00 worth of the Company's common stock. If the Company is acquired in a merger or similar business combination transaction at any time after a person has become an Acquiring Person, each holder of a right (other than the Acquiring Person and certain related parties) will be entitled to purchase a similar amount of stock of the acquiring entity.

2014 Public Offering of Common Stock and Warrants

On January 29, 2014, the Company closed a public offering of 5,834,234 units at the price of $2.40 per unit for total gross proceeds of approximately $14.0 million. Each unit consists of one share of common stock and a warrant to purchase 0.20 of a share of common stock (the "2014 Investor Warrants"). The 2014 Investor Warrants are exercisable at $3.00 per share and callable by the Company at $6.00 per share if certain conditions are met.

Placement Agent Fees

In connection with the 2014 Public Offering, the Company paid Dawson James Securities, Inc. (the "Placement Agent"), a cash fee equal to 7% of the gross proceeds from sale of the units, which resulted in a payment to the Placement Agent of an aggregate of $980,151 (the "Placement Agent Fee"). In addition, the Company entered into Warrant Agreements with the Placement Agent pursuant to which the Placement Agent received 175,027 warrants, or 3% of the aggregate number of shares sold in the offering (the "2014 Placement Agent Warrants" and together with the 2014 Investor Warrants, the "2014 Warrants"). Each 2014 Placement Agent Warrant entitles the Placement Agent to purchase one share of the Company's common stock at $3.00 per share. The cash payment of the $980,151 2014 Placement Agent Fee and the $121,707 aggregated initial fair value of the 2014 Placement Agent Warrants were directly attributable to an actual offering and were charged through additional paid-in capital in accordance with the SEC Staff Accounting Bulletin (SAB) Topic 5A.

Warrants

The 2014 Warrants are exercisable at any time commencing after January 29, 2014. Subject to the call right described above, the 2014 Warrants shall expire and no longer be exercisable on November 29, 2018. The 2014 Warrants cannot be exercised on a cashless basis. There are no redemption features embodied in the 2014 Warrants and they have met the conditions provided in current GAAP accounting standards for equity classification.

2015 Issuance of Additional Shares to Aspire Capital

During the first quarter of 2015, we sold a total of 2,653,199 shares of common stock to Aspire Capital Fund, LLC ("Aspire Capital") under the stock purchase agreement dated November 8, 2013 with aggregate gross proceeds to us of $4,292,349. No shares remain available for sale to Aspire Capital under the terms of the November 8, 2013 agreement with them.

On May 26, 2015, we entered into a new common stock purchase agreement with Aspire Capital Fund, LLC, which provides that, upon the terms and subject to the conditions and limitations set forth therein, Aspire Capital is committed to purchase up to an aggregate of $25.0 million of shares of our common stock over the 30-month term of the purchase agreement. Concurrently with entering into the purchase agreement, we also entered into a registration rights agreement with Aspire Capital, in which we agreed to file one or more registration statements, as permissible and necessary to register under the Securities Act of 1933, registering the sale of the shares of our common stock that have been and may be issued to Aspire Capital under the purchase agreement.

2015 Offering of Common Stock and Pre-Funded Warrants

In June 2015, the Company entered into a Placement Agent Agreement with Roth Capital Partners, LLC. and Dawson James Securities, Inc. (the "2015 Placement Agents"), pursuant to which the Company issued and sold an aggregate of 1,454,003 shares of common stock at the purchase price of $1.15 per share and pre-funded warrants to purchase 3,610,997 shares of common stock (the "Pre-Funded Warrants") at a purchase price of $1.14 per share for net proceeds of $5.2 million after deducting $577,790 of offering expenses (the "2015 Offering"). Each Pre-Funded Warrant is exercisable for $0.01 per share, subject to adjustments from time to time and certain limits on each holder's beneficial ownership of common stock of the Company. Each Pre-Funded Warrant is perpetual in duration.

Placement Agent and Other Fees

In connection with the 2015 Offering, the Company paid the 2015 Placement Agents a cash fee of $463,091, including reimbursement of the legal fees incurred by the 2015 Placement Agents of $57,886, and incurred legal fees of $114,699.

Outstanding Warrants

As of September 30, 2015, warrants to purchase 8,244,423 shares of common stock are outstanding including:

	Outstanding Warrants to Purchase Shares	**Exercise Price**	**Expiration Date**
2011 private placement	4,252,050	$1.25 - 1.60	June 23, 2016
Acueity warrants	325,000	5.00	September 30, 2017
2014 public offering	1,166,849	3.00	January 29, 2019
2015 offering prefunded warrants	2,210,997	0.01	Perpetual
Placement agent fees for Company's offerings	242,027	2.12 – 12.43	March - November, 2018
Outside consulting	47,500	$4.24	January 14, 2018
	8,244,423		

NOTE 11: NET LOSS PER SHARE

The Company accounts for and discloses net loss per common share in accordance with FASB Accounting Standards Codification ("ASC") Topic 260, *Earnings per Share*. Basic net loss per common share is computed by dividing net loss

attributable to common stockholders by the weighted average number of common shares outstanding. Diluted net loss per common share is computed by dividing net loss attributable to common stockholders by the weighted average number of common shares that would have been outstanding during the period assuming the issuance of common shares for all potential dilutive common shares outstanding. Potential common shares consist of shares issuable upon the exercise of stock options and warrants. Because the inclusion of potential common shares would be anti-dilutive for all periods presented, diluted net loss per common share is the same as basic net loss per common share.

The following table sets forth the number of potential common shares excluded from the calculation of net loss per diluted share for the three and nine months ended September 30, 2015 and 2014 because the effect of them would be anti-dilutive since the Company recorded net losses for all of these periods:

	Three Months Ended September 30,		**Nine Months Ended September 30,**	
	2015	2014	2015	2014
Options to purchase common stock	4,407,409	3,464,232	4,407,409	3,464,232
Warrants to purchase common stock	8,244,423	6,033,426	8,244,423	6,033,426
	12,651,832	9,497,658	12,651,832	9,497,658

NOTE 12: INCOME TAXES

Deferred income tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between the financial reporting and tax bases of assets and liabilities and are measured using enacted tax rates in effect for the year in which those temporary differences are expected to be recovered or settled. A valuation allowance is provided for the amount of deferred tax assets that, based on available evidence, are not expected to be realized.

As a result of the Company’s cumulative losses, management has concluded that a full valuation allowance against the Company’s net deferred tax assets is appropriate. No income tax liabilities existed as of September 30, 2015 and December 31, 2014 due to the Company’s continuing operating losses.

NOTE 13: CONCENTRATION OF CREDIT RISK

Financial instruments that potentially subject the Company to concentration of credit risk consist principally of cash deposits. Accounts at each institution are insured by the Federal Deposit Insurance Corporation (“FDIC”) up to $250,000. At September 30, 2015 and December 31, 2014, the Company had $7,864,439 and $8,250,718 in excess of the FDIC insured limit, respectively.

NOTE 14: COMMITMENTS AND CONTINGENCIES

Affymetrix Purchase Commitment

On September 1, 2013, in connection with the development of the NextCYTE test by the NRLBH, the NRLBH entered into an "OwnerChip Program Agreement" with Affymetrix, Inc. ("Affymetrix"), a manufacturer of GeneChip Systems, where Affymetrix has agreed to loan a GeneChip System 3000Dx v.2 ("instrument") to the Company if it purchases and takes delivery of a minimum thirty GeneChip Human Genome U133 Plus 2.0 (30-pack) arrays at $21,590 per 30-pack for the next three years for a total purchase obligation of $647,700 with a minimum purchase of ten 30-pack arrays per contract year. At the end of the three-year contract, upon fulfillment of the purchase commitment, the instrument title and ownership transfer to the NRLBH at no additional cost. Because the Company takes ownership of the equipment at the completion of the three-year contract, the Company determined that the arrangement represents a capital lease for the equipment. The Company recorded $206,702 as a capital lease for the equipment and began amortizing the equipment on a straight line basis over five years. In addition to the GeneChip Human Genome, the NRLBH must purchase a two-year service contract for $51,600 to cover maintenance of the instrument during the contract period. The NRLBH placed an initial order for four 30-pack arrays during 2013 for $94,723. In September 2014, the NRLBH purchased six additional 30-pack arrays for $142,005. On September 29, 2015, the Company entered into a new agreement with Affymetrix to purchase the instrument for $129,000. All of the prior purchase commitments under the old agreement were terminated.

A5 Software Development Commitment

On June 10, 2013, the Company entered into an irrevocable license and service agreement with A5 Genetics KFT, Corporation ("A5 Genetics"), pursuant to which the Company received the worldwide (other than the European Union) exclusive license to the software used in the NextCYTE test. The Company has the right to prosecute patents related to this software, two of which the Company has filed in the United States. The patent applications have been assigned to the Company. The Company paid a one-time fee of $100,000 to A5 Genetics in 2013 and in March 2014 the Company completed software validation and paid an additional $100,000 to A5 Genetics. The Company is obligated to pay up to an additional $1.2 million to A5 Genetics upon receiving the regulatory clearance for the NextCYTE test. The Company must also pay a royalty of $50 for each NextCYTE test performed and a service fee of $65 for each NextCYTE test performed. The NextCYTE test is still in validation stage and no royalty or service fees have been paid as of September 30, 2015. The agreement terminates on the later of June 10, 2023 or the expiration of the latest patents covering the software.

Luminex Reagent Rental Agreement and Assay License Agreement

On September 2, 2014, in connection with the development of a pharmacogenomics test by the NRLBH, the NRLBH entered into a three-year rental agreement with Luminex Corporation (Luminex), which provides that the NRLBH acquires the right to use Luminex instruments, including accessories, peripherals and options (the "System") at no cost if the NRLBH purchases goods (the "Products") at agreed upon quantities and prices for the next three years. The minimum purchases of Products under the agreement are $452,408 per year. The title to the System remains with Luminex and the NRLBH is required to return the System to Luminex at the end of the three-year rental agreement.

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Targeted Medical Education (TME) Master Service Agreement

On September 1, 2014, the NRLBH entered into a three-year agreement with TME Research LLC (TME) which requires TME to provide to the NRLBH 100 tissue specimens in connection with the development of the NextCYTE test. Fees payable to TME under the agreement include $99,600 up front, $31,500 upon supplying the first 25 specimens and $31,500 at the time of final delivery of all specimens. The agreement is terminable with 60 days prior written notice or immediately upon a material breach. As of September 30, 2015, the Company has paid $172,600 in fees, which were recorded as R&D expenses.

Besins Healthcare Luxembourg SARL Agreement

On May 14, 2015, the Company entered into an Intellectual Property License Agreement with Besins Healthcare Luxembourg SARL (“Besins”). The agreement provides the Company with an exclusive worldwide license to develop and commercialize Besins’ patented gel formulation of 4-Hydroxytamoxifen, or Afimoxifene Gel, for the potential treatment and prevention of hyperplasia of the breast.

The agreement requires that the Company pay a royalty of 8% to 9% of net sales for the first 15 years of commercialization. The Company has the non-exclusive right to also develop Afimoxifene Gel for breast cancer and other breast diseases, subject to the payment of the following milestone payments for these additional indications: (i) $5,000,000 for the exclusive right to review, access, and reference a Besins investigational new drug application (IND) for each additional indication; and (ii) $20,000,000 when the Company commences a Phase III clinical trial for each additional indication. If and when Atossa decides to sublicense its rights to commercialize the Afimoxifene Gel in a country in the territory, Besins has the right of first refusal to commercialize the Afimoxifene Gel on a country-by-country basis in countries where Besins has a marketing presence.

The agreement automatically expires on a country-by-country basis fifteen years after the first commercial sale of Afimoxifene Gel in the particular country. The Agreement may be terminated (i) by either party upon a material breach of the agreement that is not cured by the breaching party, (ii) by mutual agreement of the parties, (iii) by the Company at its discretion if it elects to stop developing or commercializing Afimoxifene Gel, (iv) by Besins on a country-by-country basis or indication-by-indication basis if the Company fails to commercialize or commence commercial sales within a specified time, or (v) by Besins if Atossa fails to accomplish any aspect of the development plan within six months of target date set forth in the development plan. The development plan covers an 18-month period and is required to be updated by the Company every six months during the term of the agreement.

Litigation and Contingencies

On October 10, 2013, a putative securities class action complaint, captioned Cook v. Atossa Genetics, Inc., et al., No. 2:13-cv-01836-RSM, was filed in the United States District Court for the Western District of Washington against us, certain of the Company's directors and officers and the underwriters of the Company's November 2012 initial public offering. The complaint alleges that all defendants violated Sections 11 and 12(a)(2), and that the Company and certain of its directors and officers violated Section 15, of the Securities Act by making material false and misleading statements and omissions in the offering's registration statement, and that we and certain of our directors and officers violated Sections 10(b) and 20A of the Exchange Act and SEC Rule 10b-5 promulgated thereunder by making false and misleading statements and omissions in the registration statement and in certain of the Company's subsequent press releases and SEC filings with respect to its NAF specimen collection process, its ForeCYTE Breast Health Test and its MASCT device. This action seeks, on behalf of persons who purchased the Company's common stock between November 8, 2012 and October 4, 2013, inclusive, damages of an unspecific amount.

On February 14, 2014, the Court appointed plaintiffs Miko Levi, Bandar Almosa and Gregory Harrison (collectively, the "Levi Group") as lead plaintiffs, and approved their selection of co-lead counsel and liaison counsel. The Court also amended the caption of the case to read *In re Atossa Genetics, Inc. Securities Litigation.* No. 2:13-cv-01836-RSM. An amended complaint was filed on April 15, 2014. The Company and other defendants filed motions to dismiss the amended complaint on May 30, 2014. On October 6, 2014 the Court granted defendants' motion dismissing all claims against the Company and all other defendants. On October 30, 2014, the Court entered a final order of dismissal. On November 3, 2014, plaintiffs filed a notice of appeal with the Court and have appealed the Court's dismissal order to the U.S. Court of Appeals for the Ninth Circuit. On February 11, 2015, plaintiffs filed their opening appellate brief. Defendants filed an answer on April 13, 2015. On May 18, 2015, Plaintiffs filed a reply brief in support of their appeal. A hearing for the appeal has not been set.

The Company believes this lawsuit is without merit and plans to defend itself vigorously; however, failure by the Company to obtain a favorable resolution of the claims set forth in the complaint could have a material adverse effect on the Company's business, results of operations and financial condition. Currently, the amount of such material adverse effect cannot be reasonably estimated, and no provision or liability has been recorded for these claims as of September 30, 2015. The costs associated with defending and resolving the lawsuit and ultimate outcome cannot be predicted. These matters are subject to inherent uncertainties and the actual cost, as well as the distraction from the conduct of the Company's business, will depend upon many unknown factors and management's view of these may change in the future.

NOTE 15: STOCK BASED COMPENSATION

Stock Options and Incentive Plan:

On September 28, 2010, the Board of Directors approved the adoption of the 2010 Stock Option and Incentive Plan, or the 2010 Plan, to provide for the grant of equity-based awards to employees, officers, non-employee directors and other key persons providing services to the Company. Awards of incentive options may be granted under the 2010 Plan until September 2020. No other awards may be granted under the 2010 Plan after the date that is 10 years from the date of stockholder approval. An aggregate of 1,000,000 shares were initially reserved for issuance in connection with awards granted under the 2010 Plan, such number of shares to be subject to adjustment as provided in the plan and in any award agreements entered into by the Company under the plan, and upon the exercise or conversion of any awards granted under the plan.

The following table presents the additions to the 2010 Plan since inception:

January 1,	**Number of shares**
2012	450,275
2013	516,774
2014	742,973
2015	983,362
Total additional shares	2,693,384

The Company granted options to purchase 1,640,822 shares of common stock to employees and directors during the nine months ended September 30, 2015. There are 703,003 options available for grant under the 2010 Plan as of September 30, 2015.

Compensation costs associated with the Company’s stock options are recognized, based on the grant-date fair values of these options, over the requisite service period, or vesting period. Accordingly, the Company recognized stock based compensation expense of $317,986 and $703,726 for the three months and nine months ended September 30, 2015, respectively. The stock based compensation expense for the three months and nine months ended September 30, 2014 was $147,399 and $545,115, respectively.

Stock-based compensation expense was included in the following captions in the condensed consolidated statements of operations for the periods shown:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Selling expenses	$ 29,374	$ 26,755	$ 74,773	$ 68,592
Research and development expenses	32,124	15,997	75,914	30,763
General and administrative expenses	256,488	104,647	553,039	445,759
	$ 317,986	$ 147,399	$ 703,726	$ 545,114

The following table presents information concerning stock option grants for the nine months ended September 30, 2015:

	Employees		Executives & Officers	
Date of Grant	January – September 2015		January – September 2015	
Fair value of common stock on date of grant	$ 0.76 – 1.59		$ 1.21 – 1.59	
Exercise price of the options	$ 1.40 – 1.88		$ 1.44 – 1.88	
Expected life of the options (years)	6.03 – 6.13		6.06 – 6.11	
Dividend yield	0.00	%	0.00	%
Expected volatility	107.1 – 115.0	%	111.3 – 113.5	%
Risk-free interest rate	1.64 – 1.81	%	1.72 – 1.74	%
Expected forfeiture per year (%)	10.00	%	10.00	%
Weighted average fair value of the options per unit	$ 0.82		$ 1.46	

Options issued and outstanding as of September 30, 2015 and their activities during the nine months then ended are as follows:

	Number of Underlying Shares	Weighted-Average Exercise Price Per Share	Weighted-Average Contractual Life Remaining in Years	Aggregate Intrinsic Value
Outstanding as of January 1, 2015	3,675,634	$ 2.86		$ 344,000
Granted	1,640,822	1.53		-
Forfeited/canceled	(559,047)	2.01		63,223
Expired	(350,000)			
Exercised	-	-		-
Outstanding as of September 30, 2015	4,407,409	2.31	8.6	$ 500
Exercisable as of September 30, 2015	1,618,524	3.38	7.9	$ -
Vested and expected to vest (1)	4,047,912	$ 2.37	8.6	$ 406

(1) vested shares and unvested shares after a forfeiture rate is applied

As of September 30, 2015, there were 2,788,885 unvested options outstanding and the related unrecognized total compensation cost associated with these options was $2,250,594. This expense is expected to be recognized over a weighted average period of 2.85 years.

NOTE 16: SUBSEQUENT EVENTS

All subsequent events requiring recognition as of September 30, 2015 have been incorporated into these consolidated financial statements and there are no subsequent events that require disclosure in accordance with FASB ASC Topic 855, “Subsequent Events.”

ITEM 2. MANAGEMENT’S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion of the financial condition and results of operations should be read in conjunction with the financial statements and the related notes included elsewhere in this report. This discussion contains forward-looking statements, which are based on assumptions about the future of the Company's business. The actual results could differ materially from those contained in the forward-looking statements. Please read "Forward-Looking Statements" included below for additional information regarding forward-looking statements.

Forward-Looking Statements

This report contains, in addition to historical information, certain information, assumptions and discussions that may constitute forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act") and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). We have made these statements in reliance on the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These statements are subject to certain risks and uncertainties, which could cause actual results to differ materially from those projected or anticipated. Although we believe our assumptions underlying our forward-looking statements are reasonable as of the date of this report, we cannot assure you that the forward-looking statements set out in this report will prove to be accurate. We typically identify these forward-looking statements by the use of forward-looking words such as "expect," "potential," "continue," "may," "will," "should," "could," "would," "seek," "intend," "estimate," "anticipate," or the negative version of those words or other comparable words. Forward-looking statements contained in this report include, but are not limited to, statements about:

- whether we maintain our clearances from the U.S. Food and Drug Administration, or FDA, and foreign regulatory bodies, and the CE Certificates of Conformity granted by our notified body, to sell, market and distribute our medical devices;
- whether we can achieve our revenue forecast and other financial projections for 2015;
- our ability to successfully commercialize the FullCYTE Breast Aspirator in the United States and our ForeCYTE Breast Aspirator outside the United States;
- our ability to successfully continue selling and servicing pharmacogenomics and NAF cytology testing in our laboratory;
- our ability to successfully sell our products and services at currently expected prices or otherwise at prices acceptable to us;
- our ability to successfully develop and commercialize our pharmaceutical candidates, including Afimoxifene Gel and drugs such as Fulvestrant delivered via our Microcatheters, and our ability to manufacture sufficient quantities of the active ingredients, enroll and successfully complete clinical studies and obtain necessary approvals from the FDA and other regulatory authorities;

- our ability to successfully develop and commercialize new tests, tools and treatments currently in development and in the time frames currently expected;

- our ability to maintain our business relationships, including with our distributors, suppliers and customers;

- our ability to engage third party suppliers to manufacture the ForeCYTE Breast Aspirator, FullCYTE Breast Aspirator, FullCYTE Microcatheter, other devices under development and their components at quantities and costs acceptable to us;

- our ability to satisfy ongoing FDA, European Union (EU) and foreign requirements for manufacturing, distributing, and promoting the FullCYTE Breast Aspirator, ForeCYTE Breast Aspirator, NAF cytology test and FullCYTE Microcatheter and to obtain regulatory approvals, clearances and CE Certificate of Conformity for our other products and services in development;

- our ability to successfully defend ongoing litigation, including the securities class action law suit filed against us on October 10, 2013, and other similar complaints that may be brought in the future, in a timely manner and within the coverage, scope and limits of our insurance policies;

- the benefits and clinical accuracy of our laboratory tests, including the NAF cytology and pharmacogenomics tests;

- our ability to establish and maintain intellectual property rights covering our products and services;

- the willingness of health insurance companies, including those who are members of the MultiPlan, FedMed and HealthSmart networks, and other third party payors to approve our products and services for coverage and reimbursement;

- our ability to establish and maintain an independent sales representative force, including with our current and future distributors and their sub-distributors, to market our current products and services and those that we may develop;

- our expectations regarding, and our ability to satisfy, federal, state and foreign regulatory requirements;

- the accuracy of our estimates of the size and characteristics of the markets that our products and services may address;

- our expectations as to future financial performance, expense levels and liquidity sources;

- our ability to attract and retain key personnel;

- our ability to sell additional shares of our common stock to Aspire Capital under the terms of our purchase agreement with them; and

- our ability to obtain, maintain and defend our intellectual property rights covering our devices, specimens, collection kits, diagnostic tests and compositions.

These and other forward-looking statements made in this report are presented as of the date on which the statements are made. We have included important factors in the cautionary statements included in this report, particularly in the

section titled “ITEM 1A. RISK FACTORS,” that we believe could cause actual results or events to differ materially from the anticipated results as set forth in the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any new information, future events or circumstances that may affect our business after the date of this report. Except as required by law, we do not intend to update any forward-looking statements after the date on which the statement is made, whether as a result of new information, future events or circumstances or otherwise.

Company Overview

We are a healthcare company focused on the development of locally-administered pharmaceuticals for the treatment of pre-cancer and early stage breast cancer. Our leading pharmaceutical under development is Afimoxifene Gel, which is in Phase II clinical development. We are also planning a Phase II clinical trial using our patented intraductal Microcatheters to deliver Fulvestrant to treat ductal carcinoma in-situ, or DCIS, and breast cancer. We have also developed and are commercializing proprietary laboratory tests and medical devices which, subject to receiving regulatory approvals, we may also develop to act as companions to our pharmaceuticals. Our laboratory tests are being developed and performed by our wholly-owned subsidiary, The National Reference Laboratory for Breast Health, Inc., or the “NRLBH.” The NRLBH has developed and is currently marketing nipple aspirate fluid, or NAF, cytology tests and pharmacogenomics tests.

In May 2015, we acquired the world wide exclusive rights to develop and commercialize Afimoxifene Gel for the potential treatment of hyperplasia of the breast and the rights to expand the license to other indications including breast cancer (which would require that we pay milestone payments for each additional indication). Afimoxifene Gel has been used in 16 Phase I and Phase II studies conducted in a variety of indications with over 450 patients. We are in the process of re-establishing the clinical supply of Afimoxifene Gel and plan to commence a Phase II clinical trial in mid-2016. 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.

In October 2015 the FDA accepted our investigational new drug application, or IND, to commence a Phase II clinical study using Fulvestrant administered via our patented intraductal Microcatheters to treat DCIS and breast cancer. We expect this study will be performed by Columbia University Medical Center and will commence in December 2015.

Our medical devices include the ForeCYTE Breast Aspirator for distribution outside the United States and the FullCYTE Breast Aspirator for the U.S. market. These devices are intended for the collection of NAF for cytological testing at a laboratory. The current version of the ForeCYTE Breast Aspirator is not cleared by the FDA for marketing in the United States; however, this device is CE-marked and is therefore available for sale in the European Union and the countries of the European Free Trade Association (EFTA). The FullCYTE Breast Aspirator has been cleared by the FDA for the collection of NAF for cytological purposes and is available for sale for the U.S. market through Atossa’s distributors. Other devices under development include intraductal microcatheters for the collection of ductal lavage fluid and for the potential administration of targeted pharmaceuticals, and various tools for potential use by

breast surgeons.

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Our key objectives are currently:

(1) Pharmaceutical Development: We plan to advance our pharmaceutical candidates through Phase II trials. A Phase II study of Fulvestrant administered via our patented intraductal Microcatheters is planned to commence in December 2015. A Phase II study of Afimoxifene Gel is planned to begin enrollment in the mid-2016.

(2) Breast Aspirators: Our FullCYTE Breast Aspirator is FDA-cleared and is available in the United States through our distributors, which are currently Thermo Fisher Scientific and Henry Schein Medical. Our ForeCYTE Breast Aspirator is CE-marked and is available in the EU and related markets through Rhenus Logistics. We plan to commence approximately three clinical studies in the EU and related markets of our ForeCYTE device to demonstrate clinical utility of the ForeCYTE device and/or to identify biomarkers in NAF that, subject to additional regulatory clearances, may enhance clinical utility of the device and the laboratory test of the NAF specimen. In September 2015, we received approval from the institutional review board to commence the first of these studies using the ForeCYTE device in Israel.

(3) Laboratory Tests: We plan to grow our revenue by promoting the pharmacogenomics test currently being offered by the NRLBH, and by developing and commercializing additional laboratory tests. We reported total gross revenue of $5.3 million for the nine months ended September 30, 2015, substantially all of which was from pharmacogenomics testing. In October 2015, we hired four additional fulltime sales and marketing professionals and beginning in October 2015 substantially all of our internal sales and marketing resources are being devoted to our pharmacogenomics test. An adverse Medicare local coverage determination, or LCD, was made on June 22, 2015 that limits the medical conditions and drugs that are covered by Medicare for our pharmacogenomics tests. As a result, our revenue from Medicare as well as from commercial payers has been negatively impacted. Due to the uncertainty around the impact that this change is having and could continue to have on our business, we are not at this time providing a revenue forecast for 2015 and are withdrawing any forecasts that we have previously provided. The NRLBH has in-network arrangements with Meridian Health Plan of Michigan and Washington Medicaid and is in the process of securing additional in-network arrangements with Medicaid and commercial payers.

The ForeCYTE Breast Aspirator will not be launched in the United States unless and until we receive additional regulatory clearance from the FDA. Our planned pharmaceuticals and our devices and laboratory tests under development, either separately or in combination, will require clearance and/or approval from the FDA prior to commercialization. No assurance can be given that such approvals and/or clearances will be obtained in a timely manner.

Our common stock is currently quoted on The NASDAQ Capital Market under the symbol “ATOS.”

Intellectual Property

As of September 30, 2015, and based on a recent periodic review of our patent estate, we own 147 issued patents (45 in the United States and at least 102 in foreign countries), and 22 pending patent applications (10 in the United States, and 12 pending international applications) directed to our products, services, and technologies. Our patent estate consists primarily of the following:

	United States			Foreign/PCT		
Description	**Issued [1]**	**Expiration**	**Pending [1]**	**Issued [1]**	**Expiration**	**Pending**
ForeCYTE Breast Aspirator Program	7	2016 – 2031	4	12	2016 – 2031	8
FullCYTE Microcatheters & FullCYTE Breast Aspirators Program	20	2019 – 2031	5	53	2019 – 2031	4
NextCYTE Test Program	0	2031	1	0	2031	1
Intraductal Treatment Program	12	2030	3	47	2030	1
Carbohydrate Biomarkers Program	2	2022	0	3	2022	0
Acueity Tools	12	2015 – 2024	0	2	2015 – 2024	0

(1) The total number of patents issued or pending, as applicable, in the respective descriptive columns exceed the totals because some patents and applications contain more than one type of claim directed to methods, kits, compositions, devices and/or technology and the patent counts disclosed herein are subject to change.

Atossa, Atossa Genetics (stylized), MASCT, ArgusCYTE, and National Reference Laboratory for Breast Health (stylized) are our registered trademarks. We have pending allowed applications with the United States Patent and Trademark Office for registration of the use of the marks FullCYTE and NextCYTE.

Summary of Our Products and Services

Our products and services currently being offered and currently under development consist primarily of the following: